1033
Y 4.Ap 6/2:Sen 1/981
Y 4.Ap 6/2:Sen 1/981

Senate Hearings

Before the Committee on Appropriations

DOCUMENTS
MAY 14 1980
FARRELL LIBRARY
KANSAS STATE UNIVERSITY

Departments of:
—Labor
—Health and Human Services
—Education
—and Related Agencies Appropriations

KSU LIBRARIES
A11500 698386

Fiscal Year 1981

96*th* CONGRESS, SECOND SESSION

PART 1—(Pages 1–979)

PUBLIC HEALTH SERVICE:
- HEALTH SERVICES ADMINISTRATION
- CENTER FOR DISEASE CONTROL
- NATIONAL INSTITUTES OF HEALTH
- ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
- HEALTH RESOURCES ADMINISTRATION
- ASSISTANT SECRETARY FOR HEALTH

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE

NINETY-SIXTH CONGRESS

SECOND SESSION

PART 1 (Pages 1–979)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Printed for the use of the Committee on Appropriations

U.S. GOVERNMENT PRINTING OFFICE
61-400 O WASHINGTON : 1980

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402

COMMITTEE ON APPROPRIATIONS

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

WARREN G. MAGNUSON, Washington, *Chairman*

ROBERT C. BYRD, West Virginia
WILLIAM PROXMIRE, Wisconsin
ERNEST F. HOLLINGS, South Carolina
THOMAS F. EAGLETON, Missouri
BIRCH BAYH, Indiana
LAWTON CHILES, Florida
QUENTIN BURDICK, North Dakota
DANIEL INOUYE, Hawaii

RICHARD S. SCHWEIKER, Pennsylvania
CHARLES McC. MATHIAS, Maryland
MARK HATFIELD, Oregon
LOWELL WEICKER, Connecticut
HARRISON SCHMITT, New Mexico
MILTON R. YOUNG, North Dakota, *ex officio*

Professional Staff
TERRY L. LIERMAN
JAMES SOURWINE
SAM HUNT
CRAIG E. BURY
MARY ARONSON
Minority Staff
GAR KAGANOWICH, PETER MICHELSON
Administrative Support
OLGA TROLLINGER
SHARON BAUMAN-LEACH
SHIRLEY BROWN

CONTENTS

THURSDAY, JANUARY 31, 1980

Page

Department of Health and Human Services 1

FRIDAY, FEBRUARY 1, 1980

Department of Health and Human Services:
Health Services Administration 99

MONDAY, FEBRUARY 4, 1980

Department of Health and Human Services:
Center for Disease Control 213

TUESDAY, FEBRUARY 5, 1980

Department of Health and Human Services:
National Institutes of Health 295
National Eye Institute 371
National Institute on Aging 393
John Fogarty International Center 409
Division of Research Resources 425
National Institute of Environmental Health Sciences 435
National Institute of Child Health and Human Development 461
National Institute of Arthritis, Metabolism, and Digestive Diseases 491

WEDNESDAY, FEBRUARY 6, 1980

Department of Health and Human Services:
National Institutes of Health 521
National Institute of General Medical Sciences 537
National Institute of Allergy and Infectious Diseases 561
National Institute of Neurological and Communicative Disorders and Stroke 589
National Institutes of Health 623
National Institute of Dental Research 635
National Heart, Lung, and Blood Institute 653
National Cancer Institute 711

THURSDAY, FEBRUARY 7, 1980

Department of Health and Human Services:
Alcohol, Drug Abuse, and Mental Health Administration 751
Health Resources Administration 849

FRIDAY, FEBRUARY 8, 1980

Department of Health and Human Services:
Office of the Assistant Secretary of Health 929

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

THURSDAY, JANUARY 31, 1980

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

The subcommittee met at 2:35 p.m. in room S–128, the Capitol, Hon. Warren G. Magnuson (chairman) presiding.

Present: Senators Magnuson, Hollings, Eagleton, Bayh, Schweiker, Hatfield, Schmitt, and Weicker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF THE HONORABLE PATRICIA ROBERTS HARRIS, SECRETARY

ACCOMPANIED BY:
NATHAN J. STARK, UNDER SECRETARY OF HEALTH, EDUCATION, AND WELFARE
FREDERICK M. BOHEN, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
WILLIAM B. WELSH, ASSISTANT SECRETARY FOR LEGISLATION
ALAIR TOWNSEND, DEPUTY ASSISTANT SECRETARY, BUDGET

BUDGET REQUEST

Senator MAGNUSON. Before we begin, I would like to make a few comments to keep this in perspective.

Even though we dropped education from HEW when we formed this new Department of Health and Human Services, most of HEW, in terms of dollars, is still left. This new department still commands 35.6 percent of the Federal budget, compared with 37.5 percent for last year's fiscal 1980 budget.

Expenditures provided for in this Department's budget for the health and human needs of the less fortunate in our society will total about $220 billion in fiscal 1981. Most of this money will come out of the social security trust fund, which means the jurisdiction of this subcommittee will be over only about $56 billion of the total.

I always contend we should keep social security out of the budget and let it stand on its own. So, we'll take a look at this $56 billion request. We have only effective control from one year to the next, without changing the basic authorizing legislation, of less than $13 billion, or about 24 percent. The rest are uncontrollable.

So, we're going to take a good, long look at your budget, Madam Secretary, to assure that it adequately provides for the human needs. We may cut some; we may give you some. We'll see. So, you go ahead now with your general statement.

Senator SCHWEIKER. I have a short opening statement.

Senator MAGNUSON. Excuse me.

We'll let you go ahead, but Senator Schweiker has a short statement.

STATEMENT BY SENATOR SCHWEIKER

Senator SCHWEIKER. Thank you, Mr. Chairman.

Madam Secretary, it's a pleasure to have you here to present the 1981 budget for the new Department of Health and Human Services.

As you know, Congress and the American people are very concerned about the inflation that is eating away at their security. Although there are many causes of this inflation, one of them is surely the deficit spending which this Government has engaged in for so many years. It is striking that the budget for your Department, even with education moved out, still represents 35.6 percent of all Federal outlays.

I am well aware that most of the growth in your budget is the result of the spiraling costs of the entitlement programs administered by HHS. Given the uncontrollable nature of these programs, a major concern of this subcommittee must be how effectively we can manage these as well as the other programs covered by your $223 billion budget.

We must again bend to the task of overseeing your management of the taxpayers' dollar, to insure that savings are effected, and that sufficient funds are made available for essential programs in health and other areas.

Our concern, quite frankly, is with the diligence of the Department in making savings where it can. For example, the General Accounting Office recently issued a report listing 100 health-cost reduction initiatives it has recommended the Department to take. Thus far, HHS has not acted on these. We would, obviously, like to find out the reason.

We must also be concerned by HHS' belief that it cannot save the $500 million mandated by the Michel amendment. Why, for example, is HHS 2 months late in issuing regulations requiring the reduction of AFDC and medicaid error rates to 4 percent by September 30, 1982? Does this not indicate a slowness on the part of the Department to come to grips with the problems in the area of reducing waste, fraud, and abuse?

I hope you can achieve meaningful savings in this budget and also target funds to needed areas. This budget reflects the difficult task that our Government faces this year. The human needs of our people must be met, but the pace of Government spending must be slowed down.

Thank you very much.

Senator MAGNUSON. Senator Eagleton, do you have a statement?

Senator EAGLETON. No, I don't, Mr. Chairman.

Senator MAGNUSON. Senator Bayh?

Senator BAYH. Mr. Chairman, I don't have an opening statement, but out of respect to the esteemed Secretary, I certainly want to be here on this particular occasion, since we have had the privilege of fighting several common battles together.

I am going to be called out of here for another committee meeting and I would like to ask unanimous consent to submit some questions for the record.

STATEMENT BY SENATOR BAYH

But I would like to call special attention to concerns that I have had. I know that there are forces that go above and beyond the role of the Secretary in determining what the final figure of the budget is that reaches the Congress. I think that it is important for us in the legislative branch to probe and to find out what the real amount is that is needed to serve the people and not necessarily meet some criteria that is established by somebody down at OMB that may be very well intentioned but may be having to serve several different masters or trying to accomplish several different goals.

I am particularly concerned about the commitment that has or has not been made in the various institutes out at the National Institutes of Health. We have made significant progress in those areas, and we have the enemy on the run and now is not the time to retreat. It's rather like driving down the field and then punting when you get to the 5-yard line. And that doesn't make sense.

Just to pick out one area, I am concerned about nurses scholarships, which I find woefully inadequate, and it's difficult for me to understand. And I would submit that in question form.

I would also like to call particular attention to the CDC and other areas within your Office in the area of education for smoking. I think this is the one habit, if we can rear a generation that doesn't have the habit——

[Laughter.]

Senator BAYH [continuing]. That that will be easier than teaching the elders.

Senator MAGNUSON. You mean cigarette smoking? [Laughter.]

Senator BAYH. I am going to take the fifth amendment on that one, Mr. Chairman.

Senator SCHWEIKER. Yeah, I won't comment.

Senator MAGNUSON. All right, Senator Schmitt.

Senator SCHMITT. Thank you, sir.

I am, I guess, stuck with being deeply involved with the HHS budget, since those are also my initials, and I am looking forward to this discussion today as well as others.

As the chairman has pointed out, only about $12 or $13 billion of the total budget is discretionary at this time, and of that there are a number of programs that the administration has assumed will be enacted which have not been enacted—I am sure the Secretary will speak to that—among them, hospital cost containment, reimbursement for nursing care, nurses training programs, health insurance programs, the disability insurance program, and the Mental Health Systems Act.

The total there is considerable of programs that have not been enacted by Congress but nevertheless are assumed to have been enacted in this budget, if I understand it correctly. So the committee will have that additional complexity in sorting out exactly what we should do with the budget.

I thank the chairman for his courtesy and look forward to the testimony. Good old HHS.

Senator MAGNUSON. I don't want the committee to get into saying that all entitlements must be appropriated. We have often, Madam Secretary, taken a look at medicaid and questioned your estimates and cut the budget considerably. We've always been right and you've always been wrong in the estimates. We can cut a lot of the entitlements. As to the question of whether or not your estimates are correct, we think they are. We think the Department does the best job they know how.

All right, does anybody else have anything to say? [No response.]

If not, go ahead with your statement.

OPENING STATEMENT—SECRETARY HARRIS

Secretary HARRIS. Mr. Chairman and members of the committee, I have presented to the committee a full statement of 40 pages, while, which it may seem long, might be appropriate for a budget this size. I would ask that that statement be entered for the record. And in lieu of that statement, I should like to make a brief opening statement and then run through some charts that I have that I think graphically present the budget of the Department.

Senator MAGNUSON. OK.

[The statement follows:]

PATRICIA ROBERTS HARRIS

Secretary of Health, Education, and Welfare

Patricia Roberts Harris was sworn in as Secretary of Health, Education, and Welfare by Justice Thurgood Marshall on August 3, 1979. President Carter nominated her for the post, her second cabinet appointment, on July 20. She was confirmed by the Senate on July 27.

Mrs. Harris had served as Secretary of Housing and Urban Development since January 23, 1977.

She is a former Ambassador to Luxembourg, serving in that diplomatic post from 1965 to 1967.

She served as Alternate Delegate to the 21st-22nd General Assemblies of the United Nations, and was a member of the Commission on Causes and Prevention of Violence and the Advisory Committee on Reform of Federal Criminal Law.

Mrs. Harris was a partner in the Washington, D.C. and New York law firm of Fried, Frank, Harris, Shriver and Kampelman and a director of the Chase Manhattan Bank, Scott Paper Company, National Bank of Washington, and IBM. She is a Trustee of the 20th Century Fund, and of the American Bar Foundation.

Born in Mattoon, Ill., she received her AB degree, summa cum laude, from Howard University and the Juris Doctor degree, with honors, from George Washington in 1960. A member of Phi Beta Kappa and the Order of the Coif, she has been elected to the American Academy of Arts and Sciences.

Mrs. Harris was admitted to the D.C. Bar in 1960. She served as a trial attorney in the Department of Justice from 1960 to 1961 and joined the Howard University staff as associate dean of students and lecturer in law, and later became a professor of law and dean of the School of Law.

She has served as a member of a number of Boards and Commissions. At the time of her appointment as Secretary of Housing and Urban Development, she was Chairperson of the District of Columbia Law Revision Commission.

She and her husband, William Beasley Harris, live in Washington, D.C.

August 1979

STATEMENT OF PATRICIA ROBERTS HARRIS

Mr. Chairman and Members of the Committee:

It is a pleasure to appear before you today to present the 1981 budget for the Department of Health and Human Services.

We are, as you know, in transition to the actual implementation of the separate Cabinet-level Department of Education, expected to take place this spring and well before the beginning of fiscal year 1981. Since her appointment and confirmation by the Senate, I have been working closely with Secretary Hufstedler to ensure the smoothest and most effective transfer of program activities that have traditionally been the responsibility of the Department of HEW and remain the concern of this Committee. Many of the most important issues in connection with the detachment of Education from HEW have been resolved, including the budget and staffing for the new Department, and I understand that Secretary Hufstedler will be meeting with you shortly to present the Administration's plans for Education in 1981.

In a real sense, I, too, am here to talk about the programs and FY 1981 budget for a new Department -Health and Human Services -- whose responsibilities continue to be great and absorbing in areas of social policy where the Federal role is large and long-established.

In a year when an energy-driven inflationary spiral is eroding the value of what a dollar will buy and threatens the quality of all our lives, the necessity for fiscal responsibility is clear. Inflation touches and affects us all, and it is, as President Carter has repeatedly noted, the modern-day equivalent of the scourge for those millions of American families and individuals who live in or near poverty, including the elderly and millions of other citizens of our Nation who must live on small fixed incomes.

Therefore, the government cannot ignore the ever more pressing needs of those of our citizens least able to help themselves. I present the Department's budget confident that it charts a reasonable course between the need for restraint and the needs of those who depend, especially in hard times, upon the constancy of government policy -- the poor, the aged, the sick, the handicapped, and the young.

Our 1981 proposals build upon the demonstrated concerns and priorities evidenced by the President and his Administration during the last three years. Our budget and legislative proposals emphasize:

- In all major respects, a policy of current services funding for social security retirement and survivors benefits, including the full adjustment for cost-of-living mandated under current law;

- The Administration's continuing commitment to welfare reform, which includes provisions to simplify administration and reduce costs as well as an additional $800 million in

FY 1981 to establish a minimum national benefit and provide fiscal relief to the States;

- Funding increases of $63 million for selected nutrition and social services programs that serve the Nation's elderly, and $23 million to support new approaches to providing selected health services and benefits received in one's home;

- An improved and expanded program of low-income energy assistance, for which the President will request $2.4 billion as soon as the authorizing legislation is enacted;

- Additional funding of $90 million for Head Start -- a governmental initiative that for nearly a generation has given millions of disadvantaged children a better chance to realize their full potential in life;

- Funds totalling $510 million in FY 1981 to back up the President's long-standing support for two legislative initiatives for children still pending in Congress--the Child Health Assurance Program (CHAP) and the legislation to reform Child Welfare Services;

- $141 million, or nearly a 13% increase in funding for selected Public Health Service programs-- particularly Community and Migrant Health Centers-- that provide health services to the underserved;

- New funds in both 1980 and 1981 to implement pending legislation that would redirect and reinforce mental health activities along lines supported by President Carter's Commission on Mental Health as well as start new alcoholism projects focused on the problems of women and teenagers;

- $139 million in new funds for biomedical research to carry out an Administration commitment to stabilize the number of annual, new grant awards that can be supported by the National Institutes of Health;

- Continued emphasis and support for legislation and management initiatives that control health costs, and funds to expand programs--such as HMO's and a host of health promotion activities to encourage wider public awareness of behavior that improves health;

- Management initiatives to reduce waste and inefficiency, and to insure that the resources we have are spent productively and with the accountability the American taxpayer expects and deserves.

Overall, the FY 1981 Budget for the Department of Health and Human Services provides for budget authority of $222.9 billion and

outlays of $219.3 billion. Of this total, we will seek the approval of this Committee for appropriations of $56 billion.

In FY 1981, the Department's outlay total of $219.3 billion is 35.6% of the President's total budget, up from 34.3% of the total in the current fiscal year. Largely because of the growth in Social Security and medical expenditures, the $26 billion increase in HHS outlays between FY 1980 and FY 1981 constitutes 50% of the overall increase in Federal outlays.

Labor-HEW Appropriations Bill

I have highlighted HHS's total budget, which includes outlays from trust funds as well as the appropriation requests considered by the Labor-HEW Appropriations Subcommittee.

For fiscal year 1981, as I indicated above, the President's budget would provide HHS with an appropriation of $56 billion, including about $1 billion for new legislation proposed in the President's budget. This is an increase of $5.5 billion over our current request for 1980, largely because of increased requirements in entitlement programs, but also because of enhancements in selected discretionary programs.

I will now turn to a more detailed discussion of the budgets of each of HHS's operating components. Although primary emphasis will be placed on items that come before this Subcommittee, I will mention other items if it is essential for understanding the themes of our budget.

SOCIAL SECURITY ADMINISTRATION

The budget and legislative program for the Social Security Administration:

-- Protects the value of Social Security and SSI benefits in the face of rising inflation.

-- Proposes short-term remedies to maintain the integrity of the Social Security trust funds.

-- Continues to advocate the enactment of welfare reform, which will make cash benefits for the poor more equitable across the Nation and improve incentives to work.

-- Proposes an expanded low-income energy assistance program to protect the poor against rising energy costs next winter.

-- Requests adequate resources to meet the immediate human needs of the increased flow of refugees arriving in this country and assist them to become productive members of American society.

With the exception of disability reform--which Congress is actively considering for enactment in the current session--the budget does not propose any major legislative changes in Social Security

benefits. A number of important reviews of the Social Security system are either in progress now or have recently been completed. These include the report of the Social Security Advisory Council, the HEW study of the treatment of men and women under Social Security, the universal coverage study, and the National Commission on Social Security. Changes, if any, will be proposed only after careful review and analysis of these recommendations.

Social Security Benefits (OASDI)

Trust fund spending for the Old-Age, Survivors, and Disability Insurance program will reach $136.9 billion in 1981, $19 billion more than in 1980. The major factor in this increase is the benefit adjustment required to maintain the purchasing power of benefits. The budget estimates that a 13 percent increase will be required in July 1980 and a further 9.9 percent increase in July 1981. The number of people receiving benefits is expected to reach 35.9 million, up 600,000 from 1980.

There has been a great deal of public concern that the Old-Age, and Survivors Insurance trust fund will soon run out of money. The problem is created by the fact that current inflation is much higher than originally projected and unemployment is expected to increase during the coming months. This stress has been placed on the system before the full impact of the Social Security tax increases enacted in 1977 has been realized. Because the three trust funds combined -- Old-Age and Survivors, Disability, and Hospital Insurance -- will have adequate reserves through 1985, based on current economic assumptions, we are proposing legislation to permit borrowing among the three funds. This step will insure that all Social Security benefits will be paid even if there is a temporary shortfall in the Old-Age and Survivors Insurance trust fund.

Cash Assistance for the Poor

The budget requests for Supplemental Security Income (SSI) and Aid to Families with Dependent Children (AFDC) also reflect the costs of protecting benefits from the impact of inflation. SSI benefits will be increased next July at the same rate as Social Security retirement and disability benefits. This is the principal factor in the $551 million increase which raises total SSI spending to $6.9 billion in 1981.

Total outlays for AFDC under current law are expected to reach $7.7 billion in 1981, up $385 million from 1980, approximately an 8 percent increase. The average monthly benefit per family is expected to rise by 5.9 percent, indicating that States are not fully protecting the poor from the impact of inflation. This underlines the need for Congressional action on Welfare Reform, which would establish a minimum benefit floor with built-in protection against inflation as well as more effective work incentives. A bill very close to the Administration's proposal has passed the House and is now awaiting action in the Senate. The allowance for contingencies in the President's budget includes funds to begin implementation of this new legislation in FY 1981.

The budget authority requested for AFDC is distorted by the need to restore FY 1980 budget authority which was withdrawn to meet part of the $500 million reduction made by Section 201, also known at the Michel amendment. Because it is necessary to distribute the $500

million reduction to appropriated line items, we calculated that $350 million of the line item for AFDC would be saved if States achieved a 4 percent payment error rate in FY 1980. Since the Michel amendment itself does not mandate this rate until the end of FY 1982, it is unlikely that States will actually operate at this level. Therefore, to honor fourth quarter awards to States, it will be necessary to borrow from the 1981 appropriation. We currently estimate that $300 million of the $350 million removed from fiscal year 1980 will have to be restored in fiscal year 1981.

Low-Income Energy Assistance

The budget for the Executive Office of the President includes $2.4 billion for the second year of the Low-Income Energy Assistance program. This program, which we hope to have longer lead time to put into place, should correct some of the structural problems of the emergency effort now underway. The authorizing legislation for the 1981 program is now pending in Congress. We hope that action will be completed expeditiously.

Assistance for Refugees

The American tradition of extending a helping hand to those driven from their homes by war and political upheavals is exemplified by the President's policy to accept 14,000 Indochinese refugees per month as well as accommodate an increased flow of refugees from the Soviet Union and other parts of the world. Providing for the immediate needs of these people, who generally own no more than the possessions they carry, and helping them become a productive part of American society are responsibilities shared by all levels of government and by many private individuals and organizations as well. Under the comprehensive refugee legislation proposed by the President last year and now being considered by a House-Senate conference committee, the Federal Government would provide 100 percent of the cost of cash, medical assistance, and special educational and social services for two years after the refugees arrive in this country. Of the total 1981 budget request of $598 million, $87 million is requested under existing law. Appropriation of the remaining $511 million must await enactment of the new bill. For fiscal year 1980, we are proposing a spending level of $524 million, of which $416.9 million can be financed through the Continuing Resolution and $107 million is requested as a supplemental appropriation under existing legislative authorities.

Although most of the funding proposed for 1980 and 1981 is needed for cash and medical assistance, our major effort to help refugees become productive participants in the American economy is our request for social and educational services. In FY 1981, we are requesting $180 million for these activities which will emphasize English language training, elementary and secondary education for refugee children, and job counselling. The elementary and secondary education portion of this effort--for which we are requesting $23 million in the 1980 supplemental and $44 million in FY 1981--will be administered by the Department of Education. These services are essential if refugees and their children are to avoid becoming permanently dependent on public assistance programs.

HEALTH CARE FINANCING ADMINISTRATION

Through Medicare and Medicaid, the Health Care Financing Administration will finance health care for 47 million beneficiaries in fiscal year 1981. Total outlays are expected to reach $53.2 billion, $5.4 billion higher than the current estimate for 1980. Although the major factor in the budget increase is the continued rise in the cost of health care and the growth of the aging population, the budget and legislative program contains a number of new proposals to extend coverage to underserved populations, reimburse new services and providers, and continue to fight for effective restraints on health cost inflation.

Child Health Assurance Program

The Administration's Child Health Assurance Program (CHAP) would extend Medicaid eligibility to two million children in low-income families and to 100,000 low-income pregnant women. This group is particularly vulnerable to illnesses which, if left untreated, can cause long-term disability or premature death. By emphasizing follow-up services, as well as initial screening, CHAP should lower infant mortality rates, improve the health of poor children, and reduce serious illness in later life. If enacted by July 1980, this program will cost $403 million in Federal funds in fiscal year 1981.

Clinic Services

Reimbursement for care provided in comprehensive primary care clinics is optional in Medicaid but is not utilized as much as it should be by the States. We are proposing legislation to require coverage of comprehensive clinic services as a regular part of Medicaid State plans. Because many States do not reimburse comprehensive clinics, and because of the low rate of physician participation in Medicaid, many beneficiaries seek care in hospital outpatient departments and emergency rooms, a practice which is unnecessarily expensive and a poor substitute for community-based primary care. The legislative proposal would add $52 million to Federal Medicaid matching payments in 1981.

Home Health Benefits

We are proposing legislation to facilitate access to home health care by both Medicare and Medicaid beneficiaries. Home health care is often a preferable substitute for institutional care. In many cases home care is both more appropriate for the patient's needs and less expensive than institutional care. In addition it could be a major factor in helping people stay in their homes rather than entering institutions.

For Medicare we are proposing to eliminate the current three-day prior hospitalization rule before home health services will be reimbursed under Part A. This change should reduce unnecessary hospitalization and provide care to many people not now receiving care at home. This legislation is expected to cost $7 million in 1981.

We are also proposing to remove a provision from the Medicaid legislation which creates a bias for patients to enter nursing homes.

We propose allowing States to use the same income and medical need criteria for persons receiving care in their own home as for those who enter a nursing home. This change is expected to cost $15 million.

In addition, we are proposing a Medicare demonstration project to evaluate the costs and benefits of permitting home health aides to make longer visits so that homemaker service can be provided on a regular basis to ill or disabled beneficiaries.

Puerto Rico

The budget proposes to raise the statutory ceiling on reimbursements for Puerto Rico and the territories to $64 million by FY 1982, double the current ceiling. The current ceiling has not been increased since 1972, although costs have more than doubled since that time.

Measures to Control Costs

The President continues to support strong legislative and administrative actions to control the rapid rise of health care costs. Of particular urgency is the need to enact a hospital cost containment bill which places a meaningful limit on the growth of inpatient costs for all Americans. If the Administration's proposal can be put into effect by October 1, 1980, the health care system as a whole could save $2.0 billion in FY 1981, of which $780 million would be saved in Federal Medicare and Medicaid spending. This can be done without risk to the quality of health care provided to our citizens. Its enactment would be a major victory in the fight to control inflation in the Nation's economy.

We are also proposing a number of less far-reaching actions which would further serve to moderate the rise in health care costs. These include revised limits on Medicare reimbursements to hospitals and legislation to put an end to the practice of paying a special differential for routine nursing services provided to Medicare beneficiaries. If fully implemented in FY 1981 these actions will save over $300 million.

Professional Standards Review Organizations

PSROs have demonstrated their ability to curtail unnecessary hospitalization. Our evaluations have shown that a well-managed PSRO can make a significant reduction in hospital utilization rates in its community. This Committee has been understandably concerned about the cost of this program. I believe, however, that we are now at the point where continued excessive restraints on PSRO hospital review can cost more in unnecessary health care reimbursement dollars than they save in the PSRO budget.

Our 1981 budget proposes an overall program level of $195 million for PSROs, an increase of $51 million over 1980. This budget increase would allow 91 percent of all Medicare and Medicaid admissions to be covered by PSRO review, finance more aggressive efforts to control unit costs while maintaining the quality of the reviews, and expand the scope of review to include other hospital-related services.

Medicaid Supplemental

The fiscal year 1980 budget substantially underestimated requirements for Federal Medicaid matching funds. We are requesting a 1980 supplemental of $2.3 billion to meet State estimates of their need for Federal matching funds. Of this amount, $558 million was borrowed from 1980 to pay for 1979 funding requirements. Because of the failure of our national estimating model to project Medicaid requirements accurately, we have returned to the practice of basing our budget request on the aggregate estimates made by the States. Their estimates have been within two percent of actual expenditures in recent years. We believe that this change will improve accuracy of our budget requests. Of the total supplemental requested, $1.5 billion is the result of the Department's underestimate of State requirements in FY 1979 and 1980; $500 million is the increase in the State's own estimates for FY 1980, and $300 million is for prior year claims that will be paid this year.

PUBLIC HEALTH SERVICE

The fiscal year 1981 budget request for the Public Health Service (PHS) is $8.6 billion of which $7.5 billion is for programs considered by this Subcommittee:

The major emphases of this request are:

- To increase the availability of health services to underserved people in inner-city and rural areas, as well as to develop the health care system to be more responsive to the needs of these people;

- To seek innovative and better coordinated forms of prevention and treatment related to mental disorders and alcoholism;

- To promote health and to increase protection against disease and illness;

- To stabilize the number of new and competing NIH research grants, at an appropriate level, in order to facilitate planning and management of the national biomedical research effort.

Providing Services to the Underserved

To increase the availability of services to the underserved the budget includes funding of $1.2 billion, an increase of $141 million over 1980. This will permit the Department:

- First, to expand funding for community and migrant health centers by 14 percent. These centers provide accessible, quality health services to over 5.2 million people annually. Also included is $5 million for selective demonstrations involving State and local governments which will establish networks to plan, provide, coordinate and monitor preventive and primary care programs.

61-400 O - 80 - 2

- Second, to increase funding for the National Health Service Corps by 62 percent. A full strength of 4,528 Corps personnel will be providing primary health services, many in areas of the country where only three years ago there were no medical services whatsoever. The scholarship program will fund 6,700 health professions students who will later serve in these areas; and

- Third, to expand funding for maternal and child health and for family planning programs by $15 million and $12 million, respectively.

Mental Health and Alcoholism

Implementing the recommendations of the President's Commission on Mental Health is a high priority of the HHS budget. The report of the Commission pointed to the need for greater attention to be devoted to the care of the chronically mentally ill, and the special needs of minorities, children and the elderly. The funding requested for mental health services totals $380 million, of which $90 million will support new approaches by community organizations and States in providing services to these target groups through the proposed Mental Health Systems Act.

In 1980, $50 million is requested as a supplemental appropriation to begin implementation of the pending Mental Health Systems Act. However, we are asking you to consider our request for funds at this time in the hope that the authorization and appropriation processes can run parallel so that we may initiate these new programs rapidly.

The alcoholism prevention initiative announced last year, targeting efforts on women and youth, fetal alcohol syndrome, occupational alcoholism programs, and domestic violence, will be implemented in 1980 with a $15 million supplemental. This program will be expanded in 1981 with a further increase of $15 million.

Improving and Developing the Health Care System

Our budget includes an increase of $41 million for developing and improving the health care system.

This budget emphasizes expansion of the availability of primary care services as opposed to more general support for health professions schools. It provides an $18 million increase over 1980, for a total of $83 million, to train additional primary care physicians. There would be over 7,600 Federally supported residency positions.

Past Federal efforts to expand medical school enrollment have been so successful that projections for 1980 are that the supply of physicians will exceed the need. However, there has been a trend toward greater specialization within medical practice and a decline in the number of primary care providers.

The budget also proposes terminating capitation grants to all health professions schools and eliminating Federal assistance for starting new schools. A rescission of the $88 million appropriated in 1980 for capitation grants also is proposed. We are requesting a reduction of $78 million in the support of nurse education programs because the aggregate supply of trained nurses is adequate. The task

now is to keep a higher proportion of trained nurses actively in the profession.

Another important component of the Department's effort to improve the health care delivery system and moderate the growth in health care costs is the Health Maintenance Organization (HMO) program. In the last three years, the Department has helped to establish 107 Federally qualified HMO's, two and one half times the number qualified in 1978. These organizations have proven to be cost-effective alternatives to the traditional fee-for-service approach. HMO development will continue in 1981 with a 19 percent funding increase. In addition to operational support we will be providing specialized training to HMO managers as well as supporting the development of ambulatory facilities.

We also propose first-year funding of $10 million for the newly established conversion and discontinuance demonstration grant program. The Nation's health care system is burdened with a surplus of 130,000 acute care hospital beds. Especially in many of our urban areas, these surplus beds and facilities should be closed or converted to other uses--such as long-term care and outpatient clinics--but the resources for such conversion are not available. Through this new grant program, we can provide financial and technical assistance to a limited number of non-profit hospitals to liquidate outstanding debts, retrain, or relocate affected employees, and convert the facilities to other health services.

Prevention, Protection and Health Promotion

In 1979, the Department published Healthy People, the landmark report of the Surgeon General relating to health promotion and protection, a major initiative of this Administration. In few areas has the Public Health Service so carefully examined the need, developed strategies to meet the need, and computed expected payoffs in terms of savings in future medical requirements, increased productivity, and enhanced well-being of our people.

The budget targets increased funds at the major areas of concern noted in this report. Programs to promote health education in the workplace and community involvement in risk reduction will be expanded by 21 percent. Fluoridation, with its impressive 50 to 1 benefit-cost ratio, will be increased by 41 percent. Programs to disseminate information on how people can improve their health status and/or reduce the chances of serious illness will grow by 148 percent. Also targeted for expansion are programs to protect against environmental hazards.

The FY 1981 request includes funds for a major facilities construction proposal that will, over the long term, improve our research capability to prevent serious illness and disability. A new facility costing $25 million will be built in Morgantown, West Virginia, to enable the National Institute for Occupational Safety and Health to conduct more effective research on the health effects of mining.

Biomedical Research

The National Institutes of Health will receive an increase of $139 million for a total funding level of nearly $3.6 billion. The principal objective of this increase is to provide sufficient funds to stabilize at 5,000 the number of new and competing

research grants awarded annually. The prior years' shifts in the numbers of new grants have made it difficult for both the government and the research community to plan and manage national biomedical research efforts, a problem which this budget seeks to overcome. This is the first time in 8 years that a President has sent a budget to Congress asking for a substantial funding increase for NIH. The Congress has traditionally appropriated considerably more in this area than the President has proposed. In 1981, I believe the $139 million increase for NIH is sufficient to sustain the Nation's biomedical research enterprise.

Also included in the NIH budget is $23 million, for a total of $80 million, to expand the National Toxicology program. Both we and the Congress have been concerned with the need to develop better scientific information to protect the health of the American public from damage by exposure to environmental chemicals.

We are requesting $5 million to staff and equip the new Environmental Health Sciences Facility in North Carolina, due to open in late 1981. It will be one of the most modern and innovative facilities of its kind in the world. We are also continuing renovations of the NIH Clinical Center, thus allowing its functions to be integrated with those of the Ambulatory Care Research Facility, due for completion in FY 1982. A total of $7 million is included for this modernization project.

HUMAN DEVELOPMENT SERVICES

The Office of Human Development Services operates programs which assist and protect some of the most vulnerable people in our society. The fiscal year 1981 budget maintains this basic system of social services and directs budget increases to help those least able to withstand periods of economic adversity. The budget increases permit the Administration on Aging to maintain the current number of meals provided through the Aging Nutrition program despite the increase in the cost of food, direct Head Start funding to serve more migrant children and low-income children in urban areas, especially those living in public housing; initiate a program to aid victims of domestic violence; and implement reforms in child welfare programs which we expect Congress to pass shortly.

Title XX

The foundation of the social services system administered by the Office of Human Development Services is the program of Federal matching grants for social services authorized under Title XX of the Social Security Act. Our 1981 budget will provide funding for services to 4 million people, half of whom are AFDC, SSI or Medicaid recipients. The budget proposes a statutory funding ceiling of $2.9 billion for both fiscal years 1980 and 1981, $400 million higher than authorized by current law. The bill which would increase the Title XX ceiling is now in conference and should soon be enacted.

We are also requesting an increase in funding for State and local training to insure that Title XX funds are used most effectively. The fiscal year 1980 Appropriation Act limited funding for training to $75 million. We are asking that in 1981 training be limited to 4% of the Title XX ceiling, which would provide $116 million. These additional funds are urgently needed to provide the

training appropriate for the implementation of the Department's new day care regulations. We are also asking in the 1980 supplemental that $14 million be provided so that 1979 State claims which spilled over into 1980 will not restrict current training activities.

Aging Programs

The Aging Nutrition program has proven its effectiveness in reaching isolated older people and assuring not only that they have a nutritious diet but also take an active part in the social activities sponsored by the projects. An increase of $30 million is recommended for Aging Nutrition, providing for a total 1981 budget of $350 million for congregate and home-delivered meals. This increase will cover the projected 10-percent increase in the cost of meals during 1981, thereby maintaining total daily meals at the 1980 level of 410,000, up 20 percent from 1979.

The 1978 Amendments to the Older Americans Act established a number of additional planning, management and service requirements which State programs for older Americans must meet. We are recommending an additional $33 million in 1981 to help States provide legal services to defend the interests of older people, hire ombudsmen to protect the elderly in nursing homes, extend services to rural areas, and provide increased in-home services as well as establish community focal points to coordinate services to older persons.

Head Start

Head Start has proven itself as an effective way to help poor pre-school children develop their potential.

This program is vulnerable to the impact of inflation because labor costs increase automatically with statutory changes in the minimum wage. We are seeking an increase of $55 million to offset minimum wage increases and other increased costs of operation to maintain total enrollment at the current level of 373,000 children.

We are also seeking an additional $30 million to expand Head Start services.

- o $10 million of this amount would be directed to the migrant children's program, where we are now serving only about five percent of the eligible children as compared with 20 percent in the regular program. This would serve 15,500 migrant children, up 5,000 from 1980.

- o $20 million would be added to the regular Head Start program to expand opportunities for low-income children in poor urban areas, especially children living in public housing projects. We expect to serve an additional 8,600 children through this effort.

Domestic Violence

Spouse abuse and family violence is a major problem in many communities. Studies show that 4 million incidents occur each year and nearly always the victims are women. Our 1981 budget totals include $10 million to carry out legislation now pending in Congress

to authorize a new program of services to victims of family violence. These funds would support crisis centers and shelters. With the funds requested, we could help 150 projects serve 100,000 victims of family violence.

Child Welfare Services

Legislation proposed by this Administration over two and a half years ago making long overdue improvements in foster care and adoption programs will soon be enacted. When this happens we will propose a 1980 supplemental of $62 million and an additional $107 million in 1981.

Our reforms, which are in both House and Senate bills, stress family reunification of children now in foster care, the avoidance of institutional care where feasible, and the provision of adoption assistance to help in the placement of hard-to-adopt children.

IMPROVED MANAGEMENT

The efficiency of HEW operations has been subjected to unusually intense attention because of the allegation that literally billions of dollars in HEW's annual budget were lost to "fraud, abuse and waste." The debate which stormed around the Inspector General's report and the slogans that it engendered has created the impression that the recipients of the benefits of HEW's programs have been defrauding the Department of staggering sums. This is not true. According to the Inspector General's report itself, only about one-tenth of one percent of HEW's budget costs could be attributed to fraud by beneficiaries.

The key point in the Inspector General's report (which was missed by nearly everyone) is that there is a substantial opportunity in this Department, as in all large organizations and enterprises, to introduce changes in management systems which can achieve our goals at lower costs. It is possible to design intake and eligibility review systems which have a higher degree of reliability than those that now exist. It is possible to design computer systems which review claims for payment and do a better job of eliminating duplicate billings or rejecting ineligible expenditures. Our principal concern is to prevent program misuse and management inefficiencies. Fraud is one aspect of program misuse and we will use all resources available to us to prevent fraud and punish it when it occurs. However, reducing fraud will not produce major savings. What is required to achieve substantial savings is working systematically with managers at all levels of government to design more effective ways of doing the public's business.

I intend to get the highest possible program return on the money in the HHS budget. I am putting new management review procedures in place and I have directed that good financial management be a high priority. I have further directed that new ways to manage more effectively should be pursued systematically throughout the Department in order to achieve savings and and efficiencies in the use of funds. In connection with this budget I can report that for FY 1979 we have so far documented $1.1 billion in savings against an overall plan of $1.3 billion, which is an update of the semi-annual report on documented savings that I sent to the Appropriations Committees on January 9. When the final reports are in we expect to

achieve the $1.3 billion target. These overall amounts include savings in programs which will be transferred to the new Department of Education. Taking these out of the calculation, we have documented $642 million in savings against an overall target of $847 million for the Department of Health and Human Services. For fiscal year 1980, plans are now being developed to save $1.5 billion in HHS programs alone. If these efforts are successful, they will lead to nearly $2.2 billion in savings in 1981. This is an ambitious goal and one we believe we can reach.

Despite this record of progress, Congress had added provisions to the last two HEW appropriation bills which made unspecified budget authority reductions of $1 billion and $500 million respectively, which the Department then had to take from specific line items, based on the presumption that further reductions in "fraud, abuse and waste" would occur. Since the provision does not recognize anything in the Department's savings plan already reflected in the budget, these savings can only be achieved by new actions. We are constantly searching for new economies, but it is ridiculous to assume that the Department can discover and implement systems changes that will produce savings of this magnitude in current year appropriations. This has proved impossible to do in FY 1979 and it cannot be done in FY 1980.

The result is that the cuts in appropriations are reflected in the line items for the open-ended entitlements, specifically, AFDC and Medicaid. When State claims exceed the lower amounts, we borrow from the succeeding year's appropriation and then seek additional appropriations. This is a wasteful diversion of staff time and energy from the important task of management improvement. I urge you not to adopt such a provision in the current appropriation bill.

Staffing

The Department's staffing requirements have been subjected to searching and rigorous review, first within the Department and then by the Office of Management and Budget. The staffing proposals which have survived this arduous review are essential for managing the initiatives in this budget.

Although the Department is requesting this Subcommittee to authorize 1,926 new jobs, 1,708 of them are for National Health Service Corps personnel to be assigned to medically underserved areas, and 55 are for expanding the intramural research staff of the National Institute of Environmental Sciences. This leaves a net increase of only 163 for general management functions.

To make room for higher priority increases in other program areas, we are proposing staffing decreases totalling 499 positions. This trade-off permits us to allocate 662 jobs to high priority management areas.

-- 100 new jobs are requested for the Office for Civil Rights. The 1981 budget places increased emphasis on compliance reviews at health and social service agencies and facilities. Under the Department of HEW this was given inadequate emphasis because of court orders requiring reduction of backlogs of unresolved educational desegregation matters. With the establishment

of the Department of HHS we propose to achieve proper balance.

-- The budget requests 100 positions for the Office of Human Development Services. Although the programs in the agency have grown rapidly in the last few years, the staff available has actually declined. The new staff would better manage OHD's many new responsibilities and the substantial program growth. A major priority will be to improve monitoring and accountability for Federal funds.

-- 88 new jobs in 1980 and 16 in 1981 are for the refugee program. This rapidly growing program needs strong management to get the resources where they are needed at the right time. Forty of the new positions would be assigned to the Public Health Service to monitor the conditions in refugee camps abroad and strengthen initial health assessments when the refugees arrive in this country. Staff would also be made available to the Department of Education to administer aid to elementary and secondary school districts.

-- 170 new jobs are for the Health Care Financing Administration. This new staff is needed to improve the management of this rapidly growing agency. In addition to managing the program initiatives which I have described in the HCFA section of this statement, a portion of this staff will be assigned to promote better understanding of beneficiary rights and benefits under Medicare and at the same time encourage better personal health habits. This effort will involve special mailings to beneficiaries, public service announcements, training beneficiary aides to work among the most severely isolated and disabled, and contracts with public agencies to expand child health outreach.

-- 218 jobs are for Public Health Service programs. They will be used primarily to manage the planned growth of programs to deliver both general health and mental health services to the underserved. We also plan to allocate additional staff to prevention and health promotion activities, particularly for the Center for Disease Control, to provide more active technical assistance to States.

* * * * *

As you review the details of the budget I hope that you will reach the conclusion that it merits your support. This budget is a prudent response to genuine social needs. The President's new foreign policy initiatives have not been bought by retreating from domestic priorities. This budget follows through on major legislative commitments and provides greater resources for those past initiatives which have proved to be effective.

This concludes my prepared statement. I will be happy to answer any questions you may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary HARRIS. It's a pleasure to appear before you today to present the President's fiscal 1981 budget for the Department of Health and Human Services. In a year when an energy-driven inflationary spiral is eroding the value of what a dollar will buy and threatens the quality of all of our lives, the necessity for fiscal responsibility is clear. Inflation touches and affects us all. And it is as President Carter has repeatedly noted the modern-day equivalent of the scourge for the millions of Americans who live in or near poverty. Therefore, the Government cannot ignore the evermore pressing needs of our least fortunate citizens.

I present the Department's budget confident that it charts a reasonable course between the need for restraint and the need of those who depend, especially in our time, upon the constancy of Government policy—the poor, the aged, the sick, the handicapped.

Our 1981 proposal, builds upon the demonstrated concerns and priorities evidenced by the President and his administration during the last 3 years. Our budget and legislative proposals emphasize: in all major respects a policy of current services funding for social security retirement and survivors' benefits, including a full adjustment for cost of living mandated under current law; the administration's continuing commitment to welfare reform, which includes provisions to simplify administration and reduce costs, as well as an additional $800 million in fiscal year 1981 to establish a minimum national benefit and provide fiscal relief for the States; an improved and expanded program of low-income energy assistance for which the President will request $2.4 billion as soon as the authorizing legislation is enacted.

Senator MAGNUSON. Madam Secretary, would you like to be interrupted, or would you like to finish your statement?

Secretary HARRIS. If I could finish the opening statement, and then I will be repeating some of this in an explication of the charts.

Senator MAGNUSON. I just caught one thing in your statement I would like to pursue further—fiscal relief for the States.

Secretary HARRIS. As I said, I will finish this brief overall statement, then with the charts, any interruptions are all right.

The budget includes funding increases of $63 million for selected nutrition and social services programs that serve the Nation's elderly, and $23 million to support new approaches to providing health services and benefits received in one's home; for children, increases of $90 million for Head Start, and a total of $510 million for the two pending legislative initiatives—the child health assurance program, CHAP and the legislation to reform child welfare services; nearly $400 million in increased funding for the Public Health Service; continued emphasis and support for legislative and management initiatives that control health costs; and management initiatives to reduce waste and inefficiency.

INTRODUCTION OF WITNESSES

Prior to moving to the charts, I would like, for the record, to identify, on my left, the Assistant Secretary for Management and Budget, Fred

Bohen, who will assist me here at the table. And with me is also Alair Townsend, who is Deputy Assistant Secretary for Budget at HEW. And to her right, William Welsh, who is the Assistant Secretary for Legislation.

I expect, with your permission, to be joined shortly by the Under Secretary, Nathan Stark, who is before a committee of the other House at this minute. And if you will permit when he arrives, he will join me at the table.

GRAPHIC DISPLAY OF BUDGET

We now have a set of charts which, as I indicated earlier, graphically depicts the budget that we will present.

At the outset it is important to note that these charts exclude those programs dollars and staff that will be transferred to the new Department of Education, and that is true not only of the 1981 figures that we will see in some of the charts, but also for any comparative data for the years 1979 and 1980. We have adjusted all figures to show them without those programs transferred to the Department of Education.

Chart No. 1——

UNAUTHORIZED PROGRAM

Senator MAGNUSON. Before we go into your charts—we try to adhere to a rule that we among the committees deal with things as they are at the time we hear the witnesses, at the time we prepare the bill.

How much of this program is unauthorized, anticipating legislative action that may or may not take place?

Secretary HARRIS. I am told that the total amount is $1.1 billion for such programs as I noted in my statement: child health assurance program, welfare reform, and——

Senator MAGNUSON. Well, now, we have from the Department that it involves $2 billion unauthorized budget items. The National Health Services Administration, $133 million; Center for Disease Control, fluoridation; the National Institutes of Health——

Secretary HARRIS. Mr. Chairman—excuse me.

Senator MAGNUSON. Anyway, they all add up. Put them in the record here. They all add up here to $2 billion.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FISCAL YEAR 1981
UNAUTHORIZED BUDGET ITEMS
(BA in millions)

PUBLIC HEALTH SERVICE		
Health Services Administration		
National Health Service Corps	$133.8	
Center for Disease Control		
Disease Prevention Program		
Fluoridation	$ 3.1	
National Institutes of Health		
National Cancer Institute	$985.1	
Cancer Control		$ 65.1
410A (Research)		920.0
National Heart, Lung, and Blood Institute	$517.4	
National Institute of Arthritis, Metabolism and Digestive Diseases	$ 17.1	
Diabetes Research and Training Center		$ 8.6
National Diabetes Advisory Board		.2
Arthritis Demonstrations		---
Arthritis Data Systems		.2
Multi-purpose Arthritis Centers		7.9
National Arthritis Advisory Board		.2
Alcohol, Drug Abuse, and Mental Health Administration		
General Mental Health		
Community Programs	$367.8	
Health Resources Administration		
Health Professions Education	$309 (which includes all items except "Program Support" funds)	
OFFICE OF HUMAN DEVELOPMENT SERVICES		
Administration for Children, Youth, and Families		
Runaway Youth	$ 11	
TOTAL	$2,344.3	

SUPPLEMENTAL ACTIVITIES

Secretary HARRIS. Mr. Chairman, if the record would note, the Under Secretary, Mr. Stark, has arrived.

Senator MAGNUSON. All right.

Secretary HARRIS. On that figure, I believe that $1.1 billion is the amount that is requested for fiscal year 1981, which has not been authorized. There are additional amounts in the supplemental for activities which have not been authorized. Those would show up in 1980.

Senator MAGNUSON. Well, what is the use of talking about the programs that haven't been authorized?

Secretary HARRIS. One example that would indicate——

Senator MAGNUSON. You could alert us to the problem, but if they haven't been authorized, there's no use in us discussing them.

Secretary HARRIS. May I respectfully submit that something happened today which provides an example of why we believed it prudent to include in the budget certain figures representing legislation not enacted at the time the budget was submitted. This morning, the Senate, as I understand, passed the disability bill.

Senator MAGNUSON. I know. We're aware of it. We've been up there voting all day long on that.

Secretary HARRIS. But the impact of that bill is in our 1981 budget. Both the cost and the savings are represented in this budget, although on the day we sent the budget over that bill had not yet been adopted.

Senator MAGNUSON. It hasn't been adopted yet.

Secretary HARRIS. But it seems to us that it is very likely to be adopted. It would be imprudent for us, given the knowledge we have of the apparent intentions of the Congress, not to provide a full analysis of the costs that would be incurred were the pending legislation enacted. I don't believe in sending up supplementals unless we absolutely have to send up supplementals.

I happen to be one who very much opposes the use of supplementals except where essential. This judgment was made not only with respect to the HHS budget but also with respect to other departmental budgets.

Senator MAGNUSON. I know, but they ought to be separated.

Secretary HARRIS. Well, we have noted those points—for example, the mental health bill, where there is not yet authorizing legislation.

Senator MAGNUSON. Well, what I'm pointing out is that there isn't much use in there being a long discussion on those items until they've come along. We have to deal with the law as it is. I just want to separate them. To restate: unauthorized requests would be about $2 billion.

Secretary HARRIS. For the 2-year period. But for 1981.

Senator MAGNUSON. For that period, $2 billion hasn't been authorized.

All right. Go ahead with your statement.

BUDGET REQUEST

Secretary HARRIS. The overall budget for fiscal year 1981 provides a budget authority of $222.9 billion, and outlays of $219.3 billion. In fiscal year 1981, the Department's outlays of $219.3 billion are, as you

noted in your opening remarks, Mr. Chairman, 35.6 percent of the President's total budget, up from 34.3 percent in the current fiscal year.

Largely because of the growth in social security and medical expenditures, the $26 billion increase in Health and Human Services outlays between fiscal years 1980 and 1981 constitutes 50 percent of the overall increase in Federal outlays in the President's budget.

Chart No. 2: Up to this point, I have highlighted the Health and Human Services total budget which includes outlays——

Senator MAGNUSON. What do you mean by HCFA?

Secretary HARRIS. That is Health Care Financing Administration.

Senator MAGNUSON. And SSA?

Secretary HARRIS. Is Social Security Administration. OHDS is Office of Human Development Services, and DM is departmental management. PHS, as you know, is the Public Health Service.

Until this point, I've highlighted the Health and Human Services total budget which includes outlays, as I noted, from trust funds as well as the appropriations requests considered by this and other appropriation subcommittees.

PROGRAMS CONSIDERED BY LABOR-HEW SUBCOMMITTEE

For programs considered by this subcommittee, the President's 1981 budget requests appropriations of $56 billion including about $1 billion for new legislation proposed in the President's budget—that's the figure you were just questioning me about. This is an increase of about $5.5 billion over our current request for 1980, largely because of the increased requirements in entitlement programs, but also because of enhancement of selected discretionary programs.

I will now turn to a discussion of the budget by agency, beginning with the Public Health Service.

As the third chart indicates, the fiscal year 1981 budget request for the Public Health Service is $8.5 billion of which $7.5 billion is for programs considered by this subcommittee. Overall, the requested funding increase is $372 million with the largest increases proposed in the Health Services Administration and the National Institutes of Health.

Chart No. 4 shows the budget of the Public Health Service by theme.

Senator MAGNUSON. At least you, instead of letters, spell out what the programs are. We're not too familiar with these letters. ADAMHA?

Secretary HARRIS. Alcohol——

Senator MAGNUSON. Well, why didn't you say alcohol? [Laughter.]

Secretary HARRIS. You don't know, Senator, how much easier you are making my job, because that's what I say to my staff. I pick up the telephone and say, "What on earth is GM?" I would not be surprised one day if they told me it stands for good morning. Everything is acronymic in the HEW lexicon, and I must say we are totally together on that, and I hope that the chartmakers are advised.

And it is not just the Secretary who understands the needs, but it includes the Appropriations Committee chairman.

PHS BY THEME

When the Public Health Service budget is organized by themes, the priorities emerge very clearly. They are to increase the availability of health services to the underserved, to stabilize biomedical research, to provide innovative and better coordinated mental health and alcoholism services, and to increase protection against disease and illness.

If we turn to Chart No. 5, we can see the first of the themes and the consequences. Health services for the underserved are increased by $141 million in the President's budget. There is a $49 million increase in community health centers and a $5 million increase in migrant health which would provide health care to an additional 1 million poor people and migrants through 14 new centers and 51 expanded centers. A 62-percent increase for the National Health Service Corps would enable us to assign 4,528 members of the Corps to underserved areas, an increase of more than 1,700 assignees compared to 1980.

Senator MAGNUSON. Now, on the Health Service Corps, $52 million will provide about 2,000 additional members?

Secretary HARRIS. 1,700 is the estimate we make, given the costs.

Senator MAGNUSON. Extra additional?

Secretary HARRIS. That is correct.

Senator MAGNUSON. To what they have now?

Secretary HARRIS. That is correct.

Senator MAGNUSON. It's a good program.

Secretary HARRIS. We think it is, and we think it's very cost-effective.

Senator MAGNUSON. All right.

Secretary HARRIS. An additional $8 million would maintain the Corps scholarship program at the 1980 level of 6,700 health professional students and provide an increase of 7 percent for family planning that will enable 4.1 million women and adolescents to be served.

Senator MAGNUSON. Wait a minute here. Let's get this straight.

Adolescent health—oh, I see. There's no change in that. That's $18 million.

Secretary HARRIS. That is correct.

Senator MAGNUSON. OK.

Secretary HARRIS. But there is an increase, as you can see, in family planning, which includes planning and advice to women, some of whom may indeed be adolescents as part of the family planning activity. But the two should really be seen together.

Senator MAGNUSON. They should be put together.

Secretary HARRIS. We certainly consider them together in looking at the impact of the budget on meeting the needs of underserved communities.

Senator MAGNUSON. OK.

Secretary HARRIS. These efforts to expand services to underserved groups and areas are complemented by programs to develop and improve the health care system more generally.

A funding increase of $41 million is requested to expand by 19 percent the funding for health maintenance organizations; to assist

nonprofit hospitals to close or convert their excess beds to other uses, thereby reducing costs of the remaining beds and expanding the supply of long-term or ambulatory care facilities; and to expand the number of general practice doctors with support for over 7,600 primary care and family residency training positions, despite projections of a general oversupply of doctors.

HSA RESCISSION

There's been a decline in the number of primary care facilities, which this budget seeks to remedy. Because of this projected oversupply of doctors, the budget also proposes terminating capitation grants as well as a rescission of the $88 million appropriated for them in 1980. There may be a correction of that general $88 million figure, as the result of a new analysis by OMB, to no less than $82 million.

NURSING TRAINING

Senator MAGNUSON. Now on the question of nursing, how come you've cut out everything in there?

Secretary HARRIS. We have not provided any funding in the 1981 budget, and as I recall Senator Bayh asked about that and said he was going to have questions about it.

Our analysis of the needs for nursing training shows that we have trained and are continuing to train an adequate number of nurses. The problem is a problem of retention of nurses. Nurses who are trained do not remain in the profession for some reason. Even though they are registered and qualified, they leave the profession; therefore, the need is not for funding of nursing education but for ascertaining why people do not stay in the profession.

Senator MAGNUSON. Well, if they don't stay in the profession, the need is greater, isn't it?

Secretary HARRIS. Not for training, sir. We may have a need, but we don't know what it is. I've been saying for the last several days that I do not think we should use nursing scholarships to train secretaries, and that's what we are doing now. We have a distributional problem. We have a level of competency problem for nurses who have already been trained, who want to do something other than nursing. For that, we have provided additional funding for the training of nurse practitioners and are seeking ways to permit the reimbursement of nursing and various kinds of practice situations.

We are firmly convinced—and I say this, whenever I face those who want nursing scholarships—we're firmly convinced that the problem is a problem within the profession, not a problem with training—that the use of these funds is neither necessary nor justified, given the numbers of nurses that we've trained over the last several years.

Senator HATFIELD. Mr. Chairman?

Senator MAGNUSON. Just a minute. I just want to put these figures in. We've reduced the amount from $106 to $28 million. We've been asking for proof of what you say for a long time, and we've never gotten it. Job openings for nurses are great. We'll go into that. But I'd like some documentation that there's no longer a shortage of nurses. I just don't believe that's the truth.

Secretary HARRIS. Senator, I'm sorry that I do not have——

Senator MAGNUSON. Oh, you're studying it. HEW's been studying this for 6 years that I know of, but hasn't given me any documentation.

Secretary HARRIS. On the first question, Dr. Richmond, the Surgeon General, at the press briefing on Saturday, gave the figures showing the number of nurses in the population. We can give you those figures, which indicate that the numbers of registered nurses have increased in terms of the number of persons that they would serve.

What the reasons are that nurses do not remain in the profession is quite another matter, which the Institute of Medicine is now studying. But we will send you the data on the number of nurses trained. We will give those figures for the period—certainly, I think, the last decade.

At least what I've said about the number of people trained can be documented.

[The information follows:]

Supply of nurses—Trends and projections

Year	Number (000's)	Nurses per 100,000 population	Nurses to population ratio	Graduates from nursing programs (000's)
1960	504.0	282.2	1 : 355	30.0
1970	722.0	356.0	1 : 281	46.4
1975	906.0	427.0	1 : 234	77.1
1980 estimated	1,152.0	520.0	1 : 192	87.4
1985 projected	1,345.0	579.0–584.0	1 : 171–1 : 173	89.2

CAPITATION GRANTS

Secretary HARRIS. Why we have the distributional problem is not quite so clear.

Senator MAGNUSON. Well, that's a substantial funding drop—from $106 to $28 million.

Senator HATFIELD. Madam Secretary, on this question of rescinding capitation grants, you feel there has been sufficient notification given to the institutions so that they can accommodate to this change? As I understand, the notification for rescission came at the time that we received the budget. Institutions have budgetary periods, in which they have to prepare for their programs. They have to consider this in terms of those governing bodies that will have to make an adjustment, perhaps in raising tuition, because I'm sure there will be an impact on the tuition factor in the education program.

So consequently, my question to you is, do you feel by your rescission request coming at this moment that there has been sufficient notification for these institutions that have grown dependent upon this capitation grant program to make such adjustments, not only at the institutional level but at the governing board level, as they will have to, as I said, I believe at least in the State of Oregon, make some compensation in the tuition fee?

Secretary HARRIS. The answer is, yes, I do believe that there has been more than adequate notice, at least of the intention of this administration to try and eliminate these grants. There was indeed the same recommendation made to the Congress last year. Congress provided a partial rescission. Every institution knows that it is the policy of the

Carter administration to attempt to target more effectively the funds that are used for the training of MD's. Institutions that have these kinds of grants would be required to take certain kinds of action even if this budget were not approved by this committee until midyear.

And it's done all the time. As a matter of fact——

Senator HATFIELD. Well, Madam Secretary, let me remind you that there are many States like Oregon that have legislative sessions that meet only biennially. Therefore, they're projecting budgetary requirements not on an annual basis but on a biennial basis. And to announce that in one year and to expect that to be adjusted and accommodated to within that year is just unrealistic in a State like mine.

Now in a State where they have annual sessions of the legislature that can handle those budgetary changes, that's one thing. But I think that once the legislatures and States and schools saw the appropriation, the schools would naturally seek to plan its use. I think it's a lot like this revenue sharing. We said when we extended it, "This is the end. No more revenue sharing."

The Carter administration has come out and said, "We're going to extend revenue sharing." So the record of the Federal Government really meaning what it says about prospective cutoffs of grants and programs that States have grown accustomed to has not always been fulfilled.

I think there has been a little bit of question in their minds whether we're really going to follow through with this capitation. I would be very happy and enthusiastic in supporting your proposal, provided there is sufficient time given for these States to adjust to the elimination of the capitation program.

Secretary HARRIS. The indication that this was going to come was clear a year ago when this budget came over and that a prudent legislature—and I would hesitate to suggest yours is not——

Senator HATFIELD. What is a prudent legislature? [Laughter.]

Secretary HARRIS [continuing]. That a prudent legislature would have provided for a fallback when they met last year—what I call a safety net provision, in the event that this body had agreed to the administration's proposal.

Senator HATFIELD. One last question.

Senator MAGNUSON. We've been phasing out capitation about 20 percent each year, but we haven't agreed to a meat axe cut like this.

Senator HATFIELD. One last question. What sort of study has the agency done to project or to anticipate what kind of dislocations will be experienced by the rescission of capitation at this point?

Secretary HARRIS. There have been, as you know, continuing manpower analyses, and it is the judgment of the Department, as well as those outside the Department—people who are not part of this budget process—if one accepts the analysis that this program is not needed at this moment.

We have not just cut capitation. We have provided for certain other kinds of support. For example, the exceptional need scholarships will deal with first-year students who have exceptional needs and cannot pay medical tuition if it rises. The National Service Corps scholarship pro-

61-400 O - 80 - 3

gram, which is a 3-year program—I guess it's more than that—it would cover the full period of medical education—also provides for full tuition, and I believe a $485 a month stipend.

So support for those students who cannot meet the tuition requirements is to be found in this very budget. And it is student-directed and student-centered, rather than institution-centered, but the result is the same. The money goes into the coffers of the institution.

Senator HATFIELD. If you have any studies, could you provide them for the committee?

Secretary HARRIS. Yes, we would.

[The information follows:]

EFFECT OF RESCINDING CAPITATION FUNDS

When the administration first proposed the phase-out of capitation several years ago, a number of studies and analyses were done. These analyses came to two major conclusions: (1) provision of capitation was not a significant factor in influencing the geographic and specialty maldistribution of physicians; (2) capitation represented only a very small porton of medical school budgets. Very little has changed in the last 2 years which would indicate that these factors have changed. For example, at the $87.7 million level for fiscal year 1980, only 2 percent of the revenues of medical schools are represented by capitation.

In addition, projections reflect that there are now an adequate number of medical school slots available to produce the personnel required for the future. Favorable earnings of health professionals and other attractions of these occupations will continue to draw a large number of qualified applicants for these positions. There are many alternative scholarship and loan programs, both at the State and Federal level, to aid in support of qualified students. The loss of capitation support to the medical schools will not seriously affect these students.

PREVENTION, PROMOTION, AND PROTECTION

Senator MAGNUSON. We have to go up and vote.

[A brief recess was taken.]

Senator MAGNUSON. All right, go ahead.

Secretary HARRIS. The seventh chart shows our prevention, promotion, and protection budget. You'll see the prevention at the head. You have that chart.

In 1979, the Department published, "Healthy People," the landmark report of the Surgeon General relating to health promotion and protection, a major initiative of this administration.

The 1981 budget continues to stress the importance of preventive and protective measures and includes an increase of $46 million for these purposes.

In particular, I would call your attention to our $10 million request for prevention grants to the States, to increases in environmental and occupational health programs, and the $25 million requested for a new occupational safety and health facility for conducting health research on miners.

BLACK LUNG FUNDING

Senator MAGNUSON. Regarding the mining program; we have all kinds of money in the black lung appropriations, and there's a great deal of money for research.

Now isn't this overlapping?

Secretary HARRIS. No. It's reinforcing. It's a facility within which to do necessary research.

Senator MAGNUSON. I think we've appropriated $1 billion, $2 billion for black lung. Included in that is all kinds of occupational safety and health money for prevention and things of that nature.

Well, we'll take a look at it, but I want to see for the record whether there's any duplication.

Secretary HARRIS. The black lung program is essentially a program to compensate those with the disease.

Senator MAGNUSON. I know what it is. I've been on it for years. But there's a lot of money in there for prevention, to protect miners' health and everything else, as well as occupational safety money.

It includes a lot of extra things, besides just black lung.

Secretary HARRIS. I understand. This is a facility within which research will be conducted, a facility that is designed——

Senator MAGNUSON. We shouldn't have any facility on just black lung because there are millions of dollars on black lung already.

Secretary HARRIS. This is health research on the overall problems of mining.

Senator MAGNUSON. Well, we'll see. Let's not have any overlapping. Then, on to smoking and health; you have no change.

HEALTH EDUCATION AND PROMOTION

Secretary HARRIS. We have no increase in that item. We believe that the items in this budget are all reinforcing of each other, and that funding for health education and promotion will assist us to move toward the understanding of all of those activities that are required to improve the quality of life. And that is increased by $7 million.

And, in addition, we have a new item in the budget of $10 million called prevention grants to the States. As you can see there, there's the $10 million right below the $7 million.

PREVENTION GRANTS

Senator MAGNUSON. What would be the nature of that?

Secretary HARRIS. The grants will go to States.

Senator MAGNUSON. For what?

Secretary HARRIS. For the purpose of developing prevention strategies and programs in local communities to change lifestyles.

For example, if you needed community facilities to bring together local nutrition programs which are partially preventive——

Senator MAGNUSON. Not any new organization?

Secretary HARRIS. As a matter of fact, the kind of thing that might be very useful would be to have a one-stop shopping activity where everybody in the family could receive preventive health counseling.

Senator MAGNUSON. But it's an overall approach.

Secretary HARRIS. That is correct.

Senator MAGNUSON. I think it's good that you're starting that.

Secretary HARRIS. A major concern of the Department is lifestyle change rather than treatment support.

We are finding that if people change the way they eat, the way they live, they may not need so many hospital facilities to cure them.

BIOMEDICAL RESEARCH

The next chart, Chart No. 8, shows that a major achievement of this budget—provision of funding to stabilize the number of new and competing research grants of the National Institutes of Health at approximately 5,000 each year.

In the past 5 years, the number of new and competing research grants has vacillated widely from year to year averaging about 4,700 a year.

The administration's decision to use the 5,000 level as a guide to the present and future funding for NIH will greatly facilitate planning and management of national biomedical research efforts.

This is a major policy improvement, I believe, for the NIH budget to focus——

Senator MAGNUSON. We'll be taking a look at that.

Secretary HARRIS. I know. You will make the whole research community happy if you agree with us on the 5,000 steady State funding.

The ninth chart indicates that we are implementing the recommendations.

RESEARCH TRAINING

Senator MAGNUSON. Wait a minute. How much of an increase for training do you have in there?

Secretary HARRIS. We do not have an increase in the number of training grants. We have, in fact, a decrease in the number. We have an increase in research support, amounts for individual stipends.

But we have decreased the total amount of money because we have looked at the training needs and have determined in terms of overall strategy that we would be better served to have a reasonable annual stipend and reduced numbers of persons.

Senator EAGLETON. What does that mean, Madame Secretary? Could you spell that out a little bit more?

Secretary HARRIS. Yes; again, we believe that rather than having a dollar target for the number of training stipends that we provide, we ought to look at the overall needs of the scientific community and come up with the number of training grants necessary to have a reasonable growth in the number of new researchers. We have not set any given number for any given period the way we have with research grants. We will see in every year what the number will be to maintain the level that is required.

We went back and forth over this at some length, and it is my belief as I have interrogated the research community at NIH, that the level of training grants will make certain that people of the right age, the right status, and the right research needs will be accommodated by these training figures.

Senator EAGLETON. OK.

Senator MAGNUSON. You have put all your eggs in the research grant basket, then? You have allowed nothing for training centers, equipment, or any new programs?

Secretary HARRIS. That is not nothing. It is that we have looked very carefully at the places where we wish to put the money.

The new and competing grants are in themselves in support of maintaining levels of research personnel. They're not disconnected. They are not separate programs.

And in order to determine what is needed in research personnel, you have to see how many people there are in intermural research, and how many there are in intramural research, to see whether or not the level is adequate.

It is not just the Federal Government that provides this training; it is the Federal Government with the private sector scientific community.

Obviously, it would be good—I suppose it would be nice in a different period to have a surplus of people beyond that which is actually needed.

STABILITY IN RESEARCH

But we believe that we are funding the real need for maintaining stability in training.

Senator EAGLETON. I might say, Madame Secretary, I think you've got a difficult burden of persuasion on this issue. But we'll certainly want to go at it in great detail when Dr. Fredrickson and his colleagues are here.

Secretary HARRIS. Yes; as I say, these decisions have been made in cooperation and consultation with them.

And we also assume that this body will continue its concern to get what in another age was called the biggest bang for the buck.

And we have made the kind of analysis of need that in my judgment has not deprived the scientific community of those basic supports that are essential to maintain all our goals.

That means some places may not get everything that is nice to have, but I believe that this budget provides everything we need, which has been the test for this budget.

MENTAL HEALTH

Chart No. 9 shows that implementing recommendations of the President's Commission on Mental Health is a high priority of this budget.

The report of the Commission pointed to the need for greater attention to be devoted to the care of the chronically mentally ill and the special needs of minorities, children, and the elderly.

Our funding request for mental health service programs totals $380 million, of which $90 million will support services through the proposed Mental Health Systems Act.

That, again, is an unauthorized program. It is one that we believe we should provide the opportunity for funding.

Senator MAGNUSON. All right. You've called our attention to it. Let's skip it.

HEALTH CARE FINANCING ADMINISTRATION

Secretary HARRIS. Chart No. 10, which is the Health Care Financing Administration. The bulk of our health dollars, of course, flow through the medicare/medicaid programs administered by the Health Care Financing Administration.

HCFA will finance health care for 47 million beneficiaries in fiscal year 1981, 700,000 more than in 1980. Total outlays are expected to reach $53.2 billion, $5.4 billion higher than the current estimate for 1980.

For the programs of HCFA subject to the appropriations process, we are requesting $25.7 billion. Although the major factors in the budget increase are the continued rise in the cost of health care and the growth of the aged population, the budget and legislative program contains a number of new proposals to extend coverage to underserved populations, reimburse new services and providers, and continue to fight for effective restraints on health cost inflation.

MEDICAID PROGRAM

The majority of HCFA appropriations are for the medicaid program. Our request under current law is for $15.7 billion. You'll find that on the chart under pending requests, Mr. Chairman.

The President's total request for medicaid is $16 billion, which includes $403 million to implement the administration's child health assurance program, which would extend medicaid eligibility to 2 million poor children and 100,000 low-income pregnant women.

Again, that has not been adopted, but it has been passed by the House of Representatives, is in the Senate, and is a piece of legislation for which we have provided funding information and requests to this committee.

HOSPITAL COST CONTAINMENT

Senator MAGNUSON. Last year, the Presidential budget was developed on the assumption that significant savings were to be realized in the enactment of the hospital cost containment bill. And that enactment isn't happening, and it doesn't look to me like it's going to happen. I'm personally all for it.

Secretary HARRIS. Mr. Chairman, I must say to you in advance that this budget, too, proposes savings from the hospital cost containment legislation. And as we will show with a chart that comes later, we have put into this budget significant savings from hospital cost containment which we urge upon this body.

Senator MAGNUSON. I know, I know. You have a sympathetic ear with the chairman and with the Senator from Missouri and others here.

But it isn't going to happen. I don't think it's going to happen this session. I hoped it would.

I talked with the President about this on many occasions during our breakfast meetings, which you've been to. He keeps talking about the necessity of hospital cost containment.

The Speaker of the House is all for it, and most everyone else. It's a No. 1 priority. The House got the bill last year, but it just doesn't look to me like it's going to happen.

Anyway, you're calling our attention to it.

Secretary HARRIS. If we don't, the costs that will be reflected——

Senator MAGNUSON. Will be greater.

Secretary HARRIS. 16.3 percent will be the increased costs.

HEALTH CARE FINANCING ADMINISTRATION

Senator MAGNUSON. I notice that you have administration costs rising from $59 million in 1979, to $65 million in 1980, to $75 million in 1981.

Secretary HARRIS. $3 million of that is pay raises that were approved by this body in 1979.

Senator MAGNUSON. That's a reasonable amount.

Secretary HARRIS. We believe so. $2 million would represent the combined cost of the administration of CHAP, should it be enacted, and the cost of hospital cost containment, should that be enacted.

MEDICAID SUPPLEMENTAL

Before we move on to social security, I do want to call to your attention to the medicaid supplemental, on the same HCFA appropriations summary chart.

The fiscal year 1980 budget substantially underestimated requirements for Federal medicaid matching funds.

This is the chart that I was on before.

Senator MAGNUSON. By how much?

Secretary HARRIS. $2.3 billion to meet State estimates of their needs for Federal matching funds.

Because of the failure of our national estimating model to project medicaid requirements accurately, we have returned to the practice of basing our budget estimates and our budget request on the aggregate estimates made by the States. Their estimates have been within 2 percent of actual expenditures in recent years.

We believe that this change will improve the accuracy of our budget requests and that the total supplemental requested of $1.5 billion is a result of the Department's underestimate of State requirements in fiscal years 1979 and 1980. $500 million is the increase in the State's own estimates for fiscal year 1980 and $300 million is for prior-year claims that will be paid this year.

DELAY IN STATE MATCHING FUNDS

Senator MAGNUSON. Have they been paying their costs?

Secretary HARRIS. I'm sorry?

Senator MAGNUSON. Have the States been matching?

Secretary HARRIS. They've been matching, yes, sir.

Senator MAGNUSON. And paying it cash on the barrelhead?

Secretary HARRIS. I wouldn't quite go down the line and say that in every instance it's cash on the barrelhead.

We only pay our share.

Senator MAGNUSON. We pay our share and they delay with their share. Some of them are so far behind—take a look at that. You're new down there. Take a look at it. We had to have a stipulation last year in the appropriation that they had to pay within 2 years. Some of them are still behind.

Secretary HARRIS. We are adamant about not paying claims until they have been certified by the State.

Senator MAGNUSON. I was going to say that some States are 4 years behind. But some States are up to 7 years behind.

Secretary HARRIS. What payments are they 7 years behind on?

Senator MAGNUSON. Well, medicare payments.

Secretary HARRIS. Not to the beneficiaries. Are these on claims that we have made that we should not have made to them?

Senator MAGNUSON. If States don't match, we shouldn't make the payments. But we've been doing it anyway. We are a very compassionate organization.

In a compassionate organization, we've been paying our share and the States have been falling behind.

Secretary HARRIS. I know now what you're referring to. This is the late claims by States which we tend to pay over time.

We are recommending with this budget that we give them 2 years to make their claim.

Senator MAGNUSON. Because we directed within at least 2 years. [Laughter.]

Secretary HARRIS. We agree with this and we do propose that there be the limitation of 2 years. We believe a 1-year limitation is not a realistic one, that it does not give States——

Senator MAGNUSON. We'll be lucky if we get them to pay it within 2 years.

Secretary HARRIS. I've been saying that I don't think that we have any disagreement, that 4 and 7 years is too long.

Senator MAGNUSON. Well, that's an extreme case.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Secretary HARRIS. In addition, our 1981 budget proposes an overall program level of $195 million for PSRO's—professional standards review organizations.

Senator MAGNUSON. What is that?

Secretary HARRIS. Professional standards review organizations.

Senator MAGNUSON. What organization is that?

Secretary HARRIS. It's an institution that reviews the admissions to hospitals, and the appropriateness of admissions to hospitals. Their efforts in reviewing the utilization of medical facilities has resulted in a reduction in unnecessary hospitalization.

We have found over the years that——

Senator MAGNUSON. Who are they composed of?

Secretary HARRIS. They're composed of health professionals who understand when it is necessary to utilize medical facilities.

Senator MAGNUSON. Have they saved money?

Secretary HARRIS. Yes, they have saved money.

Senator MAGNUSON. They apparently haven't saved much money. Isn't that the same amount? You've got $31 million requested for them.

Secretary HARRIS. We're proposing an expansion of the program. We believe that the PSRO is a much better utilization review process than the utilization review committee.

We are required to do these reviews by law. Failure to have them done by PSRO's, which operate under the guidance of the Department,

means that they will be done by utilization review committees and the Government will pay for them. They will pay for them either out of the medicare/medicaid——

Senator MAGNUSON. What does the Government have to pay? Their salaries?

Secretary HARRIS. They have to pay the cost of the review of utilization of the facilities.

Senator MAGNUSON. What mainly is the cost of the review?

Secretary HARRIS. It really is a kind of audit cost. What it costs to go in and take a look at the reason a patient was put into the hospital.

Senator MAGNUSON. It wouldn't be salaries?

Secretary HARRIS. Well, partly salaries. But whatever it is——

Senator MAGNUSON. Well, there can't be any equipment.

Secretary HARRIS. There could be calculators and accounting machines. It is that cost per unit of review represented by the total of what goes into making the review.

We will be getting the cost of PSRO review down to about $8.70 a patient in utilizing the PSRO's.

Senator MAGNUSON. How are the review members appointed?

Secretary HARRIS. They're organized by the local community. I'll submit more details for the record.

[The information follows:]

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Professional standards review organizations (PSRO's) are designated by the Department. They are private, nonprofit organizations whose membership consists of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery. These local organizations are responsible for reviewing the quality of care provided to medicare, medicaid, and title V patients, and for determining whether the care is provided in the appropriate setting.

CERTIFICATION OF PSRO'S

Secretary HARRIS. We evaluate the effectiveness of the PSRO's and we have, as a matter of fact, defunded and refused to continue certification of inefficient, ineffective PSRO's. But they are locally established and determined. But we review.

Senator MAGNUSON. Well, who picks them?

Secretary HARRIS. The medical society, basically.

Mr. STARK. The State board.

Senator MAGNUSON. Do they pick out certain doctors?

Mr. BOHEN. These doctors are independent of the institution being reviewed. And that distinguishes——

Senator MAGNUSON. How can a doctor be independent of a hospital?

Mr. BOHEN. That distinguishes this from the utilization review program, which is part of the hospital.

Senator MAGNUSON. I'm not saying that this is wrong.

Mr. BOHEN. They're in the same fraternity, but they are not reviewing themselves.

Secretary HARRIS. They're part of the panhellenic, but not in the same fraternity.

Senator MAGNUSON. All right.

Secretary HARRIS. We are asking for the increased funding, as you know, for the PSRO's. If you don't have any more questions about that chart, we'll move on to the Social Security Administration and the appropriations amounts for that responsibility of this committee.

SOCIAL SECURITY ADMINISTRATION

As you know, this committee appropriates only a small portion of the funds expended by the Social Security Administration. On an overall basis, as I mentioned earlier, the only social security benefit reforms are of a minor, largely technical nature. We estimate 35.9 million social security beneficiaries, 600,000 more than in 1980, will receive cost-of-living increases projected at 13 percent in 1980, 9.9 percent in 1981.

I'm sure that this committee has recently heard about the impact of current economic trends on the social security trust fund.

However, the combined trust fund—old age and survivor's, disability and hospital insurance—is healthy and includes adequate reserves.

Thus, the Administration is proposing legislation to enable the old age and survivor's fund to borrow from the other two funds to meet short-term requirements.

We believe that this is a logical short-term response. Obviously, however, the increased payroll tax rate and wage basis built into current law will be required to maintain the trust funds overall.

Senator MAGNUSON. Well, now, let's get this straight. We appropriate for assistance payments.

Secretary HARRIS. That's correct.

Senator MAGNUSON. Approximately $6.8 billion—no, $6.7 billion.

Secretary HARRIS. Yes, that's 1980.

Senator MAGNUSON. Out of the General Treasury.

Secretary HARRIS. That is correct.

Senator MAGNUSON. And what specifically is that for? I know it's for some disability payments.

Secretary HARRIS. Aid for families with dependent children, and an additional amount for supplemental security income, the SSI program.

Senator MAGNUSON. Well, I'm not talking about supplemental program. I'm talking about just social security. I understand the supplemental, the SSI program, but that's another issue.

Secretary HARRIS. That is correct, and so is the aid for families with dependent children.

Senator MAGNUSON. That's in addition?

Secretary HARRIS. That's correct.

Senator MAGNUSON. There are certain disability payments?

Secretary HARRIS. The disability payments come under the trust fund.

Senator MAGNUSON. The $6 billion then is mainly for welfare programs.

Secretary HARRIS. That is correct.

Senator MAGNUSON. Programs that are in addition to regular social security. Is that correct?

Secretary HARRIS. That's correct.

FEDERAL GOVERNMENT PAYMENTS

Senator MAGNUSON. So that the Federal Government is paying out of the general fund $6 billion, close to $7 billion a year.

Secretary HARRIS. For SSI?

Senator MAGNUSON. No, no, no. Leave SSI out. For system payments. It's an additional $6 billion for SSI; that's close to $13 billion total. The total trust funds for social security amounts to $100 and some——

Secretary HARRIS. $137 billion.

Senator MAGNUSON. $135 or $140 billion. So when we talk about social security staying on its own feet, which is what we intend it to do, we're having to dip into the General Treasury for other related matters.

Secretary HARRIS. Other matters which are not concerned with the trust funds and are not intended to be.

Senator MAGNUSON. Which is why it should be by law.

Secretary HARRIS. That's correct.

Senator MAGNUSON. I know people don't understand that because lots of people have the impression that social security pays its own way, and should. But this trend I don't like. But I can't do anything—one lone Senator can't do much about it.

If I had my way, social security would be run by an independent agency and just be an insurance program, which is what it is.

Put this in the general fund where it belongs under welfare.

Secretary HARRIS. Along with the welfare programs——

Senator MAGNUSON. It shouldn't be hooked onto the social security trust fund.

Secretary HARRIS. But some of this income is used to supplement social security income.

Senator MAGNUSON. I know, but it shouldn't. It should be listed as a line item in welfare. As for the SSI program, if you want to give some people more money, we ought to say so and not attach it to social security, which people have been paying out of their salaries and things of that sort.

Anyway, there's about $13 billion extra added to regular social security payments.

Secretary HARRIS. $16.9 billion we're requesting here.

Senator MAGNUSON. Added to the regular social security.

Secretary HARRIS. That is correct. Of which $8.1 billion is for assistance payments and $6.9 is for the SSI program.

REFUGEE ASSISTANCE

Senator MAGNUSON. And then there is refugee assistance.

Secretary HARRIS. Refugee assistance is included.

Senator MAGNUSON. That shouldn't be in social security.

Secretary HARRIS. In this appropriation we fund programs that are administered by the Social Security Administration.

ADMINISTRATION OF SOCIAL SECURITY

Senator MAGNUSON. We get social security mixed up in the end with a lot of welfare programs.

Secretary HARRIS. The difference is that they're administered by an institution that knows how to deal with the people who are beneficiaries.

They're not financed out of a trust fund, but they're administered by a program.

Senator MAGNUSON. I know. We're mixing welfare payments with social security, and we shouldn't.

Social security should stand on its own feet as a social insurance program, which is what it is.

Secretary HARRIS. But we have added benefits.

Senator MAGNUSON. In fact, social security shouldn't be in the welfare budget.

Secretary HARRIS. I feel it necessary to say that at this point, I see no reason to argue that issue.

Senator MAGNUSON. Well, I tell you. You want to know how it happened? It was political bookkeeping. It's still political bookkeeping.

Secretary HARRIS. Well, Mr. Chairman——

Senator MAGNUSON. This is because one administration was accused of spending too much money for defense and not enough for social needs and said, well, let's put social security in the budget. Then we can show we're spending more for social needs than we are for defense.

And it's been in there ever since. It's political bookkeeping, that's what it is.

Secretary HARRIS. But we have made some decisions that we will provide a retirement base for people that is not purely dependent on the exact amount that persons who have retired have paid into social security.

Senator MAGNUSON. All right. But I'm not questioning that. I'm questioning where you place it in your budget.

The budget should be separate and limited to welfare payments, and not include social security.

Secretary HARRIS. Well, I'm not sure that we ought to make the distinction by terminology.

Senator MAGNUSON. Oh, but this is getting a foot in the door to the Treasury, to the general fund.

Secretary HARRIS. Well, let me say that in the long run, we will have to make policy decisions about the kinds of benefits we wish to provide for the retired.

Senator MAGNUSON. All right. Then put them over there as welfare payments.

Secretary HARRIS. I think we differ about whether or not income replacement programs should be distinguished on the basis of whether they are financed from payroll taxes or financed some other way.

Senator MAGNUSON. Why shouldn't we make a distinction? Why shouldn't we let the people know what they're paying their taxes for other than just knowing that it's taken out of their pay?

Secretary HARRIS. I think the question is whether the burden should be forever at the payroll tax level for every income replacement program that we provide for workers.

PAYMENTS TO SOCIAL SECURITY TRUST FUNDS

Senator MAGNUSON. Oh, no. I'm not questioning these programs. But they ought to be listed as welfare programs. Social security didn't start out this way. It started out as social insurance; everybody that paid in could take it out.

It didn't have anything to do with welfare at all. But it's gradually getting there. And this will increase that trend.

Now, payments to social security trust funds; what's happening? Why do we have to pay into the trust fund? I see that's dropping.

Secretary HARRIS. These are the people who are, indeed, not covered by their own contributions to social security. These are people who reach age 72 and, by what I consider excellent legislation of this body, are entitled to social security payments even though they have not paid into social security.

This is a replacement to the funds under social security for everybody who reaches 72 but was not covered at the time that he or she was in the work force.

This is an excellent example of the use of the Social Security Administration and general revenues to achieve income replacement without calling it welfare or suggesting that it is, but providing for it through a replacement by general revenues.

Senator MAGNUSON. Well, it is welfare.

Secretary HARRIS. I think social security is welfare in the sense that the preamble to the Constitution——

Senator MAGNUSON. With social security you pay your wages in as insurance. This is welfare. And let's call it what it is.

All right, go ahead.

UNCASHED SOCIAL SECURITY CHECKS

Senator SCHWEIKER. Could I ask a question on social security?

Madam Secretary, I understand there's $150 million in uncashed social security benefit checks. And I understand that because of these uncashed checks, this budget authority goes into limbo and deprives the trust fund of the use of the money.

My question to you is: What administrative procedures might it take to resolve this problem? And has SSA done anything to restore the budget authority that it's losing?

Secretary HARRIS. We do have a proposal that we expect to move to this body which will permit us to credit these uncashed checks to the States and appropriately utilize the funds.

We have not had an appropriate procedure for dealing with that.

Senator SCHWEIKER. So you feel you need additional legislative authority?

Secretary HARRIS. We believe we do.

Senator SCHWEIKER. I would be supportive of that because I could see where it would be a real hindrance to administering the program if you get people who, for one reason or another, don't cash their checks.

Senator SCHMITT. Would the Senator yield? Would you expect that to be a certain percentage of the uncashed checks or, after a certain period of time, an uncashed check would be considered invalid?

Secretary HARRIS. I have not seen the proposal. But I would assume that we ought to have a temporal limit on the checks, that old checks ought to be dealt with after people are given a reasonable amount of time to cash them.

I would think a percentage would not acheive the goal at the end, which would be to bring up budget authority in order to take care of the trust fund means.

Senator SCHMITT. It might be administrative.

Secretary HARRIS. Our proposal, I'm advised, will provide for 3 years. Checks that have not been cashed for 3 years.

Senator SCHMITT. I'm just suggesting that, administratively, it might be simpler just to look back and do an analysis of the cashing history and say that, at any given time, 75 percent of that can be assumed to be available without risk, 75 or 25 percent.

From an administrative point of view, it might be simpler just to figure a percentage and adjust it, and, with time, come up with the right percentage.

Secretary HARRIS. If we start now, we'll certainly be much better off if we go back 3 years and everything before and deal with that.

And I think it will not be necessary to do that kind of estimate until we've dealt with the backlog from the past.

REFUGEE EDUCATION

Senator SCHWEIKER. One other question on social security.

As I understand your budget message, you are not requesting funds under the authority of the Indochinese Refugee Assistance Act. Congress appropriated $12 million under this act in last year's continuing resolution. This year it appears the Social Security Administration will be running all of the refugee programs. SSA's expertise is in the welfare field. Why are no funds requested for the Department of Education?

In other words, this was education money that we passed for the education of refugees and we're putting it into the Social Security Administration.

My question is why?

Secretary HARRIS. First of all, we made a budget decision to concentrate all of the funds for refugees within the HEW budget.

The education programs will be administered by the Department of Education. We will not administer those programs that relate to State education. But because when I got to HEW I discovered that everybody had responsibility, nobody had focus, we've been persuasive in concentrating and coordinating the analysis of what we need to do with refugees, and, under the leadership of the Under Secretary, we have proposed this budget, which was coordinated with the new Secretary of Education.

ADMINISTRATION OF REFUGEE EDUCATION PROGRAMS

And the education portions, I can assure you, will be administered by the relevant sections of the Department of Education.

Senator SCHWEIKER. I guess, Madam Secretary, what I'm still not clear on is, will the money be used for specific education programs administered by the State education agencies?

Secretary HARRIS. Yes.

Senator SCHWEIKER. Or will it be used for some kind of welfare benefit program?

Secretary HARRIS. It will be used for education programs.

Senator SCHWEIKER. Through the State agencies?

Secretary HARRIS. Through the State agencies, yes, as a matter of fact.

Senator SCHWEIKER. I'm confused as to why you're putting this money in the budget of the Social Security Administration which runs welfare programs?

Secretary HARRIS. We're not putting it in welfare.

Do we have a line item chart to show where that is, so we can identify it in the budget? We are putting it in the overall refugee budget that shows up in the HEW budget. But it will be administered through the relevant State agency that reviews—English language instruction, for example, which we're very concerned about.

Senator SCHWEIKER. OK, fine.

Senator MAGNUSON. So you've pulled together the refugee program?

Secretary HARRIS. We have put in all the amounts for refugees, except, I think, the State Department's voluntary agency. That's not in there, is it?

Senator MAGNUSON. You may have to chop off some of this as you move along.

Secretary HARRIS. We expect to, but we will farm it out.

Senator MAGNUSON. To the Department of Education and to the Department of State and to the States?

Secretary HARRIS. The Under Secretary is coordinating this through the Office of Refugees which is attached to the Office of the Secretary. Somebody must coordinate these activities.

REFUGEE HOUSING

Senator MAGNUSON. This is a little bit beside the point, but something that you would be interested in. I find at home in Seattle, and I guess in Portland, too—they're both ports and all these people are coming in—the real problem is housing. Where do we house refugees, and how would you handle that? Turn that over to Housing, to your old Department?

Secretary HARRIS. Well, I don't know what recent decisions have been made. The Under Secretary may want to speak to this. But we have been talking to the people at HUD about whether or not there is any surplus public housing that might be used.

But given the waiting lists of U.S. citizens in public housing, it's going to be a very, very——

Senator MAGNUSON. You're going to have trouble.

Mr. STARK. That's going to be the No. 1 problem.

Senator MAGNUSON. You get a lot of flak putting a refugee in when someone else is waiting.

Mr. STARK. You put your finger on the No. 1 problem. All around

the country you find vacancy rates of about 1 to 1½ percent. And if they can find additional housing on top of that, low-rent housing, it is very difficult.

The Secretary has spoken to that very forcefully.

Senator MAGNUSON. Seattle has one-half of 1 percent vacancies.

Secretary HARRIS. I used to go around the United States explaining to people, we're having a middle-income housing shortage develop under our noses. There would be no rental housing in this country available to the middle class. I was doing this 2 years ago and nobody paid any attention. And it was clear 2 years ago that we would have this.

And I don't know what we're going to do. I don't have any answers.

Senator MAGNUSON. I guess there's no answer at this time. But find out what you can; get HUD to take a look at it.

All right, let's go on.

REFUGEE LEGISLATION

Secretary HARRIS. I do want to point out a couple of things, though, about the refugee figures. Of the total 1981 budget request of $598 million, $87 million is requested under existing law. Appropriation of the remaining $511 million has to await the enactment of new authorization.

You asked me that at the beginning. I promised I would try to point those out.

For fiscal year 1980, we are proposing a spending level of $524 million, of which $416.9 million can be financed through the continuing resolution and $107 million is requested as a supplemental appropriation.

Senator MAGNUSON. All right.

Secretary HARRIS. If we can go on to the next chart.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Senator MAGNUSON. Now you've got the title XX programs listed. Break that down for the record.

Secretary HARRIS. The title XX, services and training; we're requesting now for 1981 $2,618 million, and with proposed legislation $3,034 million, for a total of $30,198 million for title XX.

Senator MAGNUSON. Break that down—title XX services.

Secretary HARRIS. I'll give you the justifications.

Senator MAGNUSON. Just break it down.

Secretary HARRIS. The grants to States for social services would be $2,751 million; for child day care, $200 million; for State and local training, $116 million; for child welfare services, $163.6 million; for evaluation, $2.5 million, which comes to a total of $3,233 million. That's budget authority.

For outlays it would be $3,150 million.

Senator MAGNUSON. In the charts you've got title XX services, $2,006 million; $57 million for child welfare services; a total of $2,675 million.

Secretary HARRIS. I'm sorry, I didn't hear your question.

Senator MAGNUSON. In title XX, services and training, which you've broken down, you have a pending request of $2,618 million; for child

welfare services, $57 million; which makes a total of $2,675 million. How do you get your $3 billion figure?

Secretary HARRIS. That's with the pending legislation.

Senator MAGNUSON. All right.

Secretary HARRIS. You see, we have it broken down there. One is the pending request.

Senator MAGNUSON. Don't bring up the $3,198 million, because you haven't any authorization.

Secretary HARRIS. As I've indicated, we felt it would be responsible for us to give you those two items broken down and available for you to identify.

Senator MAGNUSON. But actually, you're asking—under present law, you're asking for $2.6 billion?

Secretary HARRIS. That is correct.

Senator MAGNUSON. All right.

Secretary HARRIS. But we would like the $3,198 million. [Laughter.]

Senator MAGNUSON. Why do you keep coming back to the pending legislation? You come back when there's a supplemental. We just don't appropriate money without authorization unless there is an emergency or unless we get to a point before we mark up the bill where we can see the legislation looks like it's 99 percent going to pass.

Secretary HARRIS. That's where we hope you will be at the time you mark up.

Senator MAGNUSON. You stick to appropriation and stay away from legislation with money.

Secretary HARRIS. We will. But you know I don't like supplementals.

Senator MAGNUSON. I don't like them either.

Secretary HARRIS. We try to bring as few supplementals as we can. Therefore, we try to put them in.

HEAD START PROGRAM

Senator MAGNUSON. All right. Now, children in Head Start, you've increased that, which I'm glad to see.

Secretary HARRIS. We have an increase of $90 million for Head Start, and that will maintain the present enrollment and expand it by an additional 14,000.

AGING PROGRAMS

Senator MAGNUSON. And as for the aging programs and nutrition?

Secretary HARRIS. We will maintain that number of persons who receive nutrition services at 410,000.

Senator MAGNUSON. Is that the difference between hot meals, delivered meals, and programs of that sort?

Secretary HARRIS. This will be both. This will be for congregate meals and home-delivered meals.

Senator MAGNUSON. This includes institutional meals and home-delivered? There was an argument last year with us about the total amount of money. But within the fight there was argument between the home-delivered meals program and the institutional meals program over funding.

61-400 O - 80 - 4

Secretary HARRIS. We have told both groups: Go ye forth and do good.

Senator EAGLETON. Those increased dollars do not reflect additional people to be served. That merely reflects the increased price of food?

Secretary HARRIS. That is correct, Senator. We will maintain the present level. We will not increase the number of meals served.

Senator MAGNUSON. In the institutional program, they have an increase of 5 to 6 percent, to provide a hot lunch?

Secretary HARRIS. We provided an increase of about 9 percent to finance all nutrition programs. Then there is also on that chart $280 million, an increase of $33 million, to carry out the provisions of the 1978 aging amendment requiring States to provide legal and other social services for the aging.

And then, finally——

Senator MAGNUSON. Now, I have read an analysis of the budget, but I haven't had a chance to look at it all. There was one statement in the paper that said that 26 percent of the budget was going for the aging.

Secretary HARRIS. I'd say that was for controllable programs and entitlements.

Mr. BOHEN. It was a discussion and analysis across the budget as a whole, including the trust fund.

Senator MAGNUSON. That 26 percent includes everything?

Mr. BOHEN. We're just concentrating here on the nutrition programs.

Senator MAGNUSON. The special programs, yes. This would be included in that?

Mr. BOHEN. This would be included.

WORK INCENTIVES

Senator MAGNUSON. Then let's discuss work incentives.

Secretary HARRIS. Work incentives are not programs, obviously, for the aging. This is the program which is administered basically by the Department of Labor, but for which one is registered at the time AFDC benefits are received. This is the program to encourage AFDC recipients to move into the work force by the provision of certain training and other funds.

Senator MAGNUSON. Are you giving the money to the Department of Labor? I thought the administrative arrangement was just the reverse; that the Department of Labor got the money in their appropriation, and they transferred it to HEW.

Mr. BOHEN. I believe we get the money and they administer the program.

Senator MAGNUSON. So Labor administers the program? That's a program we have to look at when we get to them.

Secretary HARRIS. This really provides opportunity to move.

AUDITS AND THE OFFICE OF HUMAN DEVELOPMENT SERVICES

Senator MAGNUSON. Now for the Office of Human Development Services.

Secretary HARRIS. Yes. We are asking for resources to increase by 100

the staffing for the Office of Human Development Services in order to manage better its programs and improve program accountability. That area is very thinly managed. We need to have annual audits and additional management capacity—we have a whole new set of responsibilities in the day care area.

Senator MAGNUSON. Why don't you take some of your audit staff and give them to some other Department?

Secretary HARRIS. That was one of the questions you were going to ask me about later, why we had not had a better audit management process. We need everybody we have, plus a few more for human development programs.

HEW EMPLOYMENT

Senator MAGNUSON. Well, have you figured out how many people are employed by HEW?

Secretary HARRIS. Most of them——

Senator MAGNUSON. Don't say "most." Give me a figure.

Secretary HARRIS. About 80,000 are employed by Social Security.

Senator MAGNUSON. How many are employed?

Secretary HARRIS. You're talking about the people in addition to the some 140,000-odd at HEW who are funded by HEW programs? We would estimate that we have about 136,000 as of 1979 directly reporting and theoretically reporting to the Secretary. [Laughter.]

Then in addition to that, through our funding, State operations, the funding of activities at universities and nonprofit institutions, community organizations, we estimate that we probably support 701,068 people.

So that would mean that if you wanted a total including those who are employed by the Department in 1979, it would be 837,246.

Mr. BOHEN. We've deleted the education portion.

Senator MAGNUSON. You're coming down a little bit because you haven't got the Education Department?

Secretary HARRIS. That is correct, and we're happy about that. [Laughter.]

Senator MAGNUSON. But out of the Federal till, including education, HEW employees total 1,144,000. That's bigger than the rest of the U.S. Government. If you had a Harris clan picnic on a good July day and gathered all the kids and everything else, you'd get about 200 people, wouldn't you?

Secretary HARRIS. I doubt it.

Senator MAGNUSON. Well, one of them's got to be working for HEW; its bound to be.

Secretary HARRIS. Possibly, possibly.

Senator MAGNUSON. At least one of them.

Secretary HARRIS. Do you know, Senator, how I see those? I see those as jobs that keep people off the unemployment rolls.

Senator MAGNUSON. Oh, don't explain that to me. [Laughter.]

Secretary HARRIS. But you must understand, that's the way I see it. I'm very happy about that, as long as they are being productive.

SOCIAL SECURITY EMPLOYMENT

Senator MAGNUSON. And in all fairness, that employment figure includes thousands of people that work for Social Security.

Secretary HARRIS. Certainly it does, nearly 80,000 people.

Senator MAGNUSON. We've got an awful lot of Social Security employees. There's at least one in each county. Some counties need only 1; some counties need 20.

Secretary HARRIS. 1,300 nationwide.

EMPLOYMENT

Senator MAGNUSON. Employment is a matter that we'll take a good long look at. We'll look at that now. The Federal Government has had a pretty good record in the past few years for total Federal employment; we've had about a 1-percent rise in 10 years.

Secretary HARRIS. It's imperative that we not fail to staff adequately the programs that we're supposed to do, because the lack of regard for the Government is frequently due to the fact, not that people don't work hard, but that we don't provide adequate staffing resources to do the jobs we say we're going to do.

And while I am one who likes to take the fat out, I also want to be sure, especially in the area of management and audit, that we have adequate numbers of people to deal with the problems that we have.

Senator MAGNUSON. You have an adequate number.

Secretary HARRIS. We do need 100 more people in the Office of Human Development Services.

Senator MAGNUSON. You can go around to the 100 departments you have and take one out of each department.

Secretary HARRIS. Well, let me say, if the person is in an office where he or she is not now doing something, it is not because there is not something to be done, but because the person is not doing what is required there. And removing the person will simply make the gap apparent, but will not reduce the need.

Senator MAGNUSON. I should give you all a copy of Parkinson's Law.

Secretary HARRIS. I believe I know all about Parkinson's Law. But I believe that we really have been very hardnosed about the staffing in the Department and have kept the numbers very low.

Senator MAGNUSON. Well, when we go down there we find there's an awful lot of waste in staff.

BUDGET CUTS

Secretary HARRIS. You'd be surprised how many positions have already been cut in this budget. When I got there 6 months ago, I looked rigorously at requests for more people or requests for existing numbers of people, and I assure you, those cuts are in this budget. And I think people, given the reputation that I have been given of being a big spender, et cetera, were quite surprised by the number of people who were cut and the number of dollars that were cut.

Senator MAGNUSON. We're glad to hear that.

Secretary HARRIS. We can provide those details for the record.

[The information follows:]

STAFFING REQUESTS, 1981

The difference between staffing requests to the Secretary and staffing requests in the 1981 budget are shown below:

	Position requests		
	To the Secretary	To the Congress	Difference
Public Health Service	59,693	56,173	—3,520
Health Care Financing Administration	6,068	5,354	—714
Social Security Administration	79,634	78,926	—708
Human Development Services	1,676	1,597	—79
Departmental management	5,823	5,708	—115
Total, Department of Health and Human Services	152,894	147,758	—5,136

[Discussion off the record.]

DOMESTIC VIOLENCE

Senator MAGNUSON. All right. We're moving pretty good now. The next one, the highlights of the OHDS.

Secretary HARRIS. We've already covered those specific figures at your request.

Now I should note that we are asking for $10 million for a new program that services the victims of family violence and spouse abuse.

That's additional money.

Senator MAGNUSON. Now on that program, what specifically do you do? Do you pay them damages? What do you do with these funds?

Secretary HARRIS. This would provide, again——

Senator MAGNUSON. These are primarily State matters subject to State laws. So what do you do?

Secretary HARRIS. We would fund State activity in this area. This would be new programs to help the States develop programs to deal with the growing recognition of domestic violence—shelters——

Senator MAGNUSON. If there's a State that doesn't have a good law, for example?

Secretary HARRIS. We might give them technical assistance for development.

Senator MAGNUSON. But you don't actually give a direct grant to the victim or something like that.

Secretary HARRIS. No; the State might propose to do that and might develop funding for achieving that goal.

Senator MAGNUSON. And do you implement foster care and adoption reform legislation?

Secretary HARRIS. These funds will be used to enable States to develop programs and fund programs to help adopt children, or to return them to their parents.

This will be administered through the States, but the States do not and have not developed programs to achieve these goals.

The problem of the hard-to-adopt children, the problem of reuniting foster care children with their parents, providing the resources to permit this would be funded through this program, which the Congress has initiated.

And this has been adopted in the Senate.

Senator MAGNUSON. Well, we didn't include any adoption clause as such because we couldn't do that. We couldn't have a Federal law of adoption because that's a States' rights matter.

Of course, that isn't much to help out.

Secretary HARRIS. This, again, is legislation that has not been finally enacted, but it has passed both Houses and it's a matter of the conference working out the differences. And it is certain that it is going to be enacted.

Senator MAGNUSON. All right.

SUPPLEMENTALS

Secretary HARRIS. I thought we'd turn to our supplementals and rescissions.

The supplementals for PHS are the ones I particularly want to discuss. We're asking for four supplementals—$10.8 million for the National Health Service Corps, which will enable us to put 970 additional assignees in the field, raising the total field strength to 2,820.

Senator MAGNUSON. We've discussed that.

Secretary HARRIS. This is for the 1980 supplemental. And then $15 million would enable us, again in 1980, to expand the program of grants for alcoholism community services that will be targeted in the high-risk groups of women, teenagers, and selected minority populations.

We're also proposing to transfer $7.2 million from those institutes of NIH with clinical training programs to the buildings and facilities appropriation, to continue modernizing of the clinical center.

It's a very important renovation.

Senator MAGNUSON. When will the center be finished?

Mr. BOHEN. It's a multiyear effort, Senator. It will take place over 6 or 7 years.

Senator SCHWEIKER. What's the total package?

Mr. BOHEN. On the order of $40 to $50 million for about 8 years. We submitted a plan to this committee.

Senator MAGNUSON. Well, you're taking money out of training programs again. I don't want you to come up with a cold turkey of a building.

Mr. BOHEN. Senator, we have done that in the 1981 appropriation. We did not include it in the original 1980 budget because we weren't sure that we could begin this in the 1980 fiscal year.

There is a $7 million request——

Senator MAGNUSON. Yes, we'll take a look at it.

Secretary HARRIS. Finally, we're requesting $2.4 million for financial distress to meet critical deficits in three health professions institutions that provide training for minority health personnel: Xavier School of Pharmacy, the Tuskegee School of Veterinary Medicine, and the Meharry Medical and Dental Schools.

Senator MAGNUSON. These are black schools.

Secretary HARRIS. All three are historically black.

Senator MAGNUSON. All historically black. Tuskegee might have a lot of whites, too.

Secretary HARRIS. That's why I corrected it to say they're historically black.

Senator MAGNUSON. They're mainly black. All right.

Medicaid?

Secretary HARRIS. Yes. That I discussed earlier, indicating——

Senator MAGNUSON. Are you sure your estimates are right?

Secretary HARRIS. Let's say experience indicates that we'll be much better off utilizing State estimates than the national model.

The States have been 2 percent off. But they have been only 2 percent off.

Senator MAGNUSON. We've had it—because these underestimates are going to cost extra. And therefore, we have to have extra people.

Secretary HARRIS. As you know, we spend a good deal of time auditing these figures and these claims to make certain that they are not being padded.

I think I've noted in the discussion on refugees the supplemental we are requesting—I went into detail on the others. I think we also discussed the rescissions at an earlier time. I think some questions were asked about that.

RESCISSION

A $16 million rescission for student assistance loans does not mean the end of that loan program because there will be repayments to the schools' revolving funds. And these repayments will be available for scholarships.

We will simply not be utilizing new money. We're asking for a rescission of the additional amount of $16 million because we believe that the health education scholarships——

Senator SCHWEIKER. The HEAL loans?

Secretary HARRIS. The HEAL loans. And the exceptional need scholarships and the National Health Service Corps scholarships meet our needs.

One of the charts that we have alluded to, the next chart, shows savings in the 1981 Health and Human Services budget. It shows $4 billion in savings that have already been subtracted from the 1981 budget, including $1.7 billion in savings on proposed legislation, such as hospital cost containment.

And of that, the hospital cost containment figure is $780 million.

We believe we must have that savings. Without it, as I indicated earlier, the increases in medical costs will come to 16.3 percent.

We are asking for the elimination of the medicare nursing differential, saving $191 million, and for an implementation of the proposal that there be medicare/medicaid coverage for the working aged.

There's no reason why that insurance should not be paid for people who are working and for other health care financing—child support, eligibility, and management improvement. We also expect to have some savings resulting from welfare reform legislation and $67 million from the disability insurance reforms.

The amount for disability may be altered in conference, but we think it will be somewhere around that.

And then other social security savings.

We have listed a series of management actions under existing law, and we are prepared to give you a chart of the kinds of savings that we have proposed specifically and that we expect to achieve.

But we really need hospital cost containment and all of the program savings that we have noted in our budget if we are not to exceed the appropriations levels that we propose in this budget.

GAO REPORT—NOVEMBER 1979

Senator MAGNUSON. You've read this report from the GAO? Well, anyway, I'll tell you what it says.

It's dated November 1979. Between January 1974 and December of 1978, the GAO issued 84 reports containing 260 new cost-saving recommendations for Federal and State health programs.

At the time I read this report, which you have in your hand, there were only 98 of these recommendations that had been put into effect.

Do you know of any reason why this is?

Secretary HARRIS. Some of them—the first one I note here——

Senator MAGNUSON. Some of them you rejected?

Secretary HARRIS. Some of them we probably rejected. This has not come to me and it did not come to Mr. Bohen.

I have not spoken to the Inspector General about this specifically.

Senator MAGNUSON. Well, there are 164 remaining recommendations.

Secretary HARRIS. But some of these, for example, "the Secretaries of Defense and HEW and the Administrator of Veterans' Affairs can develop a coordinated Federal approach for planning and using computer tomography scans," merely to set up the kind of review among those three agencies.

Senator MAGNUSON. There's no use going into it. Some you're going to reject, and some you're not.

But you keep that report and take a look at it. [Laughter.]

Secretary HARRIS. Let me say that insofar as we find those recommendations with which we agree and that we can implement, you can rest assured that we will move immediately to implement them.

Some of these don't even apply to HEW. For example, "Establishing criteria regarding the number, size, and furnishing of Presidential suites and required Department of Defense approval of the establishment of future suites."

We don't have anything to do with that.

So that's the reason some of these——

Senator MAGNUSON. Most of them apply to HEW.

HEALTH COST CONTROLS

Secretary HARRIS. We have $2.6 billion in savings for health costs resulting from health cost controls that we have implemented ourselves at HEW over the past 24 months.

Senator MAGNUSON. Well, I'll take a look at it.

Senator SCHWEIKER. I'd like to just follow that up.

On page——

Senator MAGNUSON. Just a minute. Go ahead.

Senator SCHWEIKER. On page 174, Madame Secretary, there is a list of things to do specifically for HHS. There are a hundred of them.

So there are very specific things that they do list and I sure think that we'd like to get a progress report on these hundred recommendations.

It just seems to me that when the Comptroller General, whom most of us have a great deal of respect for and who has very practical insight into some of these problems, does list a hundred ways to save money, we really ought to get some feedback as to whether you agree with his finding and what you're doing about them.

But I would like to see a progress report on how you're implementing the savings.

You spend a lot of money, and this report, I'm sure, cost a lot of money. And you can't dismiss arbitrarily a hundred suggestions he's come up with, all affecting health and human services.

I hope to have some followup from you as to what you're doing on it.

Secretary HARRIS. May I comment?

Senator SCHWEIKER. Sure.

Secretary HARRIS. I hope this is a report on which the Comptroller General and the GAO staff have consulted with the Department. I have had the experience over the last few years where there have been reports from the GAO which were commissioned and reported to this body, in which there was not full consultation of the involved Department.

I would hope that this is not one. If it is, it would explain why there has not been full response.

It is my experience that this has happened on very serious matters, and then the Department is held to accountability for something that is here, but without any prior consultation with the Department about why these things have not been done.

We do not know if this is the case. All I know is that the first recommendation which was made—this is the November report—made in November, requires that kind of cooperation between Departments and Agencies that I can tell you does not happen, not only overnight, but in a matter of 2 or 3 months.

I will see to it that we go through these recommendations and ascertain whether or not we have dealt with them.

I will also say to you that just looking very quickly at this with respect to 11–B on page 174, 11–A and B involving St. Elizabeths, that we have certainly been looking at St. Elizabeths as an institution and its management.

In addition, we are looking at the long-range function of St. Elizabeths.

So we will let you know what we have done, what we would have done without GAO's urging, and what we will do because of GAO, and what we cannot do.

Senator SCHWEIKER. One other footnote. On the cover of this report it says the GAO states that 84 of its reports issued from January 1974 through December of 1978 contained these 262 recommendations. So far, only 98 of those going back to 1974 have been put into effect.

So some of these recommendations were communicated to your Department quite a while back.

One policy they always follow in dealing with these reports, in my experience, is they give an advanced copy of the report to the agency people involved and ask for comment on it before they go into final print. And I'd be surprised if you didn't have that.

I'd be interested to know if you didn't have that because that is their policy. That's what they do.

Secretary HARRIS. Senator, may I say that if you had told me this 3 years ago, I would have sat silent. But, unfortunately, as a Cabinet officer that takes these things very seriously, I have had the experience, not at HEW, but at the Department of Housing and Urban Development, of having newspaper stories appear about GAO reports, of which my people have never heard prior to the time that the report appeared, recommending action and condemning the Department.

So I do not know whether this report, indeed, went to the Inspector General and did not go to the Assistant Secretary for Management and Budget.

It did not come to the Secretary; I have not seen it. So I can only say that it is not universally true that the GAO consults with the Department before it makes judgments about what the Department ought to do.

I know that as a matter of personal experience and not as a matter of theory.

I regret it, and as a matter of fact, the day the President announced that I was changing Cabinet posts, I had an appointment to have lunch with the Comptroller, with Mr. Staats, to discuss this very matter.

So it is a matter of some concern.

Senator MAGNUSON. It's incredible that you haven't seen it. It's 4 months old.

Secretary HARRIS. I will check to see whether HEW is responsible and if it is HEW that is responsible, we will implement a procedure such as the one that I put into effect at HUD, which makes it possible for us to know the minute a GAO report is received in the Department. I received at HUD a regular calendar of GAO reports.

Senator SCHWEIKER. Let me just read the opening message from Mr. Staats, Madam Secretary. "We are sending copies of this report to the Director, Office of Management and Budget, the Secretaries of Defense, and Health, Education, and Welfare, the Administrator of Veterans Affairs, and the Director, Office of Personnel Management."

That's in the opening paragraph.

So I'm not disputing what you say, but I think that has been their policy. I'd just be astounded if it wasn't here when it says here on the first page——

Secretary HARRIS. As I say, I do not know with respect to this report. But you may rest assured that I will know by this time tomorrow. [Laughter.]

Senator SCHWEIKER. I believe you. [Laughter.]

REDUCTION OF TRAVEL

Senator MAGNUSON. I've just got a few more quick questions, then I must go.

We mandated in the continuing resolution, a government-wide, although it could be worldwide [laughter] reduction of travel expenses in the amount of $500 million.

What is HEW's share of this reduction?

Secretary HARRIS. $9 million.

Senator MAGNUSON. Have you implemented that?

Secretary HARRIS. Yes; with great difficulty and considerable concern. I am very serious. The alternative to our sending people to do jobs that need to be done away from their normal workplace is that we will be requiring people to come to Washington. There are some things that require a face-to-face analysis of problems.

We certainly are going to take all the fat out, but we reserve the right to come back to you and to suggest that maybe this is not exactly the way to cut. Travel is very important.

Senator MAGNUSON. I get on an airplane coming from Seattle to here, and half of the airplane is filled with Federal people coming and going.

Secretary HARRIS. That may be necessary.

Senator MAGNUSON. Each day, 44,000 Federal employees are traveling. Each day—44,000.

Secretary HARRIS. I can't say that that is bad. It's a question of why they're traveling.

Senator MAGNUSON. Anyway, you are doing it. And that is reflected in your statement.

Secretary HARRIS. That's right.

REPORT OF PAPERWORK REDUCTION

Senator MAGNUSON. The committee requested in its report on last year's bill for the Department to submit by January 15 a full report on its paperwork coordination and reduction activities. It is now almost February, and we haven't got the report yet.

Secretary HARRIS. I thought you had that report. If you didn't receive that report in a timely fashion, I apologize. I thought you had it.

Senator MAGNUSON. Well, get it up here.

Secretary HARRIS. I will get it up here.

Senator MAGNUSON. Otherwise, we're going to ask you how much money you spent for the paper and cut it right in half. [Laughter.]

[The information follows:]

The report on paperwork coordination and reducation, as required in the committee report, was delivered to the committee on January 28, 1980.

Senator MAGNUSON. I mean, actually buying paper. Just cut it in half.

Secretary HARRIS. Senator, the results of that would be that we would probably have problems of inability to monitor eligibility for programs. Paperwork is not generated by people who like to have pieces of paper, but is a result of meeting administrative and legal requirements.

Senator MAGNUSON. You've been around the Federal Government enough to know that paperwork is the love of the Federal Government.

Secretary HARRIS. May I respectfully submit that we do a lot of talking about paperwork. But I don't know how we can avoid having every applicant for social security fill out an application form. That is paperwork.

Senator MAGNUSON. You could simplify the applications.

Secretary HARRIS. Then we will increase the opportunity for fraud.

Senator MAGNUSON. You've got questions and things that it would take a Philadelphia lawyer to answer. [Laughter.]

Secretary HARRIS. With all due respect, Mr. Chairman, I think we can simplify the questions, simplify the forms, and avoid the copies. But as this body becomes more and more concerned about fraud, it is imperative that we have the machinery for checking the validity of applications.

Senator MAGNUSON. You spend 10 times as much for paperwork to eliminate a couple of cases of fraud than the fraud itself.

Secretary HARRIS. This body accepts that. I agree with that. Except that that is fine.

Senator MAGNUSON. Oh, come on, now. You know that you can simplify a lot of the paperwork.

Secretary HARRIS. That we are trying to do. And I think we've done it. But there is a line below which we cannot go. I will assure you I get regulations that are being revised and recommendations for form changes.

PROCESSING OF REGULATIONS

Senator MAGNUSON. The President of the United States did issue an order some time ago when he first came into office, in which he said that every Department head must look at a regulation before it goes out. Do you read all the regulations?

Secretary HARRIS. I read all the regulations I am required to sign. I read them.

Senator MAGNUSON. No; not just that you're required to sign. All regulations.

Secretary HARRIS. No, because there are some that have been delegated by this body to people like the Commissioner of Education. I may review the policy involved. I do not do that any longer. But I do not read those. But those that I sign, I read.

Senator MAGNUSON. You couldn't read them all.

Secretary HARRIS. The ones that I sign? Oh, yes, I can.

Senator MAGNUSON. Well, those that you sign. But you can't read all the regulations that come out of HEW. They're so thick that that's all you could be spending your time doing. But you know——

Secretary HARRIS. The ones that I sign. That's all.

Senator MAGNUSON. The number of regulations is just fantastic.
Secretary HARRIS. I think we've done very well on that, Senator.

PHS HOSPITALS

Senator MAGNUSON. You set up some of the regulations. But let's take a look at them, a lot of the new ones. The school bills, they used to have papers this thick. There's a hospital in Spokane: They have 39 beds, and they have to employ 6 people—they should get along with 3 or 4 to do their Federal forms. Some of these eligibility things are terrible.

And a person that's going on medicare, he can't even sign them himself. He wouldn't know how to sign them. They should be simplified, or get somebody else to do it; H. & R. Block or somebody. It's just terrible.

Well, we went into nurses training. Now, last year, we received the fourth HEW study on Public Health Service hospitals. Does this budget request allow the full implementation of all those recommendations? I mean, you couldn't get all of them.

Secretary HARRIS. We have not made a final decision, Senator, about the future of the Public Health Service hospitals.

Senator MAGNUSON. About the future?

Secretary HARRIS. That is, it seems to me——

Senator MAGNUSON. You don't think you're going to abolish it and get away with it with this committee, do you? [Laughter.]

Secretary HARRIS. The role the hospitals have now is assigned statutorily. In determining a future role, and in evaluating the future role, we must look at the present role and we must look at future needs in the communities in which the hospitals are found. We must examine the budgetary consequences of various approaches.

I have asked that certain questions be answered as we look at the future role of these hospitals in the context of the recommendations that were made last year. It is my hope and expectation to resolve these issues as soon as possible. But there are some major questions of policy with respect to both the PHS hospital system, and their relationship to the communities in which they find themselves.

Senator MAGNUSON. We've gone into that. I don't think you need to make any decisions. This committee has made decisions on Public Health hospitals not once but 25 times. The public wants them.

Secretary HARRIS. That is correct. But how extended should their role be? How do we relate an extended role for PHS hospitals to our statements that many communities are overbedded—communities in which public hospitals exist?

Senator MAGNUSON. Now, that overbedding issue—the administration always comes up with overbedding. We have no proof of that. Public Health Service hospitals are not bed hospitals, to begin with. They only handle emergency cases and a few maritime people, for example, such as they take over at Seattle Hospital. The Seattle Hospital expanded; it's got research facilities; it's got outpatients; and they're located in the worst part of town. And I think they get 20,000 people a month just off the street.

Secretary HARRIS. The Seattle Hospital is literally the flagship hospital of PHS.

Senator EAGLETON. Be sure and protect the flagship. [Laughter.]

Senator SCHWEIKER. That's the bottom line. [Laughter.]

APPOINTMENT OF INSPECTOR GENERAL

Senator MAGNUSON. Now, in the most recent quarterly report, the Office of the Inspector General—oh, say, why haven't you made an appointment for the Office of Inspector General?

Secretary HARRIS. We just haven't gotten to that yet.

Senator MAGNUSON. It's been months.

Secretary HARRIS. We have what no other Department that I know of has. We have a Deputy Inspector General who has been confirmed by the Senate of the United States. The Deputy Inspector General, Mr. Lowe, is an advise-and-consent Presidential appointee. For that reason, he is a person whose credentials have been examined by this body and who has been confirmed by this body. So, it is not as if an appointee of the administration who has not presented himself to the Senate is managing that program. It is that we have an advise-and-consent person who is there, and I have not yet moved to a decision on what will be the final recommendation that I will make to the President for a permanent appointment. It will be as soon as possible.

Senator MAGNUSON. How long will that be?

Secretary HARRIS. I can't tell you that, only because I have not yet come to a decision.

CONSULTANTS

Senator MAGNUSON. There are some questions for the record.

We also requested that HEW cut down on consultants considerably. Has your budget reflected those cuts?

Mr. BOHEN. Yes, sir.

Senator MAGNUSON. As long as the budget reflects it. OK.

Go ahead.

HOURS OF PAPERWORK

Senator SCHWEIKER. Madam Secretary, going back a minute to the paperwork, I just had some other statistical questions. Apparently, IRS generates the biggest paperwork burden in terms of the hours the public must spend filling out its forms. HEW is second, with 58.8 million hours. Labor is third, with 55.5 million hours. Obviously, that's quite a burden that falls on you in that capacity.

Senator MAGNUSON. Is that the amount of paper they buy? [Laughter.]

Senator SCHWEIKER. It's the hours of work in terms of filling out forms.

Apparently, you made some progress. I want to give you some credit. Between 1977 and 1978, HEW did reduce their paperwork some 7½ million hours, which is a rather significant reduction. Unfortunately, in 1978–79, it dropped to 1.2 million.

So, my question is: Whatever you were doing in 1977 and 1978 seems to be productive. Is there any way that we can continue along that line? Because that did appear to be rather effective. That was about a 15-percent reduction, which was really quite a dip between 1977 and 1978, but not nearly as much as between 1978 and 1979.

Secretary HARRIS. First of all, since 1977, this body added 30,307,000 burden-hours through statutory increases in our programs. But let me return to what I said earlier to the chair. I think a look at gross hours is not always productive in terms of making real improvements in programs. I think we should look at it, analyze it, and make sure everything is all right. But everytime we increase the number of people who fill out a social security form, we increase the number of burden-hours.

In preparation for these hearings, I took a look at the burden-hours as opposed to the number of people filling out forms. In the individual form areas, medicare-medicaid, it does not seem unreasonable. The place we get a great deal of burden is when we get into something like hospital reports—when a hospital has to report its management system. And that's probably where you're getting your complaints.

Senator SCHWEIKER. We've got an awful lot from them. No question about that.

Secretary HARRIS. We're trying to improve the program. We'll be certain that SHUR has disappeared. But there is no alternative, Senator.

It's imperative—and I say this for the record—there is no alternative to providing ways to document the things that we need to know in Government, because this body, quite rightly, and the American people, quite rightly, want to avoid fraud in our programs, want to avoid program misuse. And until we have accounting systems that we can depend on, accounting systems that can be easily utilized in determining the activities of those providers of services with whom we deal, we cannot be sure that we do not have program misuse.

We want to make sure that recipients of benefits are the persons which this body intended to receive those benefits. I am very impatient, personally, because I have run small institutions that have had to hire people to fill out forms. In another role I must fill out monthly forms. I don't hire anybody to do it; my husband and I do it.

I don't know any alternatives for securing that information. My household help is entitled to have me record on a quarterly basis what I pay them, what the social security number is, and how much money has been paid. That's paperwork. Everytime somebody hires another domestic worker, we've increased the paperwork burden.

So, while I want to relieve the burden, I also want to put the burden into perspective of what it is we're doing and why we have a burden.

PAPERWORK BURDEN

Senator SCHWEIKER. I can't argue with that. But I can throw up a case that you can't put at HEW's feet, but I am sure putting it at Labor's feet: Whereby there was a contractor for the Federal Government who had three employees and he subcontracted out eight more employees, so he was a Federal contractor. He got called to task for not hiring any women. He has three people that work for him. No office, no secretary. Of the total empolyees, four were laborers.

So he got a notice from the Labor Department saying that he had not complied with affirmative action requirements. Under the affirmative action program you have to hire 5 percent women laborers, which in his case would have been two-tenths of a women laborer.

They threw at him a 10-page conciliation agreement that he had to sign. They made him go through 43 compliance and paperwork steps, including that he post a notice of all parties and company picnics and that he provide separate toilets.

And you could justify completely filling out a social security form, but I'd just throw back at you many silly, asinine regulations like this. You're dealing with, first, no secretary, no office, two laborers, and a 43-page enforcement document as to why he didn't hire two-tenths of a female. You know, they threw the whole book at him. That's the kind of thing that sends these people up the wall.

Now, that wasn't your department, Madam Secretary, so I am not putting that at your door. But that's what drives the people up the wall, and that's what really gets them sore. There's just an awful lot of that out there that we get into our offices.

Secretary HARRIS. May I say to you that I think the person who is angry with us is absolutely right. That is not paperwork burden. That is the lack of good judgment of some employee of the Federal Government who should have looked at the situation and said, "It is not reasonable to apply this rule."

If the system doesn't respond to different kinds of people in different kinds of institutions, it's not a paperwork burden we're looking at; it is the ability of the system to adapt for all of the people who relate to it.

Now, I hope that there was no legislative requirement that made it necessary to have the forms you described. But I would say to the employee who did that, "Your mistake was not taking this to your supervisor and suggesting that he take that to his supervisor and say we should not be asking the people to fill out these forms." He probably—you should excuse me—he probably should have gotten on a plane and gotten out to take a look at that if it was out of town.

But that's the reason we need to keep track of this. [Laughter.]

OMB REGULATIONS ON PAPERWORK

Senator SCHWEIKER. Under the new procedures, I understand that OMB has issued preliminary regulations on paperwork. I don't know if you've had a chance to receive these as yet.

My question is, do you think those will be effective in response to the centralized program for paperwork reduction? I believe you have to submit some kind of an annual plan in terms of collection from the public, including an estimate of the number of hours needed.

But my question is, how is the new OMB proposal affecting you? Are we going to see any results from it, or do you see any problems with it?

Secretary HARRIS. We have sent the OMB regulations to the operating agencies, and we will not be able to answer the question you have raised until we get the responses from the specific operating areas.

There is one thing that pressure always does. It makes people stop doing the unnecessary and the ridiculous. Things that are unnecessary

really do get stopped, even if it sometimes takes a gross effort that may not be totally appropriate. So we will probably have people getting the fat out and the unnecessary things out. Whether or not we can meet the requirements in the Department, we do not yet know. We have assumed we can and we're going to make every effort.

REDUCTION IN AFDC AND MEDICAID

Senator SCHWEIKER. In my opening remarks, I made reference to two things: One was an area that the conferees in the last supplemental appropriation bill directed that by November 30, 1979, final regulations be promulgated to provide for a reduction in the AFDC and medicaid excess payment rates of 4 percent by September 30, 1982, in all States.

The regulations were due last November 30, but we didn't get them until a week ago today, the 24th. I just wonder if there's any explanation for this? There was a clear explicit directive from this committee in conference.

I realize you're new to the job in that respect. But do you have any insight as to what the problem was?

Secretary HARRIS. Well, the problem was not across the street. The problem was essentially in this building. I'm not sure that there is a statute yet embodying that. But let me say that I believe the Department acted in good faith.

Before even the continuing resolution was adopted, the Department put out a notice, a proposal, NPRM, a notice of proposed rulemaking on September 25, 1979. We allowed, I believe, 60 days for comment. And the 60 days, as you can see, came out at November 25. Then we needed the additional 60 days in order to analyze what was a very hotly contested—I have not said it in my comments, but a really questionable requirement that this body has made of the Department.

We have analyzed the comments. We have completed the regulations. And I believe that, despite the fact that Congress did not act with respect to the legislation as legislation, did not devise the continuing resolution, until the beginning of this fiscal year, that we have more than acted in the best faith in which the Department could act on a matter as contentious and questionable as the matter with which we dealt, on January 25.

In short, it could not have been done in accordance with the conference report.

STATE COMPUTERIZATION

Senator SCHWEIKER. One of the biggest areas of potential savings is in the area of computerization of State programs. I have been asking the Department to support a bill that I have gotten as far as conference. Computerization can reduce medicaid costs by 5 percent because it does detect duplication, it does detect the obvious cheating, and it does detect gross fraud.

Now, the fault here primarily lies with the States in not installing the medicaid management information system (MMIS). I have put in a bill that mandates the States act or they will lose funds. I'd be very appreciative if the Department would support that position. I'm not quite

61-400 O - 80 - 5

clear what HHS's position has been on mandatory compliance. I know my own State has been one of the abusers. I'd be the first to admit it, they have dragged their feet on getting their computerization system in. They have five people processing hundreds of claims. They couldn't even turn pages fast enough to tell what the numbers are, let alone look for fraud.

So my question to you is, What might we do to have strong support of the Department for this computerization program? My amendment is now in conference.

Secretary HARRIS. We are supporting the computerization program and giving financial support to them.

I do want to issue a word of caution, as one who would very much like to see the savings in the near term. The mere fact that we get the States to go to computerized recordkeeping does not mean that we will see in the near term the savings you're talking about. It takes a long time to get computer programs and computer systems operating. It always takes longer than I can understand.

We must get started, and the sooner we get 100-percent agreement from the States that they will go this route in the last two decades of this century—we're going to have savings, but it's going to take a while, years.

Senator SCHWEIKER. The problem is that we pay the Federal match for going to computer programs and they've been taking that money for 6 years in Pennsylvania, and we're no nearer a computer program than the man in the Moon. And they've taken this money.

Unless we get tough in the law and say that they can't get that money for computerizing unless they in fact do so within a given time period, it's sort of pretty silly. That's my only point.

It does take awhile. But you know in Pennsylvania it should have been straightened out in 5 years maximum, 3 to 5 years, for computerization. Even now we're not as close to computerization as we should be in my State; I can tell you that.

This kind of situation was exactly what my amendment was directed to. That's just my own State. But there are 20-some States that are very much in that same category. It's a very easy way to save a lot of money quickly. About 20 States have done it, and 20 States have avoided it.

As New York City shows, you can save at least 5 percent of your total costs, and most of the States that have installed this system have saved that much. So it's an easy way to save money. But the Congress and the administration have not been tough enough in saying, you can't have it both ways. We haven't mandated it, either. But I have to get some support from you on this.

Secretary HARRIS. Well, let me say that we are committed to achieving the goals.

Senator SCHWEIKER. I'd still give them a year and a half, or something like that. But you know, they've been at it for 5 years. A company would go broke in the private world if they just said, wait 5 years to computerize the operation.

Secretary HARRIS. They would take 5 years to develop a new paper towel.

Senator SCHWEIKER. The software is all there. They have the procedure. All they have to do is implement it, really. That's not a great deal.

Secretary HARRIS. Senator, I did not spend a good deal of time managing programs in the private sector. But I do know that when the private sector moves into new areas, that 5 years is not an unreasonable length of time. We have to start from where we are. It seems to me we have to look at a situation from where we are and look realistically at what it would take to achieve the goals we have in mind. I think in looking at that, you're absolutely right, we should stop playing footsie with States that have the capacity and we should get tough with them.

But whether an arbitrary period is appropriate, I think is highly questionable. We ought to look at it in terms of each State's present posture and what it would take to get where we want them to go.

Senator SCHWEIKER. That's all, Madam Secretary. We have some questions for the record. I know that Senator Weicker has some questions and we will submit them for the record. Thank you very much.

MANAGEMENT INITIATIVES

Senator EAGLETON. I have a few questions for you, Madam Secretary. In your prepared statement, you mentioned some new management initiatives and review procedures that are being put into place, and I'd like to go into one or two of those with you.

We have here a copy of the September 28 memo to you from the Inspector General and from Mr. Bohen relating to HHS's backlog of unresolved audit reports that are over 6 months old. As reported by the Inspector General, there were 47 reports as of September 30 of last year that were over 6 months old and have dollar questions of $250,000 or more, totaling $96 million.

What steps have you taken to resolve this problem?

Secretary HARRIS. I raised the question of audits management at HEW before I was confirmed as HEW Secretary, because I had heard some of the reports of lack of resolution. I have not been satisfied with the recommendations on the resolution of audits that have come to me in the last 6 months.

I have asked the Assistant Secretary, Mr. Bohen, to give better recommendations for cleaning up the backlog, first; and, second, for establishing a process to avoid a backlog in the future.

I cannot tell you, Senator, that I am satisfied with the proposal I think I'm going to be getting next week on this. I've already said to Mr. Bohen that some parts of it appear to me to be useful, but that I am not yet satisfied about getting the backlog cleaned up. I would like to be able to report to you the next time I'm here that the backlog is gone.

The Under Secretary and I are going to be talking about the audits management process. I'm not satisfied with it. I do have a very good record to point to at the Department of Housing and Urban Development. Everybody, including Elmer Staats, agrees to that.

Senator EAGLETON. Mr. Bohen, how many outstanding audit reports are there today?

Mr. BOHEN. There are a total of 1,200-plus, Senator, that are 6

months old or longer with a dollar value outstanding of about $104 million. A very substantial fraction of that total dollar value is tied up in about 40 reports that are worth $250,000 or more, some of which have been around for a long time.

AUDIT BACKLOG GROWTH

Senator EAGLETON. I see. Apparently the figure keeps growing. It's worse, rather than better. In June there were 981. The document we have here indicates that. Today it's 1,200. You all seem to be growing like Topsy.

Could you report back to us at a decent interval—not 48 hours or something, but after you have had a chance to go over the various recommendations, et cetera? Could you report back to us some time, say, in the next 3 months, if you could, as to what steps you've put in place and what progress you've made in that area?

Secretary HARRIS. The nature of backlogs is that they keep getting bigger. We don't have any management process to avoid the backlog. They will grow, and I'm very disturbed about it.

Senator EAGLETON. The same September 28 document stated that HEW program officials aren't all that aggressive in resolving audit findings—that's a direct quote—and that HEW has no clear-cut guidelines for resolving outstanding audit reports.

It goes on to mention that comprehensive policies and procedures were drafted by the Assistant Secretary for Management and Budget, Mr. Bohen, and that comments were requested from principal operating components by September 15. Now, have these, "comprehensive policies and procedures" been adopted by the Department?

Secretary HARRIS. I must say to you that the preliminary proposals that I have seen are not adequate, and we have not adopted comprehensive proposals. The Under Secretary, I think, had not then been confirmed. When the Under Secretary came to the Department, I asked him if he would take over the responsibility for managing the process of determining how we'd get rid of the backlog and keep it from building up.

As you know, we have to deal with many disparate institutions and institutional relationships at HEW. We have been working with the operating components to see what it is they are now prepared to do. As I said, I'm not satisfied and I really intend for us to move aggressively in the immediate Office of the Secretary to deal with the kind of backlog elimination that I think is the first step; and then the second step, the prevention of the building of that backlog in the future.

MISSPENDING GRANTEE FUNDS

Senator EAGLETON. I think that's a very logical way to proceed. Just keep us informed as to what progress is being made.

One final question on that same memo, not just to harp on it, but the memo really raises lots of questions. It points out that there's nothing to deter a grantee from misspending Federal funds and no incentive for timely resolution of audit reports. Obviously, the memo points out, it takes 2 to 3 years.

So the suggestion is made that HEW require payment by a grantee of interest on moneys identified as misspent or misapplied under the grant. Further recommendations would require that an institution's future awards for a specified period of time be reduced by a percentage of the cost element that was misspent or misapplied in the past.

Do you have a view as to these two recommendations?

Secretary HARRIS. Let me say they are very beguiling. The General Counsel has serious doubt about our authority to move in that direction. But I have not yet rejected this as a possibility. To take a long time in resolving audits and to pay back Federal dollars without interest, in cheaper dollars, seems to be something we ought not to encourage. Clearly, we do not wish to be punitive. But by the same token, we do not wish to confer unwarranted benefits on grantees who have received funds that they should not have received.

GRANTS APPEAL BOARD

Senator EAGLETON. All right. Well, likewise on that, say in a 3-month time span, let us know what your view is. And if by that time you think remedial legislation is necessary, if you don't have the inherent authority to do it and if you think you need further statutory authority, please bring it to my attention.

Now, I understand, moving on away from that memo to other matters, that one major stumbling block has been that decisions from the HEW Grants Appeals Board take an inordinate amount of time. Your predecessor was planning to make some changes in the grants appeal board structure to streamline the procedures.

Do you plan to pursue changes in that grants structure procedure?

Secretary HARRIS. Let me say that the Under Secretary and I, along with Mr. Bohen, have been very concerned about that. The Under Secretary has been looking at it. He may want to comment.

Mr. STARK. Just to say that we are far advanced now, and I think that by tomorrow we should be well on our way to resolving that problem. We think that we know what the causes are. Now it's a question of putting into place actions to eliminate these problems.

MEETINGS BETWEEN INSPECTOR GENERAL AND POC'S

Senator EAGLETON. All right. Last March, Mr. Bohen, you testified before the House Committee on Government Operations that you and the Inspector General planned to meet personally with the head of each operating agency to examine their organization, staffing, and procedures for audit resolution.

Have these meetings been held, and what's been the outcome?

Mr. BOHEN. Yes, Senator. Mr. Morris, who was then the Inspector General, and I met not just once but several times in the areas where the audit problem is the greatest. It is a complicated problem, as the Secretary has indicated. The volume alone is 6,500 audit reports completed a year.

The conclusions that I reached in this area and the preliminary recommendations that the Under Secretary has considered have been

drawn from those conversations, and they involve considerations of certain specific policies you've identified as well as really quite major internal reorganization and procedures for accountability change within the Department.

INSPECTOR GENERAL VACANCY

Senator EAGLETON. Well, I think all of this causes me to conclude, as did Chairman Magnuson, that it ought to be a top-priority matter to get an Inspector General in place as soon as possible. We realize it's an important position. We just don't want to heedlessly appoint someone to it.

But as you know, it's been vacant since September 30. I take some comfort from the fact that the deputy auditor is a Presidential appointee and confirmed by the Senate, but that really doesn't resolve the question that there isn't an Inspector General in place and functioning.

Secretary HARRIS. The problem of the resolution of the audits backlog is not due to failure to have a permanent Inspector General. As a matter of fact, I raised these issues prior to the time of my confirmation hearings, because I knew this was going to be a major issue. Arriving at a judgment of how these audits should be resolved was, at that time, beyond Mr. Morris, and the memorandum comes as a consequence of the fact that this is a very high priority.

I did not propose to go into the Department and say, "Do it my way." I went in saying, "This is an area that I am very concerned about, that I know can be dealt with." And Mr. Morris was unable to deal with it while he was there. We are still in the process of ascertaining how we can achieve my goal, which is to get rid of the backlog that is now there. And I do not want people to come to me after I have said, "Do it," and say, "We can't do it." I want to work with them.

But I intend within the next month, month and a half, to have a process in place. If we hadn't had the budget to deal with, it would have been in place much earlier, but I don't think this is something that you can play games with.

Senator EAGLETON. No, it's very, very serious. And I know it doesn't instantaneously resolve itself.

Anyway, give us a status report.

Mr. BOHEN. I just might add here that Secretary Harris' predecessor on several occasions worked on this problem, and figures suggest that very little progress was made. There was very divided counsel about what is desirable. There was also disagreement about what is legal.

The Secretary will be sorting through this.

Senator EAGLETON. That's good. And if you need further legislation, the sooner we can have it, the more likely it is that we can process it in a timely way.

So some of us on this committee are obsessed, as it were, I guess, by what we think can be the beneficial impact of Inspectors General and audits and the likes of that. Maybe we're overly obsessed.

I handled the Inspector General bill. That's why I'm interested in it, and I know that this can transcend what we're talking about here, the Inspector General himself, but the whole process is important at a time

when there's increasing emphasis on saving dollars and spending them prudently. You're just as interested in that, Mrs. Harris, as we are because you know how precious the dollars are.

Secretary HARRIS. May I say, Senator, that it is the opinion of the Comptroller of the United States, Mr. Staats, that the experience at the Department of Housing and Urban Development on this matter was exemplary, and I know that it can be done. It is a question of making certain with 10 times the number of people that we get the kind of cooperation from the operating components that I was able to get at HUD. But I inherited with this Department a much more intractable set of backlog audits.

There was a very good Inspector General at HUD, but because the HUD Under Secretary was known to have the responsibility for seeing to it that the audits were resolved, we got rid of the backlog in 6 months. And while we may not get rid of the backlog at HEW in 6 months because the grantees are a little more remote, I just want to assure you this is not a matter of who is Inspector General or the Inspector General going it alone. It is something that must have the cooperation and the clear understanding of operating components that is central to the management process.

That is what the Under Secretary and I intend to have happen with the audits management process at HEW.

Senator EAGLETON. That's very good. I have maybe some additional questions, but we'll submit those in writing.

Thank you, Mrs. Harris, Mr. Bohen, and Mr. Stark.

[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 Magnuson

TRANSITION TO THE NEW DEPARTMENT OF EDUCATION

Question: Madame Secretary, how is the transition of education programs from your Department to the Department of Education going?

In particular, what problems are arising in shifting functions and staff for your Office for Civil Rights to the comparable office in the Department of Education?

Answer: Our overriding goal in separating the civil rights resources for the new department is to insure that current civil rights activities such as complaint investigations and civil rights compliance reviews of HEW recipients are in no way delayed or diminished by the process of separation. We have not yet encountered any difficulties in the technical processes (e.g., assignment of staff, allocation of space, etc.) which will significantly affect the conduct of civil rights enforcement activities.

Question: Will the new Education Department be able to open its door officially in April as now planned?

Answer: While I cannot guarantee the resolution of every contingency which may arise, I can assure you that HEW will fulfill its obligation to meet whatever activation date the Administration sets.

DEPARTMENT OF EDUCATION

Question: With the establishment of the new Department of Education, there appears to be some confusion about who is currently in charge of education.

Is it correct to say that any policy decisions in eduction programs will be delayed until April when the Department of Education becomes effective?

Answer: No. Secretary Hufstedler and I, the Secretary's staff, and the Education personnel at HEW are all working to insure that no education program is adversely affected by a lack of policy direction.

Question: What is your current involvement in education programs?

Answer: I will continue to execute my duties as Secretary of Health, Education, and Welfare. Secretary Hufstedler will fulfill her responsibilities, and I will work closely with her to insure that our activities are compatible.

Question: Are Federal education programs suffering from a lack of leadership during this transition period?

Answer: I don't believe so. At her request, Secretary Hufstedler is reviewing the activities of the Commission. I continue to review the activities of the Office of the Assistant Secretary for Education, a very limited area.

STATUS OF APPROPRIATIONS REPORTS

Question: Can the Secretary account for the high number of delinquent reports and explain the priority such reports requested by the Committee receive at HEW?

Answer: Senate Report No. 96-247 that accompanied the Departments of Labor and Health, Education, and Welfare, and Related Agencies Appropriation Bill for 1980 specified a total of 33 items for which the Department of Health, Education, and Welfare was required to provide a written report to the Committee. Of this total, 31 reports were due to the Committee in advance of the fiscal year 1981 appropriations hearings. Only two reports were not provided to the Committee prior to the start of the hearings, and the Committee was kept informed of their progress.

Several factors contribute to the timing for submitting these reports. In many cases, Senate Report No. 96-247 indicates that a report is due in a certain month, without stating a due date. In the future, staff from the Department will confer with the Committee staff at an early time on the schedules for submitting reports.

In addition, many of these reports concern items of significant public policy, and demand the collaboration of persons both in and out of the Federal government. In those cases where additional time was required, the Committee was notified that a report would be delayed, and a new date was set for its submission.

The reports required by the Committee have always been assigned the highest priority, and are the direct concern and responsibility of the Assistant Secretary for Management and Budget. The system that the Assistant Secretary for Management and Budget has established for tracking, reviewing and transmitting these appropriations reports is, in large measure, responsible for the success the Department has had in being able to deliver to the Committee ninetyfour percent of the reports required in advance of the hearings.

Question: Madame Secretary, as you know, in November 1979, GAO issued a report listing all the recommendations they have made which would have resulted in cost savings in Federal Health Programs. Pages 174-187 of that report list a total of 100 recommendations made to the Secretary of HEW which have not been implemented.

- The GAO estimates that many millions of dollars could be saved by implementing these recommendations, does it not seem risky to enact Hospital Cost Containment Legislation which would be administered by a Department which ignores recommendations to save many millions of dollars in the health program it already runs?

- How can you push a program to force savings on hospitals when you can't or won't make obvious savings in your own programs?

- GAO has, in effect, written its own Cost Containment Program for you. Why has this been ignored?

According to a GAO report dated November 1979 between January 1974 and December 1978, the GAO issued 84 reports containing 262 cost-saving recommendations for Federal and Federal/State Health Programs. At the time of the November Report, only 98 of these recommendations had been put into effect.

- o Of the remaining 164 recommendations, how many does Health and Human Services have the responsibility for implementing?

- o What is the status of the implementation of these remaining recommendations?

Answer: The Department is in the process of preparing an analysis of what has been done in each of the cases outlined in the report. We will prepare and send to the Committee the results of our analysis by March 15, 1980.

Question: In our Fiscal 80 Report, the Committee expressed deep concern about the Department making use of programmatic funds to absorb pay and other extraneous costs. The Committee directed that no line item appropriation be forced by Executive Branch directive to either absorb more than its share of mandatory increases or to pay for other programs.

- o How is HEW complying with this directive?

Answer: The Department has been mindful of the Committee's direction in formulating its request for Fiscal Year 1980 supplemental appropriations for pay cost increases.

Specifically, we are not requiring that program line items be cut back to absorb increased pay costs, and we have taken special steps to assure that Congressional funding increases are used as directed by the Appropriations Committees.

As the result of this policy, the Department's 1980 supplemental request for pay reflects absorption of about 21 percent of the total cost, compared to our FY 1979 supplemental request which reflected absorption of 43 percent of the total pay cost increase.

The 1980 absorption which totals $40.4 million is being accomplished by:

	(Thousands)
o reductions in travel and transportation of persons and things, as required by Section 112 of P.L. 96-86	$7,200
o offset of receipts for parking charges against funds appropriated to cover costs of parking	1,800
o filling vacant positions slower than planned because of delays in normal recruiting processes	23,100
o all other management initiatives which will make it possible to shift funds to increased pay costs from amounts available for other administrative expenses	8,300

Question: As of January 22, 16 of the reports were still outstanding - leaving one working week prior to the hearings. As HEW has been contacted 3 times in the last two weeks to emphasize the need for these reports and verify the number and subject matter of

each report to be sure of no misunderstandings, can the Secretary explain this further inaction?

Answer: The Department delivered to the Committee ninety-four percent (29 of 31) of the reports due before the start of the hearings. The status of the two reports that were not delivered was discussed with the staff of the Committee.

This does not represent inaction. On the contrary, a great deal of work has been invested in this process to assure that the Committee obtains the information it requires from the Department through these reports.

The Committee is aware of the complexities associated with the items that we have been directed to report on. Issues that have significant implications for public policy require careful collaboration with groups in and out of the Federal government. Many are intimately related to important budget decisions not made final until December. The reports requested by the Committee are given very serious attention and care during their preparation and while in review so that the final product delivered to the Committee represents the best effort of the Department. The Committee staff is informed if additional time is needed to complete the reporting process. The staff has never refused to extend a deadline when additional time has been requested.

The Committee should be assured that its directives are given the highest priority by this Department. The Assistant Secretary for Management and Budget personally oversees the system for preparing, tracking, reviewing and submitting these reports, and is accountable to the Secretary for meeting the Committee's reporting requirements. The system established has resulted in improvements in the timely submission of these reports, and will enable even better performance in the upcoming year.

Two priorities in assuring this better performance are: establishing a specific due date for each report and defining "prior to hearings on the budget." These improvements will be effected in collaboration with committee staff.

HHS MANPOWER PROPOSALS

Question: It is my understanding that HEW was to have sent its health manpower proposals to Congress by May 15, 1979. Can you tell me when we can expect to receive these proposals?

Answer: We intend to have the legislation to the Congress prior to March 6, 1980

SHARE OF EMPLOYMENT LEVELS

Question: Is HHS receiving its fair share of the OMB ceilings imposed as a result of the Leach Amendment which placed a limit on the people you could hire? Would you recommend that this Amendment be removed?

Answer: OMB's administration of the employment ceilings available under the Leach Amendment has provided the Department with ceiling increases of 3,500 for 1980 and an additional 1,800

for 1981. Under the 1980 ceiling of 140,900 only 3.3 percent of authorized positions are expected to be vacant at the end of 1980 and that same vacancy rate is expected to be maintained through the end of 1981.

If ceiling limitations were removed, under normal circumstances 2 to 3 percent of authorized positions would be vacant due to turnover and the time necessary to recruit for these vacant positions.

We believe that the Department is receiving a fair share of the employment ceiling available in 1980.

We believe the Leach Amendment should be permitted to expire after 1981. OMB is administering 1980 and 1981 ceilings so that employment in the Executive Branch is projected to be somewhat below (12,421 in 1980 and 46,621 in 1981) the Leach Amendment limitation.

Question: Many HHS programs, especially services and research, have grown much greater than the inflation rate. Don't you agree that HHS should receive a greater share of personnel quotas as a result of this growth?

Answer: Growth in the Department's programs has normally been accompanied by a request for increased staffing by the President, or increased staffing provided by the Congress when it has appropriated increased resources over the President's request.

In the past few years, this increase in staffing (permanent positions) has not been totally accompanied by a concomitant increase in ceiling, largely because of the restrictions of the Leach Amendment.

The President's decision to increase the Department's ceiling by about 3,500 in 1980, however, largely compensates for these past shortfalls.

In 1981, an appropriate relationship between permanent positions and ceilings is maintained, and the Department is requesting 2,015 additional positions to support the various program increases in the budget.

SECRETARY'S STAFF

Question: How much has your office grown in the past five years compared to the rest of the Department?

Answer: During the five year period of 1976 to 1980, staff assigned to the Immediate Office of the Secretary increased by 8%, from 107 in 1976 to 116 positions in 1980.

During the same five year period, Departmental staffing increased by 8%, from 134,977 in 1976 to 145,743 positions in 1980.

DEPARTMENTAL POSITIONS

Question: Last year you recommended that we cut positions from Human Development programs. This year you want to add 100 positions. Why the change in policy?

Answer: The cut proposed last year was a technical one which had no impact on Human Development Services (HDS) staffing levels: no staff member in any HDS agency was terminated as a result of that cut. The 100 position reduction was in the number of positions authorized by the Congress for HDS programs. Because the Administration had not requested and the Congress did not appropriate funds in recent years to fill approximately 150 of the 1,600 positions authorized by Congress, the 1980 budget proposed eliminating 100 of them. This reduction was made to bring authorized positions more in line with the actual number of HDS staff.

For 1981 the budget proposes 100 new positions for HDS, divided among several agencies. They are intended to meet a growing workload caused by new programs and expansions of existing ones. Of the 100 positions, 40 would assist States in carryng out new Child Day Care regulations covering the Title XX, Work Incentives, Child Welfare and other HDS programs; 25 would enable the Administration on Aging to better manage expanded project grant activities authorized by the Congress in recent years; and the remaining 35 would help manage increased project grants and contracts in several other HDS programs--including the Head Start and Native Americans programs--and provide better direction and guidance for programs affecting families.

Question: How many HEW positions are you requesting for the Public Health Service which also has received new mandates and large increases in funding?

Answer: In the 1981 budget the Department is requesting 2,078 new positions for the Labor-HEW accounts of the Public Health Service (PHS) and is requesting that 365 positions be deleted from existing PHS programs; the requests would net to an increase of 1,713 positions for the Public Health Service. It is important to note that we are asking for additional positions in all areas we believe to be necessary to support program increases.

Significant changes are requested in the following programs:

- o the National Health Service Corps for assignment to medically underserved areas..... +1,708

- o for program support to Community Health Center projects, implementation of the Migrant and Seasonal Farm Workers and Hispanic Health Initiative, and support of additional National Health Service Corps assignees..... + 134

- o the Preventive Health programs of the Center for Disease Control emphasizing expanded study of epidemic type diseases, expansion of the nutrition surveillance

program and increased capability for dealing with concerns of exposure to toxic chemicals..... + 41

- o intramural research staff increases for the National Institute of Environmental Health Services..... + 55

- o for workload increases related to State mental health grant programs and community mental health programs..... + 16

- o for the Compliance and Conversion program to promote effective utilization of existing health facilities and to further cost containment..... + 21

- o for increased monitoring for compliance and for loan and loan guarantees in the Health Maintenance Organization program..... + 21

- o for Saint Elizabeths Hospital patient care services..... + 30

- o reductions made possible by management improvements in organization of administrative operations at Saint Elizabeths Hospital..... - 171

- o reductions made possible by reduced workloads in HRA's Health Professions Education and Health Planning Information Center programs..... - 152

- o discontinuance of statistics gathering for Health Manpower and Health Facilities within National Center for Health Statistics..... - 20

CONSULTANTS

Question: Last year's Fiscal 1980 bill included language to limit HEW consultant costs to $170 million. HEW had estimated consultant costs would be $194 million -- the amount to which we limited you in 1979.

The Committee will continue monitoring the Department's progress in reducing consultant costs; yet the quarterly consultant reports have arrived late, or not at all. For instance, the Committee has not received the report for the first quarter of Fiscal 1980 -- which is already one month late.

Answer: The reporting requirement for consultant services, as understood by the Department, is that established by Senate Report 94-366 which, on page 101, requires semi-annual reports. These reports are submitted with effective dates of September 30 and March 31. Accordingly, there is no report for the first quarter of Fiscal Year 1980.

SMOKING CESSATION PROGRAM FOR FEDERAL EMPLOYEES

Question: Several years ago, HEW officials announced that the Department would pay for smoking cessation programs for Federal employees who wished to stop smoking. What sources of funding were being used to pay for this initiative?

Answer: The smoking cessation course was funded from Public Health Service funds which provide money for salaries, travel, equipment, training and other personnel-related expenses.

Question: What is the status of this program?

Answer: The final session of the smoking cessation course was held in fiscal year 1979.

[THE FOLLOWING QUESTIONS ON PAPERWORK WERE SUBMITTED BY SENATOR SCHWEIKER]

NEW OMB REGULATIONS ON PAPERWORK

Question: I notice that OMB has issued preliminary regulations on paperwork reduction. Have you reviewed these and do you think they will be effective in reducing the number of forms to be filled out?

Answer: We are currently reviewing the proposed OMB regulation on paperwork reduction. While we have not yet received the comments from our component organizations and developed a final Departmental position on the regulation, our initial assessment is that the new processes and controls the agencies must implement will be effective in reducing paperwork burden.

OTHER PAPERWORK ISSUES

Question: Between 1977 and 1978 you reduced the HEW paperwork burden by 7.5 million hours, yet the reduction between 1978 and 1979 was only 1.2 million hours. What is the reason for the lower level of reduced hours between 78 and 79?

Answer: In the beginning of the intensive burden reduction initiative, great effort was made to identify and eliminate reports of major opportunity. This involved removal of all obviously dispensable reports. It also involved removal of obviously unnecessary data elements in high volume reports.

In later periods, there were fewer reports to select from and the reports to be eliminated involved fewer hours. Data elements analyzed for removal were closer to "bare bones" and produced lesser results.

In the late 1978 and early 1979, it was necessary to implement major new reports, such as the establishment of an extensive system for uniform hospital reporting and the implementation of a detailed quality assurance program for Social Security's Old Age and Survivor's Program. These two initiatives alone account for one million new burden hours that detracted from savings in existing areas.

Question: What do you presently do to avoid duplicating the collection of information by other agencies? How successful is this effort?

Answer: In general, the programs managed by HEW are discrete programs and there is little opportunity for overlap in data collection. However, where the possibility of overlap exists, HEW has instituted arrangements to avoid duplicating the collection of information by other agencies. Examples of such arrangements are:

- o HEW works closely with the Department of Labor (DOL) and Commerce in the development of data collection vehicles involving population, labor, and income distribution as a matter of practice. The Social Security Administration (SSA) coordinates its labor-related studies with DOL, and all SSA research studies are automatically distributed to both DOL and Commerce.

- o HEW and the Veterans Administration (VA) have agreed on joint surveys of long-term care facilities. VA currently accepts HEW's fire and safety evaluations of these facilities.

- o HEW has had a Health Data Policy Committee (recently redesignated the Health Data Advisory Committee) to assure coordination of health statistics activities within the Department, with other Federal agencies, and with other levels of government. The Commission on Federal Paperwork recommended that the Health Data Policy Committee be officially commended for its work in reducing unnecessary and duplicative Federal paperwork in the health field.

On the whole, we consider these and similar efforts by the Department to avoid duplicating the collection of information by other agencies have been reasonably successful.

Question: I understand there have been unsuccessful efforts to cut back on the data collected in the Case Service Reports of the Rehabilitation Services Administration on grounds that the information required is excessive. Is it excessive? Where does the matter stand?

Answer: We do not believe the data requirement is excessive. We believe the Rehabilitation Services Administration (RSA) needs the data for the effective administration of its program and for reports to the Congress. RSA has procured the services of a contractor to review its information needs and to design and implement a management information system. While this effort may revise the existing data system to reflect current information needs, we do not expect that it will result in a substantial reduction of data collected.

REJECTED REPROGRAMMING

Question: Last year the Committee rejected a $24.6 million reprogramming that sought to take funds earmarked for both health programs and additional health staff in order to cover October, 1978 pay costs. You later boiled down your reprogramming to only $450,000 which we agreed to.

Our committee was very adamant about the $24.6 million and we want to make certain that the funds were used for their proper purpose. Would you tell us how they are being used?

Answer: According to the Public Health Service, all funds earmarked for health programs were obligated for that purpose. No funding in the rejected reprogramming was used to finance pay costs.

MEDICAID SUPPLEMENTAL

Question: As you know, HHS's estimates for Medicaid reimbursement to the States have been quite inaccurate for the past several years. For this year (FY 1980), HHS's Medicaid estimate was a full $529 million below the Congressional Budget Office estimate of Medicaid outlays. Now we learn that the deficit in Medicaid costs may be as high as $2 billion, necessitating a Spring supplemental.

How do you explain the error made in the FY 1980 and what steps are you taking to improve the accuracy of Medicaid estimates ?

Answer: The basic cause of the error has been the use of a Federal estimating model rather than the use of State estimates which have been much more accurate.

Estimating for a program like Medicaid is a process marked by uncertainties. The normal difficulties were compounded this year by higher inflation than anticipated.

The supplemental has three parts: $1,472 million is the understatement due to the Department's Medicaid model in FY 1979 and FY 1980; $488 million is the understatement of the November State estimates for FY 1980; and $329 million is our estimate of claims for prior year State expenditures that will be paid in FY 1980.

The Department has changed the basis for its Medicaid estimate, giving individual State programs the responsibility for producing budget estimates. By moving from a national model to the aggregate of States' estimates, we feel that we will be able to produce more accurate budget requests.

61-400 O - 80 - 6

We believe that this will be the case based on an examination of the history of the size of the Department's and the States' estimating error. While the Department's original budget requests for the 1972 to 1979 period have been within 5.2% of actual adjusted expenditures, the aggregate of the November States estimates have been within 2.1%.

HOSPITAL COST CONTAINMENT

Question: What effect did the failure of the mandatory hospital cost control program have on the FY 1981 budget?

Answer: Because the Adminstration's Hospital Cost Containment legislation was not passed, the Federal government lost an estimated $520 million in savings in FY 1980, and $1,210 million in FY 1981. These are actuarial savings projected on the basis of the following assumptions: 1) the voluntary phase of the legislation takes effect January 1, 1979; 2) the hospital voluntary guideline is not met and the mandatory program is triggered January 1, 1980; and 3) the same economic assumptions concerning inflation that are contained in the President's FY 1981 Budget.

It is important to point out that these savings estimates are lower than those contained in the President's FY 1980 Budget. This change is almost totally attributable to changes in economic assumptions used by the Adminstration. Specifically, as our projected inflation rates for 1979 and 1980 increased, the hospital voluntary guideline was estimated to increase from 9.7 percent to 12.4 percent.

Question: Do you anticipate a renewal of efforts to see the cost containment legislation passed by Congress this year?

Answer: We have always believed that an effective Hospital Cost Containment program is an essential component of a successful national health insurance plan and we still do. We will continue to seek passage of Hospital Cost Containment legislation and hope that the House will reconsider our proposal. The voluntary approach currently supported in the House cannot bring the rate of increase in hospital costs down to an acceptable level or achieve needed Federal savings.

Question: If so, will there be any changes in the proposed legislation?

Answer: No; the savings estimates contained in the President's FY 1981 Budget are based on the Administration's original bill with technical improvements agreed to by the Administration and reported out by the Senate Human Resources Committee last year as S.570.

[THE FOLLOWING QUESTION WAS SUBMITTED BY SENATOR SCHWEIKER]

INEQUITIES IN HEALTH CARE

Question: Your recent report on the state of the Nation's health shows that the death rate for blacks is nearly 2½ times the death rate for whites, especially in the young and middle years of life. The same report also states that the infant mortality rate for blacks is twice the rate for white infants. What accounts for these differences? What do they indicate about the depth and quality of health care in the United States? What are you doing to

provide greater, more effective assistance for disadvantaged groups so as to reduce these death rates?

Answer: In order to explain the differences between black and white death rates, one must look at specific age and sex groups. While United States death rates for blacks are certainly almost always higher than the comparable rates for whites, the discrepancies vary a great deal depending on the specific population group. For instance, in 1977 black females, 10-14 years of age experienced a death rate about 13 percent higher than the comparable white rate. Black women in their 50's experience death rates approximately double those for the comparable white women, but black women in their 80's experience lower rates than do white women of the same ages.

The greatest differentials are found among men. Ratios of 2½ to 1 and higher are seen in the rates reported for black males aged 25-39 compared to white males of those ages. Since these are the age groups for which there is a severe undercount of black males in the decennial census, the reported ratios are somewhat exaggerated. Nevertheless, the true rates for blacks are certainly a great deal higher than those for whites. The major cause of the discrepancy in these young adult years is in homicide rates. For instance, black males aged 25-29 suffered more than eight times the homicide rate of white males in 1977. This accounts for about half of the excess black deaths among males in that age group. The ratio of black to white death rates for cirrhosis of the liver is approximately five to one, but this cause is too rare to account for a major portion of the differential in total rate. A wide variety of causes, ranging from heart disease to cancer, makes up the remainder of the difference between white and black rates.

Among middle-aged men the toll of circulatory diseases begin to outweigh accidental deaths. Although homicide still accounts for 25 percent of the difference between white and black rates among men aged 35-39, the circulatory diseases are a close second with 20 percent. Hypertension is a major contributory factor to mortality from circulatory diseases and blacks have about twice the rate of hypertension as do whites. The reasons for this difference is unknown, although it has been suggested that nutritional differences may be involved.

It should be noted that in the 15-19 age group in 1977, white males have exactly the same death rate as black males. White teenagers, because of their higher socio-economic status, have greater access to automobiles than do black teenagers. The death rate from motor vehicle accidents for white males aged 15-19 was, in 1977, twice as high as the rate for black males. On the other hand, the black homicide rate was several times that of the white race. The two differences balanced each other nearly exactly.

Obviously, lifestyle differences contribute markedly to the black-white mortality differentials. We have seen how various forms of violence are involved among young adult males. In the older age groups, chronic diseases account for a vast majority of the deaths. Even there, lifestyle differences are important: a larger proportion of blacks smoke than whites; obesity is far more prevalent among black middle-aged women that white; a larger proportion of blacks than whites appear to eat unwisely. Furthermore, blacks may be exposed to more occupational hazards than whites.

However, differences in access to high quality medical care also probably makes some difference. Blacks receive considerably fewer preventive services, on the average, than do whites. Treatment is delayed until later stages of disease more frequently among blacks than among whites. Blacks with a diagnosis of cancer do not survive as long as do whites, even if the stage at diagnosis is taken into account. Thus, increased access to medical care would probably improve the death rates for blacks somewhat, particularly if coupled with a healthier lifestyle.

. Infant mortality rates for blacks are about twice as high as those for whites. The reasons for this difference are not entirely clear. One study of New York City births in 1968 found that 73 percent of black births were high risk (based on either adverse socidemographic or medical factors) compared to only 38 percent of white births. Furthermore, 46 percent of black births were judged to have inadequate health care compared to 16 percent of white births. To make matters worse, the high risk births were least likely to receive adequate care.

Just how much these differences in characteristics of births contribute to the higher black infant mortality is not known. If the outcomes of all black births were as good as those black births with adequate care (and the same conditions held for whites) the ratio of black to white infant mortality would have been reduced from 2.35 to 1.67. However, it is not clear that such a reduction is possible since women who received adequate care are different in many ways from those who did not.

It has also been suggested that black-white differences in infant mortality may be the result of nutritional deprivation over the past two or three generations. This view holds that a mother's pregnancy outcome is influenced by her mother's nutritional status and her own nutritional status throughout childhood as well as during the current pregnancy.

The hypertension program and the sickle cell clinics program, funded under the Health Services appropriation, focus specifically on major health problems of black Americans. The hypertension screening and counseling program focuses on the disease which is the major cause of death among blacks. This disease strikes black men nearly twice as frequently as it does white men. The FY 1981 budget requests $20 million to enable this program to screen 7.8 million people for hypertension, and to provide counseling and follow-up services where necessary.

Sickle cell anemia primarily strikes people of African descent. The sickle cell clinics program supports 20 sickle cell screening and education clinics. The 1981 budget request for the clinics is $3.7 million. This will enable them to screen 183,000 persons and provide counseling on sickle cell disease and its treatment.

In addition to the two categorical programs directed at specific diseases, the Health Services appropriation supports major primary care health services delivery programs whose design effectively target their services to disadvantaged populations. The criteria for establishing Community Health Center and National Health Service Corps sites specifically favor areas of high poverty and high infant mortality. The effectiveness of the programs in reaching disadvantaged groups is shown by the fact that 67 percent of the people served by Community Health Centers are black. At

the 1981 funding level of $374.4 million, these clinics will serve a total of 5.2 million people.

A recent study also showed that a majority of the people served in projects funded by the Maternal and Child Health Services program (Title V of the Social Security Act) are black (66 percent in Children and Youth and 53 percent in Maternity and Infant Care projects). Of special importance are the Improved Pregnancy Outcome projects now supported in 34 States. Projects have been established in States with the highest infant mortality rates. Efforts are focused on areas where the problems are most severe -- inner cities and rural pockets of poverty. Teenagers and others at greatest risk in high poverty areas constitute the prime target populations for improved prenatal care, adequate delivery services, and post-natal counseling, including infant care, family planning, and the like.

Blacks also account for about one-fourth of the clientele in family planning clinics funded under Title X of the Public Health Service Act. A major aim of these clinics is to provide health services, information, and training in an effort to decrease the high infant mortality rates and other health problems associated with teenage pregnancies.

Blacks are not the only disadvantaged group being offered effective health care services through HSA programs. The Migrant Health program's 112 clinics serve a population which is predominantly poor and Hispanic. At the 1981 budget level of $44.7 million, these clinics will provide comprehensive primary health care services to nearly 600,000 migrant and seasonal farmworkers.

Outside the Health Services appropriation, the Indian Health Service provides funding to improve the health status of American Indians and Alaska Natives, minority populations which have chronically been characterized by extremely poor health indicators.

RALPH NADER SUIT

Question: Nine years ago, the Public Health Service Surgeon General, Dr. Jesse Steinfield, proposed cutting off reimbursement through Medicare and Medicaid for prescription drugs which have not been found to be effective. The Food and Drug Commissioner, Dr. Donald Kennedy, made the same recommendation a year and a half ago.

Now Ralph Nader's Health Research Group has filed suit against HEW in an attempt to stop the Department from paying for about 350 prescription drugs for which the National Academy of Sciences/ National Research Council has found a lack of evidence of effectiveness. Do you plan to fight this suit? If so, why?

Answer: Yes, the Department does plan to fight the suit. The Nader lawsuit implies that the Medicare and Medicaid programs offer Federal reimbursement for drugs that we know to be ineffective. This is not the case. The process by which the FDA determines whether a drug is ineffective for any of the conditions it is intended to treat

is multi-faceted. The Bureau of Drugs within FDA first makes a determination that a drug does not meet the statutory standards of effectiveness and issues a notice of opportunity for hearing (NOOH). At that time, the drug's manufacturer has an opportunity to respond by presenting its evidence that the drug is effective. The Bureau's determination rests not so much on evidence it has of the drug's ineffectiveness as it does on the manufacturer's failure to affirmatively demonstrate by substantial evidence the drug's effectiveness. Moreover, the Bureau's decision is not a decision of the FDA as a whole or its Commissioner. Only when the administrative record is complete does the Commissioner make a final agency decision on the drug's effectiveness. Because the Bureau's determination is not a final agency decision and because, short of such a decision, the manufacturer has not had its statutory opportunity to contest the Bureau determination, the drug remains lawfully on the market until the Commissioner makes a final determination. Accordingly, Medicaid and Medicare continue to provide Federal reimbursement for a questioned drug until the Commissioner has made a determination that the drug has not been determined to be effective as the statute requires.

ABORTION POLICY

Question: What are your recommendations on abortion language in the fiscal 1981 Labor-HEW bill in light of Judge Doolings' ruling?

Answer: The provisions in our appropriations act that limit the Federal funding of abortions recently have been declared unconstitutional, to the extent that they prohibit Federal funding of medically necessary abortions, by the U.S. District Court for the Eastern District of New York in a case called McRae v. Secretary, DHEW (decided January 15, 1980). As a result of a February 19, 1980 U.S. Supreme Court decision not to stay the District Court ruling, we are presently under court order to provide Federal matching funds under Medicaid for abortions determined to be medically necessary by a woman's physician.

The Supreme Court soon will be deciding the constitutionality of limitations on the Federal funding of medically necessary abortions, on appeal of the District Court decision in the McRae case. Accordingly, we believe it would be premature for us to make any recommendations at this time.

Question: How do you plan to administer Medicaid funding for abortions pending final Supreme Court review of Judge Dooling's ruling?

Answer: On January 15, 1980, in a case called McRae v. Secretary, DHEW, Judge Dooling of the U.S. District Court for the Eastern District of New York declared unconstitutional the HEW appropriations act restrictions on the Federal funding of abortions.

Judge Dooling ordered HEW to stop enforcing these restrictions and to provide Federal matching funds under the Medicaid program nationwide for abortions determined by a woman's physician to be medically necessary. At the same time, Judge Dooling stayed his ruling until February 14. On February 4, Judge Dooling refused to extend this stay beyond February 14, but on that date, U.S. Supreme

Court Justice Marshall extended the stay until the full Supreme Court could rule on the question. On February 19, 1980, the Supreme Court denied the government's application for a stay pending appeal of Judge Dooling's decision.

As a result of the Supreme Court decision, the Department is required to cease enforcing the limitations on Federal funding for abortions contained in our 1980 appropriations acts until the Court decides on the constitutionality of those limitations. For this time period, the Department will provide Federal matching funds for all medically necessary Medicaid abortions. We have notified the Regional Administrators of the Health Care Financing Administration of this change, and instructed them to notify the States who will in turn notify Medicaid providers, as Judge Dooling's order requires.

FAMILY PLANNING

Question: In your confirmation hearing before the Senate Finance Committee, you were asked whether teenagers served in the adolescent pregnancy program should be informed of the option of abortion. At that time you said that "so long as this is a protected right, that information is almost a duty."

What assurances do you have that these pregnant teenagers -- indeed, that all women receiving federally subsidized family planning services -- will be informed of all pregnancy options in an objective manner and that appropriate referrals will be made?

Answer: Title VI of Public Law 95-626 (Health Services and Centers Amendments of 1978) requires that projects receiving adolescent pregnancy grants must assure that each pregnant adolescent receiving services will be informed of the availability of counseling (either by the entity providing health care services or through a referral agreement with another entity which provides such counseling) on all options regarding her pregnancy.

The intent of Congress was to require grantees to inform participants of the availability of counseling "on all options" regarding pregnancy but not to make such counseling mandatory.

If a referral agency is being used to provide counseling on all options, a description of the referral agency should be included in the application narrative, including the agency's experience in providing counseling on all options.

MENTAL HEALTH GRANT PROGRAMS TO STATES

Question: In last year's budget (Fiscal Year 1980) no funds were requested nor appropriated for section 314 G under the Alcohol, Drug Abuse and Mental Health Administration. It is my understanding that these funds are made available to states in order to assist them in carrying out regional mental health programs. Connecticut and other states will be forced to cut back on these programs because of the lack in federal aid.

In the President's proposed budget for FY 81, $12.1 million has been requested for section 314 G. Could you please explain:

(1) Why there was no request for 314 G funds last year.

(2) What, if any, are your plans for FY 80 supplemental in regards to reimbursing the states for these lost 314 G funds.

Answer: No supplemental funds were requested for 314(g) formula grants because we believed emphasis was properly placed on seeking our supplemental funding request of $50 million to implement the proposed Mental Health Systems Act.

Because passage of the Mental Health Systems Act on the time schedule we originally assumed now seems unlikely, the Administration is reconsidering the issue of 314(g) funding. The results of this reconsideration will be communicated to the Congress in the near future.

RECRUITMENT AND RETENTION OF PERSONNEL
IN PUBLIC HEALTH SERVICE HOSPITALS

Question: In August 1978 the Department of Health, Education and Welfare's Public Health Service Hospitals Ad Hoc Advisory Committee reported that "The recruitment and retention of adequate and competent staff is the most crucial problem facing the hospital. Appropriate steps must be taken to enhance recruitment efforts. The negative impact of position ceilings must be eliminated." (p. 9)

More than a year later, HEW's Office of Management has reported that the eight PHS hospitals are 740 positions or 15 percent short of staffing standards of comparable non-federal positions. In nursing personnel the hospitals were found to be 489 positions or 38 percent short of community standards. The 27 free-standing clinics are reported to be 100 positions or 20 percent of comparable non-federal HMO facilities staff.

Are the Administration's budget and staffing requests designed to close these gaps and implement the Advisory Committee's recommendations?

If not, why?

Answer: The Administration has submitted a budget and position request that is adequate to maintain the Public Health Service Hospitals in compliance with Public Law 93-155. At the present time, the Administration is reviewing various options regarding the appropriate future role of the PHS hospitals and clinics system. While that review is going on, we do not intend to request additional staffing based on the study done by the Office of Management. Before we implemented any part of this study, we would need to do further analysis in each hospital and clinic to ascertain whether the standards of non-federal facilities were directly applicable to the PHS system.

Question: What does the Administration plan to do to correct these deficiencies, especially in the area of nursing?

Answer: Although we do not yet have a final decision on the future of the hospitals, we are examining the internal allocation of positions within the hospital system and plan to make reallocations as needed to improve the quality of care and patient safety. It should be noted that the hospitals and clinics have been allocated a personnel ceiling at 100 percent of budgeted positions, thus maximizing staffing within congressionally-approved levels.

PUBLIC HEALTH SERVICE HOSPITALS

Question: As you know, this Committee is concerned about the implementation of the excellent report by the Ad-Hoc Committee on PHS Hospitals. In particular, I'm concerned about:

1. Expanding the mission to include the medically underserved.

2. Permitting PHS to provide services to retired seamen and dependents of seamen.

3. Authorizing PHS to collect reimbursements and use them flexibly.

Could you tell us where you stand on these issues and when they will be implemented?

Answer: The Department is presently looking at options regarding the future mission of the PHS hospitals. This is a very complex issue which merits a fresh review and discussion. No final decision has been made, so no recommendations are being implemented.

With respect to the specific points made above, the draft report does suggest that the hospitals' beneficiary base be expanded. If such an expansion were authorized, it would be accomplished on a reimbursable basis only. Also, additional legislative authority is needed for such an expansion except in the case of the medically indigent. Finally, it is clear that additional staffing would be needed for the hospital system to carry out this expansion.

We are at present following Congressional direction in the 1980 appropriations bill to collect reimbursements from Department of Defense outpatients, and we plan to use the reimbursements within the hospital system.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP (NHSC)

Question: In response to a question by Senator Hatfield justifying your elimination of capitation payments to medical schools, you seemed to suggest that an alternative source of funding available to medical students was the NHSC scholarship program.

On numerous occasions, however, we have heard from representatives from the Administration that student support is not the primary purpose of this program but, rather, getting practitioners into underserved areas.

Would you please comment?

Answer: You are correct that the primary purpose of the National Health Service Corps scholarship program is to assure an adequate supply of physicians, dentists and nurses to work in underserved areas. However, there will be over 6,700 students receiving scholarships in 1980 and 1981 that average $12,700 to $13,800 annually. A scholarship pays for all tuition and fees as well as a $485 monthly stipend. In addition to supplying health professionals for the Corps, NHSC scholarships are also one of the best student assistance programs available to needy students.

NURSE TRAINING

Question: In fiscal 1979 and 1980, the nurse training programs received $106.2 million. Why has the President requested only $28.6 million to support the nurse training programs in fiscal 1981?

Answer: After 22 years of Federal support to increase the supply of nurses, the current capacity to train an adequate supply is now in place. We no longer need to develop this capacity.

Nursing schools are graduating nearly 80,000 nurses annually, over twice the number of only 15 years ago. What is disturbing, however, is that 30 percent of the trained nurses are not working, as nurses. It is not logical to continue using the taxpayers' money to train nurses who then choose not to practice. Restoration of nurse training money in those programs which have been cut back will not solve nurse supply problems which are admittedly occurring in many areas. We will be initiating a study with the Institute of Medicine to look at why nurses are trained and do not remain active.

We do have in the budget $29 million to aid the training of nurse practitioners, nurse midwives, those who move beyond the traditional nursing services. These specialized training efforts will help solve problems of poor distribution of nursing services. There is a need in this area and we have expanded the budget to support this type of training.

Question:. What documentation do you have that there is no longer a shortage of nurses?

Answer: As indicated above, we believe that the capacity is in place to train an adequate supply of nurses. We concede that there are supply shortages of nurses in certain areas and under certain conditions. It is equally true that restoration of funds decreased in the 1981 budget request will not in our judgment affect the supply situation which you have cited. As I have indicated, there is no logic to us educating nurses at taxpayers' expense, if those nurses then work outside the field. The following table is an indication of how federal financial support has influenced the supply of nurses educated over time.

Supply of Nurses - Trends and Projections

Year	Number (000's)	Nurses Per 100,000 Population	Nurses to Population Ratio	Graduates from Nursing Program (000's)
1960	504.0	282.2	1:355	30.0
1970	722.0	356.0	1:281	46.4
1975	906.0	427.0	1:234	77.1
1980 est.	1,152.0	520.0	1:192	87.4
1985 proj.	1,345.0	579.0-584.0	1:171-1:173	89.2

CON GAME WITH FEDERAL GRANTS?

Question: A recent article in Business Week alleged that some $700 million is used for salaries and services for which there are no supporting documents, or for research projects that are not entitled to the funds.

I assume you are aware of this article. What is your comment on it?

Answer: In his March 31, 1978 annual report to the Congress, HEW's Inspector General noted that his reviews of charges to research grants and contracts being performed at colleges and universities led him to question $13.2 million and to set aside $419.7 million as unauditable in calendar year 1977. In his report dated March 31, 1979, it was noted that $3.5 million had been disallowed and $86.5 million set aside during calendar year 1978. In calendar year 1979, the auditors disallowed $13.5 million and set aside $187 million.

The Inspector General indicated that the recordkeeping and documentation of those schools that had been audited was so unreliable as to require the auditors to disclaim an opinion on those charges which it had set aside. The General Accounting Office concurred in the Inspector General's assessment of the recordkeeping practices of the schools. The costs disallowed and set aside by the auditors were claimed by the institutions primarily for salaries and consulting services.

It would be improper to conclude that all, or even most, of the $693 million set aside in audits over the last three calendar years was misspent, but there is no reliable evidence available to the auditors to indicate how many of these charges were proper and there was some evidence of questionable transactions which indicated that at least part of the charges were improper. For example, the auditors commonly found cost transfers, made months after-the-fact, from grants that were "over-expended" to grants that were underexpended and charges for consultant services without any evidence of work performed. HEW has been concerned over the accounting and business practices of universities for many years and have testified to that concern to several committees of the Congress. The General Accounting Office has given comparable testimony. We are even more concerned about the allegations made by respected researchers who have testified that universities have improperly used Federal funds for activities not related to grants and to practices which are improper. Although these allegations have not been proven, it seems clear that the stewardship and reporting of Federal funds at colleges and universities is not all that it could and should be.

It has been the practice of the Department to give the benefit of the doubt to the universities in those instances where questions have been raised about the propriety of claims against grants but where there is no clear proof of misspending. As I have indicated, the preponderance of the auditors' findings ($693 million) concerned inadequate documentation. Therefore, recoupments against colleges

and universities have been very small in relation to the total amount of dollars disallowed and set aside by the auditors.

Question: The charge that some universities are misusing NIH grant funds is challenged on grounds that individual research projects are rarely self-contained but rather are part of a larger program of investigation. Thus, it is argued, this may make it difficult, if not impossible, to abide by the rule that Federal funds that are awarded to a project must be spent only on that project?

What is your comment on this?

Answer: It is true that there is some interrelationship between individual research projects and that some individual research projects are part of larger programs of investigation. But we believe that the effect of this interrelationship on the use and accountability of funds is exaggerated. This interrelationship does not seem to be an obstacle to individual researchers and their institutions in developing research prposals and related budgets for specific projects. Indeed, the proposals are submitted and peer evaluated as viable discrete projects. Thus, we think the matter is less a question of ability and more a question of will. The problem of accounting for interrelated projects, is certainly not beyond the state-of-the-art. It can be accommodated with relative ease when that relationship is agreed to in advance and the costs are properly recorded. The broader issues are how much flexibility research institutions should be allowed to shift funds awarded for a given scope of work to perform other work and the degree of confidence that Congress and the awarding agencies have in the fiscal oversight of colleges and universities and the integrity of their budgeting and accounting. This issue goes to the heart of the project grant concept and is a matter we would need to consider more fully before giving a firm answer.

Question: How realistic is it to try to impose Federal accounting requirements on the traditional university research process? What would be the effect of doing so -- wouldn't it be costly to the schools?

Answer: The accounting requirements with which colleges and universities are asked to comply are the bare minimum necessary for any reasonable level of accountability of Federal or any other funds given the project award system and are substantially less stringent than those that apply to other types of organizations. In our opinion, those requirements do not, and will not, adversely affect the conduct of research. For example, one of the requirements which universities have objected to in the past is the need for their professional staff to certify periodically the effort they expend on Federal projects. This certification is the basis for computing the proper salary and wage charges to the projects. The reports were previously required once each month for each professional. They are now required only once each semester. Moreover, they are asked to certify their best estimate of how their compensated effort was spent. Absolute precision is not required. We cannot see how any professional can insist that the filling out of such a report will deter him or her from their research responsibilities. Where comparable research is performed outside the

university environment, in non-profit research institutes or in commercial research firms for example, monthly or more frequent time reports are the norm and this norm is established not by the Federal Government but by institutional administrators who want and need to know how effectively their research funds are being expended.

To the extent that colleges and universities already have effective administrative oversight and checks and balances built into their operations, the Federal requirements will not be costly to implement. To the extent that schools do not have these fundamental management tools in place, it may very well require important additional costs on their part.

Question: Some university people argue that projects are so interrelated that assigning costs is a judgment call -- and probably not a very precise one. What is your reaction to this?

Answer: As we indicated above, there is some interrelationship between some grant projects and judgment is a factor in virtually any management or accounting process, but we believe this argument is overdone. Again, we believe that if a researcher can distinguish the work that is to be done in developing a proposal requesting Federal funds then he or she ought to be able to segregate that work when accounting for it after-the-fact.

Question: One remedy suggested for the problem is for Federal agencies to delegate to universities the authority to shift Federal funds within and among related projects. How do you stand on this?

Answer: The question is related to the prior one on the interrelationship of grant projects. As I indicated, the question goes to the viability of the project grant concept and we would need to give it further consideration before reaching a final conclusion. But we think that such a delegation should not be used as a mechanism to avoid an honest accounting of Federal funds or to subvert either the intent of Congress or the intent of the awarding agency in making a grant for a specific research endeavor. As I noted earlier, the scope of a research project is determined by the researcher, not the Federal Government. It is the researcher who sets the parameters of a project, be it narrow or broad, and not the granting agency. Thus, if the proposals are properly developed, one is necessarily led to the conclusion that the projects are sufficiently discrete to permit a reasonable measurement of the costs incurred to carry out the project.

The authority to shift funds between and among grants also raises questions within the budget and accounting systems of the Federal Government. To the extent that shifts would cross appropriations lines, the Department clearly does not at this time, have authority to sanction such shifts.

Question: How do we assure appropriate university stewardship for funds spent in support of research without imposing excessive controls, direction and administrative burden on university research grantees?

Answer: There is no easy answer to this question. In the

last analysis, it comes down to a judgment as to what is the proper balance between the need for controls to assume proper accountability of public funds and the need to avoid the imposition of costly administrative requirements on the schools. This issue has been debated for years and was most recently debated during the development of the revised cost principles issued in February, 1979 by the Office of Management and Budget. Although the issue will undoubtedly continue to be debated and further improvements made, we believe that the principles do strike a reasonable balance between these competing concerns. We feel, however, that the universities need to honestly reappraise their administrative practices and governance. Universities are big business and the management of big business is not an easy task by any means. Many universities are, in fact, predominantly supported now by public funds. That support comes in the form of Federal research grants, State appropriations, student financial aid, and student tuition. Thus, schools have a special responsibility for the sound stewardship and honest accountability of those funds. We think that needed stewardship and accountability will not detract from innovative research or erode the academic independence of these institutions; to the contrary, it is necessary to reinforce those cherished objectives.

Question: In a recent report to Congress, the Comptroller General suggested that during fiscal 1974 through 1977, perhaps 80 percent of Federal grants, for a total of $192 billion, were not audited by or on behalf of Federal agencies.

In the reply to the Comptroller General you indicated the Departmental Audit Agency is developing a computerized system for tracking and monitoring mandated non-Federal audits.

What is the progress of this system?

Answer: As presently designed, the tracking and monitoring system will include detailed information on Federal and non-Federal audits of student financial aid programs. It is an expansion of the existing OIG audit information system which contains data on all audit reports issued by the Audit Agency.

System design tasks and computer programming work for the new system have been completed. The various reports which will be routinely generated by the tracking and monitoring system have been designed. Prototype formats have been produced from the system. The universe file of institutions participating in the student financial aid programs has been created and we have begun testing the information. Work on data input and full field testing of the tracking and monitoring system is continuing.

The basic design and related computer programs for the system will be made available to the audit staff of the new Department of Education for their use in managing audits of the student aid programs. The system can be modified to accomodate other types of audits and could be used to monitor the organization-wide audits called for by OMB policy.

Question: Does it appear workable?

Answer: As with any major information system, problems can be expected in the implementation phase. One problem already identified is the maintenance of a current and accurate institutional universe

file. Work performed to date, however, convinces us that the problem can be overcome and the system will be workable.

Question: Is this system just going to cost more money or are there going to be cost savings resulting from the elimination of duplication?

Answer: The primary objective in establishing the tracking and monitoring system for student financial aid audits was to obtain better information on the audits performed by non-Federal auditors. We believe that this system will aid us in discharging our responsibility for evaluating the quality of non-Federal audit reports under OMB Circular A-73 and will result in a more efficient use of audit resources. As GAO pointed out, however, the most significant cost savings will be realized when a system such as this can be applied to organization-wide audits which will reduce duplication in audit coverage.

RESTRUCTURING SOCIAL SECURITY

Question: Various ideas for restructuring the social security system recently have been surfaced. These include taxing one-half of Social Security benefits, extending the age for receiving full benefits from 65 to 68 and removing Medicare from the Social Security trust funds and paying for it out of general revenues.

Do you support any of these suggestions? What is your view of how the Social Security system may be able to achieve long-term financial stability?

Answer: These proposals, among others, were included in the report of the Advisory Council on Social Security released in December 1979.

We do not yet know enough about the impact of these proposals on taxpayers, beneficiaries, other pension systems or the general economy to support or reject any of them. In addition, before the Administration makes any recommendations of this magnitude concerning the Social Security system, we would want to evaluate the recommendations of the National Commission on Social Security and related study groups due to report within the next year or two.

With regard to your second question, the long term financial stability of the Social Security system is dependent on a variety of factors--primarily the relationship between the growth of wages and prices and the ratio of taxpayers to beneficiaries.

The latest actuarial report of the Board of Trustees issued in April 1979 shows that the system begins to face major financing problems well after the turn of the century--this will give us adequate time to evaluate alternatives to deal with the problem of long term stability.

WHAT TO DO ABOUT SOCIAL SECURITY?

Question: Your recently departed Commissioner of the Social Security Administration, Stanford Ross, said in an interview before he left that he believed general revenues would have to be used to underwrite the cost of the Social Security program. Do you agree with this assessment?

Mr. Ross also counselled that the American people need to be educated as to the limits of Social Security. He indicated he feels that the Government should limit the growth of Social Security while emphasizing the development of pension plans as a supplement to the Social Security program. Do you agree with this approach?

Answer: The Administration's proposals to permit borrowing among the Old-Age, Disability and Hospital Trust Funds should be sufficient, based on the 1981 budget assumptions, to deal with the systems short-term financing problems. This will allow us to examine more carefully the kind of fundamental changes in Social Security financing principles which may be desirable in the future. This analysis will include consideration of general revenue financing.

In regard to "educating" the public about Social Security, there is a continuing need to inform and communicate with the American people on a wide range of Social Security issues. We agree that efforts should be maintained to make our citizens aware of the choices to be made concerning the future of Social Security and we have been doing this.

Whether the growth of Social Security should be "limited" is a subject to be debated by the people and the Congress through the American political process.

The Social Security system was established to provide only a basic floor of income maintenance, upon which beneficiaries could build other forms of income protection. Indeed, the Social Security law encourages such arrangements by exempting income from pensions, investments, and other forms of nonwork income from the earnings test. This design permits the Social Security program to be described accurately as a base upon which workers can build financial security. We agree that private pensions play, and should continue to play, an important part in the personal and family financial planning of the American people.

INDOCHINESE REFUGEES

Question: During the past year with the large increase in the number of Indochinese refugee admissions, there has been concern over the general health of this group and, particularly, any possible threats they might pose to public health after their arrival. The Center for Disease Control and the Health Services Administration were requested last June by then-Secretary Califano to evaluate the medical screening of Indochinese refugees abroad and the delivery of health services to them here. What were the findings of the agencies with regard to these questions?

Answer: The general finding was that the Indochinese refugees entering the United States do not present a public health problem. Because of screenings in the overseas camps, no refugee is admitted

to the United States who has infectious tuberculosis, infectious leprosy, narcotic addiction, or chronic alcoholism. Only 4% of all refugees screened overseas are denied admission because they have one of these conditions.

Question: What is the general health condition of the Indochinese refugees and what types of health services are necessary upon their arrival here?

Answer: The great majority of refugees are free of serious contagious disease. If they do have an illness, it is generally a personal rather than a public health problem. Malnutrition, dental disease, and anemia are the most common illnesses found among refugees.

When the refugee enters the United States, PHS quarantine officers briefly examine the refugees, review the medical records, and may quarantine them for more extensive examination and treatment if significant medical problems are suspected. The quarantine officers notify State and local health agencies within 24 hours after the refugee's arrival. In cases of active but non-infectious tuberculosis, PHS immediately contacts the local health departments by phone and makes written follow-up contacts during the refugees' first 90-days in the United States.

PHS recommends that State and local health departments conduct a general medical examination with particular attention to malnutrition and skin conditions. PHS also recommends that immunizations be provided as needed.

Question: To what extent is new Federal funding needed to provide a minimum level of health care for refugees?

Answer: The principal method of financing health care for refugees is to build on the Medicaid programs conducted by the States. HHS pays for those costs which would normally be borne by the States. Our budget proposes to allocate $90.5 million for medical assistance in fiscal year 1980, up $57 million from 1979. In fiscal year 1981 we estimate that $109.5 million will be needed for medical assistance, assuming enactment of the Administration's refugee legislation.

In addition to the services provided through Medicaid, we are requesting $4.5 million in the 1980 supplemental to conduct health assessments for those refugees who find it difficult to adjust to the American medical care system. The objective of this program is to identify medical problems not previously diagnosed and to help the refugee become oriented to the American health care system.

Question: What is being done to integrate refugees into existing health and social service programs?

In general, the refugees are served through programs that also serve American citizens. We have been careful not to set up a separate delivery system just for refugees. The refugee program appropriation provides extra funds to State and local welfare departments, health providers, educational institutions, and social service agencies to defray the additional cost of serving this new group of beneficiaries. Once the special Federal funding arrangement ends, the refugees will continue receiving those services that are needed on the same basis as other residents in the community.

HEAD START ENROLLMENT ESTIMATES

Question: Last year's appropriation request for Head Start was $700 million, to serve 414,000 children. Why is it although the Congress appropriated $735 million, you now indicate only 384,000 children will be served in fiscal 1980?

Answer: The reduction is based primarily on three factors not fully anticipated at the time the 1980 budget was presented to the Congress.

1. Inflation was higher than expected in 1979, and the many projects were unable to offset rising costs through management improvements or by obtaining funds from other sources.

2. Many Head Start projects used appropriation increases in 1979 and in 1980 to convert existing summer projects to full year projects. Since the average cost per child for full year projects is almost seven times as much as that for summer projects, estimates of the total number of children served decrease.

3. The new statutory allotment formula, in 1979 and again in 1980 caused a greater proportion of total Head Start funds to be alloted to States with higher service costs. This shift increased the average cost per child and, as a result, decreased the number of children expected to be served.

Question: How much reliance can we put on your estimates that 397,000 children will indeed be served by your $825 million fiscal 1981 request?

Answer: We think this is a fairly reliable estimate. It is based on experience with two years of substantial budget growth in Head Start under the new allotment formula in the Head Start legislation. The estimate makes realistic assumptions about increases in the cost-of-living during 1980 and 1981 about the ability of Head Start projects to absorb those increases. The projection also assumes that some existing projects will use the funding increases to convert summer projects to full year projects.

HEAD START - PUBLIC SERVICE JOBS IMPACT

Question: What impact has the cutback in public service jobs (from 725,000 two years ago to 467,000 for fiscal year 1980) had on the quality of Head Start services?

Answer: We have not observed a significant impact on the total Head Start effort from the recent reductions in public service jobs. Program experience indicates that Head Start centers do not rely heavily on public service jobs. However, in selected Head Start centers, there has been a reduction in the quality of services as a result of the cutback in public service employment.

Question: Will the Head Start program still be able to effectively use CETA public service job participants now that enrollment is limited to 18 months?

Answer: The program should still be able to use CETA-funded staff effectively, even under the 18-month limitation. However, the change in CETA policy will require Head Start projects to find alternative funding sources to continue CETA staff earlier than under previous policy.

WHITE HOUSE CONFERENCES

Question: What is the current status of planning for the White House Conference on Aging, the White House Conference on Families, and the White House Conference on Children and Youth?

Answer: Planning for all three conferences is well underway, with plans for the Families Conference in the final stages. The status of plans for each conference follow:

Families -- A full conference staff was hired and an executive director appointed during 1979. Regional conferences designed to debate issues and develop an agenda for the national conference have been recently completed. A national conference to take place in three major cities is scheduled for June and July of 1980. We expect that conference recommendations will be made by the end of 1980, and presented as appropriate to the Department at that time.

Aging -- A staff of 21 is being assembled during 1980, whose principal activities include assisting a technical committee of the national conference, providing guidance to the States and responding to inquiries from the public. During 1980 a 55-member advisory committee and 96-member technical committee will meet to manage the identification of issues and agenda for the national conference. Individual State conferences are planned to take place between the fall of 1980 and the spring of 1981. A national conference is now set for November, 1981.

Children and Youth -- Current plans call for a national conference in Washington, D.C., during July of 1981. The national conference is expected to attract 4,000 youth and parents, who will debate issues and concerns for children and youth. The purpose of of the national conference is to advise the public on issues affecting children and youth, and to act as a road map for resolving problems and issues during the next decade. Current plans anticipate a staff of 20 to be located within the Department's Administration for Children, Youth and Families.

Question: How is it that you are able to get by on the $3 million already appropriated for the 1980 Aging Conference, when $10 million was appropriated for the 1970 Aging Conference?

Answer: We are proposing a total budget of about $9 million for the 1981 White House Conference on Aging. In addition to the $3 million already appropriated, the 1981 budget proposes another $3 million, mainly for travel and attendence cost of some 1,800 some 1,800 delegates to the national conference. Moreover, the Administration on Aging has set aside about $2.5 million in research and education funds to help States pay costs of State conferences and forums for special aged subpopulations or for special problems of the elderly. Finally, the Department's National Institute on Aging will also commit about $.5 million for support of research and technical papers on specific health-related issues affecting the elderly. We believe that these these Federal funds together with funds provided by States will result in a meaningful and productive conference.

Question: Is there any overlap in the planning and issues to be considered by the Conferences on Families, and Children and Youth?

Answer: It is clear that many of the concerns and issues affecting families also affect children and youth, as well as the elderly. However, many of the problems children and youth face today are related to factors outside the family. In the tradition of a National Conference on Children and Youth, which began in 1901 and has occurred each decade since then, the 1981 White House Conference will focus on the unique problems and needs of children and youth.

Similarly, just as the Families Conference will not deal with all of the issues affecting today's children and youth, the Children and Youth Conference is not designed to cover the concerns of all families.

For this reason, we believe that both groups require a separately-focused review to develop meaningful and workable recommendations.

To reduce duplication between the two conferences to an absolute minimum, we have placed management responsibility for both in the Administration for Children, Youth and Families (ACYF) where day-to-day oversight of conference activities will occur.

AGING NUTRITION

Question: What steps have you taken to prevent recurrence of the overspending by States of nutrition-for-the-elderly funds, which made it necessary for Congress to provide a supplemental appropriation late in fiscal year 1979?

Answer: The Adminstration on Aging (AoA) has taken two actions which should help the States carry out their programs at levels consistent with Nutrition appropriations. First the Aging Commissioner has sent detailed program instructons to regional staff directing them to conduct ongoing analyses of States' spending in the Nutrition program. Secondly, the

Administration on Aging has held a special financial management training workshop for regional staff to improve their review of State records and to help them assist States in program planning within annual appropriation levels.

Neither the Older Americans Act nor the Department's program regulations encourage or permit States to spend at levels in excess of the annual Federal appropriation. Beginning with program guidance provided to the States in 1976, the Department has repeatedly asserted that States must conduct their programs within the budgetary limits of the Nutrition appropriation. If not, then it is the responsibility of the States and local projects to fund the additional costs with their own resources.

SUBCOMMITTEE RECESS

Senator EAGLETON. The committee will stand in recess until 10 a.m. tomorrow when it will begin its deliberations on health services.

[Whereupon, at 5:30 p.m., Thursday, January 31, the subcommittee was recessed to reconvene at 10 a.m., Friday, February 1.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

FRIDAY, FEBRUARY 1, 1980

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, Hon. Richard S. Schweiker presiding.

Present: Senators Schweiker and Schmitt.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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
EMILY L. HALEY, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT
WILFORD FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET POLICY COORDINATION

BUDGET REQUEST

Senator SCHWEIKER. The Labor-HEW Appropriations Subcommittee will please come to order.

We will begin our hearings today with witnesses from the Health Services Administration. Dr. George Lythcott, the Administrator of HSA, is the lead witness. I would like to extend a welcome to you, Dr. Lythcott, and your colleagues who have come here this morning with you.

For the record, as the name implies, the Health Services Administration is responsible for the provision of health services to our Nation's citizens. These services range from general health care services for our country's migrant and seasonal farmworkers to information and counseling services in the area of genetic diseases and family planning.

Among the HSA's activities are programs to control hypertension, to bring emergency medical care to areas lacking such services, to provide information and counseling to parents of babies who have died from sudden infant death syndrome, to develop demonstration programs in the area of home health services, to provide maternal and child health services to those in need, and much more.

It is clearly an agency with a large but critical mission. The Health Services Administration is asking for $1,437,280,000 for fiscal year 1981, an increase of $118,498,000 over the previous fiscal year.

The subcommittee has a number of questions to ask Dr. Lythcott, but before we begin with our questions, Doctor, would you please introduce your associates for the record, and then proceed with your opening statement.

INTRODUCTION OF STAFF

Dr. LYTHCOTT. I think my staff has been introduced.

On my far right is Mr. William Forbush from the Office of the Secretary; on my immediate right is Ms. Emily Haley, Director of the Office of Financial Management; on my left is Dr. Edward Martin, Director of the Bureau of Community Health Services; next to him, Dr. James Erickson, Director of the Bureau of Medical Services.

And that's it, sir.

Mr. Chairman and members of the committee, my staff and I welcome this opportunity to discuss with you the fiscal year 1981 budget request for the Health Services Administration.

The programs administered by the Health Services Administration deal with the accessibility, delivery, and quality of health care to the medically underserved and unserved people of this country.

As we enter a new decade, the importance of the programs administered by the Health Services Administration will continue to be of major importance.

Not only will the Health Services Administration continue to provide health services to the medically indigent urban and rural populations, especially to the poor and to minorities, but we will also provide the leadership, the technical assistance, and the management expertise necessary to enhance the quality of health care services, and the efficiency with which they are provided.

In addition, we will continue to provide direct delivery of health care to Federal beneficiaries through the PHS hospital and clinic system and through the Indian Health Service.

The Health Services request presently before you is for the Bureau of Community Health Services, the Bureau of Medical Services, and the Office of the Administrator, all operating within the Health Services Administration.

The budget request for the Indian Health Service, the fourth component of this agency, will be considered by the Department of the Interior and Related Agencies Subcommittee.

For fiscal year 1981, we are requesting $1.4 billion for the Health Services programs. This level represents an increase of $118.5 million over the comparable fiscal year 1980 funding level.

I should mention that almost the entire increase being requested is specifically for those programs which focus on bringing health care resources into medically underserved and health care manpower shortage areas.

Therefore, the real beneficiaries of this budget request before you are the residents of medically indigent urban and rural areas, predominantly the poor and minorities.

I would now like to discuss with you some of the key activities which will assist this agency in expanding the provision of preventive, curative, and rehabilitative ambulatory services to the medically underserved population of this country, specifically:

COMMUNITY HEALTH CENTERS

We are requesting $391 million for the community health centers program, an increase of $49.5 million over the comparable 1980 level.

This level will support 1,070 projects, including 886 primary health care centers located in urban and rural medically underserved areas, 132 black lung clinics, and 52 rural primary health care research and demonstration projects.

When fully operational, these projects will provide access to health care for an estimated capacity of 6.3 million people or approximately 21 percent of the 26 to 30 million residents of rural and inner-city areas who are without a regular source of primary care.

The requested increase will establish a service capacity for an additional 200,000 people who are desperately in need of health care services.

NATIONAL HEALTH SERVICE CORPS

An essential goal for the Health Services Administration is to improve the delivery of health services in health manpower shortage areas and to reduce the number of such areas by the appropriate placement of health professionals and resources. The request for the National Health Service Corps, which serves as the principal means for carrying out this goal, is $133.8 million, an increase of $51.3 million above the comparable 1980 level. This funding level will support the placement of 4,528 health professionals, an increase of 1,708 over the projected 1980 level. These assignees will provide health services to an estimated 1,498 rural and urban communities.

FAMILY PLANNING

We are requesting $176.9 million for the family planning program, an increase of $11.9 million. This level of funding is needed in order for us to continue our efforts toward reducing unwanted adolescent pregnancy and insuring that clients who do become pregnant are referred for appropriate prenatal medical care.

Emphasis will continue to be directed toward increasing community awareness of the problems and issues related to early childbearing and parenthood and establishing additional formalized networks for referral services to and from our clinics. In 1981, an estimated 4.1 million low-income and high-risk individuals, including 1.6 million adolescents, will be provided family planning services in title X funded clinics.

MIGRANT HEALTH

The budget request also includes $44.7 million for comprehensive health care services to migrants and seasonal farmworkers, an increase of $5 million above the 1980 level. This request represents a portion of the renewed efforts of the Department to address the needs of His-

panics and will provide for services to an estimated 591,000 people in 112 existing projects. This represents an increase of 10,000 people over the 1980 level.

MATERNAL AND CHILD HEALTH

We are requesting $360.5 million for the maternal and child health grants to States program, an increase of $15 million over the 1980 level. These funds will be used to continue our efforts to establish State-based systems of maternal and child health care, reduce infant morbidity and mortality, and expand our support of the child health initiative by establishing 24 new newborn screening programs.

HOSPITALS AND CLINICS

Another important and continuing role played by the Health Services Administration is the direct delivery of health care services to Federal beneficiaries. For 1981, our budget request includes $165 million for the continued operation of the 8 Public Health Service general hospitals, the National Hansen's Disease Center, and the 27 Public Health Service outpatient clinics. This level of funding is sufficient to maintain the Public Health Service hospitals at the 1973 level of services in compliance with Public Law 93–155.

Finally, the 1981 budget request includes $7 million for the buildings and facilities activity, a $4 million increase over 1980. These funds will enable the hospitals to meet various life and safety requirements, complete renovation of the remaining patient dormitories at the National Hansen's Disease Center at Carville, and will provide for modifications to the physical plant to conform with Public Law 93–112, which requires that Federal buildings be accessible to the handicapped.

FISCAL YEAR 1980 SUPPLEMENTAL REQUEST

I would like to mention at this time that in conjunction with our fiscal year 1981 budget request we are submitting a fiscal year 1980 supplemental request of $10.8 million for the National Health Service Corps. The amount requested was not considered by Congress during the 1980 budget process due to a lack of authorizing legislation. As a result, this program is currently operating at a funding level of $70.5 million instead of the $81.3 million requested in the 1980 President's budget.

The supplemental funds will be used to recruit and place 970 new health professionals, staffing 161 additional sites, and providing health care services to an additional 223,525 people.

Mr. Chairman, I have attempted to summarize for you and your committee the highlights of the fiscal year 1981 budget request for the Health Services Administration, and to explain the need for additional funds in 1980 to supplement the National Health Service Corps.

As I have previously stated, the majority of the program increases contained in the 1981 budget are specifically designed to expand the availability of primary and preventive health care services to underserved people in inner-city and rural areas and to develop the health care system to be more responsive to the needs of the poor and underserved.

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

COMMUNITY HEALTH CENTERS

Senator SCHWEIKER. According to the departmental information provided Congress last year, the Community Health Services programs supported development of health service delivery capacity by funding projects in rural and urban medically underserved areas where health resources are scarce or nonexistent.

How many medically underserved areas are there in the United States, rural and urban?

Dr. LYTHCOTT. There are 7,473 medically underserved areas. Of the 3,139 counties, Mr. Chairman, and independent cities in the United States, 2,431 or 77 percent are—or contain—medically underserved areas.

Senator SCHWEIKER. Do you have a rural/urban breakdown?

Dr. LYTHCOTT. Yes; of the 2,431 counties which are, or contain, MUA's, 16 percent are, or contain, a standard metropolitan statistical area—that is, are urban; and 84 percent are essentially rural; 23.6 million persons live in the urban areas, and 27.6 million persons live in the rural areas, for a total of 51.2 million persons.

Senator SCHWEIKER. How many of these are covered by a health center program?

Dr. LYTHCOTT. With the 1981 budget we'd be reaching about 6½ million people, roughly equally divided between urban and rural areas.

Senator SCHWEIKER. That's 6½ million of what?

Dr. LYTHCOTT. Of the 51.2 million, right.

Senator SCHWEIKER. To what extent does the community health center program coordinate activities with the maternal and child health program?

What kind of liaison coordination?

Dr. LYTHCOTT. We work very closely with the States with the maternal and child health program. And I would like to ask Dr. Martin to tell you how we coordinate those programs since he is at the operational level.

Dr. MARTIN. Yes, sir. Senator, the expectations both in maternal and child health State plans require that, in developing the high-risk plan for mothers and children where there are community health centers, they work in the centers to develop a shared effort in those communities. Specifically, every community health center is required to have a formal written agreement with the crippled children's agency in the State, and where there are high-risk maternity populations, the community health center is required to participate in the maternity and infant care programs.

At the committee's direction, 3 or 4 years ago the agency was expected to implement a formal system of linkage and liaison in all of the States. This has proceeded quite well in many of the States and is still being aggressively pursued so that the relationship is simply not coordination, but referral, consultation, and written agreements between the State MCH program and the community health centers program.

Needless to say, there are places where that has been less than successful. We are aggressive about implementing that need.

EMERGENCY MEDICAL SERVICES

Senator SCHWEIKER. What about the same question applying to emergency medical services? Does that come under you, too?

Dr. LYTHCOTT. No, it doesn't come under Dr. Martin, sir. It comes under the Bureau of Medical Services.

Senator SCHWEIKER. In other words, what coordination or relationship is there between your program and the emergency medical services program?

Dr. LYTHCOTT. The Bureau of Medical Services is responsible for the emergency medical services systems programs and in that Bureau is the Division of Emergency Medical Services. That division works directly with the States and the regions, actually. There are 304 regions across the country among the 50 States and there is a direct relationship between our own support of maternal and child health, community health centers, and emergency medical services programs and the States, all of whose governments support these programs.

Do you want to add anything to that, Dr. Erickson?

Dr. ERICKSON. Yes, sir, Senator. Just to add that we coordinate the work through the 10 HEW regional offices. We provide grants on a competitive basis to the 304 regions that the States divided themselves into, the 304 that Dr. Lythcott mentioned.

It's a competitive grant basis, year by year. The law divides the grants into planning grants, initial development and advanced development for advanced life support.

Dr. LYTHCOTT. Formal working agreements are being arranged with the States for the title V poison control centers and perinatal centers.

COMMUNITY HEALTH CENTERS

Senator SCHWEIKER. Last year, Doctor, Congress allowed an additional $67 million for the community health centers program. The Senate said very clearly that the first priority for these funds should be "first be used for increased operational grants to centers which are experiencing financial difficulty."

It is important that we make sure all existing centers are solidly on their feet before moving to new ones. My question, basically, is what was done in this regard?

Dr. LYTHCOTT. Let me first tell you what we did with the $67 million, Mr. Chairman: $52 million was used to fund 240 approved but unfunded projects; $6.4 million was added to allocations for ongoing projects which were experiencing financial difficulty; $5.9 million was used to cover the cost of converting 41 HURA projects to CHC's. These HURA projects had completed their research and demonstration activity; $1.6 million was allocated to increase mental health services and referral linkages in CHC's and $1 million will be used to fund 10 planning and development projects under the hospital affiliated primary care centers program.

Specifically, we carried out the committee's directive of increasing operational grants to centers experiencing financial difficulty by adding, as previously mentioned, $6.4 million of the 1980 increase to allocations for ongoing projects which are experiencing financial difficulty.

Senator SCHWEIKER. OK. Forty-six new rural projects were to be funded with this money. What's happened in this regard?

Dr. LYTHCOTT. What was the breakdown of those 240?

Dr. MARTIN. Actually, there was a total of 107 new rural projects funded with the 1980 increase.

Senator SCHWEIKER. 107?

Dr. MARTIN. Yes, sir.

Senator SCHWEIKER. You exceeded the goal. [Laughter.]

We have to give you credit for that.

PRIMARY CARE RESEARCH AND DEMONSTRATION

That's been one of the areas I've been concerned about. I think your own figures show the need in the rural areas. I'm glad to see that you more than met that goal.

I do note that you propose to reduce the so-called HURA projects from the $14 million that we provided in fiscal 1980 to $9 million in fiscal 1981. My question is, Why do you propose that?

Dr. LYTHCOTT. I think about 29 of those projects had finished their research and demonstration activity, and since the interest and the priority in the agency is on the underserved, and since they do not provide significant levels of service in those demonstration projects, we decided not to refund those 29 and to put the money into services for the underserved.

Senator SCHWEIKER. What did we learn from the 29 projects you just mentioned? In other words, what do you feel we gained from those demonstration projects?

Dr. LYTHCOTT. Dr. Martin, do you want to go into detail on that?

Dr. MARTIN. Yes, sir. We can submit a more detailed response for the record. But among the more important things that we assessed in those demonstration activities were a series of very important questions about the nature of communications technology, what was the cost-effective way to use communications technology. The committee had raised some years ago—I think it was 1975—a set of questions about computer-based technology and satellite technology, to which I think we've got some definitive answers on cost effectiveness.

In addition, there were a series of important questions about the best ways to attract and retain primary health care program people, particularly midlevel practitioners. There were demonstrations that looked at third-party financing relationships and how to work with communities in supporting health promotion education within the community for preventable diseases.

Essentially, each of the 29 projects is targeted toward a specific set of questions, and we could put a more expansive answer into the record since a number of the expectations came from the committee itself.

Senator SCHWEIKER. Fine.

Senator SCHMITT. Did you find that these advanced technologies could be cost-effective?

Dr. MARTIN. No, sir. That was a part of the great debate. But basically, satellite technology and the high-level communication technology in a clinical setting in isolated areas turned out to be significantly differently utilized in general than telephone technology and telephone transmission technology.

Now, there were exceptions to that. For example, there are the unique problems of Alaska, and some more isolated areas. Essentially, we're not testing that. We were testing the applicability of advanced technology for areas like rural Pennsylvania, east of the divide. And basically, it turned out that the telephone-based technology is a lot more cost-effective and much more used.

Senator SCHMITT. So the decision was that it was not that broad-band communications were not cost-effective; it's just that the use of satellites was not?

Dr. MARTIN. The broad-band technology for areas with other good communication forms, where there was reasonable physical access, was not cost-effective.

[The information follows:]

Some of the findings of the primary health care research and demonstration projects are:

—methods of attracting and retaining primary health care professionals for practice in medically underserved areas;

—different types of organizational models that will best serve under different situations to provide health service;

—methods of improving the provision of health promotion, and disease prevention, including the elimination of environmental hazards and health education;

—means of reducing emergency room care by making primary care readily available; and

—utilization of telecommunication systems in connecting remote sites with centralized health centers.

The findings could, with adequate resources, be distributed to rural projects or communities with instructional materials on how findings could be implemented. Technical assistance could also be provided by HEW or through contractors, as appropriate, to implement significant findings. Findings on the preliminary evaluation of technology projects, laboratory evaluation of teleradiology and an analysis of the demonstration potential of computer based health information systems have been published and disseminated at professional meetings, and to HEW regional offices and interested parties.

Dr. LYTHCOTT. It turns out that was very useful to us. Alaska turned out not to be very useful to us in rural areas——

Senator SCHMITT. I see. Is this because of the cost of the terminal facilities?

Dr. MARTIN. Yes, sir. It's the cost-benefit over time.

Senator SCHMITT. Was the principal problem the cost of the hardware?

Dr. MARTIN. The hardware and the maintenance of the software activity and upkeep, which turns out to be a very large——

Senator SCHMITT. You would have to do that with any broad-band communications. If you're going to use software, you'd have that problem.

Dr. MARTIN. Agreed. But again, when you use telephone transmission technology, most of those activities don't require the same kind of maintenance and specialized upkeep.

We have a fairly extensive report that's been developed within——

Senator SCHMITT. That's a report we shall look at. I hope that report will indicate the bounds of the study.

Dr. MARTIN. Absolutely.

Senator SCHMITT. What was included and what wasn't, because sometimes that can make a difference. For example, the cost of terminals, reception of satellite transmission, is going down very rapidly. I think the Japanese are marketing an antenna, less than $1,000, that had been previously a major cost factor, and seems to be disappearing.

Dr. MARTIN. Our applications are within study designs of those limitations. The observations were against specific hypotheses being tested, and that's why it's important to provide those to you.

RESEARCH AND DEMONSTRATION PROJECTS

Senator SCHWEIKER. Of the 29 projects that will no longer be funded, how many will actually continue in operation in fiscal year 1981, even though they are not funded under the HURA appropriation?

Dr. LYTHCOTT. I think we plan to continue them all.

Dr. MARTIN. The bulk of the service elements of those 29 projects have already been converted into section 330 grantees. So that the service components are already picked up by our alternate grantees.

Senator SCHWEIKER. So you're saying they all are continuing service componentwise?

Dr. MARTIN. Yes. The R. & D. effort was funded for that period of time, and their final reports will have been submitted in the hypothesis testing.

Senator SCHWEIKER. How many new grantees will the $9 million proposed in your appropriation allow for?

Dr. LYTHCOTT. I'm sorry? Which appropriations? HURA?

Senator SCHWEIKER. Yes, still on HURA.

Dr. LYTHCOTT. There will be no new HURA projects, as I understand it.

Senator SCHWEIKER. What is the $9 million for?

Dr. MARTIN. The $9 million is to continue 52 existing projects. They are normally funded for 3 to 4 years apiece.

Senator SCHWEIKER. I see. So you're continuing existing and not adding new ones?

Dr. LYTHCOTT. Yes.

HYPERTENSION

Senator SCHWEIKER. Hypertension has long been known as a risk factor in coronary heart disease, renal disease, stroke, congestive heart failure—all life-threatening or severely debilitating disorders. It is among the most common physical disorders among adults, and probably one of the most treatable and preventable.

There is a higher incidence of hypertension among both black men and women than among white men and women. There seems to be a greater incidence of high blood pressure among poor people as well.

Given the two aforementioned correlations, what kind of emphasis is given to these populations in the screening, diagnosis, treatment, and followup programs funded under this program?

Dr. LYTHCOTT. We work very closely with the States in this program, and until last year it was basically a State program. We now have discretionary funds available for the hypertension program, and the importance of that is that we are able to zero in on the high-risk areas. In other words, it isn't just a State program; it is a State program that is competitive with other State programs in their effort to serve the high-risk populations which you just mentioned.

Senator SCHWEIKER. Do we know why medically blacks have a higher hypertension rate on the average? Is that medically known yet or not?

Dr. LYTHCOTT. I don't think we know entirely. I think there are a number of factors that have been suggested. I think probably diet and problems of anxiety and tension. I think that there is undetected kidney disease in childhood. Black children are a group of people who don't get the best of care.

We know that the major complication of nephritis, for example, is hypertension in later years. And I suspect that the majority of minorities who are now showing this hypertension had undetected kidney disease back 30, 40 years ago, when they were children. That has not all been worked out entirely.

Senator SCHWEIKER. As I understand it—incidentally, Jack, any time you want to interrupt, just do so. Don't hesitate to interrupt.

Senator SCHMITT. All right.

FOLLOWUP AND PATIENT EDUCATION

Senator SCHWEIKER. As I understand it, one of the major problems in treatment of hypertension is getting the patient to follow the medical regime prescribed; that is, taking his or her medication on a regular basis, following dietary instructions, et cetera. Consequently, it would seem the followup services and patient education activities are very important.

To what extent are followup and patient education services funded under this program?

Dr. LYTHCOTT. Followup and patient education services are funded in the program from the point of view of clinics that we run and point of view of outreach following a visit. We work very closely with the States in this effort and much of the State effort is related to followup.

Dr. Martin, did you want to say a few words on that?

Dr. MARTIN. Yes, sir. Each State, in getting an approvable application, must have a staff mechanism within its State mechanism for treatment and followup. So at least the level of compliance with treatment can be assessed.

In all of our other service programs—community health centers, migrant health centers, and the like—there is a requirement for continued funding, that the medical staff put under effective medical treatment all of those patients with hypertension. We expect a 90-percent followup on all of those patients at risk. We have a very aggressive agency posture, and since most of our programs serve those at highest risk, it has a

significant impact upon the population at risk. We are quite aggressive about our expectations of our centers, our clinicians, and our grantees, sometimes to their discomfort.

But we feel that it is inappropriate to do otherwise than be very aggressive.

Senator SCHWEIKER. How many new people will you be able to reach in fiscal 1980 now, with the increased appropriation?

Dr. LYTHCOTT. In 1979, we reached 4.8 million; in 1980, 7.8 million; and in 1981, the same number. With cost effectiveness we can increase this number.

Senator SCHWEIKER. How many people theoretically will we not be able to reach? We know hypertension is a major problem. Obviously, we're not going to able to reach them all by any means. Do you have any estimate on that?

Dr. LYTHCOTT. 7.8 million of the estimated 35 million people with hypertension will be screened in 1981.

Senator SCHMITT. Mr. Chairman, could I interrupt?

We might as well keep these in sequence. Are you through with hypertension?

Senator SCHWEIKER. Yes, go ahead.

HOME HEALTH

Senator SCHMITT. On the home health area, obviously relatively speaking, there's not a lot of funding. Is there a reason for that, for writing that out of your program now?

Dr. LYTHCOTT. We have decided to write it out of our program, because we feel that the Federal Government has done what it is supposed to do. It has served as a catalyst in developing interest in home health programs. Since these programs are reimbursable by third-party payers, it has become a very popular instrument for the private sector and we have no doubt in our minds that the home health programs, which are good programs, will be continued by local and State governments.

Senator SCHMITT. Could you expand on that some for the record—your rationale now for showing us that, in fact, it is taking off in the private sector, because this is a tremendous alternative—for example, even to hospital cost containment, Mr. Chairman.

Dr. LYTHCOTT. Senator Schmitt, you should also know our program did not supply the reimbursement of these programs. It supplied the training for persons in the program to make the program eligible for third-party reimbursement. The major moneys for these programs are——

Mr. FORBUSH. I would just like to add that part of our legislative program this year—we're making two proposals to expand the availability of this universally. Under medicare, for example, current law requires you be in the hospital for 3 days before you can take advantage of the home health benefits. We are proposing to eliminate that 3-day period.

In medicaid, we are proposing a change in the eligibility criteria. Now it's easier to get into a nursing home than it is to get the care delivered in your home. We want to make the eligibility criteria the same.

61-400 O - 80 - 8

Senator SCHMITT. Have you made any estimates—what budget does this come under?

Mr. FORBUSH. In the Health Care Finance Administration.

HOME HEALTH COST SAVINGS

Senator SCHMITT. Have you made estimates on cost savings of this kind?

Mr. FORBUSH. We are estimating very conservatively. We have estimated the costs—the cost of increased home health benefits, about $30 million.

Senator SCHMITT. That's a net increase?

Mr. FORBUSH. It's really not. It's a gross increase.

There are presumptions. Many people say that this substitution factor will create a savings, but there's also an induced demand. More people will be getting services than are getting them under the current system. It's hard to say.

The Health Care Finance Commission—it's my hope that the net costs will not be increased.

Senator SCHMITT. Ideally it would be less?

Mr. FORBUSH. Yes.

Senator SCHMITT. People would stay home rather than go into a hospital or nursing home. It should be less.

Mr. FORBUSH. Also, a lot of people are getting care who weren't getting it at all. For example, if they don't want to go into a 3-day——

Senator SCHMITT. Looking at the relevant costs, that number is going to increase by a factor of 3 to 4, where you could still save money.

Mr. FORBUSH. On paper that's the way it looks. But oftentimes we've made assumptions like that and they turned out not to be true.

Senator SCHMITT. I understand.

Thank you, Mr. Chairman.

Dr. LYTHCOTT. We'll expand on the question for the record.

[The information follows:]

The home health program has been successful in accomplishing its objective. It has demonstrated cost effectiveness based upon comparison of the average cost of $24 for a home health visit to the average daily cost of $246 for an inpatient hospital visit. Also, the program has demonstrated that small amounts of funding to dedicated local groups can develop new home health agencies as well as expand existing agencies.

We expect the program to continue through State and local groups now that the Federal program has demonstrated the efficacy and viability of the concept. Also, expansion of existing home health agencies as well as development of new agencies can be continued by States and localities by utilizing third-party reimbursements under the Social Security Act, public funds, and private funds such as those from foundations and charitable organizations.

It should also be noted that the Administration continues to be supportive of home health. The 1981 budget request for the Health Care Financing Administration (HCFA) provides for increases of $23 million to fund liberalized home health benefits.

TEENAGE PREGNANCY PROGRAMS

Senator SCHWEIKER. According to information supplied by the Department last year, title V is a major national resource for the provision of basic preventive maternal and child health services, with emphasis on reduction of infant and maternal mortality and morbidity and teenage pregnancy.

Now I was one of the sponsors—in fact, worked very hard to get our teenage and adolescent pregnancy bill through the Congress, and through abortion fights, and everything else. It wasn't very easy to do, frankly.

So my question is: How are your teenage pregnancy direct activities different from those carried out under the adolescent pregnancy program in the Office of Assistant Secretary for Health or your family planning program?

Dr. LYTHCOTT. Let me say, basically, our activity in family planning and teenage pregnancy has to do with the delivery of health services. The function of the program in the Assistant Secretary's Office is to provide the glue for all of those kinds of influences that impact on teenage pregnancy. That would include education and jobs. It would include legal support, day care, and so forth.

Ours is specific health; theirs is generic, in which health and other things fit.

Senator SCHWEIKER. Do you think there is any duplication or overlap here, No. 1?

And, No. 2, can we combine them in some way?

Dr. LYTHCOTT. I don't think there's any duplication or overlap. We work very closely with that Office—and Dr. Martin can develop that a little more—and with other agencies that have dollars for family planning and teenage pregnancy.

I think the closer these offices work together, the better the result. I think that's what you're getting at, and I would not hazard a guess as to whether they ought to be put together.

But I say, sitting where they are, we work very closely with several groups, several agencies, including the Office of Adolescent Pregnancy Programs, in the Assistant Secretary's Office.

Senator SCHWEIKER. Let me just ask one other question, and perhaps you can answer.

I know the President's budget for the adolescent pregnancy program is the same as for this past year, $17.5 million.

How much money will you be spending in this area, in the same area?

Dr. MARTIN. The nature of the relationship I think Dr. Lythcott has spelled out very clearly. There is an interagency agreement essentially being established to delineate responsibilities to insure there is no overlap.

We don't anticipate that there will be that kind of programmatic overlap, because indeed what Dr. Nix is doing is using those resources to tie together the Department of Labor, or the WIC program and OHDS programs, HCFA reimbursement and the Department of Education activities along with health activities.

When dealing with pregnant teenagers, that ability to get those resources together in the health care provider's point of view is imperative. And simply being able to medically treat a pregnant teenager isn't enough. You need that range of other services, and that's what the program does.

In regards to the amount we spend on health services—for example,

in family planning alone, about 31 percent of the total title X dollars are utilized for ages 18 and below.

The maternal and child health program—we can submit precise figures for the record—makes significant expenditures for maternity, infant care, postdelivery, family planning as well.

Again, it's important to point out that those funds being utilized by all other programs for teenagers, well in excess of $150 million, are for a set of services which are not being duplicated. Those are provided in medical services and health services as a part of day care, vocational rehabilitation, counseling, housing, legal services that go on with the pregnant teenager.

Frankly, without those other services, a lot of what we're trying to do will not be successful.

IMPROVED PREGNANCY OUTCOME

Senator SCHMITT. Mr. Chairman, if you will yield——

Senator SCHWEIKER. Sure.

Senator SCHMITT. We've had an unbelievable decrease—and it's still too high—in mortality rate for babies down in New Mexico as a result of—a fairly locally based network was set up, which does not particularly concentrate on the prenatal, but on the first 24 hours after birth, on monitoring of children, and the transportation network to get them to intensive care centers if they need it.

Is that some thing happening nationwide? Is your agency working with these kinds of issues.

Dr. LYTHCOTT. Yes, sir. We have what are called improved pregnancy outcome programs, and they exist in several States. And they exist for precisely the same reason that you mentioned. Actually, they are in 28 States in 1981.

Dr. Martin, would you tell the Senator a little bit more about how these programs function?

I think they're 5-year grants at a time, and we have them in 28 States in 1981, and they include exactly what you are recommending.

Senator SCHMITT. Have you been assisting New Mexico?

Dr. MARTIN. Yes, sir. In fact——

Senator SCHMITT. I couldn't remember whether they organized it on their own or if they had assistance.

Dr. MARTIN. Well, the important part of how we work this particular grant activity is that we are delighted to hear that you felt it was locally and State generated, because that's the design of the money we've put in.

What we did some number of years ago was look at——

Senator SCHMITT. Let's say we don't see very many Feds involved in the program, mostly local people.

Dr. MARTIN. Actually, in the New Mexico program there are four National Health Service Corps assignees.

Senator SCHMITT. We'd like to think of them as potential residents.

Dr. MARTIN. Precisely.

I think, to the heart of the point, effective intervention programs, with family planning, with prenatal care, early detection, good nutrition

for the mother, good prenatal care, good delivery, and the referral services are responses which must be developed at the local community and State levels.

To be effective, you have to build that capacity within those localities and States.

The money we have sent to the State of New Mexico and some 28 other States includes money for increased targeting of prenatal services.

There's been much of an improvement in the WIC services provided to pregnant women in the State of New Mexico. We funded the perinatal intensive care activity, which is tied in, I would also add, to the EMS system in New Mexico for transportation.

We have provided prepregnancy——

TRANSPORTATION TO FACILITIES

Senator SCHMITT. Do you assist in their transportation?

Dr. MARTIN. In the actual funding? No, sir.

We help put together the technology and train the people who are involved in perinatal intensive—infant transfer is a complex activity.

Senator SCHMITT. I understand, but it's absolutely essential in these fairly large rural areas. The whole system will break down if you can't move the crisis.

Dr. MARTIN. The actual vehicles themselves are provided, and a set of other resources with which we work. So basically the evolution of that system in New Mexico is being aggressively pursued in some number of other States, basically using comparable models.

Community and local systems development, State assurance development, State transportation capability, and medical centers—and there the University of New Mexico is central, because that is the tertiary perinatal care center in the State of New Mexico.

Our funds, under title V, are being expended specifically for that development.

Senator SCHMITT. It's my understanding in the first year of major operation of the system we have they cut the death rate in the first 24 hours by a factor of 2, something like that. A very impressive change for a short period, but it's still too high, far too high—I think one of the highest in the Nation.

NATIONAL HEALTH SERVICE CORPS

Senator SCHWEIKER. I'd like to turn now to the National Health Service Corps. As I understand, one problem experienced by the National Health Service Corps is getting a health care professional to remain in an area beyond his or her obligatory payback period.

To what extent is this a factor presently?

Dr. LYTHCOTT. It still is a factor, Mr. Chairman, but when we look at where we have come from, I think we are progressing rather nicely. In 1974, for example, we had about a 3-percent retention. In 1979, we had about a 53-percent retention. I don't think it's going to go up over the next 4 years to that degree, but we think it will steadily rise as we increase our effectiveness and increase our ability toward understanding

problems and encouraging young people to come into these areas and remain there.

Senator SCHMITT. What has made the difference?

Dr. LYTHCOTT. I think a number of things have made the difference. Dr. Martin can go into the details on it, but we spend a great deal of time matching the Corps assignees to communities and encouraging them to enter dialog and encouraging them to become a part of each other as the years go by.

We have been able to place the assignees in systems of care rather than in isolated areas, as we used to do. In other words, we still have some in isolated areas, but we have found out the hard way that the way for the best retention is to put these young men and women in systems of care where they can relate to other health professionals, have continuing education, and can feel they are progressing and improving and expanding as professionals, as they deliver the health care services.

Dr. MARTIN. I think that's the critical factor. The largest reason for physicians to leave areas has to do with professional satisfaction. You work 7 days a week, 24 hours a day. When you don't have the professional dialog with your colleagues and when there's an enormous amount of pressure on you as an individual as opposed to you as part of a group, it has a significant impact.

Our experiences in 1973, 1974, and 1975 were, not only from the retention point of view, but from a management point of view, a very serious problem. Not only did we lose a lot of assignees, but we had a lot of assignees who became problems because of that isolation. So that when we talk about placing corpsmen in integrated systems, we mean systems that provide that whole support capability, whether they be community health centers or State-sponsored programs, whatever is the mechanism to develop those services.

Another big and important factor has been the fact that we are getting more physicians who have completed their training. A great deal more work has gone into getting the physician ready to go and, after they are there, trying to provide support. We've got more to do there, but there has been over the last 5 or 6 years a vast growth in our support capability for assignees. It's really a critical factor.

Without that support——

RETENTION OF SPECIALISTS

Senator SCHMITT. What you are saying is that you have discovered the same thing that the communities have discovered. If they want to retain new young physicians, they have to provide other new young physicians an opportunity to work together in the same community area, same general area. That's been true in New Mexico.

But the biggest problem has been internists. Do you find that in your program—that internists are the hardest to attract, to retain in the service?

Dr. LYTHCOTT. Do we have that kind of breakdown? That isn't my impression.

Dr. MARTIN. We can provide that.

I can say unequivocally psychiatry, obstetrics, and gynecology are the

toughest areas at this time, in rural areas. For example, in northern New Mexico, there is a serious problem in trying to get those kinds of skilled professionals.

I think the difference between internal medicine and pediatrics isn't that great. Between those two professions and family practice, there is a difference. In other words, family practitioners are better trained to work in rural communities as part of a small group. They're better prepared. They also have different coverage requirements from different hospital expectations, so that it's really a three-tiered system. Family practitioners are the best prepared by their training and their residencies.

The next group would be internal medicine, with pediatrics about the same. The third group, which is very difficult, includes obstetrics, psychiatry, and some of the specialty groups which simply are ill adapted because of training and inclination to want to move into those areas. In rural America, that's a serious problem, particularly in obstetrics.

RETENTION RATE

Senator SCHWEIKER. How do we calculate—what's our definition of retention? In other words, you said you went from 3 to 53 percent. By what terminology or definition?

Dr. LYTHCOTT. We calculated on the basis of having finished the obligation, returning to a health manpower shortage area, either as an extension of the original contract or by going into private practice in the health manpower shortage area.

Dr. MARTIN. Importantly, when we say "private practice," we do not limit that to private solo, fee-for-service practice. That is, there are many group practices. There are many supportive practices.

Senator SCHWEIKER. Any kind.

Dr. MARTIN. But they are not on the Federal payroll.

Dr. LYTHCOTT. We feel we should get credit for those people who re-up for another 1 or 2 years, despite the fact that they're still in the National Health Service Corps. If they chose to stay 1 or 2 years, it meant they had an exciting experience.

Senator SCHWEIKER. So it's people who sign up for another year or so, and it's also people who opt to stay in some private sector or group practice.

Dr. MARTIN. Or State-supported activity in the same area. I think, again importantly, the 53 percent has been the retention rate for the last 2 years. One must remember it has only been as of 1976 or 1977 that there were significant numbers of people beginning to extend, so our experience is with respect to their staying for 3 or 4 or 5 years.

These are the first 2 years we've had this kind of a very positive experience, so it's difficult for us to say what it will be after 5 or 6 years.

Senator SCHWEIKER. Do you have a longer range study underway now, such as a 5-year study? I recognize you're saying the rate has only come up in the last 2 years, so a 5-year study right now wouldn't mean anything.

My point is, do you have the thing in place so that you will be able to get that answer as population moves through a 3- to 5-year period?

Dr. MARTIN. We have a study which includes all alumni since 1973 of the entire National Health Service Corps program. Each subsequent year will be tracked in this contract evaluation, so that by next year we will have 8 years of experience. It's a continual study conducted with rural health manpower.

Senator SCHWEIKER. It is a continual study of that body?

Dr. MARTIN. Yes, sir.

COORDINATION WITH PRIVATE SECTOR

Senator SCHWEIKER. What efforts have been made by HSA to assure that the BCHS grants do not interfere with delivery of health care services by the private sector in these underserved areas?

Dr. LYTHCOTT. In the first place, Mr. Chairman, by law we must put these community health centers or National Health Service Corps personnel into medically underserved areas or in health manpower shortage areas. In other words, those areas are listed—they're listed in the Congressional Record—and if they are there, it is sine qua non that they are manpower shortage areas. Therefore, there is nobody already there.

As a second issue, we have review and approval by the local planning agencies—mainly the health systems agency in these areas. They must tell us indeed that this applicant is in a bona fide, a medically underserved or health manpower shortage area. That's a prerequisite of a grant proposal. Local HSA and other local planning activities must agree and concur. That comes in as a part of the review that the regional office looks at. If that isn't there, it's an incomplete proposal or presentation.

I might add that once a year I send a memo to the field reminding them that it is important that local professional societies and certainly local practitioners be apprised in advance of the plan to put either a community health center or to put National Health Service Corps personnel in an area, so that they can respond. So we go out of our way to make certain that we're not infringing upon the private sector.

I could provide for the record that memo that went out in August of last year and the response I got from the AMA thanking us for doing it and their memo to the local AMA chapters, saying this is the position that the Federal Government takes and they support it.

Senator SCHWEIKER. I think it would be helpful to have that.

Dr. LYTHCOTT. We'll provide that for the record, sir.

[The information follows:]

LETTER FROM DR. JAMES H. SAMMONS, M.D., EXECUTIVE VICE PRESIDENT, AMERICAN MEDICAL ASSOCIATION

January 22, 1980

George I. Lythcott, M. D.
Administrator
Health Services Administration, PHS
Department of Health, Education, and Welfare
Room 14-05, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20852

Dear Doctor Lythcott:

Thank you for having Doctor Martin forward a copy of Regional Memorandum 79-32, dealing with community involvement in development of projects supported by HSA.

The Association has long been of the opinion that such programs will be far more effective if they have the input of the local medical profession while they are being developed.

As you will see from the attached, we are giving the Memorandum, and your efforts in this regard, wide distribution to the profession.

Sincerely,

James H. Sammons, M. D.

MEMORANDUM FROM DR. JAMES H. SAMMONS, M.D.

January 19, 1980

TO: Executive Directors
State Medical Associations
County Medical Societies

SUBJECT: Involvement of Local Medical Profession in Placement of Health Services Administration (HEW) Projects

Attached for your information is a memorandum from the Administrator of the Health Services Administration (HEW) to all Regional Health Administrators calling for assurance from project applicants that medical or dental societies and individual physicians and dentists serving a particular underserved area are involved in project grant decisions.

Considerable emphasis is placed on the innovative suggestions which can result from such involvement, the fund of good will and encouragement, and the importance of mutually supportive relationships with other health care providers in the area.

The memo applies primarily to Community Health Centers, Urban Health Initiative and Rural Health Initiative projects, and placement of National Health Service Corps practitioners. Grant applicants must provide assurance that they have informed and sought comment from organized medical and dental societies and from individual physicians and dentists in the area to be served before an award will be granted.

This approach is consistent with long-standing AMA recommendations for local input to such programs. Doctor Lythcott is to be commended for his efforts to increase involvement of the medical community in Health Services Administration programs.

Sincerely,

James H. Sammons, M. D.

MEMORANDUM FROM DR. GEORGE I. LYTHCOTT, M.D., ASSISTANT SURGEON GENERAL

TO : Regional Health Administrators, PHS Regions I - X

DATE: OCT 22 1979

FROM : Administrator

SUBJECT: Bureau of Community Health Services (BCHS) Regional Memorandum 79-1 32
Community Involvement in the Development of Health Services Administration (HSA) Supported Projects

Community involvement is essential for the effective operation and support of health service projects and systems. Under Regional Memorandum 78-33, we advised that failure to involve medical or dental societies and individual physicians and dentists serving a particular underserved area is a serious deficiency in the administration of our programs and violates the intent of our regulations. Applicable regulations were cited in that memorandum.

Many innovative suggestions may be elicited and a fund of good will and encouragement may result from the appropriate involvement of practitioners in underserved areas. Applicants should be aware of the importance of the development of mutually supportive relationships with the other health care providers in the area in order to promote the most effective functioning of the projects.

We continue to receive complaints that medical societies and individual practitioners, notably minority organizations and individuals, are not involved in decisions to place HSA resources in their areas and often are not even notified of impending placements of Community Health Centers, Urban Health Initiative projects, Rural Health Initiative projects, or National Health Service Corps practitioners in their area. This is a disservice to those individuals and may deprive us of their good will, cooperation, and assistance.

Applicants for HSA projects must inform individual physicians and dentists practicing in the area of the intent to develop a project and invite any suggestions and support they may be able to provide, in addition to contacting organized medical and dental societies, including any minority societies.

Henceforth, an assurance that such notification has taken place should be required before the award of a grant.

/s/ George I. Lythcott, M.D.

George I. Lythcott, M.D.
Assistant Surgeon General

ASSISTANCE TO SMALL HOSPITALS

Senator SCHMITT. Mr. Chairman, will you yield?

Senator SCHWEIKER. Yes.

Senator SCHMITT. Has the HSA looked at the problem that I'm sure is not confined to New Mexico where in past times there were built small hospitals which are no longer economically used even though they could be very useful. They just are not economic. We have a number of them in New Mexico, some of which have become economic because of centralized management by St. Joseph's or Presbyterian or other organizations, but others just haven't been able to operate. One of them is a very fine facility in Carrizozo but you just can't make it operate. The same goes for Santa Rosa and others.

Have you looked at the possibility of setting up the Health Service Corps as a way in which some of these could begin to operate and possibly find their way back to economic status?

Dr. MARTIN. A number of those communities faced with that problem have requested National Health Service Corps assignees and even following that have asked, for example, for rural health initiative grants.

I think it is important, though, that most physicians in the National Health Service Corps would be admitting patients to a hospital near to them when they need admission. I think in some cases the total number of admissions that can be put into a hospital that has good medicine are less than make it economically efficient.

We do not encourage our practitioners to fill up the hospital. Now a number of these hospitals when faced with this further dilemma—now they've got three doctors, and they are admitting what they think are the medically indicated admissions, and they still have available space—in a number of places, these are being converted to ambulatory facilities, to long-term care facilities or to nursing homes so that the space of the facility is being used.

And we see more and more of this. It's a really cooperative effort between the Health Systems Agency, the communities, and State certifying agencies.

Senator SCHMITT. How would a community get involved in that? For example, the Santa Rosa Hospital has been trying for years to get back on its feet and could, I think, fit very neatly into that kind of a system if they had the assistance and encouragement and managerial consultation necessary to get it started.

How would they apply to get into some program like that?

Dr. LYTHCOTT. Almost all of our technical assistance comes from our regional office. From the Dallas regional office, which serves New Mexico, we could provide people who could give advice and counsel in this area.

Senator SCHMITT. So if they have not done that, we could suggest to them that they get in touch with your regional office and see what might be——

Dr. LYTHCOTT. That's the first step, sir.

Dr. MARTIN. We average about 20 requests a month very similar to that. "Here's our dilemma; can you provide assistance?" And we dispatch a group of people from our regional offices, and a significant number are successfully engaged.

Senator SCHMITT. Thank you.

MANAGEMENT OF GRANTEES

Senator SCHWEIKER. What activities have been undertaken since the beginning of fiscal year 1979 to improve the management, record-keeping, and auditing efforts of all the BCHS grantees in all their activities?

Dr. LYTHCOTT. We have a problem in this area, because we see in a year or years of tight budget that the only expansions we have are going to be on the basis of increased efficiency.

Dr. Martin, would you like to tell the chairman the kinds of things

that we do to support better efficiency and management and audit and so forth?

Dr. MARTIN. Yes, sir.

Senator, with the assistance I might add of the committee, a few years ago we implemented a very firm common reporting requirement—administrative indicator system with our projects—where we required all projects to establish approved accounting systems. We had financial management expectations. We began to do regular audits. I think we now do in excess of 120 audits a year. We have dropped our administrative cost down to about 21 percent, which is very healthy compared to what it was.

We have been able to drop significantly the cost of per delivery of services. For example, some of the older GAO reports had a series of recommendations, all of which we have been able to implement in that we have been agressive about decreasing the cost per service. You can do this by increasing productivity, cutting unnecessary services, and decreasing overhead.

The cost now for urban centers, for example, is less expensive in the aggregate than for comparable emergency rooms or OPD's. This is the real heart of the success of what we have been able to do in our centers.

Now we are in the process of establishing standard charts of accounts, standard accounting systems with a required annual audit where we will be asking the independent auditors to go in against a specific protocol to tell us this, this, and this is done. The 1973–78 concern that was raised mostly on centers before 1976 about fraud and misuse of funds has become the rare exception which proves the rule now.

We have very few cases—other than very complicated community situations and management situations—where facilities are in trouble. For example, the city of New York, we have some centers that have great difficulty. We also have about 20 voluntary hospitals equally in difficulty.

Those kinds of problems, though, aren't a reflection of the center management. We've been very, very aggressive about that, and we can submit for the record an overview of these activities which I think is a significant testament to managers of the centers themselves and, I think, belies any suggestion that they are not well managed.

Dr. LYTHCOTT. As a matter of fact, Mr. Chairman, I am in the process of developing a relationship with Harvard Medical School, which is putting on a special program for midlevel managers, and we will make this an encouraged, allowable expense on the part of the center sending their senior people to a 6-week course. We do everything we can to improve the management and expertise there.

PHYSICIAN SUPPLY

Senator SCHWEIKER. In planning the expansion of the National Health Service Corps and the other BCHS programs, how has HSA accommodated the increased supply of physicians that will be available by 1985, and the impact of these individuals in underserved areas. The debate, as you know, is going on about just when our physician supply

will become adequate. I realize it depends a lot on the areas that you are talking about.

My question, obviously, is how do we integrate that rising supply of physicians in terms of where you propose HSA programs to be in 5 years?

Dr. LYTHCOTT. Mr. Chairman, there is a report I would prefer not to preempt by discussing it. It is in the hands of the Secretary and the Office of Management and Budget right now, which spells out how we see our relationship, where we see ourselves going, what we see the numbers to be, to be supported, the numbers of physicians that will be needed and the numbers of physicians the Corps should supply.

If you don't mind, sir, I would like to wait until that document is——

Senator SCHWEIKER. When might we expect that?

Mr. FORBUSH. It's hard to tell. [Laughter.]

Senator SCHWEIKER. What kind of an answer is that? You have to do better than that.

Mr. FORBUSH. It requires——

Senator SCHWEIKER. He whet my appetite here.

Senator SCHMITT. Both honest and wishy-washy. [Laughter.]

Senator SCHWEIKER. I'm glad there's a study underway. I think it's very helpful.

But we really need that kind of managerial tool ourselves. So I hope that we can get it.

Mr. FORBUSH. The difficulty is making a decision. It really is for the next 10 years. It's hard to get any administration to really come down with something that far in advance.

Senator SCHWEIKER. I realize when you get that far away, a lot of it is guessing.

Mr. FORBUSH. This program has a very long leadtime. The scholarship recipient today doesn't go on line for the next 7 years. You've got to think in those long-range terms.

We have not been able to achieve a closure on policy with OMB.

Dr. MARTIN. I think, Senator, for the record it's important to point out two things: First, the expansion proposed in the President's budget for 1981 is importantly targeted to areas where there is no evidence whatsoever that the increase over the last 10 years, which was about 70,000 practicing physicians, has had any impact at all.

So the way we target our programs is to areas where in the face of a significant increase in the last decade, there has been no impact at all in isolated rural areas.

Certainly, the debate going on is not about the worst areas where there——

Senator SCHWEIKER. I realize that it's a long-range debate.

Dr. MARTIN. That's where we are targeting these resources for the next 2 or 3 years.

REPORT ON FUTURE PROJECTIONS

Senator SCHWEIKER. Why don't you release half the report to us, then? [Laughter.]

Look, I'm not arguing 10 years because who knows about 10 years?

Is there any way if you are really going to get hung up on support, that we could break out the 5-year projections, which I think would be a lot more relevant to this committee for this work than would be 10 years?

With 10 years you're moving to a guesstimate, anyway.

Mr. FORBUSH. What we can and are doing is a projection of what our current policy would require for the out-years, the current rate of scholarships, how many people will that require us to place in these areas and what the impact would be of the growing supply of medical manpower, generally.

Dr. Foley testified yesterday in the House that there is an increased rate of people locating in these areas, anyway, apart from the National Health Service Corps. When he comes before the committee next week, I think you might want to focus on there.

Senator SCHWEIKER. Where are we on this report, though?

I'd still like to get the administration pinned down on something.

In other words, can we get 5-year projections of some kind?

Mr. FORBUSH. I think in a matter of a couple of weeks, we can get the projection of current policy, which is very substantial.

Senator SCHWEIKER. We'll start with that because it's really very helpful to us.

I realize, you know, you have to clear your hurdles, and I think it's not easy when you get a long-range projection, that has a lot of differing philosophies in it.

But it helps us do our job better, too, when you have this kind of informed approach.

I appreciate your mentioning it.

We respect the need for the administration to clear their bases first, if it isn't too long.

Mr. FORBUSH. We've been trying for over a year.

INTEGRATION OF ACTIVITIES

Senator SCHWEIKER. That's what I mean, if it isn't too long.

OK, what efforts are made by HEW to incorporate multiple initiatives such as hypertension, family planning, genetic counseling, migrant health into a single community health center in terms of an overall effort?

Dr. LYTHCOTT. If you're speaking to the issue of comprehensiveness of our centers, Mr. Chairman, we are doing that and have been doing it for quite a long time. And we will continue to provide as many services as are efficient in a single setting.

We are getting away more and more from the categorical types of programs where patients must go from one building to another crosstown for other services.

So we are integrating our activities wherever we can. That's the name of the game from here on out.

FEDERAL SUPPORT AND SELF-SUPPORT

Senator SCHWEIKER. What technical assistance or other support serv-

ices are provided to the centers, communities, or National Health Service Corps personnel to help them convert their federally funded program or practice to a self-supporting program or basis? And what progress are we making in that regard?

Dr. MARTIN. There are three types of support. The most fundamental importance of what we provide is technical and management assistance in developing a strong management system and effective building capabilities so the bulk of the costs are borne by third party and cash receipts at the site. This has been successful in the aggregate in the almost doubling of third-party receipts over the last 3 years.

The second type of assistance that we provide has to do with the professional type of consultation that we provide and the expectations that we provide to tie in our providers with other parts of the health care system in the community.

The third has to do with an additional series of activities. We had the private practices grant program for the National Health Service Corps, which, once those communities or physicians have reached that point in time, facilitates conversion into a nonfederally supported activity.

I think it's important to point out that the priority we accord for where we put our centers and our corpsmen makes those, by definition, the very most difficult areas to do that.

We're not putting them in areas where the conversion is very simple because, indeed, the areas where it is easiest are not the ones in greatest need of the assignment of Corps personnel.

Senator SCHWEIKER. You mentioned these figures and it would be helpful if we could have them in detail.

As regards the retention status of the National Health Service Corps personnel who have completed their obligated service, I wonder if we could have a detailed breakdown for the record. We don't want names or anything personal, but we would like to see the trend that you are so encouraged about because that certainly has some bearing on the way we look at some things.

If you can give us a detailed breakdown on that——

Dr. LYTHCOTT. We'd be pleased to do that.

[The information follows:]

61-400 O - 80 - 9

NHSC Retention by Region and State, Fiscal Year 1979

	Number of Assignees Retained in HMSAs												Number of Assignees Leaving HMSAs			
	Extending with NHSC				Converting to Private Practice in HMSA				Total Retained in HMSA							
	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total
Region I																
Connecticut	--	1	--	1	--	--	--	--	--	1	--	1	--	--	--	--
Maine	4	3	--	7	--	--	--	--	4	3	--	7	3	1	--	4
Massachusetts	3	--	1	4	--	--	--	--	3	--	1	4	1	--	--	1
New Hampshire	1	--	--	1	4	--	--	4	5	--	--	5	2	--	--	2
Rhode Island	--	--	--	--	--	--	--	--	--	--	--	--	--	--	1	1
Vermont	1	3	--	4	1	--	--	1	2	3	--	5	2	--	--	2
Total	9	7	1	17	5	--	--	5	14	7	1	22	8	1	1	10
Region II																
New Jersey	1	--	--	1	--	--	--	--	1	--	--	1	3	--	1	4
New York	3	--	2	5	3	--	--	3	6	--	2	8	7	--	2	9
Puerto Rico	3	4	1	8	1	--	--	1	4	4	1	9	4	2	--	6
Virgin Islands	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Total	7	4	3	14	4	--	--	4	11	4	3	18	14	2	3	19
Region III																
Delaware	1	--	--	1	--	--	--	--	1	--	--	1	--	--	--	--
District of Columbia	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Maryland	1	--	--	1	2	--	--	2	3	--	--	3	8	--	3	11
Pennsylvania	8	1	8	17	4	1	2	7	12	2	10	24	5	2	1	8
Virginia	4	2	--	6	3	--	--	3	7	2	--	9	3	--	1	4
West Virginia	6	4	4	14	1	1	--	2	7	5	4	16	10	3	--	13
Total	20	7	12	39	10	2	2	14	30	9	14	53	26	5	5	36
Region IV																
Alabama	--	1	2	3	3	1	--	4	3	2	2	7	4	1	1	6
Florida	4	3	--	7	1	1	--	2	5	4	--	9	3	2	2	7
Georgia	1	1	1	3	--	1	--	1	1	2	1	4	4	1	2	7
Kentucky	1	4	2	7	--	--	--	--	1	4	2	7	4	1	2	7
Mississippi	2	--	1	3	1	--	--	1	3	--	1	4	2	1	8	11
North Carolina	5	1	5	11	1	--	--	1	6	1	5	12	9	--	3	12
South Carolina	--	--	--	--	--	--	--	--	--	--	--	--	1	--	2	3
Tennessee	1	2	7	10	--	4	--	4	1	6	7	14	5	1	2	8
Total	14	12	18	44	6	7	--	13	20	19	18	57	32	7	22	61

	Number of Assignees Retained in HMSAs												Number of Assignees Leaving HMSAs			
	Extending with NHSC				Converting to Private Practice in HMSA				Total Retained in HMSA							
	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total
Region V																
Illinois	--	--	1	1	--	--	--	--	--	--	1	1	3	1	3	7
Indiana	2	--	--	2	2	--	--	2	4	--	--	4	3	--	--	3
Michigan	2	--	--	2	3	1	--	4	5	1	--	6	3	--	--	3
Minnesota	--	--	--	--	--	--	--	--	--	--	--	--	--	1	--	1
Ohio	1	1	--	2	1	--	--	1	2	1	--	3	1	--	--	1
Wisconsin	2	--	--	2	4	--	--	4	6	--	--	6	2	--	--	2
Total	7	1	1	9	10	1	--	11	17	2	1	20	12	2	3	17
Region VI																
Arkansas	2	1	--	3	--	--	--	--	2	1	--	3	4	1	1	6
Louisiana	--	2	--	2	--	--	--	--	--	2	--	2	--	--	2	2
New Mexico	2	2	4	8	2	1	--	3	4	3	4	11	6	1	3	10
Oklahoma	1	--	2	3	--	--	--	--	1	--	2	3	1	1	--	2
Texas	4	1	2	7	1	--	--	1	5	1	2	8	15	1	8	24
Total	9	6	8	23	3	1	--	4	12	7	8	27	26	4	14	44
Region VII																
Iowa	--	--	--	--	1	--	--	1	1	--	--	1	1	--	--	1
Kansas	--	--	--	--	--	1	--	1	--	1	--	1	3	1	--	4
Missouri	--	3	--	3	--	1	--	1	--	4	--	4	3	1	1	5
Nebraska	2	--	--	2	--	1	--	1	2	1	--	3	2	1	--	3
Total	2	3	--	5	1	3	--	4	3	6	--	9	9	3	1	13
Region VIII																
Colorado	5	--	3	8	2	--	--	2	7	--	3	10	4	--	2	6
Montana	2	--	--	2	2	2	1	5	4	2	1	7	6	1	2	9
North Dakota	1	2	--	3	--	1	--	1	1	3	--	4	1	1	--	2
South Dakota	2	--	--	2	1	--	--	1	3	--	--	3	4	3	1	8
Utah	2	--	1	3	1	--	--	1	3	--	1	4	--	--	--	--
Wyoming	--	--	--	--	--	--	1	1	--	--	1	1	--	--	--	--
Total	12	2	4	18	6	3	2	11	18	5	6	29	15	5	5	25

	Number of Assignees Retained in HMSAs												Number of Assignees Leaving HMSAs			
	Extending with NHSC				Converting to Private Practice in HMSA				Total Retained in HMSA							
	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total	Phys.	Dent.	Other	Total
Region IX																
American Samoa	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Arizona	4	1	3	8	--	--	--	--	4	1	3	8	2	--	1	3
California	7	2	7	16	3	--	1	4	10	2	8	20	12	--	4	16
Guam	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Hawaii	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Nevada	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Trust Territory	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Total	11	3	10	24	3	--	1	4	14	3	11	28	14	--	5	19
Region X																
Alaska	--	--	2	2	--	--	--	--	--	--	2	2	--	1	2	3
Idaho	--	--	2	2	--	--	--	--	--	--	2	2	2	--	--	2
Oregon	2	--	3	5	5	--	2	7	7	--	5	12	--	--	1	1
Washington	8	--	7	15	4	--	1	5	12	--	8	20	7	--	4	11
Total	10	--	14	24	9	--	3	12	19	--	17	36	9	1	7	17
Grand Total	101	45	71	217	57	17	8	82	158	62	79	299	165	30	66	261

NONPHYSICIAN HEALTH PROFESSIONALS

Senator SCHMITT. Do you think some kind of geographic breakdown could be included, though not necessarily by State, although that would be useful to see if it is working in some areas and not in others?

Dr. LYTHCOTT. I think that that will be a spinoff of what we would put together for you, sir. Yes, sir.

I don't know what it would mean, but at least that reading would tell you where the majority of them are.

Senator SCHMITT. Mr. Chairman, maybe for the record could we have some indication of how some of these issues we have discussed today would apply at the technician level rather than physician level?

Senator SCHWEIKER. You mean a physician's assistant?

Senator SCHMITT. Physician assistants or others, medical technicians required within a rural or underserved setting.

Are you concerned about that?

Senator SCHWEIKER. Is that a problem or not? I don't know if that's a problem.

Dr. LYTHCOTT. I think you're absolutely right, sir. I hear what you are saying. They are an integral part of the Corps. I like to call them non-MD health professionals.

They, for the most part, are dentists. They are nurse practitioners. They are physicians' assistants. They are sometimes social workers.

We have a clear need for these people, especially in rural areas. They can man clinics where the doctors are some miles away but within direct contact, and we rely heavily on these people.

Almost everything that we have said can be related to the total Corps. And these people are as much a part of the Corps as far as I am concerned as the physicians are.

I think the physicians would say the same thing.

Senator SCHMITT. Will the data that you supply us include an indication of how that is working?

Dr. LYTHCOTT. Yes.

SUDDEN INFANT DEATH SYNDROME

Senator SCHWEIKER. Sudden infant death syndrome. The Senate Appropriations Committee report which accompanied the 1978 Labor-HEW bill provided funding for various program support and management items in HSA. In particular, we provided for increases in a number of staff positions with HSA, six of which were to be clearly identified for the sudden infant death syndrome program.

What is our follow-on to that report? How many projects are they serving in SIDS families? And what results have we found in that input?

Dr. LYTHCOTT. As of September 30, 1979, Federal grant support had been awarded to 37 SIDS projects in 32 States. Approximately 6,000 to 7,000 deaths attributed to SIDS occur annually. The 37 projects provide counseling services to 4,500 families annually. I think you know one of the major things we do in that program is be certain that autopsies are done on these children, so that we can learn as much as we can about why they are dying.

I cannot respond to the question on the six additional persons, Dr. Martin, that the chairmen talked about. Did they get into the program?

Dr. MARTIN. They got in. There are four full-time people in the program now, and of the other two—one is essentially a full-time person in communications, who develops films and communications devices. The other is a support person.

The clear intent of the committee was to bolster the SIDS program to a more visible, effective effort, and I think that's been done. The best indicator of that, of course, is the accomplishments of the program, which have been substantial and gaining each year.

Senator SCHWEIKER. As I see it's level funded for this coming year, we haven't solved the SIDS problem. I have a little trouble understanding how we can level fund it with an 8- or 10-, 13-percent inflation rate, and say we are making adequate progress.

There have been no new breakthroughs that I'm aware of in SIDS. There may be a few findings, if we were to look, but no real breakthroughs. How do we justify level funding in the program, which means, really, a 10- to 12-, 15-percent cut?

Dr. MARTIN. I think an important distinction has to be made that this particular part of the President's budget reflects the counseling and the support services provided to families after the death of the child. The concern that you raise in regard——

Senator SCHWEIKER. You do nothing before? No preventive work here?

Dr. MARTIN. The difficulty is that the key question is what causes SIDS. And that question is reflected in the NICHD budget. It's very difficult to prevent something that you don't know how it happens. I know NICHD considers SIDS a formidable priority.

Senator SCHWEIKER. How many of the families are you reaching that have had SIDS deaths?

Dr. LYTHCOTT. Of the 32 States in which we have the program, in 29 we're reaching the entire State. In the other three we are reaching nearly all the State. Among the States in which we're operating we feel we have excellent coverage. The number of families counseled for example, has increased over the last several years from 3,300 to 4,500. That, of course, is in keeping with increased identification of cases of SIDS.

Dr. MARTIN. I think it is important that a substantial amount of effort is on the part of volunteer groups, on the part of State agencies, on the part of medical examiners and the police. This is the heart of the success of this program, anyway. And basically, again, what our dollars do is pay for the developmental activity and the support of that much broader system. And frankly, there is a much more expensive system that is carried out through other programs.

This is the developmental grant support.

Senator SCHWEIKER. I would like to turn to genetic information and counseling.

ACCOMPLISHMENTS OF SIDS PROGRAMS

Senator SCHMITT. Mr. Chairman? Could you, in 30 seconds, tell us how you are doing on the SIDS? Are we learning anything?

Dr. LYTHCOTT. If you're asking about the first part of SIDS, which is

the research effort, that's an NIH response. I personally don't know all the details of what they're doing, sir. What I know is that we are increasing our contacts with people who have SIDS. We're getting more autopsies done and counseling people.

The question you're asking, I can't answer. We shouldn't answer about what's happening in NIH from the point of view of their research activity.

Senator SCHMITT. In order to justify a level funded budget, shouldn't you have coordinated with them to find out if the job is getting done?

Dr. LYTHCOTT. The job is getting done. I thought you were asking a specific, detailed question of what's happening in SIDS research.

Senator SCHMITT. I'd think you'd want to assure yourself of the autopsies and everything are having a positive effect——

Dr. LYTHCOTT. That we can assure you. We can assure you they're getting more information, but what's coming out of the other end of the horn, we don't know any more than anybody else does.

Senator SCHWEIKER. Maybe part of his question is: Are we learning anything from the autopsies that we didn't know before? Or is this just a medical documentation that ultimately may help us when they find something on research.

Dr. MARTIN. Two important things. First, all the technological or medical things we learn from NICHD, we know about almost immediately and communicate out to professional groups. But this particular problem is very much like medical detective work, and a lot of what has been found out over the last 4, 5 years, is what does not cause SIDS.

Reflecting back to 4, 5 years ago, when the SIDS groups were discussing with committee the concern about SIDS, the biggest single problem with SIDS at that time was the perception that it was caused by trauma, that it was caused by parent neglect, that it was caused by a whole host of things, which the NICHD work has disproved, and which we have communicated effectively. This becomes an important part of the counseling process.

The actual germ organism or causes are unknown, whether it's biochemical or bacterial or viral. You know, you were asking a question, "Do we know that?" No, we don't. But we know a lot of what isn't, and we are no longer leaving parents with the feeling—and that's what our responsibility is—that it was something they did wrong that resulted in this infant's dying.

I think that's the crucial part of our responsibility. And that's been, I think, very successfully expanded and accomplished.

Senator SCHMITT. I think you're sanguine enough to see a reduced budget. If you include inflation, it's a reduced budget.

Dr. LYTHCOTT. I think we have economies of scale, Senator, that would allow us to continue doing what we do up there, within the budget that we have. I'm sure the budget for NICHD is not reduced where they are looking actively for the cause.

STATISTICAL INFORMATION ON SIDS

Senator SCHMITT. For the record, you are under the authorization for what you are asking by about $1.2 million. Does the program that you are undertaking include some kind of attempt to get information on—statistical information on babies that may relate to those that die from sudden infant death, for example, sleep disorders? Is that normally collected information that you would have on babies and be able to then apply statistically back on those—relative to those that have died?

Dr. MARTIN. There is a set of studies within the National Institute of Mental Health, within NICHD and within the MCH research and training program which seeks to delve into the whole range of connected problems. The SIDS program itself does not focus on that; it is a service counseling program.

But the set of questions you are raising which are related——

Senator SCHMITT. You're working on post mortem. I'm talking about the kind of data that would be useful to have on all babies in order to correlate backward.

Dr. MARTIN. To the degree to which that information is being collected to determine whether the death was caused by one of the set of factors, it is being collected—the bulk of that activity, again, is being carried out by NICHD. I think Dr. Kretchmer would be——

Senator SCHMITT. Do you understand what I mean? If you feel you have a contribution to the post mortem, it may be through your existing data collection network, if you have one—and I presume you do—that you can provide—I don't know whether "premortem" is the word, but provide that kind of information.

For example, the sleep-induced death could, in fact, never show up, and it wouldn't, I guess, show up other than suffocation, as in the autopsy.

Well, anyway, you've answered my question. You don't do anything specifically in the predeath collection.

Dr. MARTIN. We do collect information which is requested of us by NICHD. We can submit it, I think, in more detail for the record.

[The information follows:]

In cooperation with the NICHD collaborative epidemiological study on high-risk factors for SIDS, six SIDS information and counseling projects are collecting data. For all the SIDS cases and controls, comparable data has been collected concerning the infants' health status and behaviors prior to death.

A number of the control population died of SIDS during the study period. For each of those infants, data was collected in the predeath period. The actual number of SIDS deaths in the control group and the analysis of the data is not available yet.

Isolated incidences of SIDS in infants known to SIDS projects (most generally subsequent siblings of SIDS infants) or in cohorts of infants participating in research projects are being reported more regularly to the SIDS research program at NICHD and the SIDS service program in the Office of Maternal and Child Health. For these babies, predeath data is available.

While no system yet exists for predeath identification of the specific infant who may die of SIDS, we now know more about the group characteristics of those infants, who are different from normal, healthy babies—anatomically, histologically, chemically, and physiologically.

Senator SCHMITT. All right. I think the concern of the committee will be that you are under authorization in a very serious area. You, in fact,

are saying that you can continue what you are doing with less money, and we'll just have to look at that.

Dr. LYTHCOTT. Yes, sir.

GENETIC DISEASE PROGRAMS

Senator SCHWEIKER. Genetics. I would like to turn to genetic counseling. The purpose of the genetic disease program is to provide information, testing, and counseling in the area of genetic diseases. Senator Magnuson considers this, along with hypertension, to be one of our best prevention tools.

Legislation instructs the Secretary to operate such a program primarily in conjunction with the maternal and child health and crippled children's services legislation.

What progress are we making in this area, and what particular breakthroughs or progress can we report in this program?

Dr. LYTHCOTT. During the last 3 years, Mr. Chairman, we have developed 21 areawide genetic systems. We have increased the number of persons screened, for example, for sickle cell anemia, from 157,000 to 183,000. And we've increased the number of persons treated in hemophilia centers from 2,300 to 2,500. We have made the sickle cell programs a part of the State genetic disease programs, which makes for better coordination in many States. We have them all——

Senator SCHWEIKER. That's a very serious problem, obviously, among blacks. How much of the population are we reaching, really, that could utilize this advice?

I realize that's a big goal. I recognize that, but I just wonder what the number is in sickle cell. I was one of the sponsors of that original authorizing bill in research.

Dr. LYTHCOTT. We're serving 20 million persons in the sickle cell program, for example—I'm sorry, 200,000 in the sickle cell program.

Senator SCHWEIKER. I was going to say, if we were [laughter] it would take a lot of money, I'm sure. I know you don't control the budget. I recognize that, but you're only asking for a $178,000 increase, which is really, as the Pakistani general would say, "peanuts," in terms of solving any problems. The total request for this item for fiscal 1981 is $3.7 million. Tell me who you're serving again.

Dr. LYTHCOTT. We're serving 200,000 people in sickle cell clinics, while in the areawide systems, we will serve 1.1 million.

Senator SCHWEIKER. I've got to believe this is one of the biggest needs of the whole genetic disease program. I don't know the figures on hemophilia. I don't know the figures on Tay Sachs disease or any others, but I've just got to believe this is the biggest need we have in the genetic care. Would you agree with that?

Dr. LYTHCOTT. Yes, I would agree with that. I don't have the charts in front of me, but it has a substantial piece of the pie among genetic diseases. Clearly, it is more common than the others, as you mentioned.

Senator SCHWEIKER. We surely could use a lot more than a $178,000 increase, I've got to believe.

You said you're reaching 200,000 of what total number?

Dr. LYTHCOTT. We serve 1.1 million in the areawide systems.

Senator SCHWEIKER. Say that again?

Dr. LYTHCOTT. We serve 1.1 million people in areawide systems and we are serving in our sickle cell clinics 200,000.

FAMILY PLANNING

Senator SCHWEIKER. OK. Family planning. Grants are available for family planning projects with a variety of family planning methods and services. Traditionally, family planning services have been available to medically indigent individuals through medicaid, and of course a little over a year ago, as I mentioned earlier, the adolescent pregnancy program was established, which has been administered through the Office of Assistant Secretary of Health.

What progress are we making in the family planning program?

Dr. LYTHCOTT. Dr. Martin, do you want to talk about family planning?

Dr. MARTIN. There has been a steady progress in, I think, three major ways. First the numbers of adolescents and numbers of people at risk being served by the programs has been steadily increasing and the number of people in need of those services or at risk unserved has been steadily decreasing over the last 4 or 5 years.

Second, more importantly, the number of access points or the places to which people can go for these types of services, which is very important in rural areas, has increased very substantially over the last 3 or 4 years.

Third—again very importantly—there has been, I think, a substantial improvement in the quality of the counseling services and the quality of the services provided to the individual who received services.

I think if you looked at programs that have been showing steady growth in program activity, and the steady improvement in quality, I think that there is a clear record that has been established there.

NATIONAL HEALTH SERVICE CORPS

Senator SCHWEIKER. I'm going to come back now to the National Health Service Corps for a moment. One problem mentioned in the report that you sent to this committee on the organization and the location of the National Health Service Corps is that the corps' rapidly accelerated growth might outrun the policy, program and administrative support capabilities of both HRA and HSA. And how do you propose to solve this problem that's enunciated in the report?

Dr. LYTHCOTT. I think you're speaking to the Young report on the National Health Service Corps. That report has become available. It has given the Assistant Secretary several options, and recommends one of these options. The option is that the programs probably ought to be combined in a single agency. The Assistant Secretary has not made a judgment. But the report is being studied at this time.

Senator SCHWEIKER. And that report proposes which agency?

Dr. LYTHCOTT. The recommended option of the report proposes to put it in the Health Services Administration.

Dr. MARTIN. In regards to the other part of the question, Senator, the administration has requested, I think, 128 additional positions just for

the service side of the program, to help administer and carry out the expansion of this program. So that's a significant part of the requested increase, explicitly attempting to deal with that problem of needed administrative staff.

BLACK LUNG CLINICS

Senator SCHWEIKER. OK. Black lung, HSA. Last year we provided you with $7.5 million to develop centers which diagnose, examine, and treat victims of black lung. Has this funding level been sufficient to provide continuation funding for assistance centers?

I just want to say, black lung is to Pennsylvania what the Public Health Service Hospital is to Washington State. [Laughter.]

It's a flagship, as we said yesterday.

Dr. LYTHCOTT. Let me say that there are two influences which allow us, despite level funding, to increase the program, sir. One of these influences is the fact that it costs us more the first year in developing that clinic, putting the equipment in, in one-time costs to fund the program, which means that in the second and third years there is money available to expand and develop new clinics.

As a second issue, we increase our third-party reimbursements during the second and third year considerably, and those savings are used to expand the program in other areas. So we are expanding the program with a level budget and we're doing all right.

Senator SCHWEIKER. What percentage of eligible black lung victims will you cover with the existing and additional centers combined?

Dr. MARTIN. We're anticipating this year we will be serving roughly 16.1 percent of the total number of people in need against one of the definitions now. Very importantly, the program is targeted to a smaller group of that population, which is about half as large, which would increase the proportion served to about a third.

And we are starting a program—we now have 132 centers proposed for 1981—which will pick up a substantial number of people in areas where we're not. So part of it is the growth of the program and the population density of miners with pneumoconiosis. So we are going against that need as rapidly as I think programmatically would be sound.

REDUCTION OF DUST LEVELS

Senator SCHWEIKER. Is it too early yet to see—and maybe you can't measure this—to see a decline in this disease because of the legislation that our Labor Committee passed on cutting back the minimum dust exposure level permitted in mines and forcing much tighter health standards in this area? Or is that something that you can't measure in the clinics because it's such a long incubation period?

Dr. LYTHCOTT. I would say that the latter, sir, is the major part of the problem. I would hope that in a few years we would be able to get this kind of data for you. We have been involved in the program only about 2 years, although, as you know, it's a much older program than that. It is one of the things that I would like to look into, but I don't think we have the data for it yet.

Senator SCHMITT. Mr. Chairman, just a point of information. In New

Mexico we not only have some old black lung problems, believe it or not. One of our problems has been to make people aware that they're eligible. There are no centers in that general area, I believe, that is black lung centers, planned or existing.

Dr. MARTIN. I would have to check on New Mexico specifically. But I am sure about Wyoming. So that the strip mining areas and the old deep mining areas, particularly in the Great Plains and the Far West, are clearly on our list of places for centers.

Senator SCHMITT. There is one existing underground coal mine and there were several others in Colfax County. And in most cases they are older people that worked in those coal mines.

But we have found, Mr. Chairman, that the regulations on dust levels appear now to have significantly decreased the incidence of lung cancer in uranium miners. We do not see after 1970—any lung cancer problems, although 7 to 9 years is about the time frame in which you would expect to see lung cancer start to appear if it were still a serious problem.

Prior to that, of course, lung cancer levels were quite high in uranium miners, most of it being attributable to those who mined and smoked simultaneously.

So it looks like those regulations are having an effect, at least in uranium mining; and I would suspect would have a comparable effect in coal mining.

Senator SCHWEIKER. But it takes so long to see.

I have some other questions that I'm going to submit for the record, Doctor, and I also have some questions from Chairman Magnuson on the Public Health Service hospitals, which I'm sure you will pay particular attention to in answering for the record.

Dr. LYTHCOTT. Yes, sir.

Senator SCHWEIKER. Senator Schmitt may have some questions now.

HEALTH SERVICES FOR MIGRANT ALIENS

Senator SCHMITT. I have one further question, Mr. Chairman. I guess it's more of a search for information. I'm very interested in the issue of Mexican migrant labor, as you might expect, being from New Mexico. And it is a significant issue to the country. One aspect of that is the degree to which migrant labor from Mexico or from any country, but particularly from Mexico, has access to health services or does not have access. And if they do, what is the situation in terms of costs borne by the local health delivery system as a result of that labor, much of which is illegal at this time.

Do you have any general comments on that from the perspective of your agency? I know your migrant health programs are aimed at U.S. citizens who are migrant laborers, are they not?

Dr. LYTHCOTT. We as Public Health Service officials do not look closely at where the people have come from. If they arrive at our doorstep and they have a problem, we accept the address that they give us and we go on and treat them. That's the only thing to do. That is the general philosophy of the agency.

So I'm sure we're seeing a large number of people among our mi-

grant and seasonal farmworkers who may not be bona fide citizens of the United States. But we justify that on the basis that they're people in need when they arrive. We're seeing, as I say, about 581,000 of them in 1980; 219,000 are migrants; and the balance, 362,000, are seasonal farmworkers.

Senator SCHMITT. Do you have any estimates or do you try to make any estimates or determinations if they are legal residents?

Dr. MARTIN. I think, from the anecdotal information and from some of the studies done by the National Migrant Council, the reason we are perceived as a source of care, whether it be for migrants or other undocumented aliens in the United States, is that we in fact do not gather that information and we do not check. Where the system is set up to check that, as in some State agencies and in some private agencies, basically the migrants don't come back or the undocumented aliens do not come back.

Some of the estimates in our New Mexico centers—the CCS in northern New Mexico—are very high. This is the only place they feel they can go. And I think we will continue to be a source of care as long as we don't look too critically and in depth at what is the legal status of those patients.

COSTS OF TREATING ILLEGAL ALIENS

Senator SCHMITT. And what about the question of reimbursement of expenses borne by other health care delivery groups as a consequence of treating, on an emergency basis usually, the so-called illegal aliens?

Dr. MARTIN. That presently is not the responsibility of the migrant health program, nor are funds provided for that, except where the centers are providing some money for their patients who receive those services. But the hospital costs, the emergency costs assumed by State and private providers, are not provided for in this appropriation.

Senator SCHMITT. I understand that. But has your agency any discretionary way to look into this particular problem as a part of the overall problem of health services? It is a cost borne by hospitals often which is not reimbursed and therefore is borne by other participants in that delivery system.

Dr. MARTIN. The Department is presently underway with the Department of Labor of looking into a whole set of those kinds of issues around third-party reimbursement and emergency costs. Labor, housing standards, a whole set of issues like that are a part of the administration's concern about migrant and seasonal workers, and that is explicitly one of the questions where there's an attempt to develop better documentation.

Our documentation right now, frankly, is very poor.

TEMPORARY LEGAL MIGRANTS

Senator SCHMITT. Well, it's very difficult, understandably. Have you by any chance included in that study an attempt to estimate what would be the consequences of most of these migrants being legal migrants, temporary legal migrants and having legal access to health care?

Dr. MARTIN. We'd have to submit that for the record. I'm unaware of the nature of that particular policy paper being developed. But we certainly can check it and provide it for the record.

Senator SCHMITT. What I'm suggesting, then, is to establish a legal or temporary worker visa program by which these people then would, for a period of 8 months, say, be legal residents, but would not be permanent legal residents. That, of course, would potentially increase the burden on health care delivery services. But I'm sure many of them don't even go to you because you're a part of the Government and they're afraid they'll be caught.

If you have information, could you provide some of that?

Dr. LYTHCOTT. We'll provide what we can, sir. I'm not sure we have the kind you're asking for, but we'll look through it carefully and get it back to you for the record.

[The information follows:]

The legal status of migrant workers has never been an issue with our program. Our understanding is that health care was to be provided to agricultural migrant workers because they are a deprived population, particularly vulnerable and dependent because of their transient life style. I am providing for the record a bibliography that we compiled recently on migrants and undocumented aliens. The bibliography gives primary emphasis to their impact on the economy as a whole.

BIBLIOGRAPHY

1. Interagency Task Force on Immigration Policy: Staff Report, Departments of Justice, Labor and State. March, 1979.

Report provides background research for further study of existing immigration laws and policies by the Select Commission on Immigration and Refugee Policy.

2. Interagency Task Force on Immigration Policy: Staff Report Companion Papers. Departments of Justice, Labor and State. August, 1979.

Three (3) studies which provide background and scholarly support for those segments of the Staff Report pertaining to the economic consequences of immigration. These papers were authored by three consultants to the Task Force, Professors George E. Johnson, University of Michigan; Michall J. Greenwood, University of Arizona; and Michael L. Wachter, University of Pennsylvania.

Both of the above staff reports can be ordered from:

Immigration and Naturalization Service
Planning, Evaluation and Budget Office
425 "I" Street, N.W.
Washington, D.C. 20536
(202) 633-3242

3. "Reports and Comments: Mexican Migrants", Medical Care Review, Vol. 36, No. 9, October, 1979.

Reprinted article by Lou Cannon, "Three Cheers for Illegal Aliens," Washington Post, 102:16, August 5, 1979.

This article asserts that illegal aliens, contrary to a persistent and growing belief, do not drain tax supported services, but, rather, are more likely to subsidize them.

4. Immigration Literature: abstracts of Demographic, Economic, and Policy Studies. U.S. Department of Justice, Immigration, and Naturalization Service, Planning, Education, and Budget Office. June 1979.

A bibliography of books, government documents, and articles about illegal aliens compiled by Jeannette H. North and Susan J. Grodsky.

A reproduced copy of the above is provided for your convenience.

Senator SCHWEIKER. Any other questions?

Senator SCHMITT. I was just informed that I believe that Dr. Martin is working on a report. Is that the one you were referring to, on migrant care?

Dr. MARTIN. There are two reports being worked on in the Department. The first, which was the report I spoke of, is a more general part of the rural development activity being pursued by the White House, with five or six Departments, which look broadly at migrant health issues.

The second is a specific report which was carried out under a contract that looks at migrant health as a function of labor and housing standards in migrant camps. That's a much more specific question and did not have to do with third party reimbursements.

Senator SCHMITT. Did one of these reports result from a conference in Dallas some time recently?

Dr. MARTIN. Yes, sir. That was part of the process of coming up with the recommendations about immigration. And members of this committee, Senator Inouye among them, were involved in that process. That was a much bigger migrant issue. That was an undocumented alien issue. So that would be a third set of questions.

Senator SCHMITT. And so there is activity on that issue specifically as a consequence of that?

Dr. MARTIN. As well as, as a matter of fact, the Under Secretary was testifying yesterday about the issue of undocumented aliens and a whole host of problems related generically and not simply migrants.

Senator SCHMITT. Is that report going to be one that's going to take some considerable time to develop?

Dr. MARTIN. I'd have to submit that for the record, since I'm unaware of the status of that report.

Senator SCHMITT. Would your agency be involved?

Dr. LYTHCOTT. To the degree that it would be significant to them, and I suspect they would be involved; not directly, but certainly in the provision of the data.

Senator SCHMITT. As you can see, my questions are understandably vague, because I don't know the degree to which your agency has been involved in this or could be. But any information you might have on the migrant issue, not only has an appropriations consequence, but it affects how do we approach this problem overall.

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:]

The Public Health Service is currently revising a report that addresses the Primary Health Care needs of Migrants, including a broad range of problems that go beyond the issue of undocumented aliens.

PUBLIC HEALTH SERVICE (PHS) HOSPITALS AND CLINICS

Question: In 1978, a report by the Ad Hoc Advisory Committee on the Public Health Service Hospitals made certain recommendations for the PHS system, including increased service to the community outside the usual PHS facility population. It also encouraged a focus on primary care services, particularly to the underserved. When we discussed this report and its implementation in last year's hearings (page 106 of Part 2), you told us that you were awaiting the implementation plans from a task force the Secretary had directed to study the recommendations. Has the Task Force taken any concrete steps to implement the Ad Hoc Committee's recommendations?

Answer: Yes, the Task Force, working through the individual hospital directors, has identified 9 recommendations which can be implemented within existing authority and 3 recommendations which require legislative or departmental policy changes. All of the 9 recommendations which could be implemented within HSA authorities have been implemented. These actions include emphasizing ambulatory and preventive health care services, reordering research and training priorities in line with Advisory Committee recommendations, changing recruiting practices as pertains to women and minorities, expanding support of the Patient Advisory Committees, and developing productivity standards.

POPULATION SERVED BY PHS FACILITIES

Question: Are PHS Hospitals and Clinics providing health care services to persons outside the traditional PHS facility-service population?

Answer: Cooperative arrangements consistent with existing authority provided in Section 327A of the Public Health Service Act are being made by each hospital. These agreements frequently center on providing services to support a National Health Service Corps site, an agreement with a local government agency, or direct hospital support of a community need. All arrangements are being coordinated with local planning agencies through the approved implementation plans. Similar activities are being carried out where resources permit in the free-standing outpatient clinics.

Question: Are they reaching out into their communities to reach the medically underserved?

Answer: There is no question that, within the resources and authority available to the PHS hospitals and clinics, emphasis has been placed on agreements and services which reach those in need of care.

OCCUPANCY RATE OF HOSPITALS

Question: What is the average daily occupancy rate of Public Health Service Hospitals? Is it up to the 80 percent requirement found in the National Health Planning Guidelines?

Answer: For fiscal year 1979, the occupancy rate of the eight general hospitals of the Public Health Service was 66.3 percent, up from 64.7 percent in Fiscal Year 1978. Occupancy is not yet up to the 80 percent level, but the increase in occupancy was achieved while admissions increased by 8% from 32,772 to 35,355 and length of stay declined by nearly one full day. Outpatient visits also increased from 907,704 to 986,932 during the same period. Reduced length of stay, in combination with increased admissions, suggests a substantial increase in the utilization of PHS facilities, while the 9% increase in ambulatory care services shows that the hospitals are effectively shifting from an inpatient to an ambulatory care emphasis as recommended by the PHS Hospitals Ad Hoc Advisory Committee. For these reasons improvements in the level of occupancy in the PHS Hospitals are more significant than using a specific percentage rate as a touchstone of efficiency.

ACCREDITATION STATUS OF PHS HOSPITALS

Question: Were all the Public Health Service Hospitals successful in obtaining accreditation from the Joint Commission on Accreditation of Hospitals? If not, what were the reasons?

Answer: All PHS Hospitals are currently accredited by the JCAH.

RECRUITMENT OF PHYSICIANS FOR PHS TRAINING PROGRAMS

Question: Are the Public Health Service Hospitals having any difficulty in recruiting physicians to participate in their house staff training programs?

Answer: During the training year which began on July 1, 1979, the Public Health Service Hospitals experienced no difficulty in filling all available house staff positions.

RECRUITMENT OF SUPPORT STAFF FOR PHS FACILITIES

Question: Are these facilities having difficulty recruiting support staff? If yes, what is being done to ameliorate this?

Answer: Overall, the PHS Hospitals are experiencing no significant difficulty in recruiting support staff. However, one continuing recruitment difficulty is the problem of hiring a sufficient number of qualified nurses. This is part of a national problem. While nationally there is a sufficient number of trained nurses, there is a problem in retaining them in the workforce, in the nursing profession, for a number of reasons

61-400 O - 80 - 10

including difficult hours. Efforts to overcome these recruitment difficulties are: publicizing nursing opportunities in the Public Health Service at Health and Job Fairs, visiting schools of nursing, having open house sessions, providing recruitment booths at nursing meetings and conventions, and advertising in nursing journals and papers.

COORDINATION OF PHS HOSPITAL'S RESEARCH

Question: How are the clinical and health services research programs discussed in the Department's budget justifications for Fiscal 1980 coordinated with other Federal research programs, particularly other Public Health Service funded research?

Answer: Coordination of research relies heavily on interaction among the professionals engaged in the programs. The principal mechanism by which coordination occurs is joint membership on review committees and, to a lesser extent, participation in symposia. An example of joint membership is the participation by Division of Hospitals and Clinics researchers in National Institutes of Health study sections such as renal or cardiovascular disease. Similarly, the scientific review council for health services research for the Division of Hospitals and Clinics includes in its membership representatives of the Veterans Administration, the National Center for Health Services Research, Indian Health Service, and Department of Defense. Coordination also occurs through joint membership on committees such as the Joint National Committee for High Blood Pressure and membership on special interagency task forces and advisory committees of the National Institutes of Health. Finally, there are symposia, such as the annual International Symposium on Hansen's Disease sponsored by the USPHS Hospital at Carville, or the Clinical Trials Symposium of the National Institutes of Health. These meetings maintain a much narrower focus and establish broad research policies and directions among their participants.

PHS HOSPITALS' ROLE IN THE COMMUNITY

Question: The main reason for the Public Health Service Hospitals in our view is the key role they can and should play in providing a community service. Please highlight for the Committee what each of the hospitals is doing to meet this mission.

Answer: The Secretary is currently considering various options concerning the proper role of the PHS Hospitals and Clinics system in the area of community services. However, pending the Secretary's decision; selected PHS hospitals are responding to a number of community needs within the constraints of section 327A of the Public Health Service Act and the limited resources available for this purpose. Programs currently operating or under development which deal with community services are as follows:

Baltimore:

--Expansion of psychiatric inpatient care through a contract with the Maryland State Mental Health Administration.

--Development of an alcoholism program for the Hampden-Woodberry-Remington community.

--Development of an active patient care program in connection with the Cooperative Center for Occupational and Environmental Health, a joint venture between the Hospital, the Johns Hopkins University, and the National Institute for Occupational Safety and Health; and

--Conducting a hypertension study and treatment program in the elderly population surrounding the hospital.

Projects were selected for their relevance to primary care, potential availability of support, and feasibility of implementation. They supplement existing programs including Geriatric Day Treatment, an agreement with the North Baltimore Center, a community mental health center; and the augmented ambulatory care programs of the hospital.

Boston:

--Development of a full service community health center in cooperation with the Allston-Brighton Community Health Center and with the Allston-Brighton Mental Health Center. The hospital is also exploring linkages with other Bureau of Community Health Services programs in the area.

--Expansion of community services to include screening for Indo-Chinese refugees and coordination with city and state agencies to provide care to this special needs population; provision of space for the City of Boston Family Planning and Methadone Maintenance Programs; support of the Commonwealth Health Improvement program at a neighboring city-owned low income housing project. Consultation and educational support services include nutrition, physical therapy, pharmacy, Public Health Nursing, and health education.

--Development of alcoholism detoxification and rehabilitiation programs designed to integrate services with the Allston-Brighton Council on Alcoholism.

--Development of a comprehensive cancer treatment program to provide medical care and counseling to patients terminally ill and to those who have achieved remission; and

--Exploration of the feasibility of developing a primary care track Internal Medicine training program with Harvard University.

Nassau Bay:

--Creation of a Family Practice Center with a residency program affiliated with the University of Texas Medical Branch. The first residents will begin training on July 1, 1980.

--Establishment of a Partial Hospital Care Program, the outgrowth of a program to increase patient involvement in personal health maintenance. This program provides access to hospital services prior to admission and convalescent and rehabilitation services on discharge to ambulatory patients who live beyond commuting distance from the hospital.

--Provision of space and consultation services through a 327A agreement with the Galveston County Health Department in the operation of a community clinic.

--Operation of an alcoholism program including physical examinations and medical treatment for the Galveston Community Action Council Detoxification Program.

--In support of the shift of emphasis from specialty to primary care, training programs for PHS residents in orthopedics, ophthalmology, and otolaryngology have been discontinued to concentrate on the family practice program.

New Orleans:

--Continuation of obstetrical, nutrition, and maternal counseling services by agreement with the New Orleans Protestant Home for Babies and the Jefferson Community Action Program.

--Expansion of comprehensive secondary care services in support of neighborhood health centers and the NHSC site in the Desire community of New Orleans.

--Development of a rural health initiative project in cooperation with the NHSC site in Frankling, Louisiana.

--Expansion of primary and secondary services by agreement with the State of Louisiana through the Louisiana Handicapped Children's Program.

Norfolk:

--Development of an Internal Medicine track family practice program in cooperation with the Eastern Virginia Medical School. This program will expand community primary care services and provide clinical experience for the residents. It begins operation on July 1, 1980.

--Participation in a community effort to establish a Hospice in the Tidewater area. The PHS hospital will provide the inpatient portion of the program.

--Expansion of inpatient support for the Migrant Health program on the Eastern Shore.

--Providing consultation services to the Norfolk Juvenile Detention Center.

--Expansion of the alcohol rehabilitation unit by agreements with the city and county mental health and rehabilitation units.

San Francisco:

--Development of a 327A agreement with the San Francisco Medical Center Outpatient Improvement Program, Inc., to provide technical assistance, outreach services, preventive services, and clinical support to Hunter's Point community residents.

--Expansion of the existing Geriatric Screening and Referral Program operated in cooperation with District Five of the City Health Department to become a community/hospital sponsored multicultural, geriatric-psychiatric-medical program.

--Improving services to Native Americans and expanding the existing program of hospital services to rural and urban Indian clinics.

--Operation of an Indochina Refugee Screening and Initial Follow-up Program.

Seattle:

--Continuation of existing affiliations with community-run clinics providing primary care to predominately indigent patients.

--Continuation of emergency support to the Seattle-King County jail's medical dispensary.

--Further development or expansion of a comprehensive health care system in collaboration with Federal and local agencies and community clinics, to serve Federal beneficiaries and medically underserved people.

Staten Island:

--Participation in activities of the local Health Systems Agency, including participation in four working subcommittes.

--Development of a geriatric care program concentrating on the needs of the frail elderly.

--Continuation of a cancer treatment and support program organized using the Hospice model.

--Provision of geriatric services including a program in support of the frail elderly.

--Expansion of participation in emergency medical services plan for the Staten Island community.

PHS HOSPITAL'S COST BENEFIT STUDY

Question: In the budget justifications for fiscal 1980, "the Secretary directed a comprehensive and systematic cost-benefit study on direct provision of inpatient services." The information obtained in this study was to be used to assist in making informed decisions about continued provision of inpatient services compared to the purchase of services in the private sector.

What were the findings of this investigation?

Answer: A contract for the study was awarded in the fall of 1979 to Abt Associates of Cambridge, Massachusetts, and the contractor has begun work on the study. We anticipate that the study's findings will be reported to the Secretary before the end of the year.

STATUS OF FACILITIES

Question: Several of the hospitals are in dire need of renovation, modernization, and in some case, new construction. What is in your budget for this?

Answer: The request for Fiscal Year 1981 contains $6,969,000 for facilities repair and improvement and includes funding for the completion of the renovation project upgrading the patient dormitories at the National Hansen's Disease Center, Carville, Louisiana. Funding is also requested for projects to eliminate some of the more critical life safety code deficiencies in the hospitals and remove barriers to access by the handicapped.

Question: How much would be needed to bring all the hospitals up to standards--including facilities for outpatient care?

Answer: The $6,969,000 requested in fiscal year 1981 for facilities repair and improvement should assure that each hospital will be granted full 2-year accreditation at the time of their next survey.

STAFFING

Question: Are you able to fill all of the patient care positions which the Congress has allowed--or do they fall under the ceiling too?

Answer: In the past few years, we have been provided ceiling equal to the number of positions allowed by the Congress.

DEPARTMENT OF DEFENSE REIMBURSEMENTS

Question: How much do you expect Defense to reimburse you for care provided to servicemen in 1980 and 1981?

Answer: The F.Y. 1981 President's budget for PHS hospitals and clinics includes estimates of gross reimbursements from the Department of Defense for F.Y. 1980 and F.Y. 1981 totalling approximately $41,100,000 each year. These estimates were originally developed prior to the end of F.Y. 1979 so the only full year data available was that of F.Y. 1978. Preliminary data for the first quarter of F.Y. 1980, indicates a slight decrease in DoD inpatient workload and an increase in DoD outpatient visits. Unfortunately, these preliminary workload counts for the first 3 months of F.Y. 1980 does not provide a sufficient sample for any meaningful statistical analysis. However, we currently estimate total DoD reimbursement to PHS hospitals and clinics in F.Y. 1980 will be approximately $42,800,000. It is further estimated that the PHS hospitals and clinics will reimburse DoD approximately $2,700,000 in both F.Y. 1980 and F.Y. 1981 for services provided at Defense Facilities. It should be noted that these figures reflect only the reimbursable costs being incurred by the Public Health Service Hospitals and Clinics. The cost of care being provided by DoD to dependents of Public Health Service beneficiaries etc., and funded by the Office of the Assistant Secretary for Health Retired Pay and Dependent's Medical Care appropriation is not included.

IMPLEMENTATION OF AD HOC ADVISORY COMMITTEE RECOMMENDATIONS

Question: How many <u>new</u> DHC (Division of Hospitals and Clinics) positions would be required in fiscal year 1981 to permit the hospitals and clinics to begin effective implementation of their proposed <u>expanded</u> mission and are there community service plans drawn up for this purpose?

Answer: At the present time the Secretary is reviewing a range of options regarding the appropriate future role of the PHS Hospitals which include the associated funding and staffing requirements necessary to implement these options. She expects to make her final decision and submit her plan including resource requirements to Congress at a later date.

Each hospital has developed a plan to facilitate the transition to the proposed expanded role and the implementation of the recommendations of the Ad Hoc Advisory Committee. These plans have been coordinated with the local planning agencies for the areas in which each hospital is situation in order to fully integrate the PHS facilities with their respective communities.

Question: How much would the Fiscal Year 1981 <u>start-up</u> costs be for undertaking the PHS Hospitals' expanded mission as reflected in their community service plan?

Answer: The Secretary is reviewing a range of policy options concerning the future roles of the hosptitals. She expects to make her final decisions and will submit her recommendations to Congress at a later date. Should additional funding be required, the amounts will be reflected in the Secretary's submission to Congress.

Question: To what extent could these costs be covered by anticipated reimbursement income in following years as opposed to appropriated funds?

Answer: As stated previously, Secretary Harris is reviewing a range of policy options - and their associated funding requirements - on the future roles of the PHS Hospitals. She expects to make her final decisions and submit her recommendations to Congress at a later date.

Until the Secretary's final recommendations are received it is impossible to determine the kinds of costs, or funding requirements and reimbursements that would be involved.

Question: Is there enough money requested in the Buildings and Facilities category to permit the renovations and expansions recommended by the Advisory Committee for both the existing and proposed mission of the DHC?

Answer: Funds requested for Fiscal Year 1981 will complete the dormitory renovations at the National Hansen's Disease Center, Carville, Louisiana, correct some urgent life safety code problems in the general hospitals, and focus on bringing all hospitals into compliance with Public Law 93-112 which requires the elimination of barriers to access by the handicapped. The President's request does not directly address the resources required to implement any Advisory Committee recommendations. All projects expected to be funded with the 1981 request are fully compatible with the existing and any proposed mission of the hospitals.

Question: How much would it take to accomplish this both in Fiscal Year 1981 and over the next five years?

Answer: The Secretary is currently reviewing a list of policy options on the future of the hospitals. This includes associated funding requirements such as funds needed to renovate and modernize the hospitals. The recommendations to the Secretary identify sufficient resources to meet the needs of the system over a five year planning horizon. However, until the Secretary's final recommendations are received, it is impossible to determine the kinds of costs or funding requirements that would be involved.

PAYMENTS TO HAWAII

Question: How many Hansen's Disease patients are treated by the State each year?

Answer: A total of 463 Hansen's disease patients were treated by the State of Hawaii last year. As of January 1980, 6 inpatients were treated at Hale Mohalu, 124 at Kalaupapa and a total of 333 outpatients at all facilities.

Question: How many new Hansen's disease patients were diagnosed in the State each year?

Answer: For the years 1974 through 1978 an average of 30 new active cases of Hansen's disease were diagnosed in the State each year, of which 26 patients were newly arrived immigrants and 4 are native born.

Question: What is the federal cost per patient?

Answer: In 1979, the latest full year of actual data, the average federal cost per patient was $3,456.00.

Question: What is the State match?

Answer: In 1981, the estimated State match per patient is $1,365.

Question: Are these generally long-term residents of Hawaii?

Answer: The patients that are treated as inpatients for Hansen's disease are long-term residents of Hawaii.

Question: Does the new flux of immigrants from Southeast Asia present new problems in terms of the numbers of Hansen's?

Answer: There has not been any noticeable trend with the reporting of new cases of Hansen's disease in the United States as a result of the influx of Indochina refugees. The incidence of reported cases is as follows:

1975	1976	1977	1978
162	145	151	168

EMERGENCY MEDICAL SERVICES

Question: The purpose of the Emergency Medical Services program is to support emergency medical services systems in communities so that these systems could pull together the medical resources needed to provide prompt and competent care to an emergency victim. It is my understanding that if funding is kept at the present level for the next 5 years, by 1985, 85 percent of

the emergency medical services systems would have achieved advanced life support status, i.e., the ability to employ the most sophisticated and up-to-date medical techniques to save lives. Under the President's budget request for fiscal year 1981 which includes a substantial reduction in the Emergency Medical Services program and proposes a phaseout of the program in 2 years, how many designated emergency medical services regions will achieve this most advanced level of service delivery?

Answer: The decision to phasedown, not phaseout, the program is based on the Administration's belief that emergency medical services has been a highly visible and useful health initiative. It is expected that the decrease in Federal funding will be balanced by a noticeable increase in the State and local financial support to local Emergency Medical Services programs.

Following the award of grants in fiscal year 1981, 18 regions will complete development of an advanced life support system and 50 regions will have achieved the advanced life support level.

DEVELOPMENT OF EMS SYSTEMS

Question: How many emergency medical services systems have been developed through this legislation, and what level of sophistication have they achieved?

Answer: With the award of grants for fiscal year 1980 the status of regional emergency medical services system development is as follows:

Status of Regional EMS System Development
(Following award of grants for fiscal year 1980)

Section of Act	Description of Activity	Number of Regions
1202	Feasibility Studies and Planning (to determine the feasibility of and prepare plans for the development of a basic life support system.)	76
1203 First Year	Establishing and Initial Operation (To begin development of a basic life support system.)	33
1203 Second Year	Establishing and Initial Operation (To complete development of a basic life support system.)	67
1204 First Year	Expansion and Improvement (To begin development of an advanced life support system.)	71
1204 Second Year	Expansion and Improvement (To complete development of an advanced life support system.)	9
Completed	Completed eligibility under title XII of the Public Health Service Act.	41

Other Regions	No funding under Title XII
Total	304

Question: What percentage of the population still lacks protection of emergency medical services systems?

Answer: With the award of grants in June 1980 it is anticipated that:

76 emergency medical services regions will be in the planning phase covering a population of 53,200,000;

180 emergency medical services regions will be in some phase of operations development serving a population of 126,000,000; and

41 regions serving a population of 35,000,000 will have completed their eligibility under title XII.

These totals indicate that approximately 3 percent of the population has not received funding under title XII.

Question: How many more will be established in fiscal 81?

Answer: In June 1981, grants for emergency medical services systems development will be awarded to 56 emergency medical services systems. Two regions will determine the feasibility of and prepare plans for the development of a basic life support system. Six regions will begin the establishment and initial operation of an emergency medical services system under section 1203. Thirty regions will progress to the second year of operations under section 1203 and 18 regions will complete development of an advanced life support system under section 1204.

BURN, POISON, AND TRAUMA INJURIES PROGRAM

Question: The recently enacted extension of the Emergency Medical Services (EMS) legislation continues the basic project grants program and establishes a demonstration grant mechanism to evaluate the best methods for providing poison control and major trauma services on a regional basis. How many demonstration grants for trauma and poison control centers do you expect to fund during FY 81?

Answer: The new Poison and Trauma Portions of section 1221 were not requested by the Administration. The Administration's position is that the current Emergency Medical Services program, and continuation of State and local support of emergency medical services systems are sufficient to achieve the objective of improving the delivery of care for poison and trauma. In

addition, the supporting programs of the National Institute of General Medical Sciences and the Food and Drug Administration will assist for a total effort.

Question: What is the status of the Burn Center program?

Answer: The six contracts for the Burn Injury Demonstration Projects have been awarded and the project is in the final year of a 3-year plan. A report of this effort will be delivered to the Congress in February 1981. Under the continuing resolution funds were made available once again for the burn program. These funds would support 20 contracts in 1980. They are 1-year projects and require no additional funding in 1981.

STATUS OF EMS REGIONS

Question: Please list the status of the 300 regions under the EMS program. How many are in each stage of the funding cycle and how many have completed the cycle and are on their own?

Answer: The following chart summarizes the status of the 304 regional emergency medical services systems following award of grants in fiscal year 1980:

Section of Act	Number of Regions
1202 Planning	76
1203 First Year	33
1203 Second Year	67
1204 First Year	71
1204 Second Year	9
Completed	41
No Activity	7
Total	304

Question: Have you kept an eye on the regions that have completed their Federal funding to see how they are doing on their own? Are any of them experiencing any difficulty maintaining their self-sufficiency?

Answer: To the best of our knowledge, all EMS regions that have completed their eligibility for funding under title XII are still funded at a level of service which is at least as effective

as that maintained at the conclusion of the Federal support. We believe there will be some changes in regional emergency medical services systems after the period of Federal grant support. We are concerned about this topic and have contracted with the University of Pennsylvania to conduct a limited case study. We expect to receive the final report in May of this year, at which time we will 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.

SOURCES OF NON-FEDERAL FUNDING

Question: Are the predominantly rural regions having any difficulities securing adequate local funding sources to keep their EMS systems operations viable?

Answer: To our knowledge they are not having difficulty. A survey conducted in fiscal year 1979 shows that State and local government funds for support of emergency medical services have increased significantly over the past 5 years.

Emergency Medical Services
Federal, State and Local Government Funds

Fiscal	Source of Non-Federal Funds			Federal
Year	State	Local	Total	Funds
1979	42,969,953	309,673,378	352,643,331	35,500,000
1978	35,687,486	270,791,685	306,479,171	36,027,800
1977	30,914,371	234,346,879	265,261,250	32,775,000
1976	29,902,517	200,389,021	230,291,538	29,115,300
1975	19,846,273	189,744,871	209,591,144	32,242,800

BURN INJURY PROGRAM

Question: What is the status of the Burn Injury program?

Answer: The initial effort of the Burn Injury program was to conduct a 3 year prospective study in 6 demonstration areas to describe the current burn care delivery system.

Question: Has the three-year study authorized in 1976 been completed?

Answer: We are just beginning the third year of this effort. The accomplishments to date include:

- Development of a common patient care and financial data set.

- Initiation of data collection for all burn patients from point of entry into the hospital system through outcome. This process was begun May 1, 1978 and to date we have collected data for 12,000 admitted patients and 56,600 emergency patients.

- Quality control measures indicate 90 to 95 percent of the patients using the hospitals are being counted and tracked.

- All research tasks including a burn severity index and an evaluation of the "team care" approach to specialized burn care are on schedule.

The program's major effort during the third year will be to complete the data collection and prepare all final reports.

Question: What is the next step?

Answer: The demonstration reports will be used to complete a full report to Congress in February 1981. We are hopeful the result will permit the presentation of a strategy for burn care with appropriate recommendations.

Question: The 1979 legislation authorized appropriations of $10 million for FY 1980 for the Burn program. What are you requesting under this authority and what will the money be used for?

Answer: Of the funds appropriated in 1979, $3.6 million was used to fund the third and last year of the burn demonstration site projects. The continuing resolution provided $3.0 million for burn injury projects in fiscal year 1980. We are currently reviewing the methods of implementing the new legislation.

BURN, POISON, AND TRAUMA INJURIES PROGRAM AUTHORIZATION

Question: In view of the fact that Congress has indicated its intention in the EMS authorizing legislation to expand the Burn Injuries program to include Poison and Trauma Injuries, why are you not requesting funds for the implementation of the program?

Answer: The Burn Injury Demonstration Projects are fully funded and a report of this effort will be delivered to the Congress in February 1981. We see no need to support other Burn Injury Demonstration projects until this reports is completed and considered.

The new Poison and Trauma Portions of section 1221 were not requested by the Administration. The Administration's position is that the current Emergency Medical Services program and continued strengthening of State and local emergency medical services systems are sufficient to achieve the objective of improving the delivery of care for poison and trauma. Therefore no funds were requested for the Burn, Poison, and Trauma Injuries program for fiscal year 1981.

BURN INJURY PROGRAM DEMONSTRATION PROJECTS

Question: The authorizing committee has stated that "appropriations would not be effectively used in further studies of Burn Injury Programs." What is your reaction to this?

Answer: We concur that additional demonstration projects would not be in the best interest of the Department, until the results of the current 6 projects are evaluated.

Question: If appropriations were cut off for the existing Burn program in both research and services, who would pick up the funding?

Answer: No additional funding would be required at this time. The Burn Injury Demonstration projects are fully funded and a report of this effort will be delivered to Congress in February, 1981.

Question: In your opinion, should we be developing even more centers so that they are evenly distributed throughout the U.S.?

Answer: It is too soon to answer that question. When we complete the current work with 6 demonstration sites we will have better information on the demand or need for critical burn beds and the use of existing burn centers.

Question: What should the Federal government's role be in the actual provision of services to burn-injury victims?

Answer: Potential magnitude and priority of Federal involvement in providing care to burn victims should await completion and evaluation of our current demonstration projects.

COMMUNITY HEALTH CENTERS

Question: There are many, many health care and food programs targeted toward children.

Give us some specific examples of how you coordinate your efforts with each of them--both within and outside the Department?

Answer: Many activities have been initiated which are designed to improve the coordination of health care and food programs targeted on children. These include:

a) The Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA) have issued several interagency memoranda to their State and local counterparts on specific problems of concern, i.e. April, 1977 - Federal agency statement on Nutrition Education and the Special Supplemental Food Program for Women, Infants and Children (WIC); October 1977 - Interagency Memorandum on Special Formulas for Children with Inborn Errors of Metabolism.

b) Funding criteria for Community Health Centers (CHCs) include the requirement that the projects make necessary application for, or establish appropriate linkage with WIC.

c) To promote maximum utilization of food and nutrition resources in the community, the Bureau of Community Health Services published a listing of Federal and non-Federal resources for nutritional information and services and distributed it to all CHCs and other Bureau programs and projects. This publication provides current information about USDA food programs which can be utilized to improve diets of CHC clients.

d) In order to strengthen and extend the benefits of supplemental food programs to clients of CHCs, the Bureau assessed the extent of participation in WIC and worked with USDA and State health agencies to improve participation.

e) A Bureau staff member serves as DHHS representative to the USDA National Advisory Council on Maternal, Infant and Fetal Nutrition, providing information and technical assistance related to health and nutrition services for mothers and children and working to improve coordination between health care and food assistance programs.

Question: How can areas with hospital facilities be considered medically underserved areas?

Answer: In designating a medically underserved area, various factors are considered regarding the people's need for care and the ability of persons to get needed care. These factors include the physician-to-population ratio of the area, the incidence of poverty within the area, infant mortality, and the percentage of elderly in the population. In addition, special factors such as geographic barriers to access to care (distance, time factors, etc) and the

unwillingness of some physicians to take Medicaid patients can also be considered in designating an underserved population or area.

The existence of a hospital may not, of itself, significantly affect the physician-to-population ratio or geographic access to health care. In fact, the nature of the hospital plant investment is such that the existence of a hospital may inhibit other development of health care services and people may have to travel long distances to get to the hospital for care.

Many people use hospital emergency rooms as their principal sources of medical care. Hospital emergency room care is, by far, the costliest form of ambulatory care and it is the most limited in terms of quality. Hospitals generally provide only acute/episodic care and do not meet the needs of people for preventive and routine care such as routine check ups, well baby care, and immunizations.

The existence of a hospital does not overcome racial and economic barriers to care.

Question: Are many areas with hospitals classified as medically underserved? Do medically-underserved areas with hospital facilities tend to occur primarily in urban or rural areas?

Answer: We do not have information regarding the relationship between the existence of hospitals and the classification of an area as a medically underserved area.

HYPERTENSION

Question: What are you doing to coordinate the Hypertension program with the many health education programs we have?

Answer: At the national level the program has been developed and implemented in close coordination with the National Heart, Lung, and Blood Institute (NHLBI) and the National High Blood Pressure Education Program (NHBPEP). We have jointly sponsored a number of conferences, have participated in several regional conferences together and have collaborated on guidance materials to assist our primary care projects in meeting their hypertension goals. Informally, our staffs have almost daily contact with NHLBI and NHBPEP staff as we rely very heavily on them as the technical and scientific experts in the field.

At the local level, States are required to coordinate their activities with those of other Federal, local, private, or voluntary organizations as an essential part of their assurance role. States are required to document this coordination in their applications and it is used as one criterion for funding decisions.

Question: When a patient is referred to a private physician for treatment of hypertension, who is then responsible for follow-up care, the private physician or the grantee?

61-400 O - 80 - 11

Answer: The grantee is responsible for assuring that patients are referred to a follow-up system. That follow-up system may be managed by the grantee, by a private provider or group of providers, by other public providers or by voluntary organizations. Grantees are specifically prohibited from using 317(a)(1) funds for treatment but they should use the funds for management and reporting systems to assure that referral and follow-up care is available to patients. For example, States may establish a referral relationship with HSA supported primary care centers. The HSA supported primary care centers are mandated to provide hypertension follow-up care and to have systems in place to track patients. If the grantee (State) has such a referral relationship with a particular primary care center, if they document that the patient is referred to the primary care center, and if they document that contact has been made between the primary care center and the patient, then they have met their responsibility for assuring follow-up care.

Question: How many new people will you be able to reach in fiscal 1980 with the increased appropriation? How many people will still remain undetected?

Answer: In 1980, about 4 million additional persons for a total of 7.8 million, will be screened by the State Hypertension programs. These screenings are expected to reveal 624,000 new cases or cases of inadequately treated hypertension. It is estimated that 10.1 million people in the U.S. have undetected hypertension, while another 14.5 million receive inadequate therapy or no treatment at all. Thus, about 24 million people would still have undetected, untreated, or inadequately treated hypertension after the operation of the programs in 1980.

HYPERTENSION REPORT

Question: The Committee has received a report on the hypertension program from a distinguished group of citizens interested in this important program. By and large, it is a favorable report, but it does make two good recommendations: One recommendation is that there be better coordination among State and local groups and your program. The key seems to be improving planning, developing better data bases and more open communication. There are obviously some communities that simply are not interested or are doing a poor job. Give us some specific ideas as to what you can do to address these points.

Answer: As part of the application materials for the fiscal year 1980 supplementary funding we have required States to list the organizations/programs that are involved with their program, and we have taken the position that States must build linkages and coordinative relationships with others if they are to fully meet our funding criteria. This should stimulate them to assume more of a leadership, assurance, and coordinative role among local groups.

Simultaneously, we have been providing information about the program to other organizations that have local ties, i.e., American

Heart Association, Citizens for Treatment of High Blood Pressure, NHBPEP, etc., in the hopes that they will be stimulated to contact the States for funding and thereby increase the opportunities for coordination. We have also been encouraging our federally funded primary care centers to make contact with States to coordinate their hypertension control activities and to build mutually beneficial relationships. This is an area where we need to concentrate much more effort at the national and regional levels.

With the shift this year from an entitlement program to a project grant program, we have placed a great deal of emphasis on planning and data bases. We have established long range goals, have required specific action plans for meeting them, and required States to establish a data base. The funding for state programs in fiscal year 1981 and beyond will be contingent upon States demonstrating and documenting progress toward those goals.

Question: A second recommendation is that inter-agency cooperation must also be improved. Specifically, how can you improve this?

Answer: Building cooperative, positive working relationships at the staff level is a slow and deliberate process of opening opportunities for interchange, encouraging and rewarding staff for the extra effort which is involved, and choosing the appropriate issues and areas. We have had extremely effective working relationships at the formal level with the NHLBI over the past five years, and we feel that this is being reflected more and more at the staff level. The communication between our staff and staff at the NHLBI is exceptionally good now and we expect it to get even better as we continue to place deliberate emphasis on it. We need to open more doors with other agencies as the program develops over the next year.

Question: What are you doing in the Aging Institute regarding elderly hypertension programs?

Answer: Although highest priorities this year have focused upon shifting from a formula grant to a project grant program, along with emphasis on establishing long-range goals and needed improvement in data reporting at the State level, we are aware of the need to strengthen and improve coordination at all levels. We have begun a dialogue with the Aging Institute, but no formal coordination of program policies have transpired. However, we recognize the high rate of hypertension among the elderly and we expect that improved coordination will soon take place.

MATERNAL AND CHILD HEALTH

How are the your teenage pregnancy-directed activities coordinated?

Answer: In the interest of strengthening coordination, HSA and the Office of Adolescent Pregnancy Prevention are finalizing an

interagency agreement that will describe joint efforts and identify specific ways in which coordination can be facilitated.

MCH RESEARCH AND TRAINING

Question: In fiscal 1980, Congress restored the $17 million cut in Maternal and Child Health Research and Training proposed by the President. How has this additional $17 million in funding been used?

Answer: Most of the additional $17 million in funding was used to prevent the discontinuance of existing programs. A modest amount was used to expand or enhance programs through existing projects.

Question: Were the anticipated cutbacks carried out and was the money used to fund other projects, or were the FY 1979 activities continued unchanged?

Answer: The anticipated cutbacks were not carried out. The FY 1979 activities continued unchanged.

Question: How are the research and training activities in Title V coordinated with the University Affiliated Facilities activities mandated in the Developmental Disabilities Act?

Answer: Coordination occurs between staff of the BCHS Office of Maternal and Child Health and the Developmental Disabilities Office, primarily through:

1) joint meetings,
2) review and comment on new or modified major policy changes, and
3) shared reviews of funding proposals.

Question: Are any University Affiliated Facilities run solely by Title V funding or solely by Developmental Disabilities funding, or is there generally a commingling of funds?

Answer: One university affiliated center is funded entirely by Title V. The remaining 20 centers have dual agency support from Title V and the Developmental Disabilities Act. While there is a relationship between the programs supported, in no instance is there commingling of funds.

Question: What percentage of UAF funding comes from Title V? Developmental Disabilities Act? Other Public sources? Private funding?

Answer: University affiliated funding comes from:

Title V	- 25 percent
Developmental Disabilities Act	- 9.6 percent
Other Federal	- 14.6 percent

These sources are:
PHS Formula Grants to States
Alcohol, Drug Abuse and Mental Health Administration
Office of Education, Bureau of Education of the Handicapped
National Institute of Education
Rehabilitation Services Administration
DHHS, Office of Human Development
Health Care Financing Administration, Bureau of Program Operation
Social Security Administration, Supplemental Security Income
Head Start

State Grants - 37.0 percent
Private funding - 13.8 percent

Question: This program has had no increase for inflation in over two years. What impact has this had?

Answer: Research and Training has been maintained at approximately the same level for several years. Because of this, competition has increased. The result has been a strengthening of the quality of applications, which has been beneficial to the program.

We believe, within the context of the overall Federal budget and of the priorities of the agency, the funds provided in past years and the funds requested are appropriate.

GENETIC INFORMATION AND COUNSELING

Question: To what extent does coordination among the Genetic Counseling and Testing, Family Planning, and Adolescent Pregnancy programs occur?

Answer: The regulations and guidance material developed for this program require that projects be developed in conjunction with Title V and other health programs as mandated by the legislation. All application kits contain a copy of the regulations and guidelines plus a list of Title V, Hemophilia, Sickle Cell and other Genetic projects. A covering memorandum which specifically addresses the issue of linkage between programs is included with the lists. In addition, staff provide technical assistance to projects and stress the need for coordinated development. Reviewers of applications are also instructed to look specifically for such coordination. Since these projects are just completing their first year of operation, we cannot yet assess how effective these linkages will be.

Question: What happens when it is determined that a pregnant woman is carrying a fetus with a hereditary disorder? What type of counseling and follow-up services are provided?

Answer: A woman who learns that her fetus is affected by a hereditary disease receives counseling. This is non-directive, and

includes a discussion of the diagnosis in terms of implications for the future of the affected individual and the family. Continuing support would be offered by appropriate professionals (private physician, geneticist, nurse, social worker). The diagnosis would be confirmed following delivery of the child and the results discussed with the couple. Long term follow-up plans would depend on the nature of the disorder in question, the parents' future plans for reproduction and their individual needs.

Question: Are individuals who receive counseling and testing services through this program primarily Medicaid eligible? What percent are?

Answer: Individuals receiving services through this program are primarily infants tested in newborn screening programs, pregnant women at risk for genetic disease and their families, and families which have a member born with a genetic related disease. Data are not yet available on the service recipients' eligibility under Medicaid. It is anticipated that the percentage will be low initially, but increase rapidly as education and outreach programs are implemented.

Question: What percentage of services are provided to couples who are expecting a child and what percentage to couples who are merely planning a family?

Answer: Data are not available on this. Services fall into two broad categories: those which are population based (such as screening for specific target populations, e.g., newborns) and those which are proband based (such as diagnosis and counseling for affected individuals and their families). Both categories are covered in these grants.

Question: Do you provide these funds on a grant basis to an individual group or through the States?

Answer: Any public or non-profit private group is eligible to receive a grant. Awards to date have been to State Health Departments or Universities primarily because of their capability to implement statewide programs and develop appropriate linkages with MCH and CC programs as mandated by the legislation.

Question: This is a new program which the Committee first funded three years ago. What problems are you encountering?

Answer: The primary problem is the development of effective linkages with <u>all</u> appropriate health service delivery agencies and organizations within the catchment area due to the diversity and numbers of these organizations, their particular program interests and focus.

Question: Give us a list of the top ten centers in your judgment?

Answer: We are not funding centers as such but are focusing on broad networks which include catchment areas that are statewide or regionwide if appropriate.

During the last three years, the Genetic Disease Services Program has provided support for 21 comprehensive State or areawide genetic service programs and 20 sickle cell screening, education and counseling programs. In nine States, the sickle cell programs have become an integral part of the genetic service system.

The 21 areawide network plans, though variable in modality, assure that all Bureau of Community Health Services programs including primary care sites such as Community Health Centers, Family planning programs, Migrant Health programs, Children and Youth programs, Maternal and Infant Care programs, Appalachian Health programs, local county or city health department primary care clinics serve as entry points. Secondary care sites, such as community hospitals, public health facilities, newborn screening programs, satellite genetic centers, community based genetic screening programs, and sickle cell programs, also are key components of the network. Genetic testing and genetic counseling are offered either directly at the site or by referral to tertiary centers which are usually university based and supported under Title V, or to a private physician when appropriate or indicated.

Question: It is felt by many that it is critical that potential genetic problems, when possible, be avoided before conception. That is where the information or education part of the program enters in.

Now that we have started a health education program in the Assistant Secretary's office, Center for Disease Control, and the Department of Education, how are you seeing to it that your program is tied together with all three of them?

Answer: We agree with the prevention concept that potential genetic problems should be avoided, when possible, before conception.

To this end both long and short-range strategies are being pursued.

For example, the short range effort has focused primarily on the development of a National Clearinghouse for Human Genetic Diseases which makes education and information materials available to providers of services in clinical, university and other provider settings and to the general public.

In support of long-range goals, a small grant has been awarded to develop curriculum materials for junior high and high school students, for use by science and health education teachers.

An ad hoc working group has been established to review current activities and accomplishments and to make recommendations for future program directions. The group involves interagency representation which includes persons from the Department's

Secretariat for the International Year of the Child and the office of Health Information and Promotion. It is anticipated that this group will provide the basis for establishing effective linkage with all of the above organizational segments to insure their input and develop an ongoing interchange of ideas and concepts.

MIGRANT HEALTH

Question: Grants are made to plan and develop health centers for the care of migrant agricultural workers, seasonal agricultural workers, and the families of such workers. As I understand it, however, emphasis is given to applications for projects in areas with migrant workers rather than those with seasonal workers. Is this emphasis still in effect?

Answer: Prior to the most recent amendment to the Migrant Health Centers authorization (P.L. 95-626), the highest priority for the provision of assistance through the program was, "to areas in which reside the greatest number of migratory agricultural workers and the members of their families for the longest period of time (P.L. 94-63)." Although this language has been amended to read, "areas where the Secretary determines the greatest need exists," other portions of the current authority place priority emphasis on service first to migrant farmworkers and then to seasonal farmworkers.

Question: Why? Are the needs of migrant agricultural workers different -- greater?

Answer: The economic status and health needs of migrant and sasonal farmworkers are similar. However, the financial and health problems confronting migrant farmworkers are generally more severe. Both groups have incidences of illness that are much higher than that of the U.S. population at large. For example, data from a number of studies indicate a much higher incidence of upper respiratory infections, gastrointestinal diseases, dermatitis, venereal disease, hypertension, tuberculosis, depression, alcoholism, and malnutrition. Infant mortality is at least 50 percent above the national average. The rate of industrial injuries and accidents is among the highest in the Nation.

Question: What are the needs of each group?

Answer: Major distinctions between the health care needs of migrants and seasonal farmworkers exist with respect to access and continuity of care. Because migrants are alien to the community in which they work, which is reinforced by racial and cultural differences, migrants are regularly denied access to care in health systems set up to serve the resident poor and needy, as well as health care systems which serve people with the ability to pay for services. Such systems include Federal, State and county health services and Medicaid and Medicare programs. The seasonal farmworker, on the other hand, tends to be eligible for health care services in systems designed for the poor if they are available.

Moreover, the seasonal farmworker, like the resident poor, can seek continuing care from the aforementioned services in his community. In contrast, continuity of care for the migrant is fragmented as he moves from one job location to another.

The lack of transportation or unavailability of health professionals who speak Spanish represent two additional barriers to care encountered by migrant farmworkers.

Question: How many migrant workers are there nationally?

Answer: Nationally, there are estimated to be 700,000 migrant agricultural workers.

Question: How many of these receive services through this authority?

Answer: This authority will serve 223,300 migrant workers in 1981.

Question: How many seasonal agricultural workers are there nationally?

Answer: Nationally, there are an estimated 2,000,000 seasonal agricultural workers.

Question: How many receive services through this authority?

Answer: This authority will serve 367,700 seasonal agricultural workers in 1981.

ANNUAL EXAMINATIONS

Question: According to information submitted to this committee by the Department last year, 47 percent of the women over 17 years old who were users of the migrant health clinics received annual Pap smears and breast examinations. It seems to me that this figure should be 100 percent -- that every woman who comes to the migrant health clinics should have an annual breast examination performed. Why isn't this being done routinely?

Answer: The rates for provision of these services in Migrant Health clinics are equal to the rates for the U.S. population as a whole and better than the rates at which such services are provided to poor women in this country -- which is 37 percent for Breast exams and 33 percent for Pap smears. Although these potentially life-saving services should be provided to all women at regular intervals, there is increasing evidence to suggest that annual exams in asymptomatic women may not be the best use of scarce resources. The National Cancer Institute will conduct a consensus meeting on the subject of Pap smear frequency this summer which may help us set appropriate intervals. A distinguished Canadian task force appointed by the Conference of Deputy Ministers of Health recommended in 1976 that if a woman has had two consecutive normal

Pap smears early in adulthood, "future smears should be taken at approximately 3 year intervals until the age of 35, and thereafter at 5 year intervals until the age of 60" and that women over the age of 60 who have always had normal smears may stop undergoing Pap smears.

Consistent with the Canadian Task Force recommendations, we require all centers to have patients with Pap smear abnormalities promptly evaluated and treated by gynecologists. Since Pap smear abnormalities may appear as much as 10-20 years before the actual onset of cervical cancer, we think that identification and aggressive management of those few women with significant abnormalities will do much more to reduce cervical cancer in our patients than enforcing annual smears.

Question: How successful is patient education in self-breast examination with women who visit these clinics, i.e., how often do women who come to these clinics report possible pathology discovered on self-examination, compared to women who are seen in private practice or other clinical settings (e.g., Medicaid recipients)?

Answer: We know of no data on this subject in our programs, although we would vigorously support any activity which might reduce the terrible toll which breast cancer takes on middle-aged and elderly women. Unfortunately, even the efficacy of breast self-examination is controversial, as indicated in an August 1978 editorial by Dr. Francis Moore in the New England Journal of Medicine. Furthermore, less than 20 percent of women served by the Migrant program are in the high-risk over-45 age group.

From a human, rather than a statistical perspective, we believe in the principles of personal responsibility for health and of education to enhance health. For this reason, our health care providers are in general enthusiastic about the concept of breast self-examination.

NATIONAL HEALTH SERVICE CORPS

Question: What percentage of the Corps people work in areas which are rural? Urban?

Answer: At the end of fiscal year 1979, of 1,824 NHSC assignees, 1,162, or 64 percent, were assigned to rural areas and 662, or 36 percent, were assigned to urban areas.

Question: Does there tend to be a preference for service in one type of medically underserved area over the other, i.e., rural vs. urban?

Answer: Although young health professionals in general prefer to settle in urban or suburban communities, Corps assignees often exhibit a preference toward rural areas. We believe that this is due to the fact that the NHSC has had a rural emphasis which is reflected in its recruiting literature. Thus, those health

professionals who would prefer rural areas are drawn to the NHSC as an attractive means of fulfilling their preferences.

Question: Is there a greater retention rate in one versus the other?

Answer: We have only in the past two years begun assigning large numbers of assignees to urban areas. Data to provide an analysis of retention for urban areas as compared with rural areas will not be available until this fall, after a large number of urban assignees have completed their initial service commitments.

Question: Is the retention for certain types of practitioners greater than for others, i.e., nurse practitioners, physicians, nurses, etc.?

Answer: Of 299 NHSC assignees extending with the Corps or converting to private practice in shortage areas in 1979, the greatest retention was for dentists, that is 67 percent of those dentists eligible to leave the Corps either extended or converted to private practice. A greater percentage of physicians and dentists converted to private practice than did physician assistants, nurse practitioners and other health professionals. However, a greater percentage of physician assistants, nurse practitioners, and other health professionals extended with the Corps than did physicians.

NATIONAL HEALTH SERVICE CORPS REPORT

Question: Many problems affecting either HSA or HRA administratively, need to be solved either separately or jointly in order for NHSC to continue to function in its current organizational position. The report suggests that joint resolution of policy and program problems is an effective, least-costly alternative to total organizational change. Would you comment on the political and administrative feasability of this proposal?

Answer: The report states that, of the five alternatives recommended, the one requiring the least organizational change at a relatively low cost is to maintain the organizational status quo of HSA and HRA and designate the Administrator of either HSA or HRA as the final authority on NHSC issues.

The program has been administered effectively within the Public Health Service and few differences between the scholarship component and services component have had to be resolved at the Assistant Secretary level. The programs can continue to operate in the present organizational structure without disruption. Organizational changes, however, are under consideration with a view toward greater efficiency and continuity of direction and purpose. The need for organizational change is also being considered as a possible means of addressing future growth.

Question: The Report suggests that personnel involved in NHSC programs feel that the service elements of the NHSC in Bureau of Community Health Service (BCHS) should be merged with the scholarship elements of NHSC now located in the Bureau of Health Manpower (BHM). The consensus was that this organizational merger should occur in HSA. Would you support this? Why?

Answer: Everyone would agree that neither the scholarship nor the service component can be considered in isolation. The final decision on which, if any, of the five alternatives recommended in the report would be most effective will be determined by the Secretary in whose office the report is now being scrutinized. We do, however, view the purpose of the NHSC scholarship program primarily as a source of health professionals for service in the NHSC in health manpower shortage areas. Whatever organizational policy is finally implemented, we can assure you that this "service" focus will continue.

Question: Would such a merger or change account for improving:

-- responsibility, heretofore lacking, for overall NHSC daily operations?
-- smoother program function and decision-making?
-- greater efficiency and Corps member faith in NHSC activities?

Answer: We do not feel that responsibility for the NHSC daily operations has heretofore been lacking. Currently HSA utilizes 290 positions in the central and regional offices who are responsible for the placement and monitoring of approximately 1,850 NHSC assignees in over 875 sites. While there are some personnel problems due to the rapid growth of the NHSC, measures are being taken to alleviate them.

When the responsibility for administering a program is lodged in two separate agencies, there will be differences of opinion which will affect the decision-making process and continuity of program implementation. Up to now, policy resolution has been handled well, and the organizational split has been beneficial in achieving desired balance and constructive evolution of policy from differing perspectives. Whether re-organization is now warranted is under consideration by the Secretary.

We feel that one motivation to change the organizational structure has been the perception of the operation from the outside. Students start out in the scholarship program under HRA and then are transferred to the service component under HSA. We are making great strides in making this transition as non-disruptive as possible, by working closely with HRA while students are still in school. A merger might, however, facilitate smoother program functioning and, thus, promote an improved image for the Corps.

Question: What incentives are necessary to encourage better specialty and geographic distribution of physicians?

Answer: Beyond the fixed salary and benefits that are available to NHSC physicians, such incentives would include the following:

a) Type of practice configuration and mix of health professionals. The placement of health professionals from several disciplines in group practice settings maximizes the range and quality of services offered and better facilitates professional interaction, peer review, and backup. Internists, pediatricians and obstetricians should be placed with general practitioners and other health professionals to the extent possible to better utilize their specialty training in providing comprehensive primary health care services.

b) Personal situation. Both personal and professional factors should be considered when matching specialty physicians to assignment locations. Although patient population health care needs determine the basic rationale for placement, personal and/or spouse characteristics may contribute to placement in some geographic areas. The specialist or spouse may desire assignment to certain areas because of professional opportunities, social or cultural attractions, or other personal reasons.Health care professionals interested in an area should be familiarized with all aspects of the area before final decisions are made. The group practice setting facilitates meeting the physicians' needs to spend time with their families and to continue their professional education. In smaller practices it is still necessary to make special arrangements for adequate time away from service responsibilities.

NATIONAL HEALTH SERVICE CORPS AUTHORIZATION

Question: As you know, the authorization for the National Health Service Corps expires at the end of fiscal year 1980. In recent years there has been a problem in getting legislative authorizations renewed in time for the Appropriations Committees to consider the budget requests for many programs. What would the impact be if that were to happen with respect to the National Health Service Corps this year and the program were forced to operate at the fiscal year 1980 level in fiscal year 1981?

Answer: Assuming that the Corps receives the fiscal year 1980 supplemental and therefore would begin fiscal year 1981 with 2,820 assignees on board, the Corps would have to terminate 2,020 assignees on June 30, 1981, leaving only 800 assignees on board for the remainder of the fiscal year. Approximately 1 million people would be affected with a reduction in health care services.

Question: What would be the impact on the Community Health Centers program if the National Health Service Corps were forced to operate at the 1980 level in 1981?

Answer: About 1,100 physician and mid-level practitioner vacancies would be created in Community Health Centers. Approximately 1,000,000 persons would suffer a decrease in services at both Community Health Centers and other Corps sites.

Question: Why is such a large number of National Health Service Corps personnel being assigned to Community Health Centers and Migrant Health Centers?

Answer: It is our goal to reach populations most in need and to serve them effectively with systems of health care. To create such systems usually requires the combination of grants and NHSC assignments. This is so because the high need areas by their very nature are very difficult to staff and often only the commitment of NHSC volunteers or the obligated service of the scholarship recipient will allow the establishment of constant medical service capacity.

Assignment of NHSC personnel to comprehensive health delivery systems, such as CHCs and MHCs reduces professional isolation, permits increased coverage on a year-around basis and provides necessary support services.

NHSC FY 1980 SUPPLEMENTAL REQUEST

Question: What will happen if you do not receive a supplemental?

Answer: If the Corps does not receive the supplemental, the 1979 field level of 1,850 will be maintained. However, this level allows us to bring on only 400 new assignees in 1980 to replace up to 400 who terminate their service in 1980. Up to 500 scholarship assignees must be told that they will not be able to serve their obligation with the Corps; we must also discontinue recruiting volunteers for placement in 1980.

Question: How soon do you need it?

Answer: We feel that a supplemental appropriation is needed immediately. While I recognize the difficulty that the Congress may have in accomplishing this, we face severe recruitment problems. We are currently recruiting highly qualified professionals who are completing their medical training at the end of the current school year. These individuals are seeking to make commitments for employment as soon as possible. We face the possibility that individuals who cannot receive a firm employment commitment from the National Health Service Corps will accept other offers.

A supplemental which is not received by the beginning of the fourth quarter will have little practical benefit.

Question: What would be the impact of not receiving the supplemental request for the National Health Service Corps in terms of people not served, scholarship obligees not assigned, etc.?

Answer: If we did not receive the supplemental appropriation, 223,525 people would not refeive services in 1980; 161 sites would not be staffed; and 970 assignees would not be placed, of whom up to approximately 500 would be scholarship recipients.

Question: What would the impact be on the Community Health Centers if the Corps did not receive the supplemental request?

Answer: Many of the HMSAs which are to receive NHSC health professionals are in areas which also are designated as medically underserved and which have existing or new CHC projects. The 970 new NHSC assignees requested in the supplemental will be placed in those HMSAs and MUAs which have been identified as having the greatest need - that is, areas with high infant mortality rates, with high numbers of migrants, with large numbers of poor, and with large elderly populations. Therefore, if the Corps did not receive the 970 new assignees, the services to be provided to many residents of MUAs served by CHC projects would be significantly reduced, or at least delayed, pending the recruitment of other health professional personnel by the projects or the availability of additional NHSC personnel, possibly in late 1981.

STATE LEGISLATION

Question: Is there a significant problem in using nurse practitioners given the great variability in State laws governing autonomy of practice of such individuals?

Answer: The majority of the problems experienced by the National Health Service Corps relate to the States' interpretations of what constitutes medical practice, specifically in the areas of medical diagnosis, medical treatment, and providing medications to patients. State legislation affecting nurse practitioners is continually being passed and new regulations are continually being written.

It is important to understand that the nurse practitioner, unlike the physician assistant, has been able to practice in some States without significant changes in regulatory statutes. The nurse practitioner performs in an expanded role, which can be interpreted as an extension of the nursing role which has been included in legislation for many years.

The NHSC will continue its efforts to develop effective communications between the primary care clinics employing NHSC nurse practitioners and State medical, nursing and pharmacy licensing agencies, as well as State professional organizations. Through the efforts of the NHSC central office, regional offices, and NHSC professionals, we have seen dramatic changes in some States. For example, the NHSC placed 22 nurse practitioners in Mississippi in 1977 and today as result of that effort, Mississippi has developed a certification program for nurse practitioners.

The NHSC experience is that each State's medical, nursing and pharmacy practice acts must be reviewed on an individual basis to determine the scope of nurse practitioner practice. One problem in reviewing State practice acts is the false assumption that States with similar legislation are also similar in their interpretation of the legislation. The NHSC experienced this problem in New York and Colorado. Colorado modeled their nurse practice act of 1974 on

the New York nurse practice act of 1972. In 1976, the New York attorney general interpreted the New York act as not specific enough to cover the nurse practitioner, but the attorney for the Colorado State Board of Nursing interpreted the Colorado nurse practice act to include the practices of nurse practitioners.

The NHSC believes the legal recognition of nurse practitioners and the great variation in State laws will remain a controversial area for the next five to ten years.

Question: Are physicians' assistants eligible for Corps scholarships?

Answer: No, the Corps has been able to recruit a sufficient number of volunteers in this category and therefore it is not necessary to offer NHSC scholarships to physicians' assistants.

Question: Are nurse practitioners and physicians' assistants more likely to stay in a medically underserved area than physicians because of the greater autonomy the former would have?

Answer: NHSC nurse practitioners and physician assistants placed in solo practices experience the same problems as physicians who are placed in solo practices. Some of the problems experienced by physicians and mid-level providers that have resulted in decreased retention rates are: lack of adequate continuing professional education; lack of peer and professional relationships; and a general burn-out syndrome resulting from community expectations. For example, like physicians, a nurse practitioner and/or physician assistant in a remote area is frequently called upon for assistance even on nights when he is supposedly not on call. This can generate a feeling of never being off duty and result in mental and physical fatigue.

The NHSC has been most successful in retaining nurse practitioners in those health manpower shortage areas where the nurse practitioners have established roots. Nurse practitioners most likely to remain in the community are usually over twenty-five years of age, married and/or have relatives in the area; and have a commitment to improve that area's primary health care delivery system.

RETENTION

Question: Generally, how long do NHSC members remain in an assigned area after completion of their tours of duty?

Answer: We shall provide for the record a table which indicates that 33 percent of all assignees who had served with the Corps as of September 30, 1978, had remained with the Corps for more than two years.

[The information follows:]

61-400 O - 80 - 12

Length of Assignments for NHSC Assignees
Fiscal Years 1972 - 1978

	Total Assignees Since Inception	Breakdown of Assignees Who Have Left the NHSC by Length of Assignment							Breakdown of Assignees Still on Board 9/30/78		
		1 Year or Less	1-2 Years	2-3 Years	3-4 Years	4-5 Years	Over 5 Years	Subtotal	Obligation Completed	Obligation Being Served	Subtotal
Physicians	1,459	167	425	133	33	4	3	765	81	613	694
Dentists	351	24	75	34	8	--	--	141	35	175	210
Other	586	66	90	29	12	3	1	201	44	341	385
Total	2,396	257*	590	196	53	7	4	1,107	160	1,129	1,289

*Includes 89 physicians, 12 dentists, and 55 other who stayed less than one year because of death, illness, or other adverse reason.

Question: Is there a difference in retention rates between those who are volunteers and those who are scholarship recipients?

Answer: 1979 is the first year in which any significant number of scholarship assignees were eligible to terminate their service. Of 103 eligible, 16 (or 16 percent) extended with the Corps and 11 (or 11 percent) converted to private practice in HMSAs. The remaining 76 (or 73 percent) left the HMSAs. While the percentage of scholarship assignees (17 percent) remaining in a HMSA Corps varies significantly from the percentage of volunteers (59 percent), we believe it is still too early to predict the future retention of scholarship assignees. However, we would expect that with the improved selection process now used in making scholarship awards, the retention of these assignees in HMSAs would be greater than in 1979 when many scholarship recipients selected in the early years of the program were first eligible to terminate their service.

Question: What happens with the capital purchased with grant funds, e.g., equipment, etc., in the event that after the required one or two years, a physician decides to leave the shortage area? Does he/she take such capital with him/her or is it reclaimed by the Feds or the community?

Answer: The Department of Health and Human Services (DHHS) grant procedures require that title to capital equipment purchased with Federal grant funds remain with the Federal government.

COMPARATIVE EFFICIENCY

Question: Has HSA conducted studies on the relative efficiency of CHCs, MHCs, and the NHSC compared to similar centers and personnel in the private sector (e. g., annual number of patient visits; cost)?

Answer: There have been no recent studies with the specific purpose of making comparisons among the programs and between the programs and the private sector. However, data are available from various sources which make some comparisons possible.

Question: What do these comparisons show?

Answer: I shall submit for the record a table which displays the average cost per medical encounter for each of the programs and for the private sector and the average annual encounters per physician for the CHC and NHSC programs and for the private sector.

[The information follows:]

	Cost Per Medical Encounter	Average Annual Encounters Per Physician
Community Health Centers.....	$24	4,015
Migrant Health Centers.....	$16	*
National Health Service Corps....	$21	3,754
Private Sector.....	$22	4,900

* We assume that the productivity for Migrant Centers is the same as for Community Health Centers.

SUDDEN INFANT DEATH SYNDROME

Question: In the Senate Appropriation Committee Report which accompanied the FY 1978 Labor-HEW Appropriations bill, this body provided funding for various program support and management items in the Health Services Administration. In particular, we provided for increases in the number of staff positions with HSA, six of which were to be "clearly identified for the Sudden Infant Death Syndrome Program." Have these six positions been filled: If "yes", please provide the names and titles of the six individuals filling the positions?

Answer: Staff positions for the Sudden Infant Death Syndrome Program are as follows:

1. Geraldine J. Norris, R.N., M.S.
   Director, SIDS Program
   Public Health Analyst GS-685-14

2. Carol J. Bohannon, M.A.
   Consultant, SIDS Program
   Public Health Analyst GS-685-12

3. Vacant Since June 10, 1979
   Staff Assistant, SIDS Program
   Staff Assistant GS-301-9

4. Connie H. Ecton
   Secretary, SIDS Program
   Secretary GS-318-5

5.-6. Two man-year equivalents of program support are contributed from a variety of functional areas within the Bureau of Community Health Services and at other levels in the Health Services Administration and the Public Health Service.

Question: What sort of effect will the recent amendment to the Sudden Infant Death Syndrome Act and the requirement that there be an identifiable administrative unit within HEW to administer the SIDS program have on the already existing personnel in the Bureau of Community Health Services?

Answer: The Sudden Infant Death Syndrome Program has been carried out by the Secretary since the initial legislation was enacted. The authority for the Program was delegated through the various levels of the Public Health Service to the Director of the SIDS Program in the Office of Maternal and Child Health on 4/9/78. Prior to this date, the program was carried out without full-time staff. The personnel with primary responsibility for the program were not located in the same office. More recently, staff have been assigned full-time to the program office (see previous response to question concerning program positions).

Question: How many projects are there serving SIDS families? What percentage of the population in need is being served?

Answer: There are now 37 Federally supported SIDS projects. Based on the most recent final natality statistics available from the National Center for Health Statistics (1977) and applying the formula for estimating a national average of SIDS deaths (2 SIDS deaths occur per 1,000 live births), approximately 6,800 SIDS deaths occur annually in the United States. The estimated number of SIDS deaths occurring in the areas served by the 37 Federally supported grants is 4,500 or 66 percent of those families in need.

Question: Geographically, what percentage of the States are being served?

Answer: As of September 30, 1979, Federal grant support was received in 32 States. Of these, 29 States had statewide SIDS information and counseling projects and 3 States had projects with services available in defined areas of each State. There presently are 20 States, the District of Columbia, as well as 5 territories and possessions without Federal support for SIDS information and counseling services. Therefore, approximately 51 percent of the States have Federally supported statewide SIDS services (29); 5 percent of the States have Federally supported SIDS services in a portion of each State (3); 44 percent of the States, possessions, territories and the District of Columbia do not receive Federal funds for SIDS services (26).

Question: The diagnosis of SIDS is one which is made by a process of ruling out other diseases and is, therefore, extremely dependent upon high quality post-mortem examinations.

What can the Department do to foster changes in State laws and systems regulating post-mortem examinations so that there can be better uniformity and higher quality and, therefore, a more accurate diagnosis of SIDS?

Answer: Under P.L. 96-142, the Department has been given the mandate and responsibility for conducting a study of State laws, practices, and systems relating to the investigation of sudden, unexplained deaths in infants. The study is to consider mechanisms for improving the quality, frequency, and uniformity of post mortem examinations performed under these laws, practices, and systems. The Department shall report to Congress the results of this study together with recommendations for Congressional or Departmental action concerning the conduct of post mortem examinations in all SIDS cases. Model State laws governing infant death investigations and pilot projects for centralized post mortem and specimen examination systems on a statewide or regional basis are among the means that could be considered for recommendation.

In addition, the Department will periodically revise the 1975 protocols for conduct of investigative and autopsy studies necessary in instances of sudden and unexpected infant deaths. The revisions will be based on scientific findings resulting from research efforts of cooperating programs, such as those at the National Institutes of Health, or from clinical findings of the information and counseling service projects.

INTERAGENCY COORDINATION

Question: Is there any coordination of effort between your program and the research program at the National Institute of Child Health and Human Development.

Answer: Yes, there has been and there continues to be a concerted effort to coordinate and maximize the efforts of the service and research programs. For example:

- NICHD has consistently invited the SIDS program office to participate in their SIDS research planning meetings.
- NICHD has regularly participated in the review process for determining the awards of service grants and contracts.
- NICHD is represented on all SIDS service program ad hoc advisory panels.
- NICHD participates in the service program annual meetings and the SIDS program staff participate in the NICHD research meetings.
- Six SIDS Information and Counseling projects have been active participants in the design, conduct and analysis phases of the SIDS Cooperative Epidemiological study supported by NICHD.
- The SIDS Program Office widely distributes literature on SIDS produced by NICHD and NICHD, in turn, uses the service literature produced by the SIDS program office.
- The directors and staffs of both program components confer regularly regarding questions that require investigation as well as ways and means of incorporating relevant research findings into clinical programs.

Question: Please give us some specific examples of how SIDS funding is being used to inform law enforcement agencies about SIDS?

Answer: Several educational and informational initiatives have been targeted for law enforcement agencies. Among them are:

- A 16 mm color film entitled "A Call for Help" was produced to inform all first responders (police, fire fighters, and emergency medical technicians) about SIDS and to increase their awareness of the lasting effect their behavior can have on newly bereaved parents and siblings. This film was originally distributed through the International Association of Chiefs of Police. Because the demand for this film has been so great, copies were made available to all State health departments, SIDS Information and Counseling projects, voluntary parent organizations, and numerous police academies. It is shown approximately 1,000 times annually.

- A training manual entitled "Training Emergency Responders: Sudden Infant Death Syndrome" has been developed for use by police and emergency medical technicians. Copies have been distributed widely to police and emergency medical training academies. Project grantees are using the manual in their classes for first responders.

- All projects plan and conduct several training sessions for emergency workers in their areas annually.

- Several projects, including Florida, Maryland and Pennsylvania, have produced guidance manuals, in-service materials and video training tools for police and other emergency workers.

- Many of the projects have successfully introduced SIDS into the curricula of law enforcement academies. The Houston project, for example, developed a training module which is used regularly by the training program for Justices of the Peace in San Marcos, Texas.

- The program is reviewed periodically with appropriate national organizations and agencies concerned with emergency programs. Good working relationships have been established with several of the organizations.

INTERCHANGE OF INFORMATION

Question: Dr. Lythcott, during questioning on HSA's SIDS program, you were asked by Senator Schmitt how close we were to finding an answer to the cause of this disorder which is the leading cause of death in infants between one and twelve months. You responded by saying that you did not know, as the research activities were carried on by the National Institute of Child Health and Human Development (NICHD), and not HSA.

Since, 1) under the SIDS law the Secretary is mandated to "carry out coordinated clearinghouse activities on SIDS, including the collection and dissemination . . . of biomedical research activities" . . . and that law is administered in your agency, and 2) the diagnosis of SIDS is made by ruling out other causes of death through autopsy, information from which is collected by HSA's SIDS projects and, we would hope, disseminated through your agency to NICHD causing there to be a continuous dialogue between your office and NICHD, how can you justify your lack of information?

Answer: I and those responsible for the administration of the SIDS counseling and information program are kept informed of the knowledge gained so far from the research efforts of NICHD. We know that, as a group, infants who die of SIDS are different from normal infants, even prior to birth. These subtle differences are anatomical, chemical, histological, and physiological. Unfortunately, there is still no reliable nor valid means of predicting which individual infant is at high risk of succumbing to SIDS. We are awaiting the findings of current NICHD-supported

studies which hold promise for identifying risk markers for SIDS or a risk prediction scheme that will identify specific vulnerable infants during the early weeks of life.

Since, 1973, the Federal programs associated with SIDS and related issues have engaged in active and continuous dialogue:

- The Interagency Panel on SIDS, established by the Assistant Secretary for Health in 1974, has been an effective means for exchanging information, raising questions that require research efforts, communicating research findings for implementation into clinical settings, and preventing overlapping efforts.

- At the program office level there is almost daily communication with NICHD. The program staff is fully aware of the areas of research being supported, the findings of research efforts and the prospects for clinical implementation. Joint planning for research on problems identified in clinical practice is discussed.

- The legislative mandate to implement a SIDS Clearinghouse was enacted on December 12, 1979. Contract authority will be used to develop and maintain this component of the SIDS program. The legislation explicitly states that biomedical research activities and findings will be included.

Question: Given the fact that there are approximately 6-8 thousand SIDS deaths each year, which means that you are reaching only a little more than half the families in need, how do you justify level funding?

Answer: Priority for increased funding has been given to health service delivery programs serving underserved and disadvantaged populations. The SIDS program does not fall into that priority category.

BLACK LUNG CENTERS

Question: How many Black Lung Centers do you plan in fiscal year 1980 and 1981?

Answer: We plan to fund 105 centers in FY 1980 and 132 in FY 1981. This represents an increase of 27 centers in 1981.

GAO REPORT

Question: Last year at these hearings we talked about a 1978 GAO report on Community Health Centers that showed inefficiency, overstaffing, underutilization and unnecessary costs at some neighborhood health centers across the country. You responded that you were dealing with certain problem centers by changing grantees, providing technical assistance, terminating grants and other

methods. Can you tell me whether, with the passage of a year, you have been successful in cutting down on the waste and inefficiency in this program?

Answer: In our testimony last year, we pointed out that the six centers mentioned in the GAO report were not representative of the program as a whole and were, indeed, six of the nine worst centers at the time of the GAO review. Although we deny any implications that waste and inefficiency are widespread, we do acknowledge that there are areas of this program which need improvement. To that end we have augmented our ability to monitor the operation of the centers in terms of quality of care, productivity, and administrative costs. In every area we have experienced steady improvements.

Question: What procedures do you follow to monitor the effectiveness of the Community Health Centers?

Answer: Effective monitoring is performed through the Bureau's Common Reporting Requirements indicators. All projects are expected to be in compliance with the program indicators by the end of their second full year of services delivery under a grant award administrated by BCHS. The program indicators include clinical effectiveness standards and administrative efficiency standards.

The clinical effectiveness indicators were developed primarily to cover comprehensive services in ambulatory health care centers so as to assure quality care and effectiveness in each of their clinical components. These indicators include, for example, standards for immunization of children, pre-natal care, family planning counseling for adolescents, pap smear follow-up, hypertension screening and anemia screening.

The administrative efficiency indicators provide a mechanism to evaluate the average cost per medical encounter, and cost attributable to administration. The analysis of the above factors in relation to the grant dollars received reveals the level of services provided and the cost associated with those services.

Question: How regularly are center operations audited and evaluated?

Answer: It is our policy that each center be audited and evaluated annually.

PLACEMENT OF COMMUNITY HEALTH CENTERS

Question: How do you ensure that Community Health Centers are started or expanded in the areas where they are most needed?

Answer: In considering and awarding Community Health Centers projects, the Bureau of Community Health Services (BCHS) must first meet the requirements of the law to serve medically underserved areas (MUA's) and, for new awards, ensure that new service capacity in either rural or urban areas does not exceed 150

percent of the new capacity created in the other. In allocating resources among MUA's, BCHS has developed a priority system which considers 4 needs criteria:

1. MUA - A scoring process of BCHS which considers (1) physician-to-population ratio, (2) population which is aged (3) population which is in poverty and (4) infant mortality. Lower scores represent areas with greatest degree of medical underservice.

2. Health Manpower Shortage Area (HMSA) - physician-to-population ratio of 1:3,500 or worse.

3. High infant mortality.

4. High migrant impact.

Program guidelines define how these needs criteria are to be applied in determining development and funding priorities for programs/projects. A study completed in January of this year reflects that:

- 24 of the 35 counties in the U.S. which meet all four of the need criteria fall within the service area of Community Health Centers

- 223 of the 532 counties meeting three of the four need criteria fall within the service jurisdiction of centers

- 375 of the 1,577 counties meeting two of the four criteria are within the service scope of currently funded centers.

In the aggregate, nearly one third of all designated U.S. counties are reached by the Community Health Centers funded by the Department of Health and Human Services - a truly impressive observation.

Question: In last year's budget justification, Department officials spoke of two new hospital-based Community Health Centers "whose objectives were to provide incentives to expand the use of hospital outpatient departments and to control inappropriate use of hospital emergency rooms for routine care." How successful have the two hospital-based Community Health Centers been in meeting their aforementioned objectives?

Answer: The fiscal year 1980 budget justification describes two categories of hospital related programs funded under the Community Health Centers account: (1) Hospital Affiliated Primary Care Centers funded under section 328 of the Public Health Service Act, and (2) Hospital Linked Community Health Centers funded under section 330 of the Public Health Service Act. In 1980 Community Health Centers have been encouraged to develop linkages with hospitals for the provision of needed inpatient services and a number of Community Health Centers are located in and sponsored by hospitals. Under the Hospital Affiliated Primary Care Centers program, 10 projects will be started in their planning and development phase with the $1 million provided under the fiscal

year 1980 appropriation. Each of these projects will be funded on the basis of its capability, willingness, and commitment to change inappropriate utilization of emergency rooms for routine care and to expand proper use of outpatient departments. We are encouraged by the cooperation and response we have received with this program.

PRIMARY CARE, RESEARCH AND DEMONSTRATION PROJECTS

Question: The Secretary is authorized to make grants and enter into contracts to demonstrate new and innovative methods for the provision of primary health care services and to conduct research on such methods, particularly with respect to underserved populations. In FY 1979, $10.6 million was provided and in FY 1980, $14 million was appropriated for this section. In the FY 1981 budget, the President has requested $9 million. What sorts of new and innovative delivery methods were developed per this authority in FY 1978 and 1980? Be specific.

Answer: During the period, fiscal year 1978 through fiscal year 1980, a number of new and innovative health service delivery methods were developed first under section 1110 of the Social Security Act and later, when Primary Care Research and Demonstration funds became available, under section 340 of the Public Health Service Act. The program has experimented, on a planned basis, with several modes of health care delivery in underserved rural areas with a view toward finding more effective ways to bring services to areas having varying demographic settings. A few of these modes of practice are listed below.

1. Establishment of satellite clinics in scattered communities that are attached to and supervised by a larger more fully staffed central clinic.

2. Staffing of some satellite clinics with nurse practitioners and physician assistants supervised by physicians practicing in a central clinic. Contacts are maintained with the central clinic by telephone, other more sophisticated telecommunication systems, and by regularly scheduled visits to the sites by a physician from the central clinic.

3. Experiments have been conducted to determine whether more effective and lasting service can be provided by sending a provider out from a pre-existing base to serve full-time at a satellite clinic and, in contrast, by utilizing a provider residing in or near the community being served. The latter arrangement has been found to be more successful.

4. Experiments have been tried in which private practices in an area serve a satellite clinic and carry a part of the financial risk as opposed to a similar setting in which the private practice bears no financial responsibility. Experience indicates the satellite clinic will be moved more rapidly to expand its patient load and to improve staff productivity when the practitioners are financially at risk.

5. Rural hospitals that are underused have been utilized in launching new clinics in their service area. This approach has proven to be very successful with the exception that, when established physicians in the service area object to the incursion of the new service centers, the plan is less likely to succeed.

6. Centralized support facilities to serve a number of satellite clinics in areas such as staff recruitment, clinic facilities acquisition, financial management and technical assistance have been found to contribute measurably to the success of new practices and to bring about economies in operation.

7. Several efforts have been made to integrate categorical programs into primary care projects in rural areas. While the concept is sound, efforts have met with varying degrees of success. Experience indicates that such efforts are more likely to succeed if the organization administering the categorical programs has the responsibility for developing and administering the primary care unit.

Question: What additional activities do you anticipate supporting with the FY 1981 allotment?

Answer: No additional activities are expected to be supported with the fiscal year 1981 allotment. Twenty-nine projects are expected to complete their research and demonstration activities with fiscal year 1980 funding; therefore, funds will no longer be needed for them. The requested funds will be used to support the continuation of the research and demonstration projects that are on-going.

Question: To what extent are the service delivery activities supported here duplicative of those supported by other agencies -- i.e., the National Institute of General Medical Sciences or the Health Resources Administration, or the Health Services Research program?

Answer: The Primary Care Research and Demonstration Program is directed toward research and demonstration of methods for the provision of primary health services and dental health services. In FY 1979, Congress approved a reprogramming request to transfer the service delivery projects from the research and demonstration program authorized under section 340 of the Public Health Service Act to the Community Health Services Program authorized under section 330, Public Health Service Act. The National Institute of General Medical Sciences is engaged in research and training in the general or basic medical sciences and related natural or behavioral sciences, not in the provision of primary health services. Similarly, the Health Resources Administration is primarily concerned with health planning, health facilities, and manpower development, rather than research and demonstration of the delivery of primary health services.

The Bureau of Community Health Services is working with the National Center for Health Services Research, so that research activities being conducted will be complementary, rather than duplicative. For example, the first use in a rural area of a

computer to store an ambulatory record system was a project developed by the National Center for Health Services Research.

HOME HEALTH SERVICES

Question: The President has requested no funds for home health agencies authorized by Section 339 of the Public Health Service Act. How many such grants have been made over the past two fiscal years with the $11 million appropriated?

Answer: The $11 million appropriated in fiscal years 1979 and 1980 will fund a total of 139 service grants and 44 training grants. In 1979 the $6 million appropriated funded 79 service projects and 22 training projects. The $5 million in 1980 will fund 60 service projects and 22 training grants.

Question: Is there Federal continuation support for such projects, or are they subsequently run independent of Federal funding sources?

Answer: Federal project funds for a Home Health Agency are awarded for the cost of development or expansion. These funds are for a period of 12 to 18 months. Projects then become financially viable without the support of Federal project funds. Each applicant for a Home Health Agency is required to submit a detailed financial plan specifically structured on how it will achieve financial self-sufficiency. This plan includes such items as quarterly cash flow projections, identification of revenue resources and marketing plans.

It shall be noted, however, that much of the operating revenues that these agencies will collect will be from Federal sources as Medicare and Medicaid.

Question: What happens to these projects if non-Federal funding is not available?

Answer: These projects continue to operate with funds generated from State and local governments, from private sources, and from Federal reimbursement programs such as Medicare and Medicaid.

Question: What percentage of the Medicare population could be kept out of institutions with such home health support?

Answer: It has been estimated that approximately 1,200,000 older persons who are impaired and live alone could be kept out of institutions with home health support.

Question: Of this percentage, what portion is being provided home health care via the Section 339 authority? Other home health projects?

Answer: An estimated 19,600 person are provided Home Health Care services during 1980 via Section 339. The latest available

data indicate that approximately 1,000,000 older persons are being provided Home Health Care services by non-Section 339 projects.

Question: How many more projects are necessary to support the rest of the Medicare population in need of such services?

Answer: We would estimate that the nation's capacity for providing Home Health Care would have to be increased by approximately 15 percent, or an additional 500 projects.

Question: What is the cost for these additional projects?

Answer: We estimate that the additional 500 projects would cost approximately $33.5 million in grant funds.

MATERNAL AND CHILD HEALTH

Question: Half of the Maternal and Child Health appropriation is apportioned to the States through formula grants and the remainder is divided into: (1) project grants for services for mentally retarded children; (2) project grants for special projects of regional or national significance; and (3) formula grants to State health agencies according to the number of live births and the financial need of each State in carrying out its State plan. What type of activities have been funded by the Maternal and Child Health special project grants of regional and national significance?

Answer: The following types of programs are funded as special projects of national or regional significance: the Improved Pregnancy Outcome (IPO) program; the Improved Child Health (ICH) program; the Childhood Accident Prevention program; the Immunization Tracking program; child development clinics; adolescent health; biochemical and cytogentic laboratories; and University Affiliated Facilities for Interdisciplinary Training.

SERVICES TO THE MENTALLY RETARDED

Question: How are services to the mentally retarded provided through the Title V authority coordinated with the other service activities for the mentally retarded provided through the 57 State and territorial developmental disabilities councils?

Answer: Coordination at the State level is achieved through representation of the Maternal and Child Health and Crippled Children's programs on the State Developmental Disabilities Council and through use of the University Affiliated program to provide technical assistance and training for State delivery systems in areas which have support from Title V, Developmental Disabilities and the Bureau of Education for the Handicapped/Office of Education (BEH/OE). On a regional and national basis, there is coordination through some joint reviews, joint plans, and an ad hoc coordinating committee on the Federal level.

Question: How many project grants for the mentally retarded are funded through the Title V authority?

Answer: There are: 21 University Affiliated programs; 21 grants to institutions of higher learning for biochemical and cytogenetic laboratory programs; 19 grants for demonstrations and training; and 11 service and demonstration grants through regional offices.

Question: The Developmental Disabilities Act requires that 65 percent of each State's allotment be spent on "priority services" for the developmentally disabled population, a large part of which is composed of mentally retarded individuals. Are the Title V services for the mentally retarded extended to other developmentally disabled individuals as well, or are they strictly limited to the mentally retarded population?

Answer: Title V services are not strictly limited to the "diagnosed" mentally retarded as such. Mental retardation is broadly defined to include children suspected of retardation or showing evidence of developmental delay. The emphasis of the newborn screening program is placed on adequate diagnosis, "unlabeling" some children, designing an individualized management program, and developing a "prevention" effort. Thus, the newborn screening program essentially deals with "normal" infants, as do those projects dealing with antenatal diagnosis and counseling. Through linkages with the State Crippled Children's programs, the Title V programs for mental retardation become involved with and provide a wide range of services for broad categories of physically handicapped children who, because of the physical disability, are retarded in physical, social and intellectual development.

Question: To what extent do the services provided to mentally retarded individuals through Title V reflect the "priority services" required under the Developmentally Disabilities Act?

Answer: Services through Title V reflect the priority services required under the Developmental Disabilities Act primarily in the preschool population served, which is a priority target group within the mandate of serving handicapped children up to 21 years of age. Mental retardation components of Title V administered under the MCH program which deal with prevention, including such areas as antenatal diagnosis and maternity and infant care as preventive measures in terms of mental retardation, are not age limited to the group served.

IMPROVED PREGNANCY OUTCOME

Question: The Improved Pregnancy Outcome (IPO) program was created administratively under Title V, Maternal and Child Health, of the Social Security Act in 1976 to improve maternal care and pregnancy outcome in States which have an excessive incidence of infant mortality. How many States currently have an IPO program?

Answer: There are presently Improved Pregnancy Outcome (IPO) programs funded in 34 States.

Question: How has the program improved pregnancy outcome?

Answer: The program is focused on the development of regionalized perinatal care systems within States. These systems are becoming formalized and are now joining other primary care providers in improving patient coverage for low-income families. High-risk mothers and infants are identified and referrals are made to secondary and tertiary centers. The quality of care has improved; outreach has been improved; and barriers to care, such as transportation and communication, have been ameliorated.

Question: Describe other special initiatives the MCH Bureau has undertaken in recent years.

Answer: Several special initiatives have been undertaken in recent years by the MCH program:

- Improved Child Health Projects: These are jointly funded projects to serve the needs of children in medically underserved areas including Indian reservations. There are 13 such projects which are funded jointly with Community Health Centers, Family Planning, and Maternal and Child Health funds. Three of the projects are on reservations - in North and South Dakota, Idaho, and Washington. Other projects are in North Carolina, South Carolina, Alabama, Mississsippi, Georgia, Texas, Tennessee and the District of Columbia.

- Two projects designed to improve the accessibility of care have been developed, one highly rural (Northern Idaho Panhandle), and the other highly urban (Southwest Baltimore), by integrating services already available in the areas. Services include health, public assistance, housing, and education.

- Immunization tracking and followup projects have been funded on a demonstration basis in Ohio, Alabama, and South Dakota. These projects are also expected to provide spinoff benefits in following high risk and handicapped children.

- Since accidents are a leading cause of death for children under age 14, the Office of Maternal and Child Health has funded three childhood accident prevention projects. Projects are funded in conjunction with Emergency Medical Services programs in California, Virginia, and Massachusetts.

- Other areas of activity include the support of definitive diagnostic laboratory services to back up newborn screening, mental retardation, and genetic disease programs.

PEDIATRIC PULMONARY CENTERS

Question: Through the Office of Maternal and Child Health, your agency has been supporting a network of Pediatric Pulmonary Centers for a number of years. In our report last year, this Committee expressed interest in and support of these Centers. Could you bring us up-to-date on your plans for this program? How many pediatric pulmonary centers are funded under the Title V programs?

Answer: There are 11 pediatric pulmonary centers funded.

Question: What services are provided by these centers?

Answer: They provide comprehensive health services encompassing inpatient and outpatient care, referral and followup, social, nutritional and supportive services.

Question: How have they improved the health status of children?

Answer: They have improved the health status of children through the provision of comprehensive health services and the training of health professionals in order to extend the availability and quality of services.

Question: Are any efforts planned to expand this program?

Answer: There are no plans to expand the program at the present time.

FAMILY PLANNING

Question: Grants are available for family planning projects which provide a variety of family planning methods and services including natural family planning methods, infertility services and services for adolescents. Traditionally, family planning services have been available to medically indigent individuals through Medicaid. A little over a year ago, the adolescent pregnancy program was established which is administered through the Office of the Assistant Secretary for Health. What is being done to see to it that these three programs are not duplicative in their efforts?

Answer: The three programs have different purposes: Family Planning is a health services delivery program; Medicaid provides reimbursements for certain services; and the Adolescent Pregnancy program integrates several types of services, for example, education and child care. There are regularly scheduled meetings of an Interagency Coordinating Committee on Adolescent Pregnancy which includes representatives from these three organizations. In addition, numerous formal and informal meetings take place between the Deputy Assistant Secretary for Population Affairs, the Director of the Office of Adolescent Pregnancy Programs and the Title X Program Director.

Question: How does coordination take place, given the fact that three separate entities have responsibility for running these three programs?

Answer: Regularly scheduled meetings of the Coordinating Committee provide for a useful exchange of information on family planning and pregnancy related activities. These meetings also provide a forum for seeking ways to improve coordination of services and to develop linkages for joint funding possibilities. The preparation of the Five Year Plan for Family Planning Services and Population Research is also used as a vehicle to coordinate activities. Each program has input to the final document prepared by the Deputy Assistant Secretary for Population Affairs.

Medicaid is a reimbursement program and as such does not provide services. Medicaid does, however, require that family planning services be included in all State plans as a reimburseable service. Many of the Family Planning (Title X) beneficiaries are eligible for Medicaid. Family Planning clinics have provider status and routinely bill Medicaid for eligible services provided in Title X clinics. Coordination between Medicaid and Title X occurs at the State level where reimbursement arrangements are made. The grant programs, family planning and adolescent pregnancy, are more easily coordinated centrally and regular contact between the programs encourages coordination.

Question: In your budget justifications for FY 81, you state that the target population for family planning services priority was 10 million women at risk of unplanned pregnancy. What is being done to foster a sharing of the responsibility for family planning with the male partner?

Answer: As part of a new initiative that began in FY 1978, the Family Planning program is endeavoring to improve male involvement in family planning decisions and contraception. Particular emphasis has been placed on involving adolescent males in the decision making process.

One method of reaching males is through Job Corps Centers. The Bureau of Community Health Services is working with the Department of Labor to offer Title X services at Job Corps Centers. In this setting, family planning information, education, and clinical services are provided for both male and female trainees. Sexuality training is conducted for staff/Corps members to enable them to have the skills to discuss sexuality attitudes, values and concerns with trainees. Four linkages were established in 1978, 4 more in 1979, and 16 in 1980, for a total of 24. The capacity of these 24 sites is about 20,064, of whom 13,000 are young males. The cost of these projects will be $2.3 million.

Sixteen demonstration projects also have been funded ($1.5 million) to reach and educate males beyond the clinic setting and to improve local services for males. The purpose of these programs is two-fold; (1) to provide information and skills development for responsible decisionmaking; and (2) to introduce males to the health care environment. Film and curriculum models to increase male knowledge and responsible decisionmaking will be completed in

61-400 O - 80 - 13

the spring of 1980. These educational aids will be used by teachers, counselors and others working with young males.

Question: What types of services are there for the sexually active male?

Answer: The primary services are education and counseling. Some clinics offer a full range of preventive health services for males. Males are an integral part of natural family planning methods instruction and infertility services.

Question: Are they available through Family Planning clinics funded by Title X? Medicaid? Adolescent Pregnancy?

Answer: Services for males are available through Title X funded clinics. Medicaid, as a reimbursement program, provides reimbursement only for those services spelled out in the State plan and only to those eligible for Medicaid. Whether or not these services for males are reimbursable varies from State to State.

In projects funded by the Office of Adolescent Pregnancy Programs, males are provided services in the context of a specific pregnancy or as part of a family group. The services provided males are generally counseling and education. Other services are provided as available, needed or requested by the male.

FUNDING LEVEL

Question: In light of limited funds, it is especially important that the highest priorities be placed on programs where the greatest and most urgent need exists and where the money can be most cost-effectively utilized. As you know, more than 6 million poor women, including about 2 million teenagers, are still in need of organized family planning services. Further, the Family Planning program is our best preventive vehicle to reduce the rate of abortion, and under Title X it has been demonstrated that $1 invested yields $1.80 in government savings (medical and social services). In light of these factors, why have you requested a budget that would hold this program only to current services levels?

Answer: The budget request for 1981 does not hold the program to current services levels, but includes an increase of $11.9 million for family planning. The $11.9 million increase will provide services to an additional 146,100 persons including 65,300 adolescents for a total of 4,088,800 persons served. An additional 2,040 clinic staff will receive training, for a total of 13,740. An additional 15 services delivery improvement research projects will be funded for a total of 24. And 4 additional information and education projects will be supported for a total of 10.

PRIVATE PRACTICE GRANTS

Question: The Public Health Service Act enables the Secretary to make grants to former National Health Service Corps members who agree to enter into private practice in a health manpower shortage areas for one or two years or more. For the past several years, the Committee has recommended against funding this authority because it was felt that National Health Service Corps members had ample opportunity to establish "contacts for future patients in private practice," and that this opportunity, coupled with anticipated future income and the fact that the Government had already paid for the education of the physician, led the Committee to believe that such a grant was simply not necessary.

What is the Department's analysis regarding the cost effectiveness of the private practice grant:

-- How much is saved through not having to draft and replace a health professional who is vacating a medically underserved area because his/her tour of duty has been completed?

-- How much is being saved through the requirement that physicians, receiving a private practice grant, accept Medicare/ Medicaid patients on assignment?

Answer: We estimate the average salary and benefits and field support costs for a National Health Service Corps assignee will be $42,000 in 1981. Supporting the medical education of a scholarship assignee would cost $14,000 additional per year based on the scholarship award cost estimated for 1981. Therefore, a National Health Service Corps assignee could cost $56,000 a year, while the private practice grant is a maximum of $12,500 a year, a potential savings of $43,500 a year.

PROGRAM SUPPORT

Question: Two years ago, the Labor-Department of Health, Education and Welfare (DHEW) Appropriations Bill specifically authorized positions for health services. Are you operating at that ceiling?

Answer: We are operating within the ceiling. The ceiling authorized was 9,198 positions. Our FY 1979 end-of-year employment was 9,147.

Question: Are patient care positions under the National Health Service Corps counted within this ceiling?

Answer: Yes, National Health Service Corps positions are counted within this ceiling.

Question: What impact will the reduction in the Corps people have on future recruiting efforts and what problem does it pose now?

Answer: There is no reduction of Corps personnel as the result of an administrative ceiling imposed by the Executive Branch.

Question: How much is spent on travel costs for all HSA in 1979, 1980 and 1981?

Answer: We are providing for the record a table that shows actual obligations for travel for FY 1979 and estimated obligations for travel for FY 1980 and FY 1981.

[The information follows:]

Health Services Administration
Obligations for Travel and Transportation
(in millions of dollars)

Appropriation	1979 Actual	1980 Estimate	1981 Estimate
Health Services	$7.5	$10.0 1/	$12.9
Indian Health Services/Indian Health Facilities	23.6	19.6	21.5
	$31.1	$29.6 1/	$34.4

1/ Includes $2.1 million associated with supplemental request for the National Health Service Corps.

Question: Are the Congressional ceilings on travel and consultant services having an adverse impact on the operation of your programs? If so, please explain.

Answer: The congressional ceiling on consultant services should be sufficient to meet program requirements. However, we may experience an impact on the operation of our programs due to the travel ceiling. Some of the areas which may feel an impact include:

1. Site reviews of hospitals and clinics by field and headquarters staff may be reduced.

2. Audit of quality of care and costs as they relate to contract patient care providers may be reduced substantially.

3. Testing of required manpower productivity standards could be delayed or postponed.

4. Investigations of EEO violations and other prsonnel issues could become less effective.

5. Other areas such as recruitment, training and research grant monitoring and technical assistance, could also be reduced by the travel ceiling.

ADMINISTRATIVE COSTS

Question: What have you done to control the administrative costs of your projects?

Answer: Funding criteria developed by the Bureau of Community Health Services have been used as performance measures in determining appropriate levels of project continuation grant applications

- Criteria include program indicators such as uniform standards for project administration, housekeeping and maintenance

- Administration, housekeeping and maintenance costs of projects in operation for 2 or more years should not exceed 20 percent of total project ambulatory costs
- Total funds allocated annually to regional offices for continuation funding of projects include downward adjustments for projects that exceed the 20 percent standard
- Decreases in regional allocations represent the project losses which could be made up by improved management of administrative costs

Based on recent BCHS studies, administrative cost standards have been revised to recognize differences between large scale and small scale projects

- It is reasonable to expect that large scale projects, over $125,000, can meet a revised standard of no more than 16 percent of total ambulatory costs attributable to administration

- Small scale projects, under $125,000, can operate efficiently under a revised standard of no more than 26 percent of total ambulatory costs attributable to administration

Technical assistance contracts provide training, system development, and other administrative management assistance to projects.

Question: What are the criteria for the designation of medically underserved areas, health manpower shortage areas, high impact areas, and high infant mortality areas? What efforts have been made by Department of Health and Human Services (DHHS) to refine and/or consolidate these measures?

Answer: The designation criteria for Health Manpower Shortage Areas are complex and are specific to the different category and type of shortage areas - primary medical care, dental care, psychiatric and, or vision care, etc., geographic area, population group or facility. Rather than attempt to repeat the criteria here, we shall provide for the record the "Summary of Criteria for Designation of Health Manpower Shortage Areas."

High Impact Area is defined as an area having not fewer than 4,000 migratory and seasonal agricultural workers residing within its boundaries for more than two months in any calendar year.

Medically Underserved Area is designated in consideration of the following factors:

1. Ratio of primary care physicians to population;
2. Infant mortality rate;
3. Percentage of the population which is age 65 or over; and
4. Percentage of the population with family income below the poverty level.

High Infant Mortality Area is one for which the infant mortality rate must be computed as an aggregate rate for the 5-year period 1969 through 1973, or more recent period of 5 consecutive years, as follows: the total number of deaths of infant residents (deaths between birth and age 1) during the 5-year period in the county containing the identified area is divided by the total number

of live births to residents of the county during the same period and the result multiplied by 1,000.

Studies are underway to improve the methodology for identifying and designating Medically Underserved Areas. Although there is no process for formally consolidating all four types of designation, under an approach which we call "positive programming" we take all four into consideration when setting our priorities for starting or expanding Community Health Centers and placing NHSC assignees. A recent analysis demonstrates the results of this kind of approach. Of the 35 U.S. counties which meet all of the aforementioned criteria, 24 are in CHC service areas; 223 of the 532 counties that meet 3 criteria and 375 of the 1,577 that meet 2 criteria are served by Community Health Centers.

[The information follows:]

Summary of Criteria for Designation of Health

Manpower Shortage Areas

General Procedures for Designation

Using data in our files and the criteria summarized in this report, the Department has prepared a preliminary list (by State and Health Service Area) of possible health manpower shortage areas. Relevant portions of these lists are being sent out to the appropriate HSAs, SHPDAs, and Governors with a request that they review the preliminary list and offer their recommendations, if any, within 45 days, as to which geographic areas, population groups, and facilities in areas under their jurisdiction should be designated. Their recommendations and comments will be considered in developing the list of designated health manpower shortage areas, which will be published in the Federal Register.

In addition, any agency or individual may recommend the designation of a particular geographic area, population group, or facility as a health manpower shortage area. Before any request is evaluated, however, the appropriate Health Systems Agency, State Health Planning and Development Agency, and Governor will be provided at least 30 days to comment on its validity. In order to shorten the designation process, it is recommended that persons submitting a request solicit the assistance and/or endorsement of these parties. At a minimum, they should send a copy of the request to each at the same time as they submit the request, in order to shorten the designation process. Once comments have been received or the comment period has expired, the request will be evaluated to see whether the criteria for designation have been satisfied. If the information in a request is inadequate, the applicant will be informed of the deficiencies. Notification of any final action taken on a designation request will be sent to the applicant, the appropriate Health Systems Agency, State Health Planning and Development Agency, Governor, the NHSC Director, and PHS Regional Offices.

All requests should contain information on the supply of health manpower available to serve the area population, the availability of resources in contiguous areas, and the presence of any special needs of the population, using the measures specified in the criteria. They should also include a map showing the location of resources within the areas and in contiguous areas. Data sources should be cited, and any adjustments to practitioner supply or population figures should be explained. In addition, the rationale for the selection of a particular service area definition (in terms of travel times, composition of the population, etc.) should be provided. Since it will not be possible to respond immediately to all designation requests, applicants are advised to indicate whether there is a special need for immediate action on a particular request (for example, if a project grant or tentative placement is involved). Requests for designation should be sent to:

Bureau of Health Manpower
Manpower Analysis Branch
Center Building, Room 4-41
3700 East-West Highway
Hyattsville, Maryland 20782

CRITERIA FOR PRIMARY MEDICAL CARE MANPOWER SHORTAGE

I. Primary Care Manpower - Geographic Areas

A. Service area considerations - area must be rational for the delivery of primary care services. The area may be any one of the following:

1. a county (or a group of contiguous counties whose centers are less then 30 minutes travel time apart)

2. an isolated portion of a county (or an isolated group of portions of counties), specified in terms of minor civil divisions, census county divisions, or census tracts, wherever possible

3. urban neighborhoods which have limited interaction with contiguous areas and generally have a minimum population of 20,000, specified in terms of census tracts wherever possible

B. Criteria to be applied to service area:

1. Basic ratio of population to number of primary care physicians to indicate shortage is 3,500:1 (instead of the former 4,000:1).

2. Shortage ratio can be further reduced to 3,000:1 if either (a) or (b) below is applicable:

(a) Unusually high needs for primary care, as measured by one of the following:

i. high fertility rates, more than 200 births per 1,000 women aged 15-44, or 40 births per 1,000 women aged 13-17

ii. infant mortality is greater than 20 per 1,000

iii. more than 30 percent of population (or of households) below the poverty level

(b) Insufficient capacity of existing primary care providers, as measured by any two of the following:

i. more than 8,000 visits per year per physician

ii. unusually long appointments waiting times - 7 days for established patients and 14 days for new patients

iii. excessive average waiting time at providers' office - more than 1 hour if appointment and more than 2 hours if first-come, first-served

iv. excessive use of emergency room facilities for primary care

v. 2/3 or more of area physicians do not accept new patients

vi. low utilization - 2.0 or less visits per year

3. Population adjustments

(a) Population may be age/sex adjusted to reflect needs of different components (see table in criteria).

(b) Tourist or migrant population may be taken into account, multiplying proportion of year they are present by their average daily number when present (also a factor of .5 for tourists).

4. FTE practitioner counts

(a) Interns and residents counted as .5

(b) FMG's not U.S. citizens or on permanent visa will not be counted

(c) Other FMG's not fully licensed will be counted as .5

(d) Practitioners who are semi-retired or part-time may be counted according to number of hours worked (in both ambulatory and in-patient settings) compared to 40 hours

(e) Allowances for restricted practices will be made on a case-by-case basis (i.e., refusal to accept certain types of patients or to accept Medicaid reimbursement)

C. Contiguous area considerations - primary care manpower in contiguous areas must be shown to be overutilized, excessively distant, or otherwise inaccessible.

1. Considered overutilized if ratio in contiguous area is 2,500:1 or more

2. Considered excessively distant if contiguous area resources are more than 30 minutes travel time away.

3. Inaccessibility may be indicated by one of the following:

(a) significant differences between service area's demography and that of contiguous areas

(b) high poverty population in service area, and few contiguous area physicians accept Medicaid

II. Primary Care Manpower - Population Groups

1. Automatic designation of American Indians and Alaskan Natives (reservations, treaties).

2. Possible designation of other Indians, migrants, and other population groups within specific geographic areas, if both of the following exist:

(a) Access barriers prevent the population group from use of the area's primary medical providers.

(b) The ratio of the number of persons in the population group to the number of FTE primary care physicians serving it is at least 3,500:1 (3,000:1 where unusually high needs exist).

III. Primary Care Manpower - Facilities

A. Prisons will be designated as having a shortage of primary care manpower if both of the following criteria are met:

1. at least 250 inmates

2. The ratio of internees per year to number of FTE primary care physicians serving the prison must be at least 1,000:1.

B. Public or nonprofit private medical facilities

1. Facility must provide services to a designated area or population group.

2. Facility must have insufficient capacity to meet the primary care needs of that area or population groups, as shown by two of the following:

(a) more than 8,000 visits per year per primary care physician on facility staff

(b) excessive use of emergency room facilities for primary care

(c) appointment waiting time more than 7 days for established patients, 14 days for new patients

(d) office waiting time more than 1 hour if appointment, 2 hours if walk-in

CRITERIA FOR DENTAL CARE MANPOWER SHORTAGE

I. Dental Manpower - Geographic Areas

A. Service area considerations - area must be rational for the delivery of dental care services. The area may be any one of the following:

1. a county (or a group of contiguous counties whose centers are less than 40 minutes travel time apart)

2. an isolated portion of a county (or an isolated group of portions of counties), specified in terms of minor civil divisions, census county divisions, or census tracts wherever possible.

3. urban neighborhoods which have limited interaction with contiguous areas and generally have a minimum population of 20,000, specified in terms of census tracts wherever possible

B. Criteria to be applied to service areas:

1. Basic ratio of population to number of dentists to indicate shortage is 5,000:1.

2. Shortage ratio can be further reduced to 4,000:1 if either (a) or (b) is applicable:

(a) Unusually high needs for dental services, as measured by one of the following:

i. more than 30% of population (or of households) with incomes below the poverty level

ii. area does not have fluoridated water supply

(b) Insufficient capacity of existing dental care providers, as measured by one of the following:

i. more than 5,000 visits per year per dentist

ii. unusually long appointment waiting time - more than 6 weeks

iii. 2/3 or more of area dentists do not accept new patients

3. Population adjustments

(a) Tourist population may be taken into account with a weight of .5

(b) Migrant population may be taken into account

4. FTE dental practitioner counts

(a) Use equivalency weights, by age or by both age and number of auxiliaries (from tables 1 and 2 in criteria).

(b) Practitioners who are semi-retired or part-time may be counted according to number of hours worked ratioed to 40 hours.

C. Contiguous area considerations - dental manpower in contiguous areas must be shown to be excessively distant, overutilized, or inaccessible to the population using one of the following:

1. excessively distant if more than 40 minutes travel time away

2. overutilized if ratio in contiguous area is 3,000:1 or more

3. inaccessibility may be shown by one of the following:

(a) significant differences between the area's demography and that of contiguous areas

(b) more than 30% of population (or of households) with incomes below the poverty level

II. Dental Manpower - Population Groups

1. Automatic designation for American Indians and Alaskan Natives (reservations, treaties).

2. Possible designation of other Indians, migrants, and other population groups within specific geographical areas, if both of the following exist:

(a) Access barriers prevent the population group from use of the area's dental providers.

(b) The ratio of the number of persons in the population group to the FTE dentists serving it is at least 5,000:1 (4,000:1 where unusually high needs exist).

III. Dental Manpower - Facilities

A. Prisons will be designated as having a shortage of dental manpower if both of the following criteria are met:

1. at least 250 inmates

2. ratio of internees per year to number of FTE dentists is at least 1,500:1

B. Public or nonprofit facilities

1. Public or nonprofit facilities will be designated as having a shortage of dental manpower if both of the following criteria are met:

(a) Facility is providing services to a designated area or population group, as shown by either of the following:

i. A majority of the facility's dental care services are being provided to residents of designated dental shortage areas, or to population groups designated as having a shortage of dental manpower.

ii. The population within a designated dental shortage area or population group has reasonable access to

dental services provided at the facility (i.e., is within 40 minutes and non-physical barriers not present).

(b) Facility has insufficient capacity to meet the dental care needs of that area or population group, as shown by either of the following:

i. more than 5,000 outpatient visits per year per dentist

ii. unusually long appointment waiting times - more than 6 weeks

CRITERIA FOR PSYCHIATRIC MANPOWER SHORTAGE

I. Psychiatric Manpower - Geographic Areas

A. Service area considerations - area must be rational for the delivery of psychiatric services. The area may be any of the following:

1. An established mental health catchment area, as designated by the State Health Planning and Development Agency.

2. An isolated portion of a catchment area whose population has a travel time greater than 40 minutes to psychiatric resources in the rest of the catchment area.

3. A county or metropolitan area which contains more than one mental health catchment area, where data are unavailable by individual catchment area.

B. Criteria to be applied to service areas

1. Basic ratio of population to number of psychiatrists to indicate shortage is 30,000:1.

2. Shortage ratio can be further reduced to 20,000:1 if area has unusually high need for mental health services, as measured by two or more of the following:

(a) More than 30 percent of population (or of households) are below the poverty level.

(b) Ratio of children under 18 to population 18-64 is in excess of 60 percent.

(c) Ratio of persons aged 65 and over to population 18-64 is in excess of 25 percent.

(d) a high prevalence of alcoholism in the population

(e) a high prevalence of drug abuse in the population

3. Population - use total permanent resident population of the area, excluding inmates of institutions.

4. Psychiatrist practitioner counts

(a) Psychiatric residents counted as .5.

(b) FMG's not U.S. citizens and not on permanent visa will not be counted.

(c) Other FMG's not fully licensed will be counted as .5.

(d) Psychiatrists who are semi-retired or part-time may be counted according to number of hours worked compared to 40 hours.

(e) Allowances for restricted practices will be made on a case-by-case basis.

(f) Psychiatrists assigned to outpatient or other short-term care units in mental health facilities or institutions will be counted.

C. Psychiatric manpower in contiguous areas must be shown to be overutilized, excessively distant, or otherwise inaccessible to residents of the area, as follows:

1. Considered excessively distant if mental health manpower in contiguous area are more than 40 minutes travel time from center of the area.

2. Considered overutilized if contiguous area population-to-psychiatrist ratios are in excess of 20,000:1.

3. Other indicators of inaccessibility could be geographic, cultural, language, or other barriers.

II. Psychiatric Manpower - Population Groups

Population groups within particular catchment areas may be designated if both of the following conditions prevail:

1. Access barriers prevent the population group from use of the area's mental health resources.

2. The ratio of the number of persons in the population group to the FTE psychiatrists serving it is at least 30,000:1 (20,000:1 where unusually high need exist).

III. Psychiatric Manpower - Facilities

A. Correctional institutions and youth detention facilities will be designated if both of the following criteria are met:

1. at least 250 inmates

2. The ratio of internees per year to number of FTE psychiatrists must be at least 2,000:1.

B. State and county mental hospitals will be designated if both of the following criteria are met:

1. Average daily inpatient census must be at least 100.

2. Number of workload units per FTE psychiatrist must exceed 600, where workload units = average daily inpatient census + 2 x (number of inpatient admissions per year) + 0.5 x (number of admissions to day care and outpatient services per year).

C. Community mental health centers and other public or nonprofit private facilities will be designated if:

1. The facility is providing psychiatric services to a designated area or designated population group.

2. The facility, by Federal or State statute, administrative action or contractual agreement, has responsbility for providing and coordinating a wide range of alcohol, drug abuse, and/or mental health services for the area or population group.

CRITERIA FOR VISION CARE MANPOWER SHORTAGE

I. Vision Care Manpower - Geographic Areas

A. Service area considerations - area must be rational for the delivery of vision care services. The area may be either of the following:

1. a county (or group of contiguous counties whose centers are less than 40 minutes travel time apart)

2. an isolated portion of a county (or an isolated group of portions of counties).

B. Criteria to be applied to service areas:

1. The estimated number of optometric visits required in the area must exceed the estimated number of visits supplied by at least 1,500.

2. Computation of visits required:

Number of visits required =
0.11 (pop. under 20) + 0.20 (pop. 20-29)
+ 0.24 (pop. 30-39) + 0.35 (pop. 40-49)
+ 0.41 (pop. 50-64) + 0.48 (pop. 65 and over)

3. Computation of visits supplied:

Optometric visits supplied =
3,000 x (optometrists under 65)
+ 2,000 x (optometrists 65 and over)
+ 1,500 x (ophthalmologists)

C. Contiguous area considerations - vision care manpower in contiguous areas must be shown to be overutilized, excessively distant, or otherwise inaccessible.

1. Considered overutilized if requirement in contiguous area exceeds the supply (as computed above).

2. Considered excessively distant if contiguous area resources are more than 40 minutes travel time away.

3. Considered otherwise inaccessible if specified access barriers (such as economic or cultural barriers) exist.

II. Vision Care Manpower - Population Groups

A. Access considerations - members of the population group must not have access to optometric services within the area (or in contiguous areas) because of specified non-physical access barriers.

B. Criteria to be applied to population groups - the difference between the number of visits required by the population group and the number supplied by practitioners serving the group is at least 1,500 visits.

CRITERIA FOR PODIATRIC MANPOWER SHORTAGE

I. Podiatry Manpower Shortage - Geographic Areas

A. Service area considerations - area must be rational for the delivery of podiatric services. The area may be either of the following:

1. a county (or group of contiguous counties whose centers are less than 40 minutes travel time apart)

2. an isolated portion of a county (or an isolated group of portions of counties)

B. Criteria to be applied to service area:

1. The differences between the area requirement for foot care practitioners and the supply is at least 0.5.

2. Computation of requirement for foot care practitioners:

$$\text{Requirement} = \frac{\text{adjusted population}}{28{,}000},$$

where adjusted population = resident civilian population $\times \left(1 + \frac{2.2 \times (\%\text{ of pop. 65 \& over}) - 0.44 \times (\%\text{ of pop. under 17})}{100}\right)$

3. Computation of supply of foot care practitioners:

No. of foot care practitioners =
no. of podiatrists under age 55
+ 0.8 x (no. aged 55 and over)
+ 0.15 x (no. of orthopedic surgeons)
+ 0.02 x (no. of general and family practitioners)

C. Contiguous area considerations - podiatric manpower in contiguous areas must be shown to be overutilized, excessively distant, or otherwise inaccessible.

1. Considered overutilized if the population-to-foot care practitioners are in areas of 20,000:1.

2. Considered excessively distant if contiguous area resources are more than 40 minutes travel time away.

3. Considered otherwise inaccessible if specified access barriers (such as economic or cultural barriers) exist.

CRITERIA FOR PHARMACY MANPOWER SHORTAGE

I. Pharmacy Manpower Shortage - Geographic Areas

A. Service area considerations - area must be rational for the delivery of pharmacy services. The area may be one of the following:

a. a county (or group of contiguous counties whose centers are less than 30 minutes travel time apart)

b. an isolated portion of a county (or an isolated group of portion of counties)

B. Criteria to be applied to service areas:

1. The estimated requirement for pharmacists in the area must exceed the active supply of pharmacists by at least 0.5.

2. Computation of requirement for pharmacists:

(a) for areas with at least 20,000 population:

$$\text{est. requirement} = 0.15 \times \frac{\text{population}}{1{,}000} + .0\,35 \times (\text{no. of patient care physicians})$$

(b) for areas with less than 20,000 population:

$$\text{est. require.} = \frac{(40{,}000 - \text{pop.})}{20{,}000} \times \left(0.15 \times \frac{\text{pop.}}{1{,}000} + .0\,35 \times (\text{no. of patient care physicians})\right)$$

3. Counting of pharmacists: all active pharmacists in the area will be counted, except those engaged in teaching, administration, or pharmaceutical research.

C. Contiguous area considerations - pharmacy manpower in contiguous areas must be shown to be overutilized or excessively distant.

1. Considered to be overutilized if the number of pharmacists is less than or equal to the requirement as calculated above.

2. Considered excessively distant if contiguous area resources are more than 30 minutes travel time away.

CRITERIA FOR VETERINARY MANPOWER SHORTAGE

I. Food Animal Veterinarian Shortage - Geographic Areas

A. Service area considerations - area must be rational for the delivery of veterinary services. The area may be one of the following:

1. a county (or group of contiguous counties whose centers are less than 60 minutes travel time apart)

2. an isolated portion of a county (or an isolated group of portions of counties)

B. Criteria to be applied to service area:

1. Ratio of veterinary livestock units (VLU) to number of food animal veterinarians must be at least 10,000:1.

2. The computed food animal veterinary shortage must be least 0.5, where shortage = $\frac{\text{VLU}}{10{,}000}$ - (no. of food animal vets.)

3. Computation of VLU:

Veterinary livestock units = no. of milk cows
+ 0.2 (no. of other cattle and calves)
+ 0.05 (no. of hogs, pigs, and sheep)
+ 0.002 (no. of poultry)

4. Determination of number of food animal veterinarians:

Number of food animal veterinarians =(number of vets practicing exclusively in large animal, bovine, porcine, or poultry practices) + 0.75 (no. of mixed practice vets with greater than 50% of practice in large animal care) + 0.50 (no. of mixed practice vets with about 50% of practice in large animals) + 0.25 (no. of mixed practice vets with less than 50% of practice in large animals).

C. Contiguous area considerations - veterinary manpower in contiguous areas must be shown to be overutilized or excessively distant.

1. Considered to be overutilized if ratio of VLU to food animal vets is 5,000:1 or more.

2. Considered excessively distant if contiguous area resources are more than 60 minutes travel time away.

II. Companion Animal Veterinarian Shortage - Geographic Areas

A. Service area considerations (same as IA above).

B. Criteria to be applied to service area -

1. Ratio of population to number of companion animal veterinarians must be at least 30,000:1.

2. The computed companion animal veterinary shortage must be at least 0.5, where -

$$\text{shortage} = \frac{\text{population}}{30{,}000} - (\text{no. of companion animal vets.})$$

3. Determination of number of companion animal veterinarians -

Number of companion animal veterinarians = no. of vets practicing exclusively in small animal or equine practices + 0.75 (no. of mixed practice vets with greater than 50% of practice in small animal care) + 0.5 (mixed practice vets with about 50% of practice in small animal care) + 0.25 (mixed practice vets with less than 50% of practice in small animal care)

C. Contiguous area considerations - veterinary manpower in contiguous ar[illegible]st be shown to be overutilized or excessively distant.

1. Cons[illegible]e overutilized if ratio of population to comp[illegible]l vets is 15,000:1 or more.

2. Consi[illegible]ssively distant if contiguous area resources are m[illegible]60 minutes travel time away.

Question: What type of needs analysis is performed before grants are made for a CHC or MHC or before NHSC personnel are assigned to an area? Is a demand analysis ever made?

Answer: Before a grant is made to a Community Health Center, the Bureau of Community Health Services must first meet the requirements of the law to serve medically underserved areas (MUAs). In addition, program guidelines define how certain criteria are to be applied in determining funding priorities for Community Health Centers projects. A priority system is used which considers 4 needs criteria:

1. Medically Underserved Areas (MUAs) - a scoring process which considers (1) physician-to-population ratio, (2) percentage of population which is aged, (3) population which is in poverty, and (4) infant mortality rate. MUAs with lower scores represent areas with greatest degree of medical underservice;
2. Health Manpower Shortage Areas (HMSA) -- physician-to-population of 1:3,500 or worse;
3. High infant mortality;
4. High migrant impact -- an area having not less than 4,000 migratory and seasonal agricultural workers residing within its boundaries for more than 2 months in any calendar year.

Before a grant is made to a Migrant Health Center, it must serve a high migrant impact area, as defined above.

Before National Health Service Corps personnel are assigned to an area, it must be designated as a Health Manpower Shortage Area. Current policy is to attempt to place Natonal Health Service Corps professionals in areas with greatest need.

As part of the needs assessment process, all potential applications for Community Health Centers, Migrant Health Centers, and National Health Service Corps professionals are reviewed by local Health System Agencies, which try to ensure the participation of all provider and interest groups.

Formal, scientific demand analyses are not conducted for our projects. Our projects are community-based, having boards of directors from the communities being served, thus demonstrating a desire for the project on the part of a significant portion of the communities' population. We recognize, however, that in many of the communities where we place projects, there are substantial proportions of the population who might not initially express a desire to use newly organized primary care services. This reluctance could arise from ignorance of the benefits to themselves and their families of regular primary and preventive health services or from a suspicious attitude toward "outsiders." We believe that our projects can overcome these attitudes through education and demonstrated service to the community over time. Therefore, we forego the expensive process of a scientific demand analysis and place our emphasis on the more relevant needs analysis.

NATIONAL HEALTH SERVICE CORPS REIMBURSEMENTS

Question: What proportion of NHSC personnel generate income sufficient to offset all or part of their Federal salary?

Answer: Of 471 sites billed, 333 or 71 percent reported income sufficient to offset all or part of assignees' salaries.

Question: What proportion (and dollar amount of such income) is returned to the Treasury?

Answer: The $9.3 million billed to the sites in 1978 represents the amount which should be returned to the Treasury. Our experience with collections in prior years would leave a reasonable estimate that 72 percent of the billings would be returned to the Treasury.

Question: How many waivers have been granted and what is the average dollar amount of such waivers?

Answer: In 1978, 291 sites received full or partial waivers of reimbursable costs at an average of $36,044 per waiver.

RESEARCH AND DEMONSTRATION

Question: How many projects are currently funded under HURA?

Answer: During 1980, we expect to fund 81 projects under the Primary Health Care Research and Demonstration program. We expect that 29 of these projects will have complete their research and demonstration efforts. As a result, 52 Primary Care Research and Demonstration projects will be funded during 1981.

Question: What proportion of funds serve urban areas?

Answer: The Primary Care Research and Demonstration projects are serving rural areas only.

Question: What types of cross-program analysis is done within the rural health initiative or elsewhere in BCHS in order to assure that a grant to an area does not duplicate existing services or overlap services to be provided by another BCHS grant?

Answer: All grant applications must first meet the legal requirements of providing services to a medically underserved area. The proposed service population of the project is reviewed against nationally tabulated criteria to see if the area to be served can be considered medically underserved by these area specific criteria. Regional Office staff frequently make site visits or otherwise verify the need for the proposed project based on their knowledge of the other service delivery providers in the Region and the proposed service area.

The Health Systems Agency with reponsibility for the area reviews the proposal to assure there is a need for the project and there is no duplication or overlap of existing services based on its own profiles of the needs and service delivery providers within the planning area.

Question: What efforts are made by Department of Health and Human Services (DHHS) to audit grants and to assure by site visits and review of grant records that services contracted for are provided?

Answer: Two major activities have been recently undertaken by the Bureau of Community Health Services to monitor and evaluate programs. First, in 1979, the Secretary commissioned the establishment of a Primary Care Program Review, which specifically emphasizes the analysis of the project's performance in the areas of administration, fiscal management, clinical management, and dental management. The instrument focuses upon a determination of whether or not the key elements of these systems are in place, and if not, what actions are necessary to correct the identified problems.

The instrument was pre-tested in each of the ten Regional Offices and an additional thirty reviews were carried out by December 31, 1979. Forty more reviews are now scheduled for 1980. In selecting candidates to be reviewed, Regional Offices, which now manage the process, are placing priority emphasis upon projects which have shown that problems exist in meeting both administrative and clinical indicators. The second major emphasis is placed upon validating Bureau Common Reporting Requirements and other programmatic data.

In addition, site visits to sixty (60) Bureau of Community Health Services projects are taking place to attempt to validate accuracy of the data that are being reported in the Bureau Common Reporting Requirements.

Question: What guidance does Department of Health and Human Services (DHHS) provide to grantees on proper recordkeeping and audit techniques to insure proper utilization of funds?

Answer: Over the years, the Bureau of Community Health Services has provided grantees leadership and guidance for establishing sound financial systems. Specifically, the following activities have been undertaken:

1. Training of Regional Office and grantee staffs on financial management for non-financial managers and on accounting for non-accountants.

2. Training of Regional Office staffs in the compliance, tracking, and implementation of the Health Services Funding Regulations.

3. Technical assistance has been provided by professional consultants to assist grantees in the areas of budgeting, financial management, cost-based fee schedules, sliding fee scale development, and third-party billing and collections.

4. The publication of a common accounting manual for all grantees funded under the following categorical programs:

   Community Health Centers
   Migrant Health Programs
   Family Planning Programs
   Maternal and Child Health Programs

5. The inclusion of three financial tables in the Bureau of Community Health Services Common Report Requirements which are used to determine how the grantee's financial management system is functioning; and

6. A review of the grantee's fiscal management systems is included as part of the activities carried out in the Primary Care Program Reviews.

Question: To what extent does a local health systems agency review all proposals for BCHS health care delivery grants?

Answer: By law, local health system agencies have review and approval authority for BCHS proposed grants. This authority, at the present time, is exercised in accordance with the level of development and capability of the health system agency. Some health system agencies are not yet capable of fully evaluating the grant proposals and, therefore, provide only comments on their review. It is anticipated that eventually all health system agencies will be developed to the point where they will perform a complete review of the need for proposed BCHS health service delivery projects against profiles of the service areas which are developed and maintained by the health systems agencies.

PRIMARY HEALTH CARE NEEDS OF IMMIGRANTS

Question: Would you describe some of the efforts your Administration has undertaken to address the unique Primary Health Care needs of our nation's immigrants?

Answer: The Department is acutely aware of the barriers to health care experienced by all medically underserved populations, including immigrants. All of the various primary care programs funded by HSA, such as community health centers and migrant health centers, have the potential of serving immigrants because the health care services do not have citizenship status eligibility requirements. The primary care projects which serve a sizeable non-English-speaking clientele must provide bilingual, and when possible, bicultural staff and outreach services. As long as the applicants meet the statutory requirements of the Bureau's grant programs and the applicants serve a medically underserved area, they may offer services to any and all clientele, including immigrants.

In Hawaii, HSA funds the following three programs which specifically serve a large number of immigrants:

1. The Department of Health, State of Hawaii was recently awarded a grant with particular emphasis on offering immigrant health services. The grant was offered through Section 330 of the Public Health Service Act which provides grants for development and operation of community health centers. The grant awarded $325,000 to the Kohus Halihi Valley Health Center to provide services.

2. Kaiser Permanente Medical Group is an ongoing project which received an Urban Health Initiative grant to offer prepaid health services to immigrants. The fiscal year 1979 grant was for $1,848,527 and recognizes the fact that immigrants have a higher ratio of visits and hospitalization than other prepaid members.

3. The Wainae District Coast Comprehensive Health and Hospital Board receives a Section 330 grant to serve a largely

immigrant population. They are an ongoing project and received $681,137 for fiscal yar 1979.

The Public Health Service, San Francisco Regional Office, through its Urban Health Initiative encourages applications from high immigrant impact areas.

Immigrants in general are not eligible for care in the PHS Hospitals and Clinics system. However, under existing legislative authority, the facilities have taken an active role in providing primary care and health screening to Indochinese and Haitian refugees.

The major activities for Indochinese refugees have consisted of primary health assessments performed in the high impact areas of the West Coast served by the hospitals in San Francisco and Seattle and the outpatient clinic in San Pedro, California. Other PHS facilities around the country have provided similar assistance to local health departments and voluntary agencies.

The PHS outpatient clinic in Miami has given assistance to the Dade County Health Department in providing screening services and primary care to Haitian refugees.

COMMUNITY HEALTH CENTERS PHYSICIAN ATTRITION

Question: What is the physician attrition rate in Community Health Centers after their service obligation ends?

Answer: In 1979, the Community Health Centers experienced a 51 percent attrition rate for National Health Service Corps physicians.

Smoking Cessation Programs for Federal Employees

Question: Several years ago HEW officials announced that the Department would pay for smoking cessation programs for Federal employees who wished to stop smoking. What sources of funding were being used to pay for this initiative?

Answer: The smoking cessation course was funded from the Public Health Service (PHS) Service and Supply Fund. This fund finances common-user and service operations for certain centralized activities. The Service and Supply Fund is an intra-governmental fund which does not receive a direct appropriation. The fund receives reimbursement for services rendered from various federal appropriations, primarily those of PHS agencies. Reimbursements come from budget activities which provide money for salaries, travel, equipment, training and other personnel-related expenses.

Question: What is the status of this program?

Answer: The final session of the smoking cessation course was held in fiscal year 1979. There are no other smoker education programs contemplated.

HURA AND COMMUNICATION LINKAGE SYSTEMS

The health underserved rural areas program (HURA) was established in fiscal year 1976 as a research and demonstration program. Among the initial responsibilities, the program was expected to look critically at the potential of biomedical communications linking isolated service sites to larger backup centers and facilities. At that time the NLM's Lister Hill Center served as the focal point within DHEW for the technologic aspects of biomedical communications and the National Center for Health Services Research had conducted a number of important studies on telecommunications and computer-based systems.

The HURA program, prior to developing a contract research and demonstration plan for telecommunications convened an intramural work group to establish R. & D. priorities and to establish guidelines for telecommunications use based upon existing knowledge. This group included experts in rural health care services delivery, evaluation, and research, Dr. Wooster from the NLM's Lister Hill Institute and Dr. Maxine Rockoff from NCHSR.

One important source document for the HURA intramural work group was "A Cost-Performance Analysis of Alternative Manpower Technology Combinations for Delivering Primary Health Care." The summary and excerpts from this unpublished study are included in tab A.

The HURA intramural work group reviewed the state of biomedical telecommunications throughout 1975 and early 1976 and the indications for the priority research areas were that broadband technology options utilizing video bandwidth communication systems to link remote clinics with physician-based practices appeared generally less desirable in terms of cost and improved accessibility than did technology options based on narrowband.

Dr. Rockoff and others in NCHSR, with the active support of the Center, essentially became the intramural research and evaluation group of the HURA program.

In May of 1978, the "Telehealth Handbook—A Guide to Telecommunications Technology for Rural Health Care" (tab B), was published by NCHSR. This effort, however, was a component of the larger HURA effort and was supported through conferences and staff and contractor assistance from the BCHS-HURA office.

In addition, the Bureau of Community Health Services took the lead through its HURA technology projects in demonstrating the use of narrowband communications for support of primary health care services in rural areas. In the past 3 years, HURA has explored the use of slow-scan television to transmit EKG, X-ray, and electronic stethoscope sounds via telephone (tab C). Most recently, it has implemented a computer health information system linking five rural clinics by telephone to a centralized data base (tab D). For the first time, extensive data on the health status of a rural population, services provided, and quality of health care will be available. Evaluations are currently underway to examine the costs and impact of these narrowband applications (tab E).

SUBCOMMITTEE RECESS

Senator SCHWEIKER. All right. The committee will stand in recess until 2 on Monday, when Senator Schmitt will hear testimony from the Center for Disease Control. Thank you very much.

[Whereupon, at 11:40 a.m., Friday, February 1, the subcommittee was recessed, to reconvene at 2 p.m., Monday, February 4.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

MONDAY, FEBRUARY 4, 1980

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

The subcommittee met at 2:17 p.m. in room S–128, the Capitol, Hon. Harrison H. Schmitt presiding.

Present: Senators Schmitt, Chiles, and Schweiker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTER FOR DISEASE CONTROL

STATEMENTS OF:

DR. WILLIAM H. FOEGE, DIRECTOR
JAMES D. BLOOM, EXECUTIVE OFFICER
DR. ANTHONY ROBBINS, DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
DR. DONALD R. HOPKINS, ASSISTANT DIRECTOR FOR OPERATIONS
DAVID E. JOHNSON, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
TONY ITTEILAG, DIRECTOR, DIVISION OF BUDGET POLICY AND MANAGEMENT

BUDGET REQUEST

Senator SCHMITT. The hearing will be in order. Our hearings this afternoon will focus on the President's budget request for the Center for Disease Control. Dr. William Foege is the Director. Dr. Foege, I would once again like to extend to you the subcommittee's welcome and tell you how much I look forward to participating in this hearing with you this afternoon.

The CDC in Atlanta, although located far from the rest of HHS's central control office, which is probably fortunate for the Center—I worked at a NASA center; I know what it's like to be away from Washington. [Laughter.]

The Center is entrusted with responsibility for the control of infectious diseases and environmental health hazards, health education programs, guarding safety and health in the workplace, and many disease prevention programs.

The President has requested $391,036,000 for the CDC in his fiscal 1981 budget, and that is budget authority request, an increase of $31,786,000 over the previous year.

The subcommittee has numerous questions to ask you, Doctor. But before we begin our questions, would you please introduce your associates for the record, and then proceed with your opening statements, summarizing as you see fit.

INTRODUCTION OF ASSOCIATES

Dr. FOEGE. With your permission, I will enter our opening statement and summarize the highlights.

Senator SCHMITT. Please do, and the entire statement will be part of the record.

[The statement follows:]

STATEMENT OF DR. WILLIAM H. FOEGE

Mr. Chairman and Members of the Committee: These are important times for health in this country. In the Surgeon General's report on prevention it is pointed out that we stand at the brink of what could be the second public health revolution. Against such a backdrop, it is a pleasure to be discussing the 1981 fiscal year request for preventive health services budget. I will review a few of our accomplishments, discuss some of the challenges we face in prevention, and, lastly, relate our budget request to those challenges.

Accomplishments

I cannot discuss CDC's accomplishments without once again mentioning during 1979, the world witnessed a landmark in medical history--two years had passed with no case of naturally occurring Smallpox being reported. (EXHIBIT 1. SMALLPOX CHART). We are proud of the role the United States played in working with the World Health Organization to successfully eradicate a dread disease.

Not all of the excitment has been in the international scene. During 1979, we successfully concluded one part of the childhood immunization initiative with over 90% of school children immunized against measles, polio, diphtheria, tetanus, and pertussis. At school entry the figures are running 92% for measles, 89% for rubella, 81% for mumps, 95% for polio and 96% for DTP. With these immunization achievements have come dramatic declines in the number of cases of measles, rubella, and mumps. In 1979, we set new records for the lowest number of reported cases of diphtheria, tetanus, measles and mumps. For measles in particular, the record is extremely promising (EXHIBIT 2. MEASLES GRAPH). We keep setting new records for fewest number of cases being reported in a year or even in a given week with only sporadic outbreaks occurring. With funds appropriated by Congress, we have been able to embark on a special program to eliminate indigenous measles in the United States by October 1, 1982.

Hopefully, we will soon have another disease that can be prevented by immunization. CDC is working cooperatively with the manufacturer and with health departments to evaluate a prototype hepatitis B vaccine. The study will be done among high-risk groups in several large metropolitan areas. Should the trials prove successful this will represent a unique accomplishment for American science--we will have developed a vaccine without having first been able to isolate the organism in the laboratory.

With another group of infectious diseases, the sexually transmitted diseases, our control efforts are paying off. The incidence of gonorrhea was skyrocketing until 1976, and in 1979 we see our first indication of a downturn (EXHIBIT 3 GC GRAPH). We blunted the upward course of the epidemic; we met the challenge of a penicillin resistant strain of gonorrhea (which accounts for as much as 40% of the gonorrhea in some countries but which has not been allowed to spread in the United States); and we have recognized the special circumstances of "women as victims." The burden of gonorrhea complications is borne predominately by women (the most frequent and severe complication is pelvic inflammatory disease which can cause sterilization or atopic pregnancies or fetal deaths). (EXHIBIT 4 GC COMPLICATIONS CHART). The funds added by Congress in 1980 will permit us to keep the pressure on to prevent more gonorrhea, to prevent pelvic inflammatory disease among women, and to permit a renewed emphasis on syphilis which rose slightly in 1979 after several years of decline.

CDC has continued to provide assistance to other nations in the control of communicable diseases and is currently working with the State Department, the American Red Cross, and other international health organizations on the refugee problem. We have personnel assigned to Southeast Asia who are monitoring the health screening activities being undertaken in the camps.

While engaged in campaigns against age-old public health enemies, our scientists have been working to learn more about the newest bacterial disease--Legionnaires' disease. The most effective treatment has been identified, more rapid diagnostic techniques have been developed, and environmental sources are being narrowed down. Of particular importance is the discovery that legionella is not a single organism but actually a group of organisms.

These are examples of kinds of efforts that must be made to capitalize on or to maintain the advances we have made in the first three quarters of this century--particularly in the prevention of infectious diseases. Our situation has been likened to trying to maintain a clearing in the jungle; without a continuing effort the jungle can easily reestablish itself.

Our accomplishments have not been limited to the communicable diseases. In occupational health we are now able to begin to strengthen the service components of the Center's National Institute for Occupational Safety and Health (NIOSH). We conducted nearly 140 health hazard evaluations in 1979 and expect, in 1980, to exceed 200. In addition to these formal requests to investigate hazards at the worksite, in 1979, NIOSH: responded to 50 requests for technical assistance, continued approximately 50 industry-wide studies, responded to some 3,000 requests for technical information, and distributed approximately 200,000 documents. These service oriented activities reflect the continuing maturation of the organization and the nation's occupational safety and health effort.

In our diabetes control program, we are developing an approach to the prevention of the serious consequences or progression of diabetes. This fiscal year we will be expanding the number of projects to a total of 20. We are expecting to achieve measurable results; we also believe we have developed a model that can be applied to other chronic diseases.

Work in the general environment has expanded also. During the past year:

1. Within 7 days after being notified of three cases of metabolic alkylosis, CDC conducted a systematic survey; discovered 30 similar cases linked to the use of certain infant formula; and the products were recalled by the Food and Drug Administration. Further, the episode led to an FDA reappraisal of the contents and manufacturing process of the infant formulas.

2. CDC assisted the Idaho Department of Health and Welfare in investigating the contamination of food with polychlorinated biphenyls (PCB). Studies showed that in this case no adverse health effects could be expected from the PCB exposure.

3. CDC has been conducting a study of the population of Triana, Alabama, looking for possible adverse health affects from prolonged and heavy exposure to DDT. While results are not yet in on the study, some new and much needed information has been added to our store of knowledge about the chemical--that the human body can continue to accumulate DDT over the years, a fact which may stimulate considerable research and rethinking of what we think we know about DDT.

I spoke earlier of a second public health revolution. The first one took place during the 20th century, for instance, a child born in 1900 could expect to live an average of 47 years, a child born today has a life expectancy of 73 years. Or looked at another way, most of this progress can be attributed to our success in preventing and controlling infectious diseases, but the figures are in part misleading because this "average" life-expectancy has improved because of our success in preventing death during the early years of life. Looked at another way we can see that in 1900, a person of about my age could expect to live an additional 21 years, whereas my expection is only 6 years longer than that. (EXHIBIT 5. LIFE EXPECTANCY CHART). We now possess the knowledge and skills to make a significant impact against today's most frequent causes of death or disability such as heart disease, cancer, and accidents. It is against health problems of this nature that a second public health revolution would take place. The first steps have been taken, there is a national concensus group that is developing national prevention goals for the year 1990. We at CDC have had an ad hoc group helping us determine the high priority prevention problems of today, and even the World Health Organization is spear-heading an attempt to have countries set goals for the year 2000. Beyond that, CDC and the Public Health Service have been working with the American Public Health Association and health officers to develop model standards for prevention in public health.

It is within that framework that our request for 1981 funds has been developed. We are emphasizing the prevention of chronic diseases, health promotion and health education, environmental health, occupational health and increased preventive health services. Our intent is to maintain and take advantage of

the progress of the first 8 decades while preparing to move into the future toward new vistas of health and quality of life for the nation.

We once again are asking that you fund the preventive health formula grant program. I personally believe that this program can be the cornerstone upon which we build our strategies and meet our goals for preventing the leading causes of unnecessary death and disability. (EXHIBIT 6. LEADING CAUSES OF YEARS LOST).

A companion to this is our request for additional funds for our health education/risk reduction programs. A new emphasis would be placed on developing prevention and health promotion programs at the worksite. Just as we use the school setting as a means for bringing preventive services to children, we should be able to use the worksite for improving the health and quality of life of millions of workers.

We are requesting that you continue to support our efforts to improve dental health through an increase of nearly $3 million for our fluoridation grant program. The first fluoridation of water by a community as a result of support received under a fluoridation grant began in late November of 1979. Our aim is to have reached more than 700 communities by the end of 1981, and over a ten year period to reach near universal fluoridation of approximately 8,600 currently fluoride deficient water systems.

We are requesting more than $600,000 and 12 positions to further expand our nutrition and diabetes programs. Both of these programs, which have been of special interest to Congress, are at a point where we must concentrate on building up our central staff. The field programs have grown to the point where they are stretching the capacity of the Center's staff to provide needed backup and direction.

With prior support from Congress we have developed at CDC a small toxicology laboratory that is unsurpassed in its ability to identify unknown substances. Building on this capacity and our epidemiologic approach to prevention and control, we are requesting nearly $3 million and 10 positions in order to expand significantly our capacity to respond to toxic emergencies, to identify environmental hazards, and to prevent toxic exposures.

I mentioned earlier the maturation of our occupational safety and health program and this too is reflected in our 1981 request, where we are asking for 6 positions and $1 million to expand our health hazard evaluation activities, and $25 million to expand the facilities of our Appalachian Laboratory for Occupational Safety and Health (ALOSH) in Morgantown. We are looking for ways to increase the scope and usefulness of the health hazards evaluations conducted by NIOSH. These research based services are a valuable tool in our campaign to improve occupational safety and health that deserves greater emphasis.

In the epidemic services activity we will, of course, continue our disease diagnosis identification and epidemic aid services, and this year for the first time, we are requesting additional funds for our work in Legionnaires' disease. We need additional resources in order to exploit what we have learned about this group of organisms, the illnesses they cause, their treatment and the method of spread. In addition, we are requesting an increase in the number of epidemic intelligence officers the Center will be able to support. We want to strengthen our general field assignments and add another 5 officers in our occupational safety and health programs.

We are asking Congress to provide funds that will upgrade our facilities in Atlanta. We are asking for design money for new construction in the Atlanta area as well as a small amount of money to upgrade our animal facilities in order to meet certification requirements.

Lastly, I must point out that our budget is not all one of asking for increases. The requests include the $10 million decrease of non-recurring buildings and facilities items, and a decrease of $18 million in three of the grant programs. I will be happy to answer any questions you have about the requests or the Center's programs.

EXHIBIT 1.

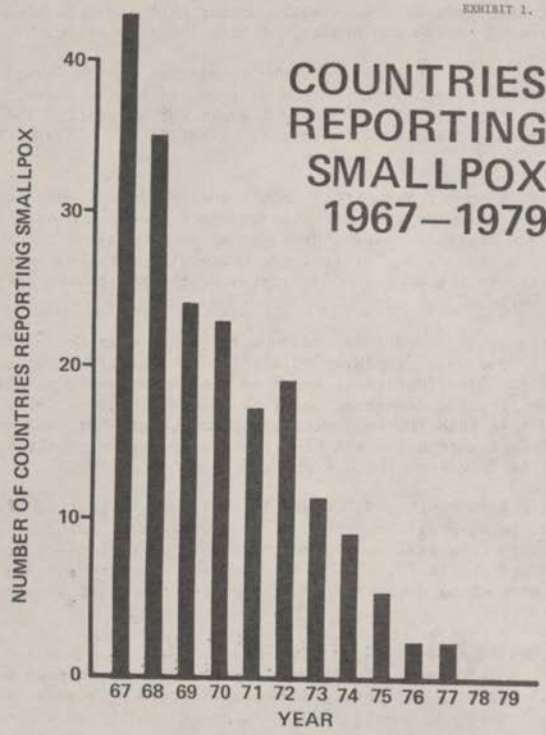


EXHIBIT 2.

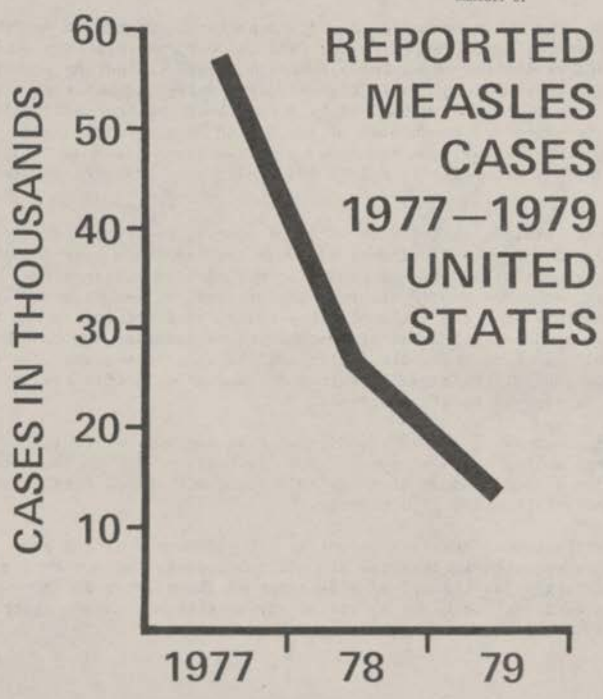


EXHIBIT 3.

REPORTED GONORRHEA U.S. 1972 – 1979

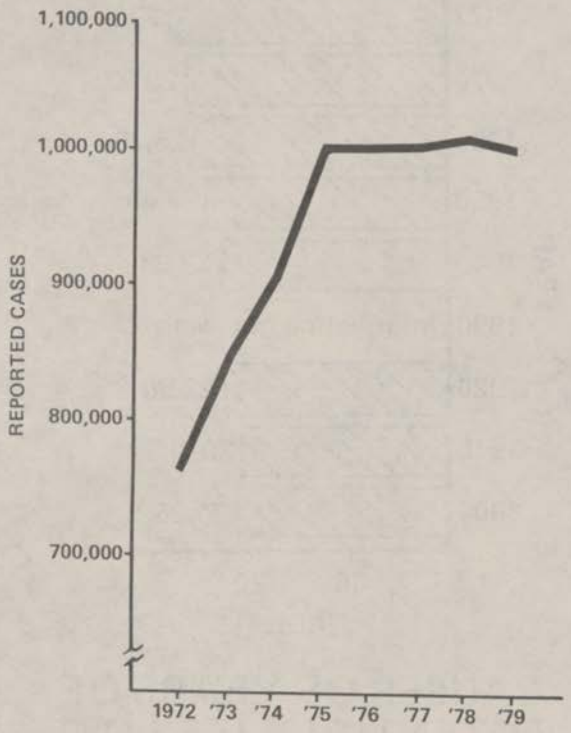


EXHIBIT 4.

GONOCOCCAL PELVIC INFLAMMATORY DISEASE ANNUAL ESTIMATES

235,000 ■ CASES

75,000 ■ STERILIZATIONS

75,000 ■ HOSPITALIZATIONS

36,000 ■ OPERATIONS

10,000 ■ ECTOPIC PREGNANCIES

EXHIBIT 5.

LIFE EXPECTANCY AT AGE 50

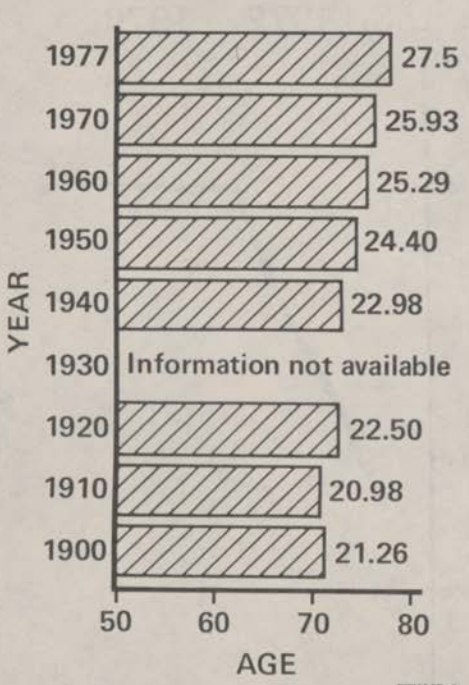


EXHIBIT 6.

CAUSES OF YEARS OF POTENTIAL LIFE LOST U.S.A.

1900

TUBERCULOSIS
INFLUENZA & PNEUMONIA
DIPHTHERIA
ALL ACCIDENTS
DIARRHEA & ENTERITIS

1975

ALL ACCIDENTS
CANCER
DISEASES OF HEART
HOMICIDE
SUICIDE

SMALLPOX ERADICATION

Dr. FOEGE. I will start with some of the accomplishments of the last year, beginning with infectious diseases. I would like to point out that in 1979 the World Health Organization officially declared smallpox to be absent from the globe, having gone 2 years without a reported case due to natural causes. And this is the first time a disease has ever been eliminated from the world.

The U.S. Public Health Service had a large role in that, and we are very proud of that.

Senator SCHMITT. If I could interrupt you, I have a little bit of scientific skeptability about whether you are in a position to claim success. Obviously, you have been successful in minimizing, if not eliminating, the occurrence of this historic disease. Have we done the basic scientific testing necessary, say in the last areas where we knew there were outbreaks of actual smallpox, to be able to say it has been eradicated without fear of contradiction and without getting ourselves in trouble?

That is to say, we get complacent, as we have maybe with polio now.

Dr. FOEGE. I think our strongest defense is skepticism, and the program was designed to have a very strong surveillance component for 2 years in each country after the last case of smallpox. At CDC we have had more specimens since smallpox has died than we had before that time, because people were sending in specimens from all kinds of rash diseases. I think in our opinion there is no question that we look very carefully. We have investigated carefully in each country. An international team has gone in and looked at what has happened over the last 2 years. They tried to find cases and they simply have not been able to.

When you recognize that each case is part of a chain, it has to develop from another human case; so it is not as if there was a reservoir someplace waiting to get back into the human population. I think the evidence is very strong.

Dr. Hopkins has been involved in this. Maybe he wants to say more.

One of the strongest arguments might be that in each country, as smallpox disappeared, we begin to offer rewards if someone could produce a case of smallpox. The reward is now $1,000. It is worldwide. And nobody has been able to claim this for over 2 years.

Dr. HOPKINS. One of the best examples of surveillance was after the case of monkey pox was discovered in Liberia. In order to get to it, they had to fly out of Monrovia in a small aircraft, travel by car, take a canoe, and then walk, in order to get to this remote part of Liberia. So I think that is one indication that even in very remote areas we have had people looking for smallpox, sometimes stimulated by the reward, as Dr. Foege mentioned.

I also feel confident that there are no more cases.

Senator SCHMITT. We appreciate your confidence and we appreciate the effort that your group, in cooperation with the World Health Organization, has done to get as far as we have. And we hope that the disease is truly eliminated.

Dr. FOEGE. Let me reassure you that we will continue working on pox viruses, because our best effort to find similar viruses will probably convince us that there are no more smallpox cases. And we continue to

61-400 O - 80 - 15

have a reservoir of smallpox vaccine in this country in case there is another case discovered.

Senator SCHMITT. Is that reservoir permanent? Is it indefinite?

Dr. FOEGE. It is an indefinite reserve, 20 million doses, that can be diluted to 200 million doses for use with jet injectors. And we will keep that.

Senator SCHMITT. There is no aging problem with that?

Dr. FOEGE. The vaccine has been kept since the 1940's without any—without any significant decline in potency. So we believe that this will keep for decades.

If it begins to show decline, we will produce more vaccine.

IMMUNIZATION

Also in the infectious diseases, I would like to mention what has happened in immunization. Last year the committee asked whether we could reach our goal of immunizing 90 percent of the children in this country by October 1, 1979. We have reached that goal. In fact, in many States they have reached 95, 96, 98 percent.

Last year we reported that all seven of the vaccine preventable diseases had declined as compared to 1977. Now we can report that in last year, 1979, six of the seven declined even further, the only exception being polio, which was found in an outbreak in the Amish community this year.

I think of particular note is that with measles there has been a dramatic decline. In 1979 there were 13,500 cases, which is by far the lowest ever recorded in this country. We have been looking every week now at every case of measles in this country. We believe it is feasible to eliminate indigenous transmission in this country by October 1982.

GONORRHEA

We feel very good about the immunization program and appreciate the support that we have had from this committee in order to achieve that. Also, under infectious diseases, in gonorrhea, the program that started in 1972 is paying off. For the last 4 years, we have had a level incidence, and this is in the face of better diagnostic techniques and improved reporting.

Now, we place more attention on the effects of gonorrhea, such as pelvic inflammatory disease, trying to reduce the incidence of sterilization and hospitalization costs resulting from this particular problem. We are also putting increasing emphasis on other sexually transmitted diseases, such as herpes and hepatitis B.

LEGIONNAIRES' DISEASE

Last year we reported that Legionnaires' disease was clearly a new family of bacterial organisms, and we proposed a name, *Legionella pneumophila*. In the last year we have been able to improve tests, both for environmental detection and for detection in humans. We now know that this is very common. We can find it in lakes, creeks, mud. We can get it from cooling towers of air-conditioners and so forth.

We now suspect that the disease is the organism that is responsible for about 25,000 cases of pneumonia a year in this country, and we are asking for more money in 1981 to improve our diagnostic techniques and to see if we cannot control Legionnaires' disease.

Senator SCHMITT. Is it your feeling that it was around and just not recognized prior to the outbreak in Philadelphia?

Dr. FOEGE. Yes; we think it was around for as long as we have known. We have been able to trace it back, interestingly, to the 1940's, because we have been able to find specimens in a refrigerator that someone had kept. And we can now go back to show that it was the Legionnaires' organism.

SOUTHEAST ASIA REFUGEES

Also in infectious diseases, in international health, we have been working a great deal on the health problems of refugees from Southeast Asia. We have been working with the World Health Organization in child immunizations. They now have a program where they hope to make childhood immunizations available to all children in the world by 1990.

We have also been working in diarrheal diseases with the World Health Organization, where there have been some breakthroughs in therapy, and other infectious disease problems of the world.

Occupational health——

POLIO

Senator SCHMITT. Excuse me. Could you elaborate a little bit more on the polio situation? The committee, as you recall, Senator Schweiker and I particularly were concerned on the basis of doctors' statements from our States that we were potentially getting ourselves into difficulty. Would you elaborate a little bit further on why you feel relatively comfortable?

Dr. FOEGE. I would be happy to. I think 2 or 3 years ago the immunity levels in this country had gone down to dangerously low levels. The childhood immunization program, however, brought those levels up to over 90 percent. So that when polio appeared in the Amish community, we were quite comfortable that the surrounding non-Amish immunity was high enough that the disease would not get out of that community.

In fact, that is what has happened. There were cases, of course, in four different States in the Amish community. And I might incidentally say, one of the benefits of the technology explosion in recent years has been that until a year ago we could only classify polio as being type 1, 2, or 3. In the last year we have been able to take the isolates from the Amish community in Pennsylvania and actually fingerprint them, based on genetic material, and show that it was the same virus that went through the Amish community in different States and not several viruses. This strain could then be traced back to introductions in Canada the year before; the Canadian introduction came from the Netherlands, from a religious community in the Netherlands, and probably the outbreak in the Netherlands came from Kuwait.

I mention this because it gives us some precision in being able to follow an organism. And indeed, the organism did not get out of the Amish community. I think it demonstrated how good the immunity was in the country as a whole at this time.

Again, that is the product of the last several years in the childhood immunization initiative.

Senator SCHMITT. Didn't it drop; the emphasis dropped, and now it is going up again?

Dr. FOEGE. It is going up again. We were down to immunity levels in the 60-percent range. We are now over 90 percent for polio in children in this country.

Senator SCHMITT. Do you see any danger to the adult population of any significance?

Dr. FOEGE. From the vaccine or the disease?

Senator SCHMITT. From the disease.

Dr. FOEGE. I think there is pretty good immunity in this country now to polio. In fact, I think it is rare for us to find a wild strain of polio. Because we can fingerprint viruses, in the future we will be able to take every polio isolate and say, This is a vaccine virus or wild virus. My guess is we will find very few wild viruses left in this country.

OCCUPATIONAL HEALTH

In occupational health, we have increased the number of health hazard evaluations that we have done. I think we have improved the definition of hazards in the workplace, and we are putting new emphasis now on getting information on these hazards directly through the workers and through industry, in addition to giving it to regulatory agencies as we have done historically.

On environmental health, we have improved our ability to react to chemical problems in the environment.

Senator SCHMITT. Do you feel that, say, the office of OSHA, Occupational Safety and Health Administration—do you feel that they are using the information that you develop on safety problems or nonsafety problems in the workplace?

INTERACTION WITH DEPARTMENT OF LABOR

Dr. FOEGE. I think we have a much closer relationship with them than we have ever had before. I will ask Dr. Robbins to react.

Dr. ROBBINS. One of the things that has happened over the last year is that the Department of Labor has developed a so-called NIOSH planning group, and they have laid out their priorities and needs from NIOSH. And we are responding to them and working with them very closely on a variety of issues.

For example, they have just issued a new regulation on a generic cancer policy, and we are setting up the mechanisms to give them recommendations on carcinogens in the workplace, specifically meeting the needs of the policies that they have laid out.

Senator SCHMITT. Why wouldn't you have done that before they laid out a policy?

Dr. ROBBINS. We have done that in a general way. Their policy had the advantage of eliminating the problem of repeatedly looking at the question as to what level of evidence must be put forward before they accept the notion that something is a carcinogen. They went through that once, and now we will simply be able to provide them information against those criteria.

Senator SCHMITT. What if they put out unrealistic criteria? Do you have a veto over those?

Dr. ROBBINS. No; but we certainly argue with them.

Senator SCHMITT. Are there examples where they may have gone beyond where you would have recommended they go?

Dr. ROBBINS. There probably have been in the past. There haven't been recently. We have been working very closely with them and most of what comes out is very much to our liking. OSHA is doing a good job in tackling the real problems in the occupational health and safety.

Senator SCHMITT. At what levels and in what way does the interaction occur? The working level is a continuous, ongoing effort; is that correct?

Dr. ROBBINS. Yes; for example, we have a group that is developing criteria documents that respond to the new cancer policy, and we have a joint working group with OSHA to lay out our recommendations, because within the next 6 months they are going to need to compose two large lists of confirmed and suspected carcinogens. That is cooperation at the staff level.

MANAGEMENT OVERSIGHT

Senator SCHMITT. What is the management oversight over that work? How often, say, do you meet with your counterpart at OSHA or the Department of Labor to make sure that this process is working?

Dr. FOEGE. I don't meet with them often separately, but I have met with Dr. Robbins frequently to work out our own priorities.

Senator SCHMITT. But you don't normally interact with your same level in Labor?

Dr. FOEGE. I meet occasionally with Dr. Bingham, who is the counterpart of Dr. Richmond. I have met with her.

Dr. ROBBINS. We have two Assistant Secretaries in the Labor Department, one for occupational safety and health and one for mine safety and health, with whom I work regularly and meet with each of them at least once a month, usually more often.

Dr. FOEGE. This is a dramatic improvement over the kind of working relationship we had even 3 or 4 years ago. It is a much closer feed-in of scientific material from NIOSH than we were able to have before.

Senator SCHMITT. The one thing that still seems to be lacking in some areas is the operational input. What are possible ways of mitigating the effects of carcinogens you all may identify and the policy which OSHA may undertake to control as a result. There still seems to be an operational ignorance within this whole thing. It doesn't mean that you can't do the job. There is just a lack of expertise to know what are the possible ways to get things done. When it comes down to the working level, out there among my constituents, it is a very dictatorial operation, still.

CONTROL TECHNOLOGY

Dr. ROBBINS. That is perceptive. The problem that we run into is that it is one thing to make a determination that a certain level of exposure will cause so much disease. What we are finding we have to spend more and more time on is looking at kinds of control technology that is available to eliminate the problem.

When we originally made recommendations on reducing vinyl chloride exposures, the plastics industry told us they would go out of business; they couldn't afford the change. What turned out a year later, after this standard had been imposed, is that they enclosed the process, they recaptured a great deal of the raw material they previously lost, and were producing vinyl chloride and then polyvinyl chloride in a safe environment and actually more efficiently than they had in the past.

That happened, I think, because everybody was alarmed at the cancer-causing products of vinyl chloride. I think as we approach new substances and try to make recommendations, we have to do our homework in the area of control technology and be able to say, "Look at Company X; it does a job effectively. All of the companies ought to be able to protect workers that well. And we are spending more time"——

Senator SCHMITT. We hope that in the tax legislation we will be able to provide some appreciation incentives for companies to move more rapidly toward implementation of technologies which right now do put them in a crimp, particularly when they are competing in the foreign market where most other countries aren't quite as insistent as we are.

I can recognize the resistance to change because they are afraid of change. But also sometimes because change is often mistaken for progress, as I think Winston Churchill said; it goes both ways. And what I hope you are telling me is there is developing more internal expertise as well as more interaction with the external community on the operational constraints. They have a lot to learn, but also so do we about what is possible or what may be a better way to get the same job done.

Dr. FOEGE. Let me finish up by summarizing——

Senator SCHMITT. For the record, could you provide an outline of just what the process is for your work with OSHA, what levels of interaction exist; and also, how you reach out to the private sector, or at least the operational sector for input and involvement in what you do to develop your standards?

Dr. ROBBINS. We will try to do that.

[The information follows:]

COORDINATED ACTIVITIES

Both NIOSH and OSHA work diligently at assuring coordination of their activities. The most visible mechanisms to improve coordination are:

NIOSH planning group.—The agencies within the Department of Labor that need NIOSH information, OSHA, the Mine Safety and Health Administration, and the Employment Standards Administration, all participate in NPG and prepare a list of their needs. NIOSH assigns high priority to research topics identified by NPG and is committed to providing information in each of the areas identified by NPG.

Interagency agreement.—NIOSH and OSHA have signed a formal interagency agreement that defines responsibilities and provides the framework for coordination.

Joint advisory council.—NIOSH and OSHA use the the same National Advisory

Committee for Occupational Safety and Health comprised of representatives of labor, business., and universities.

The critical element that assures coordination of activities is the commitment of the management of NIOSH and OSHA toward cooperation. For example, NIOSH is restructuring its output and reordering research priorities to accommodate the new cancer policy announced by OSHA. A series of joint NIOSH–OSHA task forces are addressing specific issues such as sharing of data; improved coordination between field studies and OSHA inspections; and enhancement of OSHA capacity by building grants under the new directions program.

INTERACTION WITH PRIVATE SECTOR

As you know, NIOSH is responsible for identifying occupational safety and health hazards, for determining methods to control them, and for recommending Federal standards to limit the hazards, as well as for providing and training to alleviate the critical shortage of occupational safety and health manpower. The intramural and extramural processes necessary to carry out these responsibilities require continuous interaction with the private sector. Selected examples include:

The Institute's health hazard evaluation and broad technical assistance programs interact with employers and employee representatives requesting investigations of reported worker exposures. Evaluation reports from these investigations are widely distributed and made available to the private sector.

The Institute currently has a very active program of control technology assessment and works very closely with the private sector to examine the latest available control technology for prevention of occupational hazards.

A very important part of our interaction with the private sector is the tripartite arrangement between the Institute, industry, and labor in terms of our health hazard evaluations and industrywide studies programs and our commitment to meet with both labor and industry to listen to their ideas on our planned activities in these areas.

Through the DHEW network of regional offices, NIOSH regional program consultants and industrial hygienists interact with the private sector on an ongoing basis conducting HHE's, providing them with technical assistance, information, and generally keeping them informed of Institute activities.

The Institute published a broad array of technical information in an effort to keep the private as well as the public sectors informed of recent research findings and technical recommendations.

FUTURE OPPORTUNITIES

Dr. FOEGE. Let me summarize some of the opportunities that we see, looking ahead. To do this, we have looked back at the last three-quarters of a century to figure out what has been happening in the way of excess mortality, years of life lost in this country.

It is clear in 1900 that the infectious diseases were the main reason for years lost. There has been in the last 75 years a remarkable reduction in that. The quarter-of-a-century increase in life expectancy that is often mentioned——

Senator SCHMITT. Let me see that.

Go ahead.

Dr. FOEGE. The quarter-of-a-century increase in life expectancy really comes because infant and child mortality has been reduced. If we look at the future, at what is happening now to excess death, what is striking——

Senator SCHMITT. Infant mortality wouldn't appear on that?

Dr. FOEGE. This just looks at potential life lost, and because much of this was infant mortality, it added to many years lost per each person as compared to a person dying at age 64 from heart disease.

The point I want to make is that if you look at what has happened to people in my age group, something different has happened concerning that 25-year increase in life expectancy. In fact, I can expect only about 6 years more than my grandfather could at my same age, which means that all of 20th century science at this age of life can only offer me 6 more years of life. That is quite in contrast to the 25-year increase in life expectancy at birth.

But we know from studies that Dr. Breslow has done in California that some fairly simple changes in life habits—not smoking, modifying drinking habits, exercise, diet, and so forth—can add 10 or 11 years, which means that what persons do for themselves can be more powerful than all of 20th century science. That is the challenge that we really face now in the 1980's and 1990's. How do we get that kind of information to people? We, in fact, have to do some experimenting with education to get the message across.

OBJECTIVES FOR PREVENTIVE MEDICINE

Several years ago Senator Javits asked us how do we go about choosing our priorities at CDC, and I think over the last several years there has been a system developed, a national system. We now for the first time have been able to come up with a consensus on what should be the objectives for preventive medicine in the United States by 1990. People from around the country met in June of this year and in 15 different areas they decided on logical goals and objectives for 1990. For example, in infant mortality they said we should be able to get down to 9 from 14 deaths per 1,000 live births by 1990. We should be able to compete with the rest of the world.

STANDARDS FOR PREVENTIVE MEDICINE

In addition to objectives, we have been able to come up with model standards for preventive medicine. This was developed by State health officers, by county health officers, city health officers, and the American Public Health Association.

And we have several systems now for drawing priorities. The Surgeon General's report on prevention was one approach. There have been several others. I think there is general agreement now on what are the 10——

Senator SCHMITT. Do we have those books in our records? Could we have those?

Dr. FOEGE. You sure can.

[The information follows:]

PREVENTION PUBLICATIONS

These publications are "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention"; "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention, Background Papers"; and "Model Standards for Community Preventive Health Services."

These publications have been provided to Senator Schmitt and the subcommittee staff.

PREVENTION STRATEGIES

Dr. FOEGE. There is now agreement on what the strategies should be. Our strategy, based on what has continued over the last year, would be: One, to maintain the gains that we have made in the area of infectious diseases. When one looks at resistance to antibiotics and so forth, it will require a good deal of effort to maintain the gains that we have achieved in the past.

Two: To attack the leading causes of death. And much of this will involve increasing our education of the public.

Three: To improve the health potential of workers in this country.

Four: To capitalize on technology and knowledge and experience. For instance, with measles, now that we have some better understanding of how measles spreads, we think we can, in fact, eliminate indigenous transmission. With Legionnaires', we are gaining more experience and we are in a position to exploit that.

And five: To solidify our abilities to react to chemical problems of the environment. While we have done a great deal with DDT problems in Alabama, with paraquat and marihuana, asbestos in Arizona, we need to expand our capabilities in that area.

We think the prospects of improving health through prevention are greater than they have been for three or four decades.

Thank you. We would be happy to answer questions, Mr. Chairman.

Senator SCHMITT. This whole issue of preventive medicine, can't we come up with a better chart? Who wants to prevent medicine?

Dr. FOEGE. "Health promotion" is a better term.

Senator SCHMITT. It sounds like you're going to prevent health. But preventing sickness and disease is clearly what you have just been speaking to. And as the principal national alternative to national health insurance, I think it has to rank very high.

Frankly, I am one of those who don't think you can afford the kind of massive national health insurance program that has been discussed, no matter how psychologically appealing it may be. And it is appealing to me, but we still have to be able to afford it.

The thing you can afford is prevention so that people don't really need health care.

Do you really think that we can significantly deter people from doing those things which prevent the climb in life expectancy: smoking, overeating, drinking?

SMOKING

Dr. FOEGE. I think, Mr. Chairman, that this is obviously the challenge. But I am heartened by what has happened in areas such as smoking where we have seen the percentage of adult smokers declining, and particularly we have seen——

Senator SCHMITT. But it is rising in the female population.

Dr. FOEGE. In certain age groups of teenagers, there is an increase.

Senator SCHMITT. We are losing ground. We are getting older people to stop, and now the kids are smoking.

Dr. FOEGE. The question is how long will they continue smoking. And certainly, the number of adult females smoking has gone down.

I am particularly heartened by what has happened with the medical profession. Only three decades ago doctors were probably the heaviest-smoking population in the entire country. And now the percentage of doctors smoking has decreased to 21 percent. This is an indication of where we can get with education.

Senator SCHMITT. Did you include marihuana smoking in your statistics for smoking?

MARIHUANA SMOKING

Dr. FOEGE. We are talking about cigarette smoking, nonmarihuana. It is estimated that someplace between 10 and 20 million Americans smoke marihuana.

Senator SCHMITT. If you add that, does that erase all of the progress that you have made?

Dr. FOEGE. I don't know how much overlap there is. It is very difficult to get figures on marihuana smoking. We have tried this because of our interest in paraquat and how dangerous it is. It is difficult to get good figures.

Senator SCHMITT. Does marihuana affect the clearing function of the lungs the same way that tobacco does? Do we know that?

Dr. FOEGE. First, it took so many decades——

Senator SCHMITT. Nicotine.

Dr. FOEGE [continuing]. With tens of millions of cigarette smokers not concerned about relating their habits. It took decades to get the information on cigarette smoking. It is hard to get this same sort of information on 10 to 20 million marihuana smokers who are reluctant to discuss how much they smoke.

But let me give my educated guess——

Senator SCHMITT. I will let you go on, but what I am referring to is the specific biological function being inhibited. Can't we test that in some laboratory way, whether the ingredients of marihuana affect the clearing function? Because isn't a great deal of the problem that we have with smoking is that it prevents you from cleaning your lungs? Isn't that correct? It acts to paralyze the cilia, if I remember correctly, in the lungs so that the clearing function is not performed as well; there is a sharp correlation in the New Mexico mine cancer problem between those who smoke and those who don't. If you smoke, the chances of getting cancer from inhaling dust in a uranium mine go up by many, many factors compared to those who do not smoke.

Dr. FOEGE. That is certainly part of the problem. Part of it is also the direct carcinogenic effect of certain chemicals.

But the answer is that everything seems to indicate that marihuana smoking will have the same long-term effects as cigarette smoking, and perhaps even greater effects if one adjusts for the amount of marihuana smoked versus tobacco.

Senator SCHMITT. In terms of actual effect on the lung?

Dr. FOEGE. That's right. I am not an expert in this field. There is an agency of the Public Health Service which deals just with drug abuse problems.

Senator SCHMITT. When you get back, if you see anything that could assist our records in this, as well as in other major causes of disease,

could you provide that to us? Your perspective, I think, will be very useful.

HEART ATTACKS AND STROKES

Dr. FOEGE. Let me follow up on your question about is there any hope. I think the real hope lies in what has happened in the last 10 years. There has been a 22-percent reduction in fatal heart attacks. There has been a 30-percent reduction in fatal strokes. We aren't totally clear on what has led to all of this, but it seems to be a combination of decreased cigarette smoking, better treatment of hypertension, better attention to exercise, more attention to diet, such as less fat intake.

Senator SCHMITT. But also maybe there is better treatment after the attack. Right? Have we seen that kind of progress in the last 10 years?

Dr. FOEGE. Yes, but most people conclude that is not the reason for the dramatic change in 20- to 30-percent reduction for the decade. I think people by and large figure that this is prevention, but they are not sure how you divide out the differences, the segment due to decreased smoking versus exercise and so forth. Hypertension treatment has had a great influence on this.

CDC EMPLOYEE SURVEY

At CDC we have also been conducting a program with our own employees. They fill out a form giving all of their habits. They receive, in return, a computerized statement that tells them what their risks are in the next 10 years; how this compares with the average; what they can do to change their risks. And, they get information that says, "You may be 42 years of age, but you're living as if you are 46. If you would do the following things, you could be 39 again." That is an important way of putting it, rather than, "You can live 4 extra years." To tell people they can be 39 again might have more influence.

We did a survey of 1,500 people and 70 percent said they changed some habit in the last year because of this effort. I am not discouraged, because we obviously have to do this—we need a lot more information to know how to do it most effectively.

Senator SCHMITT. That information has to get to the people who need it, and most importantly in the preschool and the early school years, where the habit patterns—at least the approach to habit patterns—may be formed.

If I could break for 2 or 3 minutes to make a phone call which apparently is rather urgent—and then we will get into the detailed questions. We will recess for just a few minutes.

[A brief recess was taken.]

FORMULA GRANTS

Senator SCHMITT. It will be difficult to go through the entire program. We will have questions for the record, and I hope that in the course of our previous questions and also in the course of the following discussion we will cover most of the highlights and those areas of concern to the committee. We know that you will promptly answer any other questions that we may find appropriate.

In the area of formula grants—and I believe that is section 315 of the current law, 95–626, the President has requested $10 million for States for preventive health services. This new program would help to identify the five leading causes of death in each State. And then help to establish a prevention program. I suspect this has been led into by our previous conversation.

Now, to what extent does this program directed toward morbidity rates—duplicate the progress by other offices such as the antismoking programs, hypertension programs, cancer control programs, diabetes, genetic programs already in existence?

Dr. FOEGE. I don't think that they compete; in fact, it seems to me that we are now getting a very logical approach to prevention in that the health education grants can provide a broad approach to prevention, while the 315 or prevention formula grants can allow a State to pick out one or more specific problems that they will concentrate on. These will not be the same for all States.

For instance, in Alaska the leading cause of mortality turns out to be accidents rather than heart disease or cancer. We think that this should be a good supplement to the other kinds of programs, to allow a State to concentrate on one or more problems.

They also have the possibility under this act to concentrate on leading causes of morbidity, if they wish, although, our guess is that most of them will take one or more of the leading causes of mortality.

JUSTIFICATION FOR NEW PROGRAM

Senator SCHMITT. Again, why wouldn't this be more appropriate as part of some other effort rather than a new program of its own? I realize the Congress has authorized it, but I ask you——

Dr. FOEGE. The real reason is to provide flexibility. With the other programs there is not the flexibility to concentrate totally on one problem. Some States—for instance, I would believe that hypertension, hypertensive heart disease, could be one of the leading causes of death. This would allow a State to concentrate on a particular problem.

Senator SCHMITT. We could change the other programs and let them concentrate——

Dr. FOEGE. The other programs give a broad-base approach.

Senator SCHMITT. Why couldn't we earmark some of the hypertension funds for a program like this rather than starting a new program? I think that is the question, whether we ought to start a new program.

Dr. FOEGE. I think part of the reason, both in Congress and the administration, for promoting this is that until we concentrate on the leading causes of death——

Senator SCHMITT. I understand that. It is purely an administrative thing. Why is it better administratively to have this happen under section 315 rather than earmarking or allocating funds in one of the ongoing hypertension or other programs, to do the same thing?

Dr. FOEGE. The real reason would be that the hypertension program might only apply to certain States that would be interested in that. No matter what we would add on to another program, it would not allow the flexibility for a State to choose one area that wouldn't be included in that other program.

Senator SCHMITT. You have got programs going in just about every area, do you not, and each one of those areas could—what you might do is get the States to make the designation, but—as an agency, get them to do that. And then parcel it out, depending on where the program might best lie within the existing programs.

Dr. FOEGE. This will have to be coordinated with the other programs. But again, it seems to me that it is hard to get the flexibility from the health education program or from a smoking program or from a hypertension program. It is hard to get the flexibility in a particular State to put all of those things together aiming at a cause of death, and be able to show a reduction in that cause of death.

Section 315 requires people to set objectives, measurable objectives, and show a reduction in mortality.

Senator SCHMITT. We can do that. I am arguing administratively. We can do that with these other programs. We can say, these are earmarked, and everything in 315 must happen—but must happen within the administrative structure already existing, rather than establishing a new administrative structure that attempts to coordinate the whole process.

Dr. FOEGE. In one sense, there won't be a new administrative structure, in the sense that most of this is being administered with the 314(d), where the States do have to come back with an annual plan. And 314 and 315 would have a general plan, and then subplans for how the two would be spent.

PERSONNEL REQUIREMENTS

Senator SCHMITT. Is this going to require any new personnel slots?

Dr. FOEGE. We are not planning to have people in the field, but we are planning to have three people at headquarters to help administer this.

Senator SCHMITT. Are they in the form of block grants?

Dr. FOEGE. They will be individual grants. They will not be part of the block grants; they will be individual grants to the States.

STATE BUDGETS

Mr. BLOOM. It will be a formula grant. It will be distributed on a formula, but there will have to be an application from the State, where they will lay out a program of what they plan to do.

Senator SCHMITT. Why don't we just let the States do it? In a time of tight budgets, you are helping them develop their expertise in each of the individual areas. Why don't we let them make a decision with their own funds, on where they concentrate in using that expertise?

Dr. FOEGE. The response that we have—the States feel that they are finding a decrease in their prevention money.

STATE BUDGET SURPLUSES

Senator SCHMITT. But every one of their budgets, except two or three, are in surplus, and the Federal budget is in deficit. Why should we take the pressure off of them to fund some of these great things that we want to do for them?

Dr. FOEGE. I think they have great pressures on them, in the sense that two-thirds of prevention money comes from State and local resources. We have seen in the past year, some States are cutting back on laboratory services because they do not have basic prevention money. They are having trouble getting——

Senator SCHMITT. Probably because they think you are going to have a $10 million kitty to start to dole out in this area. I am being the devil's advocate to some degree, and I hope you realize that, but—because I know there will be other members of this committee that will ask me or the staff questions like that.

It is the same as in the revenue-sharing case. Why should the States be getting revenue-sharing money when their budgets are in surplus?

Dr. FOEGE. If you look at prevention, their budgets are not in surplus.

Senator SCHMITT. But their overall budgets are in surplus.

The question is: Are they ever going to take the responsibility for allocating their resources to these kinds of efforts, if Sugar Daddy keeps funding programs of this nature?

Dr. FOEGE. I think prevention has trouble competing on the State and Federal level. We simply don't compete well with health care dollars. I don't think that it is going to be realistic to expect the States to increase their prevention money.

Senator SCHMITT. It won't be realistic if we keep increasing it for them.

I just had a note handed to me that total Federal budget has $83 billion in grants to States. So one might argue, what is another $10 million? [Laughter.]

PROGRAM DURATION

Would this be a one-time-only program, using the seed money in the individual States, and then be phased out?

Dr. FOEGE. It has not been seen as that; in fact, it has been seen that the first year is a planning phase, and then going into actual delivery programs.

Senator SCHMITT. You would anticipate once you got into it in a State you would fund it forever?

Dr. FOEGE. I am not sure we would fund it that long—but it is not a one-time-only program.

Senator SCHMITT. Why would you not use it as seed money and then phase it out over a period of time, so that the States either take it up or drop it?

Dr. FOEGE. It is again our experience that the States have a hard time in the prevention area, competing with other programs for money. We have seen this in tuberculosis and in polio. Whenever the attention diminishes on a national level, the States have a hard time maintaining their prevention budget.

Mr. BLOOM. Congress had in mind, also, when they passed this legislation, that while the support might continue over time, that the States would in fact move from one cause of morbidity and mortality to another. As they conquered one problem, presumably they would move on to other challenges. The whole business of public health and preventive health is rather weak.

MATCHING REQUIREMENTS

Senator SCHMITT. It would be nice if they knew how to do it on one and then they could do the others by themselves. How much State and local matching money would be involved in a program like this?

Mr. BLOOM. There is not a specific matching requirement.

Senator SCHMITT. You have the discretion to require matching?

Mr. BLOOM. Not to require it. But we do have the discretion to have them identify what expenditures they are making currently, and what expenditures they plan to make in connection with the programs for which funds have been applied. It is approached that way in the legislation.

VENEREAL DISEASES

Senator SCHMITT. On the issue of venereal disease, last year the Senate provided, and the House agreed to, $40 million for venereal disease. This is up from $32 million for the preceding year.

For fiscal 1981, you are requesting $47,749,000. Historically the VD program has focused on the two diseases we most often think of as VD, syphilis and gonorrhea. But it has been suggested that these diseases comprise less than 30 percent of all cases of sexually transmitted diseases. And that suggestion is from the discussions with the American Social Health Association.

Do you agree with that 30 percent?

Dr. FOEGE. I would think that is in the right neighborhood. I would like to point out that the $47,749,000 is a total of the VD grants and direct operations requested for 1981. This total includes $40 million for VD grants, the same level as 1980.

Senator SCHMITT. You indicated in your earlier testimony that you are giving more attention to other diseases. I think you said hepatitis B.

Dr. FOEGE. I think that is in the neighborhood. We emphasize there are about 10 million sexually transmitted diseases per year in the country, and it is something in the neighborhood——

Senator SCHMITT. That doesn't include colds, flu, and that sort of thing? [Laughter.]

Dr. FOEGE. Twenty or thirty percent would be in the traditional gonorrhea and syphilis category. There is now a category called nongonococcal urethritis, caused by a variety of different organisms, that accounts for many cases of diseases that look a lot like gonorrhea, but which cause pelvic inflammatory disease.

There is the problem of herpes. We don't have good methods for controlling herpes. We are learning more about it. Hepatitis B is very common, particularly in male homosexuals. This year we have started a vaccine trial in five areas of the country. We would expect that by summer of 1981 we will have field results of whether it is effective in diminishing hepatitis B.

Senator SCHMITT. Could you provide us for the record a rough breakdown of the diseases that you would include in the overall classification of VD?

Dr. FOEGE. We will be happy to provide this for the record.

[The information follows:]

VENEREAL DISEASES

At the present time, 13 diseases for which sexual transmission is an important means of dissemination are included in the overall classification of venereal diseases. These diseases and their estimated incidence are:

Syphilis—80,000 new cases annually.

Gonorrhea—2 million cases.

Nongonococcal urethritis in men caused by organisms such as chlamydia and mycoplasma—1.5 million cases.

Genital herpes—500,000 to 1 million cases.

Trichomoniasis—3 million cases annually.

Hepatitis B—70,000 to 100,000 cases annually.

Molluscum contagiosum—100,000 cases annually.

Scabies—700,000 cases annually.

Condyloma acuminata—200,000 cases annually.

Pediculosis pubis (crabs)—150,000 cases a year.

Lymphogranuloma venereum, chancroid, and granuloma inguinale—less than 2,000 cases a year.

Other diseases which are thought to be sexually transmitted and may be candidates for inclusion are: Group B streptococcus, cytomegalovirus, candida, and nonspecific vaginitis.

VENEREAL DISEASE EDUCATION

Senator SCHMITT. In a lot of these issues, we really come down to education, whether it is education of State constituencies and legislatures to provide more funds for disease prevention. There doesn't seem to be in this area of VD much advertising activity on television, radio, or other mass media outlets.

Do I just not watch enough television, listen to enough radio, or is that a problem?

Dr. FOEGE. I believe there has been a fair amount of advertising, but I think most of the health education of VD has been concentrated on specific audiences—the type of thing that one might find in high schools, that one might find in VD clinics, that one might find in prenatal, postnatal clinics.

It has been an attempt to concentrate the message where it would do the most good, rather than mass distribution. We spend in the neighborhood of $8 million a year on VD education and 5 percent of venereal disease project grant funds will be utilized for education and research in the future.

Senator SCHMITT. You feel you are more effective when you target your audience?

Dr. FOEGE. That's right.

Senator SCHMITT. Do you have any statistical basis to make that judgment, or is it that just—a judgment?

Dr. FOEGE. I would have to say it is a judgment, although we have behavioral scientists on the staff who have strong feelings that that seems to work better. For instance, we have a nationwide hotline for VD that has turned out to be very popular, and while it is advertised in certain areas, it is probable the general public has not heard of it.

Senator SCHMITT. I welcome Senator Schweiker to our gathering.

Senator, do you have some specific questions? We have covered the formula grants under section 315 and venereal disease, and I was about to move into our favorite subject, immunizations.

Senator SCHWEIKER. Why don't you go ahead, and maybe a little bit later on I will have a few after I look over the statement.

PRESCHOOL CHILDREN IMMUNIZATION

Senator SCHMITT. OK, sir. The President requested $30.5 million for the immunizations program in fiscal year 1981. We have already discussed some aspects of this.

What is being done to see to it that all children, particularly preschool children are immunized against preventable diseases.

Dr. FOEGE. Now that the first part—immunizing 90 percent of the children up to 15—now that that has been reached, our second attack has been in maintenance, trying to find ways to get immunizations to children before they get to school. In some areas we have started high-risk programs where children can be identified on the basis of geographic area or on the basis of information from the birth certificate in order to have a followup system.

In many States we have 2-year-old surveys which are being done to find out the immunization status of children at the age of 2. And we are beginning to encourage that day-care centers have the same requirements for entry that schools have because we found that seems to be the principal way that measles continues during the summer months—in day-care centers.

We are giving a great deal of attention to the followup aspects.

Senator SCHMITT. You are saying it is a redirection of funds, now that you have achieved considerable success in the up to 15-year-olds. You are not asking for very much more funding in this area because you can reallocate those resources?

Dr. FOEGE. That's right. Much of the earlier effort was a backlog—how to get from 75 up to 90 percent. Now that that has been accomplished, we are redirecting funds into the maintenance program and into the measles elimination program.

UNIMMUNIZED CHILDREN

Senator SCHMITT. But if we look at the new "Health Statistics Book for 1978," which is a little more than a year ago, and the children between 1 and 4 years of age, there is a great deal that hasn't been done. The figures that I am given are 38 percent of this group had not been immunized against rubella, 37 percent had no measles vaccination, and 49 percent had no mumps vaccination, and 460,000 had not had any DPT doses, and nearly 1 million did not have polio vaccine.

Do you think those figures are reasonably accurate?

Dr. FOEGE. Those come from the U.S. census survey.

Senator SCHMITT. It says—I'm not sure who published it—U.S. Public Health Service published it in 1979.

Dr. FOEGE. This was a survey that I believe is based on parental recall of what immunization a child had. We are finding that in general those figures are lower than the figures we get when we do our school surveys. That is where we actually go child by child, and they have to show a certificate or a doctor's note that they have been immunized.

We think what we are doing is more accurate than that.

Senator SCHMITT. The parents may not know that they were immunized in various school situations?

61-400 O - 80 - 16

Dr. FOEGE. That's right. We have no hesitation of saying that the school age is up to 90 percent, but the 1-to-4 year age is, we think, better than that survey would indicate.

Senator SCHMITT. Where do you get that?

Dr. FOEGE. We have been doing 2-year-old surveys—some of them on a statistical basis, some at day-care centers. Different methods have been used, but by and large these figures are better than the parental recall figures.

We believe that the figures are better than the 1978 data would indicate.

Senator SCHMITT. When will the 2-year-old—study of 2-year-olds I think would be a better way to put it—when would that be available to the committee?

Dr. FOEGE. We can put some of this in for the record. In some States, we now have good survey data.

Senator SCHMITT. Can you provide this in reference to the figures I just gave, because they are a bit alarming, if in fact they are true.

Dr. FOEGE. Yes, we can do that.

[The information follows:]

CHILDHOOD IMMUNIZATION - SURVEY OF TWO-YEAR OLDS

Care must be taken in analyzing these two-year-old survey data. In calculating immunization levels, nonrespondents were considered as unimmunized; therefore, immunization levels could never exceed the response rate. For example, immunization levels in Chicago could not exceed 37.5 percent since the response rate for their survey was 37.5 percent, and in South Dakota, immunization levels could not exceed 92.4 percent. When comparing the immunization levels to response rates, projected immunization levels are considerably higher than those indicated by the survey based on parental recall.

Summary of Standardized 2-year-old Survey Results, FY 79
Immunization Division, Center for Disease Control
(Provisional Data, 1/22/80)

Project Area	Response Rate (Percent)	Percent with 3+ DTP	3+ POL	ME	RU	MPS	Series Complete	Man-hours	Dollars
Connecticut	61.3	59.6	58.6	47.8	56.3	44.1	43.0	497	
Maine	85.5	80.6	78.7	75.3	68.1	58.3	51.9	640	
Massachusetts	75.6	73.1	72.4	71.4	71.0	71.0	69.0	1776	
Rhode Island	76.8	75.6	73.9	75.0	74.4	59.5	59.5	703	4580
New York	87.3	82.6	81.9	77.6	73.8	71.6	66.2	2408	
New York City	58.8	50.5	48.4	48.4	47.4	45.4	42.3	428	
Puerto Rico		57.2	56.0	47.3	46.2	21.1	18.7	945	
Delaware	76.8	68.1	66.7	63.0	62.1	55.3	Unk.	600	
Maryland	63.3	61.6	60.1	57.0	52.8	50.9	48.4	2050	
Pennsylvania	77.6	69.1	65.9	64.3	61.3	58.6	54.3	1312	
Philadelphia	72.3	66.4	62.2	58.5	52.0	34.8	29.1	720	
Allegheny Co.	94.7	92.2	91.6	90.6	81.7	76.9	74.2	510	4337
West Virginia	97.1	86.3	83.5	80.2	79.9	79.4	74.2	1370	12334
Virginia		92.1	87.4	86.2	85.4	82.1	78.0	1960	
Florida	79.5	71.7	55.3	63.3	63.0	63.2	48.8	Unk.	
Kentucky	71.5	61.1	55.9	60.8	59.6	43.4	38.5	Unk.	
Mississippi	85.4	73.4	61.3	81.6	81.6	81.6	50.8*	850	
Chicago	37.5	32.0	31.8	31.0	29.2	23.1	21.7	820	
Michigan	61.7	51.1	47.4	49.7	47.4	43.9	38.3	1061	
Minnesota		78.8	74.5	71.2	69.3	69.2	63.8		
Ohio		87.0	80.9	79.7	76.9	67.5	64.4		
Louisiana	93.5	86.9	86.4	82.8	82.3	81.3	79.3	Unk.	
New Mexico	79.3	73.5	73.2	71.1	70.2	60.7	59.2	740	
Oklahoma	71.0	57.0	56.0	54.0	54.0	52.0	46.0	12	
Texas	82.9	71.8	70.2	67.0	65.2	63.4	61.5	640	
San Antonio	67.0	55.6	55.4	51.9	51.4	50.7	47.5	Unk.	
Iowa	92.3	84.4	81.2	81.0	78.2	77.7	73.6	550	
Kansas	64.0	56.0	52.0	51.0	50.0	48.0	43.0	480	
Nebraska		79.5	77.2	74.5	73.2	73.2	69.8		
Colorado	57.4	52.2	51.0	48.8	48.5	47.8	45.5	471	
Wyoming	41.0	40.2	39.8	40.2	39.8	39.8	39.0	112	
North Dakota		70.0	70.0	68.0	68.0	68.0	63.0	300	
South Dakota	92.4	87.0	81.9	82.1	81.6	81.2			
Guam	69.6	27.0	27.0	25.5	25.7	24.8	23.3	840	
Washington	74.4	66.6	65.8	62.2	61.6	61.4	58.5	1121	

* 4+ DTP doses; POL - Polio; ME - Measles; RU - Rubella; MPS - Mumps

FLU IMMUNIZATION

Senator SCHWEIKER. May I ask a question on immunization?

Doctor, it is my understanding that you plan to spend $5.8 million for flu immunizations. Since Congress provided no funding for this program in fiscal year 1980, where is the money coming from?

Dr. FOEGE. I believe that is the 1979 money that was actually put out in September of 1979. The States are now spending that, so that is 1979, not 1980.

Mr. BLOOM. There are no funds requested for that.

Dr. FOEGE. That's right.

Senator SCHWEIKER. What would be the direction that spending takes?

Dr. FOEGE. 1979 money is being spent on vaccine for the States, and it is providing money for them to pay State and local people who have been hired for the influenza immunization program. Much of the immunizations have already been given for the 1979–80 flu season. We have reports on about 1,250,000 doses, but we have not received all of our reports yet for December.

Senator SCHWEIKER. I see where you moved up the date that you were going to get the formulations back to the manufacturers. Did I read that somewhere? What is happening there?

Dr. FOEGE. We are attempting to get the formulation to the manufacturers now by February 1. We have succeeded this year in that 10 days ago there was a meeting of the advisory committees of the Bureau of Biologics and the advisory committee to CDC, and they decided on what the formulation should be for the 1980–81 flu season. It is slightly different than for the current year in the sense that the influenza B will be changed from the old Hong Kong strain to a new Singapore strain that seems to be more common around the world at this time.

Senator SCHWEIKER. How is the date—the way we have done it this year—compared to the date last year?

Dr. FOEGE. I would have to look to be sure. I think we have made the target this year. I think we were behind the target last year. I would have to look to be sure on that.

Senator SCHWEIKER. Refresh my memory. What did the manufacturers say they need to really impact properly?

Dr. FOEGE. They told us they need it by February 1. We did meet that this year.

PREDICTABILITY OF FLU

Senator SCHWEIKER. I know we also have a study underway in terms of the predictability of the flu from one season to the next. Are there any changes? Are there any reports on that program?

Dr. FOEGE. If anything, Senator, it is more frustrating than it has been in the past if we look globally. There are now areas of the world where all three strains are circulating simultaneously. I think we told you several years ago that we thought it would be rare for two strains to circulate simultaneously. Now in Southeast Asia, we have B Singapore, H1N1, and H3N3 all circulating at the same time. We have outbreaks—fairly major—in the Soviet Union of H3N2. On the other hand, there is very little Russian flu this year which a year ago we thought was an up-and-coming strain.

In the United States so far this year, about 19 States have reported influenza B. There has not been a single isolation that I know of of Russian flu, and there have only been three isolations of H3N2. So it is a very confusing picture that the Russian flu, which was supposed to be replacing other strains, is dying out around the world.

FLU PROGRAM FOR 1980

Senator SCHWEIKER. What kind of program, if any, do you plan in fiscal 1980?

Dr. FOEGE. We really don't know how to answer that question. We have continued to ask both scientific people and the people in the States what their recommendations would be for the next flu season, but we have not come to a decision on what we should recommend.

The advisory committee on immunization practices continues to recommend an annual program for high-risk groups. So that recommendation will go forward.

I simply don't know what our recommendation will be for the Federal Government.

Senator SCHWEIKER. Thank you, Mr. Chairman.

Senator SCHMITT. Thank you, Senator.

MEASLES ERADICATION

Last year, Dr. Foege, you told the committee in a letter that one of the major needs of the immunization program was for the eradication of measles. We discussed that a little bit before. The Congress provided you with additional funds, $5 million, which you felt would be necessary to carry out an eradication program for measles.

Can you be somewhat more specific on how that program is progressing? When do you anticipate the achievement of your goal which you more or less set last year and you referred to earlier and that you were fairly optimistic about.

Dr. FOEGE. We still expect that the objective can be reached by October 1982. We have been taking a close look every week at the reports coming in, and we have telephonic reports from the States every week on what has happened with measles. We are becoming increasingly confident that is is not a mysterious disease. In fact there are four or five recurring problems that we identify week after week.

One has been the problem of what happens with military recruits when they get together and someone comes in with measles. That is a correctable problem in the military. They are, in fact, attempting to correct that.

The second problem has been refugees coming from Southeast Asia with measles. That is a correctable problem. And starting in January, we have been doing immunization actually in the camps in Southeast Asia to try to stop that.

The third problem has been in day-care centers where we continue to find transmission even in very young children, 18 months and younger. That is potentially correctable by having day-care requirements the same as school requirements.

And finally there is the problem of importations from other countries. That may be more difficult to correct. We have an importation almost every week. Ultimately, it may require some change in our immigration regulations, but we have been surprised by how little spread there has actually been from importations from other countries.

I feel good about the measles elimination program. If anything, it is a little ahead of schedule from what I expected to happen.

ABSENTEEISM DECREASE

Senator SCHMITT. Have you made any attempt for—not specifically with respect to measles but other disease—the Federal Government to encourage supervisors to encourage their employees to stay home if they are sick? Is that a dangerous thing to do? We are trying to do it in our office, and we have already seen a marked decrease in the absentees, because if somebody comes in with the flu, we ship them home so that nobody else gets infected.

Have you looked at the possibilities of how to work that problem and not actually get an increase in absenteeism?

Dr. FOEGE. That is an extremely good question. We put a lot of attention on health promotion with our employees, but I cannot think of actual programs that have been aimed at trying to decrease absenteeism, other than the immunization programs.

Senator SCHMITT. But if you keep somebody out of their immediate work force, you eliminate most of the exposure. Certainly within the Government that could decrease absenteeism. It is a supervisory problem. If someone comes in, you send them home if they have the flu or something.

Senator SCHMITT. Would you respond to that question for the record? See if you can imagine any way in which such a program, or at least an educational program at the supervisory level, could be carried out.

Dr. FOEGE. This has been discussed, and the usual argument has been that by the time a person has symptoms, he has already reached his peak infectivity and exposed his coworkers to infection. It is hard to get ahead of infectivity.

I would be glad to answer this in more detail for the record.

[The information follows:]

EXCLUSION OF ILL EMPLOYEES FROM THE WORKPLACE

While there have been a few studies on disease transmission in physicians' offices, we are not aware of any similar research applied to the workplace.

TEMPERATURE REDUCTION

Senator SCHMITT. Do you see any effect of lowering household temperatures and workplace temperatures on the—on disease control?

Dr. FOEGE. We have not done any measurements in that area, so I can't answer that question.

Senator SCHMITT. Do you expect that there would be an effect?

Dr. FOEGE. I would not expect that there would be an increase——

Senator SCHMITT. Decrease.

Dr. FOEGE. I wouldn't expect to see a real change due to the environmental temperatures in workplaces, but I don't know that I could prove that.

Senator SCHMITT. Isn't there evidence to indicate that at 50 or 55 or even 60 degrees various viruses and bacteria have much more difficulty surviving than they would at 70 or 75 degrees?

Dr. FOEGE. There is information for many viruses in chambers of one kind or another. It has been pointed out how many of the viral diseases actually increase during the wintertime, and it is hard to separate temperature from crowded conditions at that time.

Senator SCHMITT. My impression was that when I spent a winter in Norway that there were very few Norwegians wandering around with colds. You question whether at 50 degrees—and by God, most of those public buildings were at 50 or 55 degrees and you wore a sweater and a coat and you wore it all day. It wasn't that bad as long as you kept moving your fingers. And I was just curious.

It seems to me that the exposure level would go down, just because it is harder for the airborne virus or the resting virus or the bacteria somewhere to survive.

Dr. FOEGE. We actually found the cold temperatures to be the problem times for some diseases, viral diseases such as measles and smallpox.

Senator SCHMITT. What do you see in Anarctica?

Dr. FOEGE. One has the problem there also of population density. [Laughter.]

HEALTH EDUCATION PROGRAM

Senator SCHMITT. Talk to the penguins. [Laughter.]

Are you working with parent groups at all in your educational programs? You mentioned schools and so forth.

Dr. FOEGE. Very much so. We have one particular health education program being used in 450 districts in 34 States. We have been working with PTA's and have had contracts with PTA groups for such things as sex education programs. What is the most effective way to get sex education into teenage groups? We have done a great deal of work with parent groups.

Senator SCHMITT. Can I add another thing to the list of preventing disease, and that is: getting enough sleep.

Dr. FOEGE. Dr. Breslow's study in California that I mentioned earlier stresses that as one of the eight or seven healthful habits: getting adequate sleep.

IMMUNIZATION OF MIGRANT CHILDREN

Senator SCHMITT. Every individual has different requirements for adequate sleep. I didn't know what mine was until I tried to fly jet aircraft, and then I found out quickly what it was for me. And it is about 7 hours. But I think it varies with the individual.

Senator Magnuson has been a long-time supporter of migrant health clinics, as many other members of the subcommittee. He asked if I would ask you what you were doing to insure that all children who visit these clinics—medicaid, in particular, as well as community health centers—are adequately immunized?

Dr. FOEGE. We have been working with State health departments, but also with the Health Services Administration on improving immunization levels in those hard-to-reach groups. In fact, with the second phase, this is one of the areas where we—that we consider high risk—where we are trying to develop systems to follow children from birth on. So, we are giving special attention to those groups.

Senator Chiles, would you like to move forward with some questions?

NUTRITION

Senator CHILES. I have been particularly interested in the last few years in the development of a comprehensive nutritional status monitoring system. The nutrition surveillance system that you run at the Center for Disease Control is a vital part of this system. It is based on finding actual health problems which can be treated, and that kind of information is critical for us to understand the problems which nutritional programs ought to be solving and get some geographical targeting for those problems.

As I understand your program, it costs very little because it mostly involves technical assistance to the States, who do all of the field operations. But that technical assistance involves some staff positions. I wonder if you would tell us how many staff positions you got out of those of what you requested last year and why specifically you need the additional staff that you requested this year?

Mr. BLOOM. Last year we did not request additional positions in the budget. We got additional funds. We did redirect some positions from other parts of the organization. We directed six into nutritional programs. And this year we are requesting eight additional positions to put us in a better position to further extend the nutrition surveillance program, which is based primarily on technical assistance. We have reached our limit in terms of what we can do in working with the States in establishing improved surveillance programs.

Senator CHILES. Would you tell me how you derived the goal of expanding from 30 to 35 States this system, and when do you expect to reach all 50? My understanding is you are running ahead of schedule, and you already have 30 States in and you can get more in by the end of 1980?

Dr. FOEGE. We are hoping to add five additional programs in 1980 and there are five that we are planning to add in 1981. I think last year we told you that we hoped to have all 50 States within 3 years. We are still aiming at that target. I am hoping that we can make it.

Senator CHILES. That would be within the next 2 years.

Dr. FOEGE. I am hoping we can make it within the next 2 years.

We are simultaneously trying to expand geographically and expand to the collection data from other high-risk groups. As you know, all of our data collection is geared now to children. Some States have also added on prenatal nutritional surveillance and some are now beginning to direct their attention to the elderly. So that it is a dual expansion that is taking place. I hope the geographic expansion doesn't slow down because of the increase in efforts to broaden the data base within States.

NUTRITION—INCREASED FUNDING

Senator CHILES. One of the major uses I see for your surveillance program is giving us a way to target nutritional programs on the populations which are actually experiencing nutrition-based health problems. In fiscal year 1980 we gave you increased funds and directed you to develop surveillance activities targeted to high-risk populations and validate national estimates of the surveillance of nutritional problems by conducting surveys in selected communities.

My understanding is your initial project you were looking at nutrition problems in various segments of the Hispanic population—Cuban, Mexican, Puerto Rican. Where do you stand on getting this project underway?

Dr. FOEGE. We are in fact developing a number of validation surveys at the present time. But we have not conducted a Hispanic survey. I would be happy to provide you with what we have to date on all the surveys, if you would like.

Senator CHILES. I would like that, and would like, Mr. Chairman, to have that information reflected in the record.

Senator SCHMITT. It will be so reflected.

[The information follows:]

NUTRITION SURVEILLANCE

The nutrition surveillance program coordinated by the Center for Disease Control receives information on children including those from various ethnic segments of the Hispanic population. The numbers of children and their geographic locations is dependent on the input from States collaborating in the system. The CDC is presently developing a series of local population based validation surveys to evaluate the accuracy of surveillance information obtained through service delivery programs and to estimate the magnitude of nutritional needs in the community. We plan for one of these surveys to be conducted in a community with a large Hispanic population. The CDC system does not conduct national population based probability sample surveys. These undertaken by the National Center for Health Statistics. The NCHS is currently developing a survey of the health and nutrition status of the U.S. Hispanic population. A pilot survey is to be undertaken in the fall of 1980 with the start of the total survey in 1981. Although the sampling frame has not been completely decided upon, major centers of Hispanic populations in the United States are planned to be surveyed.

COORDINATION WITH OTHER FEDERAL PROGRAMS

Senator CHILES. One of the ways we designed the nutrition system was to draw on the nutritional screening that was already being performed by the Federal health programs, particularly medicaid. It looks to me like these programs are still not feeding into your system, even after several years of instructions from this committee.

What efforts have you made to get medicaid and the various Federal grant programs, community mental health centers, family planning, et cetera, into your program? And where are the hangups in that?

Dr. FOEGE. I think that this is really a matter of experience on our part. We are trying to do a better job of getting both the medicaid information and also the WIC program for the Department of Agriculture. There has been improvement as we have learned better where to tap in order to get information. I think in many areas now, we have a good system that not only identifies high-risk groups but is able to identify high-risk individuals and get the names of individuals back to the States for followup.

Senator CHILES. Would you provide me some information to show me how that is working?

Dr. FOEGE. I would be happy to.

[The information follows:]

COOPERATION FROM OTHER FEDERAL PROGRAMS

Because the CDC coordinated nutrition surveillance system is primarily directed at the State level, most of our negotiations are with States to determine which service delivery programs will be responsible for providing data to the system. In some of the States we receive data primarily from early and periodic screening, diagnosis, and treatment screening with additional data from maternal and child health; women, infant, and children program; Head Start; and other service delivery programs. In other States, information may be submitted from federally funded programs such as community health centers through the State health department data gathering mechanism. We continue to have contacts with the service delivery programs in their national offices to gain their support and encouragement for participation of local programs in the surveillance system. Additional efforts must be made to develop and coordinate national interagency support for the nutrition surveillance component of service delivery programs.

The identification of an individual in need of specific medical or educational intervention and followup is made at the time of the initial examination. The reports sent back to the local clinics by the surveillance system identify those individuals whose screening values were below preselected cutoff points. This information is most useful as a management tool to determine whether or not individuals and groups of individuals who should have been referred for intervention were in fact referred. In addition, these listings of individuals provide a mechanism whereby States can assess the completeness of their referral system as well as providing a base to evaluate the effectiveness of specific, targeted nutrition interventions. The material sent back to the individual States includes summary tabulations of the prevalence of nutrition problems by region, district, county, and clinic, and is used for the purposes of program planning and allocation of resources, as well as the monitoring of time trends.

HISPANIC STUDY

Senator SCHMITT. Doctor, as a followup to that, does your Hispanic study include New Mexico in the Southwest, or is it looking at the urban Hispanic population?

Dr. FOEGE. My understanding is we are doing this throughout the 30 States where we now work, that it is not concentrated just in urban areas.

Senator SCHMITT. Is New Mexico one of those 30 at this time? Would you check that out?

[The information follows:]

HISPANIC STUDY

The Southwest, the south Florida area, and the metropolitan New York area will be included in the NCHS Hispanic survey. The sampling frame is likely to include some parts of New Mexico.

MEDICAID

Senator CHILES. We've got about 2 million kids in medicaid now. My understanding is we are not really getting that information which medicaid collects on nutritional problems.

Dr. FOEGE. I am not aware of major problems with this anymore. There have been problems historically, but I will be happy to look at that, because my understanding has been that we have settled or solved some of these problems.

DIABETES

Senator SCHWEIKER. Dr. Foege, first, I want to compliment you on your leadership and initiative in the diabetes control program. You folks have done an excellent job on that. And I guess you mentioned in your report, in your initial statement, you have over 20 projects.

How much have you spent on the new projects and how does this compare with what you did spend in terms of your first projects, roughly?

Dr. FOEGE. We are asking, Senator, for an increase this year to approximately $5 million for the 20 projects. We are not expecting to increase the number of projects in 1981, in order to increase the amount going into each project. We are now into the implementation phase for 10 of the projects. Two more will enter the implementation stage soon. And eight are entering the first phase this year. So that we should be able to increase the amount of money that is going into the actual implementation of phase 2.

Senator SCHWEIKER. Do you have any figures on how many people will be served either by these in the first 12 or the last 8 projects?

Dr. FOEGE. I have information only for the 20 projects where we are working, which represent 50 percent of the diabetic community in the United States. The 20 States have a population such that it should include half of all.

Now, I should stress that each project doesn't involve each person with diabetes because the projects tend to concentrate on people who, for one reason or another, are not getting into the system. So that many people will benefit only indirectly. The projects will try to focus on those who are not having their needs met by the current system.

Senator SCHWEIKER. What about your plans for 1981? What are your plans in terms of projects?

Dr. FOEGE. 1981, we will continue with the phase 2 in 12 of the States, phase 1 in 8 of the States. In these 12 states they have already implemented 30 different approaches. For instance, some of them are using third-party payment for education, ambulatory education, with the idea that if you can show third-party payment decreases the total cost, we should be able to get a third-party payment system implemented every place. Others are using education for providers. There are a series of different intervention projects that are being used, some 30 that we have counted in the 12 States.

Senator SCHWEIKER. How successful are you in getting other sources of funding? Anything else in addition to that third-party payment thing?

Dr. FOEGE. That is the major one. The States are, in fact, rising to the challenge. In this instance the States see this as a prototype for chronic disease prevention. The States, as you probably know, have been very enthusiastic. They have been as enthusiastic about this program as any that I can remember. They are putting their own resources and time into this.

TRICHLORETHYLENE

Senator SCHWEIKER. Last summer, as you recall, I asked CDC to get involved in the problem of trichlorethylene, or TCE, in Pennsylvania. We thought it was a local problem; but we have sightings in other States, and we have learned a lot more about it. And it seems to be a national problem.

I wonder if you could give us a brief, current assessment of the problem?

I would like to ask Dr. Hopkins, who has been working on this, to summarize.

Dr. HOPKINS. We have become aware that it is a chemcial used industrially and in drycleaning. This is an example of this whole area of chemicals in the environment. We have become aware that the problem is not just limited to Pennsylvania. We are beginning to conduct a survey of people who were exposed to contaminated drinking water and also to conduct surveillance of drinking water itself.

I believe we will then be in a position to know how this changes as spring comes, when melting snow might change the amount of TCE in people's drinking water.

Senator SCHWEIKER. How many States have you had reports from or some kind of statistical record from, in regard to this problem; do you recall offhand?

Dr. HOPKINS. I don't recall the exact answer to that.

Senator SCHWEIKER. Would you get that for the record?

[The information follows:]

STATES WITH CONFIRMED TCE CONTAMINATION

At the present time, CDC is aware of only four States with confirmed TCE contamination: Pennsylvania, New Jersey, Maine, and California. Further data may be available from the Environmental Protection Agency which is surveying toxic waste dumps at the present time.

Dr. FOEGE. One of the difficulties with these chemical problems versus the infectious disease is that one of the approaches has to be to create a register and then perhaps hold that register for 10 or 15 or 20 years before one can make final answers.

Is this a health problem, or is it incidental?

LEGIONNAIRES' DISEASE DEVELOPMENTS

Senator SCHWEIKER. In your opening statement I noticed you also mentioned Legionnaires' disease, and since we can claim origin, or at least discovery of it——

Senator SCHMITT. You mean the committee? [Laughter.]

Oh, you mean Philadelphia. [Laughter.]

Senator SCHWEIKER. I just wondered whether there was any significant developments in terms of the environment or the sources of the infection since we last talked?

Dr. FOEGE. This continues to be an exciting field. Last year we mentioned that this was a whole new family. We have now found four subgroups of Legionnaires. And, in addition, the investigation of Legionnaires' disease has now led to three entirely different categories that we are calling Legionnaire-like organisms, but they are not Legionnaires. They appear capable of causing pneumonia.

We are pursuing that. But it looks like four different kinds of bacterial agents now that have resulted from that. We are finding both the Legionnaire organism and the Legionnaire-like——

Senator SCHWEIKER. Where do you classify them?

Dr. FOEGE. We are classifying them all as bacteria, but they are unlike any previously classified bacterial agents. They are new bacterial organisms. We are finding both Legionnaires and Legionnaire-like orga-

nisms widely in the environment as our system for identifying organisms has improved. We are finding it in lakes, rivers, mud. We are finding it in air-cooling systems of air conditioners. We are finding it in many areas.

We are asking for additional funds in 1981 to improve our ability to find the organisms in the environment and our diagnostic capabilities for patients, so that we can diagnose early enough to give proper treatment.

In addition, we would like, in 1981, to see whether preventive maintenance of large air-conditioner systems can prevent disease and whether there are chemicals that can be used to purify systems.

Senator SCHWEIKER. How many cases of Legionnaires or Legionnaires-like diseases were there last year?

Dr. FOEGE. We are limited to the ones diagnosed in the laboratory, and there were less than 1,000. But when we do surveys, we are convinced now that there are probably about 25,000 cases of Legionnaires pneumonia every year.

Senator SCHWEIKER. Would you provide that for the record so that we have a comparison of our analysis, as shown, since it was discovered?

Dr. FOEGE. We would be happy to.

[The information follows:]

LEGIONNAIRES' DISEASE

The following data represents the number of known sporadic cases from 1970 through 1979:

STATE	TOTAL	STATE	TOTAL
AL	24	MN	9
AK	0	MS	5
AZ	4	MO	19
AR	10	MI	2
CA	53	NE	13
CO	5	NV	1
CI	62	NH	7
DE	3	NJ	53
DC	6	NM	3
FL	86	NY	31
GA	32	NC	17
HI	2	ND	22
ID	5	OH	68
IL	58	OK	8
IN	29	OR	3
IA	53	PA	88
KS	9	RI	3
KY	23	SC	3
LA	16	SD	1
ME	11	TN	56
MD	19	TX	30
MA	37	UT	4
MI	36	VT	13
		VA	30

Total known cases 1,072

The following data represents fundings of all known outbreaks of Legionnaires' disease in the United States:

Time	Place	No. of Cases
July-August, 1965	Washington, D. C	81
July, 1968	Pontiac, MI	144
August, 1973	James River, VA	10
September, 1974	Philadelphia, PA	20
July-August, 1976	Philadelphia, PA	221
July, 1977 to present	Columbus, OH	(15)*
May, 1977 to present	Burlington, VT	Ongoing (69)
August-September, 1977	Kingsport, TN	(33)
May, 1977 to present	Los Angeles, CA	Ongoing (135)
January, 1977 to present	Bloomington, IN	Ongoing (39)
July, 1978	Atlanta, GA	8
December, 1976 to present	Norwalk, CT	Ongoing (28)
August-September, 1978	Memphis, TN	39
August-September, 1978	New York, NY	38
August-September, 1978	Dallas, TX	18
June-July, 1979	Eau Claire, WI	12
July, 1979	Jamestown, NY	7

LEGIONNAIRES

Senator SCHWEIKER. Do you have a figure in terms of how much more you are asking for in 1981 versus 1980?

Dr. FOEGE. Yes; in 1980, and in previous years, our work on the Legionnaires' has been in the epidemic services class, so we are, in 1981,

for the first time asking for money specifically for Legionnaires. We are asking for $1 million.

GONORRHEA INCIDENCE

Senator SCHWEIKER. Last year you told us that about 50 percent or less of the 2 million gonorrhea cases were being reported. Has this figure changed? And what progress are we making in terms of detection of syphilis, as well?

Dr. FOEGE. The figure has probably not changed much since last year, but now we have had 4 years of fairly stable rates for gonorrhea. And, at the same time, diagnostic tests have been improving.

We think the gonorrhea epidemic has peaked. But that still means 2 million cases a year. It is still a huge problem. We are beginning to put more of our attention now on the effects of gonorrhea—that is, pelvic inflammatory disease, sterilizations, hospitalizations, the surgical operations required.

Senator SCHWEIKER. What indications have we that interferon might be a possible cure or treatment? And I understand that we are limited because of production costs.

Dr. FOEGE. Potentially, interferon would be effective against the viral forms of venereal disease, particularly herpes and hepatitis B.

And all I can say is that I hope this turns out to be true and proves to be useful once the recombinant system begins producing.

Senator SCHWEIKER. There is no question about pursuing it once it is economically feasible?

Dr. FOEGE. My guess is once it becomes available there will be numerous clinical trials for every viral disease.

TUBERCULOSIS VACCINE

Senator SCHWEIKER. A recent study by CDC noted that two strains for TB vaccine used in developing countries were found to be ineffective. What meaning, if any, does that have?

Dr. FOEGE. We have been concerned for some time, Senator, about using the vaccine in this country for a couple of reasons. We have not found a good way to evaluate each vaccine to test whether it was good or not. It seemed the only way to do this was to look at human, clinical studies that take years to develop.

The second thing, BCG interferes with the skin test which we use as a diagnostic technique to determine who has been infected with tuberculosis. So for that reason we have not recommended BCG for routine use in this country. The Advisory Committee on Immunization Practices has said if it is used at all that it should be used in very isolated situations.

I think this study has a great deal to say about the use of BCG internationally. The World Health Organization is calling together a group in April to look at the results of this study which was done in south India, make recommendations on the scientific interpretation of this. And 2 or 3 months later the World Health Organization will call together a group of health leaders to ask the question: Should we change our systems of using BCG in the world or not?

I think it is a very troublesome study that may mean that BCG has not been very effective in controlling tuberculosis.

Senator SCHWEIKER. I understand that we have a serious setback in that we find resistance. Can you tell us about that?

RESISTANT TUBERCULOSIS

Dr. FOEGE. That is true, Senator. While the incidence of tuberculosis continues to decline in this country—and I believe we have the lowest incidence in the world—last year we reported about 27,000 cases. Despite that, we have for the first time reported an outbreak of what is called triply resistant tuberculosis. It is resistant to all of the three first-line drugs that are usually used in tuberculosis therapy. We have been very concerned with this, looking for alternative ways of treating tuberculosis.

We believe that it is possible, but it will be more expensive to treat tuberculosis with the other antibiotics.

While we have the lowest rates in the world, I think that in the coming year we will see the incidence of tuberculosis drop off even faster than it has in the past, despite the problem of resistance, if we continue to concentrate on it.

Senator SCHWEIKER. I know that Dr. Hopkins has worked on yaws. I would like a report on how we stand with the CDC on this program?

Dr. HOPKINS. We sent a team of our people to four West African countries, where they were able to confirm that there has been a resurgence of yaws in the last few years. They confirmed that in a population of 10 million people in Ghana, approximately 350,000 people in southern Ghana require treatment or prophylaxis for yaws.

We have since been able to negotiate an agreement with the Ministry of Health in Ghana to allow us to place one person in Ghana to help them control the problem.

We had some delay in that agreement because the government was reluctant to accept assistance only for yaws; they wanted us also to assist them with the yellow fever problem. We have now agreed to, at the same time, give money and technical assistance to work against both yaws and yellow fever.

We are also talking with Togo to see in what ways we can be of assistance to them.

OCCUPATIONAL SKIN DISEASE

Senator SCHWEIKER. Finally, in our fiscal 1980 report, Dr. Foege, the committee advised CDC to strengthen research, education and training, and data collection, in coordination with other agencies to step up the attack on occupational skin disease.

What have we done in this regard?

How much money will be spent on occupational skin disease in fiscal years 1980 and 1981?

Dr. FOEGE. We have had a good report on that. I would ask Dr. Robbins to summarize.

Dr. ROBBINS. Senator, as you know, both OSHA and NIOSH in the last year produced reports on occupational skin disease and indicated

that this was probably the most common form of occupational disease. It afflicts more people than any other disease reported. But it probably has not received as much attention in the past as it should have in terms of research.

Our response has been to use these reports to develop a request for applications, trying to bring researchers, mostly dermatologists, into the field of occupational health to look at the field of occupational skin disease, much as they have been using their scientific techniques to look at other aspects of dermatology.

We have gotten that out. I have met with the professors of dermatology and with the dermatological community. They are very pleased that we seem to have been able to translate what we see as occupational health problems into language that they can understand what the dermatological issues are.

We have set aside up to $2 million over the next 3 years to fund proposals in this area. In addition, my meetings with the dermatologists—I think we will work on a variety of joint training efforts. We will try to find ways to rotate dermatology residents and fellows through the NIOSH system. I have been very pleased with this.

Senator SCHWEIKER. I think it is a good report, and I think the figure that strikes me—and I am sure it strikes you—is that approximately $1.5 billion in medical costs can be attributed to skin diseases in our system. This includes nearly a half billion dollars in hospital costs. So it is a fertile field in terms of doing some preventive medical practice.

I appreciate your interest and support of this, and I think you are embarked on a meaningful program.

That's all I have, Mr. Chairman. Thank you very much.

Senator SCHMITT. Thank you.

COST BENEFITS OF PREVENTION

Some followups that came to mind as the last little bit of questioning occurred. Has your organization, Doctor, made any attempt to relate the cost benefits of prevention versus cure versus treatment? You understand what I am saying?

Dr. FOEGE. Yes, I do.

Senator SCHMITT. The committee is always faced with how to allocate resources, and one way to make that judgment is to know where those resources have the greatest cost benefit. Obviously, if you are preventing a disease, you don't have to treat it. But what is the cost of learning how to prevent it and then of implementing a prevention program.

Polio is probably one of the greatest examples of where we clearly saved a great deal, not only economically, but in human suffering, by finding a prevention. Cure is another one. Once a disease occurs, if you can cure it and you don't have to treat it forever, then that also, presumably, in theory anyway, would have an advantage.

Dr. FOEGE. We have done a number of studies. One has to classify this into two areas, areas where one can probably make a case that prevention costs more, but leads to better quality of life; and, No. 2, areas where you can show that prevention results in money being saved. In

61-400 O - 80 - 17

the last category, it is clear that polio is our best example. A dollar invested will save about $90 in health care costs.

Our second best example is in fluoridation, where a dollar spent on fluoridation probably saves about $50 in dental care costs.

For the immunization programs in general, we can show favorable benefit-cost ratios. We can also show benefit-costs of better than one for tuberculosis programs and for VD programs.

Now, in the second category, it is probably possible to make a case that if we are successful getting people to stop certain bad habits, the person, instead of dying of an acute coronary at 49, may live another 10 or 15 or 20 years. Some people have said that in both cases you end up with a terminal event that costs money, but you now have 20 more years of medical care, so that prevention of that attack at age 49 has resulted in more health care money.

I think one has to come up with a factor of person-years in this. I think the reason one does that is to improve quality of life, rather than that we can prove that there will be a reduction in health care costs.

Senator SCHMITT. Of course, you add to that argument the productivity of that human being in the time that you postpone that heart attack or the cancer, or whatever may finally kill them. Also, we are faced with the choice at times of putting money into the development of treatment systems, dialysis being one example, versus that of trying to figure out how in the world do you prevent kidney disease from ever occurring.

KIDNEY TRANSPLANT

Dr. FOEGE. This is a good example even if one cannot prevent kidney disease. There are about 50,000 people in this country with kidney disease. About half are eligible for transplants, or are people that could benefit from transplants. But we are transplanting only about 3,400 to 3,700 kidneys a year.

The problem seems to be in finding kidneys that can be used for transplantation. We have been working in a program the last several years to show that by doing education in the right places—that is, with people who are likely to find donors, such as people working in emergency rooms with emergency services in certain wards of the hospital. We have shown we can increase the number of kidneys transplanted. We can double and triple over a period of years how many kidneys are transplanted, which improves the quality of life and decreases costs.

MIGRANT WORKERS

Senator SCHMITT. You mentioned earlier the migrant, or I asked a question about the migrant workers. Do you find that you are also treating and assisting the so-called illegal migrants, particularly those from Mexico, in your activities with migrant labor?

Dr. FOEGE. We find——

Senator SCHMITT. You make no attempt to distinguish?

Dr. FOEGE. We do not. And in fact, when we have done surveys in places like southern California to look at the dislocation of resources because of Southeast Asian refugees, we find that is insignificant com-

pared to resources going into the health care for illegal migrants. So they are included wherever we can.

Senator SCHMITT. So the record is clear, again, the productivity argument relates there also. The migrant is producing through labor in the economy, which in turn helps support the cost of their care. I think that studies have pretty well shown recently, at least, that that productivity is far in excess of the total care that they are receiving, whether they are entitled to it or not.

LACTASE

Another question that came to mind as I listened has to do with lactase. Some years ago—and I don't know why it came to mind today, but maybe it is a subject—was there not a lactase, if I have the right enzyme, deficiency in the black population of the country, particularly among children? And does this create any susceptibility to disease if they are weaned prematurely, for example, if they are in fact fed by the mother?

Dr. FOEGE. I have a pediatrician I can turn to, Dr. Hopkins.

Senator SCHMITT. I was hoping we might have an expert.

Dr. HOPKINS. As far as I know, that has been shown to be a problem to a larger extent in the black population. But as I recall, it is not a significant problem in the pediatric age group. It would be a problem of increasing importance as certain people grow to adulthood. It is not associated with any increase in susceptibility to disease, to my knowledge.

Senator SCHMITT. The reason I ask, my own family, my sister had a problem of taking milk other than mother's milk, and she had a very difficult childhood. And the doctors I remember in those days were attributing many of her diseases, her problems, including an allergy to horse serum, potentially to that problem of not being able to take milk.

Now, this was in the 1940's, and I am sure we know a great deal more now. My mother could not provide her with as much milk as she required. Finally they found that she could take goat's milk, I guess.

Dr. HOPKINS. That is a different problem from the lactase one. It is not related to that enzyme. Allergy to cow milk is much more frequent, and that doesn't vary with racial differences.

Senator SCHMITT. You are saying that you don't see in children any evidence of disease susceptibility because of this problem?

Dr. HOPKINS. Because of the lactase problem.

Senator SCHMITT. That goes for adulthood.

Dr. FOEGE. We ran into that problem in the relief action in Nigeria.

Senator SCHMITT. Yes; I was visiting Nigeria and they had a—they delighted in telling me the story of all the milk they sent over there and couldn't use it. He didn't delight in telling me, but he told me the story.

Dr. FOEGE. There were a number of things that couldn't be used.

FLUORIDATION

Senator SCHMITT. The fluoridation program which you mentioned earlier, a GAO report dated April 13, 1979, said that tooth decay affects

every person in the United States and is a tremendous financial burden to the public and the State and Federal Government.

You just indicated the cost-benefit ratio of maybe 1 to 50 in fluoridation programs. The national caries program, which was established in 1971 to research tooth decay prevention, has made progress. But there has been no measurable decrease in the national incidence of tooth decay. Do you agree with that statement?

Dr. FOEGE. I am not sure that I agree with that statement. I would have to look at the figures.

Senator SCHMITT. The report goes on to say, "Greater emphasis is needed in promoting water fluoridation, a proven cost-effective technique for reducing tooth decay. Fluoridated water can prevent up to 65 percent of all children's tooth decay, which benefits going into adult life. A Public Health Service survey indicates that over 67 million Americans continue to be served by nonfluoridated public water systems."

I suppose that the naturally fluoridated systems are relatively minor, is that correct?

Dr. FOEGE. It is a small part. If I, for the record, could indicate the discrepancy between 36 and 50. We have used for years the cost-benefit ratio of 1 to 36. A study recently done in Michigan, I believe, now indicates that that may be 1 to 50 rather than 1 to 36.

Senator SCHMITT. The President included a request of $9.5 million in 1981, an increase of $2.8 million over the previous year and representing a continuous increase over the years before that. What impact will this increased funding have that you can see?

Dr. FOEGE. Two areas. We will be improving on the many community systems that already have fluoridation, because we found in a survey that 43 percent of them have inadequate fluoridation; instead of being at the optimal level they are 20 percent below. That results in a 50-percent reduction in beneficial effects.

No. 1 will be improving the systems already in effect. No. 2, this is part of an expansion which, over a 10-year period, should cover about 67 million people in about 6,000 different communities. The money for fiscal year 1981 should enroll about 5¼ million people into fluoridation systems who did not have fluoridation before this.

So it is part of a long-term, about a 10-year effort.

Senator SCHMITT. Would you expect at the end of that 10-year period to have made a significant dent in the $900 million dental health bill.

Dr. FOEGE. I would think that there would be a significant effect, particularly——

Senator SCHMITT. I am glad we didn't use the word "debt."

Dr. FOEGE. I would expect it to be——

GOALS FOR FLUORIDATION PROGRAM

Senator SCHMITT. Do you have any goals or projections or any feeling for progress?

Dr. FOEGE. We believe that, for instance, the $9.5 million being asked for this year will effect, over a period of time, a difference of 50 times that amount. We have set up some long-term goals that I don't have in

front of me for reduction in caries. But we would expect this $9.5 million would in fact mean about $400 million in savings.

Senator SCHMITT. If you spend over the next 10 years $10 million a year, that is $100 million. And I can expect to see—have the country only pay, in current dollars, $4 billion for dental health care. Is that too simplistic?

Dr. FOEGE. I would have to get some help from a good statistician to be sure.

Senator SCHMITT. Yes, certainly, a good mathematician. [Laughter.]

But we might look at that; a factor of 2 decrease in the cost of dental health care?

Dr. FOEGE. This is an area where it should all be measurable, we can say what will happen and measure to see if it happens. We believe, on the basis of the systems already in effect, that is what will happen, 65 percent reduction in caries.

Dr. ROBBINS. You are talking about reducing caries. There is a tremendous backlog in other dental needs. As you start to look at how dentists are employed and what they do, you are not necessarily going to see the amount of money going out to dentists for all dental care.

Dr. FOEGE. For caries.

Senator SCHMITT. I presume right now most of that $9 million is related to caries work, right?

Dr. FOEGE. There is a lot of reconstructive work that would be done, a lot of replacement, artificial teeth, and so forth, that would be included in that.

Senator SCHMITT. Your cost-benefit ratio will go down as you become successful, presumably. It will be harder and harder to get a dollar spent with $50 in care, as you reduce the amount of care required.

Dr. FOEGE. That's right.

Senator SCHMITT. If you kept your funding level.

COMMUNITY OPPOSITION

To what extent do communities that don't have fluoridation not have it because they are opposed to it?

Dr. FOEGE. We have found surprisingly little opposition by and large, and we are spending this money for startup costs—communities that already want to start. We are not forcing anyone to start. Communities that want to start, we are helping them with startup costs, the development of surveillance systems, technical advice, and so forth.

We are finding surprisingly little opposition.

Senator SCHMITT. There is some organized opposition.

Dr. FOEGE. There is. The organized opposition has, I think, in the last 6 months or so voiced its opposition to Congressmen.

Senator SCHMITT. Do you put any credibility or have you evaluated formally the study done on fluoridation—the relationship between fluoridation and cancer by Dean Burk and his associate?

Dr. FOEGE. We have asked the National Institutes of Health and the National Cancer Institute to look at this. It has been looked at closely. I believe they have in previous testimony indicated that they do not see this as being a valid study. They have not been able to show any

increase in cancer. The National Cancer Institute has not been able to show any increase in cancer to be ascribed to fluoridation.

HEALTH EDUCATION

Senator SCHMITT. In the area of health education, how are the health education activities carried out by you different from those run by the Office of Disease Prevention, Health Promotion, Physical Fitness, Sports Medicine, and the Office of the Assistant Secretary for Health in Washington or the school health program in the Department of Education?

Dr. FOEGE. The programs with the Assistant Secretary of the Public Health Service are very much geared toward developing policy—for the Public Health Service—for coordinating what is done, while our activities have been to work with States on grant programs. And much of what we do is grant programs or to work with grants and contracts for specific problems as it relates to immunization or as it relates to smoking, so that our health education activities are very much geared toward specific things, while the Assistant Secretary for Health has been working in a broader area, in a policy area.

I think the programs complement each other. I don't think they compete.

Senator SCHMITT. You don't find yourselves stumbling over each other as you go to educate people on health matters?

Dr. FOEGE. We work closely to prevent that from happening.

Senator SCHMITT. Is there any reason to have two entities and one in Education for health education?

Dr. FOEGE. I think there has to be some coordination at the Public Health Service level—policy people looking for generic approaches to health education. But I also believe that there is a very strong need for health education in every aspect of public health services—that venereal disease people need to be doing health education specifically for their target groups. They can't, in fact, abdicate that responsibility. Each target group is slightly different and requires different health education.

SMOKING ACTIVITIES OVERLAP

Senator SCHMITT. Then Secretary Califano announced his targets against tobacco smoking, but when last year's budget was sent to the Hill, you decided one of your objectives was "improving the health status of the American people by encouraging healthful lifestyle choices with respect to tobacco." I hope you didn't write that.

Are these overlapping activities between what you were doing and the rest—HHS was doing?

Dr. FOEGE. The smoking program in the Department is a program that we work with closely. In fact, we detail some of our people to that program. We make every effort not to overlap. Much of our smoking effort comes in the health education grants as part of a broader look at how to improve health. I think it is safe to say that we don't compete in this area at all.

Mr. BLOOM. I think you can see that we are not competing by the fact that there was a DHEW task force that was looking at what should

be done with the smoking and alcohol program run in the Office of the Assistant Secretary for Health. That task force recommended that CDC be the organization that would administer the $10 million grant program. We are providing the administrative support and tying it in with our health education grants so that we aren't having multiple competing grants out there.

And in the review process of the applications, the other members of the task force are going to participate in the review. Actually we are not competing, we are cooperating and cutting down on what could potentially be a double administrative overhead.

Senator SCHMITT. What is your prognosis for the smoking initiative that Califano put forward and presumably has been continued since his departure? Will it do any good?

Dr. FOEGE. I think it will do a great deal of good. I think there is no simple answer.

One answer has to be to make as much information available to people when they make this choice and to keep them as informed as possible. I think the actual smoking rates have decreased. If we were still as a people smoking at the rate of 20 years ago, there would be some 20 million more smokers in the population because the denominator has increased since then. I think there has been an effect, and the effect will continue.

SIDESTREAM SMOKE

Senator SCHMITT. Because of the use of highly filtered cigarettes, are nonsmokers getting significantly greater exposure to tobacco?

Dr. FOEGE. It is hard to answer the question of the effect of sidestream smoke.

Senator SCHMITT. My nasal characteristics are the result, I think, of smoke from this weekend, and I am sensitive to it.

Dr. FOEGE. There is no question that many people are sensitive to smoke, but you can actually show that children living in households where both parents smoke have higher rates of respiratory diseases and pneumonia during the first year of life. There are some indications that sidestream smoke does have adverse effects, but it has been hard to quantify.

UNWANTED ADOLESCENT PREGNANCIES

Senator SCHMITT. Another objective that was listed among last year's priorities was one "to support promising and innovative educational approaches to such high-priority health problems as unwanted adolescent pregnancies." Given the fact that there are at least two other major programs directed toward this problem, the adolescent pregnancy program run by the Office of the Assistant Secretary for Health and the family planning program run by the Health Services Administration—in addition the family planning services funded by medicaid and the social services of the Social Security Act—do we really need another program run by CDC?

Dr. FOEGE. Many of the programs are aimed at improving contraceptive advice, the supply of contraceptives. What we are specifically looking at, which I think is different from anyone else is what has been

done in sex education programs before, how many of them have had some evaluation of outcome, and are there some things that can be replicated in the future.

We found that very few sex education programs in the country have had any evaluation phase to them at all, so it is hard to tell what the results are.

We have recently published the work of two or three programs where one can show a decrease in pregnancy rates in high school students. We are learning something about what to put into health education projects in sex education.

QUALIFICATIONS FOR SEX EDUCATION PERSONNEL

Senator SCHMITT. All of these programs that relate to education at the school-age level, do you have in those positions—administrative as well as technical positions—people with experience and preparation in school health education?

Dr. FOEGE. We certainly do. But we also end up——

Senator SCHMITT. I don't mean people who came out of school with some kind of a degree, but people who have been out there working for a significant number of years.

Dr. FOEGE. We do, and the person who has coordinated the sex education project has been working in trying to deliver sex education programs up until this time. We also contract with people who have this kind of skill, so it is a combination.

Senator SCHMITT. Is it on a competitive basis or peer review?

Dr. FOEGE. Competitive basis.

Senator SCHMITT. But you evaluate the prospective contractor on the basis not of just what they've said they would charge you but on the basis of what experience they have had in this field?

Dr. FOEGE. What they have been able to do before.

Senator SCHMITT. You don't have to take the lowest bid?

Mr. BLOOM. We set up technical criteria that would take into account what is called the professionalism and experience that they are bringing to it as well as the nature of their proposal. Then after there has been a technical review, there is, shall we call it, a business management review.

ADVISORY STRUCTURE FOR SCHOOL HEALTH EDUCATION

Senator SCHMITT. Do you have an advisory structure including Government but also nongovernmental professional, or at least non-Federal Government professional experts that you consult prior to establishing school health education priorities?

Dr. FOEGE. We do not have a chartered group, but we do, in fact, for each one of these have a group that we call in to advise us.

Senator SCHMITT. I would like to have you spend a minute saying what your prediction is for general success of the programs under your jurisdiction with the level of funding that has been provided to you this year.

Do you think you can continue to make the kind of progress that I think you have articulated fairly well today? Are we in a retrenchment or hold-harmless type of situation?

Dr. FOEGE. While there are not large increases, what is significant in the budget for 1981 is how we have shifted priorities, how much money we find going into prevention facets—for instance, the prevention formula grants to States, the new health education grants, Legionnaires'. I think we are capitalizing on prevention opportunities, and I think we are very much following the recommendations of an ad hoc group that we had 2 years ago to advise us on what are the major priorities in the United States.

I feel good about having used their priorities in our zero-based budgeting system, and we are finding our budget more and more devoted to the priorities. I expect we will be able to continue the gains in the areas that we have designated: immunization, VD, and so forth.

ZERO-BASED BUDGETING

Senator SCHMITT. I am sorry you mentioned zero-based budgeting. I had forgotten about it. [Laughter.]

I am not a big fan. It doesn't mean that you don't evaluate your programs and how they are doing—I believe in that very much—but do you find in your efforts at zero-based budgeting that the big programs with the bigger constituencies tend to get more justification than the small programs with small constituencies?

Dr. FOEGE. We try hard——

Senator SCHMITT. Dollar programs.

Dr. FOEGE. We try hard in our zero-based budgeting process to start, before we look at any of the programs, with a list of priorities that we have in mind. I think there is a tendency always for a program that is large and has existed before, to be more difficult to cut back.

But I think the way we have used the system, we have improved the efficiency of CDC in the last several years.

Senator SCHMITT. I hope you are right. I know it takes an awful lot of effort to go through that every year. That is what concerns me.

My experience in NASA was that once you got to the assistant administrator level, you never did anything except go through budget cycles. It is ridiculous—absolutely ridiculous. Some day we may get smart enough to have a 2-year budgetary cycle and then get rid of zero-based budgeting as a principal base for conducting that cycle.

Mr. BLOOM. I am not sure that zero-based budgeting is to blame for the amount of time spent in the resource allocation process. At least in our case, we had been doing that even before zero-based budgeting.

Senator SCHMITT. That's what I mean.

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

HOSPITAL INFECTIONS

Question: Last year you estimated that two-million times a year, a person enters a hospital and acquires an infection he did not have upon entry; resulting in 80,000 deaths a year. This accounts for 2 percent of all beds occupied, and accounts for medical costs of $1,000,000,000 per year. Last year, CDC proposed that by 1984 it could decrease this by 20 percent -- thus, saving $150,000,000 and 12,000 lives -- if an increased appropriation were approved. How are you achieving this decrease in infections?

Answer: The Hospital Infections Prevention and Control Initiative has 3 major phases. In the first phase, improved patient-care practices and improved hospital infection control programs will be introduced through various mechanisms. Guidelines for infection control are being developed that focus on the major types of infections that are preventable and lead to the greatest morbidity, mortality, and excess costs. Guidelines for components of infection control programs are also being developed. Incentives for hospital implementation of these guidelines are being developed, both by working through other agencies and groups--such as the Joint Commission on the Accreditation of Hospitals, State Health Departments, the American Hospital Association, and the Health Care Financing Administration--and through continued education of medical care providers. State and local health departments will be supported in developing skills and resources for evaluating and assisting hospital infection control programs, through training programs as well as limited financial support for demonstration projects. Training programs and technical support are being developed for hospital personnel responsible for developing infection control programs.

In the second phase, the Initiative calls for development of monitoring systems to provide feedback about the progress of the Initiative. Infections will be monitored so that changes in the occurrence or the epidemiology of nosocomial infections can be recognized promptly and dealt with. Implementation of infection control programs in hospitals will also be monitored so that modifications in Initiative strategy can be made if necessary.

In the final phase, the impact of the program will be assessed.

Question: What has been your success to date?

Answer: Beginning in FY 1979, the first year of the Initiative, the following activities have been initiated or completed:

- Development of Infection Control Guidelines: 1) statistical analysis of data from the SENIC--Study on the Efficacy of Nosocomial Infection Control --Project, 2) development of guidelines for prevention of urinary tract infections and for hospital environmental control activities, 3) began development of 2 additional guidelines: prevention of nosocomial bacteremia and activities of effective hospital infection control personnel, and 4) planned dissemination of guidelines to all United States hospitals, to begin in FY 1980.

- Encouraging implementation of guidelines: 1) descriptions of the scientific bases of the SENIC Project accepted for publication, 2) International Conference on Nosocomial Infections planned for August 5-8, 1980, 3) liaison established with important regulatory and advisory groups that influence hospital infection control activities, 4) initiated a project to characterize existing infection control regulations at national and local levels in order to identify conflicting requirements, those in need of revision, and those that are consistent with guidelines, 5) initiated development of Information Clearinghouse for effective infection control strategies, 6) initiated inventory of existing training programs in hospital infection control, and 7) initiated evaluation of existing training programs to evaluate effectiveness.

- Monitoring of infection data: initiated design of system.

- Monitoring of implementation of programs: began design of monitoring system.

LABORATORY IMPROVEMENTS

Question: It is my understanding that clinical laboratory certification is a matter that is delegated to the States rather than the Federal government. If this is the case, what is the role of the CDC in ensuring uniform and high-quality laboratory standards?

Answer: Under an Interagency Agreement between the Public Health Service and the Health Care Financing Administration, approved on March 17, 1979, concerning the administration of Departmental programs affecting clinical laboratories, the Center for Disease Control is responsible for developing scientific and technical standards in the areas of quality control, proficiency testing, personnel requirements, and records, equipment, and facilities. These standards are applicable to laboratories licensed under the Clinical Laboratories Improvement Act of 1967--CLIA 67--and to laboratories certified for reimbursement under Title XVIII of the Social Security Act. A primary thrust of this activity includes the development of uniform standards for uniform application.

CDC is conducting a program of proficiency testing for laboratories licensed under the CLIA 67. This program includes the distribution of mailed samples on a quarterly basis, evaluation of results submitted by licensees, distribution of quarterly performance reports and summary analyses--critiques of performance, and the distribution of annual summaries of performance with recommended changes in techniques and methodologies.

CDC is monitoring the performance of State agencies and approved accreditation bodies--such as the Joint Commission on the Accreditation of Hospitals, the College of American Pathologists, and the American Osteopathic Association--with respect to an evaluation of how effectively and uniformly the State agencies and approved accreditation bodies are applying Departmental standards. Areas which are in need of upgrading are identified and remedial measures are recommended to HCFA.

CDC is also determining training needs and designing and presenting seminars and courses for State Agency Surveyors, HCFA Regional Office Laboratory Specialists, and representatives of approved accreditation bodies. Approximately 1,600 man-days of training were provided during 1979. In addition, technical consultation is provided through manuals, telephone calls, and extensive correspondence.

HCFA responsibilities under the Interagency Agreement include the initial surveys and annual resurveys of licensed and certified laboratories working through State agencies, the issuance of licenses and necessary certification documents, and the execution of any adverse actions which may be necessary with respect to the termination or limitation of licenses, or the Medicare certification status of clinical laboratories.

Question: For what sorts of activities is the $18.3 million appropriated in FY 80 being used?

Answer: The $18.3 million supports a multifaceted laboratory improvement program with the objective of improving the capability of the Nation's clinical laboratories to provide medically useful diagnostic results for patients as they provide curative and preventive services to the population. Reduction in laboratory diagnostic error rates is essential to meet this objective and as an aid in reducing health care costs. In addition to its responsibilities in ensuring uniform application of high quality laboratory standards CDC is also involved in technology transfer, diagnostic product evaluation, clinical laboratory evaluation, and methodology development.

In 1981 the CDC will be involved in conducting 170 field and headquarters courses in all disciplines of laboratory diagnostic techniques for 3,800 laboratory professionals. Also, training manuals are provided for laboratorians and teaching institutions throughout the world.

Diagnostic product evaluation involves premarket testing of commercially available diagnostic products as well as off-the-shelf testing. Efforts are directed toward products which have the most clinical and public health significance including both venereal disease and non-venereal disease reagents as well as media. Results of these evaluations are distributed to the Food and Drug Administration and to 5,000 laboratories throughout the world.

In FY 1980, in accordance with an Interagency Agreement between the Health Care Financing Administration and the Public Health Service, the Center for Disease Control is monitoring approximately 600 clinical laboratories per year as an aid in ensuring the uniform and effective application of Departmental standards by States and approved national accrediting bodies; is developing and updating

consensus standards in the areas of quality control, proficiency testing, and personnel; is conducting training sessions for 50 State surveyors with respect to the proper interpretation and application of clinical laboratory standards; is conducting research and developmental efforts with respect to improved evaluation methodology; and is conducting proficiency testing programs for approximately 3,500 clinical laboratories. Approximately 350,000 samples will be distributed in 1980.

One of the most important aspects of a total laboratory improvement program is that of assuring that effective diagnostic methodology is available to support the health care system. Emphasis at CDC is on development of new methods and improvement of existing methods for increased sensitivity, reliability, and reproducibility of results. Some examples of these developmental activities in FY 1980 are improving the test for measuring pneumococcal antibodies of recipients of new polyvalent vaccine thus enabling effective monitoring of existing strains as well as emerging pneumococcal strains using enzyme-linked immunosorbant assay technology; developing direct immunofluorescent test for demonstrating presence of Legionnaires' disease organism in body tissue, body fluids, and respiratory tract secretions as a rapid diagnostic test of Legionnaires' disease; developing an immunological test which identifies the most dangerous pathogenic fungi in 24-48 hours where previous tests required 2-3 weeks; and developing a technique to mass produce specific hybridoma antibodies to a wide variety of individual microbial strains which will be especially significant in understanding the antigenic differences between virus strains especially influenza, polio and encephalitis viruses thus enabling the development of more specific laboratory tests and more effective surveillance activities.

NEW-BORN SCREENING

Question: Virtually all infants are screened for phenylketonuria, an inborn error of metabolism. There exists a gap, however, in the screening for six other conditions -- galactosemia, homocystinuria, maple syrup urine disease, tyrosinosis, hypothyroidism, and histidinemia -- that can cause mental retardation if untreated. What cooperative activities exist between CDC and State Health Departments relative to new-born screening?

Answer: On the technical side, the Center for Disease Control has in operation a consultative and assistance program of support for new State and regional programs expanding their existing phenylketonuria programs into the screening of neonatal hypothyroidism. Collaborative testing of laboratory proficiency in these programs is in place, employing already developed testing materials mimicking the field collection of samples--blood sample--for thyroxin and thyroid stimulating hormone levels. Efforts are under way to assume the national responsibility for providing uniform testing materials for PKU analyses.

Question: When do you anticipate the adoption of a more thorough program of screening by State health authorities?

Answer: Owing to the extremely high costs of universal screening programs particularly on the basis of costs per case detected--usually below 1 in 10,000, it is imperative that the laboratory detection tests be as sensitive--i.e., miss as few cases--as possible and at the same time be as selective--avoid false positive diagnoses--as possible. Although the technology exists for detecting the listed metabolic defects, practical field methods for collecting adequate samples and the need for economical and efficient laboratory testing present problems of adaptation, development, and transfer of improved technology. These difficulties should be resolved before incompletely planned or supported programs are established. These questions and approaches to their solution were addressed in a national conference developed and sponsored by the Center for Disease Control in August 1979. A sustained program, based upon planned expansion as the means for effective testing are developed and validated, is recommended; this will require several years of State and Federal collaborative effort.

RAT CONTROL

Question: In the Department's FY 81 Budget Justification for this program, it was stated that priority for funding is given to those agencies which have developed sound programs and which have a significant local financial commitment. What happens to urban areas that do not have "sound programs" because of poor planning capabilities, but have a significant need for funds to control rat infestation? Are such communities provided technical assistance from the Department to develop sound programs, or do they go without funding until they can improve their program planning on their own?

Answer: Technical consultation and assistance in program planning and development are provided to these areas so that acceptable program plans can be developed. Management workshops for key personnel are held in order to improve grantee manage-

ment performance. Community outreach workshops are conducted several times during the year to improve skills for enlisting community support of the program. During this year, two program managers' workshops are scheduled to discuss urban rat control and related environmental health matters. These workshops are designed to improve technical and managerial skills of all rat control program managers.

Question: With the increasing fiscal crises being experienced by our Nation's largest cities, can we realistically expect urban centers to maintain a "significant local financial commitment"?

Answer: The inflation rate and movement to reduce governmental expenditures has the potential of reducing the resources available to urban rat control programs. However, to date, State and local contributions to the urban rat control grants continue to increase, though at a lesser rate than 5 years ago.

Question: How many communities are now "rat free" due to this program?

Answer: The Urban Rat Control Grant Program is based on the concept that Federal grant funds will assist communities to reduce environmental deficiencies and associated rat infestation to a manageable level and generate adequate local resources to sustain environmental improvement achieved when Federal grant support is terminated.

To date, 27 communities have achieved this goal. An additional 48 communities are in the process of achieving that goal. In most cases, these communities have assumed responsibility for sustaining the improved environmental status in some neighborhoods and have directed federally supported efforts to additional needy neighborhoods in the community.

Question: How many must we still work on?

Answer: Approximately 270 urban areas contain neighborhoods with significant rat infestations and environmental deficiences. Since 1969, when Congress first established grant authority, 97 communities have received Federal support. This leaves approximately 170 communities that require comprehensive urban rat control services. We do not know the extent of rat control efforts that State and local governments are supporting in the 170 communities which have not received Federal grants.

Question: How many communities will be receiving funding for rat control projects for the coming year?

Answer: Fifty-seven program communitites will receive Federal funding to conduct comprehensive rat control programs in the coming year.

Question: Are any of these new grantees? Or are they all repeat grantees?

Answer: We anticipate that 2 of these 57 will be new program communities. Fifty-five communities will receive continuation funds for conducting rat control programs. In addition, new subtarget areas will be designated in at least 10 of these 55 communities.

Question: What levels of local support are you getting from grantees in this program?

Answer: State and local communities commit over $25 million annually for support of this program. In addition, approximately $11 million in other Federal funds such as CETA and Community Development have been generated by local communities for support of this program. Since the inception of the program in 1969, there has been a substantial increase in State and local support of this program as follows:

Year	Local
1969	$5,504,045
1972	5,708,877
1975	17,118,456
1978	25,498,172
1979	26,703,696

Question: If any program should be locally supported it seems as this one should. Comments?

Answer: We estimate that it costs $650 per year per block within inner cities to achieve rat free status. After it is achieved, about $35 per block per year are required to maintain that status. In the past, local communities have not had adequate resources to initiate a comprehensive rat control program. Federal funds are gradually reduced and eventually terminated as State and local resources increase to sustain program accomplishments. Federal funds serve the purpose of generating local funds. For example, for every Federal dollar expended, $2 in State and local funds are used.

FORMULA GRANTS FOR PREVENTIVE HEALTH SERVICES

Question: P.L. 95-626 authorized a new program, Section 315, of formula grants to the States for preventive health services. Under this authority, each State would establish a program to reduce excess morbidity or mortality from one or more of the five leading causes of death in the States. The first year of the program, FY 1980, was to be a planning year for the States, with implementation of the program to begin in 1981. Was the planning for this program carried out in all the States?

Answer: No funds were appropriated for the planning phase in FY 1980 but some States, in anticipation of the program, have initiated planning for preventive health services.

Question: Will they be ready to implement preventive services in FY 1981?

Answer: Yes, we anticipate at least 34 States will submit applications for Section 315. However, since the planning year was not funded, we propose that certain kinds of planning and development activities be carried out during 1981 in addition to service delivery.

Question: What areas are the States concentrating on as they plan preventive services under this program?

Answer: For most States, the five leading causes of death--heart disease, cancer, stroke, accidental injury, and pneumonia/influenza--are the same as the five that lead the nation, although the order occasionally changes--for example, accidents are the leading cause of death in Alaska, Arizona, and New Mexico. In a small number of States, other causes of death make the top 5--for example, diabetes in Delaware, suicide in Alaska, cirrhosis in California.

Question: Can you see any trends toward any one or a few health areas to the exclusion of others?

Answer: There are no indications at this time. FY 1981 will be the first year that applications for grants will be submitted.

Question: Is the program getting substantial support from State and local governments?

Answer: Yes, considerable interest has been shown by State and local health officials through written communication and discussions in their public health conferences. In addition, some States, responding to the momentum of prevention, have initiated pilot programs which could serve as the base for future prevention activities.

Question: In light of the two hypertension programs we are already funding as well as the cancer control program and the alcohol, drug abuse and mental health centers--wouldn't this be a duplication of Federal dollars to provide these funds?

Answer: While prevention formula grant funds may be spent for some of the same activities as these other programs, the prevention formula grants are intended to complement, and not duplicate, the other programs. Hypertension, cancer control, and alcohol, drug abuse, and mental health program funds may be spent only in these categorical areas. Prevention formula grants, on the other hand, will allow a State the flexibility to direct funds toward reducing whatever are the leading causes of mortality and morbidity in that particular State.

In addition, efforts to reduce these major causes of death and illness must be directed at multiple risk factors and causative conditions. As an example, smoking, hypertension, elevated blood cholesterol, lack of exercise, diabetes, and stress are all risk factors associated with heart disease. The prevention formula grants provide the States with a means to coordinate all efforts to

reduce heart disease, for example, which categorical programs addressing a single risk factor, such as hypertension, lack the authority to do.

Furthermore, these prevention formula grants are geared to institutionalizing prevention as a major issue for the States to address, in concert with health care delivery. Implementation of these programs will also serve the stated legislative intent of providing initial resources to allow States to build preventive health capacity for the future. We believe this is an important long term strategy.

COMPREHENSIVE PUBLIC HEALTH SERVICES GRANTS

Question: Congress has found individual health status can be effectively and economically improved through an adequate investment in community public health programs and services. How is this task being taken out of the hands of the Federal government?

Answer: Comprehensive Public Health Service Grants are authorized under Public Law 95-626 and entitled Health Incentive Grants. The incentive aspects of the legislation allows States and local areas to receive additional grant funds if, in effect, their comprehensive public health expenditures increase from locally or State derived funds. Thus, a community which elected to make additional investments in public health during FY 1980 to utilize the incentive option would gain an additional share of the State's award in FY 1981, at what ever level of funds appropriated. The incentive, of course, becomes greater as funding increases. The State, however, has no incentive provision at the appropriation levels for FY 1980 or the level requested for FY 1981. This is a result of the legislative clause that "grandfathers" each State award when the appropriation is below the FY 1979 level. As indicated in the response to the following question, State expenditures have nonetheless been increasing, and the 314d appropriation has constituted a decreasing share of total public health expenditures in recent years.

Question: Congress has found that the Federal government and the States and their communities share in the financial responsibility for funding public health programs. What is the State "share" in these programs?

Answer: On the basis of expenditure data gathered through a uniform national reporting system maintained by the Association of State and Territorial Health Officials, we project that Health Incentive Grants provide less than 2 percent of the funding for comprehensive public health services.

Question: Congress has found that the Federal contribution to funds for public health programs should serve as an incentive to an additional investment by State and local governments. Can we in fact demonstrate that these funds are seed money or do the States just rely on this contribution?

Answer: It is too early to tell since the incentive aspect of the legislation didn't become effective until FY 1980. The result conceivably could be seen in FY 1981 when the local expenditure data is compared with 1980. Some States, as they have done for years, rely on these funds to support vital disease efforts such as tuberculosis control and laboratories that process specimens for a number of different programs. The States provide an assurance that these funds will supplement, not supplant, non-Federal funds. Since the funds for certain activities in some States traditionally came from grant funds, supplanting did not occur.

Question: In his budget request for FY 1980, the President proposed a decrease in funding of $38.0 million and 63 positions from the previous fiscal year. What is the status of these position cuts?

Answer: Positions were restored for FY 1980 through conference action and are included in the President's FY 1981 budget request.

Question: How many of these cuts have been made and how many more are yet to be made in FY 1981?

Answer: Since the positions were restored in FY 1980, no cuts were made and the Center for Disease Control continues to use the positions to assist State and metropolitan areas in the implementation of comprehensive public health programs.

BUILDINGS AND FACILITIES

Question: It has been some time since new construction or even major modernization programs were conducted in Atlanta. Does this mean that all of your buildings are in A-1 condition?

Answer: We share your concern that CDC facilities are well maintained and modernized where necessary to prevent obsolescence. In the FY 80 budget, the Center received $1,431,000 in Repair and Improvement funds, a large portion of which will be used for Atlanta area facilities. Further, an additional $3,300,000 was appropriated for laboratory safety, a portion of which will be used for facilities improvements.

In the FY 81 budget, for the Atlanta area, we have requested $1,348,000 for the design of a new high hazards laboratory for Clifton Road and $1,700,000 for a new animal facility at Chamblee. Further, for general Repair and Improvement for all CDC facilities, including Atlanta area, we have requested $1,431,000.

In addition to funds for the Atlanta area, the FY 80 budget provides $6,600,000 for an addition to the Taft Center in Cincinnati, Ohio and the FY 81 budget includes a request for $25,000,000 for an addition to the NIOSH facility in Morgantown, West Virginia.

We will continue to work in the future, as we have in the past, to insure that the CDC facilities are well maintained and that requests for funds for major new construction or modernization are submitted so that our programs will continue to be supported by an excellent physical plant.

Question: It is our understanding that you do some hazardous research at CDC. Do you have the proper equipment and containment facilities?

Answer: Four of CDC's Bureaus are regularly engaged in activities involving both indigenous and exotic infectious agents as well as a variety of toxic chemicals. The Bureau of Laboratories regularly provides reference diagnostic services and support to State public health and other laboratories dealing with the full scope of infectious diseases of humans occurring in the United States. Additionally, the Bureau of Laboratories' Maximum Containment Laboratory serves as the primary national facility for diagnosis, production of diagnostic reagents, and applied research on exotic and highly hazardous viral diseases such as the viral hemorrhagic fevers--Ebola fever, Lassa fever, Bolivian hemorrhagic fever--Rift Valley fever and yellow fever. A separate containment laboratory serves as the only national facility for the diagnosis of smallpox. This laboratory also is the principal support laboratory for the WHO Smallpox Eradication Program.

The Bureau of Laboratories' Toxicology Laboratory also regularly works with a variety of toxic and ultratoxic chemicals—e.g., dioxins—and provides support to epidemiological investigations and other environmental assessments.

The Bureau of Epidemiology's Epidemic Services Laboratory provides direct field and laboratory support and services to epidemic investigations of domestic outbreaks of bacterial diseases.

The Bureau of Tropical Diseases' laboratories regularly work with malaria, vectors of malaria and other arthropod transmitted parasitic diseases, and provide analytic support to vector control activities utilizing pesticides.

The National Institute for Occupational Safety and Health's laboratories in Cincinnati, Ohio and Morgantown, West Virginia regularly work with toxic materials, carcinogens, substances that could affect reproductive and nervous systems, and substances that could affect liver and kidney functions. The laboratories also do research in radiation and thermal stress.

Based on an assessment of the hazards involved and of the laboratory activity we are confident that appropriate primary and secondary containment equipment and facilities are provided. As the mission and function of the Center continue to evolve, it is reasonable to predict that present facilities and equipment will not be able to provide proper service for increased responsibilities. These needs could best be addressed by providing an additional laboratory facility incorporating moder laboratory design and physical containment which would further assure a high level of safety for the laboratorian, the environment and the community. Funds for the design of just such a faciltiy--$1.348 million--are requested within this budget.

INTERNATIONAL HEALTH

Question: During the past several years, CDC has expended significant funds internationally—estimated at over $7 million a year. CDC's approach to disease control and prevention is becoming more "global" in scope which would indicate even larger future international expenditures. Also, CDC has involved itself in aiding Indo-Chinese refugees. None of these activities has specific legislative authority. In what international health activities is CDC involved and why?

Answer: The Center for Disease Control conducts research pertaining to international health problems in defense of the health of the American people. Example: Lassa fever research project in Sierra Leone, West Africa.

The Center extends epidemic or disaster assistance to other countries, usually at the request of the United States Agency for International Development's Office of Foreign Disaster Assistance or the World Health Organization. Example: Evaluation of medical situation in Mauritius following storm and alleged epidemic of typhoid.

CDC undertakes operational international health programs under interagency agreements with the USAID. Examples: Assistance to government of Cameroon for Expanded Immunization Program.

The Center provides technical training for health workers from other countries—sponsored by USAID, WHO, or their own governments. Example: Global EIS program being initiated in Thailand.

The Center also assigns staff to international organization such as WHO. Example: Director of WHO's Smallpox Eradication Program was a CDC employee.

CDC has legislative authority to conduct international health research in defense of the health of the American people, to assign members of its staff to international health organizations, to undertake interagency agreements with other Federal agencies and conduct programs defined in those agreements under that other agency's legislative authority. CDC also has foreign quarantine authority.

CDC's international health activities are important because they provide the U.S. with an "early warning" of evolving public health problems before they reach the U.S., they allow us to take advantage of unique field situations, they sometimes produce knowledge and/or experience applicable in the U.S., they are a means of expressing U.S.'s humanitarian concern for other peoples, and they sometimes save the U.S. money.

The authority for CDC's international activities come from several sources. For quarantine related activities the authority is Sections 361 through 369 of the Public Health Service Act.

For activities involved with the screening of immigrants the authority is Section 325 of the Public Health Service Act.

Section 307 of the Public Health Service Act authorizes the Center's international research and demonstration activities.

Cooperation between CDC and other federal agencies concerned with international activities such as USAID is authorized by 31 U.S.C. 686, The Economy Act; Section 327 of the Public Health Service Act; and Section 632 of PL 87-195 the Foreign Assistance Act of 1961.

The Center's authority to cooperate with international organizations such as WHO comes from 22 U.S.C. 290, Executive Order number 10399.

Question: How are CDC's activities coordinated with other agencies that provide international health assistance?

Answer: CDC's international health activities are coordinated with other agencies by formal interagency agreements, by informal contacts between scientists working in areas of mutual interest, by presence of current or former CDC staff in some international agencies, and by regular, close communication with other agencies relevant to individual CDC activities.

Question: Why is CDC needed in the processing of Indochinese refugees?

Answer: The CDC has two statutory responsibilities which directly relate to the immigration of refugees to the United States: the Quarantine Division of

the Center for Disease Control, PHS, is mandated to protect the U.S. population from communicable diseases associated with entry of people into this country from foreign lands; and, the Center for Disease Control, in support of the Immigration and Naturalization Service, is responsible for developing and overseeing the procedures for and the technical validity of medical screening of foreign nationals for purposes of visa issuance.

Question: What role does it play?

Answer: The role of the Center for Disease Control within the international assistance program for Indochinese refugees is: 1) evaluate and sustain the quality of overseas medical screening of United States-bound refugees and implement immunization programs for these refugees; 2) inspect all refugees at U.S. ports of entry and their medical documents; 3) ensure prompt accurate notification of each refugee's arrival to State and local health departments with particular attention to those with active--class A--or not-active--class B--tuberculosis including immunization programs; and 4) assist in developing and implementing effective public health measures which will reduce the incidence of death and disability in refugee camps in Southeast Asia.

Question: How does it coordinate with other relief agencies?

Answer: The CDC coordinates its activities with international agencies involved in providing assistance in the refugee camps. CDC personnel assigned overseas work directly with the United Nations High Commission on Refugees staff at the camps as well as the national and international relief organizations--International Rescue Committee - IRC; Church World Services - CWS; U.S. Catholic Conference - USCC; Luther Immigration Refugee Service - LIRS; etc.--to facilitate refugee movement and resettlement in this country. An additional functional role is that of providing medical oversight to the Intergovernmental Committee on European Migration -ICEM- in directing the medical screening process overseas for refugees seeking resettlement in the U.S.

CDC has also provided medical epidemiologists to the staff of the International Committee for the Red Cross -ICRC- to work in the Kampuchean Refugee Camps in Thailand. The ICRC has had the major role of coordinating medical relief for these camps. CDC personnel define medical needs and determine resource allocations to meet these needs.

PROGRAM MANAGEMENT

Question: How much of your budget will be used on travel in fiscal 1979? In fiscal 1980? In fiscal 1981?

Answer: In fiscal 1979 $4.488 million was obligated for travel. It is estimated that $5.091 million will be obligated in 1980 with $5.320 million requested in the fiscal 1981 budget. It should be pointed out that these amounts have been reduced substantially from last year's estimates in order to effect a savings that will be applied to the cost of pay raise. Also, even without giving consideration to the travel required for new or increased program activities requested within this budget, the increase that is requested for travel will not offset the effect of inflation.

Question: How many new positions will be established within CDC with the fiscal 1981 budget?

Answer: Fifty new positions will be established within CDC with the fiscal 1981 budget; however, there will be a net increase of only 42 positions due to a program decrease of 8 positions associated with the phase out of influenza grants.

DISEASE SURVEILLANCE AND CONTROL

Question: In a March 13, 1979 letter to the Secretary, GAO recommended that the CDC Director establish information systems and processes that will assess the quality of CDC's surveillance data and changes in the States' abilities to handle changing disease problems. What efforts has CDC made to improve or test surveillance data and to identify changing State epidemiological capabilities?

Answer: A series of evaluation studies, surveys, and major and minor revisions of national surveillance systems operated by CDC have been undertaken in the last year and a half:

A national survey of State and territorial epidemiologists to examine present surveillance efforts and to obtain suggestions for improvement has been

completed. Results indicated that surveillance data are used extensively for disease control efforts, and data published weekly in the Morbidity and Mortality Weekly Report are a frequently used source of information for disease control and program development by these State officials. Two new areas of increasing interest were highlighted in this report: noncommunicable disease surveillance and use of computerized data handling systems for surveillance purposes.

Studies are underway in two State health departments to evaluate the timeliness, accuracy, reliability, and completeness of the present morbidity surveillance system, and to explore the possibilities of other surveillance approaches in providing local and national surveillance data.

A stratified random sample of 123 local health agencies were surveyed to determine the usefulness and effect of State, local, and national epidemiologic services regarding measles. A similar survey will be undertaken of hepatitis and salmonellosis surveillance activities in order to gain a better understanding of local abilities and needs.

The Manual of Procedures for National Morbidity Reporting and Public Health Surveillance Activities is used by all State and territorial health agencies as their primary guide to reporting conditions of public health importance. CDC updated this manual last year and has made a commitment to update this manual annually in the future.

The 1978 Annual Summary of the Morbidity and Mortality Weekly Report reflected the careful rethinking of content and format. The resulting publication, distributed to 50,000 persons upon request, was more readable and included epidemiologic data on communicable diseases as well as chronic and noncommunicable conditions. The response to this publication has been very positive from State and local agencies who use this data for surveillance, disease control, and program development.

A new model of analyzing pneumonia/influenza mortality data utilizing time series analysis has been developed and is being evaluated during the 1979/1980 influenza season. The design and application of this sophisticated statistical technique represents a significant first step in improved analysis of surveillance data at the Center for Disease Control.

Question: Will such effort provide information to help CDC to better determine its proper role in disease control?

Answer: All of these efforts help CDC to define an appropriate role in disease control by defining the State health agency's expectations of CDC. For instance, the national surveillance survey reconfirmed the understanding that most State epidemiologists feel current national surveillance is very important to their mission and should be continued in the same fashion in which it is being done, with the exception of increased computerization to handle data. These efforts define new priorities for furture CDC activities. For instance, CDC found that about 80 percent of the state epidemiologists think indepth national surveillance of noncommunicable diseases in selected areas of the country could provide data useful for program policy; about 2/3 feel that this program policy would lead to reduction of morbidity and mortality. These efforts also confirm or dispell CDC's perception of the role of State and local health agencies. For instance, the national measles surveillance survey indicated that most local health officials routinely investigate each reported measles case, and State health departments have a strong impact on setting local measles control policy.

Further, 17 State epidemiologists have requested and received consultation on design, expansion, and/or improvement of State disease surveillance systems. This consultation, as well as a close working relationship with the Conference of State and Territorial Epidemiologists, provides a mechanism to keep CDC up-to-date and responsive to State goals and needs which shape CDC's role.

Question: In the same report--see above, GAO recommended that CDC determine the need for its continued role in training epidemiologists and clearly identify the priority of its training program in relation to States' needs for assistance. Under what authority does CDC train epidemiologists?

Answer: CDC trains its Civil Service employees under the authority contained in the Government Employee's Training Act--PL 85-507--and its Commissioned Officers under authority contained in Section 218 of the Public Health Service Act. The formal training of EIS Officers consists of a 3-week course given at CDC during the first 3 weeks of an EIS Officer's employment, followed approximately 4 months later, by a 2-week surveillance course,

including 1 week on occupational safety and health. After the 3-week course, EIS Officers are assigned to State or local health departments or remain at CDC for the duration of their 2-year assignment. Thus, training, per se, does not interfere with service delivery. In fact, the "learning while doing" approach which the Center used for its EIS Officers during this 2-year period permits discharging of national responsibilities for disease prevention and control, obtaining and using scarce medical personnel resources to effectively assist in meeting national, State and local needs, and increasing the number of trained medical epidemiologists available for Federal employment and for the health community at large.

Question: Does training conflict with service provision?

Answer: No. The Epidemic Intelligence Service is unique and without parallel or precedent anywhere in the world. Epidemic Intelligence--the provision of immediately available, accurate and insightful, quantative epidemiological information to decision makers--is the service that CDC provides upon request to State and local health departments, as well as to other branches of the Federal government including the Department of State and appropriate international bodies, such as the World Health Organization, as well.

The formal training of an EIS Officer is provided during the first 3 weeks of an EIS Officers employment. For the remainder of the two year assignment, training and development is gained through the "learning while doing" approach. After the three week training course, EIS Officers are assigned to State or local health departments or remain at CDC. This permits the Center to accomodate the needs of the States while assuring effective supervision and training of the young officers. How this relationship actually works is best illustrated by example:

Recently, the CDC was notified of an outbreak of unusual respiratory disease among workmen who were refurbishing ore ships. The first year EIS Officer assigned to the State as Assistant State Epidemiologist discussed the outbreak with appropriate senior health officials at CDC, including NIOSH, and the State and local level, as well as with officials at the company involved. The State Health Department requested CDC's assistance in investigating the outbreak. The Center responded by assigning a second year EIS Officer with extensive specific experience in investigating respiratory disease outbreaks to assist the EIS Officer in the State and the State and local health department to investigate the outbreak. The investigation is continuing. This example illustrates several advantages of the "learning while doing" approach. The needs of the State for medical epidemiological competence are being met; the first year officer is broadening his base of experience by participating in the investigation; the second year officer is lending his experience and expertise to the investigation and consulting with State and local and company health officials; and by assisting the State in controlling the outbreak, potential interstate or international spread of disease was prevented thus fulfilling a direct Federal responsibility.

Question: Could epidemiologists be better trained elsewhere?

Answer: We believe that CDC has developed a unique and effective way to discharge national responsibilities for disease prevention and control, obtain and utilize scarce medical manpower to effectively assist in meeting national, State, and local needs, and increase the number of trained medical epidemiologists available not only for Federal employment, but also for the health community at large.

We do not believe that the Nation's need for epidemiologists is being met through the Schools of Public Health. We would cite the conclusions reached by the National Research Council and by the Task Force for Research, Planning, and Environmental Health Sciences. Both of these organizations recognized a growing need for epidemiologists. Additionally, the workshop "Matching Needs and Resources in Epidemiology and Biometry" cited by GAO referred to shortages of epidemiologists in the United States, in both acute and chronic disease areas, as well as in health service areas. At this workshop, the shortages were estimated to be in the range of 1,500 epidemiologists. The estimated number of students--with prior medical degrees--to graduate in epidemiology from the 16 Schools of Public Health surveyed in 1975--Masters and Doctorate programs--was 90. In this regard, we continue to receive large numbers of requests for epidemiological assistance, both in terms of participating in investigations or in providing advice and consultation. Furthermore, 15-20 States and major cities are actively recruiting epidemiologists.

Notwithstanding the above, the CDC is taking several actions to improve the training of medical epidemiologists.

Using 1 percent Evaluation funds the Center will, in FY 1980, carry out an evaluation of EIS training activities. Evaluation will include the descriptive enumeration of specific work functions that EIS personnel are expected to perform. Qualitative and quantitative performance measures will be established and determinations made as to gaps between what should be done and what is being done. Corrective intervention will be taken as appropriate. The evaluation will be completed by December 31, 1980, and recommendations acted upon within 3 months thereafter.

On August 2-3, 1979, the Association of Schools of Public Health--ASPH--met at the CDC to discuss with Dr. William Foege, Director, CDC, and other CDC staff prospects for closer collaboration between the Schools and CDC. A number of specific ventures were proposed and agreed to. These included that CDC will help develop with the Association of Schools of Public Health small working groups to explore each of the following areas for potential collaborative efforts.

There will be a working group on performance systems for disease prevention and control--including their development and use. The working group will be identified, the meeting will be held and the action plan developed by September 30, 1980 with implementation by March 31, 1981.

There will be a working group on preparation of future public health personnel resources--including the identification of types of qualified personnel that will be needed in the future and developing plans to ensure that these personnel are available. The working group will meet and produce an action plan by December 1980 for implementation by July 1981.

There will be a working group on Preventive Medicine Residency programs--including the purpose of the program, the best work-study experience to ensure that the purposes are accomplished, and the relationship required among the Schools, CDC, and other organizations to accomplish these purposes. The working group will meet and produce an action plan by September 30, 1980 with implementation by March 31, 1981.

DIABETES CONTROL PROJECTS

Question: In fiscal 1980 our Committee advised CDC that it intended that sufficient funds be made available to maintain current commitments on diabetes control projects and to expand the program into a total of 20 States. Have you complied with the Committee on this?

Answer: Yes. In fiscal 1980 Diabetes Control Programs in the 12 existing States will be maintained and new control programs will be initiated in eight additional States for a total of 20 States.

Question: How much will you spend on each new project? Is this sufficient and does it compare with funding for each of the first 12 projects?

Answer: Between $100,000 - $125,000 will be expended in the planning phase of each new project compared to an average of $150,000 for each of the first 12 projects. This amount is sufficient to complete the planning and assessment activities of each new project.

Question: How many people will be served in total by this program when the new Projects are in place?

Answer: While the new Projects will be selected on a competitive basis, we expect that the 20 States will encompass at least 50 percent of the U.S. population and include every DHEW region. While specific interventions in the project States reach a small, but well defined segment--5-10 percent--of each States diabetic population, demonstration results from these targeted interventions coupled with ongoing capacity building activities--epidemiology, surveillance, planning, evaluation, coordination--will potentially benefit diabetics. For example, Maine and New York are conducting Model Ambulatory Education Programs in a variety of settings--hospitals, rural health centers, Indian Health Centers--partially funded by 3rd party payors. In fiscal 1980 these programs will reach approximately 4,000 diabetics and the results evaluated to determine the program's effectiveness in reducing Diabetic complications hospital days and costs. If successful, 3rd party ambulatory education reimbursements will be extended elsewhere.

Question: What are your plans for fiscal 1981? How many additional States do you plan to have projects in?

Answer: In fiscal 1981, no new State programs will be added. Current intervention and capacity building activities in the 20 States need to be more fully implemented and evaluated before expanding from demonstration settings to comprehensive, statewide programs in order to insure maximum future benefits. More specifically, information and experience gained from all of the intervention projects will be coupled with the results from epidemiologic studies and other demonstration activities to develop specific guidelines and recommendations on a nationwide control program including patient and professional education programs, diabetic pregnancy screening and follow-up, cost containment initiatives in reducing hospital days, third party reimbursement practices, program performance standards and evaluation measures, and a national diabetes morbidity and mortality surveillance reporting system.

Question: In the administration's fiscal 1981 budget documents, it says the 20 State programs will be expanded. How much does the budget allow for this expansion?

Answer: This budget requests $380,000 and 4 new positions for this purpose.

Question: Has the diabetes control effort been successful in securing support from non-federal sources, insurance companies, and so forth.

Answer: Yes. Third party payors such as Blue Cross, Medicare, Medicaid, Home Health Agencies and Health Maintenance Organizations are actively participating in the cost containment initiatives and demonstration activities in a number of project States. Several State legislatures have also appropriated funds for their programs. There are also numerous examples of substantial in-kind contributions and resources obtained from non-federal sources. One long term goal of the national program is for the project States to not only become self sustaining but to improve the match between existing community resources and needs.

LEAD-BASED PAINT POISONING

Question: Lead-based paint poisoning received $11.8 million in fiscal 1980 and you are requesting $10.8 million for 1981. Is lead poisoning experienced primarily by children, or are adults equally susceptible?

Answer: The child up to age 6 is more susceptible to the adverse effects of lead ingestion because that is the time that the nervous system is developing. The nervous system and the blood forming system in children are susceptible to lower levels of lead than are generally considered toxic for adults. In adults the primary organs involved are the kidneys and the heart.

Question: When lead poisoning occurs in adults, it is more often occupational in nature or are there other major sources?

Answer: Lead poisoning in adults is usually occupational in nature. Among other causes are exposures that arise from the use of lead in hobbies such as cut glass surrounded with lead.

Question: What is the primary cause of lead poisoning in children? Is lead-based paint still a major source of lead poisoning today or have we seen an increase in lead poisoning from other factors?

Answer: Lead-based paint in the child's environment is the major high dose source of lead available to the child. The other high dose source of lead is soil and dust. Contributing factors of lead in soil and dust are lead-based paint, previous land use by a lead-related industry, and lead deposited from automobile emissions and industrial air pollution. Our evidence indicates that the lead in air from automobile emissions does contribute to the child's total blood lead level. In itself, it usually does not elevate the blood lead level enough to cause metabolic abnormalities. However, because of its contribution to the total blood lead level, less lead from high dose sources is necessary to produce lead poisoning in children who are exposed to lead in air, dust, etc.

Question: Has there been a significant decrease in lead poisoning due to lead-based paint since the inception of this program?

Answer: Yes. In cities where the lead program has been operating for several years, there has been a marked decrease in the number of severely poisoned children with lead encephalopathy. However, as we learn more about

the hazardous effects of lead, we are increasingly concerned about lower level toxicity having adverse effects on the child's learning ability and behavior, even if it does not produce metabolic abnormalities.

Question: How many individuals are in danger of experiencing lead poisoning due to environmental hazards?

Answer: There are roughly 15 million children ages 1 through 5 in the United States. We estimate that about 1 percent of these children will have absorbed enough lead to produce metabolic effects.

Question: How many are being served?

Answer: The Lead-Based Paint Poisoning Prevention Program is screening approximately 500,000 children per year and finding about 35,000 per year with lead toxicity.

To increase this prevention effort, we are working closely with the Early and Periodic Screening, Diagnosis, and Treatment Program, the child health programs of the Health Services Administration and the Women, Infants, and Children Program of the Department of Agriculture to increase the number of children screened and to coordinate the environmental lead-based paint poisoning prevention effort. All three of these programs are actively encouraging the screening of children being served in their programs. The Center for Disease Control has developed training to help others understand the nature of this problem and the complex interagency relationships necessary for the environmental correction. The Health Care Financing Administration has ruled that the investigation of the child's environment for lead is required as part of the treatment for children identified with lead toxicity and that this investigation is reimbursable at the same Federal Financial Participation Rate as is diagnosis and treatment. This year, the Internal Revenue Service ruled that the removal of lead-based paint hazard from the environment of a dependent child with lead poisoning is deductible as a medical expense from Federal income tax, provided it was ordered by a physician.

Question: How many individuals are being supported by other Federal governmental programs due to the long-term effects of lead poisoning, and what is the approximate amount of such support?

Answer: We do not know the number of individuals who are institutionalized for mental retardation caused by lead poisoning. However, one of the more subtle effects of lead is the psychological deficit and behavioral disorders that result in educational underachievement for children. It has been estimated by a medical economist that over $820 million in special education costs are incurred annually to correct the lead induced deficits in classroom performance of children residing in standard metropolitan statistical areas.

HAZARDS OF RADIOACTIVE FALLOUT

Question: Could you provide for us a summary of the latest findings from studies of personnel exposed to radiation during nuclear weapons tests conducted in the 1950's?

Answer: The Center for Disease Control has been trying to ascertain the health status of 3,224 military participants present at the nuclear test, Smoky, detonated August 31, 1957. Up to the present time, we have been able to contact 78 percent of these persons and have learned the following: 304 are reported to have died from all causes and 312 were expected to be dead at the end of 20 years; 120 participants have cancer of some form--not counting 31 non-melanotic skin cancers--and 98 would have been expected by chance alone if this group was no different than any other group of United States males of comparable size; leukemia and melanoma appear to be increased when compared to the expected number for each disease; cancers of the digestive system have occurred less often than expected; 9 leukemia cases have been reported--8 confirmed by medical records--in the 3,224 Smoky participants, a statistically significant increase; and 8 melanoma cases have been reported in the Smoky participants, also a statistically significant increase. If the leukemias and melanomas are excluded, there is no overall statistically significant increase in cancer incidence.

Question: Statistically, are these personnel at greater risk for contracting leukemia and other cancers?

Answer: At the present time, these participants appear to be at greater risk for the development of leukemia and melanoma than a comparable population of males in the United States. However, the small numbers involved preclude

the determination that the radiation was the sole cause of these 2 cancers and melanoma has not previously been causally associated with radiation exposure.

Question: If so, what are the economic implications?

Answer: The economic implications of our studies are that few of the nuclear participants will be affected and even if all participants who eventually develop cancer are granted service connected disability, the costs would be fairly low. A more complete review of the economic and legal ramifications has been prepared by the Department of Justice.

STATE DEATH INVESTIGATION LAWS

Question: During our S.I.D.S. discussion with representatives from the Health Services Administration, we talked about the newly-authorized death investigation study. That study is to examine the various State laws and systems regulating post-mortem examinations and to recommend ways in which HEW might improve the quality and uniformity of such death investigation practices. This study was written into that legislation because it was felt that post-mortem examinations and the quality of such examinations had a great bearing on providing an accurate diagnosis of Sudden Infant Death Syndrome. Are there ways in which the CDC can encourage improvements in or help standardize State death investigation laws and systems?

Answer: CDC has been active in the area of reproductive health, e.g. abortion and sterilization-related deaths. We have also undertaken studies in Georgia pertaining to infant and maternal deaths, by linking information on birth and death certificates. CDC has cooperated with the National Center for Health Statistics in these studies. A representative of CDC has attended meetings of State Vital Registrars.

Question: Are any such activities presently being carried out?

Answer: Except for specific problems that relate to the CDC mission, such as those mentioned, CDC is not involved in improvements in State death investigation laws.

TRICHLOROETHYLENE CONTAMINATION

Question: Last summer, I asked CDC to get involved in the problem of Trichloroethylene contamination of drinking water in Pennsylvania. Since then, I've learned that this appears to be a nationwide problem in drinking water, and perhaps also in the workplace. What is your current assessment of the problem?

Answer: The Center for Disease Control has become involved in the low level exposure of Pennsylvania residents in Bucks and Montgomery Counties. In a preliminary survey, no acute health effects were noted as a result of low level TCE exposure from contaminated drinking water. The TCE level was estimated 30 days after exposure by measurement of TCE urinary metabolites. A survey of persons exposed to continuous low level TCE exposure--Warminster Heights, Pennsylvania--is ongoing. In addition, CDC has asked to be notified of acute spills more promptly so that we may attempt measurement of urinary metabolites as early as possible in the acutely exposed population.

Since TCE is widely used as a degreasing agent and septic tank cleaner, we can expect to have more episodes reported in the future. In addition, since TCE is a commonly used chemical, it has been identified in toxic waste dumps, e.g. Chester and Pittston, Pennsylvania, and we expect it to be found elsewhere. With widespread use by industry, occupational exposure is virtually assured. In fact, the highest level measured in Pennsylvania was in a person with occupational exposure.

Question: Is CDC planning to become more deeply involved in this kind of issue in the future? Please explain.

Answer: CDC has already been involved in the epidemiologic study of chemical spills, toxic and radiologic waste dumps of which TCE, asbestos, radon and pentachlorophenol are the latest. There is no doubt that CDC, especially the Chronic Disease Division, will receive an increasing number of requests for epidemiologic assistance from other federal agencies, State, and local health departments. It is to expand our response capability that we are requesting and increase of 10 positions and $2,968,000 in 1981.

INEFFECTIVENESS OF TB VACCINES

Question: We note that a recent study funded by CDC showed that two strains of BCG antituberculosis vaccine widely used in developing countries were found to be ineffective. Even though these vaccines aren't used in the U.S., does the study have any meaning for this country?

Answer: Although the two particular strains studied in India are not used in the United States, bacille Calmette Guerin vaccines made from other strains are licensed and used in this country. Efforts to control tuberculosis in the United States are directed mainly toward early identification and treatment of cases and preventive therapy with isoniazid for infected persons at high risk of developing the disease. However, BCG vaccine has been recommended by the Public Health Service Advisory Committee on Immunization Practices for selected uninfected persons who live or work where they have an unavoidable risk of exposure to infective tuberculosis. The efficacy of current vaccines has not been demonstrated directly and can only be inferred. The study was designed to measure in a human population the protection offered by two BCG strains believed to be of outstanding potency based on laboratory assessment.

Question: Why would CDC help to fund a study that has no direct relevance to this country?

Answer: The study has direct relevance to this country. Early studies had shown wide variability in the efficacy of BCG vaccines attributed to genetic changes in the bacterial strains, differences in production techniques, differences in methods and routes of vaccine administration, and characteristics of the populations and environments in which vaccines had been studied. The study in India was designed in the hope of resolving persisting controversy about BCG vaccination, and demonstrating in humans the protective effect of two presumably potent strains which could then serve as the sources for worldwide vaccine production. A proven safe effective vaccine would be desirable both for the limited recommended use in the United States and the extensive use in developing countries which lack resources for casefinding, diagnosis and treatment.

Question: How much did CDC spend on this study in the roughly twelve years it was conducted in Southeast India?

Answer: Approximately 14.5 million rupees--about $2 million in special foreign currency program funds--P.L. 480--was spent. A small amount of financial support was also contributed by the government of Denmark, as well as staff time of project officers and technical advisors from CDC and WHO.

Question: What do we use in the U.S. to treat TB victims and how effective is this drug? Is TB under control here--or is it a worsening problem?

Answer: Chemotherapy is used to treat and prevent tuberculosis in the United States. There are approximately ten drugs currently available, four or five of which are considered "first line" drugs with the rest as reserve drugs. Treatment of tuberculosis disease uses two or more of these drugs in combination, usually isoniazid with rifampin and/or ethambutol and/or streptomycin. Chemotherapy is extremely effective, produces rapid clinical improvement, and is ultimately curative. Chemotherapy rapidly reduces the infectivity of cases and thus serves as a public health tool by stopping transmission of infection. Isoniazid is used alone to treat latent tuberculous infection in order to prevent subsequent progression to clinical, potentially infective disease. The theoretical effectiveness of chemotherapeutic agents is mitigated by the practical difficulty of obtaining patient compliance with prolonged--9 to 18 months--treatment regimens.

Tuberculosis in the United States has been declining steadily but slowly, but in certain areas morbidity rates are stable or have increased. Also in many large urban areas, and some rural areas, problems such as transmission of infection to children, development of drug-resistant bacteria, and introduction of infection and disease from other countries by immigrants and refugees, indicate that tuberculosis is not yet effectively controlled.

BUREAU OF HEALTH EDUCATION

Question: Over the past 5 years how much money has the Bureau of Health Education spent on evaluating its activities?

Answer: Lack of valid and reliable criteria and methodology has been a major obstacle in obtaining satisfactory evaluation of health education activities. Most of the Bureau's actions regarding evaluations have been

devoted to developing and testing improved methods which can be applied broadly to health education programs in general as well as to specific Bureau activities. Three hundred thousand dollars have been obligated to develop these methods.

Most of the Bureau demonstration contracts have included evaluation requirements with specific funds included for that purpose.

The only funds spent for specific evaluation of Bureau activity involved the School Health Curriculum Project. Total funds obligated for this project were $76,000 for development of outcome evaluation methodology. It is estimated that the current contract proposed to implement this methodology comparing the School Health Curriculum Project with several other school health education programs will cost about $2 million.

Question: What outcome-evaluation procedures have been developed to measure the benefits of health education projects funded?

Answer: Since evaluation of health education has been a seriously underdeveloped area in the past, CDC's Bureau of Health Education has devoted a large and increasing share of its resources in developing and testing improved evaluation methods which can then be applied both to its own projects and to the activities of other agencies.

Through a contract with the Rand Corporation we have sought first to define precisely what the diabetic patient and his family need to know with special reference to nutrition and precisely how the presence or absence of such knowledge affects preventable consequences of the disease. Results of this study will be applied to several diabetes education programs this year to yield hard data on program effectiveness as measured by specific health outcomes. Eventually the procedures and methods developed in the study of diabetes can be adapted to patient education programs in other disease categories such as heart disease, chronic lung disease and others.

Sex education programs have been conducted in many settings under a variety of auspices without clearly defined objectives or documentation as to whether so-called "effective" sex education in fact can be shown to affect rates of unwanted pregnancies or other health outcomes. Through a series of contracts initiated in FY 1978 we are defining rational expectations for sex education programs and supporting the evaluations of promising approaches against these measurable objectives.

Since 1974 the Bureau of Health Education has helped to support the development of comprehensive school health curricula for kindergarten through 7th grades. A study undertaken in FY 1979 designed a sophisticated plan for evaluating outcomes for school health education in terms of knowledge, attitude and health related behavior of young people and also of the impact of such programs on the school and community. This design is now being applied to FY 1980 and 1981 to BHE supported curricula and also to other models in use in a significant number of school systems.

A basic element of the health education-risk reduction grants program to State health agencies initiated in FY 1979 is the systematic collection of baseline data on the prevalence of risk factors associated with diseases such as cigarette smoking, hypertension, etc. These data, combined with an inventory of existing health education programs in each State will provide the basis for a continuing evaluation of the grant programs.

Question: To what extent have these procedures been applied to your projects and what results have they shown?

Answer: As indicated above, because of the primitive State of the art of outcome evaluation in health education, evaluation of projects to date has been largely process oriented. Our work with the American Hospital Association, Parents Teachers Association, Cooperative Extension Service and other organizations has demonstrated that significantly greater health education activity can be made available to children and youth, professionals in the health care system, rural communities and other target groups, and that the health education skills of health professionals, teachers, community outreach workers and others can be enhanced. As valid outcome measures are developed they are being applied to BHE projects and also made immediately available to other interested groups.

Question: What, specifically, have you done to ensure that the evaluation comments are widely used and disseminated?

Answer: The Bureau of Health Education disseminates the results of its activities by publishing and widely distributing project reports, papers describing major activities and accomplishments, and providing technical assistance on request to various health and education organizations and groups. The following three tables list examples of the activities and distribution patterns.

TABLE NUMBER 1

Publications resulting from Bureau of Health Education Activities

Number from 1974-1979		55
Examples:		Distribution
1. Health Education in the Cooperative Extension Service - Present Status and Recommendations for Future Action - 1978		5,000
2. Current Awareness in Health Education--Published Monthly, 1978-1979		1,200 per mo.
3. Focal Points--Published Monthly, 1975-1979		14,000 per mo.
4. The School Health Curriculum Project--Brochure		45,000
5. An Analysis of U.S. Sex Education Programs and Evaluation Methods - 5 Volumes		1,800 ea.
6. Review and Evaluation of Smoking Control Methods: The United States and Canada		3,500
7. State Legislation on Smoking and Health	year 1975	2,000
	year 1976	2,300
	year 1977	9,000
	year 1978	10,000
8. 1979 Immunization Survey--2 volumes		500 ea.
9. Measures of Diabetic Patient Knowledge, Attitudes, and Behavior Regarding Self-care--4 volumes		1,200 ea.
10. A Plan for the Evaluation of the School Health Curriculum Project—3 volumes		600 ea.

TABLE NUMBER 2

Presentations and/or Papers on Health Education and Promotion Activities

Number from 1974-1979 165

Examples:

1. Public Health Reports Journal - May-June 1976

   "Health Education: A Federal Overview"

2. Testimony - Select Panel for the Promotion of Child Health - Atlanta, GA. November 1979

3. PTA - Chicago - 1978 - National Conference of All State PTA Presidents and Health Committee Chairmen along with Representatives of National Public Health and Education Agencies and Organizations

   "Health Education in Schools"

4. American School Health Association - Atlanta, Georgia - October 1977

   "Issues and Challenges in Health Education"

5. American Association of Sex Educators, Counselors, and Therapists - Washington, D.C. - March 1978

"Federal Government Support of Quality Sex Education Programs"

6. 10th International Conference on Health Education - London - September 1979

4 papers for BHE

"Health Education as an Element of U.S. Policy"

"Health Education for Youth in Primary Schools"

"A National Health Education Program Administered Through Local and State Health Departments"

"Employee Directed Lifestyle Health Education Program"

TABLE NUMBER 3

Technical Assistance on Request

Approximate number from 1974-1979 320

Examples:

1. Convened a conference to develop guidelines on Professional Preparation and Practice of Health Education Specialists. Guidelines were approved by the Board of Directors of the Society of Public Health Education, Inc., at its 1976 meeting in 1975.

2. Sponsored and convened, at the request of and in cooperation with the Bureau of Community Health Services--HSA-a technical assistance group to develop health education guidelines for rural health care systems in 1976.

3. Conducted a series of national surveys on public attitudes toward influenza immunization in connection with the National swine flu program in 1976.

4. Convened expert multidisciplined group to explore appropriate Federal roles in addressing problems of sex education related to the high priority problem of teenage unwanted pregnancies vis-a-vis alternatives to abortion in 1977.

5. Convenes periodic meetings with the 10 PHS Regional Health Education Staff Representatives to increase effectiveness of communication and to improve working relationships between BHE and the Regions.

6. Convenes annual or more frequent meetings of the 8 member-organizations of the Coalition of National Health Education Organizations to review national legislative and administrative developments related to health education and identify major goals and interest of Coalition member organizations and explore possible future directions.

7. Convened a group of black health educators to discuss health priorities of the black community, and identify issues concerning health education and the black community and to develop strategies for research and services relating to these issues in 1979.

8. Under a collaborative agreement with the Ministry of Health and Welfare, Canada, developing a scientifically credible core health risk appraisal instrument which will also serve as a comparable data base. Canada has been providing this service to Canadians since 1973. A great deal of technical assistance has been reciprocally given by each government and knowledge of this working agreement has spread through the scientific community and forms the basis for more requests for technical assistance.

9. In cooperation with the Office of Health Information, Health Promotion and Physical Fitness and Sports Medicine--OHP--instituting a health education student internship program for master's level students enrolled in health education training programs. Internships are available from BHE, OHP and some State health departments that received PHS grant awards for health education-risk reduction programs.

10. Provided technical consultation to the National 4-H Council in the evaluation of their health education program.
11. Provided technical evaluation assistance to the Office of Education in OE's development of sex education programs for schools.
12. Provided technical evaluation assistance to the Alaska State Health Department in the evaluation of the Otitis Media Program.

CHILDHOOD IMMUNIZATION

Question: In the fight to immunize our children against such childhood diseases as polio, rubella, measles, pertussis, and tetanus, are we reaching all the children we can?

Answer: In 1977, immunization levels for childhood diseases ranged from 45-75 percent and as many as 20 million children under the age of 15 were not fully immunized. In April 1977, HEW launched its Childhood Immunization Initiative to raise immunization levels for children under age 15 to 90 percent by October 1979. During 1978 and 1979, over 63 million doses of vaccine were administered in public programs and over 28 million school records were reviewed to determine the immunization status.

Question: What percentage of the total number of children who should be immunized have been immunized?

Answer: Immunization surveys conducted in 1978 and 1979 indicated that immunization levels had risen dramatically. The immunization levels for school children kindergarten through grade 12 are: measles--91 percent; rubella--83 percent; polio--89 percent; diphtheria, pertussis, and tetanus-DTP--90 percent; and mumps--58 percent. The Initiative included mumps immunization only for children ages 1-6.

The immunization level among the 3.3 million children entering school are even higher. In the fall of 1978, these levels were: measles--93 percent; rubella--91 percent; mumps--83 percent; polio--92 percent; and DTP--92 percent.

These higher immunization levels have been accompanied by record low reported morbidity for measles, rubella, mumps, diphtheria, and tetanus and very low levels for pertussis and polio. Provisional morbidity for 1979 are: measles--13,448; rubella--11,633; mumps--13,899; diphtheria--65; pertussis--1,394; tetanus--75; and polio--26.

Question: How many do we expect to reach in the coming year?

Answer: During the coming year, emphasis will be placed on reaching the children who are entering the population--births--and in identifying and immunizing children over the age of 15 who, for one reason or another, are still susceptible to measles. A majority of measles cases now occurring are in the junior high, high school, and college population.

It is estimated that over 16 million doses of vaccine will be administered in the public sector to approximatley 6.3 million children during 1980.

CHILDHOOD IMMUNIZATION GOALS

Question: Have we now met our goals for childhood immunization rates? What percentages have we reached?

Answer: One of the goals of the Childhood Immunization Initiative was to raise immunization levels to 90 percent for children under age 15 against measles, poliomyelitis, diphtheria, tetanus, and rubella, and to raise immunization levels to 90 percent for children under age 7 against mumps and pertussis. Information obtained from the assessment of health records of school children and from surveys of the immunization status of children entering school in 1978, indicate that we probably met our goal. Results from school-enterer surveys conducted in the fall of 1979 are not yet available. These data indicate that 91 percent of the more than 28 million school children assessed to date in kindergarten through grade 12 are immunized against measles. For diphtheria, tetanus and pertussis, immunization levels are at 90 percent; for polio, the level is 89 percent, and mumps, 58 percent. The immunization level among the 3.3 million children entering school in the fall of 1978 are even higher: measles--93 percent; polio--92 percent; diphtheria, tetanus and pertussis--92 percent; rubella--91 percent; and mumps--83 percent. It is expected that data from the surveys conducted in the fall of 1979 will show even higher immunization levels. These higher immunization levels have been acompanied by record low reported morbidity for measles, rubella, mumps, diphtheria and tetanus.

Question: Are rates consistent throughout the States?

Answer: There is some variation in results among States, but all have made significant progress. For example, 35 of the 63 project areas have reviewed the immunization status of all children in kindergarten through grade 12. An additional 14 project areas carried out partial--i.e., kindergarten through

grade 6, kindergarten through grade 8, etc.--assessments. Data are not available from 12 project areas since these project areas plan to complete these assessments during the 1979/1980 school year. A total of 28,265,384 immunization records were reviewed in all of the various total school assessments during the 1978-1979 school year.

Of the 35 projects completing assessment in all grades, the following number have achieved an immunization level of 90 percent or larger: measles--21; DTP/Td--19; polio--18; rubella--16; and mumps--2.

In addition, a total of 61 of the 63 project areas completed the 1978/1979 school enterers assessment activity. The number of projects having an immunization level of 90 percent or larger based on 3,272,090 enrollment--Texas data excluded because school enterer data not tabulated separately--is: measles--47; polio--45; DTP/Td--45; rubella--44; and mumps--13.

Question: Does the influx of Indochinese refugees pose any special problems in this area?

Answer: During the last 24 weeks of 1979, a total of 42 cases of measles were identified among or directly linked with refugees.

Many of the refugee children who have immigrated to the U.S. are not adequately immunized. In an effort to address the problem, last summer the Secretary of HEW requested the development of an immunization program for Indochinese refugees. The Intergovernmental Committee on European Migration was awarded a State Department contract to provide immunization at the transit centers, where Indochinese refugees receive their medical screening examinations prior to departure for settlement in this country.

The status of the immunization program for the Indochinese refugees is that vaccines have now been purchased, logistical problems are being solved, and, beginning February 1, every Indochinese refugee child will receive the initial series of immunizations at a transit center before immigrating to the U.S.

A three-part standard record card will be used to document the immunization history of each child. The Quarantine Office will retain a copy at the port of entry, the refugee will retain a copy, and a copy will be forwarded to the local health department in the jurisdiction where the refugee intends to resettle. Additional immunizations required to complete a vaccine series should be provided by local health department programs.

NUMBER OF RUSSIAN FLU DEATHS

Question: Last year, in response to my question on Russian flu deaths last winter, you indicted that one child who died with Reyes Syndrome had evidence of infection with H1N1 influenza virus. You also believed that another 12 deaths may have been associated with the H1N1 virus. Have you firmed up your estimates of Russian flu deaths last winter? What do they show?

Answer: Between December 1, 1978, and March 31, 1979, 55 deaths due to Reye Syndrome were reported in the U.S. While four deaths were shown by isolation of virus or serologic tests to be caused by H1N1--Russian--flu, it is not possible to say exactly how many Reye Syndrome deaths were caused by Russian flu last year. Many of the Reye Syndrome deaths occurred in areas where Russian flu was epidemic. However, there was no significant excess of deaths in the nation shown by the surveillance of pneumonia and influenza deaths in 121 cities. This finding was consistent with the observation that epidemic Russian flu affected primarily younger, healthy individuals.

Question: What are your estimates for the current winter?

Answer: CDC does not make predictions of the amount of influenza activity or number of excess deaths that will occur during an influenza season. Because we expected that the types of flu viruses circulating and the pattern of illness occurring in 1979-80 would be similar to last year, we did not anticipate a large number of excess deaths. The predominant strain of flu virus in the U.S. this season has been influenza B, which can occasionally be fatal in both younger and older individuals. However, final data on flu deaths will have to await the end of the flu season.

Question: Last year you were supposed to conduct a survey presumably to find out why the public was apathetic to the flu immunization program. Did you conduct such a survey--and what were the results?

Answer: In February 1979, the CDC did conduct, by contract, a study of public attitudes toward immunizations, including influenza immunization. These survey data indicate that approximately 20 percent of high-risk adults had received the vaccine in the preceding 6 months, while only 6 percent of non-high-risk adults and 5 percent of children had been immunized. Sixty-six percent of all adults regarded flu vaccine as effective, and most thought it was the vaccine-preventable disease most likely to affect them; only 11 percent considered it a potentially serious disease in adults. A variety of reasons were given by adults for not intending to obtain flu vaccine. The most common "don't think it is necessary"--18 percent of those who did not intend to receive the vaccine, or "don't think I will get flu"--14 percent.

The most frequent reasons given by adults for deciding to be immunized were the protection which they felt it provided--43 percent of those who intended to receive flu vaccine, and the fact that their doctor recommended it--33 percent.

High-risk adults are more aware than others of the need for flu vaccine. They recognize the higher risk of flu to themselves, are more willing to get a flu shot--although only 20 percent actually got it, and are more likely to get a shot from a private physician.

One of the most critical factors in increasing the number of high-risk individuals who receive flu vaccine each year appears to be the active support of private medicine. In a survey of the attitudes and practices of private physicians carried out in September 1979, we found that 93 percent of the physicians thought that influenza vaccine was safe and effective and that 87 percent usually administered influenza vaccine to some of their patients. Physicians also reported that they administered vaccine to 54 percent of their elderly patients who were chronically ill, but to only one-third of their elderly patients who were not chronically ill. Seventy percent supported the idea of Federally-funded immunization programs.

Question: Did you ever find out whether Guillain-Barre Syndrome is associated with all types of flu vaccines? What can you tell us?

Answer: From September 1, 1978, to March 31, 1979, CDC received 403 reports of GBS in adults 18 years of age or over; 12 had received flu vaccine within 8 weeks of the onset of their illness and 391 had not. Using estimates obtained from a national survey of the number of adults who had been vaccinated, the relative risk of acquiring GBS after vaccine was only 1.4, which is not significantly greater than 1.0. This means that a person who received the 1978-79 flu vaccine was at no greater risk of acquiring GBS than was a person who did not receive the vaccine. Clearly, not all types of flu vaccine are associated with GBS.

VENEREAL DISEASES

Question: What progress are you making on detection of syphilis and the herpes form of VD?

Answer: The reporting of syphilis cases suffers from some of the same problems that prevent the reporting of gonorrhea cases. However because VD control programs have maintained intensive syphilis surveillance and casefinding systems for a number of years, the reporting of syphilis cases is far more complete.

The major component of the syphilis surveillance system is serologic testing. Some of these tests--such as premarital and prenatal--are required by law; others are requested by physicians for patient diagnostic and/or screening purposes; and still others are voluntarily sought by individuals because of known or feared exposure to disease. Most States require laboratories to report reactive test results to State and local health departments for followup to insure definitive diagnosis, treatment and case reporting if indicated. Such laboratory reporting is considered to be more complete than voluntary reporting by private physicians. Followup of these tests with the attending physician frequently uncovers additional cases, which are then reported. Of the approximately 45 million serologic tests performed each year, some 1.5 million are reactive for syphilis, resulting in the diagnosis, treatment and reporting of 11,928 cases of infectious syphilis. In addition to casefinding through the laboratory surveillance system, early infectious cases are interviewed and their sexual contacts are referred to appropriate medical care services. In the last 12 months, health department personnel have interviewed 87.3 percent of the early infectious syphilis cases reported by private physicians and 98.9 percent of the cases diagnosed in public VD clinics. These casefinding efforts resulted in the examination of 107,124 contacts of whom 49,093 were treated, for disease or as a preventive measure.

We are tracking the occurrence of genital herpes through our Sexually Transmissible Disease Study -- a sentinel surveillance reporting system consisting of seven widely dispersed venereal disease clinics which look for and report the frequency of some 15 sexually transmissible diseases to us on an ongoing basis. From October 1, 1978 through June 30, 1979, these seven clinics reported that of 104,874 clinic visits, 2,089 were for first occurrences and 698 for reoccurrences of genital herpes. These cases represent an incidence of 2.7 percent among VD clinic clients. This figure should not be extrapolated beyond the population attending VD clinics. We will not have information from the private medical community for some time because the International Classification of Disease Adapted has not until very recently differentiated genital herpes from other forms of herpes infections.

No effective means is available for the control of genital herpes. We are making every effort possible to counsel all diagnosed cases in VD clinics, to make them aware of the consequences of the disease and what they can do to protect themselves and their partners.

Question: Last year you also told us that "nongonorrheal urethritis is more common than gonorrhea, but is not reportable." Have you taken any steps to make NGU -- if I might abbreviate it -- a reportable disease?

Answer: No. In 1978, a Departmental Task Force examined a number of sexually transmissible diseases and made recommendations for surveillance. It recommended that until an active control program is established for any of the presently nonreportable diseases, these diseases not be made reportable. Instead, it recommended that for the purposes of determining the extent of the problem that we rely on already available external sources of data. Foremost among these is the National Ambulatory Care Survey conducted by the National Center for Health Statistics. This survey indicated that in 1975-1976, about 523,000 men per year visited office-based private physicians for the treatment of nongonococcal urethritis. These data are supplemented by the previously mentioned Sexually Transmissible Disease Study which reports that in VD clinics, nongonococcal urethritis is diagnosed as frequently among men as is gonorrhea.

Question: Are we making progress in our battle against all types of VD?

Answer: Yes, we are making progress. The reported prevalence of total syphilis has fallen from an all-time high of 575,593 cases in 1943 to 65,949 in 1979, a reduction of more than one-half million cases. Congential cases among infants less than 1 year old are at an all-time low -- only 104 cases were reported in 1979, a 98 percent decline since the initiation in the 1930's of efforts to control syphilis. The reported incidence of 23,953 primary and secondary cases in 1979 represents the tenth consecutive year that total infectious cases have ranged from 20,000 to 26,000--infectious cases totaled 25,561 as recently as 1975.

From 1965 to 1975, cases of gonorrhea tripled, climbing from 324,925 to 999,939. As a result of the control initiatives begun in 1972, this escalating trend has been halted with 1,006,489 cases reported in 1979, only a 0.6 percent increase since 1975. During 1979, through screening and outreach efforts, some 544,000 persons were placed under treatment, resulting in the prevention of an estimated 189,000 cases. Complications of gonorrhea are severe and women are almost exclusively the victims. Annual costs of these complications among women are estimated at $300 to $350 million.

Although pelvic inflammatory disease is not a reportable condition, surveys indicate that the rate of visits to office-based private physicians for PID has declined since 1973. Efforts to reduce gonococcal PID are being intensified by helping States and localities strengthen patient management systems in hospital emergency departments and to rapidly identify and treat infected sexual partners of PID patients.

Penicillinase-producing Neisseria gonorrhoeae, which produces an enzyme that inactivates penicillin, threatens the treatment and control of gonorrhea, not only within the United States but throughout the world. Since its recognition in early 1976, a total of 822 cases have been reported by 38 States, the District of Columbia and Guam. Within 3 months of the discovery of this new strain, a control strategy, including standardized laboratory confirmation, diagnosis, reporting and surveillance, had been developed and implemented in all States. Although some spread of this organsim has occurred, no endemic foci have been established in the United States.

A cooperative study of the epidemiology of sexually transmitted hepatitis B has been completed. This study clearly defined the risks of acquiring this infection and identified a population of volunteers for the vaccine trial to

begin this year. If this very promising vaccine proves to be effective, sexually transmissible hepatitis B will represent the first sexually transmitted disease for which immunization is available.

Although we have made significant progress, we have a long way to go. To control other STD, we must fill the gaps in our knowledge about the etiology of these diseases, their pathogenesis and complications, and current deficiencies in diagnostic, treatment and prevention technologies.

Question: It seems that school children would be a great place to begin educational programs in this area. Now that we have had the school health program in the Office of Education budget for 2 years, give us some examples of specific ways you have worked through the school systems?

Answer: A national survey about 5 years ago showed that over 70 percent of secondary schools in the country had units of instruction on venereal disease. Resistance to this instruction has now almost disappeared. In fact, more recent surveys in such disparate sections of the country as Utah and Connecticut, have shown that parents in particular are overwhelmingly in favor of such instruction. Our efforts now are not so much directed at getting into the schools, but on improving the quality of instruction that is already there.

During the last several years, a number of States have developed improved curriculum guides, on the sexually transmitted diseases, that have been well received by teachers. They have also been instrumental in arranging teacher workshops to provide up-to-date information, new resource materials, and ideas on how to teach this subject. We have just completed a 2-year study with the State of Ohio in which a variety of materials and approaches to in-service education have been tested. We will be sharing the results of this study with other States as soon as the findings are all in.

We are in the process of updating contemporary student and teacher materials that can be used nationwide. These will reflect our growing concern over the non-traditional VD's such as genital herpes and nongonococcal urethritis.

Our staff has also had opportunity to provide commercial film and textbook producers with suggestions to improve and upgrade their offerings.

I think we can safely say that real progress has been made in this area, and that we will continue to explore methods for better protecting our young people with facts.

Question: How is the Venereal Disease Program working with adolescent pregnancy?

Answer: The Venereal Disease Control Division, CDC, as a member of the Adolescent Pregnancy Program Interagency Coordinating Committee, has participated in ongoing public forums and presentations and is responsible for identifying informational materials for the Adolescent Pregnancy Program. Additionally, the Venereal Disease Control Division provides technical consultation to the APP for guidelines for adolescent pregnancy grant applications and assists the APP in reviewing grant applications. Title VI - PL 95-626 - mandates VD screening as one of the ten core services of APP's.

Peripheral influence on the prevention of adolescent pregnancy by venereal disease control efforts results from VD educational programs which focus on the use of disease-prevention tools such as the proper use of prophylactics and many sexually active adolescents become concerned about VD before they become concerned about pregnancy. State and local VD clinical procedures refer these patients to appropriate sources of care, such as adolescent pregnancy programs or family planning clinics.

Question: How is the Venereal Disease Program working with family planning?

Answer: At the national and regional levels assistance is provided to develop guidelines or plans or both for program components of joint interest. For example, the Venereal Disease Control Division helped develop guidelines for testing family planning clients for syphilis and gonorrhea, as well as management of other sexually transmissible diseases. At the individual program level of State and local health departments, efforts are coordinated with family planning programs so that women receiving care in these facilities are screened for gonorrhea and syphilis. These tests are usually performed in local public health laboratories receiving Federal support for gonorrhea screening. Individual VD programs also consult with family planning agencies about diagnosis, treatment and referral for sexually transmitted diseases. Although comprehensive family planning services are provided by only a few VD clinics, almost all VD clinics provide family

planning referrals to their young, sexually active patients in need of contraceptive services.

VD control efforts are closely coordinated with other HSA programs such as migrant health, Indian Health, and Federally funded rural and inner-city health centers.

Among these cooperative efforts, Public Health Advisors are assigned to two Indian Health Service areas to help disease control program efforts. Support for the Navajo areas control program is shared by the tribes themselves, the Center for Disease Control, the Indian Health Service and the States of New Mexico and Arizona.

Migrant health and venereal disease control programs have helped one another provide VD diagnostic and screening tests for migrant workers through scheduling migrant health clinics. Health departments provide referral services for sexual partners of migrants with early syphilis and gonorrhea.

Many Federally supported inner-city or rural health centers have accepted VD patients and the sexual partners of patients referred by control program personnel. Health departments often supply these facilities with laboratory support, medications, and technical and epidemiologic assistance.

Question: How is the Venereal Diseas Program working with Medicaid?

Answer: The Venereal Disease Control Division has provided advice and counsel to the Early, Periodic Screening Diagnosis and Treatment program in the development of standards and screening procedures related to the STD.

Venereal Disease Control Division interests related to the projection of data needs for evaluating potential Child Health Assessment Program activities are being represented on an interagency committee.

A review of Medicaid and EPSDT programs with implications for venereal disease clinics was presented to all State and VD program directors. Invitations to interested programs were made to jointly evaluate the potential effect of public and private third-party payment systems upon the delivery of STD preventive services.

The complications of STD often require hospitalization and excessive medical costs. Pelvic inflammatory disease and ectopic pregnancy, preventable complications and sequelae of gonorrhea and chlamydia infections, account for more than 10 percent of hospital admissions, is excluding pregnancy, in women 15-45 years of age. Medicaid pays for a disproportionate share of these admissions since disease rates are highest among the medically indigent.

Question: How is the Venereal Disease Program working with social services?

Answer: We are working with the Divison of Runaway Youth Programs, Youth Development Bureau, Administration for Children, Youth and Families on the problem of sexually transmitted diseases among adolescent runaways. We hope to develop a demonstration project to measure the frequency of gonorrhea and other STD among representative adolescents who seek care in some of the 165 shelters supported by the Office of Human Development Services; if the problem appears to be significant, we would seek to provide more widescale casefinding and preventive health services for adolescents, and their sexual partners, who run away from their homes. State and local VD programs regularly work closely with local social service agencies to assist their clients in need of such services.

THE HUMAN LIFE SPAN

Question: Life expectancy in this country has lengthened considerably over what it used to be. The big killers, such as cholera and smallpox, are extinct or under control. However, other killers are on the loose, and among these are motor vehicle and other accidents. I know that you have no direct way to deal with accidents, but I would be interested in your comments as to what can be done to reduce death in this area. Do your health education programs focus on the accident problem? What are you doing?

Answer: The current activities of the Bureau of Health Education do not specifically focus on the accident problem, although it is touched upon in several Bureau of Health Education programs. The current health education-risk reduction grant program with State health agencies provides an avenue for support of specific innovative intervention activities by local health agencies, and proposals to reduce risks from accidents would be eligible to compete for limited grant funding. The health risk appraisal system being tested by Bureau of Health

Education takes into consideration automobile accidents from the standpoint of number of miles travelled and seat belt utilization.

Question: How do you coordinate with the Departments of Labor and Transportation and other agencies to reduce death and injury from accidents?

Answer: Motor vehicle accidents are the leading cause of death from ages 1 to 25. These were accompanied by 2,000,000 disabling injuries in 1978. The costs amounted to $34.2 billion from medical expenses, wage loss, administrative and claim settlement costs of insurance, and property damage.

In 1977, 24,000 persons died in home accidents. Of these deaths, 7,500 were from falls and 5,200 were from fires or burns. One person in 58 in the U.S. suffered a disabling home injury in 1977. About 100,000 permanent impairments resulted, ranging from partial loss of the use of a finger to blindness or complete crippling. Children under 17 years of age received over 56 percent of their total injuries in the home environment during 1975. During the same year, 50.4 percent of the national injury episodes occurred in the home environment.

As with other disease control problems, morbidity and mortality from injuries is amenable to reduction through an epidemiological approach. Following a modest demonstration program in several communities, the Center for Disease Control has proposed a national program employing this type of approach to the prevention and control of accidental injuries in the residential and recreational environments. This program would focus on those groups at high risk, most particularly children, the elderly, and those living in environments that increase their risk of injury. Components of the program include a surveillance system, epidemiologic investigations, standards setting, public education, professional training, technical and financial assistance, and an information clearinghouse. The primary Federal role would be one of providing leadership, direction, assistance, and information as a stimulator of injury prevention actions undertaken by State and local health departments. State health agencies would serve as the organizational apex to coordinate the flow of resources and expertise. The local role would be both one of innovation and implementation of injury prevention techniques.

There are several components within the Department of Transportation, including the National Highway Traffic Safety Administration that have regulatory responsibilities over motor vehicle problems.

NIOSH PRIORITIES

Question: On page 125 of the Department's Budget Justification for FY 1981, Volume 1, several NIOSH priorities are mentioned. Please explain how each of these priorities are being administered in FY 1980 as each relates to the problems of mining, especially coal mining:

a. National Occupational Hazard Survey
b. Health Hazard Evaluations
c. Industry-wide Studies
d. NIOSH Planning Group/DOL

Answer: The National Occupational Health Survey as described in last year's appropriation was for general industry not mining, but the Institute has set aside funds in the mining allocation to conduct a parallel National Occupational Health Survey for mining and this is our top priority in mining research. Health Hazard Evaluations are being expanded for general industry and mining as well and industry-wide studies will include an increasing number of efforts that relate to the mines.

The National Institute for Occupational Safety and Health planning group within the Department of Labor was set up specifically to transmit the needs of the Mine Safety and Health Administration and the Occupational Safety and Health Administration to NIOSH researchers. The joint efforts of MSHA and OSHA will mean that a larger number of questions brought to NIOSH have already been coordinated so that the references are applicable to both mining and general industry.

NEW ALOSH FACILITY

Question: After the new addition to the Appalachian Laboratory for Occupational Safety and Health is completed, what programs could be transferred to ALOSH? From which existing facilities would these transfers be made?

Answer: We currently have no plans to transfer other programs to the NIOSH facilities at Morgantown, WV. We do see, however, the need for program growth in some important areas; these are mining, and safety, including personal protective equipment research and certification. Another major area that will demand growth is energy. Much of the health effects research that is being conducted in the energy area is being conducted currently in Morgantown at our facility. This again is a growth area.

Question: I note that $25 million is included in the President's Budget for the construction of an addition to the ALOSH facility at Morgantown, West Virginia. How will these funds be designated for equipment as well as construction? Are there any other purposes for which these funds might be used that do not relate directly to ALOSH?

Answer: The entire $25 million will be used for the construction of the new facility including laboratories and casework. The necessary equipment for this building will be purchased from direct appropriated funds. The $25 million will not be used for any purposes unrelated to ALOSH.

Question: Your justification states that in 1981 $25 million will be required for the construction of the Appalachian Laboratory for Occupational Safety and Health in West Virginia. You do not say it outright but I assume you are asking Congress for that much to build the lab in fiscal year 1981?

Answer: Yes, that is correct. These funds will be used for the entire construction of the new facility.

Question: Is $25 Million the full cost of the ALOSH Laboratory?

Answer: In fiscal year 1979, we were appropriated $1.5 million for the architectural and engineering design of the facility. So the total cost of the building will be approximately $26.5 million, including casework-laboratory benches, etc.

HEALTH HAZARD EVALUATIONS

Question: How many Health Hazard Evaluations -HHE's- can be performed by one employee in one year?

Answer: This depends very much on the types of requests received. An HHE can vary from a relatively simple request for an industrial hygienist to evaluate the level of a specific hazard in which the consequent health effects are well known to a complex study of an unknown hazard involving, several toxic agents, several plants, medical examinations of many employees, and possible assessment of mortality experience among the workforce.

The simple, straightforward studies can be accomplished essentially by one industrial hygienist -plus laboratory and secretarial support- in less than one month. NIOSH has one industrial hygienist who completed 14 HHE's last year.

The more complex studies often require several industrial hygienists, physicians, nurses, and health technicians to perform the medical examinations, epidemiologists to undertake the mortality studies plus laboratory, data processing, statistical and secretarial support. Some HHE's have required up to 10 man-years of effort to complete. Recently, we are seeing a trend toward more sophisticated requests for HHE's.

Question: How many HHE's were requested and how many were performed in FY 1979?

Answer: In FY 1979 we received 217 new requests for HHE/TA. During that period we completed 180 studies, some of which were hazard evaluations from previous years, and some of which were studies which were either answered by letter or referred to some other agency. We issued 130 formal final reports last year. At the end of the fiscal year we had 197 active requests. Already, the first quarter of FY we have seen a 50% increase in requests over the same period last year. Thus, the demand for HHE/TA services is growing.

Question: How many of these were in coal mines?

Answer: Of the 180 that were requested, 16 were coal mining related. Four of the 136 completed were coal mining related.

Question: What are the estimated projections for each category in FY 1980 and FY 1981? How many of these would be in coal mines?

Answer: We anticipate receiving 350 requests and completing approximately 250. Of this amount 40 requests and 25 completions would be coal mine related. In 1981 we project receiving 400 requests and completing 300, of which 50 requests and 30 completions would be coal mine related.

Question: How many employees perform HHE's?

Answer: In FY 1979 approximately 90 person-years of NIOSH effort were devoted to the HHE program for mining and general industry. This included approximately 15 NIOSH physicians, 40 industrial hygienists, and 20 health technicians actually involved in performing the field work. In addition, approximately 10 NIOSH staff are involved in undertaking laboratory analyses of biological and environmental samples, and in developing new sampling and analytical methods for the HHE program. Finally, there are the data processing staff, secretaries, statisticians, and epidemiologists who are also a critical part of the HHE program. Lastly I would like to mention that we also had contracts with 9 universities to provide physician services for the HHE program and a contract with a laboratory in Salt Lake City to undertake analysis of environmental samples for us when required.

Question: Are any additional employees requested for this activity in FY 1981? If not, why not?

Answer: The six additional positions requested in the 1981 budget are to be used for the HHE program.

RELATIONSHIP WITH OTHER AGENCIES

Question: Which research activities fall under the jurisdiction of the National Institute for Occupational Safety and Health, and which under that of the National Institute of Environmental Health Sciences and the National Cancer Institute?

Answer: All of the agencies indicated have one or more responsibilities or activities in the area of occupational or environmental health. The National Institute for Occupational Safety and Health - NIOSH- has legislatively mandated responsibilities to deal with the occupational health and safety problems of workers. NIOSH is a research and service organization directed towards protection of the health and welfare of American workers. 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. NCI is responsible for conducting basic and applied research with respect to the cause, prevention and cure of cancers of all types. NIOSH is specifically concerned with occupationally related cancer, while NCI has a broader interest in cancer in general.

Question: How does coordination take place among NIOSH, the National Institute of Environmental Health Sciences -NIEHS- , and the National Cancer Institute -NCI- , as well as the other institutes of NIH?

Answer: NIOSH has established a series of formal mechanisms to assure coordination with NIEHS, NCI, and the other institutes of NIH including a single grant review system. All applicants for NIOSH grants use the NIH grant system including the standard NIH grant application. All applications are submitted to the Grants Review Division of NIH. NIH refers appropriate applications to the occupational safety and health study section. Often applications are referred to several study sections. The National Toxicology Program-NTP- of which NIOSH is an active participant and supporter is the interagency program chartered to minimize the overlap and gaps in toxicology research. Director of NIEHS is the chairman of NTP. Finally, NIOSH has signed interagency agreements with components of NIH that further define responsibilities and identify cooperative ventures. In FY 79, NIOSH entered into 50 interagency agreements. Of those, 7 involved components of NIH. This is especially true with NCI with whom NIOSH conducts a major program in cancer research. These formal mechanisms institutionalize cooperation among the Agencies. The key to effective coordination is the desire and commitment of the management of these Agencies to cooperate. That commitment enhances sharing among the professionals of the various Agencies and improves the dialogues that occur naturally at meetings of professional societies and in the pages of scientific journals.

Question: What role will the National Institute for Occupational Safety and Health play in the Occupational Safety and Health Administration's new cancer policy?

Answer: The new OSHA cancer policy sets forth a general policy for the identification and regulation of physical and chemical substances that pose a potential carcinogenic risk to humans. The policy establishes criteria for the identification, classification and regulation of potential occupational carcinogens found in each workplace in the United States.

The criteria established by the policy for identifying and classifying potential carcinogens are based upon an extensive review of scientific data and opinions. Potential occupational carcinogens will be identified and classified on the basis of human epidemiologic studies and/or experimental carcinogenesis bioassays in mammals.

The policy provides for the classification of potential occupational carcinogens into two categories-I and II-depending upon the nature and extent of available scientific evidence. On the basis of this categorization a priority for subsequent regulatory action will be set.

In the case of category I carcinogens, the policy stipulates that worker exposure will be reduced to the lowest feasible level, primarily through the use of engineering and work practice controls. Worker exposure to category II substances will be reduced as appropriate and consistent with statutory requirements.

NIOSH will play an integral role in providing scientific review and support to the process of identifying and categorizing occupational carcinogens and the subsequent process of prioritization for regulatory action. The Institute will provide scientific review and evaluation of the information which will serve as a basis for classifying candidate chemicals as category I and II carcinogens. In this role NIOSH will also serve to critically evaluate and verify the reliability of the classification system and propose revisions for improvement if necessary. NIOSH, in helping to establish priorities for regulation will provide information as to number of workers exposed, environmental concentrations to which workers are exposed, levels of exposure associated with production of cancer, availability of substitutes and an assessment as to the lowest level feasible in the workplace as regards control of exposure to the category I potential carcinogens.

Question: The Department of Energy is working on plans for the construction of the SRC-11 demonstration plan near Morgantown, West Virginia. What steps has NIOSH taken to assist DOE in the development of health standards that would guarantee a safe working environment? Will this new initiative require new staff and budget authority? If so please explain.

Answer: NIOSH has conducted several projects that would be useful to OSHA and MSHA in the development of health standards in the emerging synfuels industry. A coal gasification criteria document was published in 1978, and a coal liquification document will soon be published. Several studies of occupational hazards of the synfuels

industry have been completed, but much remains unknown including information on the control of hazards, investigation of safety hazards, and understanding the health effects of literally thousands of chemical compounds generated during synthetic fuel processing.

The siting of the SRC-II demonstration plant near the NIOSH Laboratory located in Morgantown offers an excellent opportunity for NIOSH to conduct an ongoing program at the demonstration plant as it develops. This is only one example of an unique opportunity to study occupational hazards and their control while an industry is developing. With these studies we can derive the design criteria for safe working conditions in the synfuels industry before full production plants are constructed thus avoiding expensive "add-on" control technologies later.

An initiative to assure that such studies are implemented is currently being compiled by the Council on Environmental Quality -CEQ- in cooperation with OMB. The information that CEQ is compiling is the result of a joint effort between DHEW, DOE, and EPA. These agencies among several others are currently reviewing this information and will have their comments to CEQ before the end of the month. Future resource requirements are to be addressed in this CEQ compilation.

NEW PROGRAM RESPONSIBILITIES

Question: Please explain what steps are being taken to implement the new program responsibilities placed on the National Institute for Occupational Safety and Health -NIOSH- by the Federal Mine Safety and Health Act of 1977.

Answer: In November of 1979, the Institute developed a comprehensive plan to identify areas of program growth and development in response to the 1977 Act. It identified immediate allocations of funding towards these program goals, and the subsequent personnel and funding increases anticipated for FY 1980 through FY 1984. Specifically, these eight program areas are Industrywide Studies, Mining Surveillance, Mining Health Hazard Evaluations, Control Technology Assessment, Monitoring and Measurement Research, Development and Support, Laboratory Based Research, Standards/Criteria Development, and Training. In FY 1980 the Institute has expanded its mining health hazard evaluation program, has began a comprehensive mining surveillance program and has increased laboratory research areas related to mining. Control technologies for mining and development of sampling instruments are areas also experiencing growth. Industrywide surveys include both coal and non-coal mining activities.

Question: Please indicate the administrative unit and geographic location for the administration of each of these new program initiatives. How many will be in Morgantown, West Virginia? How many in Cincinnati?

Answer: The majority of NIOSH field and laboratory research relative to mining is conducted in the Morgantown, W.Va. facility by the Division of Respiratory Disease Studies-DRDS.

The eight program areas developed by NIOSH in response to the Act, and their location, are Industrywide Studies handled by DRDS in Morgantown and DSHEFS in Cincinnati. Mining Surveillance and Mining Health Hazard Evaluations are administered by DRDS in Morgantown, Laboratory Based Research is handled by DRDS in Morgantown and DBBS in Cincinnati. Control Technology Assessment and Monitoring and Measurement Research, Development and Support are both handled by DPSE in Cincinnati. Standards/Criteria Development is administered by DCDSD in Rockville and, finally, Training which is handled by DTMD in Cincinnati.

Question: How many new staff positions are necessitated for each of these new programs to assure proper administration? Why?

Answer: The Richmond Task Force recommended an increase of 593 positions, of which 313 positions are needed to carry out the responsibilities mandated by the Federal Mine Safety and Health Act of 1977 and to expand energy, safety and personal protective equipment research. By program area, 135 of these positions would be for mining and energy, 134 for safety, testing and certification, and 44 for administration.

Question: Under current position limitations, please estimate the rate at which these manpower requirements could be met by NIOSH. What is CDC's schedule for staffing these programs? What is the Department's schedule for staffing these programs?

Answer: As these programs continue to grow additional positions will be needed. The 1977 Richmond Task Force recommended that 1,563 positions be provided in 1983 for these programs. The current request includes funding for the required new space.

Question: When these new programs are fully operational, will existing facilities provide adequate square footage? How will the new addition to ALOSH help? How much additional space will be needed and in what locations? Do CDC and the Department agree with these estimates?

Answer: As now projected the new and increased effort in the mining initiative will result in a substantial increase in personnel. The existing facilities will not provide adequate square footage for this projected increase in personnel but the completion of the new addition in Morgantown in 1983 will provide the necessary space needed.

Question: I understand that prior to the Federal Mine Safety and Health Act of 1977, NIOSH was responsible for health evaluations of 200,000 coal miners. Is this figure correct? How many other miners were added by the 1977 Admendments?

Answer: Prior to the Federal Mine Safety and Health Act of 1977 there were approximately 200,000 coal miners in this country. The latest figures available shows that there are now approximately 250,000 coal miners and approximately 250,000 miners engaged in other types of mining operations.

Question: In what fields of mining are these miners employed?

Answer: The approximate 250,000 miners in other than coal mines extract about 50 substances including copper, mercury, gold, silver, lead, zinc, uranium, and asbestos.

OCCUPATIONAL SKIN DISEASE

Question: How much money will CDC spend on occupational skin disease in FY 81? How does this compare with FY 80?

Answer: In FY 80 NIOSH estimated that it will spend approximately $1,100,000 on occupational skin disease intramural and extramural programs. The FY 81 estimated total is $1,100,00.

Question: What additional research will you do in the area of occupational skin disease in FY 81?

Answer: As a result of this program announcement NIOSH anticipates a substantial increase in the number of grant applications in the area of occupational dermatology. Research in cutaneous hazards and diseases will include projects in biochemistry, physiology, data systems research, epidemiology, test methodology research, control technology and health education research.

Question: What particular areas of occupational skin disease are being focused in by federally-funded studies at the University of Cincinnati and Wayne State University? What results are you getting?

Answer: The Occupational Dermatology Program at the Educational Resource Center at the University of Cincinnati has made significant growth this year. This program was involved in three major epidemiologic and clinical studies in 1979 involving dermatological as well as other organ system hazards. These studies include dermatitis among rubber workers, workers involved in the manufacture of 2,4,5, T in Nitro, West Virginia, and an epidemiologic and clinical study of over 100 workers exposed at a chemical plant in Illinois to pentachlorophenol as well as

ortho and parachlorophenol. Also at the University of Cincinnati in conjunction with the Department of Dermatology at Wayne State University with NIOSH funding is sponsoring a week long course in occupational dermatology during the winter quarter of 1980. This course will be largely directed to dermatologists and occupational physicians and will incorporate the basic science aspects of environmental skin problems, diagnosis, treatment, and prevention of occupational skin disease.

COAL MINING RESEARCH

Question: In a letter to me dated July 27, 1979, Dr. Anthony Robbins stated that the option to conduct research and field investigations under contract has been rejected by NIOSH. Please explain why this work requires special training that may not be available elsewhere, rights-of-entry problems, and the "often sensitive nature of this work..." I would appreciate specific examples of the effects of these prohibitions for contractual personnel as they relate to coal mining and industry generally.

Answer: In the letter of July 25, 1979, Dr. Robbins stated "Because of special training requirements, right-of-entry problems and often sensitive nature of this work, it generally cannot be performed by contractors." This statement was not intended to imply that NIOSH has rejected the use of contract personnel in conducting field investigations, but rather to convey that we had encountered some difficulties in using the contract approach.

Under existing legislation, NIOSH has been granted right-of-entry into workplaces for purposes of evaluating potentially harmful physical or chemical agents. This right-of-entry authority cannot always be extended to NIOSH contractors or grantees. Because of medical license requirements, non-Federal Government physicians can only provide medical services within States in which they are licensed. In addition, NIOSH estimates that contract medical services are probably 15 - 20 percent more expensive than equivalent in-house services and, in detailed investigations, take 20 - 30 percent longer. A contractor is also more likely to be denied access to medical records as well as to information considered proprietary or trade secret. When these problems occur NIOSH staff must intervene directly in an attempt to obtain right-of-entry and access to records for the contractor. Credibility of contractor results for regulatory purposes has the potential to be diminished by apparent or actual conflicts of interest when a contractor is dependent on support from private industry, trade groups, and other interested parties involved in regulatory matters. It has also been difficult to find contractors who have the industrial hygiene experience as well as training in mine safety procedures and use of specialized safety equipment necessary to enter underground mines.

Although NIOSH will continue to use industrial hygiene and medical services contracts to complement NIOSH in-house efforts they can not be relied upon to take the place of a solid base of career professionals within the Institute.

Question: In the same letter, Dr. Robbins indicates that "NIOSH has been working closely with MSHA in developing priorities for health standards in mines. Among the most important candidates are oxygen deficient environments, silica, asbestos, radiation, carbon monoxide, diesel emissions, and welding."

Please explain the extent to which each of these proposed standards has been developed and their estimated effects on mining, particularly coal mining.

Answer: In development of recommended standards on silica and asbestos, information is currently being obtained on sources of exposure and extent of exposure, and an effort will be started this fiscal year to collect information on applicable controls in the mining industry. Previously developed criteria documents on these subjects will be used, which will facilitate completion of the standards of mining and milling operations, especially those involving drilling,

crushing, and bagging. Quartz is also present in varying amounts in coal mine dust. Two recent NIOSH surveys at silica flour mills have shown incidents of acute or accelerated silicosis, with 7 of 66 (11%) workers having progressive massive fibrosis after exposure durations between 2.5 and 14 years. Prevalences of pneumoconiosis in the samples of workers and ex-workers with one or more years of exposure were approximately 28% and 41% at the two mills. The occurence of disease was probably due to workers being exposed to concentrations that were well above current legal limits. Asbestos is likewise a potential hazard in many mines, except in underground coal operations. Highest exposures are associated with asbestos mines and mills, but ores at other mines may contain sufficient quantities of asbestos to make the impact of an asbestos standard quite large.

NIOSH's Division of Safety Research has recently completed a document on work in confined spaces, and that information can be used to initiate a standard for oxygen deficient environments. The estimated impact is on all underground operations where little or no ventilation is provided and where a build up of asphyxiants occurs. Also, any confined space associated with processing, storing or shipping of mined commodities from a mine property would be impacted.

A major source of oxides of carbon in the mining environment is diesel engine exhaust. The primary concern is in underground mines, and diesel powered vehicles are being used in both coal and metal/nonmetal mines. NIOSH has conducted several studies recently and is continuing research in this area. We anticipate that work on a recommended standard for exposure to diesel engine exhaust will be initiated during FY-80.

NIOSH has not developed a criteria document on exposure to radon daughters. The main effect of such a standard would be on underground metal mines, primarily in uranium mining. NIOSH is currently providing assistance to MSHA in their in-house effort to prepare a standard for radiation to address areas such as medical examinations, sampling requirements, warning signs and labels, work practices, and personal protective equipment.

This same type of assistance is being provided to MSHA by NIOSH for a welding fume standard in metal and nonmetal mines. Concurrently, NIOSH is completing a criteria document on welding for general industry, and much of the information gained from that project may be directly relevant to mining operations. Analogy can be drawn from the health effects noted in welders generally to expected health effects in welders at mines, although practically no illnesses are reported to MSHA. The risk of respiratory impairment for welders is added to exposures they might generally experience in mines. Potential respiratory effects range from accumulation of particles in the lungs through decreased respiratory functioning to the possibility of lung cancer, if specific materials, such as nickel or chrome, are used. MSHA has estimated that at least 85% of all metal and nonmetal operations perform welding, and that in addition to 7,000 classified welders, 50,000 miners perform some welding or cutting. NIOSH is working jointly with MSHA in the preparation of this standard in order to minimize the time involved in developing a final rule. Short-term research initiated in support of the standard development will be used to determine the need and direction for further NIOSH study. Because of the intermittent nature of some welding operations, measured exposures are not frequently above recommended concentration limits for individual fume components. However, the standard would primarily impact metal and nonmetal mining operations by requiring better engineered controls and more sophisticated medical surveillance than is currently used in that industry.

SUBCOMMITTEE RECESS

Senator SCHMITT. The committee will stand in recess until tomorrow morning at 10 a.m. when we will hear from the National Institutes of Health.

[Whereupon, at 4:30 p.m., Monday, February 4, the subcommittee was recessed, to reconvene at 10 a.m., Tuesday, February 5.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

TUESDAY, FEBRUARY 5, 1980

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

The subcommittee met at 10:05 a.m. in room S-128, the Capitol, Hon. Thomas F. Eagleton presiding.

Present: Senators Eagleton, Hollings, and Schweiker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. DONALD S. FREDRICKSON, DIRECTOR

ACCOMPANIED BY:

DR. DEVITA, ACTING DIRECTOR, NATIONAL CANCER INSTITUTE
DR. LEVY, DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
DR. BOWERY, DIRECTOR, DIVISION OF RESEARCH RESOURCES
DR. SCOTT, DIRECTOR, NATIONAL INSTITUTE OF DENTAL RESEARCH
DR. RALL, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
MR. ITTEILAG, DIRECTOR, DIVISION OF BUDGET POLICY AND MANAGEMENT, DHHS
DR. KRETCHMER, DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
DR. KIRSCHSTEIN, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
DR. CUMMINGS, DIRECTOR, NATIONAL LIBRARY OF MEDICINE
DR. BUTLER, DIRECTOR, NATIONAL INSTITUTE ON AGING
DR. KUPFER, DIRECTOR, NATIONAL EYE INSTITUTE
MR. NICHOLAS, ACTING ASSOCIATE DIRECTOR FOR ADMINISTRATION, NIH
DR. KRAUSE, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
DR. TOWER, DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE
DR. GOLDBERGER, DEPUTY DIRECTOR FOR SCIENCE, NIH
DR. BECKER, ACTING DIRECTOR, FOGARTY INTERNATIONAL CENTER

BUDGET REQUEST

Senator EAGLETON. The subcommittee will come to order. This morning is the first of four sessions with the various Directors of the National Institutes of Health. For the record, the fiscal 1979 budget for all of NIH was nearly $3.2 billion. For 1980 it was $3.4 billion, and the fiscal 1981 request is for approximately $3.6 billion.

The record of this committee as far as NIH is concerned is pretty well established. We are, however, troubled by decisions in spending allocations made in the 1980 budget as well as the future impact of your 1981 request.

As in past years, I would encourage each of you to speak up at any point. We are always urging interinstitute cooperation. It would be helpful to see that it works here today.

Dr. Fredrickson, we will put your statement in the record. We would be delighted if you would give us the highlights of it and summarize it, and then we will begin the questions.

[The statement follows:]

Statement of Dr. Donald S. Fredrickson

I welcome the opportunity today - my fifth as Director of the National Institutes of Health - to appear before the distinguished Chairman and members of this Committee to testify on behalf of the President's budget request for the National Institutes of Health. Both the preparation for these hearings, and the discussions generated by the Committee continue to be most helpful to me in carrying out my responsibilities during the rest of the year.

The importance of these hearings derives from two basic facts with which you are familiar: the NIH is the Nation's largest biomedical research institution, and it is also by far the largest single source of funds for biomedical research conducted in the universities, medical schools, and research institutions of this Nation. Together these activities will determine much of the quality of health care for tomorrow, and sustain the quality of health professional education today. Thus the total resources of the NIH translate quite directly into the Nation's capability and achievement in the health sciences. Although our country's leadership here is being challenged, we are still extremely powerful and influential in this area of human service.

Last year I described our efforts to set biomedical research priorities in line with budget constraints. This year a formal planning process was extended to the Department's entire health research budget to seek greater efficiency and cohesiveness in the conduct of health research.

One focus of the planning process implemented by this year's budget is the Administration's commitment to sustain one of the major activities aimed at enhancing the science base. An important part of such research is provided by investigator-initiated research project grants awarded by the National Institutes of Health. These have been selected for emphasis to signal the recognition of the Nation's intent to maintain fundamental research as an indispensable long-term societal investment. Proof of this intent is absolutely necessary to assure that young Americans will continue to make the sacrifices necessary to invest their careers in the health sciences.

The number of competing projects funded in a given year has the virtue of allowing us to predict the numbers of scientists who can count on this type of support. The ability of the NIH to fund about 5,000 competitive projects or about one-third of approved grant applications in 1981 testifies to the Administration's determination to protect the national commitment for this type of research from the erosion of inflation.

It would be inappropriate and inaccurate, however, to create the impression that support of investigator-initiated research project grants is the only critical demand that must be met in biomedical science. The government's intramural research programs offer indispensable, and sometimes unique forces in the quest for scientific information relative to agency missions. Our own NIH intramural program serves as a benchmark of excellence for our Nation's biomedical research community.

Approximately 70 percent of the NIH staff are associated with research conducted in the laboratories and clinics of the National Institutes of Health. Recent evaluations of the intramural research

program give clear indication that it provides a milieu for research productivity that is second to no other institutional form. There is no question that the assets of the intramural program at NIH: the scientists, their supporting co-workers, and the facilities at its several campuses, are invaluable and irreplaceable national resources.

As the Committee is well aware, the NIH Clinical Center is a unique institution. It is the Nation's, and the world's, largest hospital dedicated totally to research on the diseases of mankind. The Ambulatory Care Research Facility (ACRF) which will be integrated fully with the Clinical Center, and whose construction has been supported and funded by this Committee, is nearing completion.

The ACRF construction is accompanied by some essential modernization of the Clinical Center. I am pleased to report to you that for this modernization program the Buildings and Facilities appropriation request contains $7 million in 1981 and a proposed $7.23 million transfer in 1980 from the Institutes with programs in the Clinical Center . This is a part of a continuing effort begun in 1979 to integrate the Clinical Center with the new ACRF and to correct functional obsolescence and physical deterioration in the parent hospital facility. The 1981 budget also contains $1.5 million for the initiation of a multiyear project to modernize other NIH laboratory buildings which have been operational since the 1940's.

Various components of the new NIEHS facility are being completed and turned over to the Government. Our budget request for NIEHS contains $5 million and 55 positions for support staff and equipment needed to operate its new facility in North Carolina.

Other biomedical research needs are reflected in this budget as well. Last year, with your support, NIH, for the first time in six years, increased its stipend levels for the National Research Service Award program. This budget provides a further modest but essential increase in these stipend levels to partially compensate for the effects of inflation.

We are also requesting $1 million for an effort to attract promising minority high school students to careers in biomedical research. This program of short-term research experiences is a continuation of a program started in FY 1980 as part of the President's initiative to improve minority access to research careers.

Exciting advances are occurring across the full spectrum from fundamental research through clinical applications to the impact on health, care and prevention. Only three examples illustrate some of the far-reaching consequences:

Promise that greater control of the immune system may enable us to reduce or eliminate tissue destruction in such chronic diseases as arthritis.

Expectation that recombinant DNA technology will permit efficient manufacture of potent biological substances, such as insulin and interferon, and improve current vaccines.

Transfer to general medical practice the results of the recently completed clinical hypertension trial conducted by the National

Heart, Blood, and Lung Institute, revealing that treatment of mild hypertensives reduces rates of death and disability.

This year sees the fulfillment of the dream of former Senator Lister Hill that the National Library of Medicine enhance its information dissemination activities through the use of advanced technology. The completion of the Lister Hill Biomedical Research Communications Center will permit the National Library of Medicine to play this enhanced role.

The National Toxicology Program (NTP) has completed its first year and demonstrated it can join the research and regulatory agencies in common cause to determine toxicity of chemicals in the environment. NIH will increase its support for this program by $20 million, largely through a redirection of funds, in the National Cancer Institute and by $3 million in the National Institute of Environmental Health Sciences. With the increase, the NTP will begin 100 new bioassays for carcinogenicity, bringing the total at the end of the year to 320 bioassays in 1981 compared with 199 and 241, respectively, at the end of fiscal years 1979 and 1980.

The intramural programs of the NIEHS will be expanded by $3 million in such areas as pathology, behavioral toxicology, and development of test procedures and risk assessment which are especially important to the National Toxicology Program.

Adjustments cannot be made in one portion of the research budget without correction for the balance of the rest. The time scale for appropriate adjustment is often longer than a single year. Although the primary focus in Fiscal Year 1981 is on extramural research projects, activities such as clinical trials, research centers, demonstration programs and interdepartmental initiatives will continue to be strong elements of the NIH program.

NIH recognizes that there are increasing pressures on the equipment and flexibility of the institutions in which much of the nation's research is carried out. This budget contains an increase of $5 million to improve instrumentation in extramural laboratories. We will be continuing our review of the research environment this year, in the company of scientists and administrators of their institutions. We hope to discuss the results of this review with Congress in the coming year.

I will close by saying that I am prepared to answer any questions you may have concerning the National Institutes of Health and our 1981 budget request.

INTRODUCTION OF ASSOCIATES

Senator EAGLETON. For the reporter, could we have each of your associates at the table identify themselves, Dr. Fredrickson? Is everyone at the table part of your team? We would start with Dr. Devita.

If you have anything more confusing than Jones or Smith, spell it for the reporter if you would.

Dr. DEVITA. Devita. Acting Director, National Cancer Institute.

Dr. LEVY. Dr. Levy. Director, National Heart, Lung, and Blood Institute.

Dr. BOWERY. Dr. Bowery. Director, Division of Research Resources.

Dr. SCOTT. Dr. Scott. Director, National Institute of Dental Research.

Dr. RALL. Dr. Rall. Director, National Institute of Environmental Health Sciences.

Dr. KRETCHMER. Dr. Kretchmer. Director, National Institute of Child Health and Human Development.

Mr. ITTEILAG. Tony Itteilag. Director, Division of Budget Policy and Management, DHHS.

Dr. KIRSCHSTEIN. Dr. Kirschstein. Director, National Institute of General Medical Sciences.

Dr. CUMMINGS. Dr. Cummings. Director, National Library of Medicine.

Dr. FREDRICKSON. Dr. Fredrickson. Director of the NIH.

Dr. BUTLER. Dr. Butler. Director, National Institute on Aging.

Dr. KUPFER. Dr. Kupfer. Director, National Eye Institute.

Mr. NICHOLAS. Mr. Nicholas. Acting Associate Director for Administration, NIH.

Dr. KRAUSE. Dr. Krause. Director, National Institute of Allergy and Infectious Diseases.

Dr. TOWER. Dr. Tower. Director, National Institute of Neurological and Communicative Disorders and Stroke.

Dr. GOLDBERGER. Dr. Goldberger. Deputy Director for Science, NIH.

Dr. BECKER. Dr. Edwin Becker. Acting Director, Fogarty International Center.

Senator EAGLETON. Thank you, gentlemen.

Dr. Fredrickson?

Dr. FREDRICKSON. I would like to express our collective pleasure at being offered the opportunity to appear before you this morning to discuss the budget for the National Institutes of Health.

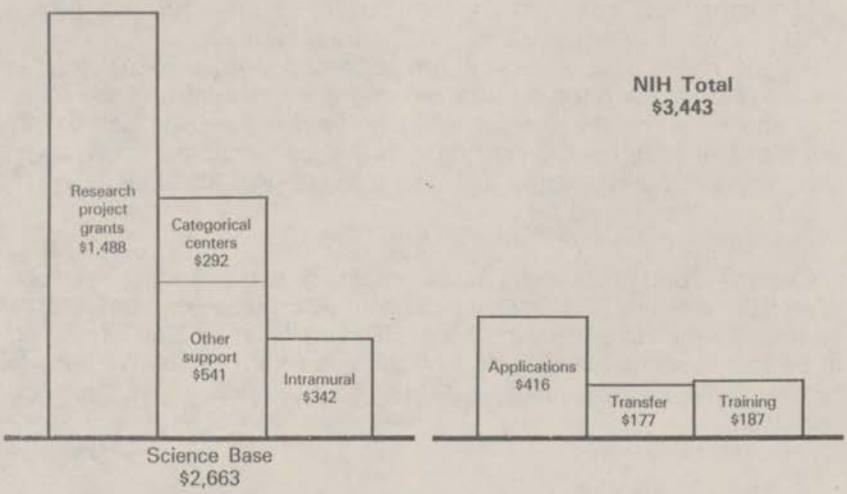
I will, with your permission, Mr. Chairman, submit my opening statement for the record and very briefly go to a summary of this budget, particularly where it changes our allocations from fiscal year 1980.

For that purpose, Mr. Chairman, we have prepared several charts that are available for you and other members of the committee. Chart A is labeled "Distribution of NIH funds, fiscal year 1980." This chart displays the resources of the National Institutes of Health by the SATT categories, a method which has been useful to us, and I hope will be useful to you and other members of the committee for viewing, in an overall way, the aggregate distribution of resources at NIH by research purpose.

[The chart follows:]

Distribution of NIH Funds, FY 1980 Est.

(Dollars in Millions)



Dr. FREDRICKSON. We referred to this method of displaying our activities last time, and here we will attempt to see if it is of any value to you and to us in describing the budget.

The 1981 budget request for NIH is $3.582 billion and 11,859 positions. This represents an increase of $139 million and 62 positions over the 1980 level of $3.443 billion and 11,797 positions.

SCIENCE BASE

Mr. Chairman, I would like to point out to you on this diagram where money has been added and for what purpose. You will note that on the lefthand margin of this chart are three bars underlined "science base." This represents fundamental investigation, the opportunities to extend our base of knowledge from which practical invention must arise.

At the extreme left within the science base, is a bar that represents the largest single activity supported by NIH in the aggregate—research project grants. It is in this area that the administration has suggested that we try to maintain a certain number of new and competing grants within the fiscal year. For this purpose, a sum of $141 million has been added to the research project grants line over that obtained in 1980. Of this figure, $112 million is from new money, and $29 million is from redirection of funds.

This should permit us to maintain approximately 5,000 new and competing research project grants and approximately 11,720 noncompeting grants. This decision, Mr. Chairman, reflects the reaffirmation of the priority placed on funding investigator-initiated research grants. It is this area of undifferentiated research from which comes much of the creative invention and new discovery.

61-400 O - 80 - 20

All research project grants are awarded extramurally to the Nation's universities and other research institutions. We feel it extremely important, as has the committee in its past actions, that a signal be sent to the scientific community that it is the intent of the NIH, and the Government through NIH, to maintain the capacity for supporting a reasonable number—at least a minimum number—of these research project grants for which we receive many applications each year.

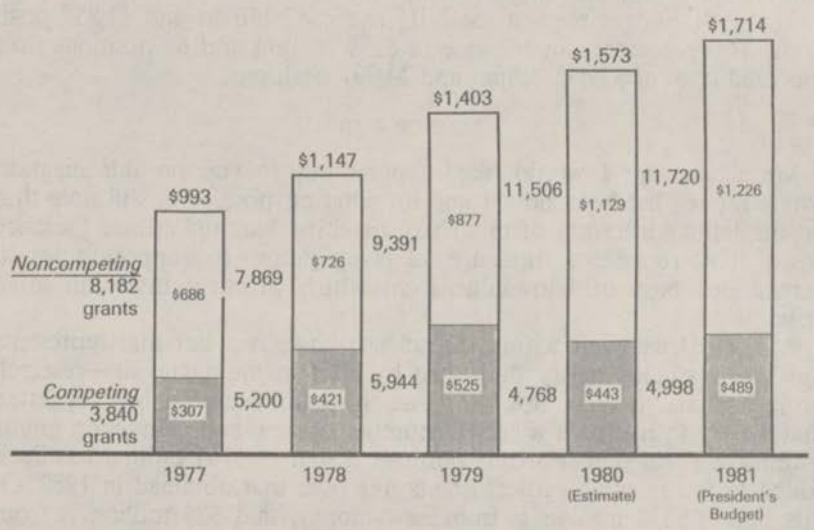
As you know, most of these grants are awarded on a 3-year cycle, so we are, during any one year, dealing with about one-third of the scientists supported by the competing grant mechanism. Applications are submitted in established cycles; they are judged by the peer review system, weighted for excellence, and then they compete for funds.

RESEARCH PROJECT GRANTS

Chart B displays the NIH research project grant funding for fiscal years 1977 through 1981. I would call your attention to the shaded area, particularly the comparison between 1980 and 1981. In 1980, we expect to be able to award about 4,750 new and competing grants. We hope to be able to fund approximately 5,000 new and competing grants in fiscal year 1981.

[The chart follows:]

NIH Research Project Grants
FY 1977-1981
(Dollars in Millions)



Dr. FREDRICKSON. You will note that the total number of research project grants in 1980 will be approximately 16,200, and in 1981 approximately 16,700. Therefore, the first priority in 1981, Mr. Chairman, is to provide some stability and predictability in the Institutes' support of investigator-initiated research through the research project grant mechanism.

OTHER SUPPORT

There are other smaller additions to the budget which I can very quickly summarize for you, Mr. Chairman. On chart A, the bar other support, adjacent to the research project bar, comprises support for research which also contributes to the science base. This category will receive $5 million more in 1981 for the biotechnology program administered by the division of research resources for the subsidy of large instruments which may be used by more than one institution, or by at least more than one department, within a particular region of the country.

In addition, $1 million has been added for a minority training program, which is a Presidential initiative. This program will create opportunities for minority high school students to participate in research during the summer and, we hope, to be encouraged by that opportunity to choose biomedical research as a potential career.

INTRAMURAL RESEARCH

Intramural research still represents an extraordinarily important part of the total biomedical research activity in the United States. Intramural research is that conducted by the NIH itself through its several Institutes. This is an extraordinarily strong program which remains vigorous and is a benchmark for excellence throughout the entire system in the United States.

This year, $5 million and 55 positions will be added to help the National Institute for Environmental Health Sciences open its new facility in North Carolina.

In addition, $8.5 million has been added to the buildings and facilities account within the NIH budget for the purpose of permitting essential modernization of the clinical center and to begin remodeling five laboratory buildings that are antiquated and far behind safety codes.

APPLICATIONS RESEARCH

In the applications bar on this chart, Mr. Chairman, we represent a set of activities that begin to move knowledge into very practical inventions for application to health maintenance, prevention, and cure of disease. This includes clinical trials. A total of $6 million will be added for these activities. Certain amounts are reprogramed to increase the capacity of the national toxicology program—a program developed last year to bring together all the activities of the Department and related departments in the Government for testing the toxicity to man of chemicals in the environment.

TRANSFER AND TRAINING

The other two bars, Mr. Chairman, are transfer and training. Transfer represents activities designed to help move innovations into the practice of medicine, and it includes much of the activities of the National Library of Medicine.

Training is the last of the major aggregates of NIH activities.

Through this program we maintain the capacity to provide for the support of some of the people who are essential for renewal of the biomedical research system.

Thus, Mr. Chairman, I have shown you, very briefly, how the $139 million in the 1981 budget over the 1980 appropriation will be distributed.

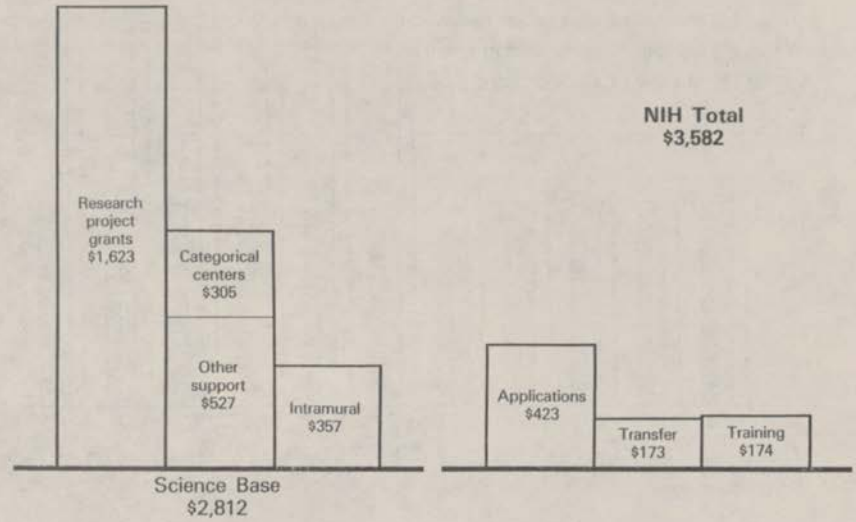
I would like to close, Mr. Chairman, by saying that it remains a time of extraordinary opportunity. I think this is the golden age in medical research, and you will have the opportunity, as we listen to the Institute directors, to hear of some changes, some new increases in the opportunity to apply various parts of the science base to benefit mankind. Discoveries—from the small—new contraceptives, the continuing surge of application of the recombinant DNA technology, on the new discoveries or to arthritis, on to a whole host of magic changes that reveal that this, indeed, still is, I think, the golden age of biomedical and behavioral research practical gains potential and real, to the welfare of man.

I have several other charts which I have not described, but would like to insert in the record. Mr. Chairman, I will be very glad to answer any questions you may have.

[The charts follow:]

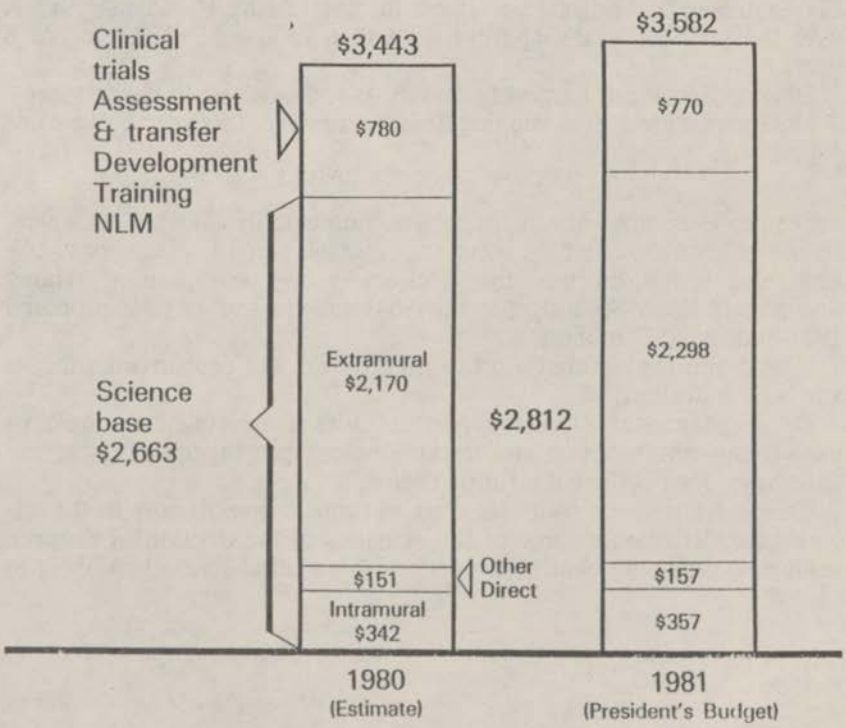
Distribution of NIH Funds, President's Budget, FY 1981

(Dollars in Millions)

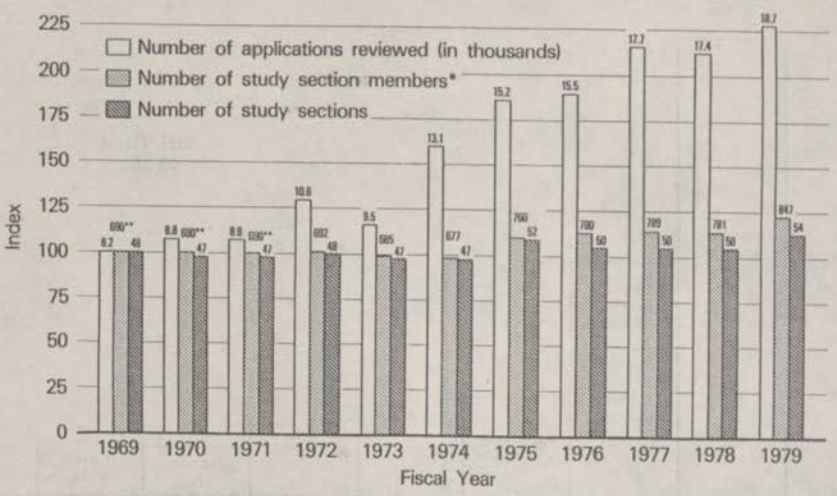


Distribution of NIH Funds, FY 1980 & 1981

(Dollars in Millions)



Numbers of NIH Grant Applications Reviewed, DRG Study Section Members, and Study Sections, FY 1969-1979



*As of 12/31 **Estimated

BUDGET INCREASE

Senator EAGLETON. Do you think your budget request is a golden age budget request, commensurate with the era?

Dr. FREDRICKSON. Mr. Chairman, somehow it is almost never possible to realize all potential opportunities in a golden age like this. It is notably an increased budget, the largest increase in the President's budget over the previous year's appropriation that we have had in the last 8 years.

Senator EAGLETON. Largest in dollars. Is it the largest in percentage?

Dr. FREDRICKSON. It is the largest in percentage, this year being some 4.4 percent.

DECLINE OF OTHER SUPPORT

Senator EAGLETON. My attention was momentarily diverted elsewhere. In the column on chart A, other support, the second science base column, that is the only one that declines—I beg your pardon, training declines. In the 1980 budget it was $541 million and in your proposed 1981 budget, $527 million.

Would you explain that a bit to me? Would you explain what that is and why it declined?

Dr. FREDRICKSON. Other support includes a variety of mechanisms used to support scientists and institutions engaged in enlarging the science base. That is the basic rubric there.

It includes research contracts used to support investigators in the science base. It includes some of the activities of the division of research resources, providing clinical centers and biomedical research support to

institutions, as well as a variety of other mechanisms including grants to support investigators. This category consists of a highly heterogeneous group of mechanisms for support of research that differ from the discrete projects or the categorical centers, like the comprehensive cancer centers.

Senator EAGLETON. Why does it decline $14 million?

Dr. FREDRICKSON. It is probably through research contracts support that has been primarily supporting activities of research, animal resource centers, many other activities that are supported in that line. We had to do some belt tightening to shift enough resources to obtain our goals for the research project grants.

Senator EAGLETON. We will get into the training figure a little later on.

FUNDING FOR RESEARCH GRANTS

Senator EAGLETON. Let's do the RO–1 column.

You have requested funds for RO–1, so to speak, $488-some-odd million for fiscal year 1981 budget.

That is for competing—I beg your pardon. Now for the competing research grants, is that a term of art? Is the figure for 1981 for $488 million?

Dr. FREDRICKSON. Yes, it is. It is $488.5 million.

Senator EAGLETON. OK. Refresh my memory. Why was there such a marked decline in that account between fiscal years 1979 and 1980?

If my figures on this sheet are right for fiscal year 1979, it was $525 million. For fiscal year 1980, it is $443 million, a decline of about 15 or more percent.

And now your fiscal year 1981 request brings it halfway back to what it was in 1979, but not all the way back.

Dr. FREDRICKSON. That is correct, Mr. Chairman. In 1979 we were able to fund about 5,900 competing research project grants.

In 1980, we estimate some 4,700, perhaps 4,750.

I think the difference is a result of the drop in purchasing power in the NIH appropriation over those 2 years.

Senator EAGLETON. It is not only the drop in purchasing power, but a precipitous drop in dollars appropriated.

So it was a double whammy. We cut back from $525 to $443 million. And then you factor in whatever the inflation rate was between 1979 and 1980. It was a severe blow.

I am trying to refresh my memory as to why that occurred.

Dr. FREDRICKSON. There are three major changes to contend with here. One is the number of noncompeting applications which had to be funded and maintained within the appropriation. Those continuations went up considerably in 1980 over 1979. You see the total number of grants.

Senator EAGLETON. Yes.

Dr. FREDRICKSON. That is probably the single largest factor. The second is the matter of inflation and the cost of new grants each year. These factors were only partially offset by a generous increase over the Presidential budget in 1980 designated primarily for research grants.

I think, Mr. Chairman, that the drop between 1979 and 1980 led the

administration to agree that we should try to avoid any further drop in this grant line in 1981.

Thus, you have been presented with this proposal today directing most of the increase in 1981 over 1980 toward research project grants.

STABILIZING THE SCIENCE BASE

Senator EAGLETON. Is this figure of 5,000 competing research grants, is that now to become a magical figure or an operative figure?

Is this the best wisdom that can be pulled together as to what a constant base should be of competing research grants funded?

Dr. FREDRICKSON. That is an important question, Mr. Chairman. Just yesterday, the Secretary released a new health planning document.

Senator EAGLETON. I am delighted to be the first one to see it. [Laughter.]

Dr. FREDRICKSON. You are the first one to see it. I regret that we could not get it to you earlier.

Senator EAGLETON [to staffer]. Read that by noon. [Laughter.]

Dr. FREDRICKSON. The document discusses stabilizing the science base as a health research initiative.

Senator EAGLETON. Where is that section?

Dr. FREDRICKSON. The document has an overview and discusses several initiatives. And on page 4——

Senator EAGLETON. Page 7 is the overview. And the first one you have is smoking. Let's skip that. [Laughter.]

Dr. FREDRICKSON. You need not go further than page 4.

Under stabilizing the science base, we discuss the rationale for attempting to set some minimums, or a floor, for Federal support for this kind of activity.

We point out several things—one is the necessity of continuing assurance for young investigators that they can compete and that there will be someone there to purchase their ideas after they have invested their whole lives in training for this particular activity.

We also point out that research grants are not the only way to do basic research. Large centers do good basic research. Our own intramural programs are extremely important. There must be a balance of activities.

But we had to select one of these that has been subject to the most variation from budget year to budget year and has had such an important single effect on the extramural community.

With regard to the designation of a particular number of new grants, there is no absolute rule or reason.

One tries to estimate, within a given series of budget cycles, what the Nation can invest. What can be a minimum level of stability?

In the body of this report, Mr. Chairman, we provide an analysis of what it would take for 5 years to maintain a certain number of new grants, 5,000, at an absolute figure or on the basis of some modest or minimal growth. That analysis appears on page 91.

In this section, NIH and ADAMHA have displayed separately the investment that would be required from fiscal years 1981 through 1984. These figures could be considered as yardsticks or possible azimuth set-

tings for us to consider as we go from year to year in an attempt to maintain some continuity of research funding.

It is a first effort in research planning on the longer range. I know that you and others have often indicated how much you would like to see that attempted. This document represents a first start.

Clearly, if we stabilize grants, we have to look at the rest of the system. Adjustments will have to be made there, too. However, the scale of adjustment is much greater than on a year-to-year basis. That is why we are trying to assist in a longer range examination.

INCREASE IN COMPETING RESEARCH PROJECT AWARDS

Senator EAGLETON. I am reading on page 91 of the first asterisk footnote that reads:

> The budget for fiscal years 1980 and 1981 have already been developed. The "modest" level of growth (alternative 1) for fiscal 1982 and later is based on the average annual increase (330) in competing research project awards for fiscal years 1976-80.

Was there an average annual increase in competing research project awards during that period?

Dr. FREDRICKSON. These are actual figures, Mr. Chairman. We tried to derive, on a real base, some means of obtaining certain projections.

Senator EAGLETON. I refer to the staggering drop between 1979 and 1980 from 5,944 to 4,768.

But even with that plummet of about 1,200, if you average the whole 1976 to 1980 period, it averages out at a 330 plus.

Is that right?

Dr. FREDRICKSON. It does, particularly if you look at chart B. You can see material growth between 1977 and 1978. It is from the benefit of these growth periods that the average comes out to be approximately 320.

Clearly, we do not know what the optimal level of growth is. We want to fund as much quality research as we can.

Other indicators have been used by all of us—priority score paylines, the percentage of approved grants, and so forth—all of which have merit in indicating what portion of the eligible research grants may be funded.

As was discussed at the Senate and House committee hearings last year, we have chosen a number of grants to fund in 1981. This approach has the virtue of indicating how many scientists can be supported. Each grant supports an average of 2.7 people.

Again, this is not a perfect index, but it does give an indication of the size of the whole system and how many people are being maintained in this important activity.

PERCENTAGE OF GRANTS FUNDED

Senator EAGLETON. Would these figures be correct? I have been handed a sheet which has no title, but it has an opening sentence: "The administration's plan for NIH of 5,000 research grants a year hardly represents a lofty goal." As these figures illustrate—there is a set of

figures, and then they use the Child Health Institute as the bottom set of figures.

Let me take you through these figures.

Dr. FREDRICKSON. These figures were developed from information we provided you. They are essentially correct.

Senator EAGLETON. What about the line, percentage of approved grants funded? That percentage goes down every year, including down on the estimate in 1981.

Now you have a process of approving grants. So in fiscal 1979, it is close to half of all of the approved grants were funded—close to 47 percent.

Dr. FREDRICKSON. That is correct.

Senator EAGLETON. In 1980, it is only 37 percent. And as we project 1981, it will be 33 percent.

So in a 2-year period, it will have gone from close to half down to a third.

And then I ask the question: Should we be totally comforted by that 5,000 figure if we were to stick to that, say, for the first half of the decade of the 1980's and if these percentages continued in the same line, 1983 we would be to about one-fourth of the grants funded, and by 1985, to a fifth.

Those are just rough guesses. I am trying to establish the record on this figure of 5,000. It is a devil's advocate question. It may be more than devil's advocate. Is the 5,000 good enough?

Dr. FREDRICKSON. The question is a fair one and I would like to answer in this way.

The change in the capacity to fund approved grants—that is, the percentage that we can fund—is a function of two major figures. One is a continuing rise in the number of applications over the period examined. The second is a decline in absolute purchasing power for this kind of mechanism.

The 5,000 figure was selected because of the background in terms of amounts that you see displayed before you on chart B. It is very clear that 5,000 research project grants, which permits the purchase of only one-third of the total pool of those approved, guarantees that you are buying blue chip ideas. You are buying very good science.

I think the question of whether 5,000 is enough, Mr. Chairman, is really how much more can we afford? What can the Nation afford to purchase from a display of opportunity?

We do think that 5,000 is a minimum, a floor figure, in our own view.

Hence, the table on page 91 that we referred to earlier refers to a maintenance of the 1981 level, but also to other factors—minimal growth and modest growth, which I think is very modestly calculated, as you mentioned earlier in reading that table.

I think it offers us an opportunity, Mr. Chairman, to try to compare need and opportunity.

GRANT APPLICATIONS

Senator EAGLETON. Why is it that in the last 5 years, especially, the number of approved grants, as distinct from grants funded, the number

of approved grants has—reviewed grants, I'm sorry—reviewed grants, has skyrocketed?

That is chart E.

Dr. FREDRICKSON. There has been a precipitous growth since the early 1970's. Again, there are several reasons why we are receiving more grant applications.

It shows something of the health of the system at the beginning and the number of people capable of competing for opportunities to do this kind of work.

I think it also reflects the need of a larger number of people to compete for grant support as opposed to being maintained perhaps in other ways and through other institutions.

Senator EAGLETON. Let's put it in layman's language. You mean as other moneys have dried up or have been constrained, it has driven, as it were, more scientists into trying to seek funding through this mechanism as opposed to other more traditional modes, that they had too many doors slammed?

Dr. FREDRICKSON. That is precisely right. In other words, in some laboratories and departments, some people have been maintained for several years on Department chairmen's funds, by private foundations, or by other mechanisms of support, and these mechanisms are no longer available to them. Hence they have had to enter the competing grant system.

Finally, there is a modest increase in the number of applications per scientist in the total group that is received by NIH. But the major reflection is the number of people capable of competing and who want to do research.

INFLATION RATE FOR BIOMEDICAL RESEARCH

Senator EAGLETON. Is there a rate of inflation in biomedical research that is identifiable, that is separable from the Consumer Price Index or some other inflation indicator?

Dr. FREDRICKSON. Yes, we think there is, Mr. Chairman. We have maintained such a deflator, the biomedical research deflator, for purposes of calculations and projections for some time. The last time that was revised was in 1977 or 1978. We have been correcting it since on the basis of that figure times the change in the Consumer Price Index.

Today the best guess we have is that the current rate of inflation for research activities is about 9.2 to 9.5 percent. One must consider two major components—the question of change in personnel costs and the change in the cost of all other objects. That 9.2-percent figure is probably a mean of two values that run somewhere between 5 and 7 percent, which represents the change in personnel costs or salaries in all of research as against much higher figures in terms of changing and increasing cost for some of the equipment, supplies, and other items that are needed to do biomedical research.

Senator EAGLETON. Before we got into the era of galloping energy costs, a cliché that all politicians used, whether an accurate cliché, was health services—and I say health services—outstripped whatever the general rate of inflation at least twice. It was the leading inflation indicator. Maybe that was an inept cliché when used.

Why, I ask, would the biomedical research inflation figures—somewhere between 9.2 and 9.5 be so considerably below the CPI which is 13.3?

Dr. FREDRICKSON. I think a major factor in holding research inflation down, as bad as it is, is the fact that personnel salaries in this system for science simply do not change at the same rate as the cost to consumers. Salaries are much lower.

Senator EAGLETON. If you break down your budget Institute by Institute with the exception of the National Institute of Environmental Health Sciences, no other Institute gets anywhere close to a 9.2- or a 9.5-percent increase.

Dr. FREDRICKSON. That is correct.

INVESTIGATOR-INITIATED RESEARCH

Senator EAGLETON. Some questions for the record. Last year the Congress urged NIH to place emphasis on investigator-initiated research. In response to this directive, you put all of the increase you received into regular research grants.

Now these questions. Do you regard this is an appropriate interpretation of investigator-initiated research, or is it too narrow?

Dr. FREDRICKSON. We did indeed put all the increase into research project grants, which are investigator-initiated. I think, for the purposes of responding to a congressional request, and to a true need in the system, that while this does not define all basic research or investigator-initiated research, it was a reasonable response.

RESEARCH CAREER PROGRAM

Senator EAGLETON. What about the research career program?

Dr. FREDRICKSON. The research career program is also an area of considerable importance in achieving the same objective of investigator-initiated research. We would like to be able to fund more than we do, but we have had to make a choice.

Senator EAGLETON. Would the research career program be as susceptible to being described as another form of investigator-initiated research?

Dr. FREDRICKSON. It is certainly intimately tied to maintaining that kind of research.

Senator EAGLETON. Is there investigator-initiated research in other mechanisms as well, such as at the centers?

Dr. FREDRICKSON. Indeed, there is investigator-initiated research at the centers, as well as in the intramural program maintained by NIH.

RESEARCH TRAINING

Senator EAGLETON. Let's get into the training. For the record, just drawing from your charts—chart A—the 1980 estimate, training, $187 million; for 1981, training, $174 million.

As we stated last year, research training continues to be one of the highest priorities of this committee. Because of that, part of the increases provided NIH was to increase its stipend level to $15,000 with no cutbacks in the number of people being trained.

Was this done for each Institute?

Dr. FREDRICKSON. It was not possible for us to increase the stipends, which we have done, and still maintain the same number of trainees for each Institute. We simply did not have the purchasing power to do that and also maintain an increase in the number of research project grants.

STABILIZATION OF TRAINING PROGRAM

Senator EAGLETON. If we are on the threshold of establishing a figure of 5,000 grants for RO–1 for basic research as a base and doing some forward planning for 3 or 4 years on that base, should we not likewise establish some form of a base, either in terms of dollars, grants, number of people trained, or whatever would be the more meaningful formula in the research training area?

Dr. FREDRICKSON. I agree completely that we must do that.

Senator EAGLETON. Are we beginning to do it in this year's budget request, as you see it?

Dr. FREDRICKSON. We are not doing it in this year's budget request. It is one of those objectives that will take longer than a single year to achieve.

Senator EAGLETON. Does this report that you handed us, does it discuss or treat this issue I have now raised with you?

Dr. FREDRICKSON. The report does not discuss training, not because it is not important, but because we had to select a set of issues first.

Senator EAGLETON. Isn't it just as important in this area of training to inject a degree of prudent predictability for the research community out there as it was to establish a similar base in the RO–1 area?

Dr. FREDRICKSON. It is, Mr. Chairman, because without training of some kind supported from some source, people will not be available to conduct research in the years ahead.

Senator EAGLETON. Right. Do you have in process a study or an analysis in this area, similar to the one that you handed us this morning in the RO–1 area?

Dr. FREDRICKSON. In response to congressional mandates some years ago, we funded a national study on the need for research manpower—a need which is continuing and getting sharper. The study focuses on the needs in various areas and what the contribution from the Federal Government should be.

Training and research project grants are slightly different, in that NIH clearly is the major source for support of research projects, but only one of several major sources for training support. In saying that, I do want to reiterate my own conviction that the Federal source of training is crucially important to the maintenance of the system.

It is not the only source of training funds, and I think it need not be. But there must be a predictable and adequate level of support for training from the Federal Government to underwrite other research activities in the long run.

Senator EAGLETON. What are the other sources, sizable sources, for funding training research?

Dr. FREDRICKSON. That is part of what the National Academy of Sciences is trying to tell us. It has access to information that we cannot

obtain directly by questionnaires. We are not certain of where all the training money comes from. We know that NIH trains about one-quarter of the people who apply for our research grants and obtain them.

These trainees are, in the main, a very successful fraction of the total participants in science, although this may be inevitable since they were good enough to get training in the first place.

Other sources of training include State support, foundation support, private subscription, and, of course, in many instances, parental support for expenses such as tuition. We do not have the degree of information we would like to have about where people get their support for training when they cannot get it from a Federal training grant.

CLINICAL INVESTIGATORS

Senator EAGLETON. Let me read to you, Dr. Fredrickson, an excerpt or two from an article that appeared in the New England Journal of Medicine of last December 6, 1979—a special article written by James B. Wyngaarden entitled, "The Clinical Investigator as an Endangered Species."

It starts off:

> This paper deals with the physician investigator as an endangered species and with the future of clinical research.

I will skip down and read the second full paragraph.

> For several years, there has been a declining interest in biomedical research on the part of medical students, health officers, postdoctoral M.D. fellows, and young faculty because the length of the pipeline from entry as a trainee to emergence as an independent investigator is 5 to 8 years. The effects may not yet be visible on the annual programs of our national societies, but they are clearly visible to department chairmen and division chiefs who find the recruitment pool of thoroughly trained physician investigators smaller each year.

Could you comment on that?

Dr. FREDRICKSON. A critical problem does exist with regard to the supply of clinical investigators in the United States. They are a crucial hybrid species who are essential if we are to translate activities from the laboratory to the bedside.

Our own data suggest that we may have bottomed out in terms of the decline in the absolute number of clinical investigators, or M.D. participants at least, although the number of people doing biomedical research today who are Ph. D.'s is considerably greater than the number of M.D.'s—a reversal of the situation some 10 or 15 years ago.

This is a very complex issue none of us completely understands. A study is underway by the Academy to deal with this specific issue. We, too, are investigating numerous aspects of it.

I think that we have a problem. We partially understand it, and we are trying to do several things to increase the number of people interested in clinical investigation. I could list several of these, if you wish, Mr. Chairman.

Senator EAGLETON. I wish you would, but how do you try to turn this trend around, if indeed there is a trend? And I will get into a chart that is part of this article by Dr. Wyngaarden.

But how do you turn that trend around by cutting the training figure from $187 to $174 million?

Dr. FREDRICKSON. The reduction is certainly not a move in the direction of helping to correct this particular deficit.

We are emphasizing our M.D./Ph. D. program for several reasons. One of the problems with science and the physician today is that science is moving so fast that it is very difficult to be both a good doctor of medicine and a good scientist. The M.D./Ph. D. route is perhaps the most sensible of all that we have.

We are now training about 600 of these people at any given time. We are beginning this year a summer training program for medical students which will allow them three summers of exposure to good clinical investigators, so that they may become interested further in research.

We increased the stipends last year. I think this is a very important move to try to compete with better salaries in clinical training for other purposes. I think that we need to continue to try to provide a good base of institutional training grants in those areas where role models exist—to take the best of these students and offer them an opportunity to invest in biomedical research as a career.

Senator EAGLETON. There is a chart in this article which we will put in the record.

[The chart follows:]

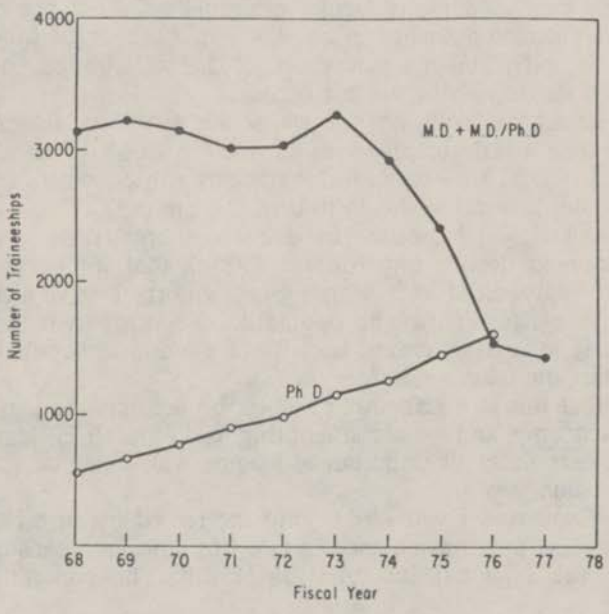


Figure 1. Postdoctoral Traineeships Awarded by the National Institutes of Health to Candidates Holding M.D., and M.D. plus Ph.D., Degrees, as Compared with Those Holding the Ph.D. Degree Only, 1968–77.

The data include renewal awards as well as first-time awards.

Senator EAGLETON. It says, referring to the chart—the caption below it is "Postdoctoral Traineeships Awarded by the National Institutes of

Health to Candidates Holding M.D. and M.D.-Plus, Ph. D. Degrees as Compared With Those Holding Ph. D. Degrees Only." And it tracks from 1968 to 1977.

The chart purports to show that in 1968, for example, there were 3,000-plus traineeships for M.D.'s and M.D./Ph. D.'s. That remained fairly constant—around 3,000, give or take a few—up to about 1973, and then it plummeted downward, so that by 1977 on this chart, the number of M.D./Ph. D.'s had dropped to—it looks to me around 1,300 Ph. D.'s—that is, Ph. D.—no other degree—has increased slightly through that same time frame. In 1968, it looks to me like maybe around 550 or 600 and gradually escalating in 1976 to about 1,300.

Now I will pass this to you, and maybe you can interpret it. When I pass it over, I will mark a sentence from this article adjacent to the chart and ask you to comment on it.

The article says: "For example, in 1977 NAS—the NAS Committee authorized 2,800 postdoctoral traineeships and fellowships in the clinical sciences but only 2,304 were filled." That is a cumbersome question, Dr. Fredrickson, but it is the best we can do.

REDUCTION IN TRAINING FUNDS

Dr. FREDRICKSON. Without further examination, I am not quite sure what Dr. Wyngaarden wishes to convey. The number of trainees supported by the NIH and the percentage of the NIH budget for training has dropped remarkably in the last decade.

Senator EAGLETON. Well, how do we, at the very least, flatten that out or have it turn a little bit upward? Maybe we won't go back to those euphoric days of 1970—whatever that chart shows, when there were over 3,000. But how do we begin to turn this around?

Dr. FREDRICKSON. I personally believe we cannot let the level of support for training decline any further. I think that we need to try to accomplish what we did for research grants and try to give a reasonable projection for what might be an optimal level of support for training. It is not as easy as it is for grants, because of the dominance that we have in supporting the latter.

I think that this is a task that can best be accomplished by working with the Academy, and we are attempting to do that. It is clearly a matter of the next order of importance. I agree with you that it is a very serious question.

Senator EAGLETON. I will read it into the record because I think it is pertinent at this point, a sentence or two from the last year's committee report on the National Institutes of Health. The committee wrote, quote:

> There are shrinking numbers of medical doctors becoming interested in biomedical research and this trend must be reversed, and students from other disciplines also are turning away from this important career. In addition to this research training funding, the Committee in other parts of the bill has also added significant amounts so that minorities also will be encouraged to enter this important area of biomedical research.
>
> At the time of the fiscal year 1981 hearings, the Committee will expect a report from the Director outlining how the research training funds are utilized and what the need will be in future years.

Although I haven't read the report, obviously, that you handed us here this morning on—in essence dealing with RO–1, I think if a future report, albeit difficult to draw together because of the unavailability or the readily—the lack of readily available figures as to other modes and methods of fundings, nevertheless, it would be an important report for this committee to have in due time, Doctor.

Dr. FREDRICKSON. We would accept that.

NIGMS TRAINING

Senator EAGLETON. Dr. Kirschstein, is it your Institute that, in essence, generates the greatest number of training researchers?

Dr. KIRSCHSTEIN. Yes, Mr. Chairman. The National Institute of General Medical Sciences is preeminent in the research training area, supporting about one-third of all of the efforts in research training of all of the Institutes and two-thirds of all of the predoctoral or pre-Ph. D. training. In addition, in an attempt to correct the situation you have talked about regarding clinical investigators, it is the National Institute of General Medical Sciences that supports the medical scientists, or M.D./Ph. D. combined degree program.

[A brief recess was taken.]

Senator EAGLETON. While we are waiting for this chart—well, here we are. We have a sheet here labeled NIH training programs. Let's go down to the Institute of General Medical Sciences, marked GMS. According to our figures, comparing the 1980 budget in place with the anticipated 1981 budget in terms of individuals, in the 1980 budget—these are individual awards, 292 in the 1980 budget; declined to 206 in the 1981 budget.

Dr. KIRSCHSTEIN. That's correct.

Senator EAGLETON. What will be the impact of that?

Dr. KIRSCHSTEIN. The National Institute of General Medical Sciences will obviously have a very marked decline in the number of individual fellowship awards that can be made. Most of these individual fellowship awards are made for a period of 2 to 3 years, and the number, of 206, proposed in the 1981 budget are those that will be entering a second year of research training.

Senator EAGLETON. Do you have available, for instance, the number of individual fellowship awards out of GMS for the last 4 or 5 years? I would like to see if there is a trend line.

I will ask Dr. Fredrickson to supply that at a later part of the hearing, take that sheet, NIH training programs, and track it backward for each Institute, if you will, for about 4 or 5 years.

Dr. KIRSCHSTEIN. Yes, since 1977 the number supported by the National Institute of General Medical Sciences has been declining from 324.

Senator EAGLETON. 1977 was what?

Dr. KIRSCHSTEIN. There were 324 which dropped to 206 in 1981. There was a period in 1979 when there were 459 individual awards.

Senator EAGLETON. How did that happen? How did you zoom upward from 298 in 1978 to 459 in 1979? I am looking at some other figures. It wasn't true of NIAID. It was true of several others. It has

61-400 O - 80 - 21

gone from 324 to 298, quite a bit upward to 459, and then back to 292 and down to 206.

Now, insofar as institutional training awards, although dollars go up from $42 to $50 million, still, nonetheless there is a modest drop of $8 million in the number of institutional training awards.

Dr. KIRSCHSTEIN. The increase of almost $8 million between 1980 and 1981 is related to an increase in the funds needed for noncompeting awards. Generally, the institutional training grants are awarded for 5 years, with a stipulated number of trainees to be supported. That number usually is smaller in the first year and gradually, over a period of the next 4 years, the number of trainees escalates as the experience of the institution in providing research training becomes greater.

And the $8 million is for support of those increased numbers of trainees.

Senator EAGLETON. All right.

[The information follows:]

NIH TRAINING PROGRAMS

Institute	Type	No.	1980 budget	No.	1981 budget	No.	Decrease
Cancer	Individual	210	$4,213,000	130	$2,828,000	80	$1,385,000
	Institutional	157	22,901,000	132	19,829,000	25	3,072,000
Heart	Individual	277	5,646,000	210	4,305,000	67	1,341,000
	Institutional	291	7,622,000	253	26,724,000	38	898,000
Dental	Individual	61	1,199,000	46	942,000	15	257,000
	Institutional	30	2,999,000	28	2,823,000	2	176,000
NIAMDD	Individual	165	3,954,000	74	1,743,000	91	2,211,000
	Institutional	210	17,111,000	172	13,449,000	38	3,662,000
NINCDS	Individual	259	5,058,000	160	3,175,000	99	1,883,000
	Institutional	47	3,854,000	38	3,920,000	9	+66,000
NIAID	Individual	107	1,985,000	82	1,804,000	25	181,000
	Institutional	78	7,883,000	58	6,537,000	20	1,346,000
GMS	Individual	292	5,330,000	206	4,220,000	86	1,110,000
	Institutional	291	42,092,000	283	50,159,000	8	+8,067,000
NICHHD	Individual	91	1,638,000	54	1,026,000	37	612,000
	Institutional	85	8,182,000	74	7,149,000	11	1,033,000
Eye	Individual	106	2,071,000	76	1,558,000	30	513,000
	Institutional	32	2,722,000	23	1,743,000	9	979,000
Environmental	Individual	23	447,000	24	486,000	+1	+39,000
Health	Institutional	41	6,121,000	42	6,228,000	+1	+107,000
Research	Individual	1	17,000	.....	.....	1	17,000
Resources	Institutional	8	639,000	8	707,000	0	+68,000
Aging	Individual	34	640,000	18	351,000	16	289,000
	Institutional	27	2,142,000	21	1,821,000	6	321,000

EARMARKING OF FUNDS

Senator EAGLETON. Let's get into the question of earmarking, Dr. Fredrickson. This committee, we think, has been fairly decent for the last 3 years. We haven't engaged in much, if any, specific earmarking in our Senate report. The House still indulges in this process in their report. By the time we get to conference, we strip out practically all the earmarking so far as the conference report is concerned.

In what position does this leave you as the Director of NIH, when you have to read all three reports? What is your policy directive if you

had lots of specific earmarking in the House report, little or none in the Senate report, and virtually none in the conference report?

Dr. FREDRICKSON. Although this committee does not indicate specific earmarking, I can say that we nevertheless certainly try to capture the spirit of what this committee intended, and to read very carefully those aspects of the report language that indicate the desire of this committee. We try as best we can, certainly, to serve the issues of the Senate as well as those of the House.

Senator EAGLETON. That is a good general answer. [Laughter.]

I don't like a lot of earmarking. As an administrator, you would prefer to have as little of that, as a practical necessity. If, however, we—this committee—come to the conclusion that by our silence insofar as earmarking is concerned we then are deferring to whatever the House earmarks and their earmarking becomes operational, it will in due time, maybe this year, force us to get in the earmarking business, too, and compound your dilemma as the Administrator.

Dr. FREDRICKSON. I understand that, Mr. Chairman. I want you to know that we respect the advice of this committee to every degree as we do that of the House. It sometimes places us in a very difficult position when the wishes are contrary.

Senator EAGLETON. Yes. Last year the House appropriation increases were earmarked basically for new grant awards. When this matter came to conference, the Senate totally rejected this. The conference report said nothing.

How much of the increase then went for new awards, what percentage?

Dr. FREDRICKSON. I will supply that for the record.

[The information follows:]

1980 INCREASE FOR COMPETING RESEARCH PROJECTS

Of the $256,951,000 increase provided by conference action over the 1980 President's budget, a total of $177,151,000, or 69 percent, was identified for funding competing research project grants in 1980. The table below shows a distribution of the conference increases by Institute.

1980 conference allowance increase over 1980 President's budget

[Dollars in thousands]

IRD's	Increase	Other increases	Total	Percent of increase
NCI	18,200	44,842	63,042	28.9
NHLBI	20,200		20,200	100.0
NIDR	1,700	500	2,200	77.3
NIAMDD	35,500		35,500	100.0
NINCDS	28,300	1,378	29,678	95.4
NIAID	23,179	2,021	25,200	92.0
NIGMS	31,800	300	32,100	99.1
NICHD	4,600		4,600	100.0
NEI	4,972	3,500	8,472	58.7
NIEHS	3,300	1,600	4,900	67.3
NIA	5,400	8,090	13,490	40.0
DRR		15,000	15,000	
FIC				

1980 conference allowance increase over 1980 President's budget—Continued

[Dollars in thousands]

IRD's	Increase	Other increases	Total	Percent of increase
NLM		2,569	2,569	
OD				
B&F				
Total	177,151	79,800	256,951	68.9

RESEARCH PROJECT GRANTS

Senator EAGLETON. By our indication—we don't have the figure handy—it was sizable. Give us a general overall percentage and then a breakdown by Institute, if you would.

Dr. FREDRICKSON. Yes.

Senator EAGLETON. I read to you the supposed directive of this committee on training grants, an increase of the stipend to $15,000, et cetera. You were not able to follow that directive because of inadequate funding or what?

Dr. FREDRICKSON. It is certainly true, Mr. Chairman, that we could not maintain the stipends at the level you directed, and we wanted, or attend to the need for more research grants, and still maintain the training grant level. We could not do all three things.

Senator EAGLETON. Well, we can ask you, Doctor, to do the impossible. Governor Connally says we can increase defense spending, cut taxes, and balance the budget. [Laughter.]

He says we can do that. We can order you to do that.

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

FY 81 FUNDING REQUEST

Question: Your fiscal year 1981 budget request provides for an increase of about $153 million over fiscal year 1980. This is slightly more than a 4% increase, hardly enough for NIH to keep pace with inflation.

How do you justify such a small increase in a program where the payoffs are high and the benefits clear?

Answer: Considering biomedical research in the context of the many competing demands facing the Nation and the overall fiscal restraints, NIH is pleased to have the sizable increase in its support for research that is reflected in the 1981 budget. In husbanding this increase, we have concluded that the best investment of the research dollar is to maintain adequate support of the science base. An important part of such research is the investigator-initiated research project grants, which is the primary mechanism for basic research breakthroughs. Such emphasis in the 1981 budget signifies the Administration's commitment to maintain and sustain fundamental biomedical research.

Question: Isn't a 4% increase actually a reduction? Won't you have to cut back in some research--or delay beginnings in other promising areas?

Answer: Although a 4% increase has not kept pace with inflation for the whole NIH program, the NIH has sought to maximize its research returns by focusing its resources on the investigator-initiated research project grants. We are committed to maintaining adequate support of the science base by placing major emphasis on competing research project grants in FY 1981. Such an emphasis will serve to provide some stability to the research community and protect an important source of new ideas necessary for scientific breakthroughs.

In order to provide this emphasis on research project grants, other mechanisms of support such as intramural research, training, contracts, and research centers remain level or slightly below the FY 1980 level of effort.

Question: What is your professional judgment as to an appropriate increase for NIH in FY 1981?

Answer: Fully considering the economic climate today and the many competing demands for the Federal dollar, I feel that the increase provided for NIH in the 1981 request is both fair and adequate.

INTRAMURAL RESEARCH

Question: Your budget contains no increases for the intramural research program. Given the affect that inflation has had on both intramural and extramural research activities, how can you justify level funding for the intramural program?

Answer: As previously indicated, the first priority for the FY 1981 budget was to provide stability of support for extramural investigator-initiated research. However, the NIH intramural

research program can be characterized as a program of investigator-initiated research and during the coming year, we will be reviewing the intramural research program in the broader context of stabilizing the science base. We are concerned with the effect of inflation and the resulting erosion of purchasing power on all of our programs, but in a time of limited resources and many competing demands, our own intramural program must also do some belt tightening.

However, we don't believe that a one-year stand still budget will seriously affect our program. We will delay the initiation of projects not yet begun, reduce the scope of some projects and increase our efforts to share scientific equipment. We believe strongly that the NIH intramural program will maintain its pre-eminent position among biomedical research institutions.

OBSOLETE RESEARCH FACILITIES

Question: In recent hearings on the House side, you stated that "The obsolescence of the nation's biomedical research facilities is becoming a serious problem, both at research institutes, universities, and on the NIH campus."

Is funding sufficient to prevent this process from evolving further?

Dr. Fredrickson, would you like to comment on this?

Answer: It is true that many United States universities, hospitals, and other biomedical research institutions are unable to provide their scientists with the full array of facilities that modern biomedical and behavioral science requires. During the late 1950's and early 1960's when there was a rapid and comprehensive expansion of biomedical and behavioral research, many institutions took the opportunity to expand and develop their research facilities with funding from the NIH and other sources. Complementing its array of research project, research center, and research training awards, the NIH was able to help fund the construction of critically needed research health facilities.

Beginning in the mid-1960's and continuing to the present, the needs and opportunities in biomedical and behavioral research have grown faster than the levels of funding (both federal and nonfederal) available for it. One of the consequences was the virtual elimination of NIH funding and major cutbacks by other sponsors for the construction of health research facilities. Many institutions thus slowed down - or stopped - the expansion or rehabilitation of the physical facilities for research and have attempted to "make do" ever since with research environments that are increasingly inadequate for the tasks at hand. Such difficult decisions almost certainly will continue to be required for the foreseeable future.

Question: What steps do you recommend for reversing this trend in terms of the fiscal 1981 appropriations request?

Answer: The NIH works to prevent - or at least retard - the progressive deterioration in the physical environment for research by defining appropriate alteration and renovation expenses as allowable charges to most types of research grants. During FY 79, for example,

the NIH awarded in excess of $5 million for alteration and renovation of research laboratories. In addition, the NIH has authority for construction grants in a few specific programs (Cancer and Eye). The NIH will continue to work closely with representatives of universities and other research-intensive institutions and the health research community at large to ensure that the maintenance of the research environment receives appropriate attention when policy and program decisions are made.

Question: Is there any funding in the various budgets that would ensure a safe working place for those labs that deal with hazardous substances?

Answer: With respect to ensuring a safe work environment for those who do research with hazardous substances, this is an appropriate use of the alteration and renovation funds identified above. Applicants for research grants regularly have the opportunity to request funds to for physical changes in laboratories to effect or maintain safety.

Since they are an integral part of the research grant applications, these requests for alteration and renovation funds are viewed and administered in essentially the same way as are other legitimate research costs.

SCIENTIFIC EQUIPMENT

Question: The quality of scientific equipment used at many of our schools and laboratories is deteriorating rapidly?

Do you consider this to be problem?

In your judgment, what should we be doing to solve this and ensure that proper equipment is available for our research effort?

Answer: There is undoubtedly a problem throughout the biomedical and behavioral research community with respect to the quality and availability of scientific equipment. Scientists need frequent and easy access to many different kinds of instrumentation and devices if their research is to be productive at the state-of-the-art. Acquiring or otherwise gaining access to the equipment needed for modern biomedical and behavioral research is a chronic struggle for the following reasons:

1. The pace and direction of research are always changing as scientific questions are answered and new leads are identified. This constantly alters the nature and the extent of the need for equipment.

2. New and improved research instruments are continually appearing partly in direct response to the perceived needs of biomedical and behavioral science and partly as a result of advances in the physical sciences and engineering. Equipment in some areas may become obsolete in the span of a few years.

3. Research instruments generally are complex and are expected to meet exacting standards of performance in terms of accuracy, precision, reproducibility and generally

reliable. Maintenance, repair, and refurbishing efforts, therefore, must be accorded high priority if the productivity and quality of research are not to suffer.

4. An increasing number of research instruments are too expensive or too complex for a single investigator to acquire and operate satisfactorily. This trend is requiring new initiatives to promate the sharing of equipment on an institutional, regional, or national basis.

5. In developing budget for research activities, especially during times of fiscal restraints, scientists generally find it necessary to give a higher priority to staff salaries and associated expenses that to equipment. This means that the equipment category is the one most likely to be under-funded relative to scientific need and opportunity and the first one that is likely to show the effects of overall fiscal restraints.

The NIH has been taking a number of steps to deal with the research equipment issues and has recently intensified its activity. The principal efforts, either ongoing or planned, are as follows:

1. Almost all types of NIH research project grants and research center grants include research equipment as an allowable expense. Therefore, applicant investigators have many opportunities to request funding for the equipment they need to carry out the research they propose. They may need a small piece of equipment to be used exclusively in an investigator's laboratory (as is typically the case for an individual research project grant) or they may need an expensive piece of equipment to be shared by several different research teams (as is frequently the case with research center awards). The NIH will continue to offer the biomedical and behavioral research community many different administrative mechanisms through which to seek funding for scientific equipment.

2. Within the class of research center grants, special attention will continue to be given to the "core" grant. This type of award promotes the sharing of expensive and complex pieces of equipment on an institutional basis. These types of grants enable scientists to have access to types of equipment and services that they need but cannot justify individually. An important example is the special instrumentation initiative undertaken by the National Institute of General Medical Sciences during FY 1979. The NIGMS awarded sixty-five grants for shared instrument facilities in an aggregate amount of $7,638,000.

3. With respect to large-scale, highly specialized instrumentation facilities that are best shared on a regional or national basis, these are funded through the Biotechnology Resources Program of the Division of Research Resources. The President's Budget for 1981 includes a request for $22.8 million (an increase of $5.6 million over the FY 1980 level) in recognition of the increased needs and opportunities for such resources. Among the activities that fall within the scope of the Biotechnology Resources Program are nationally time-shared computer

systems and associated telecommunication networks, one-million volt electron microscopes, and high-field nuclear magnetic resonance spectrometers.

REHABILITATION OF LABORATORY BUILDINGS

Question: What's the real need regarding these laboratory buildings? Are these facilities falling apart? Or do they just need minor improvements?

Answer: Many of the NIH laboratory buildings have been in operation for more than 40 years. While the facilities are not "falling apart," the ravages of time have taken their toll. This natural deterioration with age -- combined with needs to accommodate new equipment, revised safety standards, and requirements for the handicapped -- make it essential that the buildings undergo modernization.

It is our judgment that the useful life of Buildings 2, 3, 4, 5, and 8 can be extended for many years if they are renovated.

Since these buildings were erected 40 years ago, the level of sophistication in research procedures and equipment has grown tremendously. At the same time, building technology has made available major advances to correspond with improved environmental safety standards and efficient support of research needs. This rehabilitation program is thus intended to achieve in these buildings standards of operation, program flexibility, and safety common to our more recent structures.

Department of Health and Human Services
National Institutes of Health

Number of New NRSA Training Awards
(dollars in thousands)

	1978			1979			1980		
	FTE's	No.	Amount	FTE's	No.	Amount	FTE's	No.	Amount
Cancer.....	305	199	$4,572	154	107	$2,337	80	54	$1,463
Heart.....	440	204	6,577	167	101	2,440	534	272	10,758
Dental.....	24	24	318	30	30	405	50	32	982
Arthritis.....	315	232	5,155	168	148	2,585	90	90	1,959
Neurology.....	143	124	2,325	232	209	3,321	99	92	1,914
Allergy.....	208	132	3,034	147	105	2,168	43	37	776
General Medical....	513	221	6,205	625	346	7,959	346	171	5,533
Child Health.....	176	94	2,301	272	111	3,577	--	--	--
Eye.....	46	43	711	83	67	1,200	37	25	849
Environmental.....	159	43	2,190	25	20	350	3	3	57
Aging.....	46	25	629	57	29	773	44	16	798
Research Resources.	1	1	16	--	--	--	--	--	--
	2,376	1,342	34,033	1,960	1,273	27,115	1,326	792	25,089

FTEs = Full time Equivalents

NATIONAL INSTITUTES OF HEALTH
1981 Requirements to Bring Training to 1978, 1979 and 1980 Levels
(Dollars in thousands)

	1981 President's Budget		1978 Total	Increment Needed in 1981 to reach 1978 Level		1979 Total	Increment Needed in 1981 to reach 1979 Level		1980 Total	Increment Needed in 1981 to reach 1980 Level	
	FTE	AMT.	FTE	FTE	AMT.	FTE	FTE	AMT.	FTE	FTE	AMT.
NCI.....	1268	22,657	1536	268	6,635	1542	274	6,398	1555	287	6,530
NHLBI.....	1516	31,029	1402	--	--	1438	--	--	1678	162	3,317
NIDR.....	197	3,765	167	--	--	208	11	726	226	29	755
NIAMDD.....	598	15,192	863	265	6,729	832	234	6,056	827	229	6,282
NINCDS.....	372	7,095	476	104	2,294	550	178	3,755	467	95	2,117
NIAID.....	378	8,341	568	190	3,794	546	168	3,927	501	123	2,729
NIGMS.....	3836	54,379	4496	660	9,206	4391	555	8,620	3475	--	--
NICHD.....	535	8,175	829	294	6,751	779	244	5,787	597	62	1,451
NEI.....	169	3,301	222	53	1,779	316	147	2,358	220	51	1,762
NIEHS.....	448	6,714	350	--	--	387	--	--	437	--	--
NIA.....	125	2,172	183	58	1,049	177	52	944	164	39	774
DRR.....	28	707	31	3	76	31	3	76	28	--	--
TOTAL...	9470	163,527	11123	1895 1/	38,313	11197	1866 1/	38,647	10175	1077 1/	25,717

1/ This total is not equal to the difference between the base year (1978, 1979, and 1980) and the 1981 President's Budget level because the 1981 training level for several institutes exceeds the base year level.

TRAINING FOR CLINICAL RESEARCH

Question: Dr. Fredrickson, there was quite a discussion at your subcommittee hearing about the level of training you are supporting for clinical research. Isn't it true that a lot of training is effectively supported on-the-job through funding of research grants, particularly at large centers?

Answer: One of the attractions inherent in a scientific career is the opportunity, as well as the necessity, for constantly increasing one's scientific skills. It is certainly true that some research assistants and research associates may be said to be in training status in that they may be working towards advanced degrees or the acquistion of new techniques while they are employed on research projects or in research centers. The research centers normally support a critical research environment which is naturally attractive to young investigators. Training qua training, however,is not an objective of research project or center support. Where it occurs, it is an important fringe benefit for the young people engaged as assistants in the conduct of research; but this piecemeal, unstructured, and uncoordinated array of experiences cannot realistically be considered a national research training "program" nor can it be relied upon with certainty to fill critical national need effectively and efficiently.

TRAINING FUNDS

Question: The training programs of the National Institutes of Health are the foundation of our - and the Institutes' - health research effort, now and even more for the future.

Under the President's budget request, how many new or competing renewal grants will be made?

Answer: At the 1981 President's budget level for the NIH there will be no new or competing renewal training grants awarded.

Question: Is it not true that under the President's budget request only existing commitments for trainee slots will be made?

Answer: It is true that, the President's budget level for 1981, only trainee slots committed as a result of prior year awards will be filled. Training grants awarded in previous years which continue into FY 1981 will be supported to the extent of the original commitment, for both funds and numbers of trainees.

Question: Under the FY 1979 bill was there a reduction in trainee slots from the number made under the FY 1978 bill? If so what percent?

Answer: In FY 1979, 11,197 trainees were supported by the NIH Training program. This was an increase of 74 trainees over the 11,123 trainees which were supported in FY 1978. This represents an increase of slightly less than one percent over FY 1978.

Question: Under the FY 1980 bill was there a cutback?

Answer: It is estimated that in FY 1980 approximately 10,175 trainees will be supported through the NIH training program, a decrease of 1,022 trainees from FY 1979.

Question: What will be the total cutback in funds and number of trainee slots in only three years if the Administration's 1981 budget request is approved?

Answer: If the 1981 President's budget request for the NIH training program of $163,527,000 to support 9,470 trainees is approved, the total cutback from the FY 1979 level of $143,661,000 for the support of 11,197 trainees would be a reduction of 1,727 trainees. At the 1981 President's budget level, the total cutback from FY 1978 level of $143,926,000 for the support of 11,123 trainees' would be a reduction of 1,653 trainees. However, these trainees in 1981 would be supported at a higher stipend level than those supported prior to FY 1980.

EFFECT OF TRAINING CUTBACK IN FUTURE

Question: What in the opinion of our nation's scientific community will be the effect of this accumulated cutback in funds of approximately 18% within 3 years--most particularly for the future?

Answer: The nation's scientific community makes its feelings known to the NIH as individuals, through the advice and counsel of the NIH advisory and peer review system, and through professional society spokesmen. The effect of the approximately 18% cutback in research training grants, in the opinion of the nation's scientific community, is multifaceted.

There is a well known, though unwritten, NIH policy that all ongoing commitments to individual trainees will be honored wherever possible. There is, therefore, little anxiety that training program directors will have to terminate or interrupt students in ongoing programs. While no new awards will be made with NIH training funds in 1981, this fact alone will not dissolve the program. It will, assuming that no alternative sources of support are available, affect the entry of approximately 700 individuals into the research areana some 5 to 7 years later. This is estimated to be between 20 to 50 percent of the NIH new investigator pool. If funding were to be held steady at the reduced level, the nation's research manpower force could be permanently reduced.

MISUSE OF NIH GRANTS

Question: The charge that some universities are misusing NIH grant funds is challenged on grounds that individual research projects are rarely self-contained but rather are part of a larger program of investigation. Thus, it is argued, this may make it difficult, if not impossible, to abide by the rule that Federal funds that are awarded to a project must be spent only on that project? What is your comment on this?

Answer: It is true that there is some interrelationship between individual research projects and that some individual research projects are part of larger programs of investigation. But we be-

lieve that the effect of this interrelationship on the use and accountability of funds is exaggerated. This interrelationship does not seem to be an obstacle to individual researchers and their institutions in developing research proposals and related budgets for specific projects. Indeed, the proposals are submitted and peer evaluated as viable discrete projects. Thus, we think the matter is less a question of ability and more a question of will. The problem of accounting for interrelated projects is certainly not beyond the state-of-the-art. It can be accommodated relatively easily when that relationship is agreed to in advance and the costs are properly recorded. The broader issue is how much flexibility research institutions should be allowed to shift funds awarded for a given scope of work to perform other work. This issue goes to the heart of the project grant concept and is a matter we would need to consider more fully before giving a firm answer.

Question: How realistic is it to try to impose Federal accounting requirements on the traditional university research process? What would be the effect of doing so--wouldn't it be costly to the schools?

Answer: The accounting requirements with which colleges and universities are asked to comply are the bare minimum necessary for any reasonable level of accountability of Federal or any other funds and are substantially less stringent than those that apply to other types of organizations. In our opinion, those requirements do not, and will not, adversely affect the conduct of research. For example, one of the requirements which universities have objected to in the past is the need for their professional staff to periodically certify the effort they expend on Federal projects. This certification is the basis for computing the proper salary and wage charges to the projects. The reports were previously required once each month from each professional. They are now required only once each semester. Moreover, they are asked to certify to their best estimate how their compensated effort was spent. Absolute precision is not required. We frankly cannot see how any individual can honestly claim that the filling out of such a report could deter him or her from his research responsibilities. Where comparable research is performed outside the university environment, in nonprofit reserach institutes or in commercial research firms for example, monthly or more frequent time reports are the norm. This norm is established not by the Federal government but by institutional administrators who want and need to know how effectively their research funds are being expended.

To the extent that colleges and universities already have effective administrative oversight and checks and balances built into their operations, the Federal requirements should not be costly to implement. To the extent that schools do not have these fundamental management tools in place, it may very well require a cost on their part.

Question: Some university people argue that projects are so interrelated that assigning costs is a judgment call--and probably not a very precise one. What is your reaction to this?

Answer: As we indicated above, there is some interrelationship between some grant projects and judgment is a factor in virtually any management or accounting process, but we believe the argument is overdone. Again, we believe that if a researcher can distin-

guish the work that is to be done in developing a proposal requesting Federal funds, then he or she ought to be able to segregate that work when accounting for it after-the-fact.

Question: One remedy suggested for the problem is for Federal agencies to delegate to universities the authority to shift Federal funds within and among related projects. How do you stand on this?

Answer: The question is related to the prior one on the interrelationship of grant projects. As I indicated, the question goes to the viability of the project grant concept and we would need to give it further consideration before reaching a final conclusion. But we think that such a delegation should not be used as a mechanism to avoid an honest accounting of Federal funds or to subvert either the intent of Congress or the intent of the awarding agency in making a grant for a specific research endeavor. As I noted earlier, the scope of the research project is determined by the researcher, not the Federal government. It is the researcher who sets the parameters of a project, be it narrow or broad, and not the granting agency. Thus, if the proposals are properly developed, one is necessarily lead to the conclusion that the projects are sufficiently discrete to permit a reasonable measurement of the costs incurred to carry out the project.

Question: How do we assure appropriate university stewardship for funds spent in support of research without imposing excessive controls, direction and administrative burden on university research grantees?

Answer: There is no easy answer to this question. In the analysis, it comes down to a judgment as to what is the proper balance between the need for controls to assume proper accountability of public funds and the need to avoid the imposition of costly administrative requirements in the schools. This issue has been debated for years and was most recently debated during the development of the revised cost principles issued by OMB. Although this issue will undoubtedly continue to be debated and further improvements made, we believe that the principles do strike a reasonable balance between these competing concerns. We feel, however, that the universities themselves need to honestly reappraise their administrative practices and governance. Universities are big business and the management of big business is not an easy task by any means. Universities are almost entirely publicly supported. That support comes in the form of Federal research grants, State appropriations, student financial aid, and student tuition. Thus, schools have a special responsibility for the sound stewardship of those funds and an honest accountability to all segments of society of the use of that money. We think that this stewardship and accountability will not detract from innovative research or erode the academic independence of these institutions; to the contrary it would reinforce it. It is necessary to point out that many of the complaints about the excessive controls, direction, and administrative burdens are directed at requirements beyond the accounting for Federal funds per se. They are directed to the burdens placed upon institutions for implementing social oriented programs such as employee safety and health, affirmative action, handicapped, animal care, protection of human subjects, etc. Although all of these programs are commendable and fully supportable individually, the cumulative effect of the requirement makes the administration of colleges and universities much more difficult. But these are burdens which all segments of society must learn to deal with and we know of no easy solutions to that problem.

PENALTIES FOR MISUSE OF NIH GRANT FUNDS

Question: According to BUSINESS WEEK magazine and other sources, HEW is considering a rule that will charge interest on Federal money spent for purposes other than intended. Is this true and when would you put such a penalty in effect?

A second proposal we have heard of would cut up to 10% from the research grant funds of universitites that misuse research money. Is this true?

If you decide to impose such penalties, would you submit your proposal for public comment before it is put into effect?

Answer: I understand that DHHS has issued a draft policy on certain audit resolution problems which has been distributed to 10 key associations representing the interests of grantee organizations. The Department is presently reviewing the reactions from the grantee community to proposals to impose certain penalties in extreme circumstances of grant fund mismanagement. Decision on the issues involved will be made at the highest levels in the DHHS.

AUTHORIZATIONS

Question: As you know, the Appropriations Committee has the policy of deferring appropriations for any program whose reauthorization has not been signed into law by the time of the appropriations bill mark-up, funding such programs in a continuing resolution until the next supplemental. In the event the reauthorizations for the Cancer Institute and the Heart Institute have not been enacted and signed into law by the time of the mark-up of the FY1981 Labor-HEW Appropriation bill, is there not a general authorization provision for NIH which would have the legal effect of a continuing authorization and would enable us to appropriate for the Cancer and Heart Institutes in the FY 1981 bill rather than not settling their funding until probably next year?

Answer: Yes, Title III, Section 301 of the Public Health Service Act, under which all NIH Institutes and Divisions are authorized, contains provisions for authorization of both the NCI and the NHBLI. In the event that these two Institutes' reauthorization legislation has not been enacted at the time of the appropriation bill mark-up, funds could be appropriated for these programs under Section 301.

EXPERT CONSULTANTS

Question: As you may know, the Committee has drastically cut back on the use of consultants throughout the Department. It is our understanding that NIH has 400 "expert consultants." Do these experts fall under our consultant cutback?

Answer: Yes, currently these experts are included within the consultant services ceiling and consequently would be affected by the cutback imposed by the Congress. However, the experts are not consultants, and, therefore, NIH believes they should not be

included within the ceiling. These experts are, in fact, covered by another more specific ceiling and limited to 451. The matter has been discussed within the Department and with the staff of the Labor-HEW Appropriations Subcommittee. A letter is being sent to the Subcommittee requesting exclusions from the consultant service ceiling.

Question: Should these positions be counted within your hiring ceiling if they are, as they appear to be, full-time employees?

Answer: The experts are full-time employees, however, we do not believe it would be appropriate to count them against the full-time permanent employment ceilings. Although the appointments are normally for more than one year, the appointments are in fact time-limited. A nonpermanent appointment mechanism to employ individuals with highly specialized qualifications whose services are difficult to obtain through the regular appointment mechanisms is of extreme value to the NIH programs. Individuals who have a unique skill to offer for which the NIH does not foresee a permanent need are added to the staff through the expert mechanism. This permits the NIH to acquire the skills without permanently blocking a senior level position. The NIH does have a limit on the experts in that the authorizing legislation does provide for a specific number of experts.

POSITIONS

Question: Would you describe for us the effects on the NIH programs of current employment ceilings imposed to implement the Leach Amendment:

Answer: As part of the overall employment level for the Federal government imposed by the Leach Amendment, the NIH 1979 ceiling for full-time permanent employment was 11,131 compared to a budgeted position level of 11,829. We have not yet received our 1980 ceiling.

Question: Were you allowed to fill the positions which were provided for in the Public Law 2 years ago?

Answer: The 1979 appropriation act for NIH contained approximately 11,800 budgeted positions. As indicated above, the ceiling issued to NIH was 11,131. Consequently, we were not able to fill all of the budgeted positions provided.

Increase in FY 1980 NIH Ceiling

The Secretary of Health, Education, and Welfare has approved an increase in the NIH ceiling to 11,443 in 1980, an increase of 312 compared to the 1979 ceiling of 11,131. This increase will provide for the additional 153 positions provided by the Congress in 1980 and for ceiling for other purposes depending on NIH priorities. As the result of the action, the NIH ceiling for 1980 will be 97 percent of the authorized position level. This is the customary percentage in the Department and takes into account normal turnover and the time necessary to fill positions.

CONGRESSIONAL PRIORITIES

Question: What effect do Congressional priorities have on NIH funding activities?

Answer: Within the resources appropriated, we closely follow those priorities identified by the Congress and the Administration. For example, over the past years, increased emphasis has been placed on diabetes research and the effects of chemical, physical and biological environmental agents on human health. The emphasis in the latter area is also evidenced by the establishment of the National Toxicology Program.

61-400 O - 80 - 22

The following table reflects the amounts in the 1981 President's budget for Extramural and Intramural Research programs of the NIH:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Extramural and Intramural Research
(dollars in thousands)

	1977	1978	1979	1980	1981
CANCER					
Extramural	$660,925	$702,014	$753,755	$795,942	$797,350
Intramural	80,517	91,069	130,317	146,571	149,910
HEART					
Extramural	340,971	387,752	445,820	458,892	473,375
Intramural	32,438	35,002	37,217	38,951	42,777
DENTAL					
Extramural	38,612	43,094	45,822	47,353	48,878
Intramural	10,653	12,330	12,546	13,702	13,902
ARTHRITIS					
Extramural	180,085	215,224	253,442	287,435	309,777
Intramural	30,932	34,153	37,690	40,707	42,242
NEUROLOGY					
Extramural	119,762	137,808	168,950	192,718	200,679
Intramural	23,255	27,574	30,896	35,344	34,866
ALLERGY					
Extramural	104,330	119,847	145,911	166,855	178,394
Intramural	27,769	32,278	34,863	37,003	38,047
GENERAL MEDICAL					
Extramural	197,463	222,156	268,378	302,624	321,345
Intramural	379	379	445	586	589
CHILD HEALTH					
Extramural	121,430	137,889	166,541	176,167	183,676
Intramural	15,530	18,726	20,805	21,744	22,459
EYE					
Extramural	54,091	74,319	92,389	98,879	101,883
Intramural	6,973	7,965	8,969	9,744	10,343
ENVIRONMENTAL					
Extramural	35,092	43,316	51,655	54,043	60,818
Intramural	13,413	17,570	21,828	25,285	31,478
AGING					
Extramural	21,688	26,319	43,082	51,998	56,393
Intramural	6,093	7,870	9,856	13,258	13,516
RESEARCH RESOURCES					
Extramural	133,606	140,440	149,307	163,767	178,809
FOGARTY CENTER					
Extramural	1,400	1,400	1,700	1,700	1,700
LIBRARY					
Extramural	8,347	8,987	8,987	9,925	9,831
Intramural	22,993	23,432	28,446	30,278	30,308
TOTAL					
EXTRAMURAL	2,017,802	2,260,565	2,595,739	2,808,298	2,922,908
INTRAMURAL	270,945	308,348	373,878	413,173	430,437

INVESTIGATOR - INITIATED GRANTS

Question: The administration is stressing stabilizing investigator-initiated grants. It says that its budget request will stabilize the number at 5000. While I support the intent and need to provide stability to our research effort, I question what the budget request will really provide.

What has been the average number of grants for the last three years?

Answer: The number of competing research project grants funded by NIH over the past three years is 15,912, which works out to an avearge of 5,304 grants for each of the last three years. This average number is broken out in detail, by institute, on the following table.

Question: How does the number of grants projected for 1981 for each institute compare with the average number for the last three years?

Answer: The total number of competing research projects in the 1981 budget request is 4,998, which reflects a decrease of 306 awards, or 5.8%, from the average annual number of competing grants funded during each of the last three years. The following table provides an analysis by institute of the change in numbers of competing grants in the 1981 request as compared to the three year average.

Question: How much money by Institute would be needed to restore the three year average number of grants to those institutes whose number of grants under the FY 1981 budget would be under their average number for the past 3 years?

Answer: A total of $56,346,000 would be needed to restore the three year average number of competing research project grants to those institutes whose 1981 budget requests show them funding fewer competing grants than their average number for the past three years. The cost of restoration is broken out by institute on the following table.

FUTURE COST OF COMPETING GRANTS

Question: In fiscal 1981, you are proposing to stabilize competing research grants at about 5,000 (4,998). This would cost an additional $45 million over fiscal 1980--and would constitute some 32% of your planned increase of $141 million for research projects in the new fiscal year.

Why does the actual number of <u>new</u> grants for FY 81 drop by 13 from FY 80 while your costs for new grants go up by $11.5 million over the previous year?

Answer: You are correct, the number of new grants does decrease slightly in 1981. This is basically the result of our expectation that more competing renewal applications will be submitted in 1981 because of the larger than normal completion of noncompeting grants in 1981. The $11.5 million increase from 1980 represents the increased cost of conducting research. The increase averages $4,300 per grant, an increase of less than 6%.

Numbers of Competing Research Project Grants Funded -- Comparison of 1981 Budget Request to Historical Average for Last 3 Years

Institute	3 Year Average No. of Competing Grants Funded 1978 - 1979 - 1980	1981 Request- Number of Competing Grants	Change from Average No. to 1981 Request	Funds Needed to Restore 3 Year Average Number of Competing Grants (dollars in thousands)
NCI.....	841	734	-107	$13,326
NHLBI.....	766	601	-165	28,011
NIDR.....	125	194	+69	---
NIAMDD.....	694	763	+69	---
NINCDS.....	554	549	-5	311
NIAID.....	460	422	-38	2,750
NIGMS.....	924	781	-143	7,748
NICHD.....	398	341	-57	4,200
NEI.....	283	339	+56	---
NIEHS.....	109	111	+2	---
NIA.....	150	163	+13	---
Total.....	5,304	4,998	-306	56,346

Question: Why do the number of new grants for neurology decrease by 111 while the number of competing renewals increase by 113?

Answer: In 1980, NINCDS will fund 994 noncompeting and 552 competing research projects, for a total of 1,546 awards. In 1981, the noncompeting commitment will be for 1,017 awards. Therefore, 529 grants that were active in 1980 will be completing their project period, and it is expected that a large portion of these grantees will submit applications in 1981 for competing renewal grants. 1981 is an unusual year in that so many grants drop out of the commitment base during this grant funding cycle and are recompeting in 1981. The NINCDS made a conscious effort to shift its funding emphasis in order to cover the anticipated increase in the number of competing renewals.

Question: Why do competing renewals and new grants for General Medical Sciences both drop from FY 1980?

Answer: General Medical Sciences, in developing their 1981 budget request, had very high continuing commitments in research project grants. In both 1979 and 1980, NIGMS funded a large number of competing research project grants which have now converted to noncompeting status, resulting in a very high noncompeting cost in 1981. This results in less funds available for competing grants. Even though the number of competing research project grants is decreasing, the total number of research project grants is increasing by 90 grants, from 2,852 in 1980 to 2,942 in 1981. It is because of this cyclical nature of the grant process and the effect of varying levels of support from year to year that we are attempting to stabilize research project grants.

Question: Why do competing renewals increase by 254 grants over FY 80 for all of NIH?

Answer: The increase in competing renewals is due primarily to the cyclical nature of the grant process. The average length of a research project grant is 3.2 years. In 1978, NIH experienced a significant increase in the competing component of the research project grant category. Many of the grants are now completing their project period and will be recompeting for additional support as competing renewals in 1981. Many of these investigators have demonstrated the ability to perform high quality research, and will compete favorably when applying for continuation grants. Therefore, we expect an increase in the proportion of competing grants that are renewed.

Question: You are projecting an increase of 214 noncompeting grants in FY 81 over FY 80, but the increased cost over the current fiscal year is $95.5 million. Why such a huge increase in cost? That's about $450,000 per additional grant.

Answer: The $95.5 million increase in the 1981 budget request for noncompeting research project grants consists of two components. One component is the increase in funds associated with the increased number of noncompeting grants in 1981. This would amount to approximately $22 million. The other component would be for the increased cost of performing research for the noncompeting grants in the base. This would cost approximately $73 million, an average of $6,400 per grant or less than a 7% increase.

HEALTH PROMOTION AND DISEASE PREVENTION

Question: Could you summarize for us what research in NIH is being done on the behavioral correlates of health promotion and disease prevention?

Answer: At the outset, it must be emphasized that the NIH is involved only to a limited extent in behavioral studies in any areas of biomedical research, including disease prevention and health promotion; behavioral research is largely the province of the National Institute of Mental Health. Thus, the number of NIH-sponsored behavioral correlate studies is relatively small; we have, however, identified the following ongoing programs:

- Two National Cancer Institute studies, one of which will utilize interviews with residents of five Texas counties to evaluate the relative influences of smoking, occupation, and the general environment on the unusually high respiratory cancer mortality rate in the areas. The other NCI study will investigate in detail human smoke inhalation practices, the smoking profiles of high risk groups, the acute effects of smoking, and related factors.

- Two programs sponsored by the National Heart, Lung, and Blood Institute, the major effort being a thrust at increasing effective use of dietary management of hypertension. Based upon an NIH-sponsored consensus development conference on hypertension, a new Task Force has been mounted to develop recommendations on the skills knowledge, and attitudes patients need to successfully achieve a dietary regimen. This Task Force will, for the first time, propose a stepped approach to such therapy that is expected to aid both the provider and patient in prescribing and following dietary measures.

The other NHLBI program is focused upon the behavioral aspects of smoking. One project is investigating social and psychological determinants to smoking in school; another is examining the stress effects of smoking cessation in response to being informed that one is at high risk for coronary heart disease; a third is studying the effect of smoking cessation on cardiopulmonary fitness. The multi-factor risk study is studying the effectiveness of a multiple mass media health education campaign and training program in reducing cardiovascular disease. Other programs are testing means to aid individuals in maintaining tobacco abstinence, as well as to prevent smoking by the young. Lastly, new research is being developed which will identify variables associated with maintenance of non-smoking in ex-smokers.

- The National Institute of Child Health and Human Development is sponsoring three major behavioral research programs. Two in the nutrition area involve: (1) prevention-related studies aimed at determining optimal nutrition and dietary habits during pregnancy, infancy, childhood and adolescence; and (2) a new program of studies on the behavioral and cultural aspects of nutrition, designed to expand our knowledge of how the nutritional environment affects children's individual nutritional status.

- Finally, in the key prevention target area of teenage pregnancy, the NICHD is sponsoring a wide range of studies

involving the factors associated with adolescent sexual, contraceptive, and fertility behavior. Many innovative methodological techniques are being used. Family structure, which appears influential in translating the effects of early parenthood, clearly plays an antecedent role. An analysis of national data suggests that family structure variables are significant predictors of the probability of intercourse for adolescent women.

Question: In other words, what aggressive steps can be taken by NIH to better inform the public via the major national communications media on concrete approaches that can be taken to enhance their health through proper diet, exercise etc?

Answer: NIH is moving ahead in a variety of ways to inform the public about desirable health practices. For example, we are working closely with some of the major women's magazines such as VOGUE and REDBOOK, and with such mass circulation magazines as READER'S DIGEST. They have asked us to provide ideas and approaches for articles on health promotion and disease prevention and to check their copy for accuracy and validity. We hope to expand this activity in the future.

We are also producing public service spot announcements for television and radio on health subjects. These have gained wide acceptance and viewing. Currently airing are spot announcements on the necessity for regular checking of blood pressure and on avoiding junk foods and sweet snacks. All three major TV networks have agreed to use our two latest spot announcements, on the stereotyping of older people and on checking infants for hearing loss; these should begin to appear by late March. We hope to do more such public service announcements as well as news features for TV and radio on biomedical research developments of interest to the general public.

We also hope to disseminate more widely to the general public the results of our consensus development conferences on new, emerging, or controversial medical developments. Although the NIH consensus development effort is designed primarily for the health professions, many findings are of direct interest to the public. We plan to experiment with new and innovative ways of reaching the public regularly with this information.

Question: What is your view on the establishment of a new focus within NIH of an across-the-board health promotion and disease prevention initiative?

Answer: Such a focus already exists within the Office of the Director in Office of Medical Application of Research (OMAR) where an NIH Coordinator for Disease Prevention and Health Promotion has been established.

Since the establishment of the position in January 1979, OMAR has served as the focus and point of contact and coordination between the Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion) and the 11 Institutes and several Divisions of the NIH. This office has been the focus for all Congressional inquiries on prevention and has made available scientific assessments on disease prevention and health promotion programs.

INFLATION IN BIOMEDICAL RESEARCH

Question: We experienced an inflation rate of 13% + in 1979 and are anticipating an inflation rate of about 11% in 1980. What percent increase does the President's budget request for the National Institutes of Health for FY 1981 over FY 1980?

Answer: The 1981 President's budget request contains a 4% increase over the 1980 level.

Question: In projecting cost of living increases needed to keep our health research efforts equal to those of the preceeding year, is the general cost of living or inflation rate accurate--or is the inflation rate in health research higher or lower than the general inflation rate?

Answer: The inflation rate based on the projected biomedical research deflator for the period from 1980 to 1981 is 9.3%. The comparable estimate for the general inflation rate based on the Consumer Price Index is 8.6%.

INFLATION

Question: Do you feel your NIH budget for fiscal year 1981 adequately addresses the problem of inflation in each Institute and program?

Answer: The 1981 President's Budget includes an increase of 4% over the 1980 level. We estimate an inflation rate of 9.2 to 9.5% from 1980 to 1981.

LACK OF DIRECTION

Question: Dr. Lewis Thomas believes that the present drift in research affairs ought to be a source of worry for the whole scientific community. He said, in a recent House hearing (Nov. 14, 1979), "we seem to be entering a period in which basic science has itself become more like a short-order enterprise than a long-term investment. More and more of today's research is done piece-by-piece in response to specific demands with pressure for quick and usable results, and if we keep on this way the country risks a gradual, systematic reduction in the scale and quality of all its science."

- Do you feel that this is a fair indictment?
- Do you feel that this has been the direction that NIH has been moving along?
- Do you feel that there is a need for a reassessment of the NIH basic research effort in light of Dr. Thomas' remarks or is the 50-50 mix of basic applied research still what we want?

Answer: The terms "basic" and "applied" research pose difficult definitional problems which tend to impede the analysis and reporting of the distribution of resources for health research. For the past several years, the NIH has been developing and refining a new

classification and reporting system. As a result of that effort, the activities of the NIH are now classified into four major categories.

The first category, referred to as the Science Base, accounts for almost 77% of the NIH budget and is comprised of activities directed toward an elucidation of the mechanisms underlying fundamental biological processes and an understanding of what happens when these processes fail or are altered to produce disease. This category includes investigator-initiated research project grants, institutional support, and NIH intramural research.

The second category, Clinical Applications, refers to research activities in which the emphasis is on intervention. Examples include the development and testing of vaccines, and the conduct of clinical trials of drugs or other treatment modalities. Approximately 12% of the NIH budget is devoted to these activities.

The third category, Technology Transfer, involves the transfer of research findings to the health care delivery system through the development of technical consensus on new interventions and the demonstration of these new technologies in health care settings. These activities consume about 5% of the NIH budget.

Training, the fourth major category, accounts for roughly 5% of the total budget. This activity is necessary to provide a continuing influx of new ideas and to enable the NIH to undertake long-term research efforts.

Although it is reassuring to note that the science base currently receives the bulk of NIH resources, we share the concern that increasing demands for large-scale support of narrowly circumscribed research and development programs in various selective and highly visible areas of health research--especially during periods of limited resources--pose a serious threat to the maintenance of the essential base of fundamental science.

In recognition of this vital concern, the DHHS has, in fact, adopted as a major goal the stabiliztion of the science base. The policy and budget of the NIH reflects the implementation of the Administration's commitment to sustain activities designed to enhance the science base. Investigator-initiated research grants, a major part of the science base, have been selected for special emphasis to underscore the nation's intent to maintain fundamental research as an indispensable long-term societal investment.

ENVIRONMENTAL HEALTH SCIENCES

Question: In terms of the total NIH research effort do you feel that environmental causes of disease are receiving enough attention?

Answer: Environmental causes of disease are receiving increased attention. Dr. Rall has noted that the systematic scientific consideration of these problems dates only from the early 1960's; there is not a long and consistent history of investigation. I believe we are just now beginning to enter an era when these complex and difficult scientific problems can be effectively

addressed. It is important that we capitalize on this opportunity. The administration is requesting a $12.9 million dollar increase for NIEHS. This represents a more than 15% increase in NIEHS budget from FY 1980 to 1981. I believe this accurately demonstrates the importance we attribute to environmental health problems.

Question: We would like some concrete recommendations from you as to how this focus should receive increased visibility in the 1980's.

Answer: At Congress's request a task force of distinguished scientists developed a sizable agenda of recommendations for research needs in the environmental health sciences. Because many of these questions are unanswered and still to be addressed, it is difficult for our society to effectively regulate the use of toxic agents and protect the public from unnecessary and harmful exposures. Lack of competence becomes particularly apparent and acute in situations where chemical contamination has been inadvertent and insidious, or when its effects have been felt over long periods of time such as the PBB contamination incident in Michigan and Love Canal in upstate New York.

Question: In other words, as with nutrition and diabetes, how can NIH better communicate to the Congress and its constituency the real issues of environmental health in a timely manner.

Answer: NIH, through NIEHS, is taking some specific steps to lay these issues before the public. A series of publications for general audiences is underway. The first publication, Basic Concepts of Environmental Health, has been widely distributed. Copies of it was forwarded to Congress and over 14,000 copies have been distributed to the public. Additional publications on the scientific basis for public regulation of toxic environmental agents will be published soon. These papers are based on the deliberations at a conference sponsored by NIEHS. This month, NIEHS is sponsoring an international symposium on The Biomedical Impact of Technology Transfer. A similar publication will be prepared. The purpose of this continuing series of general publications is to focus the public's attention on the relationship of environments to human health and the development of threats to health in those environments.

LOW-LEVEL RADIATION

Question: At last year's hearing, I expressed concern about the dangers of low-level radiation which can cause leukemia. I believe you said NIH was going to be in charge of all DHHS research in the field. Please bring us up to date on your efforts.

Answer: Through the National Cancer Institute, which has been assigned the lead responsibility for this effort, the NIH is establishing a comprehensive program of research into the biological effects of low-level ionizing radiation, in accordance with the mandate given to the NIH by former DHEW Secretary, Joseph A. Califano, Jr. This program will address all aspects of low-level radiation research including research on leukemia, and is designed to complement, not supplant, other Federally sponsored research in this area.

The NIH maintains regular contact with other DHHS agencies, such as the Center for Disease Control and the Food and Drug Administration/Bureau of Radiological Health. The Interagency Committee on Federal Research into the Biological Effects of Ionizing Radiation, chaired by the Special Assistant to the Director, NIH, is currently reviewing all proposals in excess of $250,000 for epidemiologic studies of radiation exposures. These efforts are an attempt to coordinate Federally sponsored research in this particular area.

The National Cancer Institute is sponsoring a number of research efforts at the present time which are related to low-level radiation exposure. There are three major studies being supported by the Environmental Epidemiology Branch. A brief description of each follows:

The largest effort is a worldwide follow-up study of women who have been treated with radiation for cervical cancer; so far, no leukemias have been detected in this group. The study population is now being expanded to include all available Cancer registry patients which will bring the number of individuals to several hundred thousand.

The second study is a follow-up of patients who have received multiple chest fluoroscopies for TB. These patients are being screened for possible incidence of breast and lung cancers and leukemia. The current study population of 2,000 shows no statistically significant evidence of increased leukemia incidences. However, the study has been expanded to include 8,000 additional cases in Massachusetts, and will later include an additional 10,000 cases from Connecticut.

The third study, which has just been started, concerns the incidence of second cancers, including leukemia, in breast cancer patients who have received radiation therapy.

The NCI is also supporting, through the Bureau of Epidemiology of the Center for Disease Control, a study of leukemia incidence in children less than 15 years of age who had been exposed to radiation from fallout from nuclear tests in the state of Utah during the period 1951-1958.

Question: What are your spending plans in fiscal years 1980 and 1981?

Answer: The President's Budget contains $15,754 for low-level radiation research in 1981. The estimate for 1980 is $13,874.

Question: What work are you doing in regard to the Three-Mile-Island incident? What have you found?

Answer: In April 1979, a subcommittee of the Interagency Committee on Federal Research into the Biological Effects of Ionizing Radiation was formed under the chairmanship of Dr. Arthur C. Upton, then Director of the NCI, to assess the need for follow-up studies of the health effects on the population resulting from release of radioactive materials during the Three Mile Island nuclear power plant accident.

The subcommittee report, entitled "Followup Studies on Biological and Health Effects Resulting from the Three Mile Island

Nuclear Power Plant Accident of March 28, 1979" was published in August 1979.

The study concluded that, on the basis of available information concerning radiation exposure, no biological effects of radiation other than the normal incidence of expected health conditions would be detectable in the affected population. The committee members also indicated a responsibiltiy on the part of the represented Federal agencies to assist the State of Pennsylvania in obtaining public health-related information from the Three-Mile-Island accident. This responsibility applies to off-site population--studies in progress or proposed.

The subcommittee also reviewed various plans for followup studies on the accident. Included in those proposals reviewed was the recommendation of the President's Commission that consideration should be given to the study of blood samples for chromosome damaging effects which may have resulted from radiation released during the incident. The subcommittee concluded that there was small likelihood that such studies would yield useful information.

In the future, this subcommittee will review the follow-up measurements of occupational exposures which are being provided by the Nuclear Regulatory Commission.

Question: Is the "Radiation Research Planning Group" at NIH fully staffed to do its job? If not, why not and what effect is this having on your work?

Answer: The Radiation Research Planning Group, located in the National Cancer Institute, currently consists of four senior scientists and one secretary. The addition of two interim experts will complete this staff, which also has the opportunity to draw on support from other professional staff within the National Cancer Institute. This group has two major responsibilities: 1) planning a long-term program of research into the effects of low-level radiation exposures, and 2) participating in, and providing staff support to the Committee on Federal Research into the Biological Effects of Ionizing Radiation. Special emphasis has been placed on this later effort because of the tight timetable for the development of the Strategy for Federal Research.

M.D.'s IN RESEARCH

Question: We hear more and more about the problem of getting M.D.'s involved in Research. As you know, the Committee report last year encouraged you to do more in this area.

What are your plans so far and what success have you met?

Answer: Four major steps have been instituted to improve the recruitment of clinicians into research.

1. The first utilizes the authority granted under the National Research Service Awards (NRSA) amendments of 1978 to relieve individuals receiving research training awards of up to three months from the payback obligation. Thus it was possible to launch a short-term research training

program for students in health professional schools to expose individuals to the opportunities inherent in a research career at an impressionable time in their development. 141 applications were received and reviewed. Funds are available this fiscal year to implement the program. It will reach approximately 800 students per year for the next 5 years.

2. There was an expressed need in the biomedical research community for a recognized entry mechanism into the investigator-initiated research grants competition for well-trained junior individuals. The New Investigator Research Award was modified in the fall of 1979 to provide this mechanism. All Institutes are participating in the program, which will afford three years of limited support, including partial salary for the principal investigator. While it is too early to judge the results of this effort, the concept has been well received by the investigator community and is expected to be particularly attractive to young clinicians.

3. A relatively new program, the Special Emphasis Research Career Award (SERCA), has been developed to attract young clinicians into research which requires breadth in two or more disciplines. These awards have to date been largely focused on various aspects of diabetes where such elements as hypertension, high risk pregnancy, and so forth, are involved. These are joint programs supported by two Institutes which allow individuals with expertise in one area to acquire and use the research skills of a necessarily related discipline.

4. The stipend levels offered under the NRSA programs have not been adjusted in 6 years. Stipends were noncompetitive in all areas but especially so for young clinicians. A stipend adjustment has been announced for July 1980; the new level is still below that which fellows in clinical service training programs receive but the difference has been reduced considerably. It is expected that this increase will help remove one of the disincentives related to clinicians pursuing research careers.

NUTRITION RESEARCH

Question: There is more interest and emphasis on nutrition than ever before, yet we seem to have a difficult time zeroing in on how much each Institute is spending in this area.

Answer: Yes, we have made significant strides in our ability to report on nutrition research efforts in both programmatic and budgetary terms. The NIH Nutrition Coordinating Committee (NCC) has developed a definition for nutrition research that is used for data retrieval in nutrition by all the 11 Institutes and the Division of Research Resources. Budgetary data and program information are carefully developed, collected, reviewed, and coordinated. Nutrition dollars are identified during this process, resulting in a much more accurate accounting of our actual nutrition research effort. The data retrieval system has been computerized. The following table indicates actual obligations for fiscal year

1979 and estimated obligations for fiscal years 1980 and 1981 by Institute.

Question: Is there a need to better delineate and identify that effort as budgetary line items?

Answer: I see no need to establish separate budget line items for nutrition research at this time. In many of the Institutes, nutrition research cuts across other larger program categories. A separate budgetary line item for nutrition, therefore, would fractionate the programs, cause duplication of reporting of funds for some programs and generally complicate our reporting. As I indicated above, I believe that through the NCC and other mechanisms we are doing a much better job in program development, planning, coordination, and reporting of our nutrition program and budget.

Question: Does NIH need a visible, administrative entity responsible for overseeing and coordinating nutrition research at NIH?

Answer: Yes, I believe it is very important. That is why several years ago we established the Nutrition Coordinating Committee within the Office of the Director, NIH. The committee consists of representatives from the 11 Institutes and the Division of Research Resources, all of which support nutrition research. Liaison is maintained with additional NIH components, such as the National Library of Medicine. The committee provides visibility as well as programmatic coordination in nutrition research. At the same time, it permits the Institutes to develop specific programs based on their particular interests and responsibilities. Over the past 2 years, the NCC and the Institutes have developed 23 program announcements, requests for application, and requests for proposal in such areas as infant nutritional status, diet and cancer, diet and high-density lipoproteins, over-nutrition and obesity, nutrition and behavior, and genetics and nutrition. The committee also sponsors nutrition conferences and symposia.

Nutrition research is complex and cuts across all the Institutes because it depends on many disciplines such as biochemistry, physiology, genetics, endocrinology, molecular biology, and medical specialties such as surgery, internal medicine, pediatrics, and even subspecialties like gastroenterology. Thus, we consider the NCC to be the best mechanism to provide coordination, visibility, and a single focus for nutrition research, building on the varied and diverse approaches of the individual Institutes.

Question: We note that NIH is beginning to take a more aggressive stance in identifying the role of nutrition as a cause of diseases like heart disease and cancer.

Could you provide us with your thoughts on this controversial subject? Is research, in fact, revealing a stronger link between diet and disease?

Answer: For some years, the NIH has taken an active stand in supporting research to define the role of diet in heart disease, and more recently, on the role of diet in cancer. For example, the now classical Framingham Study was started many years ago. There are, of course, many other studies on diet as it relates to hypertension and stroke. The scientific basis that led to the development of the

pamphlet, NUTRITION AND YOUR HEALTH, Dietary Guidelines for Americans, that was released jointly by USDA and DHEW last week, was based on research funded by the NIH.

As more evidence accumulates and as trends continue to show strong associations, we feel we can take increasingly stronger stands on the associations between diet and disease. However, a great deal more research needs to be done in order to better define the associations and, eventually, precisely define cause and effect relationships between specific nutrients and the development of disease processes. Once this has been accomplished, we will be able to identify the individuals at risk for developing disease and to recommend specific preventive measures.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Nutrition Research and Research Training
(in thousands of dollars)

	1979 Actual	1980 Estimate	1981 Estimate
Cancer	$ 25,251	$ 29,300	$ 32,800
Heart	23,650	24,500	25,500
Dental	2,221	2,321	2,495
Arthritis	26,186	30,431	32,996
Neurology	2,306	2,600	2,700
Allergy	1,206	1,210	1,331
General Medical	2,971	2,600	2,600
Child Health	20,407	22,250	23,390
Eye	3,402	3,665	3,789
Environmental Health	3,740	3,880	4,095
Aging	2,739	3,970	4,399
Research Resources	13,381	14,670	15,991
TOTAL	127,460	141,397	152,086

NURSING RESEARCH

Question: Funding of nursing research has never been a high priority at NIH. How much have you spent on this on the past 5 years? What do you plan to do to improve your record in this area?

Answer: During the last 5 years, the NIH through the NCI has supported approximately $12.8 million of research grants and

contracts which have a primary relationship to nursing research, including training, distributed across the years as follows:

1975	$1,962,000
1976	3,878,000
1977	1,917,000
1978	1,342,000
1979	3,734,000

General oncology nursing training projects were established in FY 76 and continued through FY 78. In FY 79 the emphasis shifted to specialized nursing research areas such as development of courses on prevention for nurse practitioners; model post-masters fellowship programs in oncology nursing education; and oncology rehabilitation nursing training courses. In FY 80 and FY 81, the primary area of emphasis will be the continued development of training and education courses for nurses.

Nursing research in general is aimed at areas unique to the environment of the nurse and patients. Nurses have been encouraged to increase submission of research applications through, for example, their greater participation on NIH advisory committees. Contact by the NIH is maintained with the professional nursing associations to which information is provided periodically about the NIH extramural grant and contract process.

RECOMBINANT DNA RESEARCH

Question: Have there been any incidences of non-compliance with recombinant DNA research guidelines that you are aware of?

Answer: One incident at the University of California, San Francisco, in 1977 involved the use of a subsequently certified EK2 hostvector system prior to its formal certification. One incident at Harvard University in 1977 involved research proceeding without the filing with NIH of the required Memorandum of Understanding and Agreement. Each of these incidents was extensively investigated and steps have been taken to insure that similar incidents do not recur.

Question: What effects do you think court decisions will have on patenting of new life forms, particularly those of commercial interests?

Answer: The U.S. Supreme Court is expected to rule in this session on the case, "Sidney A. Diamond, Commissioner of Patents and Trademarks, Petitioner v. Amanda M. Chakrabarty," which presents the question of whether a living organism is patentable subject matter under 35 U.S.C. 101. It is difficult to anticipate the effect of this future decision on commercial interests. It may be anticipated that whatever the Supreme Court decision on patentability, this will not affect the NIH Guidelines for Recombinant DNA Research which deal with issues of safety. Neither will it affect NIH funding for recombinant DNA projects which depends upon the projects' scientific merit.

Question: What procedures have been instituted to insure public participation in the review process related to Recombinant DNA Research?

Answer: The NIH Guidelines for Recombinant DNA Research require that many actions of the Director, NIH, can be taken only after advice from the NIH Recombinant DNA Advisory Committee (RAC), and that "At least 20 percent of the members shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields." The current RAC membership exceeds these requirements. All RAC meetings are open to the public, with the opportunity for public participation.

In addition, all recombinant DNA projects subject to the Guidelines must be reviewed and approved by a local Institutional Biosafety Committee (IBC). The Guidelines require that "At least two members (but not less than 20 percent of the membership of the committee) shall not be affiliated with the Institution (apart from their membership on the IBC) and shall represent the interest of the surrounding community with respect to health and protection of the environment. Members meet this requirement if, for example, they are officials of State or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community...Institutions are encouraged to open IBC meetings to the public whenever possible, consistent with protection of privacy and proprietary interests.

CLINICAL CENTER MODERNIZATION

Question: We are pleased to see that funds have been included for the continuation of the Clinical Center modernization program. Would you highlight for us the importance of this effort to the NIH intramural clinical research program?

Answer: The obsolescence and built-in limitations of the physical facility have blocked the steps necessary for the Center to become a modern hospital. In the planning for modernization, it was realized that such services as Surgery, Clinical Pathology laboratories, Radiology, and Nuclear Medicine simply could not be brought up to modern standards within the existing Clinical Center due to physical limitations. These services, therefore, became an integral part of the justification and planning of the Ambulatory Care Research Facility (ACRF) and will be available on the opening of the ACRF in April 1982. Expanded clinic and laboratory space will also be available.

The corollary step in the modernization process was to upgrade Nursing Units, Rehabilitation, Respiratory Therapy, Pharmacy, Hemodialysis, Blood Bank, Medical Records, and other hospital and public service areas which will remain in the existing building. A number of the some 50 individual modernization projects will interface with the ACRF.

The benefits to the intramural clinical research program can be summarized as follows:

1. The Clinical Center will take its place among the best of modern hospitals and once again its facilities will meet the highest standard for clinical medicine and medical research. This will enable NIH to attract the top research talents by providing the best in hospital and laboratory facilities.

61-400 O - 80 - 23

2. The trend in clinical research is to study a greater number of patients who will be under care for shorter periods of time. The modernization program is geared to meet this increased patient load (average length of stay has declined from 30 days to 16 days and will continue to decline). Therapies, tests, etc., will be greatly increased and the expanded services will be available to meet this need.

3. The modernization program will enable the Institutes to start new clinical programs, and expand existing programs to meet challenging research potentials.

BUILDINGS AND FACILITIES TRANSFER

Question: What do the Directors of the various Institutes --who stand to lose money because of the transfer, -- Cancer, Neurology and Allergy -- think of this proposal. Each program involved in this proposed transfer should state where the money will be used if it is not transferred.

Answer: Listed below are the responses of the Institutes involved in the transfer of funds to the Buildings and Facilities Account for the Clinical Center Modernization Project in 1980.

CANCER

The NCI recognizes and supports the need to modernize the Clinical Center. In the FY 1981 President's Budget the National Cancer Institute has included a transfer of $2.133 million to the Buildings and Facilities appropriation for its FY 1980 share of the cost of modernizing the Clinical Center. The source of these funds is proposed to come from direct operations activities. If these funds were available to the NCI for FY 1980, they would be used for direct operations and intramural research to help offset the impact of inflation on our in-house activities, including cancer communications, program evaluation and the cost of experimental animals and research supplies and materials in support of such research areas as prevention, biology and immunology research, drug development, and clinical studies.

NHLBI

The NHLBI agrees with the need to modernize the clinical center research facility. In 1980, $1,193,000 will be transferred to the B&F account to support this effort.

These funds, would be utilized in the areas from which they were initially transferred, within intramural research. They would be used to: purchase a fluorescent activated cell sorter for use in clinical hematology and preparation of space for its use. This could be accomplished in 1980, rather than delayed until 1981.

Funds would also be used to maintain the existing level of catheterization studies, exercise studies, echocardiography and radionuclide cineangiographics (a procedure developed here in 1976-77). It would permit the continued increase in the number of outpatients admitted, which have been increasing annually by 500.

DENTAL

The proposal to transfer funds in order to continue updating of facilities was agreed to by our Institute both because we realize the acuteness of the general need to modernize our research facilities and specifically because we are direct users of both the laboratory and clinical space in the Clinical Center, where renovation is essential to all activities.

The funds would otherwise be used to help cover increased operating cost for ongoing studies in the intramural program, especially in the areas of immunology and microbiology as related to periodontal disease. It is important that work with experimental animals, which is ever more expensive, be restored to levels more commensurate with the demands of adequate and timely experimental design.

ARTHRITIS

The NIAMDD is totally supportive of the concept, modernization of the 1949 vintage clinical research facilities, and has no misgivings about sharing in the cost. We would, however, rather have absorbed this cost from the relatively large increase for research project grants provided in 1980, than from training funds as is the current plan.

If alternate funding were available for Clinical Center Modernization and this transfer were not necessary, the funds would be restored to the Research Training Programs.

NEUROLOGY

The NINCDS recognizes the importance of participating in funding of the Clinical Center modernization project since it will benefit the Institute's intramural program. The 1980 funds to be transferred from the Intramural Research program would be used to order equipment related to the NINCDS intramural Positron Emission Tomography research program and for research equipment to be utilized in the NINCDS laboratories in the Ambulatory Care Research Facility.

ALLERGY

The NIAID is in agreement with the need to modernize the Clinical Center and is supportive of this effort. The proposed transfer of $564,000 by the NIAID -- if not effected -- would be used to expand and pursue clinical trials in interferon and other antiviral substances.

CHILD HEALTH

The NICHD recognizes the need for and fully supports the concept of the Clinical Center modernization and the transfer of $236,000 of NICHD funds to the NIH Buildings and Facilities appropriation. If the transferred funds were available to the NICHD, the Research for Mothers and Children Program would use $137,000 for programs of research on high risk pregnancy and congenital defects. Population research would use $99,000 for support of clinical trials related to development of new and improved contraceptives.

EYE

It is generally accepted that upgrading physical facilities should be a top priority for any research institution, if required. The NEI supports the modernization proposal for the Clinical Center.

If the money were not transferred funds would be used to support 1 research and development contract and 4 trainees in one of the fields of vision research which we are currently emphasizing, for example, epidemiology.

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

In total, $933,000 will be transferred from ADAMHA intramural research funds to NIH to support the ADAMHA share of Clinical Center Modernization. Based on current and projected space in the Clinical Center, the mental health intramural research activity will contriubte $788,000 of the required amount and $145,000 will be transferred from alcohol intramural research funds.

The NIMH transfer necessitates deferral for one year of the acquisition of new and replacement laboratory equipment previously scheduled for purchase in 1980. A total of $2,258,000 had originally been budgeted for this purpose, with the result that acquisitions will be cut back by one third. The cutback will be prorated among all intramural research programs in order to minimize impact, and the 1981 budget includes a corresponding increase for equipment purchases. If the necessary funds are made available in 1981, the impact on ongoing NIMH research efforts will be minimal.

NIAAA would be required to forgo the purchase and replacement of equipment for the metabolism and preclinical studies programs. A number of experiments in brain metabolism , membrane biochemistry, and neurobehavior scheduled for 1980 would be delayed until 1981, when funds are expected to be made available for equipment purchases.

While this delay would certainly impede programs in investigating certain aspects of alcohol use and abuse, provision of the necessary funds in 1981 would permit research activities to proceed with a minimum of disruption.

NATIONAL LIBRARY OF MEDICINE

Senator EAGLETON. We have got a lot of talent at this table, and I was going to try to—I was going to release everybody but the Library, Aging, and Eye and General Medical Sciences—why don't I still do that?

Senator Schweicker may be here. Let's go with Dr. Cummings.

Dr. CUMMINGS. I would like to submit my full statement for the record and summarize, with your permission.

An impressive amount of new medical knowledge generated at the National Institutes of Health and other centers of excellence throughout the world is reflected in a vast body of scientific literature. For this literature to be used to alleviate human suffering, it must be quickly, accurately, and efficiently made available to the medical community.

The National Library of Medicine was given the primary responsibility for acquiring, organizing, and distributing this information. We believe it is a nationally recognized leader in applying modern technology to this endeavor. The most notable aspect of the Library's success in this area is in the computerized, on-line information system, known as MEDLARS. Using rapid telecommunication linkages, 1,200 biomedical institutions in the United States and abroad have virtually instantaneous access to more than 4 million abstracts and references to the biomedical literature.

It also accesses books, reports, and audiovisual materials.

[The statement follows:]

Statement of Dr. Martin M. Cummings

The National Library of Medicine (NLM), since its founding in 1836, has been dedicated to serving the information needs of health professionals. The impressive amount of new medical knowledge being developed at the National Institutes of Health and other centers of research excellence around the world is reflected in the ever-increasing body of published scholarly and scientific literature. If this knowledge is to be used to alleviate human suffering, however, it must be quickly, accurately, and efficiently made available to the biomedical community at large. The National Library of Medicine is given the primary national responsibility for handling this information and is the recognized leader in applying the most modern computer and communications technology in this endeavor.

The most visible aspect of the Library's success in this area is the computerized, online MEDLARS (Medical Literature Analysis and Retrieval System) network. Using rapid telecommunications linkages, over 1,000 biomedical institutions in the United States have virtually instantaneous access to over four million references to scientific articles, books, reports, and audiovisual materials. The acceptance of this network by the health science community has been phenomenal: growing from 165,000 computerized searches in 1973 to over 1.4 million in 1979. The online centers include a broad cross section of health-related institutions including medical, dental, and allied health schools, research foundations, hospitals, health care clinics, and other health-oriented institutions.

The uses to which the online data bases are put are as varied as the institutions themselves. From the beginning, online searching has been a boon to the academic biomedical community. Researchers, health science faculty, and students are able to keep abreast of the latest published information in their fields of work and study. We are especially encouraged by the recent increase in use by health care practitioners who have access to the system in hospitals. Responding to Congressional suggestions, the Library has made a special effort to increase the number of health care institutions in the network, and today some 400 hospitals have online access to NLM's data bases. The ability to search rapidly a vast amount of published biomedical literature has been knwon to make crucial contributions in dealing with life-threatening patient problems.

One highly successful program which has helped supplement the Library's resources is the NLM-supported Regional Medical Library network. Eleven Regional Medical Libraries, each responsible for a geographic portion of the country, are providing interlibrary loan services and coordinating access to NLM's online data bases within these regions. Some 100 "resource libraries" (primarily at medical schools) and more than 4,000 local health science libraries participate in the network. NLM provides backup services for literature that is unavailable within the regions. Approximately half (800,000) of all interlibrary loans within the network are either supported or provided directly by NLM.

1980's

Even a cursory perusal of national news magazines reveals the continuous array of products and services directed toward the improvement of information handling in our society as it prepares for the eighties. The National Library of Medicine is dedicated to

maintaining active research and development programs so that it will be able to use these new technologies in the processing of biomedical information for use by scientists, educators, and health practitioners.

During the coming year the Library will continue its efforts to improve biomedical information services through the development of a more fully automated information system (MEDLARS III). The MEDLARS III development will improve the efficiency of record creation and maintenance, increase the quality of stored information, and greatly enhance the speed with which the user can retrieve this published knowledge.

Concerns regarding the health aspects of the environment will continue to be a high priority of our society in the 1980's. In this regard the National Library of Medicine will play an important role in improving the transfer of toxicology and environmental health information. In cooperation with other Federal agencies, NLM's Toxicology Information Program collects, organizes, stores, and makes available for computerized retrieval special chemical and toxicology data needed by industry, universities, government agencies and health care providers.

NLM's grant programs, carried out under the Medical Library Assistance Act will continue to improve health information services for the nation. Special effort will be devoted to aiding small community hospitals in rural and inner-city areas to acquire the books and journals necessary to serve the basic informational needs of their primary users. Among the ongoing grant programs:

- o Resource Improvement Grants assist in the development of adequate health science library collections at the local level.
- o Resource Project Grants are aimed at facilitating user access to health information resources.
- o Publication Grants provide support for preparing and publishing scientific works of importance to the national health effort.
- o Research and Demonstration Grants support explorations in the development and applications of biomedical communications.
- o Training Grants promote the integration of computer technology with clinical teaching, practice, and research.

Within the organizational structure of the NLM there exist two unique national Centers with programs dedicated to improving the use of information and educational technology in health research, education and patient care. The first of these, the National Medical Audiovisual Center, has been a part of NLM since 1967. Its mission is to improve the quality and effectiveness of health science teaching materials and to encourage their widespread use in the education of health professionals. Research activities at this Center have explored the use of new multi-media technologies, new concepts and theories regarding adult learning, and the techniques of training professionals in community health facilities of various sizes and locations.

The second organization is the Lister Hill National Center for Biomedical Communications, created by Congress in 1968. Within this Center has evolved a team of information and computer scientists who, joined with health professionals of various specialties and backgrounds, are exploring more effective uses of information processing technology to support the health community. One research effort with great promise is to develop an integrated library system model that will provide a broad spectrum of automated functions and services useful to libraries of all sizes. Another is the Lister Hill Center's "knowledge base program" that has devised a new approach to providing information to extend the practitioner's ability to synthesize and apply to patient care large masses of the latest research-based information.

Finally, the Library is pleased to note that the dedication and occupation of the new Lister Hill Center building is scheduled for the spring of 1980. The completion of this building will permit all divisions of the Library to be together for the first time in over a decade. The transfer of the staff of the Lister Hill Center, National Medical Audiovisual Center, Specialized Information Services (Toxicology Information Program), the Extramural Program, and the Office of Computer and Communication Services into this new building will permit the resoration of the original NLM building to accommodate and maintain the integrity and availability of the books, journals, monographs and other informational materials which make up this magnificent national collection of medical literature.

Mr. Chairman, our request of $44,730,000 for FY 1981 represents an increase of $73,000 over FY 1980. I shall be pleased to answer questions and supply any additional information desired for the record.

COMPUTERIZED BIOGRAPHICAL SKETCHES

Senator EAGLETON. What is the 12 million, sir?

Dr. CUMMINGS. There are 1,200 biomedical institutions in the United States and abroad which are linked to our system, and they can access more than 4 million abstracts, references, technical reports, books, and other materials.

Senator EAGLETON. How many of the 1,200 are in the United States and how many are not?

Dr. CUMMINGS. Approximately 1,000 in the United States and 200 abroad.

This may be measured fairly, because the services are sold for a fee, and the number of computerized searches has risen since 1973 from 165,000 to more than 1.4 million last year.

Senator EAGLETON. These are requests for services?

Dr. CUMMINGS. They are bibliographic searches provided by computer. And last year more than 1.4 million were processed.

Responding to congressional suggestions, the Library has made a special effort to increase the number of health care institutions within the network, and today we have 432 hospitals with access to our data bases. Unfortunately, this service record is now somewhat jeopardized by limitations of our computer capacity, and thus we have imposed a moratorium on new institutional users until our computer capacity can be enhanced.

Senator EAGLETON. When will that be?

Dr. CUMMINGS. That is very difficult to answer. We started a new procurement in 1974, Mr. Chairman. This is the sixth year of an agonizing process for upgrading our computer system, and I am not sure that I see the end in sight yet.

Senator EAGLETON. Is it a battle against bucks or adequate technology?

Dr. CUMMINGS. It relates to the RFP for viable competition and a protest on the part of the loser. And that is where we stand now. We are at a point where we are advised that we may be in the better position to start over again.

Senator EAGLETON. Start all over?

Dr. CUMMINGS. Yes, we may start all over because the procurement that was started some 6 years ago may no longer be adequate for the 1980's.

Senator EAGLETON. Advances in technology have outstripped?

Dr. CUMMINGS. Yes. New types of computer hardware, new configurations would be much more effective and probably less costly than the original procurement.

Senator EAGLETON. If you start all over, will you be back here 6 years from now saying that it still isn't done?

Dr. CUMMINGS. I may not be back here. [Laughter.]

REGIONAL MEDICAL LIBRARY NETWORK

One other highly successful program which I believe has helped serve the Nation well is the regional medical library network. Here we have 11 regional libraries, each responsible for a geographic portion of the Nation, and they provide almost 900,000 interlibrary loans annually. They also serve as a primary coordinating point for all other kinds of medical library services. They sit between the National Library and 100 resource libraries, principally in our Nation's professional, health professional schools; and they, in turn, back up more than 4,000 local libraries in this hierarchical network.

We try to serve as the ultimate backstop for all the services that cannot be provided locally or regionally. During the coming year we intend to redesign our network and our MEDLAR's system to more fully automate some of the processes that are involved in providing services. At the same time we hope to make available a model of an integrated library system that can be transported and put in place in other institutions—small hospitals and larger institutions—so that we come to a point of compatible integrated library resource sharing.

I should point out also, Mr. Chairman, that through the NLM grant program we continue to provide resource support for the building of collections, for improving information services at local and regional levels, and we intend to maintain and sustain this activity.

UNIQUE SPECIALIZED ACTIVITIES

Within the library there are two unique specialized activities: One, the National Medical Audiovisual Center, which engages in the acquisition and distribution of materials for health professional education, in-

formation in nonprint forms, if you will. The other is the Lister Hill National Center for Biomedical Communications, created by Congress in 1968. And now I am pleased to be able to report that the facility that Congress has funded has been completed and that we have begun to occupy the new facility effective this month.

I want to close by saying that for the first time in more than a decade we will be able to bring together all of the entities of the National Library of Medicine within this facility and the present library building. Doing this, I believe, makes this national treasure of medical literature and related materials more accessible to those in need.

Our request, Mr. Chairman, is for $44,730,000. It represents an increase of $73,000 over fiscal year 1980.

Senator EAGLETON. We have you down for $44 million in 1980, $44,730,000 in 1981—we're wrong.

Mr. ITTEILAG. $73,000 as compared to the current estimate in 1980. $730,000 is compared to the congressional appropriations last year. The table is set up to compare.

Senator EAGLETON. OK. You have $44 million and then you have a $657,000 proposed pay-increase supplement.

Dr. CUMMINGS. I would be pleased to answer any questions, Mr. Chairman.

Senator EAGLETON. So the $73,000 increase, three-tenths of 1 percent?

Dr. CUMMINGS. Yes.

INCREASING LIBRARY COSTS

Senator EAGLETON. I realize, Doctor, there are libraries and then there are libraries; no two libraries are alike. I happen to be a library freak. Not everybody is. I happen to think, for instance, in the area of private education in this country, almost as serious as inflation and faculty salaries and inflation and utility bills to heat college campuses, are galloping library costs. They almost ride with those other two in terms of perhaps constituting the death knell of some private educational institutions in this country.

A couple of years ago I was at Washington University School of Law to give a speech. The dean was showing me through what was then a fairly new building. In an offhand way he told me what his library, his law library, costs were for that one school, and how they had been going upward. I unfortunately can't keep all these figures in my head, but I was stunned at the amount. I don't recall it now in precise terms, but it was a staggering amount. It was increasing by leaps and bounds, almost perpendicular, as I recall.

It seems to me, speaking generically, that nothing the Federal Government could do would be more beneficial to the dissemination of useful information across the board than to be of major assistance in library costs and exercising a leadership role in trying to avoid as much needless wasteful duplication as is possible. That happens to be my predisposition and mindset on this subject matter.

How can it be that you can adequately keep abreast of the explosion in requests for information and availability of other research materials and everything else? How can you come close to keeping abreast of that with the 0.1- or 0.2-percent budget increase?

Dr. CUMMINGS. The answer is that we cannot keep abreast fully as we have in the past. Some sacrifices will be made. We are attempting to protect services to the health professional community as the highest priority item, but we will not be able to maintain all services at last year's level.

Senator EAGLETON. The figures you gave us, 165,000, what was that in 1973? What was that?

Dr. CUMMINGS. In 1973 we provided 165,000 computer searches, and last year that number rose to more than 1.4 million. That is only one part of our service.

Senator EAGLETON. I understand. Is that a for-fee service that you run? Is it self-sustaining insofar as revenues are concerned? Does it pay for itself by the fees charged?

Dr. CUMMINGS. We returned $300,000 to the Treasury, and I anticipate we will do the same this year.

Senator EAGLETON. So that pays for itself.

Dr. CUMMINGS. It doesn't pay for itself in the true sense of business accounting, but the collections exceed the communications charges that we attribute to that system. We use the system for other purposes as well, like publishing Index Medicus, which is another product that we sell. I want to be sure that I don't confuse you by saying that this is a moneymaking venture, but we earn at the end of the year about $300,000 more than we spend for our communications and related costs.

INFLATION RATES

Senator EAGLETON. I talked earlier with Dr. Fredrickson about inflation rates. The CPI is 13.3, and Dr. Fredrickson said insofar as health research was concerned it was somewhere, he thought, between 9.2 and 9.5. Are there some inflation studies available in the library, generally speaking, research libraries or medical libraries? Can you give us any figures there?

Dr. CUMMINGS. Yes; there are. As your experience indicated, in St. Louis, all university and private libraries are facing inflationary costs. This has been carefully watched, and the inflation factor for most research libraries, large libraries, runs about 20 percent per year.

A large part of the high-inflation cost can be attributed to the greater inflation involved in the acquisition of books and journals. For example, the acquisition of foreign materials now costs 40 percent more than last year. That is, in part, due to the decline in the value of the U.S. dollar. But inflation for libraries is greater than the national price index.

BACKLOG AND RESOURCE-SHARING PLAN

Senator EAGLETON. As a practical matter, are more medical and research libraries discontinuing foreign periodicals, or at least not increasing their subscriptions to foreign periodicals because of this?

Dr. CUMMINGS. Yes, they are. And beyond that, I can tell you that even great medical libraries are discontinuing the purchase of books. I think this is a tragedy for society. But beyond that, the only rationalization that I can offer for this taking place is that we are developing,

at least in the medical community, a resource-sharing plan through which the National Library of Medicine tries to guarantee that any other library can come to us and get a copy of material that they no longer can afford to own.

But that is being threatened. Even the National Library of Medicine can no longer guarantee to provide a copy of all of these materials because of another deficit—namely, insufficient staff to index and catalog this vast growth of literature.

I am embarrassed to report to you that we have a backlog of 15,000 books that have never been cataloged. A book that has never been cataloged might just as well not be in the library. It is no help to you or anyone else if you don't know that it exists. We do have a serious problem there.

Senator EAGLETON. How many new positions are you going to get in your budget this year, Doctor?

Dr. CUMMINGS. None.

Senator EAGLETON. So if you are 15,000 behind in cataloging today, the same personnel coming back next year, you may be 20,000 behind?

Dr. CUMMINGS. We estimate about 25,000 next year.

Senator EAGLETON. This doesn't reflect on you personally, Doctor, but I find your testimony a bit depressing. It would seem to me that this would be a great area for the Institutes of Health to exercise a role of creating leadership. I think this problem is just as severe, as you have described it and by some of the statistics that you have given us, in terms of books not cataloged and great libraries finding that they can't afford all of the books coming out; there are so many of them, and the cost of foreign materials.

I am also on the Governmental Affairs Committee that has duties with respect to the postal rates, printing costs, et cetera. It seems to me that NIH and the National Library ought to be developing a 5-year plan. If you have a 5-year plan for general biomedical research or maybe a 5-year plan for training grants or what have you. It seems to me, in this business of the acquisition, dissemination, and utilization of scientific data, medical data, that we ought to have some kind of a 5-year national plan. And I know of no area, no entity, that ought to be playing more of a leadership role in this area than the National Library of Medicine.

Dr. CUMMINGS. We do have a forward plan, Mr. Chairman. And NIH has been supportive of our needs. The Library, I think, has estimated fairly and objectively both its manpower and financial requirements. I wouldn't want the chairman to believe that there has not been a sympathetic interest in our problem at NIH. Everybody is part of some group in this day and age—usually, with a Washington office. [Laughter.]

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Senator EAGLETON. Are the medical schools of this country—is there an association of medical schools? Now, have the medical schools of this country done anything, any research, on how they can better pool their services in this library area?

Dr. CUMMINGS. The Association of American Medical Colleges has

just begun its second study of a modern medical library and its role in American medical education. They did such a study about a decade ago, and it was a very remarkable guideline for administrators in the design and maintenance of their libraries.

I believe that this study will provide useful information to institutions with regard to sharing of resources. But I don't think that the end result would be available in less than 2 years. It is a very thorough, comprehensive study which we are funding. I think it is very important that there be such data available and such a planning document available as well.

Senator EAGLETON. Are the training and research hospitals of America affiliated in some kind of an association?

Dr. FREDRICKSON. Yes, they are.

Senator EAGLETON. Teaching hospitals, they have got a club?

Dr. CUMMINGS. Yes, they do.

Senator EAGLETON. What are they doing or thinking about in this area of library costs and availability of medical research data, et cetera?

Dr. CUMMINGS. Teaching hospitals and small community hospitals have begun to join in consortia through which their holdings are commonly shared. We are helping in that effort by providing funding for local and union catalogs so that groups of institutions will know where a document exists within a limited geographic area. They are searching, I think, for all kinds of new mechanisms to share resources, and I think are being successful in this effort.

Nevertheless, the overall picture is a grim one. You used the word "depressing." I would say it is a grim and critical picture for the Nation.

Senator EAGLETON. In a way it is a compliment, in that we are learning so much so quickly. That's a compliment, but the price one pays for that is the ability to print it, distribute it, index it, and have it available—we can't keep abreast of the rapid acquisition of advanced knowledge.

Is that sort of how it is?

Dr. CUMMINGS. I think that is a fair description.

Senator EAGLETON. Thank you, Doctor, very much.

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

FUNDING BREAKDOWN

Question: In your professional scientific judgment are you pleased with your funding breakdowns?

Answer: Within the budget level for FY 1981, the NLM believes the distribution of program funds is appropriate. In essence NLM is attempting to protect its basic library service functions by reducing the level of its research and development activities. It is our professional judgment that high quality medical library services must be sustained for the biomedical community.

GROWING DEMANDS

Question: In addition to the research and development programs conducted by NLM to improve biomedical communications, you have continuing demands from the biomedical community for basic library services.

How do you plan to meet these growing demands with a proposed budget that is essentially at the same level as FY 1980?

Answer: Protecting basic library services remains our highest priority and within our limited resources, every effort will be made to meet the demand of the biomedical community.

LIBRARY SERVICES

Question: in the past five years, how great has the demand for your services been increasing?

Answer: Paralleling the explosive growth in the biomedical literature, the workload and demands for library services continue to grow. During the past five years basic library and information services have increased at a rapid rate.

Question: Do you see this trend continuing?

Answer: These demands from the biomedical community are likely to continue. The following key indicators provide evidence of the growing demand for services:

	1975	1979	Increase
Serials and Monographs Processed	158,733	200,821	26%
Reader Requests Filled	73,972	140,946	91%
Reference Inquiries Processed	29,406	46,464	58%
Online Searches	421,110	1,403,655	233%

TOTAL NUMBER OF REFERENCE INQUIRIES DURING 1979

Question: Please supply for the record, the number of reference inquiries that were received during 1979.

Answer: During 1979 we received at NLM 46,464 reference inquiries.

Question: How many computer-based reference services were provided?

Answer: During 1979 1,403,655 online computer searches were performed, 5,601,417 pages were printed, 128,363 connect hours were generated, and 6,701 computer-based searches were performed for NLM in-house patrons.

Question: Is interaction with the Library of Congress timely and efficient?

Answer: The Library of Congress responded effectively to the 28 requests we made of them in 1979.

Question: Is the Library responding well to NLM inquiries and vice versa?

Answer: On occasions when we require that materials be delivered expeditiously, they have provided them within 24 to 48 hours.

Question: What is the average turn-around time for requests from both facilities?

Answer: We give high priority service to requests from the Library of Congress. Requests for documents are processed on the day of receipt and our normal response is within 24 hours. Reference inquiries are handled on a rush basis usually completed in 24 hours.

Question: Could you also summarize for us NLM services available to the Congress?

Answer: NLM provides copies of journal articles, loans other materials in the original form, provides on-site access to its vast collection, and provides reference assistance, and computer search service to the Congress. Special assistance has been provided to the Office of Technology Assessment and the General Accounting Office. Library service is available to individual members of the Congress and their staffs as well as to committees of the Congress.

INFLATION

Question: Many of the Library programs in the Department of Education claim that inflation is literally "killing" some of their book buying efforts.

Is the inflation rate for books any worse than for the rest of the economy?

Answer: The inflation rate for literature (books and journals) purchased by the National Library of Medicine has been consistently higher than the general U.S. inflation rate. The average price of books and journals purchased by NLM increased approximately 35 percent from 1977 to 1979. During the same period the consumer price index rose 21 percent. Foreign acquisitions increase at larger rates as the effect of dollar devaluation is encountered.

LISTER HILL CENTER

Question: The Lister Hill Center is almost complete. Do you have a move-in date?

Answer: The new Lister Hill Center Building is essentially complete and staff have begun to occupy portions of the facility. By early spring the Building should be operational with the dedication scheduled for May 22, 1980.

Question: What programs do you intend to run out of this Center?

Answer: This new facility will provide laboratories and other physical resources needed to carry out the mandate of the Lister Hill National Center for Biomedical Communications, the National Medical Audiovisual Center, and other NLM activities such as the Extramural Programs, and the Toxicology Information Program.

Question: Last year you said that you would come in under cost and ahead of time. Is this still true?

Answer: The Congress appropriated $26.8 million for the design and construction of this facility. The completed facility will cost approximately $22.5 million with the remaining funds to be utilized for the restoration of the Library building to accommodate conventional Medical Library functions.

Question: A part of the Lister Hill Center is responsible for strengthening our national health education effort through the development of prototypes to help learn and share medical information.

What new programs can you highlight for us which will be carried out in your new facility?

Answer: In the new Lister Hill Center, a major effort will be devoted to developing prototype systems which will bring to members of the biomedical community the information needed, when it is needed, and where it is needed. The new building provides the broad range of laboratories required to develop fully a Knowledge Base Program. The objective of this program is to develop, implement, and operationally evaluate consensus-derived and continuously updated computer-based knowledge representations of selected biomedical content areas. These knowledge bases must be immediately and easily accessible for content of variable depth, including summaries, supporting data, citations and, eventually, document delivery of the relevant literature. The knowledge will be represented in various forms, including text, graphics, tables and still and moving pictures.

To build such prototype information transfer systems requires finding more efficient and effective methods to:

1. Understand the information needs, and information dissemination and use in the health science community.

2. Analyze, synthesize, organize and update the information in ways which are useful to various users.

3. Deliver the information to the requestor in a timely manner.

The Lister Hill Center's current and proposed research activities are related to these problems. They are designed to take advantage of the products of the many hundreds of millions of dollars invested in research and development by the computer, electronics and communications industries. By study of advanced current technologies the Lister Hill Center research staff can apply the appropriate ones to medical information problems without major investments in technology development.

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: Given additional resources to supplement our intramural activities, the Lister Hill Center will work to:

1. Build an easy-to-use information system that might be a model for condensing the world's ever expanding and changing biomedical literature. This system will provide practicing physicians and other health care providers with a synthesis of up-to-date information, in words and pictures, needed for quality patient care and health maintenance. Areas of research needed include: Literature reduction and selection; text editing and expert evaluation and updating of content; improved indexing and search mechanisms; co-presentation of text and illustrations, and derivative products such as microforms and multimedia representations.

2. Use optical disc and other new mass storage technologies to allow central electronic collection and storage of the biomedical literature, more useful retrieval and rapid transmission to the biomedical community, and to provide inexpensive publication and local access to biomedical information including text, audio, still illustrations and motion pictures.

3. Build systems for automated support of all functions of biomedical libraries. The goal is to develop a total computer-based system which allows any sized medical library to know instantly the status of any item it owns, to circulate and distribute documents and to more effectively utilize the National Biomedical Library Network.

4. To establish a vigorous intradisciplinary research program in knowledge engineering to explore the fundamental scientific basis of the structure and properties of information, including relationships between the structure of language and information, statistical theories of information, automatic recognition and identification of textual information and investigations of the interface between human beings as information processors and the inanimate information systems and sources with which they interact.

61-400 O - 80 - 24

TOXICOLOGY DATA BASE

Question: The Library's Specialized Information Service is responsible for the collecting and organizing of toxicology data for computerized storage and retrieval which is then made available to a variety of sources.

Would you comment, please, on its use by universities, industry, government, and health care providers? Has this data base received increased usage during 1979 as compared to that of past years?

Answer: The Library's Specialized Information Services developed the Toxicology Data Bank (TDB) to collect and organize toxicology data for computerized storage and retrieval. The TDB became publicly available as an online file in October 1978 and, therefore, 1979 usage of this data base cannot be compared with that of any previous years.

While there are no statistics available at this time for categorizing data base users, our initial study indicates that users come from: (1) industry, (2) government, (3) health care providers, and (4) universities in order of frequency.

During 1979, the data bank continued to be improved and increased in content and currency. Training services for potential online users were provided. We anticipate that usage will increase as potential users learn about its availability.

CHEMICAL INFORMATION SYSTEM

Question: Have you asked for additional funds to secure administration of the Chemical Information System?

Answer: In FY 1980, the Congress provided funds to the National Library of Medicine to build the directory components of the Chemical Substances Information Network.

Question: Please explain this to us.

Answer: We are currently developing a Chemical Structure and Nomenclature System (CSNS) and a chemical information resources directory. The CSNS will contain information about the structures, names and file locations of the chemical substances (up to 1 million) referenced in the data bases that will make up the network. The directory will direct users to files having specific categories of information.

Question: Does the National Library of Medicine want to assume administration of Chemical Information, or does the Environmental Protection Agency and the Office of Pesticides and Toxic Substances want to retain its administration?

Answer: The Environmental Protection Agency administers CSIN and funds some of its construction, while NLM builds some of the important component files (i.e., the directory files). This

arrangement is working satisfactorily. If NLM were to be charged with these administrative responsibilities, additional manpower resources would be required.

HEALTH EDUCATION

Question: There are multiple health education programs in the Public Health Service and in the new Department of Education.

Specifically, what programs do you have that are run in conjunction with the Health Education Office in the Center for Disease Control and the Office of the Assistant Secretary of Health?

Answer: None of the programs of NLM are run in conjunction with the Health Education Office in the Center for Disease Control or the Health Education Office of the Assistant Secretary of Health. Both of these offices are charged with providing information to the public. NLM's mandate is to provide information to health professionals. Both offices have consulted with NLM staff and have presented their respective programs to the Board of Regents of NLM. We maintain liaison as appropriate and NLM provides information as required to both offices.

Question: What do you do with the Education Department's Office of School Health?

Answer: NLM has no continuing relationship with the Education Department's Office of School Health.

MEDICAL LIBRARY RESOURCE GRANTS

Question: Resource Project Grants were to aid health science libraries in fiscal 1980. Would you describe the nature of these grants and the amount of money actually spent in this area thus far for fiscal 1980, and what you plan for 1981?

Answer: The Medical Library Resource Grant program of the National Library of Medicine, authorized by the Medical Library Assistance Act, awards support to the Nation's health science libraries to provide improved access to information and effective, economical library services. Since information is a major component linking health research, education, and practice together, and since medical libraries serve as the primary contact point for health personnel, NLM's Resource Grants provide needed support for libraries to function as vital links in the health communication network. NLM administers two kinds of Library Resource Grants in response to national needs: Medical Library Resource Improvement Grants and Medical Library Resource Project Grants.

Library Improvement Grants provide support to create, improve, or expand basic library resources in local health facilities, such as community hospitals. Although support is provided to individual institutions that are geographically isolated, NLM has encouraged the development of local consortia of health libraries in order to promote resource sharing and the economical coordination of services. Since 1977, more than 250 community health libraries have received support through consortia arrangements. It is expected that

approximately 165 community hospitals will receive Improvement Grant support from FY 1980 funds in the amount of $489,000 (36 awards). In FY 1981 20 additional awards in an amount of $358,000 will be made to 114 institutions of the more than 5,000 local health facilities in need of our assistance.

Library Project Grants provide support to established health science libraries to make existing information resources available to users in a more expeditious, effective, or economical manner, or in forms better able to satisfy information needs. Projects have included the extension of health science library services to a surrounding area, the introduction of new technologies such as computers and audiovisuals, and the involvement of the library in providing information in clinical settings as a part of the health care team. These service-advances and information-access improvements are vital to individual libraries, but they are also equally important in their contribution to the development of a national biomedical information network. In FY 1980 27 resource projects are being awarded for these purposes in the amount of $1,013,000. Projections for FY 1981 are for the support of 23 awards at approximately the same level of support.

COMPUTERS IN MEDICINE

Question: The Library has supported Research Grants concerned with the application of computers in medicine. What has been your experience with this program?

Answer: In 1971, upon recommendation of the Board of Regents and consultants to the National Library of Medicine, a training program designed to train potential and existing health science faculties in computer and information science and to promote an interdisciplinary environment in health science professional schools was initiated. While this program has been very successful, its very success identified the lack of support for career development and research in computer and information science as applied to health.

Therefore, after a careful review by consultants and the Board of Regents in 1978 NLM announced new programs of research and new investigator support for study in computer and information science in medicine. Although a very short deadline for receipt of applications was necessary, 23 requests were received. Seven were judged to be highly meritorious and the available funds allowed for support of five.

Question: What are your future plans?

Answer: Current and future research is aimed at markedly increasing the efficiency and effectiveness of information transfer by utilizing computers and information science to directly approach clinical decision making and problem solving. For this purpose, knowledge representation and organization in large computerized data bases is the key. Model knowledge areas being used to pursue these studies include cancer therapy, coronary artery disease, and birth defects.

This program will continue to support better ways to use computer, information, and communication science in support of prevention, diagnosis, therapy, and care.

RESEARCH AND DEMONSTRATION GRANTS

Question: Research and Demonstration Grants were to support explorations in biomedical communications during fiscal 1980. Would you please report on those grants which have been awarded thus far? What have they accomplished?

Answer: Research and demonstration grants support activities leading to new knowledge about health information access, retrieval, and use. The program assists the discovery of new knowledge and the development of practical applications from theoretical insights. It also demonstrates new technologies under operating conditions.

Demonstration grants have led to the development of a new type of medical librarian, the clinical librarian. By making rounds with physicians, the clinical librarian can both anticipate information needs and have them available at the time of the rounds or respond by locating information relevant to questions raised but unanswered at the bedside.

Demonstration grants have also led to increasing effectiveness in sharing of resources among institutions: journal and book exchanges, audiovisual instructional units, collaborative continuing education, and cooperative technical services of participating libraries are all examples of operating arrangements now increasing in number that had their original demonstration through this source.

Research activities have been directed at improving the efficiency of the use of automated bibliographic systems by attempting to understand more fully requestors' needs. Also supported is research in convenient new computer languages in order to make sharing of computer mediated instructional material easier. These new languages also utilize "intelligent" computer terminals and eliminate the need for expensive communication with a central computer.

National Eye Institute

STATEMENT OF DR. CARL KUPFER, DIRECTOR

BUDGET REQUEST

Senator Eagleton. We will now move on to Dr. Kupfer, Director of the National Eye Institute. We are delighted that Senator Hollings is with us because he has continuing keen interest in the NIH as a whole and in this particular Institute.

Dr. Kupfer?

Dr. Kupfer. I would like to submit my opening statement for the record and just summarize some of the points that appear in that statement, if I may.

[The statement follows:]

Statement of Dr. Carl Kupfer

Research supported by the National Eye Institute is aimed at reducing the physical, emotional, and economic hardships caused by eye disease, visual impairment, and blindness. These problems seriously affect more than 10 million people in the United States--one of every twenty Americans.

Today, eye research both contributes to and benefits from a broad spectrum of biomedical investigation. At one time, the eye was studied by scientists separately from the rest of the body. Now it is regarded from the perspective of a variety of scientific and medical disciplines.

Diabetes and Other Vascular Diseases of the Eye

There is no better example of this multidisciplinary approach than in the field of diabetes. As a result of research advances which have led over the past few decades to a better understanding of diabetes and improved medical care for diabetic patients, people with this disease are living longer than ever before. But an ironic consequence of this increased longevity is a concomitant increase in the incidence of disabling complications associated with longstanding diabetes. One of the most tragic of these, diabetic retinopathy, has become a leading cause of blindness. Yet, through research, remarkable progress has been made against this disease in recent years.

We have, for instance, developed new treatments which can substantially reduce the risk of severe visual loss in people in advanced stages of diabetic retinopathy. In some cases, we can even restore vision that has been lost as a result of this disease. Through basic research, important clues to the cause and development of diabetes itself have been discovered which may point the way to better treatment and, possibly, to prevention of this disease.

Over the past few years, I have informed this Committee of the progress made in a nationwide study of treatment for diabetic retinopathy. In the most common form of this treatment, a laser beam is focused on the retina to destroy abnormal blood vessels and diseased tissue in an attempt to prevent severe hemorrhaging which can lead to blindness. In 1976, the first data from this study were reported. They provided conclusive evidence that laser treatment of advanced stages of diabetic retinopathy can reduce by more than one-half the risk that severe visual loss from this disease will occur within the next five years.

Most recently, the study has identified four distinct risk factors which can be used in predicting the chances that severe visual loss from diabetic retinopathy will occur. Thus, ophthalmologists and other physicians now have a specific guideline which they can use in determining which of their diabetic patients should be considered for photocoagulation treatment. This is an excellent example of how a controlled clinical trial can provide important and very practical information that physicians can use in their everyday practice.

Yet, as encouraging as these findings are, the fact remains that many people with diabetic retinopathy are still losing sight from this disease despite all our best efforts to prevent this from happening. Therefore, we continue to seek new and better ways of

treating diabetic retinopathy. For example, a new multicenter clinical trial is just now beginning. We call it the Early Treatment Diabetic Retinopathy Study, for its purpose is to evaluate the effectiveness of laser treatment in earlier stages of diabetic retinopathy than were treated in the previous trial. The new study will try to determine whether such early treatment can delay or prevent progression of mild diabetic retinopathy to the more severe stages of the disease where sight is most threatened. If early treatment can help keep the disease from worsening, then the risk of blindness will be even further reduced. The study will also evaluate whether aspirin in association with photocoagulation can help to prevent or delay the progression of diabetic retinopathy. Twenty-two university medical centers are cooperating in this new trial; we expect that 4,000 patients will participate.

The success of the first Diabetic Retinopathy Study has also encouraged vision scientists to initiate clinical trials of new treatments for other eye disoders. In fact, many of the scientists heading these new studies got their first exposure to clinical trial methods as investigators in the Diabetic Retinopathy Study.

One of these new clinical trials is evaluating laser treatment for retinal branch vein occlusion--the second most common retinal vascular disease after diabetic retinopathy. Another is assessing laser treatment of senile macular degeneration and ocular histoplasmosis. Senile macular degeneration is the leading cause of severe visual loss in people over age 60. Ocular histoplasmosis, a manifestation of a common systemic fungal disease, is thought to be the second leading cause of visual loss in young and middle-age persons living in area where the disease is endemic.

But clinical trials are just one of several epidemiological approaches now being used in eye research. Other types of epidemiological studies are designed to identify factors that may help in predicting an individual's susceptibility to a disease. For example, in a diabetic, information concerning immunological factors, family and medical history, duration of diabetes, diet, other ocular conditions, and the use of tobacco and alcohol may be useful in predicting the risk of developing severe diabetic retinopathy. Such information can often lead to improved treatment or even effective means of preventing disease.

A considerable amount of basic research related to the ocular effects of diabetes is also underway. I have told this Committee on several occasions of the progress being made in the National Eye Institute's intramural laboratories on diabetic cataracts. I have mentioned how an enzyme, called aldose reductase, has been identified which triggers the development of these cataracts in diabetic laboratory animals. I have also reported on the development of a series of compounds which can inhibit this enzyme, thereby slowing or even blocking cataract development. In recent years this same enzyme has been implicated as a possible cause of diabetic retinopathy and perhaps even of the small blood vessel disease that occurs elsewhere in the body in advanced diabetes.

I am now able to report that this research has progressed to the stage where compounds that inhibit aldose reductase are undergoing preliminary testing in humans. The continuing search for effective treatments for the ocular complications of diabetes, including diabetic retinopathy and cataract, is an excellent illustration of productive cooperation among intramural scientists at the National

Eye Institute and other Institutes of NIH, investigators at academic research centers throughout the United States, and private industry.

Retinal Degenerations

Diabetes and other diseases affecting the retinal blood vessels constitute one important group of disorders that affect the retina. Another group includes the retinal degenerations--either hereditary or aging-related--which are characterized by the gradual breakdown of the light-sensitive retinal photoreceptor cells followed by irreversible loss of vision. In my testimony to this Committee last year, I reported that a biochemical defect had been identified in a strain of mice and also in a strain of Irish setter dogs with inherited retinal degenerations that in many ways resemble certain types of human retinitis pigmentosa. Now, plans have been made for testing a treatment aimed at correcting this defect chemically, thereby slowing down or preventing retinal damage.

Although it is still much too early to predict whether this treatment has any clinical significance for such human diseases as retinitis pigmentosa, this type of research offers hope that it may be possible to intervene biochemically in the course of a hereditary retinal degeneration.

Tissue Culture of Ocular Tissue

One of the most promising developments in vision research over the past few years is the laboratory culture of normal and diseased cells from ocular tissue. Tissue culture permits detailed biochemical study of mechanisms involved in cellular function and dysfunction and enables direct assessment of the effect of experimental drugs on diseased tissues. The aim of a conference sponsored by the National Eye Institute last October was to stimulate more rapid application of the latest tissue culture techniques in the field of eye research. This meeting was highly successful in bringing together tissue culture experts working in vision research and in other disciplines to share their knowledge and discuss the many new and exciting developments and opportunities in this field. Information presented at this meeting will soon be published and widely disseminated to the scientific community.

One very promising new tissue culture technique discussed at the conference has the potential for permitting repair of some clouded corneas without using tissue from donor eyes. In many cases of damaged corneas, only the inner or endothelial cell layer is affected. In one version of the new repair technique, successfully applied only in animals so far, the damaged endothelial cells are scraped off the cloudy cornea and replaced with a sheet of normal endothelial cells grown in the laboratory. Investigators are now working on methods for growing human corneal endothelial cells. If this proves successful, it could help alleviate the problem of corneal donor tissue availability and storage.

Immunology and the Eye

Another scientific field with great potential for wide application in vision research is immunology. The immunological aspects of a number of difficult to treat ocular diseases, in particular inflammations and infections, are now being studied. Again, to encourage the application of the latest findings and techniques in immunology to the study of eye diseases, and to acquaint immunologists with the

many promising opportunities for research on the eye, the National Eye Institute is sponsoring a series of workshops on this topic in collaboration with the National Institute of Allergy and Infectious Diseases. The first of these was held last December. Two additional workshops will be held in March and June of this year.

New findings in immunology suggest it may be soon be possible to improve treatment of such hard to manage and worrisome conditions as uveitis, a common form of chronic ocular inflammation. Research in immunology may also lead to new approaches to the management of recurring viral infections of the eye, such as herpes simplex infections of the cornea.

Collaboration with National Institute on Aging

Because the largest portion of our nation's visually impaired population is over age 65, we are greatly interested in opportunities to study the effects of aging on the eye. At present, we are supporting over 60 grants directly concerned with ocular aspects of aging. Several other projects are indirectly related to aging problems. We have recently begun discussions with the National Institute on Aging on how our two organizations can work together to identify and develop opportunities for productive collaboration.

Program Planning

Before concluding, Mr. Chairman, I would like to mention that the comprehensive program planning which the National Eye Institute has been engaged in since 1974 will continue during the current year and into 1981. We are now beginning to update our national program plan which identifies vision research needs and opportunities through FY 1982. As in the past, our program planning will be conducted in collaboration with the National Advisory Eye Council and involve outstanding representatives of the vision research community, as well as consumer and other public participants.

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 1981 is $116,562,000, an increase of $3,594,000.

RESEARCH PROGRESS

Dr. KUPFER. I would like to report on the progress in the last 10 years that has been made possible by the appropriations provided to the National Eye Institute. I think this has been an exciting decade, and we look forward to the years immediately ahead with increased enthusiasm.

During the past 10 years, cataract extraction has been made one of the safest operations that has ever been developed. Yet, we have not wanted to stop at just perfecting the technique for removal of cataracts because this operation costs the American health care system over $1 billion per year.

What we would like now to do is to learn how to delay the onset of cataracts. It has been calculated that if we could delay the onset of cataracts by 10 years, we would reduce by 45 percent the number of people who would need this surgery.

Progress has already been made in one type of cataract, the kind that

sometimes occurs in people with diabetes. We know that diabetics develop cataracts an average 10 to 15 years earlier than people without diabetes. We are on the verge of a clinical trial of some new drugs that can be applied in the form of drops or taken as pills to slow down the development of cataracts in patients with diabetes. I think this is a very exciting possibility indeed.

In the area of corneal disease, the operation of corneal transplantation has been made much more successful today than it was a scant 10 or 15 years ago, but some new developments have occurred recently which may enable us not only to simplify this operation but increase its success rate.

One layer of the cornea seems to be the most affected in many of the conditions requiring corneal transplantation. Instead of transplanting the entire cornea, just this one layer of cells can be grown in tissue culture and then placed on the back of the diseased cornea. I think this, again, is a very exciting possibility which has been tested successfully in animals, and perhaps within the next 2 or 3 years will be suitable for attempts in patients.

In the area of glaucoma, the continued development of drugs has resulted in less and less need to resort to surgery to reduce elevated intraocular pressure. This research in the development of new drugs will continue.

A very exciting development which may have relevance to the treatment of amblyopia, the so-called lazy eye or the loss of vision due to disuse that we see in so many children, has been the first development of a drug which can reverse this condition in laboratory animals whose one eye has been deprived of vision by not allowing it to be used. Again, the possibility of drug therapy to bring back vision in an eye which heretofore has not been used is something that has been demonstrated in animals and should be ready for application to patients in the next few years.

In one area that has been most resistant to research progress, retinal degenerations, there have been some very exciting developments during the last decade. In the last 2 or 3 years, a specific enzyme defect has been identified in one type of retinal degeneration which has now been amenable to treatment by a very special type of diet.

I am happy to report that the first patient who has been kept on this diet for more than 15 months has now shown some recovery of retinal function. This is the first time that a retinal degeneration due to a specific enzyme defect has been successfully treated and, I think, may open the door to treatment of other retinal degenerations, such as retinitis pigmentosa. There are also now animals with retinal degenerations which appear quite similar to human diseases in which a specific enzyme defect has also been detected, and the possibility of developing treatment for these conditions is before us.

Finally, as I have reported previously, as a result of the nationwide diabetic retinopathy study—the laser has been shown to be beneficial in reducing the rate of blindness in moderate to severe stages of this disease by over 50 percent. Findings from this study are being put into widespread practice throughout the United States.

We have begun a followup trial aimed not only at improving the outcome of treatment for diabetic retinopathy but also at trying to prevent its progression. This is called the early treatment diabetic retinopathy study and recruitment of patients for it has already begun. I think in the next 10 years we will see marked advances in not only the prevention of blindness from diabetic retinopathy but the slowing down or even prevention of this retinal disease.

BETTER TREATMENT TECHNIQUES

On the horizon are also efforts to develop better treatment techniques for one of the main causes of blindness in the United States—macular degeneration. We are at present funding a clinical trial to see if laser photocoagulation will be beneficial in this disease which causes a gradual loss of sharp central vision, but our main thrust is trying to develop new information and gain new knowledge about the causes and development of this disease.

Last year I discussed with the committee the need for increased activity in immunology, and we have been collaborating with the National Institute of Allergy and Infectious Diseases in holding three workshops to focus attention on the problems of immunology in ophthamology. One research workshop has been held and two others are planned for March and June 1980.

The field of immunology is particularly important because one of our major causes of visual disability is inflammation of the back of the eye. New kinds of drugs are being developed and tested which hold great promise for improved treatment of such inflammations by manipulating the body's immune system. I think this is an exciting period that we are entering.

Certainly, as Dr. Fredrickson said, this is a continuation of the golden age of biomedical research. The National Eye Institute is requesting $116,562,000 for fiscal year 1981. This represents an increase of $3,594,000 over the fiscal year 1980 budget.

I would be happy to answer any questions.

Senator EAGLETON. I will yield to Senator Hollings.

BUDGET INCREASE

Senator HOLLINGS. Thanks, Mr. Chairman.

Dr. Kupfer, what would you do with this $3.5 million? There's nothing in there for intramural research. I can go down the list. What will you do with the $3.5 million?

Dr. KUPFER. The additional funds will be placed in the category of research grants, primarily used to support investigator-initiated research. This will continue the research activities in the five areas I have outlined.

BALANCE BETWEEN INTRAMURAL AND EXTRAMURAL RESEARCH

Senator HOLLINGS. On the matter of research, the budget for intramural research, in your opinion—is there a proper balance between the intramural and the extramural research program?

Dr. KUPFER. Yes, sir. I think at the present time that that balance is an appropriate one. We are looking forward in a year or so to the acquisition of space in the NIH ambulatory care research facility being built in juxtaposition to the clinical center, but at the present time, I think the balance between intramural and extramural is appropriate.

NEW POSITIONS

Senator HOLLINGS. Last year you were given 15 new positions. Did you receive these positions at all? Did you fill them?

Dr. KUPFER. There were 15 additional positions, but I think there was a modification of that for NIH in general, and we did not receive the 15 positions.

Senator HOLLINGS. If you could, would you still request those 15 positions? Could you fill them? Would you need them? That is what the committee would like to know.

Dr. KUPFER. For fiscal year 1981, we are not requesting any additional positions, Senator Hollings.

CONSTRUCTION

Senator HOLLINGS. With respect to the construction, I notice a brief statement with respect to the $3 million construction, I think it was, last year—well, is that $3 million—will that complete the construction needs? Is that right?

Dr. KUPFER. We are in the process of developing guidelines for the construction program. We have solicited opinions from the vision community—what they would think appropriate guidelines would be. We now have the results. They have indicated the need for approximately $72 million in construction funds and have offered information as to how the guidelines could be developed. We discussed this with the National Advisory Eye Council only yesterday, and we should be soliciting proposals which we hope would be reviewed and awards made by May of 1981.

I think this represents a first step in a construction grant program for the vision research community.

Senator HOLLINGS. It is a first step, rather than completion. We couldn't tell that from the justification. Would you resubmit this further information to the committee so we have it? In other words, if it is a first step, can you outline then where we are headed?

Dr. KUPFER. I would be happy to.

Senator HOLLINGS. Then we would know.

[The information follows:]

CONSTRUCTION

At the recent February 4–5, 1980 meeting of the National Advisory Eye Council, discussions of the newly authorized construction program resulted in the following guidelines.

1. Construction could be in the form of significant alterations and renovations or new construction.
2. Initially the maximum award would be $500,000.
3. A minimum of 50 percent of the total construction cost in matching funds from non-Federal sources would be required.
4. Preference will be given where the main emphasis is to expand clinical research

capabilities in the broadest sense. This includes the integration of dry lab approaches, for example psychophysical testing, related wet laboratory investigations such as experiments on animal models of human disease and dedicated clinical research activities.

In November 1979, a request soliciting letters of intent to apply for the National Eye Institute construction program was sent to eligible departments/institutions. In response, the following vision research facility needs were documented: individual square footage requests ranging from 800 to 100,000 square feet with individual costs ranging from $75,000 to $10 million. The total costs of these letters of intent equal $72 million.

CATARACTS

Senator HOLLINGS. On cataract causation, using drops to arrest it where it is diabetic related, does that have any relation whatever to just age itself or traumatic cataracts? Do you find any relation whatever?

Dr. KUPFER. At the present time, it seems that the cataract that occurs in the diabetic patient is a very unique type of cataract, and it is only for that kind of cataract that research has progressed to where we believe it may be possible to slow down development. For the individual who does not have diabetes but does develop cataracts related to age, we unfortunately do not have any immediate prospect for a nonsurgical treatment. But, we are working on it, to try to slow down the development of that kind of cataract.

Senator HOLLINGS. With the retinal degeneration because of an enzyme defect, could it also be the same with cataracts?

Dr. KUPFER. It is possible. Certainly in the group of congenital cataracts that occur in children, there is a strong suggestion that an enzyme defect may play an important causative role and we are studying this problem very actively.

Senator HOLLINGS. Do you have sufficient funds to research that—the cataracts caused through age?

Dr. KUPFER. Yes, sir. The activity is ongoing. We have managed to bring many of the Nation's leading cataract researchers together into a cooperative group, and this has increased their efficiency and their effectiveness in carrying out research on human cataracts. I think at the moment this group is adequately funded.

Senator HOLLINGS. Thank you, Mr. Chairman.

Senator EAGLETON. I think you covered it very well, Senator Hollings. I appreciate it.

We have additional questions in some of these other areas including the Library of Medicine, Eye, and everything, that will be supplied for the record at a later time.

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

CATARACTS

Question: In parts of the world where nutrition is poor, senile cataracts tend to develop at an earlier age than in this country.

What do we know about the relationship between nutrition and the development of cataracts?

Answer: It is evident that certain nutrients are vital for normal lens metabolism. Denial of these nutrients (tryptophan and other essential amino acids, riboflavin, selenium and calcium) to young experimental animals initiates a chain of events which culminates in loss of lens transparency or cataract. In such animals, cataract formation may result primarily from interference with the normal growth and development of the lens rather than from failure to meet the daily metabolic needs of this tissue.

There are no clinical or epidemiological data which would support the conclusion that inadequate nutrition contributes directly to the deterioration of the mature human lens. There is currently no reason to support the use of special nutritional supplements in an attempt to present or treat cataract, especially in populations with no obvious undernutrition. But, these animal studies provide suggestive evidence which might generate future research into the etiology of human cataract. It is possible, furthermore, that the cumulative effects of multiple mild nutritional insufficiencies plus environmental stress may play a role in cataract development.

At the present time, we believe that there are several forms of senile cataracts which appear to be an almost inevitable consequence of a multitude of physical and chemical stresses accumulated over a lifetime. More research is needed on the interactions of lens nutrients with one another or with non-nutrient factors over prolonged intervals of time and the role of this process in maintaining lens transparency and cataract formation.

In other words, good nutrition is important for a healthy lens -- but why and how are the questions which need to be answered.

GLAUCOMA

Question: Last year you were contemplating studies on the possible benefits of marijuana and its derivatives in treating glaucoma.

What research can you report, and do any of the results indicate that this drug would be of use?

Answer: In November 1978 the National Eye Institute published an announcement soliciting applications for research grants to study several aspects of the effects of marijuana and its derivatives on eyes with glaucoma and on normal eyes. We have received several applications which will be eligible for funding in FY 1980. Although we know that smoking marijuana will lower eye pressure in some people with glaucoma and in some people with normal eyes, we do not know with any certainty whether this effect will be sustained with chronic use, or whether treatment with marijuana will actually

preserve visual function in glaucoma patients. We also do not know if marijuana will interact unfavorably with other drugs used to treat glaucoma. These and other questions must be answered before marijuana or any other anti-glaucoma drugs for that matter, can be considered for widespread clinical use.

Question: Would it be a fair statement to say that you have made tremendous progress in the treatment of glaucoma and cataracts but that health professionals, for some reason are not fully utilizing your breakthroughs? It seems that you have indeed made a great deal of progress in these treatment areas but the full cost savings have not been realized because we are not utilizing the methods.

Answer: Actually, these treatment techniques are being widely utilized by ophthalmologists and other health professionals, and I know of no significant lag between the development of them and their adoption into the medical care system. To facilitate the transfer of new findings to clinical practice, the National Eye Institute has encouraged controlled clinical trials of new medical and surgical procedures. In this way, their advantages and disadvantages can be systematically compared to those of established techniques and their long-term safety and efficacy documented scientifically. Clinical trial results are widely disseminated to health professionals and to the public in a form suited for their incorporation into everyday clinical practice.

Certainly, great progress has been made in the treatment of both glaucoma and cataract. Over the past few years, we have seen the treatment of glaucoma progress from being primarily surgical to primarily medical, with the development of an array of drugs which can bring this condition under control in about two-thirds of cases. But many problems still remain unsolved. For most forms of glaucoma, there is no means of prevention or cure; we can only hope to bring them under control. One-third of glaucoma cases respond poorly or not at all to present treatments. Most glaucoma drugs produce undesirable side effects in many patients and, further, lose their effectiveness in time. The underlying cause of the most common form of glaucoma, open-angle, is unknown. For this reason, we are now conducting and supporting studies aimed at the development of new antiglaucoma drugs and new approaches to glaucoma surgery, including the use of various kinds of lasers which we hope will increase our success in preventing blindness from this disease and perhaps reduce the need for frequent medication. We are also supporting basic studies aimed at better understanding of the causes of glaucoma in the hope of finding ways of identifying people at high risk to developing this disease.

In cataract, rapid clinical advances have resulted in an operation that is highly successful and safe and which requires a minimal amount of hospitalization and postoperative recovery time. Several different approaches are now available for compensating for the absence of the natural lens of the eye, which is removed during cataract surgery, so that most people who have undergone this procedure now enjoy restoration of a high degree of useful vision. Yet, despite the availability of a highly successful treatment, cataract remains a major problem throughout the world. The high frequency with which this condition occurs, usually because of

51-400 O - 80 - 25

aging, means that unless some means of preventing or at least slowing down cataract development is found, this disease will continue to remain a leading cause of blindness despite any further improvements in surgical techniques. From an economic standpoint alone, we as a nation are spending over $1 billion a year to treat cataract patients. We have been told that a 45 percent reduction in the approximately 400,000 cataract operations performed each year in this country would be possible if we were able to slow down the development of cataract by just ten years. Thus, in cataract research, the National Eye Institute is concentrating its resources on finding out more about the causes of cataract and working toward a nonsurgical treatment or means of prevention.

DIABETIC RETINOPATHY

Question: You have several clinical trials underway which are studying the efficacy and safety of treatments for diabetic retinopathy.

Could you outline for us any new developments of the past year?

Answer: One of the most important developments of the past year arose from analysis of data collected in the Diabetic Retinopathy Study, a recently completed clinical trial to evaluate the effectiveness of photocoagulation as a treatment for diabetic retinopathy. Statisticians analyzing the study results have now discovered specific characteristics, or risk factors, that can be used to determine which eyes with diabetic retinopathy are most likely to go blind in the near future. An eye with three or four of these risk factors is about five times more likely to go blind than is an eye with only one risk factor. Ophthalmologists and other physicians can use these risk factors as guidelines in determining which of their diabetic patients should be considered for immediate photocoagulation treatment.

Yet, as helpful as these and other findings from the Diabetic Retinopathy Study are, the fact remains that many persons with advanced or moderately advanced diabetic retinopathy are still losing sight from this disease despite all our best efforts to prevent this from happening. Therefore, we continue to seek new and better ways of treating diabetic retinopathy. For example, a new multicenter clinical trial is just now beginning. Called the Early Treatment Diabetic Retinopathy Study, the new trial will determine whether treatment earlier in the course of the disease can delay or prevent the progression of mild diabetic retinopathy to the more severe stages where sight is most threatened. If early treatment can keep the disease from worsening, then the risk of blindness will be even further reduced. The study will also evaluate whether aspirin in association with photocoagulation can help to prevent or delay the progression of diabetic retinopathy.

Another recent development is that the Diabetic Retinopathy Vitrectomy Study has been expanded to include patients who have advanced diabetic retinopathy but have not yet experienced intraocular hemorrhage; many of these patients have suffered retinal changes so severe that they are at high risk of blindness even if treated by photocoagulation. The investigators will be seeking to

determine whether such patients can benefit from vitrectomy. If the findings indicate that they can, vitrectomy would have to be considered along with photocoagulation as a means of preventing the hemorrhaging and visual loss associated with advanced diabetic retinopathy.

Question: How soon will these studies yield recommendations that will be of value to practicing ophthalmologists and diabetes specialists?

Answer: The Diabetic Retinopathy Study Group has already published three reports in scientific journals. The first two papers proved the efficacy of photocoagulation in treating patients with moderate to severe retinopathy. The latest article identified factors in diabetic retinopathy which increase the risk of severe visual loss. Practicing ophthalmologists can use this information in determining when a patient's eye(s) should be treated with photocoagulation. The National Eye Institute held a press conference to announce the findings of the Diabetic Retinopathy Study and has worked intensively with the medical and general news media to ensure that the results reached the medical community and the public. The Institute has also produced fact sheets, brochures, explanations for patients undergoing treatment, and other materials that are intended to inform diabetics, health professionals, and the general public about photocoagulation as an effective treatment for diabetic retinopathy. Even more intensive efforts will be made in the future to communicate directly with professionals who treat diabetic patients. Pamphlets, teaching aids, and exhibits in professional meetings will be used to acquaint specialists and general practitioners with the findings of the Diabetic Retinopathy Study. The Diabetic Retinopathy Vitrectomy Study is expected to produce findings useful to practicing ophthalmologists within the next year or two.

INTRAOCULAR LENS IMPLANTS

Question: The National Eye Institute is currently conducting a long-term study on the safety and efficacy of intraocular lens implants (IOLs).

What were the results of the Consensus Development Conference on Intraocular Lenses that the National Eye Institute held in 1979?

Answer: The National Eye Institute Consensus Development Conference on Intraocular Lens Implantation was planned to provide an appropriate forum for addressing questions raised about the safety and use of intraocular lenses. Physicians, scientists, and consumer representatives gathered at NIH to discuss various aspects of intraocular lens implantation. In the summary report of the meeting there were broad guidelines for ophthalmic surgeons who perform intraocular lens implantation. In general, the report said intraocular lens implants should be restricted to the elderly, they should be implanted in the eyes of slightly younger patients only when contact lenses or spectacles are not likely to provide adequate visual function, and initially, they should be restricted to one eye unless the needs of the patient dictate otherwise.

Conference participants generally agreed that excellent visual results can be achieved with a variety of intraocular lens types, although the use of intraocular lenses is associated with a small but significant risk of additional complications beyond that of cataract surgery itself. Many of these complications, they said, may be transient or treatable medically and thus do not affect the visual result.

Additional studies are needed, however, to determine the long-term and short-term complication rates, to define more precisely the indications and contraindications for implantation, to compare various cataract extraction techniques and types of lenses, and to explore alternatives to intraocular lenses. In fact, some participants expressed the belief that prospective clinical trials are required to refine knowledge of both the short-term and long-term advantages and risks of lens implantation.

Question: Will the recent actions of the Food and Drug Administration in reviewing its clinical study of intraocular lenses influence your study in any way?

Answer: No. The National Eye Institute is currently supporting two prospective studies on intraocular lenses. One is a five-year study comparing the effects of intraocular lenses and contact lenses on the inner layer of the cornea following cataract surgery. The other is a randomized prospective study comparing the long-term effects of contact lenses and intraocular lenses on the cornea and on visual acuity and also the complication rates following cataract extraction.

In a presentation at the Intraocular Lens Implantation Consensus Development Conference, the Food and Drug Administration reported that its approach to monitoring the testing of intraocular lenses by gathering data from surgeons and manufacturers on complications associated with implantation was determined in large part by a Congressional mandate. This mandate, the Food and Drug Administration said, called for regulation of the lenses and institution of an immediate study while not interfering with the availability of the lenses. The Food and Drug Administration study was characterized as a data gathering effort aimed at developing information about the short-term safety of these lenses. To the best of our knowledge, it is not designed as a prospective clinical trial with the expectation that it will provide definitive data about the long-term complication rates associated with the use of intraocular lenses, nor will it compare intraocular lens implantation with alternative methods for restoring useful vision following extraction of the clouded lens of the eye.

DIABETES

Question: Diabetes has been cited as the leading cause of adult blindness in this country. Based on the National Eye Institute's work in the field of diabetic retinopathy, what percentage of diabetics' sight can be preserved or restored, using the latest advances?

Answer: The results from a National Eye Institute nationwide clinical trial, the Diabetic Retinopathy Study, showed that

photocoagulation treatment in which a laser is usually employed can reduce the risk of severe visual loss by 60 percent in people with moderate to severe diabetic retinopathy. As a result, this treatment is now offered at many hospitals and most university medical school clinics throughout the United States. The technique is rapidly becoming available to many practicing ophthalmologists. It is estimated that 300,000 to 600,000 diabetics have retinopathy serious enough to warrant consideration for this treatment.

In the Diabetic Retinopathy Study, people with moderate to severe diabetic retinopathy were studied. We now believe that photocoagulation used earlier in the course of diabetic retinopathy than in the Diabetic Retinopathy Study may further reduce the number of diabetics who lose vision, by slowing or even preventing progression of the retinopathy. Therefore, a new clinical trial, the Early Treatment Diabetic Retinopathy Study, has recently begun to test this hypothesis and to evaluate the usefulness of aspirin in the treatment of diabetic retinopathy as well.

For diabetics who have already become blind as a result of severe hemorrhage within the eye, a surgical procedure called vitrectomy, in which the blood-clouded tissue is removed, may restore sight. The National Eye Institute is currently supporting a clinical trial of the procedure involving 15 medical centers. One purpose of this trial is to compare the visual outcome of performing vitrectomy soon after the onset of a hemorrhage with that of waiting several months for the blood to clear on its own. Another purpose is to compare the use of vitrectomy with other forms of management, including perhaps photocoagulation, in patients with severe diabetic retinopathy who have not yet had a severe hemorrhage.

EYE CONSTRUCTION

Question: For the first time, in fiscal year 1980 the Senate added $3 million for construction. You are requesting zero in 1981.

By this can we assume that $3 million will totally cover your construction needs?

Answer: The appropriation of $3 million can be viewed as the first phase of an effort to fill an important need of eye research facilities. The National Eye Institute has solicited from the vision research community letters expressing their interest in constructing vision research facilities. To date, respondents indicate needs totalling $72 million.

Question: We were surprised to see that your budget justifications for this program were so lacking in information and details -- just three sentences.

Why was this?

Answer: At the time of the development of the President's budget, no awards had been made by the Institute, therefore, little information could be reflected here. We have provided for the Committee additional information for the record on our construction program.

Question: Is this not a priority program to you?

Answer: The following recommendation from Vision Research, A National Plan indicates the importance that construction of eye research facilities has for the overall National Eye Institute research program. "The National Eye Institute should expand its support for the development and operation of vision research centers. This would do much to facilitate the implementation of the research priorities set forth in this report, especially where a richer interchange between the clinical milieu and the world of laboratory research is needed. This concept of a vision research center, that is, a research/patient care/education setting in which an array of individual research project grants and other type of awards are welded into a cohesive, multifaceted and interactive program focused on a specific class of visual system disorders has much to commend it."[1/]

INTRAMURAL RESEARCH

Question: Dr. Kupfer, you spend as much time, if not more, as anyone in the Clinical Center.

What does this budget do to your clinical program?

Answer: The National Eye Institute's clinical research budget contains a stable funding level for both dollars and positions, and the Institute will attempt to maintain the same level of activity as in 1980. Projected funding for the Clinical Branch in 1981 is approximately $4.3 million.

Question: How about the Intramural research?

Answer: In total, the budget for the intramural program of the National Eye Institute was $9.8 million in FY 1980 and is estimated at $10.4 in 1981. Under this level, funds have been provided for mandatory increases, and attempts will be made to maintain research efforts at the 1980 level.

Question: In your opinion, is there a proper balance between your extramural and intramural programs?

Answer: Yes, I believe that the balance between extramural and intramural is appropriate. For the last ten years the intramural budget has been less than 10 percent of the National Eye Institute's total budget. The National Advisory Eye Council has endorsed the Institute's support of its intramural program as indicated by the following quotation from Vision Research -- A National Plan: 1978-1982, Volume I: "The National Eye Institute's intramural program is a major national resource for research and research training in vision. When the new Ambulatory Care Research Facility (ACRF) now under construction at NIH is completed, the potential of the intramural program will increase greatly. The new clinical research facilities which the ACRF will make available will permit the National Eye Institute to place even more emphasis on direct clinical research training activities than it does at present... The National Eye Institute is therefore urged to continue its efforts to foster a strong research program within its intramural laboratories and clinic."

[1/] Vision Research -- A National Plan, Volume 1, Page 14.

Question: What do you think is more successful and productive: extramural or intramural research?

Answer: I believe that both are equally successful, productive, and cost effective, but the Institute's intramural program offers an environment ideally suited for the training of clinical research investigators.

VISION RESEARCH FUNDING

Question: Between 1971 and 1980 funding for vision research has doubled twice from $29.4 million in 1971 to $113 million today.

What have you done with this funding increase?

Answer: This funding increase in constant dollars has only been about 85 percent since 1971. The Institute has been able to increase the number of research projects from 167 in 1970 to over 1,100 in the budget presented for 1981. Although this is not the only mechanism of support used by the Institute, it is by far the major one. Examples of some of the research accomplishments arising from research project grant support in the past decade can be found below.

Question: What major achievements can you cite over the past ten years?

Answer: In the past ten years, research supported by the National Eye Institute has contributed significantly to dramatic advances in the prevention, diagnosis, and treatment of eye disorders. In additon, vision research has contributed to a better understanding of disorders affecting other organ systems in the body.

Research on diabetic retinopathy has proved to be extremely rewarding both on a cost/benefit basis and in terms of alleviating human suffering. Laser therapy was found to reduce the risk of severe visual loss in people in advanced stages of this disease, which is a leading cause of new adult blindness. In some cases, vision lost because of diabetic retinopathy can even be restored. New microsurgical techniques have been developed for surgical removal of the vitreous humor when it becomes clouded with blood and impedes passage of light to the retina, thereby impairing vision.

In the field of cataract research, significant progress has been made in improving surgical procedures, suturing techniques, and microscopic instrumentation. The result has been safe and successful restoration of sight and reduced hospitalization, from a stay of six or seven days ten years ago to a stay of one to three days. New surgical techniques have also made restoration of useful vision to many children with congenital cataract a reality.

In recent years, exciting advances in cataract research conducted in the laboratory have made it possible to predict with some confidence the eventual development of a nonsurgical method of treating at least certain types of cataracts or preventing their formation in the first place.

Improved control of glaucoma, a major cause of blindness, has also been a hallmark of the 1960's. Safer and more effective medications have been developed so that treatment of glaucoma is now primarily medical rather than surgical. New approaches to surgery have been devised which also contribute to better management of glaucoma patients, as has research on new diagnostic techniques for differentiating between types of glaucoma.

The first antiviral agent to be introduced into medicine was a drug developed to treat a common viral infection of the cornea. This drug and its successors have proved to be very effective in treating herpes simplex keratitis, an infection which, if unchecked, can cause visual impairment or blindness. Recent advances in research may also lead to improved treatment of other chronic ocular disorders such as uveitis.

Our ability to restore sight to a person whose vision has been clouded by a scarred cornea has vastly improved over the last decade. In addition to the development of better surgical techniques, research on preservation and storage of donor corneas has improved the success rate of these transplants.

One very promising new tissue culture technique has the potential of permitting repair of some clouded corneas without even using tissue from donor eyes. One of the most exciting advances in vision research over the past few years is the development of tissue culturing techniques for growing bits of normal and diseased ocular tissue in the laboratory. Tissue cultures permit detailed biochemical study of the mechanisms involved in cellular function and dysfunction and enable direct assessment of the effect of experimental drugs on diseased tissues.

These are just a few of the research accomplishments which have contributed to our ever improving ability to deal in a meaningful way with blinding disorders of the eye. Perhaps even more exciting are the achievements of investigators whose work in the laboratory is only now beginning to bear fruit.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: Under the President's budget, the Institute will be able to support most of the high priority research opportunities currently identified. With these funds and monies which will become available in future appropriations, the full range of priority investigations recommended in Vision Research - A National Plan: 1978-1982 will be supported. Certainly if funds were made available sooner, the rate of investigations into these priority areas could be accelerated and the scope broadened. Some of these priority areas are:

-- Basic research into diabetes related causes of visual impairment and blindness;
-- Macular degeneration, especially its relationship to age changes in associated tissue; the formation of abnormal new blood vessels; and to the metabolism of related tissues;

-- Improved diagnosis and understanding of retinal diseases through the application of techniques from basic disciplines such as psychophysics and electrophysiology;
-- Basic research in retinal detachment, including the mechanisms which normally keep the retina attached to the back of the eye;
-- The role of viruses, especially herpes virus in corneal diseases and the development of more effective treatments for these disorders;
-- Increased studies of human senile cataract through a nationwide cooperative research group and the application of new biochemical and biophysical techniques to solving this problem;
-- Further development and testing in humans of new clinical inhibitors of diabetic cataract formation;
-- Studies to determine whether glaucoma affects blacks or other racial groups and ethnic groups more frequently, earlier in life, and/or more severely;
-- Studies on the effects of experimental strabismus on the structure and physiology of the visual nervous system in cats and monkeys;
-- Studies to apply psychophysical techniques to the improved diagnosis of strabismus and amblyopia;
-- Studies to develop and test drugs that act on the central nervous system to control abnormal eye movements;
-- Studies to apply visual psychophysical techniques to improving clinical diagnosis of retinal and sensorimotor disorders;
-- Support of the National Survey of Vision Impairment and Its Causes which will gather information on the prevalence of visual impairment in the United States. This study should provide important information for further defining research priorities but wil also allow the National Eye Institute to measure the impact of diagnosis and treatment procedures on the general population;
-- Specialized Developmental Clinical Research Center Grants to provide clinical investigators with the time and financial resources they need to specify in detail the clinical studies to be undertaken and to build up the staff and facilities required to do a broad spectrum of clinical research. This developmental award would enhance the capability of research-oriented eye care centers; and
-- In the intramural program, the National Eye Institute's Laboratory of Sensorimotor Research will move into the NIH Ambulatory Care Research Facility in FY 1982. Increased funds will facilitate collaboration with the National Eye Institute's Clinical Branch on transferring basic knowledge in neurobiology to clinical problems.

FUNDING BREAKDOWN

Question: In your professional scientific judgment, are you pleased with your funding breakdowns?

Answer: The National Eye Institute's funding breakdowns are in accordance with the recommendations and priorities of the National Advisory Eye Council's research plan.

FUNDING LEVEL

Question: Does the Director of the National Eye Institute personally feel that the Institute is lagging far behind in its projected goals due to inadequate funding?

Answer: The National Advisory Eye Council's program plan Vision Research - A National Plan: 1978-1982 projected a funding level of $143,378,000 for its second year. The plan makes recommendations for the future development of the National Eye Institute's programs in each of the five major fields of vision research. The recommendations were derived from detailed assessments of the state of the art in each of these fields and from expert analyses of the major needs and opportunities that exist in vision research. Estmates were given of the level of effort and financial resources required to carry them out. Progress has been made in carrying out the recommendations of the National Advisory Eye Council's plan. The National Eye Institute, in collaboration with the National Advisory Eye Council, is beginning to update its national program plan which identifies vision research needs and opportunities through FY 1982. As a part of this update, new projections will be made of the numbers of grants and the financial support needed to carry out the recommendations set forth.

COST/BENEFIT ANALYSIS

Question: Has the Institute done a cost/benefit analysis of some of its work on the health care costs of society? If so, would you please provide it for the record?

Answer: From analyses we have done of the direct costs of hospital and medical care for eye disorders and of the indirect costs of blindness and visual disability (primarily expressed in terms of lost earnings), we estimate that the total economic cost of visual disorders and disability in the United States is approximately $8 billion per year. The annual investment in research on these problems, as embodied in the appropriation for the National Eye Institute for FY 1980, is about $116 million per year. Thus, we are spending 1.5 percent of this sum on research aimed at reducing the financial burden to society. Although it is difficult to measure in strict cost/benefit terms what the results have been of the Federal Government's investment in eye research, one case study may serve to illustrate the potential yield in this field.

A nationwide cooperative clinical trial supported by the National Eye Institute demonstrated that treatment with a laser can substantially reduce the risk of severe visual looss in advanced stages of diabetic retinopathy, a leading cause of blindness in the United States.

In attempting a cost/benefit analysis of the application of this new treatment, we used the best available estimates of the number of persons presently blind from diabetic retinopathy and calculated what it might have cost in the past to provide them and others like them with photocoagulation therapy. Then we calculated what would have been saved in costs of social services for the blind if all of thse persons had received laser treatment as needed. Our

calculations indicate that the persons now blind from diabetic retinopathy will cost the nation at least $582 million in support services, even if they survive for an average of only six years each. Had these individuals and all others at comparably high risk of blindness been treated with photocoagulation at the time that such therapy was needed, about 28,600 persons might have been spared blindness, at a saving of $486 million in support costs. When the cost of treatment, $175 million, is substracted from this amount, the net saving that might have been realized from appropriate past use of photocoagulation amounts to $311 million. About $3 in costs for direct services might have been saved for every dollar spent on photocoagulation therapy.

Rough estimates of the potential future savings to be realized by approriate use of photocoagulation therapy suggest that the net savings may run into billions of dollars. Of the estimated 10 million diabetics in the United States, about 600,000 are believed to be developing retinal blood vessel changes of a sort that will eventually place them at high risk of blindness and make them candidates for treatment by photocoagulation. The net savings that could be realized by treating these people as they become eligible for photocoagulation has been estimated at $4.4 billion, and the ratio of anticipated benefits to anticipated costs could then be calculated as three or four to one.

These are very rough, conservative estimates which do not take into account the indirect costs of blindness to society, as expressed in loss of productivity and tax revenues. Were these factors also taken into account, the benefits of photocoagulation would exceed the costs by an even greater margin.

Our ability to conduct cost/benefit analyses should be greatly enhanced in the future by a new nationwide Survey of Visual Impairment and Its Causes, a pilot study which will get underway this year. We hope that this survey, conducted in cooperation with the National Center for Health Statistics and the Bureau of the Census, will provide us with much-needed information on the prevalence of specific eye disorders in the United States population, including trends which can be used to gauge the impact of new research advances on reducing the incidence of eye disease.

National Institute on Aging

STATEMENT OF ROBERT N. BUTLER, DIRECTOR

BUDGET REQUEST

Senator Eagleton. We will move on to the Aging Institute. Dr. Butler?

Dr. Butler. I would like to submit my opening statement for the record and perhaps just touch upon a few highlights.

[The statement follows:]

Statement of Robert N. Butler

I am honored to report to you on recent progress and to present the fiscal year 1981 budget request for the National Institute on Aging.

My report to you today could be called a review of the beginning of the commitment to improve the health of the elderly through research. In brief, we have:

- o reflected, in the growth of our program, a persistent national interest in generating and supporting research in aging;
- o encouraged a substantial number of new and established scientists to move into aging research with solid, fresh ideas;
- o spurred medical and other health professions schools to incorporate geriatrics into their curricula and practical training experiences;
- o originated or jointly sponsored conferences on topics of importance to improving the well-being of the elderly;
- o created the animal and cellular resources necessary to conduct research on aging;
- o fostered coordination among the National Institutes of Health and other Federal agencies in the development of new knowledge about the aging process and the special problems and needs of the elderly; and,
- o bolstered the work of our world-renowned intramural research facility, the Gerontology Research Center, home of the Baltimore Longitudinal Study of Aging.

I might add an eighth point, deriving from and overshadowing the others. The research funded by Congress through the Institute serves a great social function: it helps change attitudes and stereotypes that unnecessarily confine and derogate the elderly. For example, we are finding that forgetfulness, often mislabeled "senility," is frequently the symptom of a disease that may have a treatable cause, such as infection, drug reaction, or depressive illness. Moreover, we are supporting research into the possibility of preventing deterioration in the central nervous system.

As Congress expected, we support a wide variety of research activities and have encouraged many able scientists from a number of fields to turn their attention to aging research. For example, although basic aging processes are regarded as being primarily determined by genetics, for many years relatively little work in aging was done by well-recognized geneticists. Now, as a result of an initiative, the first substantial body of genetics research in the history of gerontology is underway.

The Institute now supports nearly four times the number of investigator-initiated research projects that it supported five years ago. In raising the number of research project grants from 114 to 440, the Institute has acted to increase familiarity with and interest in aging research needs and concepts among scientists. For example, there are a number of research questions related to hormones and age that trained endocrinologists can study. In the fall of 1979, therefore, we supported a conference on the endocrine aspects of aging in order to acquaint endocrinologists who have not worked in the field of aging with some of these issues.

In one very exciting study, grantees at the Fels Research Institute in Philadelphia have extended the life span of laboratory mice and reduced their rate of spontaneous breast cancer by administering a steroid hormone, DHEA (dehydroepiandrosterone). DHEA prevented mice from becoming obese without diminishing their food

intake, while apparently duplicating the life-prolonging results of chronic underfeeding. These findings have major implications to gerontology. For the first time since it was observed in 1935 that chronic underfeeding dramatically prolongs the life of laboratory animals, we have a biochemical clue to the underlying mechanism. It is believed that DHEA blocks a step in food utilization. DHEA may also play a role in the maintenance of the body's immune system at highly effective levels well into old age.

To develop expertise among faculty and to improve curricula in medical schools, the Institute has launched a Geriatric Medicine Academic Award program. Eleven grants were made in fiscal year 1979, and 12 more will be awarded in FY 1980 to schools of medicine and osteopathy. A Geriatric Dentistry Academic Award program becomes operative in FY 1980. We work closely with the Health Resources Administration in these efforts to improve the training of health professionals in the care of the old.

To assist practitioners in the diagnosis and treatment of diseases and other health problems common in later life, we have supported consensus development conferences which assess the best-informed knowledge regarding the safety and effectiveness of new procedures, technology, or information that affects the elderly. For example, the complex issue of the management of pain and discomfort in the terminally ill was considered at an interagency conference on "Pain, Discomfort, and Humanitarian Care." Another consensus conference concerned the risks and benefits of estrogen use among postmenopausal women. The results of both conferences received wide coverage in both the professional literature and popular media.

Our epidemiology program has begun analyzing currently available data sources on the nation's elderly. A conference on Federal data sources showed us that information often is presented for the elderly population as a whole, when what is needed are analyses by small age groupings. Efforts are now underway to provide previously unavailable data on minority groups. We are working with other Department of Health and Human Services components and the Departments of Labor and Commerce to improve available resources and to obtain fresh data.

The Institute recently appointed Dr. Matilda White Riley, an internationally recognized pioneer in the sociology of aging, to head our program of social and behavioral research. The program will emphasize the study of aging as part of the life continuum rather than as an event that happens when a person reaches age 65. The Institute's interests encompass social and historical changes which affect the ways in which people age; the ways older people interrelate to people of all ages; cultural influences on the aging process within one society and across societies; and the social, psychological, biological, and physiological facets of aging. One of the program's special interests is intergenerational behavior. We are in an unusual historical epoch in terms of family life; never before have there been so many three- and four-generation families. Therefore, we are examining how families respond to these new stresses and potentials.

Data from the Baltimore Longitudinal Study on Aging have been used to evaluate a concept that, if confirmed, might be a better criterion for retirement than chronologic age. Scientists are studying the concept of physiologic age -- whether a person tends to resemble people of the same, younger, or older ages in terms of performance on certain tests of organ function, ability to react to signals, and so on. A statistical analysis of the Baltimore Longitudinal Study on Aging data shows that no single performance or capacity is indicative of scores in a variety of tests. In

other words, no single "aging factor" emerged. However, there is some predictive value in scoring performances on a variety of tests and relating them to the group averages of persons of the same, older, or younger ages. Most noteworthy in the analysis was that individuals found to be physiologically more like older people in a specific number of tests tended to die sooner than those found to be more like younger people.

We are also beginning to obtain data on the female volunteers who were added to the Baltimore Longitudinal Study on Aging starting in 1978. With 200 women enrolled so far, we are learning that females lose muscle mass at about the same rate as males in middle age and after, but that women do not show the same extent of decline in oxygen consumption at rest.

The Gerontology Research Center's newest laboratory, the Laboratory of Neurosciences, has begun reporting results of basic inquiries into metabolic and circulatory patterns of the aging brain. Scientists in the laboratory have devised a procedure for safely, temporarily, and reversibly opening animals' blood-brain barriers, which protects the delicate metabolism of the brain. The laboratory is also studying ways to predict how much of a drug will reach the brain, which may enable the design of drugs which are more effective in the central nervous system.

The Institute has also enlarged its intramural and extramural research on Alzheimer's disease and other age-related changes of the brain. Alzheimer's disease and related mental impairment may be responsible for intellectual decline in one out of every 20 elderly persons, including as many as half of the one million elderly residents of nursing homes. Five years ago, relatively little research was being done on Alzheimer's disease, in spite of the toll it takes in terms of the quality of life for so many elderly persons and their families, and also despite the social costs of the disease. Today, the Institute supports clinical research designed to disclose the cause or causes of Alzheimer's disease, as well as basic research on the structural and chemical changes that take place in the nerve cells of the diseased brain. Scientists will soon begin a study of patients with senile dementia to investigate changes in brain metabolism. In addition, the epidemiology program hopes to initiate support of research on a community-based group of persons -- some having senile dementia and others as controls -- to provide a better definition of diseases of this type and to identify associated risk factors.

One of our branches at the Gerontology Research Center has reported on the ineffectiveness of digoxin, a drug frequently prescribed for the treatment of chronic heart disease. It appears that the drug can be safely discontinued in a high percentage of patients with stable, chronic congestive heart failure and normal heart rhythm. Since digoxin may be toxic if normal dosage is exceeded by even a small amount, many patients may be exposed unnecessarily to a risk that carries no benefit.

Other investigations conducted and supported by the NIA have revealed that:

- o dietary restriction may rejuvenate the immune system;
- o a hormone produced in the gut may be critical for maintaining blood sugar at healthy levels;
- o the body's ability to regulate and monitor its own temperature seems to decrease with age;
- o cells from sun-exposed skin divide fewer times in culture than unexposed cells, indicating a possible speeding up of the aging process by the sun's rays;
- o aging of the brain may act as a "pacemaker" for other forms of aging; and,

o the political behavior of the elderly in the 21st century will be marked by non-partisanship and age consciousness.

No review of the Institute's beginnings would be complete without note of professional recognition accorded to our staff. Dr. Jacob Brody, Associate Director for Epidemiology, Demography, and Biometry, has been named the new president of the American Epidemiological Society. Dr. Reubin Andres, Clinical Director, has become president-elect of the Gerontological Society. Dr. Nathan Shock, former Scientific Director and now NIA Scientist Emeritus, recently won the Gerontological Society's first Brookdale Award for his many contributions to aging research over the years.

In essence, the Institute's first years have been productive ones as defined by the Research on Aging Act. The goal of knowledgeable, sympathetic health care for the elderly and their families will continue to guide us. Our second five years, beginning in fiscal 1981, will enlarge on these beginnings. To maintain the momentum, we present a budget request for fiscal 1981 of $75,317,000, an increase of $5,089,000 over the amount available to the Institute in fiscal year 1980.

Thank you.

DEVELOPMENT OF AGING RESEARCH

Dr. BUTLER. As you know, the fields of gerontology and geriatrics are new fields. I believe our Nation, NIH as a whole, and NIA in particular have a special responsibility to address the major health and social problems of contemporary older people and our future selves.

I think a very good example can be found in nursing homes. Today we have about 1 million people over 65 in nursing homes. Demographic projections indicate that within 40 years there could be 2½ million people in America's nursing homes.

Our goals remain, of course, maintaining health and the quality of life, so there is a very special need to understand time-dependent effects upon integrative and regulatory bodily systems such as the central nervous system and the immune system. Advances in understanding these systems can reduce physical and personal dependency.

There are huge costs associated with old age. For example, the 1 million people presently in nursing homes result in annual nursing home costs of $16 billion—with a B. In medications alone, older people consume drugs that add up to $5 billion a year.

We have tried in this past year to continue to consolidate the growth of the field. We have been particularly interested in having a major impact upon American medical schools in order to increase investigator-initiated research grants, to identify major teacher models and to develop curriculums in geriatric medicine. We take some pride in the extent to which we have been able to influence medical schools.

We know from phone calls and letters we've received how frequently older people and their families believe they are not receiving sensitive care or care based upon an adequate knowledge base. I was thinking when Senator Hollings was present that the Medical University of South Carolina is one of a number of schools that call me almost weekly asking for recommendations of leaders in the field to take over units of geriatrics; in the case of the Medical University of South Caro-

61-400 O - 80 - 26

lina—to take on a well-endowed chair. At present we are not in a position to provide a name to fill that chair adequately.

COLLABORATIVE RESEARCH EFFORT

We have been collaborating with other Institutes. We will soon be engaged in a study of the problem of isolated systolic conditions with the National Heart, Lung, and Blood Institute. The National Institute of Communicative Disorders and Stroke and the Aging Institute will begin the first major examination of the epidemiology and state of the science of hearing. With the National Institute of Dental Research, we are actively cooperating to establish a parallel to our geriatric medicine academic award, called the Geriatric Dentistry Award.

I have noticed with some pride the appearance in the report of the HEW Steering Committee for Development of a Health Research Strategy, of a dementias of aging initiative. Not only are the Aging Institute, the Neurology Institute, and the Mental Health Institute participating, but also the National Institute of Allergy and Infectious Diseases and the National Institute of Occupational Safety and Health.

BASIC SCIENCE RESEARCH

We are very pleased to tell you that 92 percent of our funds go to science-base activities. We have for the first time been able to identify an important community of geneticists working actively to better understand the genetic mechanisms of senescence and the antecedents of longevity.

We have been quite active in the field of endocrinology and have an interesting finding from the Fells Institute in Philadelphia to report. Animal studies of Dehydroepiandrosterone, known as DHEA, which is a steroid hormone found in high concentration in men and women, may help provide us with an understanding of an observation that goes back to 1935; namely, that postweaning undernutrition may extend the lifespan. DHEA appears to promote long life by delaying the onset of tumors, and at the same time curbing food intake.

We have also been active in another area with respect to endocrinology; that is, the importance of the widespread utilization of estrogens in the postmenopausal woman. We brought together outstanding scientists and representatives of public groups from around the country to look at the indications and contraindications of the use of estrogen at a conference last year.

SOCIAL SCIENCE AND DEMOGRAPHIC DATA

We are very proud to have acquired one of the Nation's outstanding social scientists, Dr. Matilda White Riley, who is not only very interested in the importance of various social factors as they bear on age, but also deeply interested in the interaction of bodily changes with social changes; for example, the impact of bereavement on physical health.

We have been working actively to capitalize on existing data from other Government agencies, for example, through the National Center

of Health Statistics and the Census Bureau. So often, age data are presented only for 65-plus, rather than disaggregated in terms of finite age groups. This makes it very hard to look at specific information on 65- to 69- or 70- to 74-year-olds. When you consider that women have 18 more years of life and men 14 more years of life after 65, you can see the need for more specific and refined data.

INTRAMURAL RESEARCH

In our Baltimore longitudinal study, we are beginning to have some important findings. The search for a single specific measure of biological age is elusive. But the opportunity for developing a profile based upon a number of different measures of human performance does seem to suggest a clear relationship between certain characteristics of being old and death itself. Such information on human performance is going to prove of great value as we move from mandatory to flexible retirement.

The addition of women to the Baltimore longitudinal study has also added to our understanding, at least in some measure, of what might account for the discrepancy in life expectancy between the sexes.

Preliminary information suggests that women do not have the reduction in killer cells, a type of immune cells that plays a part in the body's defense, that men do.

One of the Institute's high priorities is Alzheimer's disease, a profound dementia that affects half a million of those million people in American nursing homes. This disease is very devastating to individuals and their families.

We have an outstanding scientist developing a new laboratory of neuroscience. He has developed an apparently safe and effective means of opening up the functional screen between the general circulation of the body and the brain circulation, called the blood brain barrier. This may prove to be of extraordinary importance in providing direct introduction of various types of medications into the brain. It has already demonstrated in certain animal species that the notion that senile dementia might be an autoimmune disease due to the breakdown of this functional system does not hold up.

In summary, I am pleased with our progress over the short life of the Institute. We request $75,317,000 for fiscal year 1981. The increase over the fiscal year 1981 commitment base will be devoted totally to competing investigator-initiated research grants.

POSITION CEILINGS

Senator EAGLETON. When we were questioning Dr. Kupfer, it was pointed out that he was allocated 50 new positions, which somehow he didn't get.

Did we allocate to you, Dr. Butler, 70 new positions?

Dr. BUTLER. Over a 2-year period, the Congress had provided an additional 70 positions, which brought us up to 303 budgeted positions. The ceiling, however, has been at 233.

Senator EAGLETON. I didn't write all of those figures down. Did you get any of the 70?

Dr. BUTLER. Of the original 70, I think we gained a total of 10 positions over the 2-year period. The first year, Congress proposed 25 additional; the second was 45. It was a total of 70 positions over the 2 fiscal years from Congress.

Mr. ITTEILAG. In this year's budget review, the President has given the Department a significant increase in the 1980 ceiling amounting to several thousand.

We, in turn, are in the process of allocating that ceiling within the Department.

The Secretary will, in the next week, be making some decisions that will result in specific allocations of increased ceilings to the Public Health Service.

As a result of that, it is my view that the ceiling of NIH will be increased significantly and consistently with the position increases provided by the committee last year.

Senator EAGLETON. As soon as you have that information, would you share it with us, please?

Dr. FREDRICKSON. And with us, Tony. [Laughter.]

ANIMAL RESOURCES

Senator EAGLETON. Research on aging requires the availability of certain resources. What would you describe to be the most urgently needed resource of the National Institute on Aging?

Mr. BUTLER. One of the most exciting types of research is the application of information from animal models to the human condition. But with respect to aging, we have a special problem. You have to be able to project the needs of scientists for various animal resources 2 or 3 years ahead. You can't suddenly have an instant older animal instantly. You have to broaden the number of animal models which we have in order to attract scientists to work in specific conditions, such as in senile dementia.

We have attacked this problem in several ways. One is to evaluate the production of animals, and look for more efficient and economical ways.

To give you some idea of the cost, rats of 24 to 26 months, which are old rats, can run $80 to $90 apiece, up to $3.70 a month in terms of maintenance.

Other Institutes not needing to look into the aging factor do not have to face this particular problem.

Many of my colleagues around the table, I think, are becoming increasingly interested in looking at age dimensions. So we have some hope that the Institutes can collaborate in looking at disease-age factors in aging animals. Another thing we have done is utilize the resource of the Institute of Laboratory Animal Resources of the National Academy of Sciences to develop the range of different animal models available for studies of the aging process.

RESEARCH TRAINING

Senator EAGLETON. It has been emphasized to me that it is important

to maintain strong training programs in emerging fields of biomedical research.

As we look at the training figures before us, I see the number of individual training awards is reduced by 16, from 34 to 18, and the number of institutional training awards is reduced by 6, from 27 down to 21.

And bearing in mind that you get calls from the University of South Carolina and other such calls for trained personnel in this area of aging, well-endowed chairs, as you said, how do you square these figures with those telephone calls?

Dr. BUTLER. I appreciate the President's effort toward the stabilization of the science base and the importance of additional funds being made available for research grants.

We do have a very special and unique problem at the National Institute on Aging. You referred earlier to the more euphoric days of the early 1970's. This was, of course, a historic period at NIH when opportunities to train large cadres of outstanding people existed.

The field of aging is new and emergent. Our Institute was not in existence during this historic era, and as a consequence has not had the same opportunity for training.

Thus, it is rare to find well-trained people. It does become a very special and serious problem for this country. We don't have either M.D. or Ph. D. clinical investigators. We do not have the basic immunologists in aging. We do not have people trained in the social and behavioral sciences in gerontology.

At one recent count, there were about 1,100 people that have been trained in any way in research on aging in the United States. Relative to the distribution of trainees and training opportunities within the other Institutes in the historic past, our experience is vastly different.

Senator EAGLETON. Dr. Kirschstein, we asked a couple of questions of you. But I have another engagement. Can we defer further questioning of you until tomorrow morning? Did you plan to be part of the group tomorrow?

Dr. KIRSCHSTEIN. Yes.

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

NATIONAL INSTITUTE ON AGING

NUTRITION AND DISEASE

Question: You have mentioned that the Health and Nutrition Examination Survey (HANES), compiled by the National Center for Health Statistics, is being used for epidemiological studies of the relationship of nutritional status and disease in the elderly. Please describe the findings of this research.

Answer: A currently ongoing feasibility study has now located over 80 percent of the participants in the original HANES. We are interviewing a sample of former participants to acquire information on health conditions that have occurred in the eight year interim between HANES I and the follow-up study. The actual study will be contracted out, with award date expected to fall in August or September of 1980. The follow-up study is expected to begin late in 1980 and carry through to 1983.

Question: From the work with HANES, has it been possible to calculate the extent of malnutrition among the elderly?

Answer: When the study is completed, we would expect data from it to provide an estimate of malnutrition problems among the elderly.

SENILITY OR DEPRESSION

Question: Recent articles I saw warn that too many doctors may issue diagnoses of senility in the elderly when, in fact, the patients' difficulties may be rooted in depression or something else. Is the Aging Institute concerned about this and, if so, what is it doing to counter unfounded diagnoses of senility?

Answer: This problem is of great concern to the Institute. The goal of the Institute in this area is to distinguish between reversible and irreversible disorders. Treatable disorders include those induced or aggravated by depression, drug toxicity and endocrine-metabolic imbalances. Even irreversible brain disorders are not hopeless, as much can be done to slow deterioration and help patients make use of residual strengths. In FY 1979, a consensus development conference on treatable brain disease was held to determine the causes of cognitive dysfunction in elderly patients, often mislabeled senile dementia, and to prescribe appropriate therapy. Strong program emphasis continues to be placed on the dementias of aging and related research. An article entitled "Senility Reconsidered" was just published in the February 2, 1980, issue of JAMA. It will reach some 375,000 physicians. A popular version of this article will be written for distribution to the public. As new knowledge develops, it will be transferred to the scientific and medical communities and to the public in general.

Question: Please explain the "Life Review" concept that Dr. Butler is said to have developed. What success have you had with this and is the approach being disseminated to other health professionals?

Answer: Only in old age can one experience a personal sense

of the entire life cycle. Old age often inaugurates the process of life review, promoted by the realization of approaching death. The life review is characterized by a consciousness of past experience, especially the resurgency of unresolved conflicts which can now be reevaluated and integrated. The old are not merely taking stock of their lives in the process. Rather, they are trying to think and feel through what they will do with the time that is left. Summing up one's life in this way has therapeutic value for it can lead to recognition of possible guilt feelings, resolution of inner conflicts, alleviation of tensions, and renewal of a sense of self-worth. Encouraging the elderly to participate in the life review process benefits both themselves and, through transmission of their experiences to the next generation, society as a whole. The concept of "life review" has been discussed in a number of articles published in professional journals such as the Journal of the American Geriatrics Society. The concept is now widely used by nurses and other health practioners in nursing homes and geriatric centers.

Question: How do you deal with depression in the elderly? Do you coordinate with the Mental Health Institute -- and they with you?

Answer: There is a large overlap of interest between the two Institutes, so every effort is made to coordinate activities. A factor of particular interest to this Institute is the increased risk of morbidity and mortality which appears to be associated with bereavement within the aged population. Bereavement, particularly widowhood, appears to impose stresses which result in increased mortality, especially in the period immediately following bereavement. For example, Adrian Ostfeld, an epidemiologist at Yale, has done a study which predicted there would be 25,000 deaths beyond actuarial estimates among survivors during the first year after a loved one's death. The Institute has encouraged research on this subject through issuance of a program announcement requesting applications. Much of the National Institute on Mental Health's research concerns diagnosis of depression and therapeutic intervention. Coordinating mechanisms include the Division of Research Grants application referral process, active collaboration by intramural scientists, and person-to-person contact in areas of mutual concern.

Question: Senile dementia accounts for the institutionalization of many older persons. What is NIA doing to find a cure for this devastating condition?

Answer: The Aging Institute supports a variety of studies examining the problem of senile dementia. Efforts are being made to discover the biochemical and physiological changes responsible for decline in mental function with age which may be responsible for Alzheimer's Disease and other dementias. Another study seeks the biochemical characterizations of the structure and function of neurofilament proteins, which may lead to an understanding of the neurofilament tangles found in the brains of Alzheimer's patients. Epidemiological studies are underway in an attempt to determine genetic, immunological, and environmental factors which may be correlated with the occurrence of Alzheimer's Disease. It is also anticipated that the new Laboratory of Neurosciences at the Gerontology Research Center in Baltimore will provide data useful to the

study of the dementias of aging.

We are proud of our leadership role in developing a major new initiative in senile dementia. This year an important initiative on Alzheimer's Disease and the dementias of aging is being undertaken in collaboration with the National Institute on Mental Health; the National Institute of Neurological and Communicative Disorders and Stroke; the National Institute of Allergy and Infectious Diseases; and the National Institute of Occupational Safety and Health. This initiative will bring together a broad range of resources in a collaborative effort to prevent, diagnose, and treat these disorders.

QUALITY

Question: Research on aging is a relatively young field of investigation. What is the single most important activity needed at this time to promote the development of quality research on aging?

Answer: Training of new investigators in geriatrics and the field of aging research is vital to development of quality investigators. Coupled with the need to train individual researchers is the need to develop a clinical research capacity, notably through improved geriatric curricula at schools of medicine and dentistry.

COST CONTAINMENT

Question: In this era of skyrocketing health costs, there is a great deal of national focus on mechanisms for containing health care costs. How does research on aging contribute to the containment of health costs?

Answer: Research on aging will ultimately help contain health costs by keeping more people healthy and independent for a longer portion of their lives. Research areas of particular consequence for health cost containment include Alzheimer's Disease and other dementias of aging, nutrition, and immunology. Approximately one million elderly are in nursing homes at any one time, about half of them due to mental disorders. If we could keep 100,000 people out of these homes through research, we would save well over one billion dollars annually. The importance of nutrition is clearly evident in the many deficiency diseases and excesses of dietary intake. Research on aging and nutrition is beginning to link dietary intake, functional responses, and regulation of body processes. Finally, in the area of immunology, certain infectious diseases are more difficult for the elderly to combat due to age-related decline in immune function. Any measure to enhance the immune capability of an individual will improve the capability of withstanding infection. The resulting savings from reduced drug use and shorter, less frequent hospital visits, not to mention the reduction in personal misery, could be substantial.

HEALTH PROMOTION AND DISEASE PREVENTION

Question: Many groups, as well as recent Administration policy statements such as Healthy People, have recommended increased medical research in the area of preventive health. It would seem par-

ticularly appropriate for the Aging Institute, because of its broader emphasis on the life span rather than a specific disease, to be involved in research in this area. Would you please describe projects which you think are relevant to this field?

Answer: The National Institute on Aging is involved in a great variety of health promotion and disease prevention projects. Current research includes among others: defining and distinguishing physiologic changes inherent in the aging process from those of disease; determination of age-associated risk factors responsible for physical and mental decline; development of interventions to prevent or moderate conditions such as hypertension, stroke, senile dementia, and osteoporosis; and studies of nutritional requirements of the elderly. Other efforts include a clinical trial on hypertension in conjunction with the National Heart, Lung, and Blood Institute and expansion of the neuroscience and stress and coping program at the Gerontology Research Center. We are also hoping to fund a clinical nutrition research center in 1980. For the lay person, we have recently published a brochure entitled "A Guide to Medical Self-Care and Self-Help Groups for the Elderly."

Question: What priority does the Aging Institute give research funding for this field?

Answer: Approximately 19 percent of the Institute's funds are spent on primary prevention research according to the NIH definition of primary research. In certain instances, the program is somewhat restricted due to a currently inadequate base of knowledge on which initiatives can be developed. An example of the latter would be immunology, which is only just beginning to provide jumping off points for new research.

PHARMACOLOGY AND THE ELDERLY

Question: It is said that 25 percent of all medications are used by the 11 percent of the population over 65. Drug testing in old people is not required in FDA's drug approval process, even though the reactions may be quite different. Does the Aging Institute fund research on the effects of drugs on the elderly?

Answer: Relatively little is known about changes in drug effects in relation to the age of an individual. The Institute is concerned about this problem and disappointed over the lack of qualified applications being received - despite a special program announcement requesting such applications - and our inability to recruit a pharmacologist to manage the pharmacology program. On the brighter side, research on estrogen use among post-menopausal women has proceeded well and one of our grantees has been successfully studying the aging heart's effect on delivery of drugs to target organs via the blood, as well as its own changed sensitivity to drugs with age.

Question: Is there any information in this field that can be made public now to practicing physicians?

Answer: Findings from research on estrogen use in post-menopausal women are available, as is more recent data on digoxin, a drug commonly prescribed for treatment of chronic heart disease.

The latter appears to be ineffective in certain elderly patients. Since it may be toxic, there is the possibility that at least some patients are being exposed unnecessarily to a risk that carries no benefit.

Question: What is the Institute doing in this important area of drug information dissemination?

Answer: As part of the Institute's science writer series, a pamphlet entitled "Drugs and the Elderly" was produced. A copy of this publication may be requested through Expand Associates, Inc., 8630 Fenton Street, Suite 508, Silver Spring, MD, 20910. We have also recently published a summary brochure of the Consensus Conference on Estrogen Use and Postmenopausal Women, which was held late in 1979.

MENTAL HEALTH OF THE ELDERLY

Question: With more research in the field of geriatric medicine it is becoming increasingly clear that mental health has a great influence on physical symptoms. What kinds of research are being performed at NIA on the effect of grief and depression on disease states?

Answer: Depression appears to be associated with increased risk of morbidity and mortality among the elderly. One research area of great potential value is the relation of emotional impact on a long-term disease such as diabetes. Persons with diabetes face the prospect of a life-long disease and possible blindness, kidney disease, gangrene and amputation. The consequent emotional pressures appear likely to adversely influence the course of their disease. Several studies have demonstrated the impact of the emotional state of the patient on non-compliance with prescribed regimen and frequent hospitalization. The behavioral and psychosocial problems of the elderly diabetic are of particular concern because of the sometimes severe loss of control over physical and mental functions.

ACCIDENTAL HYPOTHERMIA

Question: Old people can suffer a great deal more than younger adults from variations in temperature. The inability of older people to acclimate to even moderately cool temperatures of 60-65 degrees has been well documented and may lead to the potentially fatal condition of accidental hypothermia. Has the Institute made any estimate as to the effect on the elderly of the new lower settings for thermostats?

Answer: There is no strong scientific basis for establishing rigid minimum guidelines for temperatures in the homes of the elderly. However, heating the living and sleeping areas of older persons to 65 degrees Fahrenheit appears to be adequate except under special circumstances. For example, a physician may recommend higher temperatures in living/sleeping spaces if an older person has evidence of impaired body temperature control; uses medications such as certain tranquilizers that decrease temperature regulation; has severe circulatory problems; suffers from debilitating diseases of the nervous system; or is an alcoholic. In the work environment,

where an individual is generally more active and there are co-workers to provide aid should symptoms of hypothermia develop, a temperature of 65 degrees Fahrenheit is unlikely to be threatening.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: A major research thrust which we would like to fund to the highest level possible is the field of neurosciences, especially as it relates to the dementias of aging. We see this as a particularly valuable endeavor both for its potential in health cost containment and in reduction of human misery. We would also continue our efforts to develop the nation's clinical research capacity through the geriatric medicine and dentistry academic awards, as well as increase the capacity of our training program. Diversification of animal models, such as development of aging cat and non-human primate colonies, (both necessary to better understand senile dementia), is another goal - as is expansion of our current supplies of aging rats and mice to meet growing investigator needs. We are also concerned about the increased incidence of cancer associated with aging, and are planning a series of international conferences on aging and cancer with the National Cancer Institute. The last area we would like to pursue is the problem of sleep disorders among the elderly. While less lifethreatening than cancer, these problems are common and both emotionally and physically draining to those individuals who suffer from them.

FUNDING BREAKDOWN

Question: In your professional scientific judgment, are you pleased with your funding breakdowns?

Answer: I am, in general, pleased with the Institute's program balance between biomedical, social and behavioral research. I am less satisfied with the current level of clinical research funded by the Institute. The latter probably results not so much from a shortage of funds, but rather from the limited geriatric research capacity within the United States.

SUBCOMMITTEE RECESS

Senator EAGLETON. We will be in recess until 2 p.m.

[Whereupon, at 12:10 p.m., Tuesday, February 5, the subcommittee was recessed, to reconvene at 2 p.m. of the same day.]

(AFTERNOON SESSION, 2 P.M., TUESDAY, FEBRUARY 5, 1980)

JOHN FOGARTY INTERNATIONAL CENTER

STATEMENT OF DR. EDWIN D. BECKER, ACTING DIRECTOR

BUDGET REQUEST

Senator SCHWEIKER [presiding]. The subcommittee will now come to order. We are here this afternoon to resume hearings on fiscal year 1981 budgetary requests for the National Institutes of Health.

The first witness appearing before the subcommittee will be Dr. Edwin D. Becker, Acting Director of the John Fogarty International Center. This includes a request of $9,181,000 for fiscal 1981, an increase of $192,000 over the previous year.

RESEARCH TRAINING

We want to hold up on Dr. Becker 1 minute, if I may, to get at a few other questions that were a holdover from this morning relating, Dr. Fredrickson, to training. I understand you have answered a number of questions on this. And I just have a few more to finish the line of questioning.

Adding up the figures, Dr. Fredrickson, on training that you presented to this committee, it looks like we are wiping out all new awards and renewals and just maintaining continuation of existing commitments.

What kind of long-term research and development strategy will this mitigate, or is my analysis not correct?

Dr. FREDRICKSON. It is correct, Mr. Chairman, that we are now going to fund only continuations in our training program in fiscal year 1981 with the President's budget. I think that, in terms of strategy, it represents two major things.

One is that we have, from 1979 to 1981, increased the stipend level a total of 35 percent over the 2 years, of all the trainees, because that level was simply far too low to be maintained.

The second is that we have had to, in our plan, defend as a first priority the maintenance of a stabilized level of investigator-initiated grants, in preference to training.

Senator SCHWEIKER. For the record, Dr. Fredrickson, how do you justify cutting back on the number of trainees from fiscal years 1979 to 1980?

Dr. FREDRICKSON. We can justify it only on the basis of making an extremely difficult decision, which we also find in the long haul perhaps very dangerous for the research enterprise. But we feel the first step we must attempt this year is to come to agreement on maintaining a floor of competing renewal and new research grants, so we can offer to the specific community a certainty that there will be the capacity for them to compete for grant funds.

I think that stabilizing the science base must come one step ahead of accelerating our training effort.

CLINICAL TRIALS

Senator SCHWEIKER. How many new clinical trials will NIH undertake under your budget proposal?

Dr. FREDRICKSON. I do not think we will be undertaking any new clinical trials next year, although our Institute Directors may be able to contradict that with one or two examples. But our budget for clinical trials is not being increased for 1981.

Senator SCHWEIKER. Does that mean that something like the hypertension clinical trial that we just came forth with, that kind of thing we are saying we can't afford to do? Dr. Levy might want to respond to that.

Dr. LEVY. That's right, under the present budget.

Senator SCHWEIKER. We have you all the way on the left. I don't think that's significant.

Dr. LEVY. Under the present budget strategy, no trial is proposed.

Senator SCHWEIKER. Would you evaluate very briefly for the record what funding a clinical trial such as hypertension has done for us and where it is pointing us? What have we gained from it in terms of the investment we made and the return we get from it?

Dr. LEVY. The significance of the hypertension detection and follow-up program is that we now know that treatment of the patient with mild hypertension—a population group that may contain over 40 million Americans, almost one-fifth of the entire American population—is cost beneficial. That is, it is important and effective to lower the blood pressure in these individuals whose pressures are between 90 and 105 because treatment saves lives. What this trial showed is that the blood pressures of so-called mild hypertensives can be lowered and that if one does lower the pressure, one can reduce mortality by 20 percent over a 5-year period and, most importantly, reduce stroke and heart attack mortality by over 45 percent.

If we can disseminate what we have learned from this trial, Mr. Chairman, we would have both the likelihood of extending the present decline in cardiovascular mortality by a considerable degree, by hundreds of thousands of lives saved over the next several years, as well as decreasing costs for illnesses and disability by well over $1 billion. This would repay the Nation many times over, for the cost of this clinical trial, which since 1970 has cost the Institute approximately $65 million.

Senator SCHWEIKER. I might ask Dr. Whedon, will NIAMDD have sufficient personnel, diabetes personnel, to conduct the clinical trial on the relationship of diabetes control and diabetes complications?

Dr. WHEDON. Within our present budget situation, we will not be able to. Nevertheless, we are making plans for it, in the hope that some time in the future we can do it. We think it is a very important trial to carry out.

ALLOCATION OF BUDGET INCREASE

Senator SCHWEIKER. Do you intend that all of the NIH increase over fiscal year 1980 go into competing grants, Dr. Fredrickson?

Dr. FREDRICKSON. Not quite, Mr. Chairman. The increase in the budget will largely be devoted to maintaining a capacity for funding about 5,000 renewal and continuation grants. There will be additional moneys in several other areas: $5 million in the biotechnology resource program, which Dr. Bowery can tell you about later; in minority training, $1 million; $5 million in the NIH–NIEHS intramural program which will open its new facility; $8.5 million in building and facilities for modernization of the clinical center and several decaying laboratory buildings on the Bethesda campus; and finally, $6 million in the national toxicology program.

Senator SCHWEIKER. That is a total of how much that is not for competing grants?

Dr. FREDRICKSON. That will be approximately $26 million out of a total increase of $139 million in the budget for 1981.

Senator SCHWEIKER. $26 of $139 million?

Dr. FREDRICKSON. That is correct, sir.

Senator SCHWEIKER. Roughly calculated, 80 percent would be for competing grants.

Dr. FREDRICKSON. Of the increase in the budget, that is correct, Mr. Chairman. Actually, a much larger amount will be provided to the national toxicology program through a redirection of funds from other areas.

RECRUITMENT OF SCIENTIFIC PERSONNEL

Senator SCHWEIKER. At our hearings and our recent report last year, the committee expressed concern over the length of time it takes NIH to recruit and hire scientific personnel. In some cases, it took nearly 2 years to fill a vacancy.

Has there been any improvement in this situation?

Dr. FREDRICKSON. It is still about as difficult to recruit scientific personnel as it has been in the past, Mr. Chairman. One complication is that we have now begun to implement the senior executive service system, which is replacing the old civil service system.

Part of the problem, of course, is developing experience with that system.

Senator SCHWEIKER. I am getting conflicting information that I am confused about. Dr. Fredrickson, we were advised by HHS that it is delegating recruitment functions for senior scientific positions to you on an interim basis and henceforth there won't be the delays that Chairman Magnuson and I have complained about in the past, and which you also have acknowledged and felt were a problem.

In fact, is this happening? Are you now being given the authority to cut through this length of time? I am not clear where we really do stand on this.

Dr. FREDRICKSON. It is difficult to compare, because we are clearly now in a new system, gaining experience in using the senior executive service to recruit personnel. Perhaps it is due to our own inability to master the system, but it still takes considerable time to recruit senior scientists.

Senator SCHWEIKER. Well, are the heads of the Institutes—what do you hear from them in terms of this recruitment time factor? Is it some-

thing that has improved? Has it stayed about the same, or just what is the status of it in terms of the individual Institutes, in your judgment?

Dr. FREDRICKSON. In my judgment, it remains a problem.

Senator SCHWEIKER. What else can we do at this point?

Dr. FREDRICKSON. I think that as all of us become better accustomed to the senior executive service, it will improve. I have no other specific suggestions, Mr. Chairman, to offer at this time.

Senator SCHWEIKER. What seems to be the bottleneck? In other words, I realize there is a new system. That I understand. And that is unproven. On the other hand, apparently, from the reports I have gotten from other sources, and you are confirming today, too, the recruitment problem is almost as severe as it was. Yet I get a letter from HHS saying it is solved.

I would like to put it in the record because it is the last thing that has been solved around here. [Laughter.]

[The information follows:]

LETTER FROM THOMAS S. MCFEE

JANUARY 4, 1980.

Hon. RICHARD S. SCHWEIKER,
U.S. Senate,
Washington, D.C.

DEAR MR. SCHWEIKER: Secretary Harris has asked me to respond to your September 5, 1979, followup inquiry about the hiring of top-level scientists at the National Institutes of Health.

A review was recently concluded by the Secretary on the staffing practices for these positions. As a result, she has approved a delegation of recruitment authority to NIH on an interim basis until a final departmental plan for the senior executive service or another recruitment and appointment program is in place.

Under this delegation, NIH is exempt from seeking prior approval from the Department before searching for candidates for highly specialized scientific positions. In addition, staffing guidelines have been revissed and discussed with NIH personnel representatives. The delegation and the guidelines will reduce the time previously required to fill these positions. I am attaching a copy of my memorandum to the Director of the National Institutes of Health regarding this subject. The Secretary currently will make final selections of the candidates proposed for these positions, but has assured NIH that her review and decision process will be expedited.

A universal search plan is being developed for SES positions throughout the Department. Any special needs of NIH will be fully addressed in this plan. Further, the Department will monitor the success of its new approach to filling these positions and make adjustments to procedures, if appropriate.

Sincerely yours,

THOMAS S. MCFEE,
Assistant Secretary for Personnel Administration.

SENIOR EXECUTIVE SERVICE

Senator SCHWEIKER. There must be something that we can grab a handle on to help you and your colleagues, who I know want to short circuit this time problem. Is there something in the SES program that the committee might look into or follow through with, or somehow go back to the Secretary to get some further clarification on, as to why this delay continues?

Dr. FREDRICKSON. I am sure, Mr. Chairman, that the Department is as impatient as we sometimes become in filling positions. Certainly, the

committee's interest in making plans for recruitment simpler, which are now very detailed and must be approved at levels above the NIH, is appreciated. I am sure that the Department at all its levels will be very interested to learn of the committee's interest in making the timespan as short as possible.

Senator SCHWEIKER. Here is a letter from Thomas S. McFee that I will put in the record. But the essence of it is: "As a result, she"—the Secretary—"has approved a delegation of recruitment authority to NIH on an interim basis until a final departmental plan for the senior executive service or another recruitment and appointment program is in place."

Now, they are saying that until this SES is in place, which may or may not have some problems, depending on what happens here—unknown, I guess—you have been given the delegation of recruitment authority. You shouldn't have to go back to NIH at all.

Do I misread this letter here?

CHANGE IN SENIOR EXECUTIVE RECRUITMENT

Dr. FREDRICKSON. I am not sure that you are misreading it, Mr. Chairman. It is, nevertheless, true that our plans for recruitment of individuals to fill SES positions and the final choice of individuals to take those positions still requires Department approval. That has not been delegated to the NIH level.

Senator SCHWEIKER.Well now, Tony, let's have clarification of that, since the letter obviously doesn't agree with the answers we are getting here.

Mr. ITTEILAG. I would rather check on the facts and supply some information to you, on the basis that probably anything I would say now would not be precise.

Senator SCHWEIKER. I am disturbed that I get a letter like this. I am very disturbed that I get a letter like this, that tells me, after a year of asking about it and pushing about it, everything is OK, we solved the problem. And then I have to hear that in fact this letter is completely inaccurate, that it is wrong, and we have been given total misinformation about this problem.

So I am disturbed. And yes, you will have to get back. And all I can say, that is a darn poor way to run a railroad. Now, I realize there must be more to it than meets the eye. But I would certainly like to know what it is.

Why do we hand out false replies to Senators and chairmen who want to know why we can't get a problem solved that has been kicking around for some 3 or 4 or 5 years?

Is there some rational explanation for giving a kiss-off answer like this?

Mr. ITTEILAG. I would hope that Mr. McFee's information is indeed not false. I will check on it personally and I will immediately report to the staff my findings.

Senator SCHWEIKER. We will expect an answer tomorrow. Chairman Magnuson and I wrote to the Department last May about this problem, and here we get a letter back January 4, which is about an 8-month lag

61-400 O - 80 - 27

to begin with. And now we have gotten back what appears to be a totally false answer to a very serious problem.

It makes it very difficult for a chairman or the ranking member to even conduct a hearing, when we get this kind of gobbledygook here, because we have been concerned for some years that we have this problem. And then we get a letter saying the problem is solved. When I got the letter I breathed a sigh of relief that at long last we solved the problem.

And then prior to this hearing I talked to some people who are dealing with the problem every day and found out that we are nowhere near solving the problem. I certainly would like an answer, and so would Senator Magnuson, by tomorrow.

We obviously put it in our committee report. We wrote a letter about it. I don't know what other signals we can send.

It is tragic. I know how difficult it is to recruit scientific talent for NIH. It is difficult enough to deal with Government pay scales and get qualified people to accept them, but then to kick them around for a year or so I think it is inexcusable in terms of managing our scientific resources.

I realize that it is not your ultimate fault. I am not saying it is. But we need an answer from somebody who either cares about it or is responsible enough or knowledgeable enough or smart enough to lick this problem.

We would like to see Mr. McFee up here tomorrow. I think that that would be helpful. That would be helpful to get someone up here tomorrow afternoon. I will be here at 2.

It's bad enough solving the problems that are tough to solve when everybody puts the facts on the table. But when people put the facts on the table that are not correct, we are not solving the problem.

That is even worse.

RESEARCH ON LOW-LEVEL RADIATION

At last year's hearing, I expressed concern about the dangers of low-level radiation, which can cause leukemia. I believe you said that NIH was going to be in charge of all HEW research in the field.

I wonder if you would bring us up to date on your efforts and what your plans are for 1980 and 1981?

You might throw in there what part of this work involves the Three Mile Island incident.

Dr. FREDRICKSON. During the past year, at the instruction of the Secretary, I have become project manager for the research on health effects of low-level ionizing radiation for HEW.

As part of that assignment, I have accepted responsibility for congressionally mandated studies of all radiation research in the United States conducted by nine agencies in the Federal Government who have this work under their jurisdiction.

This has been carried out through the cooperation of an interagency committee on radiation research which has members from all the agencies, not only within HEW, but from all departments such as Defense, EPA, FDA, and Energy.

And we have begun a coordinated effort for the examination of all radiation research.

At the same time, we have accepted the responsibility for reviewing all projects submitted to the Federal Government for research support for epidemiological studies in this field. These projects amount to more than a quarter of a million dollars per year.

Part of our efforts were involved with followup on the Three Mile Island incident.

We were able to make some comments on proposed plans by several agencies for followup studies in that particular area.

I think that we are on course with respect to coordinating and developing a strategy and an examination of all such radiation research.

It is a rather extraordinary level of coordination. But thus far, it is progressing satisfactorily.

Senator SCHWEIKER. Why don't we go ahead now with our regular agenda? And I will, in the interest of time, ask that we put all full statements in the record, but ask for just a few highlights from the testifying Administrator or comments that they would like to make.

FOGARTY INTERNATIONAL CENTER

Dr. Becker, we will now go back to you.

Dr. BECKER. If I could I will make a few comments with regard to the Fogarty International Center.

As you know, the Fogarty Center was established in 1968 as the principal focal point for international activities at the NIH.

We coordinate international activities of the various Institutes and serve as an interface between the Institutes and those agencies that are uniquely involved with foreign research opportunities.

We also conduct a number of programs of our own. For example, we carry out the international research fellowship programs which permits young investigators from 35 foreign countries to spend 1 or 2 years in the United States studying in laboratories.

We conduct the senior international fellowship program, often known as the Magnuson fellowship program, which permits investigators in their midcareer in medical schools to study in foreign research institutions before returning to their own institution.

We make grants for biomedical research in foreign currency in those countries where the United States owns excess foreign currency. We carry out a program called the Fogarty scholars in residence, which each year brings a small number of eminent scientists to NIH to interact with each other and with the staff at NIH. There are several other programs that we conduct as well.

TASK FORCE TO EXAMINE ROLE OF FOGARTY CENTER

I would like to point out that about a year and a half ago the Director of NIH appointed a task force to examine the role of the Fogarty Center and to determine whether, after a decade of its existence the basic premise was still valid.

That task force reported last June and did conclude that the basic

mission of the Fogarty Center to serve as the international focal point is desirable, and that it is in fact an essential activity for the NIH.

The task force made a number of recommendations for strengthening and expanding our programs. I would like to just share with you a few of the things that we are planning to do and are doing currently in that line.

RESPONSE TO TASK FORCE RECOMMENDATIONS

We are initiating a new program in international issue studies in the health sciences in order to look into issues involving the international aspects of biomedical research and research training.

We are strengthening the Fogarty scholars program. I believe that we need to add a few additional scholars so that we always have a critical mass of individuals with the necessary expertise to interact with each other.

We are strengthening our ability to serve as a resource to the Director of NIH and the Institutes, by expanding the professional staff.

The task force recommended that the Director of the Fogarty Center be also designated as Associate Director for International Activities at NIH. Dr. Fredrickson has accepted that recommendation.

We are also considering ways in which we can broaden our fellowship support to provide funds for fellows who go back to laboratories in other countries, particularly less-developed countries, in order to ease their transition and get them into the mainstream of research.

PROGRAM PLANS

Now during the last 6 months that I have been serving as Acting Director of the Center, I have been looking particularly into the detailed management of our programs and trying to consolidate activities wherever possible.

We have effected some economies and are able to use the resources that have been generated to support some of these expanded activities.

That, very quickly, and in general terms, is the current status of our programs.

We are requesting $9,181,000. I would be glad to answer any questions you would have.

[The statement follows:]

Statement of Dr. Edwin Becker

This is my first appearance before you, and I appreciate the opportunity to present the programs of the John E. Fogarty International Center for Advanced Study in the Health Sciences.

The Center was created by the Congress in 1968 as a living memorial to the late Congressman John E. Fogarty to provide a focus for enhancing the role of NIH in promoting international cooperation in all aspects of the health sciences.

Specifically, the Center provides for advanced studies on international aspects of biomedical research and furnishes a focus for the assembly of outstanding scientists in research; it furthers international cooperation and collaboration in the life sciences through its research programs, conferences and seminars; it provides postdoctoral fellowships for research in the United States and abroad; supports senior scientist exchanges between the United States and other countries under bilateral agreements; coordinates NIH activities and functions generally concerned with the health sciences at the international level; and serves as a focal point for foreign visitors to the National Institutes of Health.

In FY 1979, the Center's programs were subject to careful evaluation. The Task Force to Assess the Mission and Functions of the Fogarty International Center reported to the Director, NIH, in June 1979 on its year-long study of the Center. While reaffirming the importance of the Center as a strong focus for the international aspects of biomedical and behavioral research at NIH, the Task Force made a number of specific recommendations to the Director of the Center and to the Director of NIH on ways in which the programs of the Center might be strengthened and broadened. This report is now serving as a blueprint for actions in FY 1980 and FY 1981 to effect organizational changes, realign staff functions, and make selective changes in the emphasis of present programs and the initiation of new programs within the Center's present and requested resources.

Advanced Studies

While "advanced study" is explicitly stated in the full name of the Center, there has not developed over the years a fully recognized major advanced study program. In FY 1980, and especially in FY 1981, the Center will move toward the development of such a major program activity by establishing an International Issues Study Program to address issues and topics concerning the international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to health care systems.

In 1981, the broad outlines of such a study program will be in place. Patterned after the intramural programs of the Institutes at NIH, the core, permanent staff will be quite small, perhaps two or three professionals. The main purpose of the program will be to conduct a few in-depth studies each year on issues of immediate or long-range concern to the international health sciences community and to the National Institutes of Health.

The Fogarty Scholars-in-Residence Program provides outstanding scientists and other scholars the opportunity to focus their attention on broad aspects of important issues in biomedical research. While in residence at the Center, the scholars individually and collectively engage in collaborative research with NIH and university scientists. In addition, the Scholars-in-Residence Program will serve as an extremely valuable resource for the International Issues Study Program. A modest expansion of the Scholars-in-Residence Program will insure the necessary breadth of interest and expertise to augment the new study program.

The Advanced Studies Program, consisting of the Scholars-in-Residence and the International Issue Study Program, can become a dynamic and valuable adjunct to the present NIH intramural research efforts. Together they provide the means for the NIH to reach out beyond the borders of current research programs to explore international aspects of many scientific areas. The scholarly works produced in such a program will be of value not only as a resource to the NIH but in many instances to the international scientific community.

Conferences

From its inception the Fogarty Center has, through its Conference and Seminar Program, organized discussions of many important scientific subjects. We believe that it is important to continue to conduct conferences on the NIH campus in areas of broad interest to the Institutes. Many of our conferences have been inspired and organized by Fogarty Scholars-in-Residence, and as the International Issues Study Program in the Health Sciences develops, we anticipate that here, too, conferences will play an important role.

During the last few years the Center has also served a broader scientific community in coordinating the NIH support of conferences held elsewhere in the U.S. and in foreign countries. Details of this program are currently being examined in order to optimize the scientific review and financial support procedures.

Fellowships

The International Research Fellowships Program offers a unique opportunity for the sharing of scientific information on an international basis by providing financial awards to foreign scientists at the postdoctoral level to enable them to pursue research studies in laboratories in the United States. This Program provides U.S. scientists access to the ideas of vigorous young investigators with stimulating and different viewpoints. In addition, since Fellows return to do independent research in their home countries, a basis is provided for the future collaboration between U.S. investigators and those in different environmental settings.

Each participating country (about 40) screens and recommends candidates through a nominating committee made up of senior biomedical scientists of the country. Candidates are then reviewed through the NIH peer review system. We anticipate approximately 103 awards will be made in 1981.

This Program, now in its 22nd year, has awarded fellowships to 1786 carefully selected young postdoctoral scientists from 47 countries. A recently completed comprehensive evaluation of the Program shows that 90% of the fellows have returned to their home countries, where many have achieved prominent positions in research. Current follow-up information on former fellows indicates that 75% of them continue to be active in biomedical areas of mutual concern and interest to scientists in this country. A number of fellows continue to pursue collaborative research with their former U.S. preceptors or maintain close scientific communication with them. It is reasonable to say that the Program is uniformly held in high esteem by biomedical scientists throughout the world.

The Senior International Fellowships Program is designed to provide awards to outstanding faculty members at mid-career from U.S. schools of medicine, osteopathy, dentistry, and public health to go abroad to study and share their expertise. Candidates must provide evidence of productive scholarship and recognized stature in their fields; applications are evaluated through the NIH peer review system. The award is intended to be a career-enhancing, educational experience for the individual and benefit both the foreign and U.S. nominating institutions. About 46 of these awards are made each year. We expect

also to continue to allocate a few fellowships each year in the special emphasis area of aging.

In FY 1981, the number of fellowships available through both programs will decline somewhat because of a shift of program emphasis toward the development of the advanced studies capability. Increased stipend levels to offset increases in the cost of living both here and abroad will also require some redistribution of the fellowship funds during FY 1981.

International Cooperation and Coordination

The Center provides policy guidance, coordination and general oversight for the participation of NIH, together with other U.S. agencies, in bilateral cooperative agreements between the U.S. Government and a number of other countries. These include the People's Republic of China, Egypt, France, the Federal Republic of Germany, Hungary, India, Israel, Italy, Japan, Poland, Romania, the Soviet Union, Spain, and Yugoslavia. The Center also coordinates NIH collaboration with such international organizations as the World Health Organization, the Pan American Health Organization, the European Economic Community, the European Medical Research Council and others. The report of the Task Force, described earlier, reinforced the importance of this part of the Center's mission and made recommendations designed to strengthen the role of the Center as an integrating focus within the NIH for international activities.

Special Foreign Currency Program

The Special Foreign Currency Program, funded by an appropriation to the Office of International Health, provides grants for research in several countries where the U.S. owns "excess" foreign currency. The Center's appropriation supports the staff that administers the program. As the "excess" currency funds become depleted in a given country, this type of grant is being phased out. On-going grants are currently supported in Tunisia, India, Poland, Egypt, and Pakistan, while new projects are being started in only the last four of these countries. Some State Department "special" funds provide support for a limited number of projects in Yugoslavia. The Center is developing projections for the future PL-480 grants in individual countries and will explore alternative mechanisms for support in order to ameliorate the loss of these funds. We are also coordinating the International Research Fellowship Program more closely with the Special Foreign Currency Program.

Gorgas Memorial Laboratory

The Center 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 (GML) in Panama. This Laboratory, established in 1929, has carried on tropical disease studies which have made notable contributions to medical knowledge. The Center has no administrative responsiblity for GML but maintains surveillance of its activities with respect to this funding.

Administrative Services

Another function of the Center is the administrative management of the NIH Visiting Program for the entire NIH. The purpose of this Program is to invite distinguished and talented scientists at all levels of their careers to come to NIH for an interchange of scientific information and training. During 1979, 900 scientists from 56 countries participated in the NIH Visiting Program, supported by $12 million of funds from the various Institutes. A full range of advisory and facilitative services are provided to these and some 270 other scientists (Guest Workers) who come to participate in NIH research activities, with stipends from other domestic or foreign organizations.

In summary, then, we believe that the Fogarty International Center plays a key role in advancing international biomedical research through its own programs and through its coordination of international activities of the entire NIH. For our programs and activities, the Center is requesting $9,181,000, an increase of $86,000.

I shall be pleased to reply to any questions of the Committee.

PROGRAM IMPACT OF BUDGET

Senator SCHWEIKER. How would your budget impact on your program in fiscal year 1981?

Dr. BECKER. We will be able to undertake some of the studies that I have indicated and some of the program expansions by consolidating our efforts and simply making resources available from within the Center.

We should be able to continue our fellowship programs at approximately the same level as 1980 by effecting savings internally.

GORGAS MEMORIAL INSTITUTE

Senator SCHWEIKER. How is the Fogarty Center coordinating international biomedical research, particularly the Gorgas Memorial Institute in Panama?

Dr. BECKER. We serve as a channel for providing the money that the Congress appropriates to the Gorgas Memorial Institute. We have some review authority with regard to Gorgas, but we do not determine their program. They are an independent organization. We reviewed the program 3 years ago and we'll have another review team going down to the Gorgas Laboratory, in Panama, in May.

Senator SCHWEIKER. How long do you feel we have an obligation to fund this program in Panama, and is it worth it?

Dr. BECKER. The Gorgas Laboratory has made a number of important contributions in the area of tropical diseases research.

This is a long-standing commitment by the U.S. Government and has been of considerable interest to the Congress in the past.

NIH has not had direct oversight of the Gorgas program, but has had some opportunity, as I have indicated, to review it.

The Gorgas Laboratory, in addition to using the core funds that are appropriated directly by the Congress, does apply for grants. I think some indication of the strength of their program comes from the fact that the grants that they have received, in competition, has increased from about $400,000 a year in 1975 to about $800,000 a year last year.

So they are competing for NIH grants, grants from the World Health Organization, contracts from the Army, and so on, in a fairly favorable way.

Senator SCHWEIKER. I wonder if you would explain how Fogarty is relating to other Institutes that have their own exchange programs with the Soviet Union, for example, in view of our recent developments there.

Dr. BECKER. We do coordinate exchange programs with the Soviet Union and other countries. With the U.S.S.R. there are programs in cancer research and heart research, as well as individual exchange pro-

grams which permit scientists from one country to visit those in the other.

We are operating currently under guidance from the Department of State, indicating that there shouldn't be any exchange of high-level delegations.

The delegation from the Soviet Union that was expected to be here next week to discuss increases in collaboration will not be here. That visit has been postponed indefinitely.

Senator SCHWEIKER. We are, in essence, embargoing any high-level scientific exchange programs with the Soviets at the present time?

Dr. BECKER. That is correct. Individual exchanges are still continuing under the instructions from the Department of State.

Senator SCHWEIKER. Individual, meaning what?

Dr. BECKER. Individual scientists. If there is an ongoing program and someone from one of our Institutes needs to visit the Soviet Union in order to discuss the results, that visit would not, under our present guidance, be prohibited.

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

GORGAS MEMORIAL INSTITUTE

Question: How is that Institute serving the needs of regional medical centers in Central and South America?

Answer: The Gorgas Memorial Institute through the Laboratory in Panama serves the needs of regional medical centers in Central and South America in several ways: It has close collaborative research ties to regional multilateral organizations, such as the Pan American Health Organization and the Institute of Nutrition of Central America and Panama. It is frequently consulted by the Ministries of Health of Panama and other countries on infectious disease problems, such as a recent outbreak of dengue in Central America. It serves as a training site for technical personnel from many countries of the region as well as a site for many regional scientific meetings. For example, in 1979 it trained personnel from 20 countries of the hemisphere on techniques of testing for anti-malaria drug resistance.

Question: Is the program adequately funded?

Answer: We feel that the funding for the Gorgas Memorial Institute is adequate in terms of its intended purpose, that is, as core support for operation and maintenance of the laboratory in Panama. In other words, it provides for a nucleus of key staff, facilities and programs upon which other activities and programs can be added from other sources of support. Core funding can not be expected to be adequate to do all the things that it would be useful to do. However, as noted elsewhere, the organization has been increasingly active in seeking, and successfully competing for, research grants and contracts.

Question: What new types of research are conducted in Panama and at what cost?

Answer: Much of the work of the Gorgas Memorial Laboratory is directed to constantly bringing new techniques and approaches to bear on the continuing difficult problems of malaria and other infectious and parasitic diseases. However the Laboratory has been alert to other disease problems requiring study for which its particular location and tropical setting are advantageous. For example, it is embarking on a study supported by a grant from the National Cancer Institute which investigates a locality of unusually high incidence of cancer of the cervix. Another recent subject of research under a contract from the Johns Hopkins University is on diarrheal diseases. Support for these studies amounted to approximately $38,000 and $55,000, respectively, in FY 1979.

HEALTH RESEARCH EXCHANGES

Question: Is there a need for a well-focused and centralized international health effort in NIH and in DHEW at large?

Answer: The Fogarty International Center with the approval of the Director, National Institutes of Health, serves as a focal point for international health exchanges at National Institutes of Health. At the request of the Office of the Assistant Secretary for Health (Office of International Health) the Fogarty International Center acts as a focal point also for the entire Public Health Service. In so far as the Department of Health and Human Services at large is concerned, the Office of International Health provides

overall policy guidance and a centralized health effort with the Department of Health and Human Services. The Fogarty International Center coordinates closely its work in health exchanges with the Office of International Health.

Question: Please explain how Fogarty is relating to the other Institutes that have their own exchange programs with the U.S.S.R. and other countries.

Answer: On behalf of the Director, National Institutes of Health, the Fogarty International Center coordinates its own activities with those of other Institutes of the National Institutes of Health participating in the U.S./U.S.S.R. health agreement and other such agreements. The Center is the focal point at the National Institutes of Health for the receipt of communications from National Institutes of Health counterparts abroad of a general nature and provides guidelines to the Institutes for participating in these programs. The Center also provides representation to a committee of international health representatives convened periodically by the Office of the Assistant Secretary for Health.

Question: Is this a two-way street?

Answer: There is a considerable amount of information exchanged by components of the National Institutes of Health with their counterparts in other countries under the health research exchanges. Scientists of both participating countries have an opportunity to examine each other's work and the results of unusual disease-related studies in either country. This not only enlarges the medical knowledge of both countries but the research potential for future cooperation as well.

Question: Is it worth it from our standpoint?

Answer: From the U.S. point of view, the exchange programs are worth while, since they enable the National Institutes of Health to use mutually beneficial information to continue its leadership role in biomedical research in the world. They enlarge our research capability by bringing to the attention of our scientists the results of research supported in those countries, and in several instances they permit a considerable expansion of our epidemiological research at relatively little cost to the United States.

INTERNATIONAL HEALTH INITIATIVE

Question: Over the past 2 years, the Congress and the President have come to recognize that international health programs in the Department of State, DOD, DHEW, and elsewhere are very uncoordinated and ill-defined. What are you doing to help rectify this situation?

Answer: The Department of State and the Department of Health and Human Services periodically convene meetings on major international health issues at which are representatives from the principal agencies participating in international health. Meetings convened by the Office of International Health, Department of Health and Human Services, on major international health issues include representation from the Department of State, Department of Defense, Department of Health and Human Services, and others. Although a single government coordinating council is not in existence, the principals of the various international health agencies meet within

these forums as well as in others, such as the National Council for International Health, the Interagency International Health Policy Board and the Committee on Development Assistance. Within the National Institutes of Health, the Fogarty International Center is intensifying its efforts to coordinate international health matters at National Institutes of Health on behalf of the Director, National Institutes of Health. An International Health Data System is also being established to support U.S. initiatives in international health with necessary information.

CENTER FOR DISEASE CONTROL

Question: We are also funding an International Health Program in the Center for Disease Control. How does this program differ from yours?

Answer: The Center for Disease Control program for international research is oriented toward the surveillance and prevention of diseases and oriented more toward epidemiologic services.

Question: How do you coordinate your efforts?

Answer: The Center for Disease Control and the National Institutes of Health coordinate their efforts through direct contacts between program officials responsible for cooperation in the international health program involved. A second method of coordination is in the meetings convened by the Office of International Health, Department of Health and Human Services, involving international health representatives from the principal components of the Public Health Service. Topics of international health significance are also discussed in the Department International Health Policy Board meetings.

PROGRAM HIGHLIGHTS

Question: What program highlights are you planning in Fiscal Year 1981?

Answer: We are developing an International Issues Study Program to address issues and topics concerning the international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to health care systems. We expect that the results of in-depth studies carried out in this program, augmented where appropriate by international conferences or workshops, will be of direct value to the National Institutes of Health and will serve as a resource to the other health agencies in the Department of Health and Human Services.

We are increasing our capability of providing to the Institutes and to the Director, National Institutes of Health, detailed background information on the health research capabilities in various countries and of the opportunities for the National Institutes of Health participation in cooperative international biomedical research. Special emphasis will be placed on countries with which we have had relatively little contact in the biomedical research sphere, such as the People's Republic of China and the Latin American countries.

Division of Research Resources

STATEMENT OF DR. THOMAS BOWERY, DIRECTOR

BUDGET REQUEST

Senator Schweiker. Dr. Thomas Bowery, Director of the Division of Research Resources, is the next witness.

As Director of the Division of Research Resources, you have a budget request of $184,439,000 for 1981, an increase of $15,240,000 over fiscal 1980. Again, we will put your full statement in the record.

[The statement follows:]

Statement of Dr. Thomas Bowery

I am pleased to appear before you once again to present the President's budget request for the Division of Research Resources. Through this appropriation and this Division, the National Institutes of Health supports the development and maintenance of vital and sophisticated clinical, technological, and animal resources for biomedical research. These resources assist investigators who have research grants and contracts from the Insututes and from other Federal and non-Federal agencies and organizations. This appropriation also supports two unique institutional research programs: the biomedical research support grant program, together with its companion biomedical research development grant program; and the minority biomedical support program.

As we began to develop this budget over a year ago, we knew we must deal with three interrelated issues. First, basic biomedical research is specializing and diversifying faster and faster; yet this research still requires the highest quality clinical research environments, the most technologically advanced instrumentations, and the highest quality (and humanely treated) research animals.

Second, we must assure the greatest return for each research resource dollar invested. Investments in multicategorical research resources such as those supported through this appropriation offer the best means to assist in the successful completion of investigator-initiated research projects. Similarly cost effective is the investment in biomedical research support grants to institutions. While emphasizing support to young investigators and pilot research, policies governing the use of these funds are sufficiently flexible to allow institutions to decide how best to use these funds to maintain competitive, high-quality research programs.

Third, in spite of financial constraints we must maintain our commitments to bringing ethnic minority persons into the mainstream of biomedical research. The results of our efforts to date have been excellent, but the job is not yet done—we must continue support to minority institutions, and to institutions with large numbers of minority students, to assure successful attainment of our goals in this area.

Mr. Chairman, our request this year addresses these three issues by asking for funds that will maintain our current commitments to research resources, and allow development of certain additionally needed resources. More specifically, we will continue to support 75 general clinical research centers. These centers provide about 80 percent of the NIH-supported hospitalization costs of research in the Nation; they are vital to basic, controlled clinical investigation. Within these centers, we will continue our modest program to make CLINFO data-handling tools available to investigators. We will also continue our small but effective clinical associate physician program, which has assisted 38 physicians to undertake careers in medical research.

We will continue to support work in our seven regional primate research centers. Both core staff and collaborative investigators will conduct a wide range of research projects in the centers. Also, centers' staff will continue their efforts to move toward self-sufficient primate supply. Our laboratory animal science projects will continue at

about the same level as this year, and we will make a small increase in our primate breeding acitivities, moving slightly closer to the U.S. domestic breeding goal for research primates.

In 1981, we will significantly increase the availability of biotechnology resources to the biomedical community in three major areas. This community requires additional computing capabilities and stronger efforts to develop small implantable measuring/diagnostic and treatment devices for medical research and care. Even more urgently, it needs presently available instruments to assist in the study of the structure and function of the smallest and most basic biological and biochemical units and their activities. Consequently, we plan to increase our support of those resources by over 50 percent. In addition to increasing the numbers of existing resources, we will develop new ones, using the latest laser and synchrotron radiation technologies.

As discussed earlier, we will maintain the momentum of our minority biomedical support program. Activities in 84 institutions will involve over 1,500 ethnic minority students, teachers, and scientists in important biomedical research projects. Through this activity, we can confidently look forward to the continuing increase of ethnic minority persons involved in biomedical research.

Finally, we will continue to operate the all-important biomedical research support program which awards flexible funds to U.S. institutions involved in biomedical research on a formula basis. We will conduct a study to determine if the formula should be revised in order to assure that we distribute the funds more equitably to those institutions most actively engaged in research. Again in 1981, we will strongly encourage recipients to use these funds for supporting pilot research and young investigators, and for the purchase and operation of centrally shared research equipment, animal facilities, and other necessities. In 1981 the President's minority high school student summer research apprenticeship program will be in its second year of operation. Approximately 500 youths who will participate in research projects during the summer of 1981 will be supported by this program. The biomedical research support subactivity called the biomedical research development grant program has nearly fulfilled its objectives of providing research capacity-building funds to new, small, and developing institutions: 22 institutions will be supported in 1981, as we begin a formal evaluation of the program's effects on its participants.

Mr. Chairman, the President's request for the Division of Research Resources for fiscal year 1981 is $184,439,000, an increase of $15,137,000. I will be pleased to answer your questions.

OVERVIEW OF DRR MISSION

Dr. BOWERY. I would like to make a brief overview statement, Mr. Chairman.

Our Division plays a unique and vital role in the stabilization of the biomedical research science base. Our carefully designed resource and center programs provide access to the highest quality clinical research environments, the most technologically advanced instrumentation, and the highest quality research animals.

Two other programs, which are uniquely crafted for institutional research support, provide opportunities for local decisionmaking in the use of flexible biomedical research funds and opportunities for minority faculty, students, and investigators to develop productive research careers.

The budget request before you sustains access to these multicategorical research centers and continues the opportunities for institutional flexibility and minority development. It allows for much-needed growth in providing national and regional research instrumentation resources which are used for the determination of biological structure and function and the management of laboratory and clinical data.

The budget request is $184,439,000, an increase of $15,137,000.

This request is a major element in the administration's decision to

stabilize the research environment needed by the categorical research project grant investigators.

I would be happy to answer any questions you may have.

USE OF ANIMALS IN RESEARCH

Senator SCHWEIKER. Does the outcry from public interest groups that support alternative methods of research that do not utilize animals have any bearing on the demands of the private sector for your resources?

Dr. BOWERY. Certainly, in the area of biotechnology resources, we are increasing our opportunities to explore new technologies.

It is our view that many of these technologies that are actively sought for and used by research investigators will not begin to replace the necessary use of animals in biomedical research.

Senator SCHWEIKER. Has this had anything to do with your conservation of primate use and the criteria which are designed to assure effective use of these animals?

Dr. BOWERY. The prime factor in expanding or maintaining our ability to have primates continue as a key animal for biomedical research despite the reduction of the opportunities to import these animals from foreign sources.

Conservation is also essential to our efforts to develop self-sufficiency in primate supply within the United States. We are striving for self-sufficiency within our primate research centers program and also through a series of contracts attempting to help meet the overall need for these animals both for research and in some of the testing programs of the Food and Drug Administration.

Senator SCHWEIKER. Do you screen grant requests with respect to how the clinicians or researchers plan to implement the protocols vis-a-vis animal use and care?

Dr. BOWERY. We do not have a specific screening process to look at animals per se, but certainly in the review of each of our clinical research centers, there is an opportunity to take a look at how animals may be used in the basic research. But in the programs particularly, they move from the animal research side into the use of human patients, and we have no specific process.

However, in the review of individual NIH project proposals by the Institutes, there is careful review of these to see that there is a limited number of animals used and that humane care is supplied in the use and treatment of these animals.

Dr. FREDRICKSON. This is required in all research grant applications. It must be done by the initial review groups.

Dr. BOWERY. That includes all of NIH and not just the Division's activities.

BRS GRANT PROGRAM

Senator SCHWEIKER. What level of support do you plan to allocate to biomedical research support grants?

Dr. BOWERY. We anticipate this year we will have approximately $46 million for the biomedical research support grants. The biomedical research support budget shows an overall increase of $1.3 million, but $1

million of that money is to sustain the initiative occurring this year for minority high school students' summer research apprenticeship programs. We are using the BRS mechanism to award those funds, but the amount of money for the basic BRS grants will remain essentially the same.

PRIMATE RESEARCH PLAN

Senator SCHWEIKER. Since inflation is soaring, will you have to revise last year's figures implement your national primate plan?

Dr. BOWERY. Working through the steering committee, we are updating the figures that were developed and made public recently based on 1978 data. Within our own program, we will be able to maintain reasonable momentum in meeting the Division's goals that relate to the NIH research needs.

We are approximately at 54 percent of the goal that we have set for ourselves. The present budget will allow some increase in meeting that goal.

EFFECT OF INFLATION ON DRR PROGRAMS

Senator SCHWEIKER. What do you figure your inflation rate is in terms of your Division?

Dr. BOWERY. Our inflation for essentially all of the programs is running around 9 percent. It is a little higher in the clinical research area. This budget reflects approximately an 8-percent increase, so I think we are doing quite well in trying to maintain stabilization in a highly inflationary situation.

FUNDING FOR RESEARCH EQUIPMENT

Senator SCHWEIKER. What level of funding do you anticipate in order to address the growing problems of obsolescence and deterioration of equipment and facilities?

Dr. BOWERY. In our biotechnological resources, the additional $5 million will enable us to add to our portfolio an additional 8 to 10 new resources. They will be established on a regional or national basis so that we can offer research in those centers to the largest number of research investigators. This will meet one element of the research instrumentation problem.

Senator SCHWEIKER. Dr. Fredrickson, let me ask, we hear a lot of criticism from the colleges and universities about their obsolescent, deteriorated equipment. I just wonder how you folks deal with that in terms of your programs overall.

Dr. FREDRICKSON. We think this is a continuing problem, Mr. Chairman. We do not have reliable data that deal with the biomedical research establishment to tell us precisely what the total needs might be for refurbishing both facilities and equipment.

But in the main, with the continuing issuance and reissuance of support that occurs through the Center and grant applications, we are reasonably able to keep up with the individual investigators' needs.

We are attempting to emphasize our ability to provide larger instruments that support many people in one institution or several institutions in one region. We are glad we are able to allocate additional funds for these purposes.

We are also urging institutions, however, to continue their efforts to centralize their recordkeeping and equipment maintenance. Our program at the intramural campus in Bethesda is a good example of how savings can be realized through that means.

SHARED INSTRUMENTATION

Senator SCHWEIKER. Dr. Kirschstein, do you have some comments on that in terms of your Institute?

Dr. KIRSCHSTEIN. Yes, Senator Schweiker.

Based on studies that the staff of the National Institute of General Medical Sciences made last year, we had evidence that the grantees of NIGMS, particularly in basic biomedical science departments at institutions of higher education, have considerable concerns about the level of instrumentation and the obsolescence of instrumentation of their institutions.

We, therefore, put out a request for proposals in March of 1979 stating that, on a one-time basis, we would award a certain number of instrumentation grants for the sharing of instrumentation among scientists at a particular institution. We proposed awards for instruments that were in the cost range of $40,000 to $150,000, plus a maximum of $15,000 a year for 3 years for maintenance of and technical assistance for use of the instruments.

We had estimated that we would provide $5 million for that purpose; 212 grant applications. These were of such excellent scientific merit that we actually made 65 awards, which was 15 more than we anticipated, for a total cost of $7.6 million for the first year.

The program will be monitored over the next 2 years to assure that there is sharing of these instruments. The anticipation is that senior investigators will share the use of instruments, such as, electron microscopes, for up to about 75 percent of the time. The 25 percent remaining time will be available for new and young investigators, who thus can use such equipment and gain experience. Such scientists could not themselves obtain such awards due to their youth and lack of experience.

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

61-400 O - 80 - 28

BIOMEDICAL RESEARCH SUPPORT PROGRAMS

Question: What level of support do you plan to allot to BRS programs?

Answer: We plan to allot $48,840,000 to Biomedical Research Support programs in Fiscal Year 1981. Of this amount, $1,900,000 is for the Biomedical Research Development Grant Program, and $45,940,000 is for the Biomedical Research Support Grant Program. The other $1,000,000 requested is for the NIH share of the Federal Minority High School Student Summer Research Apprenticeships.

Question: How does this level of support compare to last year's?

Answer: The amount of funds requested for the Biomedical Research Development Grant program in 1981 is $866,000 less than the 1980 level. The level allotted for Biomedical Research Support Grants is $1,190,000 or 2.7% over Fiscal Year 1980.

Question: Should this program continue to be expanded, or is this level adequate?

Answer: Since the Biomedical Research Support Program provides institutional support, this program should be expanded in 1981 just as the funding level for research project grants of the categorical Institutes expand.

NATIONAL PRIMATE PLAN

Question: Since the inflation rate is soaring, will you have to revise last year's figures of the cost to implement your National Primate Plan? The plan contained an estimate that $15.2 million would be required over a two-year period with $5.5 million needed annually for program maintenance.

Answer: Yes, our estimates of the cost of implementing our National Primate Plan will have to be revised as a result of inflation. Using an inflation rate of 9.7% for 1980, 9.3% for 1981 and 8% for the future years and implementing the plan in 1981 instead of 1979, the cost for a two year period would be $19 million. The annual cost for program maintenance beginning in 1983 would increase to $7.7 million.

GENERAL CLINICAL RESEARCH CENTERS

Question: Presently, there are seventy-five clinical research centers throughout the United States. Is the present level adequate or is there a need for expansion in this program?

Answer: The present level of funding for this program is adequate; however, if funds were available, this program could be expanded over the long term by developing high quality clinical research facilities in at least 12 additional locations--though not necessarily General Clinical Research Centers per se. While the number of medical schools has increased from 100 to 125 during the period 1968-1979, the number of General Clinical Research Centers has declined from 91 to 75. In addition to the increased number of medical schools seeking their own General Clinical Research Centers, applications have also been received from dental schools as well.

This increasing need can only be met by increasing the number of centers. Also, wide geographic distribution of centers, in addition to promoting dissemination of clinical research expertise, will be beneficial in epidemiological studies and in the investigation of regionally prevalent clinical conditions.

A similar need exists for at least modest expansion of the Clinical Associate Physician program which encourages new young physicians to participate in clinical research. The number of MDs applying for new NIH research grants has declined in recent years, and there is a general impression that the number of MDs embarking on careers in clinical investigation is declining even more rapidly. In 1977 only 900 to 1,000 MDs entered postdoctoral research training, compared with about 1,800 in 1974. As a result, the efforts of the General Clinical Research Centers program in training clinical investigators is becoming ever more important.

There is also a need to expand our efforts to provide the Centers the capabilities of computer-based data management systems (CLINFO) for the data collection and analysis needs of clinical research. These CLINFO systems are an efficient and flexible aid which assists the clinical investigator in realizing the greatest return from the data collected on research patients.

Question: What major clinical applications of research findings have been accomplished at these Centers in the past five years?

Answer: Progress continues on a number of fronts with 3,500 scientific articles and 2,000 scientific abstracts being published per year by scientists using the General Clinical Research Centers. Some recent examples of clinical applications of research findings follow:

The recent award of the Nobel Prize in Medicine for the development of the radioimmunoassay technique illustrates the importance of this method to biomedical research and medical practice. Radioimmunoassay has made possible the measurement in serum and other body fluids of almost all hormones, the proteins that transport them, a variety of drugs, and some enzymes. As a result, the bases of many metabolic diseases have been discovered, mechanisms of metabolic regulation clarified, new diseases discovered, and the diagnosis of endocrine and metabolic diseases facilitated. While the basic research that resulted in this technique was done elsewhere, one of our Clinical Research Centers has used radioimmunoassay methods to develop a simple, inexpensive screening method for hypothyroidism in the newborn, a method in use in at least half of the states. Early detection and treatment of congenital hypothyroidism can prevent the mental retardation that often demands life-long custodial care.

General Clinical Research Centers have been part of the nation-wide research effort that has resulted in dramatic recent advances in knowledge of immunologic mechanisms that have improved the prospects for organ transplant recipients. Increased information about the tissue antigen system and the specific functions of different types of lymphocytes have led to better matching of donor and recipients. Most recently, techniques for removal of certain lymphocytes have reduced rejection rates while allowing reduction in the dosage of essential but hazardous anti-immune drugs.

The observation that high concentrations of glucose lead to the addition of this sugar to the hemoglobin molecule has been turned into a useful clinical tool at one of our Centers. Since the glycosylation is irreversible, it provides a cumulative measure of the level of control of diabetes during the preceding weeks and months. This measurement is critical to the exciting prospect of automated insulin administration, instruments for which are now undergoing rapid development and testing.

Progress in the understanding, detection, and treatment of hypertension continues. A novel experimental anti-hypertension drug, Captopril, acts by blocking formation of the potent blood pressure-raising hormone angiotensin II. Captopril can lower blood pressure in many patients with either renovascular hypertension, hypertension due to renal failure, or essential hypertension resistant to multiple combinations of other drugs.

It has also been found that the action of Captopril is greatly potentiated by addition of diuretics, because it blocks activation of the renin system, which is one of the ways in which the body normally resists the action of diuretics. Captopril itself mildly stimulates sodium excretion at the same time that it helps the body conserve potassium. This is because Captopril reduces the secretion of aldosterone, the most potent salt-retaining hormone of the adrenal gland.

These studies, done at our Centers and elswhere, have outlined the mechanisms of action and demonstrated the practical value of a new drug to practicing physicians and the large hypertensive population.

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

Question: In what way do you coordinate your activities with the National Center for Health Care Technology?

Answer: Our activities are coordinated with the National Center for Health Care Technology through the HHS Technology Coordinating Committee. NIH is one of the members of this Committee, which is chaired by the Director of the National Center for Health Care Technology.

Question: How do your activities differ from those of the National Center for Health Care Technology?

Answer: The Biotechnology Resources Program provides access to the latest technologies from the physical sciences, mathematics and engineering for biomedical investigators to use in conducting their research. Unlike our emphasis on technology in support of research, the National Center focuses on technology for health care. The National Center for Health Care Technology is concerned with the carrying out of comprehensive assessments of new or existing health care technologies, or for informing interested parties about the efficacy and safety of health care technologies and their economic, ethical and other social impacts.

MINORITY BIOMEDICAL SUPPORT PROGRAM

Question: What growth is planned for the Minority Biomedical Support Program?

Answer: The amount requested for the Minority Biomedical Support (MBS) Grant Program for FY 1981 is an increase of $763,000, or 4.2%, over Fiscal Year 1980. In addition, an estimated $5.2 million will be provided by other NIH Institutes and the National Institute of Mental Health to support specific projects within MBS grants relevant to their specific scientific missions.

Question: Have we placed enough emphasis on this progam?

Answer: This program is presently receiving appropriate emphasis, and is keeping pace both with inflation and with the rate of successful competition by the program's grantees for renewal of their grant support. The program is currently concerned with stabilizing the gains made during several years of fairly rapid growth; and the next year or two will be spent working with our present grantees to assist them in becoming successful competitors for other sources of research support; increasing the extent and responsiveness of our liaison with the NIH Institutes and possibly with other agencies; and evaluating the overall success of the program in accomplishing its objectives. We then will consider resuming a moderate rate of future growth.

RESEARCH OPPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: Many discrete areas of research on research resources could lead to significantly enhanced capabilities of those resources to support biomedical research in some of the most important health problems facing the nation today. For example, while many of the General Clinical Research Centers support very high-quality research in the broad areas of metabolism and endocrinology, we need to develop a few new kinds of clinical research centers which would specifically foster more clinical research in certain key problem areas of disease and in high interest fields like nutrition. Similarly, specific clinical research centers dedicated to investigations, in the area of environmental toxicology, trauma and shock, and other scientific issues of trans-NIH interest should be developed.

Recent breakthroughs in the development and engineering of biocompatible materials, and their utility for microsensors and prosthetics, have resulted from research support in bioengineering resources. Further, the development of new bioengineering resources for attacking the particular problems of engineering biocompatible materials, could be as significant to the treatment of a number of diseases as systems for implanted insulin dispensing will be to diabetes. Similarly, a great deal more development is needed in the area of artificial intelligence (AI). The knowledge and techniques of AI are at a point where their increased support could impact significantly on the diagnosis of disease and the selection of appropriate therapeutic regimens. Research in simulation of biological systems, another promising field, will lead to greatly increased capacities for analyzing and understanding related biological functions.

The exploration for new animal models of human disease should now be expanded to include marine forms of cold-blooded

animals and invertebrates in general. While research to discover and develop these models would consume some time and costs without being sure of immediate payoffs, the long view for finding significant new test organisms is favorable. Research on lower forms of animal life is more acceptable to those most concerned about humane care of research animals, while frequently enabling research which is less expensive and more efficient. More research on animal laboratory "Bioecosystems" is another area offering promise for improving the environmental conditions under which animals are housed and studied. Such research would look particularly at lighting, temperature, ventilation, noise level, and other parameters contributing to the physical, psychological, and emotional health and well-being of research animals.

The significant presence of minority investigators in our Minority Biomedical Support Program provides us an excellent opportunity to enter more deeply into investigations of the mix of biomedical, cultural, and behavioral factors for the dissemination of health knowledge and the practices for health care delivery in minority communities. In particular, studies on incidence of disease, availability of treatment, and information about prevention can now be undertaken with greater assurance than ever before for obtaining useful results.

FUNDING BREAKDOWN

Question: In your professional scientific judgement are you pleased with your funding breakdowns?

Answer: It is our professional scientific judgement that, given the total amount requested, the distribution across activities is appropriate.

National Institute of Environmental Health Sciences

STATEMENT OF DR. DAVID P. RALL, DIRECTOR

BUDGET REQUEST

Senator Schweiker. Dr. David P. Rall, Director of the National Institute of Environmental Health Sciences, is our next witness.

As Director of the National Institute of Environmental Health Sciences, you have a budget request of $97,269,000, an increase of $13,357,000 over fiscal year 1980. We will put your full statement in the record.

[The statement follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement by the Director

National Institutes of Environmental Health Sciences
on the
"National Institutes of Environmental Health Sciences"

Mr. Chairman and Members of the Committee

It is a pleasure to discuss with you today how the National Institute of Environmental Health Sciences' Research Programs play an important role in identifying and resolving emerging environmental health issues. In previous testimony before this Committee I have discussed health problems created by an array of environmental pollutants. I have mentioned the exposure of workers to high levels of the pesticide Kepone in Virginia. I have discussed asbestos and its long-term health effects. I have talked about the PCB's and PBB, and the exposure of populations in Michigan and elsewhere in the country. Beginning in 1973 and continuing until last year, I have spoken about the problem of Dioxin, a component of Agent Orange and one of the most toxic man-made substances. In the case of each of these toxic substances, health problems can generally be linked to exposure to a single substance.

We have long been concerned about the toxicity that may result from exposure to two or more chemicals at the same time. The emerging problem of deteriorating, unsafe and overloaded chemical waste dumps presents problems of a new order of complexity. We are confronted with threats to people's health from the interactions of several chemicals in combination. An example of what we face and what we might expect in the future was brought to light in the city of Niagara Falls, New York. In this community, about 500 homes are located on and around an old dump site called the Love Canal. Chemicals have seeped into basements or surfaced in the vicinity of homes. Studies by New York State have shown an increase in the rates of miscarriages and low birth weights in the residents of this area. The incidence and prevalence of other chronic diseases have not been well studied, but many people complain of poor health.

At least 12 known carcinogens have been identified in the air and the soil around some of the houses at Love Canal, but the level of exposure or dose to particular individuals will be impossible to determine.

The direct exposure of individuals to toxic chemicals in dumps as occurred at Love Canal is not likely to be the common situation, although it presents serious economic and health problems for the people involved. A much larger problem is the potential contamination of public drinking water supplies by chemicals from waste dumps. The Environmental Protection Agency estimates that up to 75 percent of landfill sites containing chemical wastes are located in areas such as wetlands, flood plains, and over ground water aquifers. Toxic chemicals discarded in these sites may contaminate water that will eventually enter public water supplies. Improper disposal techniques have led to the pollution of surface

water; and, since chemicals can migrate steadily through the ground, can threaten water supplied from deep wells too. This threat to water supplies should not be minimized. We are becoming more aware that the amount of fresh water available is as real a constraint to social and economic development as is the amount of usable energy.

EPA estimates that there may be as many as 50,000 waste dump sites in the United States, of which 30,000 may present some hazard to human health. EPA also estimates that approximately 33 million tons of potentially toxic chemical waste is generated annually.

The number of different chemicals contained in the disposal sites is not known, but more than 200 chemicals have been identified in the Love Canal area alone. A review of these chemicals indicates that for some of the chemicals considerable toxicologic information is available, that is, previous testing provides information to predict whether the chemical is capable of causing cancer, genetic mutations, or toxic injury to a specific organ system. But for most of the chemicals, toxicologic information is deficient or missing. A reason for this is that many of the chemicals found in waste dumps are not commercial products but are raw materials or process intermediates.

The current interest in waste dumps has enhanced our awareness that people exposed to chemicals in dumps will be exposed to mixtures or combinations of chemicals. The science base for predicting effects of mixtures of chemicals is not well developed. Experience to date is limited but does tell us that interpretation of such studies is difficult and results are not always predictable. Studies at NIEHS with combinations of toxic metals like lead, cadmium, and arsenic have shown that quantities of the metals in organ systems is different than might be predicted from exposure to individual metals. However, there are few studies of complex mixtures of hydrocarbons and other synthetic chemicals.

A major objective of this research that NIEHS conducts is the development of principles which will enable us to accurately predict the toxic effect on man of such mixtures and combinations without doing time-consuming and expensive animal tests on every possible mixture and combination.

In terms of exposure to mixtures of chemicals from waste dumps, toxicologic information provides the public and physicians with some expectation of the kinds of health problems that may follow exposure.

Most of our experiences to date with exposures to chemicals in the environment have involved catastrophic effects; such as progressive neurological deficits from methyl mercury, angiosarcoma from vinyl chloride, miscarriages from chemicals in Love Canal, and mesothelioma from asbestos fibers. We need to be able to recognize more subtle effects--changes that might occur in people before they are ill. Our investigators have devised a method to make it possible to monitor populations and discover mutant cells. Their approach involves the production of different forms of hemoglobin within red blood cells by environmental agents that cause mutations. Some of these hemoglobins are sufficiently different in their chemical composition that it is possible to produce monospecific antibodies to

them. By attaching a fluorescent molecule to the specific antibody, it is possible to identify the red blood cells that contain the different hemoglobin using an ultraviolet light. In collaboration with NIEHS scientists, investigators at the University of Washington in Seattle have developed a specific antibody which reacts only with the aberrant hemoglobin for Sickle Cell Anemia (Hb-S). Using this antibody they have determined that one in ten million red blood cells will react with the antibody. Since this number is so small, it is important that the system detect many different specific types of mutations. Our investigators have now produced antibodies to as many as six different hemoglobin variants. If the variant cells have been caused by genetic mutation, then the scientists have succeeded in measuring the mutations frequency in somatic cells in vivo. To provide the necessary link between laboratory animal and clinical studies, investigators at NIEHS are developing a parallel system for detection of mutations in mice.

Since the mutations are rare events, methodology must be available to scan many cells. To meet this need, NIEHS, in collaboration with the Lawrence Livermore Laboratories is developing automatic cell counting systems. Using this technique, investigators have been able to identify 1,000 times more mutant cells, thereby making it possible to process more samples in a shorter time. Although more research is needed, it is now within our reach to develop systems for monitoring the human population for mutational events caused by exposures to environmental agents, by using readily available human material such as red blood cells.

NIEHS is the leader in this type of research which represents such an important long-term investment.

This mutant hemoglobin research represents but one of a number of basic projects that concern the influence of chemicals on reproduction, development, and metabolism.

The developing organism--the fetus and the newborn--is particularly sensitive to toxic agents in the environment. The developing central nervous system is more sensitive to the effects of pollutant exposure than the mature nervous system. The Institute therefore is mounting a multidisciplinary effort to identify and understand the neurological and behavioral effects of chemical and physical factors in the environment, and to devise sensitive and effective methods to measure them.

The long-term objective is to develop tests for predicting potential neurobehavioral effects in humans. At the present time it is well known that human breast milk can contain traces of polychlorinated biphenyls (PCB'S) and other potentially toxic chemicals. We are studying a group of young children to determine if there are any adverse health effects from their exposure in this way. One of the more toxic forms of PCB, a tetrachloro isomer has been found in our labs to produce behavioral and neurological toxicity in mice exposed in utero but not in mature mice. The toxicity was expressed in disturbances of balance and muscular coordination. The neurological development and behavior patterns of the children we are studying are being correlated with levels of PCB's and other contaminants in their mother's milk. This group has not demonstrated any detectable abnormal behavior date which can be correlated to

high levels of PCB exposure; but this experience is providing us with baseline data and some knowledge of the sensitivity of our methodology for testing neurobehavioral problems in children.

Presently the best scientific tool we have to predict adverse health effects from agents in the environment is the animal test. The National Toxicology Program (NTP) is this Department's effort to better organize and manage the conduct of chemical toxicity testing in animals, and the applied research necessary to improve these tests.

The NTP has progressed well since its inception in the fall of 1978. The Executive Committee provides linkage between the Department's research and regulatory agencies and the Environmental Protection Agency, Occupational Safety and Health Administration, and the Consumer Product Safety Commission to ensure that toxicology testing and test development carried out under the aegis of the Program's research agencies is responsive to the needs of the regulatory agencies. A non-government Board of Scientific Counselors provides scientific oversight to the NTP. The Board advises the NTP Director and the Executive Committee on scientific content, philosophy, and policy and will evaluate the merit and overall quality of the science conducted by the individual NTP components.

During fiscal year 1979, 79 bioassay tests for carcinogenic potential were started. During the year, work was completed and reports issued on 95 tests. Under the conditions of the tests, 47 (49.5%) were considered negative, 39 (41%) were positive, and 9 (9.5%) suspect carcinogens. Reports on another 33 of these tests are scheduled for issuance in FY 1980.

Among the most significant tests being conducted by the NTP are studies of dyes containing benzidine derivatives. Animals exposed to these dyes in tests alter the test substance to free benzidine which can be found in their urine. These studies are important because benzidine is a known animal and human carcinogen. Large quantities of these dyes are used by industry in a variety of products including hair dyes, printers inks, plastics, rubber and textiles. Therefore, a wide opportunity exists for both occupational exposure and from use of the consumer products containing these dyes.

Mr. Chairman, I have reviewed with you the importance and relevance of NIEHS' research and briefly touched on the National Toxicology Program. This research and testing will help provide the answers to a number of the most important environmental questions facing the American people today and will form a solid scientific base upon which we can better protect human health. In conclusion, Mr. Chairman, the budget request for the National Institute of Environmental Health Sciences for 1981 is $97,269,000, an increase of $12,963,000. I shall be happy to answer any questions you might have.

SINGLE CHEMICAL EXPOSURES

Dr. RALL. Thank you, Mr. Chairman.

I would be pleased to make a few general comments before questioning.

I have discussed before this committee in the many years past many environmental chemicals and their relationship to human health. The

polychlorinated biphenyls although now their manufacture is banned are widely distributed throughout the country, throughout the world, and throughout all of our bodies. Although they are no longer made, there are about 800 million pounds of PCB's in the environment today which will have to be safely disposed of.

We have talked about the Kepone incident at Hopewell, Va. We have had many discussions about asbestos, one of the most ubiquitous natural compounds that has been widely distributed by man's activity. I'm sure you have been concerned about the issue of asbestos in school buildings that has come up in the last 12 months.

We have discussed dioxin with you. Dioxin is the very toxic contaminant of herbicides such as Agent Orange and the common wood preservative, pentachlorophenol.

Many of these chemical problems—which are significant—are concerned basically with a single chemical and, in fact, most of the research done in environmental health in the world today is focused on problems caused by single chemicals.

MULTIPLE CHEMICAL EXPOSURES FROM WASTE DUMPS

We all know we are exposed to many chemicals at once. Nowhere is this better illustrated than the recent events at the Love Canal at Niagara Falls. The Love Canal was a chemical waste dump, in use until about 1950, when it was closed. A few years later, it was sold and an elementary school and about 500 houses were built either on or immediately adjacent to the dump site. Over 200 toxic chemicals have been identified in the dump, in the houses, in the dirt, and in the air.

Adverse health effects have been seen among those who were unfortunate enough to live in the Love Canal area. These include an increased incidence of miscarriages and abortions and a greater frequency of low-birth-weight babies. In addition to the documented problems, there have been many less specific complaints of long-term illness by the residents.

The State has now purchased most of the houses in the Love Canal area, and the residents have been able to leave. The Love Canal is only one dump and only a few thousand people are involved.

Nobody knows how many chemical dumps there are across the country. Estimates vary. A reasonable number may be 30,000, with a significant fraction of those causing a potential for human health problems. Thirty million tons of chemical waste are disposed of each year, and I gather since New Jersey has tightened its chemical dumping, some of that waste goes directly west to the State of Pennsylvania.

Senator SCHWEIKER. We, unfortunately, got more than our share. Fortunately, our State legislature at long last is going to do this same thing, but we are the recipient of a lot of it because we hadn't had a law that had any meaning, so you are absolutely right.

Dr. RALL. There are two types of waste dump problems. I believe the Love Canal type of problem where there is actually habitation on the dump site is not going to be the most common one. Most of the problem dumps are in flood plains or over streams of underground water called aquifers. Chemicals seeping from those dumps can contaminate

either the surface water or the aquifers. Underground water supplies 40 percent of the drinking water in the United States.

This aquifer contamination has already been seen in California, Tennessee, New Jersey, and Massachusetts. A number of municipal wells have been closed in Massachusetts.

Typically it is not one chemical in the well water but a half dozen or a dozen that have seeped from these toxic chemical waste dumps. The aquifers move very slowly—perhaps no more than two-tenths of 1 mile a year, so they are, in a sense, a kind of a time bomb if they have been contaminated by upstream chemical waste dumps and are slowly moving toward a tap well downstream. I might point out that we do not know how to clean up an aquifer after it has been contaminated. What we will have to do now is the research so that in the future we will know enough about the toxicity of chemicals alone and in combination to be able to tell the local communities whether they have to find alternate sources of water before people are exposed to dangerous levels of contamination.

The Love Canal situation has focused attention sharply on the problems of many chemicals acting together in combinations of toxicity. This is a major challenge for environmental health research, and NIEHS is in a good position to accept this challenge.

INCREASES IN THE 1981 BUDGET

You point out we have approximately a $13 million increase in this budget. Of that amount, $5.2 million of that will go to research grants to increase the science base that will, hopefully, let us understand the toxicity of chemicals in combination.

We received an increase of $5 million and 55 positions to staff the support activities for our new research facility. I have a photograph which shows work progressing on our new research building. I couldn't resist showing it to you all.

Finally, we received an increase of $3 million for the further development of the national toxicology program that Dr. Fredrickson, Dr. Upton, and I discussed with you last year. The national toxicology program brings together the major toxicology testing efforts within HEW to facilitate their functioning as one well-integrated organization. For instance, NTP has tested or has on test 68 of the 200 chemicals found in the Love Canal area.

I would be delighted to answer any questions you might have.

TRICHLOROETHYLENE (TCE)

Senator SCHWEIKER. Are you doing anything about TCE—trichloroethylene?

Dr. RALL. The answer is yes. We are exploring the carcinogenicity problems of TCE at the animal and laboratory level. We have at least one epidemological study underway to try to see if there is any human evidence of carcinogenicity or other toxicity.

Senator SCHWEIKER. Where is that?

Dr. RALL. The study is being done by the Environmental Health Science Center at Mt. Sinai Hospital, New York City.

Senator SCHWEIKER. What triggered that?

Dr. RALL. There was concern that the carcinogenicity of these kinds of compounds was demonstrated in animals, and large number of workers are or have been exposed.

Senator SCHWEIKER. What body or group are they studying geographically, epidemiologically?

Dr. RALL. A group of workers from drycleaning plants.

Senator SCHWEIKER. Where?

Dr. RALL. The New York area.

Senator SCHWEIKER. We worked on the TCE problem with CDC. It came to my attention with a large spill from a manufacturing concern. We thought that a county I used to represent in the House was pretty saturated with it but when we began looking into it we found contamination throughout the Philadelphia suburban area which may have been going on for about 20 years.

And now I understand that there are some six States that have similar TCE characteristics in the underground water table.

Of course, TCE, as you probably know, is used as a degreaser. Any metallurgical manufacturing process that used the degreasing element probably used TCE.

It has now become a national problem because of the six States involved and because we actually shut down some water supplies.

So I haven't made any request of you folks because of the Center for Disease Control. But we ought to coordinate what we have asked of CDC with you folks.

Dr. RALL. I will talk to the CDC people.

COORDINATION WITH NIOSH AND NCI

Senator SCHWEIKER. What kind of coordination would you have in a situation like this? I guess it would depend on your request?

Dr. RALL. It depends on the situation. I know of one interesting situation which is an example of how NTP is working very well. A group of workers in a plant producing a chemical pesticide complained to NIOSH that they thought there were problems of male teratology. That is, the male workers' offspring develop abnormally or are born with defects.

NIOSH is investigating the population of workers. NTP is studying this chemical in laboratory animals. About 6 months from now we will know what the epidemiological studies show and what we can see in animal toxicology experiments.

I think that is very nicely and mutually reinforcing.

Senator SCHWEIKER. How does the National Cancer Institute tie into something like this?

Dr. DEVITA. The Cancer Institute has had a chemical selection group that has selected chemicals for different sets of testing so that we have cast a wide net. We are also involved in the sense that we comanage the chemical testing program with NIEHS.

Senator SCHWEIKER. Would TCE fit in your present list?

Dr. DEVITA. It came in from NCI and, apparently, it is on the list from NCI.

Senator SCHWEIKER. Apparently, TCE is carcinogenic in mice but not rats.

What does that mean for humans?

Dr. DEVITA. That is a difficult question to answer.

Senator SCHWEIKER. That's why I asked. [Laughter.]

Dr. DEVITA. By and large, the correlation between one species of mouse and humans is good for carcinogens. So we would suspect that something is definitely carcinogenic and has a potential for causing cancers in humans.

We would like to see carcinogenicity confirmed in two species because of the difference in the way two species handle the compound.

I would say TCE is suspicious as a result of the testing.

Dr. RALL. NTP is doing further studies to see if we can get more evidence one way or the other. We are doing in vitro studies and further animal tests.

It would be nice to get a more clear-cut answer.

SPECIES DIFFERENCES IN TESTING

Senator SCHWEIKER. Are you looking at it from different perspectives or what? I'm not clear.

Are there many chemicals or carcinogens that fall into that category, that they are carcinogens in mice and not rats?

Dr. DEVITA. There are. I am not sure of the numbers.

Senator SCHWEIKER. There are a number that fall into that category.

Dr. DEVITA. Yes, indeed.

Dr. RALL. Typically, the results are the same in both rat and mouse. The compounds that come to public attention and cause grief to scientists and regulators are those that respond differently in two species. They are the ones that we think about and worry about.

NATIONAL TOXICOLOGY PROGRAM

Senator SCHWEIKER. The national toxicology program, which was created to review the many toxic substances we are developing, is currently scattered among the participating agencies. Would it be more efficient to centralize it somewhere, such as with NIEHS at the Research Triangle Park in North Carolina?

Dr. RALL. I don't think so, Senator. I think there is good reason for some of its geographical dispersion.

The animal testing laboratories at the National Center for Toxicological Research in Pine Bluff, Ark., are superb. It would be difficult and expensive to duplicate them somewhere else.

The association with the epidemiologists and the animal toxicologists at the NIOSH laboratories in Cincinnati has been very fruitful in the past. And I think it will be more fruitful in the future.

With respect to some of the scientists from the National Cancer Institute, we are, in fact, going to bring many, but not all of them, down to the North Carolina campus of the National Institute of Environmental Health Sciences.

We will then have an NIH core group in North Carolina concentrating on NTP.

COORDINATION WITH OTHER NIH INSTITUTES

Senator SCHWEIKER. In your report to the Senate Appropriations Committee dated December 12, 1979, you discussed activities in the area of behavioral and neurological toxicology investigating the toxic effects of environmental pollutants on the central nervous system.

You also discuss in the section entitled, "Inhalation Toxicology," the relationship between respiratory diseases and air pollution and occupational exposure.

To what extent do these studies duplicate activities being carried out by other Institutes such as National Institute of Neurological, Communicative Disorders, and Stroke, and National Heart, Lung, and Blood Institute?

Dr. RALL. To my knowledge, there is no duplication. We work very closely with people in the Neurological Institute who are interested in the same sorts of chemical toxicology.

We have planning sessions with them and so forth. There is similar cooperation with the scientists from the Heart Institute.

ASBESTOS

Senator SCHWEIKER. You mentioned the asbestos problem. How do you work, if at all, with the Environmental Protection Agency in this problem?

Dr. RALL. With asbestos, we traditionally have worked very closely with EPA. We have held a number of joint meetings with EPA on the problem of asbestos in school buildings.

We convened a meeting just 6 weeks ago with the Association of School Administrators at which EPA carried a major part of the program. At that meeting, a real consensus developed as to the best approach to the problem.

It's basically very simple. When the ceilings are really damaged, and the asbestos material goes to a powder, if you touch it, it therefore is a hazard which must be cleaned up or sealed.

If the ceiling is well cemented, hard and firm, it is not a hazard today. It must be watched and checked every year or so.

This rather reasonable approach was acceptable to EPA, to the school administrators, and to the health officials and environmental scientists.

Senator SCHWEIKER. Who decided to clean up the Senate subway ceilings?

Dr. RALL. My impression is that there was no asbestos in the Senate buildings.

Senator SCHWEIKER. Why did we seal them? What was it that we were inhaling that somebody decided to seal in the Senate subway corridors?

Dr. RALL. We tried to find out.

Senator SCHWEIKER. Are you sure it wasn't asbestos?

Dr. RALL. We were concerned about this some years ago and asked Dr. Irving Selikoff, Director of our Mt. Sinai Center, and an authority on asbestos, to send one of his mineralogists down to talk to the Architect of the Capitol.

They went over the plans and they inspected the Capitol and build-

ings on both the Senate and House sides. We were told that there was no asbestos in any of these buildings.

Senator SCHWEIKER. It may not have been asbestos, but whatever it was, we decided to seal it.

Dr. RALL. There are mineral fibers used in construction which are irritating and unpleasant, and which look like asbestos. They are not as hazardous as asbestos, as far as we know.

In a few schools, administrators have gone to great expense and effort to remove this type of material, thinking it was asbestos.

Senator SCHWEIKER. I assumed it was asbestos. I didn't know what else we would be sealing in around here.

Is there any other program for sealing anything? Maybe they are putting a videocamera behind it. [Laughter.]

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

61-400 O - 80 - 29

MARINE BIOMEDICAL RESEARCH CENTERS

Question: Several years ago, Senator Magnuson helped NIEHS to develop the marine centers program. How many centers are there now and where are they located?

Answer: NIEHS supports five marine and freshwater biomedical (MFB) centers. These centers are at the following institutions:

Duke University Marine Laboratory, Beaufort, N.C.
University of Washington, Seattle, Washington
University of Wisconsin, Milwaukee, Wisconsin
University of Southern California, Los Angeles, California
Oregon State University Marine Science Center, Newport, Oregon

Question: Please explain the type of research you conduct at these centers and their usefulness.

Answer: The Duke Marine Laboratory focuses on the toxicity of pesticides and heavy metals and mechanisms of action in aquatic species; The University of Washington on pathologic and carcinogenic mechanisms in fish; The University of Wisconsin on pharmacological and toxicologic processes and mechanisms in freshwater fish; the University of Southern California on pathologic mechanisms in marine organisms; and Oregon State University on pharmacologic, toxicologic and carcinogenic mechanisms of aflatoxins and other toxic substances in fish.

Biomedical studies using aquatic species are important in three ways. First, aquatic species provide model systems for human diseases and for human physiological processes. This coupled with their unique environment in which toxic agents can be easily identified and quantified, makes them important model systems for environmental health research. Second; aquatic species can serve as sentinels and warn man of the presence of dangerous levels of toxic agents in aquatic environments. Before we can do this, we must recognize the response of these species to various toxic agents. Finally; aquatic species are a major human food source. We must understand the effect of polluted environments on aquatic species which enter the human food supply and endanger the public health. Research programs at these centers focus toward one of these three issues.

NEW FACILITY

Question: Now that your new facility is completed, when do you plan to move in and begin research activities?

Answer: Currently only a small portion of the buildings at the new facility are completed. We have taken possession of the warehouse and shops buildings in the support services areas. Within the next two months the power plant and incinerator building will be completed. This summer the office modules of the administrative/laboratory building will be completed and we will move in. The laboratory modules of this building will be completed by the fall of 1981 and we will move in thereafter.

Question: Did the final cost come in under budget?

Answer: The construction manager's guaranteed maximum price for the entire facility is within the total amount appropriated. However the final cost will not be determined until construction is completed and all outstanding contractor claims are settled.

Question: How many new positions do you need to adequately utilize this facility?

Answer: The facility, along with the current NIEHS facilities, will accommodate a total staff of approximately one thousand full-time permanent employees plus another 200 temporary employees. Staffing patterns and proposed growth plans to reach that level were included in the Department's report to the Committee. In that report we noted that 189 employees would be required to adequately operate and maintain these facilities without significant program growth. The full-time permanent staffing level provided in the FY 1980 appropriation plus the staffing levels proposed in the President's 1981 request will allow NIEHS to attain this level of supporting staff.

Question: How about equipment? Will you have enough in your budget to meet this need?

Answer: NIEHS estimates a total requirement of $17 million to appropriately equip this facility and the expanded scientific programs which will occupy it. Of this total requirement, budgets for FY 1979 and 1980 have provided $4.8 million. An additional $2.4 million is in the President's FY 1981 request. We anticipate additional funds will be available in future years.

DETECTION TECHNOLOGY

Question: Could you inform us of the status of development of an analytical process for chemical detection, using a radio-immunoassay technique?

Answer: Radioimmunoassay has been increasingly used since 1959 as a bioassay technique for detection of low concentrations of such things as hormones, vitamins, enzymes and drugs. Although the principle of the radioimmunoassay technique has been known for some time, it has only recently been applied successfully in NIEHS laboratories to fat soluble organic compounds which include many of the synthetic organic chemicals known to persist in our environment and in human tissue. Some of the compounds we now have radioimmunoassays for include the polychlorinated biphenyls (PCBs), dioxin, dibenzofurans and the phthalate esters. At present, the assays should be applicable to screening a variety of environmental samples to minimize the demand for more costly and complex instrumental techniques. The full potential of these assays must await further validation including examination of other environmental samples, particularly human tissue samples and determining the feasibility of performing these assays routinely in clinical laboratories.

RISK ASSESSMENT

Question: What risk assessment techniques, rudimentary or sophisticated, does the Institute employ in determining whether or not to continue testing a substance in their testing chemicals program?

Answer: Risk assessment techniques and other criteria are used to select chemicals for testing and as part of the decision making process for determining whether to continue chemicals on test.

Within the DHHS the National Toxicology Program carries the primary responsibility for toxicology testing. In collaboration with the participating regulatory agencies, the NTP has developed criteria for selection of chemicals for testing. These criteria include risk assessment factors. The criteria are:

1. Chemicals found in the environment that are not closely associated with commercial activities;

2. Desirable substitutes for existing chemicals, particularly therapeutic agents, that might not be developed or tested without Federal involvement;

3. Chemicals that should be tested to improve scientific understanding of structure-activity relationships and thereby assist in defining groups of commercial chemicals that should be tested by industry;

4. Certain chemicals tested by industry, or by others, the additional testing of which by the Federal government is justified to verify the results;

5. Previously tested chemicals for which other testing is desirable to cross-compare testing methods;

6. "Old chemicals" with the potential for significant human exposure which are of social importance but which generate too little revenue to support an adequate testing program (some of these may be "grandfathered" under FDA laws);

7. Two or more chemicals together, when combined human exposure occurs (such testing probably cannot be required of industry if the products of different companies are involved); and

8. In special situations, as determined by the Executive Committee, marketed chemicals which have potential for large-scale and/or intense human exposure, even if it may be possible to require industry to perform the testing.

From a public health point of view the most important criteria are the extent of potential human exposure and the likelihood that the chemical will be shown to be toxic. However, current risk assessment techniques need to be improved if the regulatory decision making process is to be strengthened. To this end the Institute carries out research to improve the methodology of risk assessment and the science base which undergirds it.

Risk assessment issues that have received particular emphasis include low dose extrapolation, species-to-species extrapolation, and pharmacokinetic modeling. In addition, various Institute scientists have been directly involved in the estimation of potential human health risks associated with exposure to specific environmental agents. In developing these estimates, a wide variety of procedures have been employed, including extrapolation from animal feeding experiments assuming a multi-state model for carcinogenesis to empirical risk estimation based on preexisting epidemiological data bases. Finally, the Institute is in the early stages of developing a complex tier system for the screening of potentially mutagenic chemicals, which involves a combination of biological and statistical analyses.

COORDINATION WITH OTHER NIH INSTITUTES

Question: When is an area of investigation involving the effect of chemical, physical and biological environmental agents on a particular organ system carried out by NIEHS and when is it carried out by the Institute having jurisdiction over that system?

Answer: NIEHS research is oriented toward environmental problems such as the presence in the environment of hazardous chemicals and pollutants with definite adverse health effects. Many toxic agents may effect several organ systems or cause several diseases. For example, lead has been linked with damage to the nervous system, the kidneys, and the hematopietic system. It has been shown to arrest normal growth and development, may have reproductive effects, and may even be a carcinogen.

By definition, categorical institutes are oriented toward problems specific to individual organ systems or disorders. Where basic research of this nature is relevant to the understanding of the mechanisms of toxicity or the toxicity of specific agents, NIEHS builds upon these findings.

NIEHS generally does not emphasize research involving infectious biological agents, such as bacteria and viruses. NIEHS research tends to pursue an investigation from the chemical or physical agent--its toxicity and its chemcial characteristics when introduced into the living organism--to the specific organ or organ system affected by that agent. Disease-oriented NIH Institutes tend to look at disorders of specific organs or organ systems and look for the causes or origins of those disorders- -the opposite intellectual approach to the same problem. NIEHS tends to be interested in the interaction of environmental agents with the organ system. Disorders are not ignored by this approach but a specific thrust of this line of investigation is the prevention of <u>any</u> disorder to <u>any</u> organ system which could be attributable to a toxic environmental agent.

In summary, it is difficult to identify a specific demarcation between the interests of NIEHS and the interests of any of the disease oriented NIH Institues. However the problems of science in these realms of investigation are so formidable and the level of scientific collaboration sufficiently high that non-productive and inefficient duplication of effort is avoided.

Question: How do your activities in the area of occupational pollutants duplicate those of the National Institute for Occupational Safety and Health?

Answer: We are clear that the programs of our two Institutes complement rather than duplicate each other. There are a variety of means by which we assure this. Dr. Robbins, Director of the National Institute for Occupational Safety and Health, and I keep each other informed of developments which bear on the activities and responsibilities of each other's Institute. In addition we are represented in a variety of activities which provide formal mechanisms for program coordination. These include the DHHS Committee to Coordinate Environmental and Related Programs, and the National Toxicology Program.

It is a tragic truth that all too often the work place has provided us early evidence that an environmental agent is an environmental health hazard. Thus, those of us concerned with general environmental health hazards continue to look to the problems which will affect the general population. As a result of this interest, the NIEHS has for more than a decade supported Dr. Irving Selikoff's work - much of which is focused on the occupational setting but some of which extends to the broader general population. We share the results of this as well as other relevant work with NIOSH as well as Occupational Safety and Health Administration.

COORDINATION WITH POISON CONTROL CENTERS

Question: How do NIEHS programs coordinate with poison control centers?

Answer: The national network of poison control centers was specifically created to aid individuals and practicing physicians in treatment of acute poisoning caused by ingestion or exposure to concentrated amounts of highly toxic agents. NIEHS collaborates with FDA and other agencies in the support of the major printed reference used by local poison control centers: Clinical Toxicology of Commercial Products. We assume that expert toxicologists who participate in preparation of treatment information which goes to local centers have used the information resources of the National Library of Medicine extensively, including the Toxicology Information Program. NIEHS's major research responsibility is to investigate the effects of exposures of large numbers of people to small doses of environmental agents over long periods of time. NIEHS tends to be concerned with establishing human toxicity in these situations. Our scientists have often used information from these centers in assessing effects of human exposure.

CLINICAL APPLICATIONS

Question: To what extent are NIEHS findings clinically applicable?

Answer: Research at NIEHS concerns metabolism of chemicals, effects on specific organ systems, dose response in animals and human epidemiology. This information is clinically applicable in that it provides information and tools to recognize diseases caused by chemicals in humans as well as information on drugs, and nutritional and other factors that influence clinical manifestations of chemical diseases. Perhaps, more importantly, toxicologic information about specific chemicals should lead to measures that reduce exposure to people, thus preventing occurrence of clinical disease. In addition, as the metabolism of toxic chemicals is better understood, ways of providing effective antedotal treatment may become possible. Two toxins for which modes of treatment have followed metabolism and toxicology studies are methyl mercury and kepone.

NIEHS ACCOMPLISHMENTS

Question: Please list examples of accomplishments of the Environmental Health Sciences program that you would like to point to.

Answer: NIEHS must anticipate the need of regulatory agencies for information on the human health effects of a broad range of environmental agents. A few examples of accomplishments follow.

Regarding asbestos, NIEHS research has demonstrated that minute amounts of asbestos when inhaled can lead to lung cancer and other lung disorders in significant numbers of those exposed. These animal and human studies have led to a reduction in the permissable levels of airborne asbestos in workplaces, and in the limitation of the use of asbestos in consumer products and buildings where large numbers of people can be exposed to dangerous levels.

Polychlorinated biphenyls have always been regarded as toxic in large doses. However they had been confined to uses where chance of direct human exposure was low. NIEHS research demonstrated that these agents were toxic in low doses, that they are stable in the environment, and that people and animals tend to accumulate them in their bodies. Because of these characteristics Congress banned the further sale and use of PCB as part of the Toxic Substances Control Act in 1976.

NIEHS research on pharmacology and metabolism has demonstrated that the chemical which enters the body is often not as important as the alterations to that chemical that occur within the body. These findings have improved our ability to plan accurate animal tests and properly interpret the results of those tests for the human experience.

Present research advances have drawn attention to the effect of environmental chemicals on reproduction and human development. The neurological, behavioral and general developmental consequences of the exposure of fertile males and females and their offspring, in utero and after birth, is becoming better known and understood because of NIEHS research. In recognition of these research advances, regulatory agencies are requiring assays of reproductive and developmental toxicology.

There are other notable research advances NIEHS has made which have helped identify emerging and existing threats to human health. The general thrust of environmental health research is to improve the science base which is necessary to quickly and accurately predict adverse health effects. Because this knowledge base is steadily increasing, we have been able to identify a growing number of toxic agents over the past few years. The attached report details NIEHS response to regulatory needs.

NIEHS research manpower development programs are responding to the national needs to increase the pool of trained scientists doing chemical testing and other health hazard evaluation. At the time the Toxic Substances Control Act was enacted in 1976, the national workforce of environmental toxicologists, pathologists and epidemiologists was quite small. TSCA mandates a significant increase in the level of toxicity testing efforts which has demanded more trained scientists to: 1) plan and execute tests, 2) monitor testing for accuracy and quality, and 3) do the research necessary to improve test methodology. NIEHS training programs have markedly expanded the numbers of well-trained scientists entering this workforce. This increase flow of talent should continue indefinitely.

FUNDING BREAKDOWN

Question: In your professional scientific judgement, are you pleased with your funding breakdown?

Answer: The NIEHS budget can be split between applied research and research to increase the science base. Because systematic investigation into the problems of environmental health is relatively new, a vigorous basic research effort must be maintained. However, the legacy of the vast increase in the variety and quantity of synthetic agents in our general environment is rapidly coming upon us. Therefore we must deal now with the problem of selecting the most threatening agents and establishing their toxicity. This calls for the sharpest testing methods and the most accurate risk-assessment methods. I am satisfied with the balance between basic research and research to improve test methods in the 1981 Budget Request.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to pursue if you were not constrained by budget limitations?

Answer: Hazardous environmental chemicals may give rise to a diversity of adverse health effects ranging from cancer, birth defects and genetic diseases to more immediate toxicity on specific organ systems such as the brain, liver and kidney. Some of the most severe consequences of chemicals may follow alteration of cellular genetic material at the time of exposure. Cancer or other diseases due to heritable abnormalities are associated with a chain of events that start with chemical alteration of cellular genetic material at the time of exposure to the chemical agent. Molecular genetic research has now advanced to the point that several approaches to detecting and characterizing the early damage to chromosome DNA are feasible in human populations. These techniques

provide promise for identifying somatic mutations in red blood cells and germinal (heritable) mutations in sperm. Actual application of these techniques to the study of human populations awaits more research and development of methodology for rapid processing and analysis of cells.

Tests are needed to recognize small changes, particularly early or subclinical effects on specific organ systems in large numbers of people before serious clinical disease is obvious. The greatest needs at the present time are for tests to detect effects of chemicals on the reproductive systems, and to prevent disorders such as infertility and miscarriages; and for tests to recognize neurotoxicity of chemicals through early behavioral changes.

Finally, there is need to have reliable and sensitive systems to detect the presence of dangerous chemicals in people in order to establish dose levels and the extent of individual exposure. This information is necessary for reliable estimates of risk.

NATIONAL TOXICOLOGY PROGRAM

Question: What is the status of the National Toxicology Program? How long has it been in existence?

Answer: The National Toxicology Program (NTP) was established by the Secretary of DHEW fifteen months ago in November 1978. A principal objective was to create a mechanism that would effectively coordinate the Department's chemical toxicology test method development and testing activities. Appropriate programs within the National Cancer Institute and the National Institute of Environmental Health Sciences of the National Institutes of Health, the National Center for Toxicological Research of the Food and Drug Administration and the National Institute for Occupational Safety and Health of the Center for Disease Control were committed to the Director of the National Toxicology Program, Dr. David P. Rall. To enhance communication between research agencies and regulatory agencies with responsibility relating to toxic substances, and to approve and review the activities of the NTP, an Executive Committee was established. The committee is composed of the heads of the appropriate health regulatory agencies (Food and Drug Administration, Environmental Protection Agency, Consumer Product Safety Commission and the Occupational Safety and Health Administration) and the health research agencies (National Institutes of Health, National Cancer Institute, National Institute of Environmental Health Sciences and the National Institute for Occupational Safety and Health).

Financial resources committed to the NTP were $40.9 million in FY 1979 and $68.7 million in FY 1980. The President's budget provides $91.7 million for FY 1981.

NTP has made significant progress. Chemicals selected for toxicology testing have been reviewed and formally approved by the Executive Committee ensuring that testing resources are applied to chemicals of principal public health concern. Seventy-nine tests (or bioassays) of chemicals with cancer-inducing potential were initiated in FY 1979, a two-fold increase over the rate of testing

prior to establishment of NTP. The projected level of new tests started in FY 1980 is about the same as for FY 1979. This is 20-25 less than the Program's original goal. This deficit is due to:

- o a delay in final selection of chemicals for testing in order to ensure that all selected chemicals were important to health regulatory needs and health research goals;

- o the assumption of direct supervision and oversight of new contract testing activities by NTP staff rather than through a prime contract management mechanism.

Chemical testing capabilities are also being established or enhanced in other areas of toxicology such as teratology and mutagenesis.

A primary objective established for the NTP was to broaden the toxicologic characterization of those chemicals tested, and this objective has been achieved. More extensive histopathologic studies which will detect damage to organs such as the liver, kidney, pancreas, etc., are being conducted on each chemical as are hematological and biochemical studies which will yield more information. Progress has been made in developing information as to the fate in the body of chemicals being tested, knowledge that is essential for the proper interpretation of toxicology results in terms of human risk assessment. Such information is important because it may indicate that the chemical is metabolized (converted) to another chemical known to be a human carcinogen. This eliminates the need to conduct expensive carcinogen bioassays as well as providing information necessary for appropriate control of the chemical in a shorter time period. NTP research on water-soluable benzidine-derived dyes indicates that these dyes are converted to free benzidine, a known human bladder carcinogen.

Recently developed test methods that are being validated by NTP for eventual use in standard toxicology tests include neurobehavior, immunology, and teratology, as well as lung and kidney toxicity.

Question: What about its future; is it temporary or permanent?

Answer: The National Toxicology Program was established as an experimental approach to meeting the need 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. These activities were aimed at improving the flow of needed information both to the regulatory and to the research agencies.

The Program grew out of a broad consensus that a new approach was needed to meet the rapidly growing need to know more about chemical toxicity. In the year since its establishment it has been clear that the program serves a critically important purpose. However, the permanent structure of the program has not been decided.

Beginning in the Spring of this year, the Office of the Secretary will be conducting an evaluation of the Program which

will lead to recommendations to the Secretary regarding the permanent structure of the Program.

Question: What will go into the determination of whether NTP's status is temporary or permanent?

Answer: As stated previously we believe that the purposes the National Toxicology Program serves are continuing in nature, and in that sense NTP is viewed as permanent. However, the permanent organizational form of the NTP has not yet been resolved. The criteria for determining the final structure of the NTP will be developed as part of the evaluation beginning in the Spring.

CHEMICAL TESTING

Question: In total how many chemicals will NTP test?

Answer: The National Toxicology Program develops scientific information about potentially toxic and hazardous chemicals which can be used for protecting the health of the American people and for the primary prevention of chemically-induced disease.

Of more than 4,000,000 known chemical entities, about 50,000 - 60,000 are in common use. From these the NTP will select, test, and evaluate those chemicals considered to possess the most likely serious public health consequences. The Toxic Substances Control Act (TSCA) and other regulatory legislation assigns the responsibility for testing new chemicals, combination compounds, and product formulations to the manufacturer prior to manufacture and use. When regulations implementing the provisions of TSCA are in place, the NTP Executive Committee (cognizant that industry will test chemicals for health and environmental effects) will continue to select chemicals for testing following these principles:

1. Chemicals found in the environment that are not closely associated with commercial activities;

2. Desirable substitutes for existing chemicals, particularly therapeutic agents, that might not be developed or tested without Federal involvement;

3. Chemicals that should be tested to improve scientific understanding of structure-activity relationships and thereby assist in defining groups of commercial chemicals that should be tested by industry;

4. Certain chemicals tested by industry, or by others, the additional testing of which by the Federal government is justified to verify the results;

5. Previously tested chemicals for which other testing is desirable to cross-compare testing methods;

6. "Old Chemicals" with the potential for significant human exposure which are of social importance but which generate too little revenue to support an adequate testing program (some of these may be "grandfathered" under FDA laws);

7. Two or more chemicals together, when combined human exposure occurs (such testing probably cannot be required of industry if the products of different companies are involved); and

8. In special situations, as determined by the Executive Committee, marketed chemicals which have potential for large scale and/or intense human exposure, even if it may be possible to require industry to perform the testing.

The full testing agenda will not be established until a very careful testing needs study is completed in two to three years. We anticipate however that the number of long-term animal bioassays initiated each year will stabilize at approximately 100 from FY 1981 through FY 1984 and then begin to drop off. When TSCA regulations are in place, NTP will continue to test mixtures and compounds of significant public health concern not covered by TSCA but identified by the testing needs study.

Question: What will be the total cost of this testing?

Answer: We anticipate that maintaining a testing program in which 100 long-term animal bioassays are initiated annually will cost approximately $65 million per year in FY 1981 dollars.

Question: When will this part of the program be phased out?

Answer: Because there is an enormous backlog of untested chemicals and because of the requirement to test critical mixtures where testing by industry is not mandated by law, and because of the eventuality that certain compounds will have to be tested under government auspices, it is likely that NTP will have an animal bioassay testing program indefinitely.

Question: Has private industry been responsive in picking up their share?

Answer: Private industry has been responsive during the past five years. Many chemical manufacturers participate in the support of the Chemical Industries Institute of Toxicology which has recently completed a laboratory facility in Research Triangle Park. Large chemical manufacturers are strengthening their chemical toxicology programs in anticipation of the requirement to test compounds prior to marketing.

CARCINOGEN SURVEYS

Question: Out of 28 substances that have been determined to be human carcinogens, arsenic and benzene have not been confirmed by animal studies. Industry claims that this lack of animal study confirmation precludes these substances from being considered for regulations (in most cases, however, industry likes to discount the use of animal studies). Have animal studies been performed on arsenic and benzene?

Answer: Animal studies have just been completed on arsenic and benzene. These studies from Germany (on arsenic) and Italy (on benzene) and from our Environmental Health Science Center at New

York University (on benzene) appear to confirm in animals the carcinogenicity of these agents. Although animal studies are just being completed, adequate human epidemiologic studies have established arsenic and benzene as carcinogens.

Question: Does NIEHS or NTP plan to fund studies to confirm the carcinogenicity of arsenic and benzene?

Answer: Animal studies are currently underway as part of NTP. Even if the animal studies referred to above establish the carcinogenicity of arsenic and benzene, the NTP studies will continue. The purpose of the NTP studies is to establish dose-response relationships and to investigate the possibility of the presence of other toxic responses at low dose levels. During the course of these studies it will be easy to confirm the carcinogenicity results.

HEALTH EFFECTS OF PENTACHLOROPHENOL AND DIOXIN

Question: Have any studies been undertaken to determine the effects, if any, of the widely used wood preservative pentachlorophenol?

Answer: Pentachlorophenol is contaminated with a variety of toxic impurities, including chlorinated dibenzodioxins and dibenzofurans. It has been suggested that the long term toxicity potential of pentachlorophenol may be associated with these contaminants. Several toxicology studies support this view including a recent NIEHS study that also showed that these impurities are stored in cattle tissue and could pose a public health problem through consumption of contaminated meat and dairy products.

Question: Has this chemical been selected for testing under the National Toxicology Program?

Answer: The National Toxicology Program does have pentachlorophenol under test. In addition, a toxic hexachloro-dioxin contaminant of pentachlorophenol is being studied for carcinogenic potential. The results of this study are expected in a few months. Extensive studies of the chlorinated dibenzofurans are also in progress.

Question: Has it been recommended for regulation by any Federal agencies?

Answer: EPA, which is responsible for the registration of pentachlorophenol, has been advised by several advisory groups to sharply curtail the level of contaminants found in the technical-grade formulation.

TOXIC SUBSTANCES REGULATION

Question: Congress is becoming more interested in the scientific issues involved in the regulation of toxic substances. A bill has been introduced to standardize testing procedures used to evaluate a substance for carcinogenicity. To settle questions of a scientific nature, some people have recommended that the regulatory agencies establish an independent, scientific body to resolve these problems. The Office of Technology Assessment and the National Toxicology Program have been suggested as possible and appropriate locations for this independent body.

Please comment on these recommendations.

Answer: This is both an important and a complex issue. It involves essentially three different questions: 1) Should the various regulatory agencies go about the task of establishing the risk of a substance using commonly agreed upon policies and principles? The answer to that question, I believe, is clearly yes. The Regulatory Council's document on regulation of carcinogens demonstrates this approach. 2) Would it be useful and appropriate to have a central focus for determining the risk associated with a toxic substance? The answer to that question is, in general, yes. But it must be remembered that Congress has vested the responsibility for taking regulatory action based on such information in a variety of regulatory agencies. In some cases the Congress has required the manufacturer to demonstrate safety, as in the case of drugs, or freedom from unwarranted toxicity, as in the case of new chemicals. Thus, there may be practical limits to our ability to centralize responsibility for these functions. 3) Is legislation in this area necessary or desirable? While I am aware of these proposals, I have not reviewed any of them in depth. As a scientist, however, it has been my experience that great care must be taken in drafting legislation in areas such as this or it can freeze the science base by making statutory requirements based on the limits of science at a given point in time. I think any proposed legislation in this area must be considered most carefully if that hazard is to be avoided.

NIEHS RESEARCH RELEVANT TO REGULATORY NEEDS

The National Institute of Environmental Health Sciences (NIEHS) has made important contributions to the identification and control of hazards to health in the environment. Its research on the chemistry, metabolism pharmacokinetics, and toxicology of halogenated hydrocarbon chemicals has been critical to the control of highly toxic pesticides, industrial chemicals such as the polybrominated and polychlorinated biphenyls, and the highly toxic impurities "dioxins" and "furans" which occur in several industrial products, such as 2,4,5-T, hexachlorophene, and pentachlorophenol. This research also has enabled the NIEHS to respond to and alert other public agencies to the dangers and hazards from accidental exposures, such as the incident involving contamination of feed supplies by polybrominated biphenyls in Michigan and the contamination of fisheries on the James River and lower Chesapeake Bay by Kepone. In relation to Kepone, an apparently successful treatment for exposed workers has been developed through NIEHS grant-supported and contract research.

The Institute continues to pursue other courses of research, with similar public impact. These include:

- Controlled studies on the toxicity of ingested asbestos;
- A large scale six-city survey of health effects of air pollution; and
- Continuing efforts to improve the extrapolation of findings from general animal toxicity studies to human populations where doses or exposures are relatively small or occur over a long period of time.

The following are examples of programs and research efforts that have been relevant to the needs of the regulatory agencies for scientific information:

- National Toxicology Program
- Polybrominated biphenyls (PBBs) and polychlorinated biphenyls (PCBs)
- Asbestos
- Bis(chloromethyl)ether
- Diethylstilbestrol (DES)
- Air pollutants
- Nitrogen dioxide, sulfur dioxide, and carbon monoxide
- Benzene
- Methylmercury
- 2,4-D
- Mutagenicity testing
- Neurotoxins
- Risk assessment

In order to assure that the results of its research reach the regulatory agencies, NIEHS has attempted to improve the dissemination of scientific information pertaining to environmentally-caused diseases and potential hazards in the environment. It sponsors a number of conferences on topical environmental health problems and invites the participation of representatives from academia, industry, and government, as well as from Congress, public interest groups, and the science press who are called on to serve as "surrogates" for the general public.

In many cases, the proceedings of these conferences, which are usually published in the NIEHS journal ENVIRONMENTAL HEALTH PERSPECTIVES, are the most thorough compilation of knowledge relating to the state-of-the-art and the needs for research on particular compounds. Moreover, they serve as a valuable reference for agencies, governments, or individuals faced with particular environmental health problems.

NIEHS scientists and grantees also serve as expert consultants on public health disasters. For example, they provided assistance to the Italian government following the dioxin incident in Seveso, to the Michigan Department of Public Health on the PBB poisoning, and to the New York Department of Health on the toxic waste dump problem at Love Canal. Finally, NIEHS gives wide distribution to publications such as "Basic Concepts of Environmental Health" and annual research reports.

National Institute of Child Health and Human Development

STATEMENT OF DR. NORMAN KRETCHMER, DIRECTOR

BUDGET REQUEST

Senator Schweiker. Dr. Norman Kretchmer, Director of the National Institute of Child Health and Human Development.

As Director of the Child Health and Human Development Institute, you have a budget request of $217,531,000 for fiscal 1981, an increase of $8,487,000 over fiscal 1980.

Again, we will put your full statement in the record.

[The statement follows:]

61-400 O - 80 - 30

Statement of Dr. Norman Kretchmer

The National Institute of Child Health and Human Development (NICHD) is unique among the Institutes at the National Institutes of Health (NIH) because its mission is not disease or disorder oriented. It is the only Institute at the NIH whose focus is on the normal adult female and the normal adult male. Research on reproductive and developmental biology; the social and behavioral sciences; fetal and infant development; the normal and abnormal processes of pregnancy and on the health of mothers and children are supported. The events of fertilization, the nine months of pregnancy, the hours of labor and delivery, and the first few days of life are the major determinants of whether health or handicap will characterize the lifespan, and whether that lifespan will be measured in minutes, days, or nearly a century.

Problems associated with reproduction and development are among the most significant and costly health problems of our society. Infertility, premature birth, adolescent pregnancy, congenital defects, and mental retardation cost billions of dollars each year in direct health care costs and loss of productivity. The net cost to society for the maintenance and care of individuals affected with birth defects, including some forms of mental retardation, is more than $3 billion a year. These costs will continue to rise with inflation, but also because each year 100,000 children are newly diagnosed as mentally retarded.

Costs associated with premature birth are enormous, at least $8 billion per year. Although premature birth is still the leading cause of perinatal death, many babies are now surviving who only a few years ago would have died. These babies require costly, long-term hospitalization, and are at high risk for permanent brain damage or other impairment. One preventable cause of premature birth is cesarean delivery performed too soon. NICHD-supported scientists have developed a test which has the potential to nearly eliminate prematurity associated with cesarean delivery; this would result in savings of $51 million a year.

This test to assess fetal maturity and other techniques to predict birth defects and fetal distress were the subject of a major conference at the NICHD in 1979. Individuals representing a wide variety of interests attended including doctors, ethicists, members of the general public and researchers. The purpose of the meeting was to discuss the clinical application of these technologies and to increase public and physician awareness of their availability and use.

I would now like to describe some of the Institute's recent research advances and future plans. Within the increase available in 1981, the NICHD will strive to initiate several new research programs. This will require some reordering of priorities, but the Institute must pursue certain research advances and decisions that were made during the past year.

ADVANCES IN THE REPRODUCTIVE SCIENCES

Much public and scientific attention this past year has focused on <u>in vitro</u> fertilization--so called test tube babies.

While a ban on Federal support of human in vitro fertilization studies remains in effect, animal studies have continued. Currently, in our labs at NICHD, we have several monkeys carrying fetuses that are products of in vitro fertilization. The first birth is due shortly. These animal models are valuable in the study of causes and treatment of infertility and birth defects.

Last year, I described to you a promising advance concerning a group of drugs that resemble a naturally-occurring hormone called luteinizing hormone releasing factor. This year we are testing these drugs in humans. A major clinical trial involving both men and women has been started. Previous research on these drugs has demonstrated their usefulness in treating male and female infertility, while more recent studies have suggested that they are also effective as contraceptives. These compounds could constitute a new generation of contraceptives and eventually replace the oral contraceptives now used.

The use of these drugs as fertility regulators is the direct result of basic research on brain hormones conducted by two NICHD-supported scientists, 1977 Nobel Prize winners, Drs. Roger Guillemin and Andrew Schally. The development of these drugs is an excellent example of yesterday's basic science becoming today's treatment modalities.

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. Studies will be expanded on the relationship between the use of oral contraceptives and the occurrence of cancer of the breast, uterus, and ovary. A study of fatal heart attacks among women of reproductive age has been completed. Use of oral contraceptives was found to be associated with increased risk of heart attack among white women without medical problems that predispose to heart attack. Pill use did not increase the incidence of fatal heart attack among women already at risk. Data from one large study indicate that oral contraceptive use, either past or present, is associated with an increased risk of stroke. The risk was greatly increased by smoking. The risk to women who both smoke and use the pill is 22 times that of women who do neither.

A study has been completed on the effects of vasectomy on blood levels of certain male sex hormones. All hormone levels were found to be within the normal range for adult males, and changes with time after surgery were slight and clinically insignificant. Research will continue on whether the antibodies to sperm that develop in some men following vasectomy adversely affect health and on whether vasectomy hastens the development of atherosclerosis. There is some evidence from primate studies that there is a relationship between vasectomy and atherosclerosis.

The NICHD will expand studies on the changes in the structure of the American family. These changes, as indicated by the rise in the number of divorces and remarriages, the increasing number of single persons, and large number of children living with only one parent, will be studied for both cause and effect upon family size and spacing, and on the well-being of children.

RESEARCH IN PREGNANCY AND INFANCY

The NICHD will continue to support a large research program on maternal and fetal nutrition. One research priority is the determination of daily nutrient requirements of infants who are premature or of low birth weight. Many clinicians have believed that human milk is the best food for these and other babies, and now NICHD-supported scientists have begun to substantiate those beliefs. This research has found components in human milk essential for normal nutrition and growth that cannot yet be replicated in artificial formulas.

The NICHD nutrition program also examines how behavioral, social, and cultural factors affect diet and nutrition. There is special interest on the nutritional individuality that results from interaction between genetic inheritance and nutritional environment. For example, the majority of the world's population over four years of age cannot digest most dairy products, including milk. Only individuals from most North European countries and white American ethnic groups retain their ability to digest milk sugars beyond infancy. This type of information has important implications for domestic and world food policies, as well as for individual diets.

Great strides have been made in the management of diabetic pregnancies. Most dramatic has been the reduction in perinatal deaths among infants of insulin-dependent mothers. The number of babies lost has dropped from about 20 to the range of 6 to 10 per hundred babies born to diabetic women.

Undiagnosed or delayed diagnosis of Group B streptococcal infections in newborn infants continue to be significant causes of neonatal death and longterm impairment. Streptococcal infections have been difficult and time-consuming to diagnose. Investigators supported by the NICHD have now developed a rapid means to diagnose infected infants. Early diagnosis not only prevents serious illness or death but prevents the infection from spreading to other infants.

Advances such as the improved management of diabetic pregnancies and saving babies from death due to streptococcal infection are significant for both humanitarian and economic reasons. It has been estimated that reduction of perinatal deaths by one per 1,000 births results in an estimated annual savings to society of some $204 million.

The NICHD will continue its long-standing research on the Sudden Infant Death Syndrome (SIDS). As I mentioned last year, clinicians now feel that babies who die of SIDS are not the healthy infants they were once thought to be. Specific research findings are now confirming that theory.

Other studies are focused on the role of hypoxia (low levels of oxygen in the blood) in SIDS and as a cause of certain developmental defects. There is evidence that repeated, mild episodes of hypoxia, which often accompany prematurity, predispose an infant to SIDS.

Damage to the central nervous system in the form of cerebral palsy, mental retardation, seizures, and learning disabilities have all been attributed to hypoxia occurring immediately before

or after birth. The causes of hypoxia and its specific effects are poorly understood. The NICHD is supporting studies on these questions, the answers to which could significantly reduce the perinatal death rate and the number of damaged infants that are born. Improved techniques to detect hypoxia in the fetus and newborn are also being sought.

The research on hypoxia relates to the Institute's assault on mental retardation. Some 10 percent of newly diagnosed cases of mental retardation are attributed to complications of birth. Chromosomal and other genetic disorders account for a large number of cases, with Down Syndrome being the most frequent, single diagnosis. Still, causes are unknown for a large proportion of mental retardation.

Institute-supported genetic research is making progress against mental retardation. Grantees have reported that the extra chromosome associated with Down Syndrome is not always contributed by the mother as previously thought. Data indicate that the father is the source of the extra chromosome in 23 percent of the cases studied. Continuing research in this area will seek to determine if the incidence rises with increasing paternal age as it does with advancing maternal age.

There is now some evidence that the specific gene content of the extra chromosome in Down Syndrome determines the clinical symptoms of some mentally retarded persons. Thus, a major effort to map the genes on the extra chromosome and to analyze their effects on brain development and function is a central part of the Institute's attack on Down Syndrome. Mapping the genes on the extra chromosome could lead to initial therapeutic efforts in the future.

CONCLUSION

As I stated previously, the problems addressed by the NICHD are among the most significant and costly health problems of our society because they affect an entire lifetime or even a whole population. These problems are solvable, however. The answers can be found in research. Significant scientific advances seldom arise spontaneously but occur as a result of accumulated knowledge obtained for the most part through fundamental research. Examples include the development of the new contraceptives now undergoing clinical trials and the advances in understanding diabetes which have resulted in safer child-bearing for diabetic women. Although basic studies sometimes seem removed from clinical problems, they are intimately related, and represent the promise of the future for improving the quality of life and preventing developmental abnormalities resulting in functional, structural and mental defects which threaten life itself, both quantitatively and qualitatively.

Mr. Chairman, the NICHD requests $217,531,000 for FY 1981, an increase of $7,929,000. I would be glad to answer questions or to supply additional information for the record.

Dr. KRETCHMER. I would like to make a few comments, if I may, Mr. Chairman.

The National Institute of Child Health and Human Development—NICHD—is somewhat unique because it is neither disease nor disorder oriented.

It is the only Institute whose focus is on the normal adult female and male and children. The NICHD conducts research on reproduction, development, social and behavioral sciences, fetal and infant development, normal and abnormal processes of pregnancy, and the health of mothers and children.

The events of fertilization, the 9 months of pregnancy, delivery, and the first few hours of life largely determine whether health or handicap will characterize the remainder of the lifespan.

Problems of development are costly. Infertility, premature birth, adolescent pregnancy, and other problems of concern to the NICHD, cost billions of dollars a year in direct costs and loss of productivity.

The net cost to society for the maintenance of people with birth defects, including some forms of mental retardation, is calculated at more than $3 billion a year.

These costs will continue to rise with inflation, but also, because each year about 100,000 children are newly diagnosed as mentally retarded.

Costs associated with premature birth are enormous. Today it is estimated that in the first 30 days of a premature infant's life, aggregate costs run $8 billion a year.

I would like to describe just a few of the Institute's recent research advances and future plans.

Much public, scientific, and media attention has been recently focused on in vitro fertilization, the so-called test tube babies.

While a ban on Federal support of human in vitro fertilization studies remains in effect, animal studies have continued. Currently, in our laboratories at NICHD, we have several monkeys carrying fetuses that are products of in vitro fertilization.

This is the first time that in vitro fertilization has been achieved in subhuman primates. We expect the first birth in approximately 70 days.

These animal models are obviously valuable in the study of causes and treatment of infertility and birth defects.

Last year, I described to this committee a promising advance concerning a group of drugs that resemble naturally occurring hormones called the luteinizing hormone-releasing factor, which is produced by a small gland in the brain called the hypothalamus.

We are testing these drugs in humans this year. A major clinical trial has been started. Previous research on these drugs has indicated their usefulness in treating not only female infertility but also male infertility, while more recent studies have suggested that they would also be effective as contraceptives in both males and females.

Actually, these compounds could constitute a new generation of contraceptives, and eventually replace the oral contraceptives now in use.

I might mention that the use of these drugs as fertility regulators is a direct outcome of the work of two NICHD-supported scientists, Drs. Guillemin and Schally, who won the Nobel Prize in 1977.

NICHD is continuing research on infant nutrition. One research priority is the determination of the daily nutrient requirements of infants who are premature or of low birthrate.

Many clinicians have believed for many years that human milk is the best food for some of these babies. For some of them, it is the only food.

Now NICHD-supported scientists have begun to substantiate these beliefs and have found components in human milk that are essential not only for nutrition, but for normal growth of the intestine and other organs. So far, these components cannot yet be replicated in artificial formulas.

We have been doing a good deal of work on the problem of hypoxia—low levels of oxygen in the blood—in fetuses and newborns.

Low oxygen levels—hypoxia—relate to such conditions as mental retardation and sudden infant deaths. In fact 10 percent of the cases of mental retardation diagnosed in infancy are probably due to hypoxia.

The problems addressed by the NICHD are the most significant and costly health problems of our society because they affect entire lifetimes, family groups, or even whole populations.

These problems, however, are solvable. The answers can be found in research.

The NICHD request is $217,531,000 for fiscal year 1981. I would be delighted to supply any other information.

INFANT MORTALITY

Senator SCHWEIKER. In a few months the Senate Subcommittee on Child and Human Development will be holding hearings on infant mortality.

What have we accomplished in the past 10 years in lowering our Nation's ranking on the infant mortality scale? How has the United States ranked in recent years in this area?

Dr. KRETCHMER. We are constantly improving. When I first came to the NICHD 6 years ago, our ranking was about 16th in the world. Today it is about 12th in the world.

In some ways this ranking is a misimpression because it is the average ranking for the United States, rather than a breakdown for various segments of the population. For example, there is a considerable difference in infant mortality rates for white and nonwhite births.

CHILD ABUSE AND NEGLECT

Senator SCHWEIKER. What roles does your Institute play in research into the causes and effects of child abuse and neglect?

Dr. KRETCHMER. Our Institute does not support research on the overt aspects of child abuse and neglect. Rather, the NICHD concentrates on areas of study related to child development which could be applicable not only to problems of child abuse and neglect but also to many other pathological aspects of child development.

Senator SCHWEIKER. How do you coordinate your activities in this area with the National Institute of Mental Health?

Dr. KRETCHMER. We have a continuing liaison with the National Institute of Mental Health. We have conducted joint scientific conferences and there are some programs we share with the National Institute of Mental Health.

The National Institute of Mental Health is responsible for programs relating to child abuse, and we are responsible for research relating to normal child development.

MENTAL RETARDATION

Senator SCHWEIKER. How much funding does mental retardation receive in your Institute, and how much do you get from other Institutes in this area?

Dr. KRETCHMER. We invest about 20 percent of the total NICHD budget in the general area of mental retardation. That is around $39 to $40 million. This includes basic or fundamental studies relating to mental retardation.

The other Institute within NIH that is involved in mental retardation research is the National Institute of Neurological and Communicative Disorders and Stroke. They contribute about $9 million, so there is a total of about $50 million between the two Institutes.

SUDDEN INFANT DEATH SYNDROME

Senator SCHWEIKER. What is the progress, if any, that you're making on the sudden infant death syndrome?

Dr. KRETCHMER. We are making considerable progress in the area of sudden infant death syndrome. The total amount of money spent now is about $11 million. Last year I reported to this committee that we discovered that the babies stricken by the sudden infant death syndrome are not normal babies to begin with. There is a much higher rate of sudden infant death syndrome among premature infants.

Now we have found that there are particular, very specific defects in the brain stem. We have organized a general statistical survey for sudden infant death syndrome to identify risk factors. One of the risk factors associated with SIDS is hypoxia suffered before birth. The data from this survey are now in and being analyzed and should be ready within the year. We should then be able to determine what risk factors relate to SIDS and, it is hoped, be able to prevent some of these sudden infant deaths.

Senator SCHWEIKER. On SIDS, you also had another study going on about ingestion of honey and its relationship to infant death. Can you tell us about that?

Dr. KRETCHMER. Yes, that is not a large-scale program but a specific investigation. The honey that was implicated was infected with an organism that causes botulism—the same kind of organism that you would have located in or contained in a can that was infected and toxic. In this incident, there was no doubt that the infants who ingested the honey were infected with the botulism organism and died rather suddenly; therefore their deaths were classified in the general terminology of sudden infant death.

But it is not known whether the honey infected with this organism was or is responsible for the sudden infant death syndrome.

[The information follows:]

The NICHD is funding a small study in California, the only place where such incidents were reported, to clarify relationships, if any, between honey, botulism, and SIDS. No findings are yet available.

FUNDING FOR SIDS

Senator SCHWEIKER. What level of funding do we have for SIDS? What are we doing in the budget? What have we done last year for SIDS?

Dr. KRETCHMER. For 1981, it is about $11 to $12 million total. That is a composite figure for primary studies, where SIDS is the main topic, and for research related to SIDS.

Senator SCHWEIKER. I am talking primary SIDS.

Dr. KRETCHMER. That is about $5 million of the $11 million. The increase for 1981 is in the order of about $400,000. I believe that we have a very comprehensive program in the area of SIDS.

RESEARCH PROGRESS IN SIDS

Senator SCHWEIKER. Are we getting an answer? Are we getting near an answer on SIDS?

Dr. KRETCHMER. Yes. When I came here 6 years ago, there were 10,000 SIDS cases in the country. At the present time, we can only account for 6,500 SIDS deaths, and that is considered a high figure.

Senator SCHWEIKER. What's brought that down?

Dr. KRETCHMER. No. 1, I think better prenatal care has contributed to the decrease in the number of deaths from SIDS. As I said before, the SIDS babies often derive from a high-risk situation and are shown not to be normal babies. Therefore, if you manage high-risk pregnancies better, you eventually reduce the number of deaths from SIDS. For that reason, we report primary and secondary SIDS moneys. The secondary moneys are involved with these problems of high risk—not directly related but rather indirectly related to sudden infant deaths.

Senator SCHWEIKER. When will the other study be due that you told us about awhile ago?

Dr. KRETCHMER. We should have the results of the statistical survey of high-risk factors within the year.

Senator SCHWEIKER. Within this calendar year?

Dr. KRETCHMER. Yes.

DIABETIC PREGNANCY AND INFANT MORTALITY

Senator SCHWEIKER. Your statement mentioned progress in reducing perinatal deaths associated with diabetic pregnancies. This is one of the goals of CDC's stated diabetes program.

How does the rate for diabetics compare with nondiabetics now?

Dr. KRETCHMER. The rate for diabetics is still higher than nondiabetics, but the reduction over the past decade has been incredible. The

reduction has been somewhere on the order—I don't remember the exact figures—of about 25 deaths down now to about 4 or 5 or 6. I can supply the exact figures for the record.

Senator SCHWEIKER. If you would.

[The information follows:]

PERINATAL MORTALITY RATES

The mortality rate of infants born to diabetic and insulin-dependent mothers has been reduced from about 20–25 deaths per 100 births to a rate of 6–10 per 100 births. The rate for infants born to nondiabetic mothers is 2–4 per 100 births.

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

POPULATION RESEARCH

Question: According to information provided the Committee, there were $14 million worth of approved but unfunded grants in the area of population research last year. This year, according to the President's Budget request, there will be an increase of $3 million for this research activity. Have you any comments on this relatively low increase in funding for this area of investigation?

Answer: While the increase for Population Research extramural programs is $3,138,000, the increase for grant activities alone is $7,293,000. This increase for grants is offset by reductions of $3,611,000 in contract research and $544,000 in research training.

POPULATION RESEARCH: GRANTS VS. CONTRACTS

Question: Dr. Frederickson, is there a formula for determining what percentage of money goes for grants and what percentage for contracts within any one Institute, such as NICHD?

Answer: The National Institute of Child Health and Human Development does not have a formula for determining what percentage of money goes into grants or contracts. Rather, in developing the budget, we consider where there are significant opportunities for new and important findings, regardless of awarding mechanism. It has become apparent that solutions to special health problems of women, children, families, and populations derive from the inextricable relationship between research in the population sciences and research on the developmental processes in pregnancy and infancy. Thus, funds are allocated to both reproductive biology and developmental biology on the basis of scientific and health priorities, and not according to the mechanism of funding.

Question: Dr. Kretchmer, does this formula lead to problems with respect to NICHD's population research activities, especially in the research on safety and evaluation of contraceptive devices, which we are told tend to be carried out with contracts rather than investigator-initiated grants?

Answer: A problem does arise in the Population Research program, because total Institute funding for contracts is at the commitment base level for FY 1981. Two Population Research activities--contraceptive development and contraceptive evaluation--employ the contract mechanism exclusively. Therefore, overall Institute allocations of funding for contracts result in decreases in these two areas of research.

REPRODUCTIVE SCIENCES

Question: In last year's hearings there was mention of a group of new drugs that resemble a naturally occurring hormone called luteinizing hormone releasing factor. Animal studies have

shown that these drugs can block ovulation in females and possibly inhibit fertility in males as well. In 1980 the Institute was planning to initiate clinical trials using these drugs in both men and women. Is work in this area still on schedule and will these trials be carried out?

Answer: Clinical studies on luteinizing hormone releasing factor (LRF) analogs as potential antifertility agents for both men and women have been initiated and are currently in progress. Two awards for clinical studies were made in FY 1979 and two additional awards are planned in FY 1980. It is anticipated that during the next 2-3 years we should be in a position to know the full clinical potential of these drugs and to make plans for extensive evaluation of their effectiveness.

CONTRACEPTIVES

Question: In the fiscal 1980 hearings you mentioned that animal studies are beginning to show possible adverse effects of vasectomy. What adverse effects have shown up in humans after having undergone vasectomy?

Answer: No adverse effects have been demonstrated thus far in vasectomized men. However, a substantial proportion of animals and men develop an immune response to spermatozoa after vasectomy and this chronic immune stimulation could cause a variety of pathological effects. This possibility is undergoing further study. Disease of the testis and reproductive tract has been demonstrated in rabbits, guinea pigs, and monkeys, and exacerbation of atherosclerosis occurs in vasectomized monkeys. Because of the popularity of the procedure and the potential for a variety of sequelae, long-term follow-up of a large number of vasectomized men is needed as well as specific studies of the possible increased risk of atherosclerotic disease. Such studies are in progress.

Question: Is medical science on the verge of reconsidering this technique as a form of contraception?

Answer: No. Vasectomy continues to enjoy wide acceptance among American men and their physicians because of its convenience, economy, and effectiveness. No adverse effects have been demonstrated in man, and it is quite possible that effects seen in animals may not occur in man.

Question: According to Population Reports, (a publication of the Population Information Program, the John Hopkins University, January 1979), the United States shows a significant decline in the purchase of oral contraceptives according to retail pharmacy sales. The figures were current through the 12 months ending June 1978. Has this decline continued and what conclusions can you draw from it?

Answer: There is as yet no evidence documenting further decline of retail sales of oral contraceptives after June, 1978. The 30 percent sales decline between 1975 and mid-1978 may be due to continuing publicity on the adverse effects of oral contraceptives,

the increasing acceptance of permanent contraceptive methods, and the apparent increase in the use of barrier methods.

Question: Last summer a consumer advocate testified before the Senate Subcommittee on Health and Scientific Research on the issue of a cervical cap. She claimed that this effective and relatively benign form of contraception was not available to U.S. women because no drug company was interested in pursuing FDA approval. Can you comment on the cervical cap, its effectiveness, and its inavailability to U.S. women?

Answer: The cervical cap, although available for a number of years, has not been thoroughly evaluated as a contraceptive method. Because of the scarcity of information, the FDA has labelled the cap as an experimental device. In response to consumer demands for this product, the Center for Population Research of NICHD plans to initiate in FY 1980 clinical trials designed to assess the effectiveness of the cap. Additionally, a request for proposals has been issued for the development of improved versions of the cap, the diaphragm and other barrier methods of contraception.

Question: What new advances have we made in this area since the era of "The Pill"?

Answer: Since the advent of oral contraceptives in the early 1960s, there have been a number of advances made in contraceptive technology. Different versions of "The Pill" with a drastically reduced content of hormonal drugs are available to consumers. The chief aim of the reduction in the drug content has been to improve the margin of safety. In the area of intrauterine devices we have seen the introduction of copper and progesterone releasing devices. There has not been much of a technological advance made in the area of barrier methods of contraception such as diaphragms, condoms, and spermicides.

Numerous new contraceptive methods are currently being studied in both laboratories and clinics. Significant strides have been made toward the development of safer fertility regulating drugs for both men and women. Research is in progress to improve barrier methods of contraception. In the area of natural family planning, data have been provided on the effectiveness of various methods as well as on endocrine and physiological controls which contribute to the successful use of natural family planning.

The next decade will see the introduction of a variety of new family planning methods.

Question: How widely used is "The Pill" today and how serious are the dangers associated with its long term use in young healthy women?

Answer: The most recent survey information indicates that six million married women under 45 years of age were using the pill in 1976. Since then, use of the pill may have fallen somewhat, as suggested by the data showing declining sales.

While thromboembolic disease among young women taking the pill is only rarely seen, serious effects, such as cancer and hypertension, may develop after long-term use. Therefore, continued monitoring and study is essential.

Question: What advances have we made in contraceptive devices for sexually active males?

Answer: Little advance has been made in the development of acceptable contraceptive devices for sexually active males, but NIH has greatly increased its support of basic research on this topic and promising new leads are in sight. Research on reversible vasectomy devices was not successful and was suspended until more basic research has been done. The increased sales of condoms have been essentially the result of increased advertising and display activities, and changing social attitudes, rather than from any technological advance.

FUNDING FOR CONTRACEPTIVE RESEARCH

Question: It has been said that often private industry does not want to invest in contraceptive research because it is costly. When private industry receives support from NIH, the Federal government does not allow the companies to maintain marketing rights.

Last October, the President, in an attempt to stimulate the interest of private industry in research, announced a new patent policy. As I understand it, the President said that companies that developed products under Federal contracts, could have limited patent rights. What is your opinion on such a policy?

Answer: The Administration has proposed legislation which would give ownership of inventions made under Government research performed at educational institutions, small businesses, and non-profit organizations to those organizations. This legislation would also guarantee large businesses an exclusive license in those fields of use they choose to develop for commercial use, where they were the contractor who made the inventions with Government support. This policy would help to clarify the current situation and should stimulate the interaction between private industry and NIH.

FUNDING FOR POPULATION RESEARCH

Question: It is my understanding that population research funded by private foundations has decreased in recent years. Is this true?

Answer: Yes, this funding has shown a downward trend in recent years. The support of population research by the major private organizations in this field (The Ford Foundation, Rockefeller Foundation, and The Population Council) for the last five year period for which data have been provided for the Inventory of Private Agency Population Research, is as follows:

	1974	1975	1976	1977	1978
			(dollars in millions)		
Ford Foundation	7.4	5.2	4.9	6.1	6.4
Rockefeller Foundation	3.7	3.6	4.0	4.2	2.8
Population Council	5.9	4.3	3.9	5.3	4.3
Total	17.0	13.1	12.8	15.6	13.5

Question: What effect has this shrinkage of alternative sources had on the Federal pot of money for population research?

Answer: It has increased the demand and competition for Federal funding of population research.

INFERTILITY RESEARCH

Question: Besides the widely publicized test tube baby, what advances have we made in infertility research in the past five years?

Answer: Besides the widely publicized "test tube baby," one of the most significant recent advances in infertility research is the development of new substances and procedures for the induction of ovulation. Many women are infertile because eggs are not released from their ovaries. Under normal circumstances, a hormone in the body, called Luteinizing Hormone Releasing Hormone or LH-RH, stimulates the pituitary gland to release the hormones that induce ovulation. In the past five years, many new compounds that are similar to LH-RH in chemical structure (analogs) have been synthesized. Some of the LH-RH analogs are as much as 1000 times more potent than natural LH-RH in the induction of ovulation.

In addition to the development of these new and potent compounds, scientists have discovered that they are much more effective in inducing ovulation when they are administered intermittently rather than continuously. The new LH-RH analogs, and new knowledge of the most effective methods for their use, offer the potential to virtually eliminate infertility due to failure of ovulation.

Question: How viable an alternative is in vitro fertilization for our nation's numerous childless couples?

Answer: In vitro fertilization appears to work in humans at least in a handful of well publicized cases. It is also a standard procedure in veterinary practice. If research proves it to be safe and reliable in humans, it will undoubtedly be important to a significant though small proportion of infertile couples.

Question: How costly is it?

Answer: The procedure will be expensive, but we do not have a basis for estimating cost at this time.

Question: What is the status of Federal funding of in vitro fertilization?

Answer: In FY 1979, $1,500,000 was spent by NICHD to support in vitro fertilization studies in animals. Studies in the human being are still proscribed and await the Secretary's decision on the recommendation of the Ethics Advisory Board. .

Question: What sorts of infertility research are you presently funding?

Answer: Most of this research is on the basic mechanisms in reproduction and relates to the control of fertility as well as to the alleviation or cure of infertility. Current grant projects are considered in four categories:

1. Hypothalamic-Hypophyseal-Gonadal Interrelationships: Studies of the control of gonadal function and the development of sperm and ova.

2. Infections: Studies of the role of various infections, bacterial and mycoplasmal, on optimal fertility.

3. Improved Diagnostic Techniques: Studies of improved diagnostic techniques for the determination of the sperm fertilizing ability of infertile men.

4. Other: Studies dealing with changes in sperm membrane, immunological factors, and properties of cervical mucus.

Question: What percentage of the population research pot of money goes to infertility research?

Answer: In fiscal year 1979, $31.1 million were spent on research on reproductive processes. Of this amount, approximately $1.2 million were spent specifically for research on human infertility. The balance was used to support research on infertility in animals (where the use of human subjects would be inappropriate or proscribed), and for research on fertility to gain understanding of the mechanisms, requirements, and conditions for normal reproductive processes.

INFANT MORTALITY

Question: In a few months the Senate Subcommittee on Child and Human Development will be holding hearings on infant mortality. What have we accomplished over the past ten years in lowering our nation's ranking on the infant mortality scale?

Answer: Important advances in diagnosis and management of different stages of fetal and infant life have been responsible for the observed decrease in infant mortality. It has become possible to identify high risk pregnancies throughout gestation, the role played by maternal diseases (diabetes, hypertension, infections), and the effect of adverse intrauterine environment (maternal drugs, alcohol and smoking). Advancing techniques in antenatal diagnosis have allowed improvement in genetic counselling,

prenatal care, and treatment of the newborn. Studies identifying some of the causes for intrauterine growth retardation allow the recognition of infants at risk. New techniques that assess fetal maturity have evolved and are utilized in the management of high risk pregnancies and deliveries.

Question: How does the U.S. rank in infant mortality in 1950, 1960, 1965, 1970, 1977, 1978?

Answer: The U.S. ranks as follows in infant mortality:

Year	U.S. Rank	Rate
1950	NA	29.2/1000 live births
1960	NA	26.0
1965	15th*	24.7
1970	14th*	20.0
1977	12th*	14.1*
1978 (Provisional)	NA	13.6

NA - Not available
* Estimated

Question: Is infant mortality greater in non-white populations when socioeconomic factors are held constant?

Answer: Infant mortality is directly related to low birth weight rather than to socioeconomic status (SES). However, low birth weight is more common in low SES populations. For example, in New York City (1968) infant mortality for blacks was three times higher than that for whites, but the greatest part of the variation disappeared with birth weight adjustment.

MENTAL RETARDATION

Question: What major research accomplishments can you cite in the past five years in the prevention of mental retardation?

Answer: Retardation of Psychosocial Origin--Mental retardation caused by psychosocial deprivation can be prevented by a comprehensive program of education and training for at-risk infants and their families which begins in early infancy and is sustained to school age. Scientists from the University of Wisconsin Mental Retardation Research Center first demonstrated this capability for preventing mental retardation induced by environmental deprivation--the leading cause of mild mental retardation.

The Wisconsin investigators first identified families known to be at risk for producing and rearing mentally retarded children. Infants born into these families were initiated with their families into the experimental program in early infancy. Matched

61-400 O - 80 - 31

controls from other risk families were followed under conditions of the research design. At school age, children in the experimental group functioned at above average intellectual levels, far superior to control children who showed retarded or below average intellectual development.

Lead Poisoning--Concern over the possible health effects of environmental lead pollution intensified in the late 1960's after screening programs for lead unexpectedly uncovered thousands of "asymptomatic" children with blood lead levels that exceeded the upper limits of normal. Studies of the effects of low level lead exposure in children have, in the past, been of limited validity because of small sample size, poor indices of lead exposure, and lack of sensitive outcome measures. Advances on this problem have recently been made by investigators at the Mental Retardation Research Center at the Children's Hospital Medical Center in Boston. The lead concentration in baby teeth has been developed as a useful marker of lead exposure. The investigators found that children with high tooth lead levels did less well on measures of intelligence, attentional and language functions than children with lower levels of lead in their teeth. The investigators concluded that lead exposure, at doses below those producing symptoms severe enough to be diagnosed clinically, appears to be associated with neuropsychologic deficits that may interfere with classroom performance.

Fetal Alcohol Syndrome--Although the harmful effects on the fetus of excessive consumption of alcohol by women during pregnancy has been suspected for several centuries, it has only been within the past few years that scientists have described a distinct pattern of abnormalities in children of alcoholic mothers that they called the fetal alcohol syndrome. Children afflicted with the condition have a composite of defects, including growth deficiency, abnormalities of the face such as short fissures of the eyelids, a flattened elongated vertical groove in the upper lip, small head, and limb and heart malformations. Mental retardation has been noted in 85% of cases and is believed to be due to the direct insult of alcohol to the developing brain and not as a result of faulty child-rearing practice. The incidence of fetal alcohol syndrome is estimated to be between one and two per 1,000 live births, with the incidence of partial expressions at approximately three to five per 1,000 births. To date, the findings suggest that alcohol comsumption during pregnancy, in amounts considered to be "social drinking," has potentially negative effects on the behavioral development of children. Moreover, the combined effects of drinking and cigarette smoking are worse than expected--that is, infants exposed prenatally to both alcohol and nicotine suffer more effects than would be expected from merely adding the effects suffered by alcohol or nicotine separately.

Phenylketonuria (PKU)--Phenylketonuria is a genetic defect of metabolism of phenylalanine, an essential amino acid, in which mental retardation is the most serious manifestation. Phenylalanine, which is present in all natural proteins, accumulates in the blood at abnormally high concentrations in the absence of an enzyme which normally converts it to tyrosine. Damage to the

developing brain almost always results when abnormal concentrations of phenylalanine and other metabolites persist in the blood.

In order to control the levels of phenylalanine within normal limits, a collaborative study was initiated to determine the consequences of a low phenylalanine diet on cognitive, physical, and psychosocial development of children with PKU. The results of a preliminary assessment of the intellectual performance of 111 four-year-old patients with PKU showed an average intelligence quotient (IQ) of 93 for the combined sample. While the mean IQ is seven points below the normative average of 100, this result is encouraging. When compared to untreated PKU patients who are generally severely handicapped, achievement of near-average intelligence following administration of low phenylalanine diet is quite remarkable and the diet is considered to be a valuable addition to medical treatment.

Congenital Hypothyroidism--The role of thyroid hormones in the normal maturation of the brain is particularly significant because of the severity and frequency of neurological symptoms and learning disabilities associated with varying degrees of hypothyroidism. Congenital hypothyroidism occurs about 1 in 6,000 births. Effective treatment in the form of thyroid hormone replacement is readily available. The major problem has been that the diagnostic signs and symptoms of congenital hypothyroidism may develop very slowly over the first 6 to 12 months of life, leading to delayed diagnosis and treatment. Mental and physical development is more permanently impaired the longer the delay in instituting treatment. A significant development has been the establishment of newborn screening programs for congenital hypothyroidism by combining testing for thyroid levels with existing state screening programs for phenylketonuria (PKU) and other metabolic disorders. This combined approach to screening for selected genetic disorders has improved cost-effectiveness and helps guarantee quality control and efficient follow-up.

Question: How much funding does such research receive from: Your Institute? The other Institutes?

Answer: Funding for mental retardation research is as follows:

(Dollars in thousands)

	1980 (est.)	1981 (est.)
NICHD	38,182 1/	39,386 1/
NINCDS	9,100	9,160

1/ Includes an estimated $7,000,000 in research related to mental retardation in addition to the amount identified specifically for this area of research.

CONTRIBUTING FACTORS TO MENTAL RETARDATION

Question: What are the major contributing factors to mental retardation?

Answer: Over 200 causes of mental retardation have been identified. In about 75 percent of diagnosed cases, however, no organic cause for retarded development can be identified. Psychosocial disadvantage and adverse environmental conditions are considered to be the major causes of this kind of mental retardation. Cytogenetic abnormalities such as Down's syndrome, fragile X syndrome, and metabolic disorders such as phenylketonuria are the leading causes of organically based mental retardation. Other major causes of organic mental retardation are prematurity and low birth weight; infections, such as rubella (German measles); rubeola or regular measles; poisoning produced by lead; excessive consumption of alcohol during pregnancy; Rh blood incompatibility between the mother and the baby, brain injury following an accident or during the birth process; and oxygen starvation as a result of difficult or complicated delivery exemplified by premature separation of the placenta.

In a survey carried out among all children with an IQ below 50 who were born in 1958 and were living in the Province of Quebec, Canada, in 1966-1969, the following clinical groups were identified in 63-70 percent of cases (table below). In a 1965 study of 23,443 residents in 19 institutions of the West, the Western Interstate Commission for Higher Education (WICHE) studied the diagnoses made on the residents. The leading causes of mental retardation for this institutionalized population are provided below.

QUEBEC STUDY		WICHE STUDY	
Cause	%	Cause	%
Down's syndrome	23	Structural encephalopathy of unknown cause	12.2
Single recessive gene	21	Down's syndrome	11.4
Postnatal disease	8-11	Congenital cerebral defect	10.4
Postnatal injury	1	Postnatal encephalopathy due to cerebral infection	6.2
Low birth weight	3	Cultural familial (psychosocial) retardation	5.4
Perinatal damage	6-9		
Hyperbilirubinemia	1-2		

Question: What role does nutrition play--nutrition of both the pregnant woman and the young infant--in mental retardation?

Answer: Because of the confounding effects of social and economic factors, it is still not clear whether severe malnutrition during infancy causes intellectual impairment. Results of one study suggest that severe malnutrition in infancy in the context of a lifetime of generally favorable experiences for child development does not appear to cause any intellectual impairment, but when severe malnutrition occurs in a environment which is generally unfavorable for intellectual development, the early

malnutrition has a clear relation to later intellectual impairment.

The effects of milder degrees of malnutrition are even less clear-cut. However, it is generally believed that a good diet during pregnancy and infancy can help reduce the incidence of mental retardation by lessening the incidence of low birth weight infants and improving the mother's general health.

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question: Numerous articles have been published over the past couple of years regarding the correlation between the ingested honey and sudden and unexplained infant death. As I understand it, the deaths which have resulted in these cases have been diagnosed as infant botulism. How prevalent is infant botulism?

Answer: The prevalence of infant botulism for the United States is not currently known, as no national statistics on incidence exist. However, the Center for Disease Control reports that, in 1979, there were 25 cases of infant botulism reported to the Center for Disease Control. There were no deaths among these 25 cases.

Infant botulism, a disease apparently resulting from intraintestinal toxin production by Clostridium botulinum, was first recognized as a distinct clinical entity in late 1976. Botulism is caused by bacteria that produce a very potent nerve poison (or toxin) which prevents the nerves from controlling the body's muscles. Hence, a baby with botulism has muscle weakness throughout its body. Sick babies have difficulty swallowing, sucking, keeping their eyes open, holding their heads up, and moving their arms and legs. Occasionally, a sick infant may have difficulty breathing if the respiratory muscles are severely affected. The toxin also interferes with the muscles of the bowels so many babies have constipation.

Current knowledge indicates that infant botulism is not a new disease, but is only now being recognized. A spectrum in the severity of symptoms has been noted. Some infants show only lethargy, mild weakness, and slowed feeding, while others become acutely ill with obvious feeding difficulty, severe generalized weakness, and hypotonia over a 1-3 day period which, in some cases, progresses to respiratory insufficiency.

Question: What research activities are being carried out in this area?

Answer: The NICHD is currently providing support to the California State Department of Health for a research project entitled "Botulinal Toxin as One Cause of Sudden Infant Death." The objectives of this project are:

1. to determine the proportion of SIDS that is caused by botulinal toxin by examining autopsy specimens from SIDS and non-SIDS deaths for the presence of Clostridium botulinum organisms and toxin,

2. to determine by what route(s) and vehicle(s) spores of Clostridium botulinum reach an infant's gut;

3. to determine what intestinal conditions allow spores to germinate;

4. to determine why only some infants are affected;

5. to define the epidemiology of infant botulism by means of a longitudinal case-control study and to profile the high risk infant; and

6. to develop a new, rapid test to detect Clostridium botulinum organisms and toxin.

In addition, information is also being obtained as part of the NICHD Cooperative Epidemiologic Study of SIDS Risk Factors on the number of SIDS infants in the total sample found on autopsy to have Clostridium botulinum, the type of food ingested by these babies, specifically honey, and the health status of the baby before death in order to determine the possible relationship between the presence of this bacteria and the infant's sudden and unexpected death.

The Center for Disease Control, which maintains a national surveillance system for infant botulism, has several ongoing studies concerning risk factors.

Question: How much money has NICHD expended in primary, secondary and tertiary research in SIDS in fiscal years 1979, 1980, and 1981?

Answer: The breakdown of NICHD funding for SIDS research, including yearly totals, is:

Fiscal Year	Primary	Secondary	Tertiary	Total
1979	$4,912,000	$6,204,000	$8,316,000	$19,432,000
1980 est.	5,375,000	5,825,000	8,400,000	19,600,000
1981 est.	5,500,000	6,100,000	8,700,000	20,300,000

Question: What major achievements have we made over the past 2 years in SIDS research?

Answer: As a result of Institute supported research during the past two years, there has evolved increasing evidence that the victims of SIDS are not completely healthy infants before death, and further that "as a group" these infants are anatomically, histologically, physiologically, and behaviorally different from normal infants. There is documented evidence of postnatal growth retardation, chronic hypoxemia, breathing difficulties, neurological abnormalities, body temperature control problems, a variety of minor illnesses two weeks before death, and behavioral differences as reflected in activity level, cry characteristics, and feeding patterns. This represents a significant change in our understanding of SIDS, since just a few

years ago SIDS babies were assumed to be in no way abnormal before death. However, although differences between groups of infants have been described, no single predictive or diagnostic criterion exists to identify accurately the infant destined to become a SIDS victim or to identify SIDS-specific lesions at autopsy.

The NICHD Cooperative Epidemiologic Study of SIDS Risk Factors, begun in FY 1978, is progressing satisfactorily. Entry of cases into the study was completed December 31, 1979, following 15 months of acquisition of a study population of approximately 840 SIDS cases and 1,680 control cases.

During FY 1979, a number of infants in Tennessee died suddenly and unexpectedly within 24 hours following innoculation with a specific lot of diphtheria-tetanus-pertussis (DPT) vaccine. These deaths were attributed to SIDS. Data from the NICHD Cooperative Epidemiologic Study of SIDS Risk Factors specifically concerned with the occurrence of DPT vaccination and SIDS was invaluable in allowing the Center for Disease Control and the Bureau of Biologics, Food and Drug Administration, to analyze the frequency data reported by the health authorities in Tennessee. There was no evidence from the data available of a positive correlation between DPT vaccination and SIDS, but surveillance for a possible association continues.

The National Institute of Neurological and Communicative Disorders and Stroke's Collaborative Perinatal Study, a prospective study following more than 59,000 pregnancies, revealed that future SIDS victims showed evidence of neonatal brain dysfunction and a variety of neurological defects, with abnormalities in respiration, feeding, and temperature regulation. These infants also were mildly underweight for gestational age and showed other evidence of growth retardation. The frequency of smoking was greater among the mothers of SIDS victims in contrast to the other pregnant women in the sample. Mothers of the SIDS victims also had a greater incidence of amniotic fluid infection, anemia, and proteinuria. The data obtained provided supportive evidence for a primary relationship between pregnancy events, neonatal health status, and SIDS.

For some SIDS victims, there is documented evidence that while the mother's pregnancy was uneventful, the health condition of the infant during the early weeks of life was high-risk. For example, the infant might have been born prematurely or of low-birth-weight and needed a longer period of hospitalization following birth, had breathing difficulties or respiratory distress syndrome and required oxygen, or had problems in temperature regulation and needed a warmed environment.

When the factors capable of modifying the pattern of maturation of the fetus and newborn infant, or those curtailing the "adaptability margin" to stress of vital physiological functions are understood, uncovering the mechanisms responsible for SIDS should be possible and, in turn, the development of appropriate strategies for the prevention of some SIDS cases could be undertaken.

Question: How does NICHD coordinate activites with the Health Services Administration in providing to the public information on SIDS?

Answer: An important consideration in carrying out the NICHD research program pertaining to the sudden infant death syndrome is how new knowledge obtained will become incorporated into the health care delivery system. A natural conduit at the Federal level exists in the cooperative and collaborative relationship that has existed since 1973 between the National Institute of Child Health and Human Development and the Office of Maternal and Child Health, Health Services Administration. Staff of the NICHD report annually to staff members of the SIDS Program in the Office of Maternal and Child Health, and also to the operating personnel of the SIDS Counseling and Information Centers at its national meetings providing them with information about the latest research advances pertaining to SIDS. Similarly, staff of the Office of Maternal and Child Health participate in SIDS Research Planning Workshops and other planning sessions of the NICHD and work closely with Institute staff on the preparation and exchange of SIDS information documents.

Data obtained under the auspices of the NICHD Cooperative Epidemiologic Study of SIDS Risk Factors should improve our ability to identify infants at risk for SIDS and may provide new clues to effective preventive approaches. Results from this NICHD study will be shared with the Office of Maternal and Child Health and personnel of the SIDS Counseling and Information Centers, as well as with staff of State Health Departments, practicing physicians, and visiting nurses.

The NICHD makes new information about SIDS available to practicing physicians through summaries in medical periodicals such as the Pediatric Annuals and the Journal of the American Medical Association. The NICHD also supports, in collaboration with national organizations of medical practitioners, such as the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, reports of research findings and their implications for clinical practice. For example, a symposium entitled, "Physiological and Developmental Factors Associated with Risk for the Sudden Infant Death Syndrome" was jointly supported by the NICHD and the American Academy of Pediatrics during the 1979 annual meeting of the Academy. In addition, a workshop on "Near-Miss SIDS Infants" was jointly sponsored by the NICHD and the Association for the Psychophysiological Study of Sleep. The Office of Maternal and Child Health is kept informed of these efforts and is invited to participate.

GENETIC COUNSELING

Question: Does NICHD have any coordinated programs in the area of genetic counseling with other Institutes? (e.g. liaison with the NINCDS for Huntington's disease counseling?)

Answer: Staff of NICHD keep abreast of the area of genetic counseling by attending open forums on genetic diseases such as those given by the Food and Drug Administration on neural tube

defects. Staff also meets regularly with staff of the NINCDS to discuss overlap areas related to genetic diseases and congenital defects.

The NICHD currently supports two projects on genetic counseling. A project at the Eunice Kennedy Shriver Center for Mental Retardation in Waltham, Massachusetts provides testing and subsequent counseling for individuals and couples found to be carriers of Tay-Sachs disease. Antenatal diagnosis of possible hemophilia carriers is done through the second project supported at the University of North Carolina.

Question: A contract was awarded by the Health Services Administration to plan and establish a center or clearinghouse for human genetics. What has been the outcome of this contract award?

Answer: A Clearinghouse for Human Genetics has been developed under the auspices of the Health Services Administration. The Office of Research Reporting, NICHD, has furnished the Clearinghouse with documents on genetic diseases and will continue to provide new and updated documents as developed. Additionally, the NICHD has frequent and continuing contacts with the Bureau of Community Health Services of the Health Services Administration which supports genetic counseling and education activities throughout the nation.

BEHAVIORAL SCIENCES

Question: Last year, in the area of behavioral science, Dr. Kretchmer expressed concern over the lack of behavioral scientists at high, administrative levels. What have you done to remedy this situation, and have you experienced recruitment problems over the past year?

Answer: We have made several steps to remedy the lack of behavioral scientists at high administrative levels of the Institute. Most importantly, Dr. Betty H. Pickett, an experimental psychologist, has been appointed as the Deputy Director, NICHD. Dr. Pickett, who has extensive experience at the National Institute of Mental Health and the National Institutes of Health, has an important role in the management, organization, and program development of the Institute.

Another key appointment was the hiring of Mr. Philip Sapir as Chief of the Human Learning and Behavior Branch and Special Assistant to the Director for behavioral sciences and mental retardation. Mr. Sapir, former President of the Grant Foundation, has broad experience in government, university, and private programs for support of behavioral sciences research. Within the Human Learning and Behavior Branch, we have expanded the staff to include Dr. Phyllis Berman, a psychologist from Florida State University, who has principal responsibility for developing research activities in the areas of clinical and physiological psychology.

In the Center for Population Research, Dr. Wendy Baldwin, a

demographer, has been promoted to the position of Chief of the newly established Social and Behavioral Sciences Branch. Both this Branch and the Human Learning and Behavior Branch are staffed entirely by behavioral scientists.

In addition, the Institute's major policy advisory body, the National Advisory Child Health and Human Development Council, now counts five behavioral scientists among its fourteen members. The NICHD technical grant review committees, which are influential in shaping programs, include ten behavioral scientists among their membership.

Recruitment problems in this area have been the length of time required to recruit new people from outside the civil service, the difficulty in attracting scientists who have demonstrated managerial skills, and the difficulty in attracting minority candidates. These problems are being given special attention in our current efforts to fill a vacant position in the mental retardation research program.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: If we were not constrained by budget limitations, RESEARCH TRAINING in maternal and child health and the population sciences would be restored to the FY 1978 level. Also, clinical investigator awards in perinatology, obstetrics, and gynecology, pediatrics and reproductive biology would be supported in order to maintain a steady influx of future researchers in these critical areas.

Increased funding would also be directed toward expanding research in CONTRACEPTIVE DEVELOPMENT including the synthesis of antifertility drugs for men and women together with biological testing and safety studies. Applied research would be supported to expand clinical trials of drug delivery systems, long-acting injectable contraceptives, and new oral formulations. Investigations would be supported on new barrier methods of contraception and on prostaglandins as luteolytic agents. Initial clinical evaluation of a method to predict ovulation for use in natural family planning would be undertaken.

We would also undertake a new research initiative in CONTRACEPTIVE EVALUATION, to identify forms of oral contraceptives that might best be used by adolescents, such as the progestin-only pill (mini-pill) or very low dose estrogen combination preparations. A study is also planned that will specifically focus on cardiovascular risks for vasectomized males. Cardiovascular complications for the female would receive attention through studies to determine more specifically the age dependence of known cardiovascular and other adverse effects of contraceptive steroids.

Epidemiologic studies of BREAST FEEDING AND ADOLESCENT PREGNANCY would be undertaken with additional funds.

Support would be provided for four new multidisciplinary MAJOR RESEARCH PROGRAMS (MRPs)--focusing on perinatal medicine, high risk pregnancy including diabetes and maternal-infant nutrition--bringing the total to the originally planned network of twelve MRPs. Funds would also be used to institute a clinical nutrition core in each of these projects.

Additional funding would be used to expand our intramural research program in FERTILITY/INFERTILITY with special emphasis on in vitro fertilization studies in nonhuman primates. Recent success in this area requires study of the technique in a systematic, detailed manner, and suggests an alternate approach which bypasses the block causing infertility and allows normal fertilization. These new findings portend a major breakthrough in the treatment of infertility in women.

Multidisciplinary research is planned on MATERNAL SMOKING and the physiological consequences for both the mother and fetus. Studies on the effects of oxygen deprivation on brain development would be expanded to include factors such as the use of vasoconstrictive drugs by the mother and other elements encountered in the environment. Investigations on PREMATURITY AND LOW BIRTH WEIGHT would focus on maternal-fetal-placental interactions to identify factors that may be controlled through cooperative pregnancy management practices.

Research would continue on the underlying gene-controlled cellular and molecular processes that contribute to CONGENITAL DEFECTS and would include environmental and cultural factors. Emphasis would be placed on basic genetic studies, such as those that use recombinant DNA technology to isolate and amplify certain human genes. The underlying causes of neonatal dwarfism or short-limbed syndromes would be explored through clinical assessment, morphologic studies of skeletal abnormalities, and biochemical evaluations of normal and abnormal cartilage. Investigations of a lethal immunodeficiency disease, severe combined immune deficiency, would be pursued. A new important initiative is planned to develop animal models that mimic various common congenital defects in humans.

Studies on SUDDEN INFANT DEATH SYNDROME would focus on the refinement of design and testing of the monitor that would permit research on prolonged sleep apnea in infants who may be at high risk for SIDS. New behavioral research is planned to explore possible changes in relationships between mothers and infants, within families, and among siblings where an infant at risk for SIDS has been identified.

A major effort in nutrition research would be initiated on infantile diarrhea and malabsorption syndromes through studies on the maturation of cellular organization and transport functions of the infantile gastrointestinal lining. An important research priority therefore is to ascertain daily nutrient requirements and tolerances in infants of different stages of prematurity for both enteral and parenteral feeding. Behavioral and social science research is planned to support studies on aspects of weight gain during pregnancy, infantile obesity, and cerebral

control of food intake.

Major emphasis in the human learning and behavior program would be given to research on CHILDHOOD ANTECEDENTS TO ADULT ILLNESS through studies on maternal-infant relationships and family life styles. Investigations would be encouraged that examine the attachment and bonding processes that take place between mother and child immediately following delivery and the effects of this phenomenon or its absence on late psychosocial development. A major contract program on evaluation of brain function associated with information processing in reading disabled children would attempt to construct and evaluate a neuropsychological test battery that can be utilized at the preschool level to identify children predisposed to READING PROBLEMS.

Within MENTAL RETARDATION, high priority would be given to the continuing program of genetic research on trisomy 21 (Down's syndrome) with emphasis on paternal contribution to this disorder. Epidemiologic studies are planned to focus upon the contribution of social and other agents to the etiology and correction of mental retardation. In addition to studies of social agents, investigations would be initiated to identify other environmental factors that have a causative relationship to mental retardation such as intrafamily relationships.

New initiatives are planned to expand and continue research on HUMAN INFERTILITY. Studies would be supported in all areas of biomedicine concerned with infertility of the human couple with emphasis on 1) evaluation of current therapy for infertility, 2) identification of male, female, and couple factors associated with infertility, and 3) development of knowledge that may improve diagnostic and therapeutic techniques for infertility. Research activities would be increased on fertilization of the egg by the sperm and its subsequent development and transport to the uterus. Additional studies would be supported to examine the interrelationships of nutrition and reproduction including menarche, menopause, menses, the development of sperm, and fertility. The relationship of nutrition and breast feeding practices on the length of postpartum amenorrhea and subsequent fertility would also be investigated.

A substantial effort is planned in the social and behavioral sciences within population research to expand research on changes in the structure of the American family as these affect PATTERNS OF FERTILITY and the well being of children. New emphasis would be given to social and interpersonal factors that lead to early sexual behavior and affect contraceptive usage. Special problems of adolescent contraception and the psychosocial acceptability and effects of various methods of contraception would be examined.

CHILD HEALTH BUILDING

Question: Over the past few years there has been a great deal of discussion regarding the consolidation of the NICHD Intramural Research Program under one roof. Is there any remaining commitment towards construction of a Child Health Research building?

Answer: The NICHD continues to be committed toward construction of Building 33. A new building offers several advantages:

1. It creates a better opportunity for scientific exchange by providing a better working arrangement which fosters cooperation and coordination.

2. It may lead to efficiency in terms of planned facilities and equipment.

3. It may be attractive in recruiting scientists.

However, these advantages must be considered in light of competing construction programs both at NIH and the Department as a whole.

FUNDING BREAKDOWN

Question: In your professional scientific judgement, are you pleased with your funding breakdowns?

Answer: In principle, I support the stabilization of research project grants because I recognize the importance of maintaining the science base. As I noted in your previous question, if resources were unlimited, I would favor funding above the commitment level for contract programs and research training programs.

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

STATEMENT OF DR. G. DONALD WHEDON, DIRECTOR

BUDGET REQUEST

Senator SCHWEIKER. We will proceed now to NIAMDD and, Dr. Whedon, we will ask you to insert your statement in the record and go through with your highlighting, your overview of NIAMDD.

[The statement follows:]

STATEMENT OF DR. G. DONALD WHEDON

I appreciate the opportunity to report on the research programs of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) and to testify to their needs for fiscal year 1981. Institute responsibilities cover a wide range of chronic diseases that affect people of all ages and sexes, all ethnic groups and strata of society, including arthritis and connective tissue diseases; skin diseases such as psoriasis; diseases of bone and the musculoskeletal system; diabetes, cystic fibrosis and other metabolic and endocrine disorders; digestive and nutritional disorders; diseases of the kidney, urinary tract and blood.

Reports to the Congress of the respective national commissions on diabetes, arthritis and, more recently, digestive diseases, have testified to the magnitude and severity of these chronic diseases. As the U.S. population ages, and life expectancy continues to improve, the number of people with chronic illnesses will continue to increase, as will the pressures for intensified research efforts and more effective medical care. If we are ever to alleviate, or better yet, to eliminate, the disability and suffering exacted by these diseases, we must pursue new knowledge about their causes and improve methods of treatment.

I would like to describe the ways in which this Institute is meeting its responsibilities to the American people, and to give you a brief overview of research that is planned for the coming year.

Arthritis and Related Musculoskeletal Diseases

Over 31 million people in this country suffer from the pain and disability associated with arthritis and related diseases of the musculoskeletal system.

One of the most exciting advances in arthritis research has been the discovery in cellular proteins of genetic "markers" for certain types of arthritis. Recent studies of antigens in the HLA-D locus of the pertinent gene have demonstrated significant associations with rheumatoid arthritis, systemic lupus erythematosus (SLE), Sjogren's syndrome, patterns of psoriatic arthritis, and with risk factors for drug toxicity in rheumatoid arthritis patients. The significance of these associations is that more effective use may be made of protective therapies by applying them to individuals identified as at risk for various forms of arthritis by these HLA proteins.

Recent research has provided promising evidence that certain forms of arthritis may be caused by infectious agents. Lyme arthritis, a new disease transmitted by a tick bite, has now been shown to produce in some patients a chronic joint disease, resembling rheumatoid arthritis, and research from several laboratories has implicated a causal role for EB virus in rheumatoid arthritis, and for certain strains of bacteria, Klebsiella and Shigella, in two forms of arthritis of the spine.

Osteoarthritis, or degenerative joint disease, afflicts some 16 million people in the United States. As this committee knows, development of the artificial joints has restored mobility to thousands of Americans. We are capitalizing on this major advance by finding ways to eliminate some serious technical problems, particularly implant failure at the point of fixation. Animal studies have shown the value of electrically stimulating bone so that it will grow into the prosthesis. Also, two high-strength alloys have been found to be candidates to replace the stainless steel and cobalt chrome currently used for the metal part of joint implants and so may be useful in reducing the incidence of stem fracture in the total hip prosthesis.

In our dermatology program we plan to continue the long-term clinical trials of PUVA, a treatment for psoriasis that combines an oral medication with exposure of the skin to ultraviolet light, to determine the possible risks of and proper selection of patients for this highly effective but experimental treatment.

As requested, we have completed a two-year analysis of priorities and needs for research in dermatology, carried out by a task force headed by Dr. George Odland, head of Dermatology at the University of Washington School of Medicine. We expect that the Odland Report will stimulate a substantial increase in applications for research in skin diseases such as psoriasis, acne, and atopic dermatitis.

Diabetes and Other Metabolic Diseases

The infusion of increased research dollars has helped open the way to several exciting leads in diabetes etiology and management. Scientists have shown that insulin-producing pancreatic beta cells grown in tissue culture can be infected and damaged by several common viruses. Further studies of the association of genetic factors and viral infection could lead eventually to prevention in genetically susceptible individuals.

Other research advances relate to vastly increased knowledge concerning insulin receptors on body cell surfaces and mechanisms of insulin action. The most intriguing prospect on the distant horizon of diabetes treatment is transplantation of islet cells into human diabetics, but a vast extension of knowledge of immunology and of factors affecting tissue transplant acceptance must come first.

Fiscal year 1981 funds will also enable NIAMDD to capitalize on the significant progress that has been made in the development of artificial devices to administer automatically insulin at programmed intervals. Although promising, a great number of technical problems remain to be solved before an artificial device will be available outside the research setting.

Results of a Congressionally-mandated evaluation of research needs in endocrinology and metabolic diseases, headed by Dr. Sidney Ingbar of Harvard University, will serve as a basis for program activities, including research on production of peptide hormones through recombinant DNA techniques.

In cystic fibrosis (CF), recommendations of a 1978 report to the Congress will continue to guide research directions. Efforts are being made to develop prenatal diagnosis of CF, and to improve methods of identifying the one in 20 Americans who can pass the CF gene to the next generation.

Digestive Diseases and Nutrition

During the hearings of the National Commission on Digestive Diseases, it became apparent that patients, their families and the public wanted to know more about digestive diseases and their treatment. NIAMDD will establish a National Digestive Disease Education and Information Clearinghouse to help in providing such information.

Some 500,000 gallbladder operations are carried out in the United States each year at a cost of more than 1 billion dollars. NIAMDD is supporting a study of the dissolution of cholesterol gallstones through the oral administration of chenodeoxycholic acid, as an alternative to surgery. Since 20 percent of gallstones are formed mainly from pigment, we are

61-400 O - 80 - 32

also studying these stones and their formation with the hope of developing a medical treatment and preventive measures for them.

Cirrhosis of the liver is the sixth leading cause of death in the United States. Promising studies are being made on ways of either preventing the formation of scar tissue in the liver or of causing it to absorb or dissolve, a potentially valuable treatment since scar tissue is a cause of the serious complications, bleeding and ascites, that can lead to death from cirrhosis.

Hemorrhage from the upper gastrointestinal tract causes several thousand deaths a year. We are now supporting the development of techniques for stopping some hemorrhages through the gastroscope and thus avoiding surgery in patients who are dangerously ill.

Substantial gaps exist in our knowledge of nutrition, especially in the relationship between diet and certain chronic diseases. These gaps will receive continued research emphasis, as will also obesity, trace element nutrition, dietary fiber, and supportive nutrition for hospitalized patients.

To increase nutrition research in medical schools and to involve a larger number of investigators in medical training in nutrition, NIAMDD, during this past year, initiated a new program, shared with other institutes, for the establishment of Clinical Nutrition Research Units (CNRUs), as focal points for clinical nutrition research and teaching in qualified medical institutions.

Kidney and Urologic Disease

Kidney diseases, including glomerulonephritis and nephrosis, kill about 48,000 Americans each year. Dialysis and kidney transplants do, however, save the lives of 9,500 new patients each year. NIAMDD will continue to support studies to lessen the many problems that can arise during the course of dialysis treatment. Promising developments in the area of continuous ambulatory peritoneal dialysis (CAPD) will be supported so that this relatively simple form of therapy may become a viable alternative to hemodialysis.

Urinary tract infections, obstructive uropathy, and kidney stones are major causes of disability that affect at least 12 million people annually in the United States and are responsible for about 20 percent of the deaths from kidney and urinary tract diseases. The Institute will continue to support research into these and other disorders of the urinary tract, through specialized centers of research and regular research grants. One area of emphasis will be study of benign prostatic hyperplasia (BPH), a major medical problem which affects more than 50 percent of men by age 50, exploring the role of steroid hormones in its development.

Hematology

The often fatal consequence of repeated blood transfusion, the only known therapy for Cooley's anemia victims, is the accumulation of iron deposits in vital organs. Chemists now consider that a safe, effective agent to remove this excess iron could be developed with present technology. Support of research into this and other forms of anemia and other disorders of blood cells will be continued during the next fiscal year.

Intramural Research

The Institute's intramural activities provide many examples of outstanding research in basic and clinical sciences. These investigations, with emphasis on fundamental research, are continuing to broaden the foundations

upon which advances in medicine are built, and in 300 research projects conducted mainly in facilities in Bethesda, Maryland have paid rich dividends in research advances throughout the years. For instance, scientists in our intramural Diabetes Branch, led by Dr. Jesse Roth, have opened up a broad new front in diabetes research by discovering specialized "receptors" on the surface of a wide variety of cells in the body which attract and hold insulin and facilitate its effect. These findings are of fundamental importance to the entire field of endocrinology and are likely to lead to major advances in our knowledge concerning the role of hormones in health and disease. Recently, Dr. Roth received the first Lita Annenberg Hazen Award for superior achievement in clinical research, an award designed to call attention to the value of clinical research in improving the health of Americans.

The Chief of the Laboratory of Chemical Biology, Dr. Christian B. Anfinsen, who was awarded the 1972 Nobel Prize in chemistry, now is a leader in the characterization of Interferon, a highly-publicized potential agent against viruses and cancer. Produced by the human body, Interferon is extremely difficult and costly to acquire. While several laboratories are working on production of this rare and extremely important compound, Dr. Anfinsen and his colleagues, in synthesizing the first 25 amino acids of the Interferon molecule, have introduced methods which will ultimately lead to its production in the degree of purity essential for effective biological and clinical action.

Our new laboratory of Genetics and Biochemistry, led by Dr. Elizabeth Neufeld, is developing an effective therapy for victims of a group of genetic diseases known as mucopolysaccharide storage disorders, in which lack of a key enzyme can transform a seemingly normal infant into a mentally retarded, physically deformed individual. Dr. Neufeld's discovery that only a fraction of the normal enzyme level is required to correct excessive accumulation of mucopolysaccharides means that future attempts at replacing missing enzymes in these diseases might be beneficial even if only low levels are achieved.

In the Arthritis and Rheumatism Branch, we plan to continue a promising pilot project that is evaluating lymphapheresis for rheumatoid arthritis. This process removes certain white blood cells (lymphocytes) that play a major role in the body's immune and inflammatory response. Removal of lymphocytes by this process may reduce the inflammation of joint and other tissues.

In conclusion, Mr. Chairman and Members of the Committee, the budget request for the Institute is $365,711,000, an increase of $23,772,000. I shall be glad to answer questions at this time.

OPENING REMARKS

Dr. WHEDON. I appreciate the opportunity to report on research programs for the National Institute of Arthritis, Metabolism, and Digestive Diseases and to testify to their needs for fiscal year 1981. This Institute's responsibilities, as I am sure you are aware, cover a very wide range of common and important chronic diseases including arthritis, bone and skin diseases, metabolic and endocrine disorders including diabetes and cystic fibrosis, digestive diseases, nutritional disorders, and diseases of the kidney and the urinary tract, and of the blood.

Reports to the Congress of national commissions on diabetes, arthritis, and, more recently, digestive diseases have testified to the magnitude and severity of these diseases.

One of the most exciting advances in arthritis research relate to the discovery of genetic markers in body tissues for a number of common types of arthritis. The significance of the association between heredity and a proclivity for specific types of arthritis is the potential for more effective use of protective therapies by applying them to individuals identified as at risk for the various forms of arthritis by these so-called HLA genetic markers.

Recent research has also shown that certain forms of arthritis may be caused by infectious agents—both viruses and certain strains of bacteria.

Osteoarthritis or degenerative joint disease afflicts some 16 million people in the United States. Development of artificial joints has restored mobility and provided pain relief to thousands of Americans. We are working on ways to eliminate technical problems and improve methods and materials.

In dermatology, we have completed an important study providing a fresh analysis of the state of the art and needs and priorities for research. We expect that this study will stimulate a substantial increase in applications for research in skin diseases such as psoriasis, acne, and atopic dermatitis.

In diabetes, the infusion of research dollars has opened the way to several exciting leads. Insulin-producing cells in tissue culture, in experimental animals—and in the first reported and substantiated case in man—can be infected and damaged by certain common viruses. Further studies of the association of genetic factors and viral infection could lead eventually to prevention of genetically susceptible individuals.

Other diabetes research relates to knowledge about insulin receptors on body cell surfaces in health and in diabetes and mechanisms of insulin action. The most intriguing prospect on the distant horizon of diabetes treatment is the, as yet tenuous, possibility of transplantation of insulin-producing cells into human diabetics. We intend to capitalize on the significant progress that is being made in the development of artificial devices for automatic administration of insulin at programed intervals.

In cystic fibrosis, we shall be making efforts to develop prenatal diagnosis for the identification of carriers.

In the area of digestive diseases and nutrition, cirrhosis of the liver is the sixth leading cause of death from disease in the United States. Promising studies are being made on ways of either preventing the formation of scar tissue in the liver or of causing it to absorb or dissolve, a potentially valuable treatment since scar tissue in the liver is the cause of serious complications, bleeding, and ascites that can lead to death from cirrhosis.

To increase nutrition research in medical schools and to involve a larger number of investigators in medical training in nutrition, NIAMDD initiated a new program shared with other Institutes for the establishment of clinical nutrition centers.

Kidney diseases kill about 48,000 Americans each year. Dialysis and kidney transplants do, however, save the lives of 9,500 new patients each year. NIAMDD will continue to support studies directed at preventing kidney failure as well as lessening the many problems that can

arise during the course of dialysis treatment or are related to kidney transplantation.

The Institute will continue to support research into stones and other disorders of the urinary tract through specialized centers of research and through regular research grants. One area of emphasis will be the study of benign prostatic hyperplasia, a major medical problem which affects more than 50 percent of men by age 50.

The Institute's intramural investigations, with emphasis on fundamental research, are continuing to broaden the foundations upon which advances in medicine are built. In 300 research projects, conducted mainly at Bethesda—they have paid rich dividends in research advances throughout the year.

Scientists in our intramural diabetes branch led by Dr. Jesse Roth have opened up a broad new front in diabetes research by discovering receptors on the surface of a wide variety of cells in the body which attract and hold insulin and facilitate its metabolic actions.

Recently Dr. Roth received the Lita Annenberg Hazen Award for superior achievement in clinical research, which is designed to call attention to the value of clinical investigation for improving the health of Americans.

Dr. Christian Anfinsen, who was awarded the 1972 Nobel Prize in chemistry, now is the leader in the characterization of interferon, a highly publicized potential agent against viruses and cancer. Produced by the human body, interferon is extremely difficult and costly to acquire. Dr. Anfinsen and his colleagues, in identifying and synthesizing the first 25 amino acids of the interferon molecule, have introduced methods which will ultimately lead to its production in the degree of purity essential for effective biological and clinical action.

Mr. Chairman, the budget request of the Institute is $365,711,000, an increase of $23,772,000.

I would be happy to answer questions.

JUVENILE ARTHRITIS

Senator SCHWEIKER. The administration treated your Institute with benign neglect on the budget. Dr. Whedon, last year the committee expressed strong interest in the arthritis center's programs that are especially suited to meet the needs of children afflicted with arthritis.

What can you report to us on the progress against juvenile arthritis and on programs to aid its victims?

Dr. WHEDON. Currently we have 24 multipurpose arthritis centers active. I recently reviewed the reports of those centers and their work. Seven of the 24, or roughly one-fourth, have a major set of projects involving the study of juvenile rheumatoid arthritis. I cannot report to you specific progress, but I can communicate to you the level of effort that is going on with regard to this.

ARTHRITIS QUACKERY

Senator SCHWEIKER. Is there still a great deal of quackery and gross misinformation, or has this pretty much been sifted out by the progress that we have made?

Dr. WHEDON. Just when we think it has been put to rest, something new comes along. That is the problem of quackery—new bizarre suggestions come along, or old strange ideas are resurrected. I think this indicates that we have to do quite a bit more in terms of public education. That, of course, is one of the aims of the multipurpose arthritis center program.

ARTHRITIS DRUGS

Senator SCHWEIKER. If you watch the TV ads, you get the impression that the best answer to arthritis today is aspirin or some similar drug.

My question to you is, Is that still true? Is that not an accurate commercial presentation, or where do we stand in that respect?

Dr. WHEDON. In the treatment of arthritis, particularly of rheumatoid arthritis, which affects 6 to 7 million Americans in its severely crippling form, we have an armamentarium of drugs and procedures. Certainly the first method of attack that is used involves the anti-inflammatory drugs, of which aspirin is the leader.

There have been a number of drugs like aspirin which have been brought on the market in recent years. They have essentially the same analgesic anti-inflammatory action, but fewer side effects.

The physician who is particularly skilled in treating arthritis goes on from there to the use of other compounds. There are some agents which on a long-term basis can apparently bring about a remission of rheumatoid arthritis, such as gold, which is the oldest of this group of drugs.

Senator SCHWEIKER. And a lot of other stuff right now, too. [Laughter.]

Dr. WHEDON. Penicillamine is a drug that was suggested for the treatment of arthritis some years ago and through studies done in England interest in this compound was reawakened; in recent studies which we are supporting it appears to be reasonably effective.

I am sure you know about cortisone. It can be very dramatic in its effect on inflammatory, chronic arthritis cases. It has certain side effects, which are very serious. And one does not prescribe cortisone except in acute and serious circumstances when some rather dramatic help is needed.

I could go on to several other groups of compounds, the immunosuppressive drugs and some new approaches, such as giving gold orally. But we are involved in a coordination of this whole therapeutic drug program through a contract which we have with the University of Utah which really coordinates the cooperative efforts of many different research centers in evaluation of attacks on rheumatoid arthritis and other diseases through the means of these various drugs I have described.

BRITTLE BONE DISEASE

Senator SCHWEIKER. Are we making any progress in brittle bone disease?

Dr. WHEDON. The answer to that question, Mr. Chairman, has to be quite hesitant. It is a disorder about which we know something in general. There is a defect in the cartilage, and probably more specifically in

the connective tissue protein, collagen, of the bone. It is an inherited defect. We are supporting a number of studies which are beginning to characterize this sort of defect, but it is not clear yet just what it is.

There are differences in the rates of formation of the collagen in bone which lead to abnormalities, different forms of the disease, different amounts of collagen made, different kinds of collagen, different cross-linking of the molecules of the various forms. This is all going to take some time to work out.

KIDNEY DISEASE

Senator SCHWEIKER. Presently the Federal Government is spending $1.3 billion in fiscal year 1980 through the medicare end-stage renal disease service program and only about $38 million in research in renal disease. Given the state of the art in kidney research, how successful would we be in achieving a decrease in this $1.3 billion program if we spend more money in research in renal disease?

I might say, for the record, that the $1.3 billion serves about 62,000 people. It is probably one of the highest cost programs that we have per capita, although that doesn't say it isn't worthwhile. My point is there ought to be a potential for an awful lot of savings if we had any significant research breakthroughs.

Dr. WHEDON. The thrust of your question is very clear. We feel very strongly that continued support of rather fundamental research in this area is extremely important. Nephritis is a form of kidney disease which causes much of the kidney failure we see and about which we have accumulated some knowledge, in fact, a significant amount over the years. I think we really ought to attack that more forceably.

If we are successful in preventing the development of chronic renal disease, we obviously ought to be able to cut the costs of treatment of kidney failure.

Senator SCHWEIKER. I think we ought to look at our grant program in that area. When you start spending this amount of money, a little more money here in certain areas might be an awfully good investment in terms of bringing down the cost impact of the problems we haven't solved yet.

Dr. WHEDON. We have a clear idea of ways that we can go. I think that we have many investigators who would like to put greater effort in this direction.

JUVENILE-ONSET DIABETES

Senator SCHWEIKER. Viral triggers of juvenile-onset diabetes have been suspected for several years. And in May 1979 there was great excitement over the isolation of a Coxsackie B–4 virus that had caused the death of a 10-year-old boy from juvenile diabetes.

Can you bring us up to date on this research and tell us whether such findings indicate the likelihood of one day developing a vaccine that could protect people who are susceptible to insulin-dependent diabetes?

Dr. WHEDON. We are not yet at what I would call a stage of rapid progress in this direction, but nevertheless it is a very viable theory to which we are giving substantial support.

Senator SCHWEIKER. We isolated the virus, so isn't it a little bit more than theory; or did I misstate the scientific significance?

Dr. WHEDON. No; not at all. And, in addition, we also have the situation of this newly reported young patient with very severe insulin-dependent diabetes, from whom they were able to isolate a virus after death which was injected into an animal and caused diabetes in the animal. The situation is complex because these viruses have different strains which are either not very common or else, if common, do not cause diabetes primarily, but other diseases.

The way in which they bring about the disorder is not clear. Furthermore, there is apparently a great difference in susceptibility of individuals to infection by these various agents. The answers are likely to evolve through the process of genetic characterization, which is a very active part of our program.

In arthritis, as well as diabetes, there are apparently differences in susceptibility which are exhibited by different individuals with different genetic HLA markers and inherited tissue types. The hope is that in the future, when we can learn more about these viruses, and inherited susceptibility to them, we will make the introduction of vaccine much more efficient by introducing it into those individuals who have been identified as more likely to be susceptible to diabetes.

Senator SCHWEIKER. Which Institute funded that particular project? Yours? Or Allergy?

Dr. GOLDBERGER. NIDR.

Senator SCHWEIKER. The Dental Institute. [Laughter.]

Dr. WHEDON. There are some related studies also at the University of Vermont.

HORMONAL TRIGGER FOR INSULIN

Senator SCHWEIKER. Dr. Butler, I would like to come back on a related question. In your justification you note that scientists at the Baltimore Research Center have identified a gut hormone that may work as a natural trigger for producing insulin. This statement adds, "This work raises the possibility of an antidiabetes pill based on this hormone as an alternative to injected insulin or oral drugs."

Dr. BUTLER. As you know, for some years the Baltimore longitudinal study has been investigating the capacity of the aging organism, the human organism, to metabolize glucose.

We should soon have end-point analyses of various complications for diabetes in relationship to glucose tolerance measures. It has been found that there is a gut hormone that has a triggering effect on insulin in terms of maintaining blood glucose. Our investigators found oral administration of glucose produced the effect, but intravenous introduction of glucose did not. So we are quite encouraged.

Senator SCHWEIKER. What is the next phase of the research? What phase will it take to follow this up?

Dr. BUTLER. The obvious next phase is further confirmation of the experiments. The second is to find ways to use the trigger in the gastrointestinal track to obtain the glucose level in those instances in which insulin itself is not adequate.

DIABETES COORDINATING COMMITTEE

Senator SCHWEIKER. Does this ongoing study have any kind of liaison or coordination with NIAMDD on this?

Dr. BUTLER. My impression is that Dr. Andres and certain scientists of the National Institute of Arthritis, Metabolism, and Digestive Diseases—notably Dr. Lester Salans—are working closely.

Dr. WHEDON. Yes. I do know, that there are investigators elsewhere as well that we are supporting who are working on this very problem.

Dr. FREDRICKSON. Both Institutes are represented on the Diabetes Coordinating Committee. I know that they are trading information, not only between themselves but with all other Institutes involved with diabetes research.

PANCREATIC CELL TRANSPLANTATION

Senator SCHWEIKER. I am glad to hear that the Diabetes Coordinating Committee is doing something.

That is why we have it, and that is where it should be. I hope we are utilizing the mechanism.

I wonder, Dr. Whedon, would you just comment further on the area of pancreatic islet cell transplantation. Would you elaborate a little bit on where that potentially might be going?

Dr. WHEDON. Progress is being made. I think the leader in this area is Dr. Paul Lacy at Washington University at St. Louis, who has been progressively successful in preparing pancreatic cells in such a way that when they are injected into animals of slightly different genetic background that they are not rejected as is usually the case, but accepted and grow at least for a time.

It is my understanding that there is still a long road to go before we can make that process come out successfully in human beings.

INSULIN INFUSION DEVICES

Senator SCHWEIKER. I don't disagree with that.

Another question with a little more relevance concerns the different areas that look promising. What do you see as the most immediate research area that we might hope for some return on for the diabetic community?

Dr. WHEDON. The principal focus of that type of benefit for right now, the point of maxiumum interest, is in the so-called artificial devices. A number of individuals have developed mechanical systems whereby patients can wear a small pump and reservoir of insulin and the insulin then could be injected automatically and as programed into the human body. The amount introduced would vary from time to time as the body needs it—increased following meals, reduced following exercise, and so on in a preprogramed way.

And I think we are going to see some definite developments in this direction. This isn't the ultimate goal in this area of what one would like to have. One would like to have a blood sugar sensor which could be implanted in the body, which would continuously tell a miniature computer system just how much insulin ought to be taken from the reservoir and put into the body.

People have been working on glucose sensors now for at least a dozen years. The basic problem remains the same—that is, the body resists having an artificial material inside it no matter where it is located, so that within a couple of months at the longest the body puts fibrous tissue or scar tissue around the sensor and makes it inactive, so that is no longer reliable.

I would like to say there is quite a bit of interest now on the artificial preprogramed systems of introducing insulin at varying amounts.

RECOMBINANT DNA RESEARCH ON INSULIN

Senator SCHWEIKER. What about recombinant DNA research?

Dr. WHEDON. The recombinant DNA technology in this area is advancing quite rapidly, and I have estimates that in as short a time as 2 years it could result in sizable quantities of synthetic human insulin. This will, of course, not alter the situation with respect to the need for periodic injections of insulin.

It might, however, reduce the likelihood of reactions to insulin, which occasionally occur now with beef and pork insulin, which are the common ones that are used.

Senator SCHWEIKER. Short-term relief, rather than long-term cure; I recognize that is what you are dealing with.

Dr. WHEDON. Yes, some people have been concerned that there might be a future shortage of animal-derived insulin. But actually we made an investigation recently of the sources of insulin and what the prospects were of a possible shortage, and I would say one of the committees of the National Diabetes Advisory Board was instrumental in starting this investigation. The result was that there does not seem to be any serious prospect of a shortage for at least another 20 to 30 years. Nevertheless it is reassuring, of course, to know that DNA technology is providing a system that will take care of any possible future shortage.

Dr. FREDRICKSON. I wonder if I could interject the fact, Mr. Chairman, that we met in December, as we do annually, with the committee, the Diabetes Coordinating Committee, and the sense of an upbeat movement in diabetic research was very real there, the strongest I have encountered for some time.

I would be very glad to submit to you, for your own personal use, the report of my impressions of that committee meeting which described some of the movement in the field, because I know of your great interest in it. I think it might be of value to you. At no time since we have begun to coordinate the programs of diabetes have we seen such a sense that someday we are going to conquer many of the aspects of this disease, as we have now.

Senator SCHWEIKER. We will put that in the record, if we may, too.

[The information follows:]

Program Review of Diabetes

It was a pleasure to meet with you and the members of the NIH Diabetes Coordinating Committee to discuss activities and accomplishments in diabetes research. I would like to share with you my impressions and views of that meeting.

Research Accomplishments

It is encouraging to note the many scientific advancements that have been achieved in the area of diabetes research. These accomplishments occur across the spectrum of research--from fundamental studies of the mechanism by which insulin regulates cellular glucose metabolism, to the development of new techniques for more reliable assessment of the degree to which hyperglycemia is controlled in the diabetic patient, and of improved methods for controlling diabetes.

Among the significant research achievements of the NIH intramural program I note especially:

- the demonstration that both insulin and insulin receptors are widely distributed with characteristic regional localizations in the central nervous system, providing a basis for extensive regulation by insulin of central nervous system function;

- the demonstration that several common human viruses are capable of inducing diabetes in animal models and in human cells grown in culture, and the recent isolation of a virus from the pancreas of a child with acute diabetes which was found to produce diabetes when innoculated into mice;

- the demonstration that insulin stimulates glucose transport in adipose cells by activating a mechanism which translocates glucose transport systems from an intracellular membrane pool to the plasma membrane.

Among the advances supported by NIH funds are included:

- developments in gene isolation, nucleotide sequencing, and recombinant DNA technology which hold great promise for improving understanding of the genetic basis for diabetes, for identifying abnormalities causing various forms of diabetes, and for synthesizing unlimited supplies of insulin;

- accumulation of evidence that point mutations in the proinsulin molecule occur in humans, which may in some instances give rise to diabetic syndromes;

- demonstration that a soluble factor(s) generated in target cells in response to insulin is able to modulate key intracellular enzymes, revealing for the first time a possible intracellular messenger of insulin action;

- new knowledge regarding the etiologies of insulin dependent diabetes, particularly as regards genetic heterogenecity and the role of immunologic and viral factors.

These substantial accomplishments provide exciting prospects for significant future advances in understanding, treating, and preventing diabetes.

Programmatic Accomplishments

It is clear that the NIH Diabetes Coordinating Committee continues to play an active role in the initiation and development of efforts to stimulate and promote research on diabetes and related areas of science. The results of these efforts are rapidly becoming visible. For instance:

- Since the initiation in FY 1977 of the NIH-wide program announcements in diabetes, applications have increased almost threefold.

- The development of the inter-Institute Special Emphasis Research Career Award (SERCA) has resulted in three distinct SERCA programs: (a) cardiovascular aspects of diabetes; (b) obstetrical, perinatal, and pediatric aspects of diabetes; and (c) diabetes and aging.

- The response to the program announcements inviting applications for National Research Service Awards and Research Career Development Awards in diabetes has resulted in a dramatic increase in the numbers of these awards.

- A substantial level of cooperation has been achieved between the NIAMDD and the other NIH Institutes in the support of investigator-initiated research conducted at the Diabetes Research and Training Centers (DRTC) and the Diabetes Endocrinology Research Centers funded by the NIAMDD. In FY 1979, the NIAMDD awarded $7.5 million to support core facilities, pilot and feasibility projects, and information transfer programs. In addition, the NIAMDD awarded approximately $12 million to members of these centers through the support of research project grants. Other NIH Institutes supported regular research grants at these centers at a level of approximately $7 million.

Cooperation has also been achieved between the NIH and outside organizations in the support of diabetes activities. I note for instance that:

- Several Diabetes Research and Training Centers supported by the NIAMDD are developing collaborative programs with the Diabetes Control Program of the Center for Disease Control (CDC).

- The NIH, the National Center for Health Statistics, and private organizations are collaborating, through the auspices of the National Diabetes Data Group, on the analysis of data and the design of future surveys to achieve a more accurate description of the health impact of diabetes.

- The National Eye Institute (NEI), through a cooperative arrangement with the CDC, has transferred funds to the CDC to establish a central laboratory to perform tests in support of the NEI's Early Treatment Diabetic Retinopathy Study.

The National Diabetes Advisory Board

I would like to note that I am especially pleased by the cooperation and support that has been evidenced by the National Diabetes Advisory Board. I believe the Board deserves considerable credit for the imaginative and dedicated manner in which it has aided in the development of the diabetes program. And I shall convey that message to the Chairman of the Diabetes Advisory Board.

Resources for the Diabetes Program

I understand that the program has adequately met or addressed most of the substantive recommendations of the National Commission on Diabetes. I recognize, however, that the resources available to the program have fallen considerably below the funding levels recommended by the Commission and somewhat below those levels recommended by the National Diabetes Advisory Board.

The manner in which the specific recommendations of the Commission and the Board have been implemented is extremely well documented in the draft report that you prepared as background for our program review. I certainly endorse your plans to refine that draft report and distribute it widely. I would be pleased to write a foreword to such a report.

In looking at the distribution of your current resources according to the Science base, Applications, Technology Transfer, and Training (SATT) model, I note that approximately 90 percent of the funds for the diabetes program are devoted to activities in the science base category. This obviously reflects the emphasis the program places on the support of fundamental science in the broad array of disciplines underlying diabetes research.

I recognize, however, that key aspects of the diabetes effort fall under the categories of Applications, Training, and Technology Transfer.

D S Fredrickson

Donald S. Fredrickson, M.D.

ENTHUSIASM

Senator SCHWEIKER. I, too, hear from the diabetes research community and there is a great deal of upbeat enthusiasm and optimism.

Whether it is a matter of a couple of years, or 10 years, or whatever, there is certainly a whole new ball game in terms of the people who are working at it.

And I also think, from all of it—consumers, the diabetics—all of this is reflected. I appreciate that comment.

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

FUNDING BREAKDOWN

Question: Your Institute, probably more than any other, has a tremendous number of "disease of the month" type programs. It is our understanding that arthritis receives about 12 percent of your budget, diabetes 21 percent, kidney 11 percent, etc. From a scientific standpoint are these breakdowns in the proportion you think they should be?

Answer: The distribution of funds to the various programs of the Institute is based on many factors such as past history, commitments for non-competing continuation of previously awarded projects and requirements of funds for new and competing renewal projects to enable each program area to make awards to roughly comparable priority score levels. Differences in priority score levels reflect past and current Congressional and programmatic emphases. We would regard these proportions as a reasonably balanced representation of relative needs, opportunities, and emphases within the level of available funds.

FUNDING IMPACT ON TRAINEES

Question: Under the Administration's budget request, how many new full-time equivalent institutional and individual trainees will NIAMDD be able to support? How many in diabetes?

Answer: There will be no new awards of either type made in any program. Within the continuing institutional awards, however, there is a constant turnover and therefore, there will be some new people beginning their research training experience.

INTRAMURAL RESEARCH

Question: What impact will the Administration's budget request have on the intramural research activities of NIAMDD in FY 81? Projections for 82 through 85?

Answer: The 1981 request is intended to continue the intramural research program at about the same level which will exist at the end of 1980. Projections for 1982 through 1985 reflect a continuation of the same program level.

INSTITUTE STAFFING

Question: How many new slots will be provided under the Administration's NIH budget request?

Answer: No new slots will be provided.

ADMINISTRATIVE STRUCTURE

Question: With NIAMDD having responsibility for ten major research areas, do you find your administrative structure adequate for your management programs?

Answer: The current organization of NIAMDD consists of four extramural program clusters, an extramural activities program, and

an intramural research program. We have felt that the present structure might be improved by more explicit characterization of the functional responsibilities of each major program cluster and delegation of responsibility, authority, and accountability to the categorical Associate Directors. The Institute has proposed to NIH a reorganization plan that would establish NIAMDD as a Bureau within NIH with the following six divisions:

1. Division of Arthritis, Musculoskeletal and Skin Diseases
2. Division of Diabetes, Endocrinology, and Metabolic Diseases
3. Division of Digestive Diseases and Nutrition
4. Division of Kidney Diseases, Urology and Hematology
5. Division of Extramural Activities
6. Division of Intramural Research

Such a reorganization could provide for an improved mode of operations, including more orderly direction and better planning and evaluation of each major disease entity within an overall framework of effective management and fiscal accountability. After careful studying of this recommendation and the implications that it has for other Institutes, the Director, NIH, decided that it would not be wise to approve this reorganization. We understand his decision. He is continuing to give study to this important issue to assure that the NIAMDD is organized in a manner that will provide for the effective administration of the important national programs for which the Institute is responsible.

Question: Does your organizational structure reflect the priorities in your research efforts?

Answer: Yes, I believe that the four program clusters of Arthritis, Musculoskeletal, and Skin Diseases; Diabetes, Endocrinology, and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology, and Hematology appropriately reflect the Institute's research priorities.

Question: Would you please tell us what the current situation is regarding intramural research on bone diseases?

Answer: The Institute continues to have major basic science programs in bone diseases. Unfortunately, we have been unable to establish a clinical orthopedic research program. We have found that in the area of orthopedic surgery, our salary has not been sufficiently competitive to attracting a program leader of excellent caliber commensurate with the quality expected of the NIH intramural scientific staff.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: The National Institute of Arthritis, Metabolism, and Digestive Diseases believes that there are significant opportunities for pursuit of a number of clinical trials in several program areas. Multicenter, cooperative clinical trials have

usually been funded through the contract mechanism. In the absence of resource constraints the Institute could support several clinical trials exemplified by the following short list:

-Treatment of Asymptomatic Chronic Active Hepatitis.
-Efficacy of Control of Blood Glucose Concentration on the Development of Complications of Diabetes Mellitus.
-Evaluation of Selected Modes of Therapy for Osteoporosis.
-Safety and Clinical Effectiveness of Oral Retinoids in Dermatological Disease.
-Natural History and Therapy of Glomerulonephritis.
-The Evaluation of Nutritional Support versus "Bowel Rest" in Patients with Inflammatory Bowel Disease or Short-Bowel Syndrome.
-Endoscopic Therapy of Upper Gastrointestinal Hemorrhage.
-Therapy in Severe Lupus Nephritis.
-Long-term Toxicity Study of PUVA (Combined Psoralen and Ultraviolet Light Treatment) For Psoriasis.

DIGESTIVE DISEASES

Question: Last year, our Committee expressed concern about the inadequate levels of federal support for research in the area of digestive diseases, pointing out the importance of following the recommendations of the Commission on Digestive Diseases. In line with the language in our Committee's report, what have you done in FY 80 in regard to providing funding increases for the digestive diseases program?

Answer: In FY 1980, the budget for the digestive disease program was increased about in proportion to the increases in other programs. This increase was allocated entirely to research grants. With this budget, the program will be able to fund about the same number of grants as it funded in 1979.

Question: Please explain what you are doing to follow the recommendations of the Digestive Diseases Commission.

Answer: The Commission's principal recommendation to NIAMDD was for expansion of research efforts and this is being done within the total funds available. The Commission recommended primary emphasis on investigator-initiated research and this directive is in consonance with our allocation of FY 1980 funds and the present request for FY 1981. In the absence of specific legislation, NIAMDD is implementing recommendations for which it has authority and which can be carried out with present funds. The Institute has developed plans to develop an Information and Education Clearinghouse at a modest level. It also plans to cooperate with the National Center for Health Statistics in gathering epidemiological data on gallstones during the coming National Health Survey.

Question: What steps have you taken to coordinate your efforts, as our report directs, with other appropriate federal agencies, particularly within NIH?

Answer: The Digestive Diseases Coordinating Committee serves effectively to coordinate the activities of NIAMDD with those of

other federal agencies. A program to standardize the nomenclature and diagnostic criteria for digestive diseases is being developed and supported through the Coordinating Committee. Workshops in promising areas of research are being carried out in cooperation with other Institutes as appropriate. Consensus exercises are planned in cooperation with the Office for Medical Applications of Research.

CYSTIC FIBROSIS

Question: Last year you reported that cultured cells from cystic fibrosis (CF) patients are more resistant than normal cells to the toxic effects of dexamethasome, and of the potential importance this may have for prenatal diagnosis and detection for carriers of the CF trait. Has any more progress been made in this research or in other areas of CF investigations?

Answer: This test using dexamethasome and cultured cells seems to be a significant finding. Since last year, it has been used by a number of laboratories which have confirmed that the differences between CF and normal cells are significant and the results are reproducible. The next step, in progress at this time, is to evaluate the effectiveness of this test in identifying individuals who carry the CF trait.

Research in cystic fibrosis, like that in many genetic diseases, has been disappointingly slow and there is little new to report from year to year. In recognition of this, NIH initiated a major program to increase research attention to the many challenges and opportunities inherent in the study of cystic fibrosis. To apprise the scientific community of these opportunities, the Institute participated in the development of an NIH wide cystic fibrosis "Request for Applications" announcement to encourage the submission of research grant proposals in key CF research areas. In addition, a brochure entitled "CF: A Disease in Search of Ideas," which outlines research needs in this disorder, was distributed to 32,000 members of the American Federation for Clinical Research and the Federation of American Societies for Experimental Biology. Because of these initiatives, the number of applications received for support of CF investigations has nearly tripled.

Question: There has been some discussion in the press over the last few months about a supposed new theory of cystic fibrosis that challenges its genetic basis. Has NIAMDD addressed this situation, and, if so, what are your tentative conclusions or plans for future research?

Answer: A recently developed hypothesis widely publicized in lay media suggested that rather than being an inherited genetic disorder, CF may result from a selenium deficiency and improper diet. Currently, there are an estimated 200 CF patients throughout the country who are enrolled in a nutritional program designed to overcome these deficiences.

To examine this hypothesis, the NIH convened a panel of experts to review the evidence supporting the theory. The group included clinicians, basic scientists and clinical pathologists

61-400 O - 80 - 33

with expertise and active involvement in CF and/or selenium research, as well as the proponents of the hypothesis.

Based upon the deliberations of the meeting and careful review of all available information, the NIH has concluded that at present there is no substantial evidence to indicate that CF is not a genetic disease. Additionally, no findings are available that would suggest that selenium provides any therapeutic value in the treatment of the disease. It is generally agreed that adherence to conventional treatment regimens remains in the best interest of the CF patient.

It does not appear that this controversial new and unconventional hypothesis warrants serious further consideration at this time although we stand ready to support meritorious research application which can meet the competition of peer review.

ARTHRITIS INFORMATION CLEARINGHOUSE

Question: What is your opinion of the levels of awareness that the general public has about arthritis and its treatment?

Answer: Though the physical ravages of arthritis and related diseases impose great economic and social burdens on so many members of our society, a great many victims of arthritis, their families, and the general public are burdened with the false notion that little or nothing can be done to combat these diseases. Of the several hundred millions of dollars spent annually for medications for arthritis, it is estimated that a large proportion is wasted by patients on products that are falsely advertised or misrepresented. In the absence of concrete information about arthritis, the arthritis sufferer often wanders aimlessly into the pit of quackery. Awareness on the part of the public and the patient has increased in recent years as a result of efforts by the press and such organizations, as the Arthritis Foundation.

Question: What programs is the Arthritis Information Clearinghouse offering to improve the situation?

Answer: Comprehensive programs of public education and information are essential to the effective control of crippling arthritis. The Arthritis Information Clearinghouse was created to serve as a "broker" for the flow of arthritis information to health educators and health care providers throughout the country. The Clearinghouse is the central resource for information about arthritis educational programs, materials, and resources. Through the Clearinghouse, the needs of health professionals and organizations for references and other information are met in order to serve patients and their families and the general public. The Clearinghouse makes maximum use of all tools of communication to inform and educate the special publics concerned with arthritis and related diseases.

OSTEOGENESIS IMPERFECTA

Question: What has your Institute been doing to support and stimulate new research on osteogenesis imperfecta, the brittle bone disease?

Answer: The Bone Diseases Program currently supports four separate research projects and one research career development award for the direct investigation of osteogenesis imperfecta, and 23 research grants in important related areas of bone metabolism and mineralization, in the total amount of $2.3 million in 1979. A highly productive conference, entitled Collagen Metabolism: Directions for Research in Osteogenesis Imperfecta, supported by NIAMDD, was held at the National Institutes of Health in Bethesda in June 1979. The topics ranged from detailed studies of the classification of osteogenesis imperfecta to the molecular control of collagen synthesis. All participants were encouraged by the quality and promise of current research activities in their field. A two-day workshop will be held in May, 1980 on Heritable Connective Tissue Disorders. Bone mineralization and proteoglycan studies will be included along with the collagen investigations. The entire meeting is relevant to osteogenesis imperfecta, and one day will be devoted specifically to this disease. National and international experts will participate, and the results of the conference will be published.

COORDINATION OF BONE DISEASE RESEARCH

Question: Could you explain how the bone diseases programs of your Institute relate to bone disease research supported through other Institutes of the NIH--such as the National Institutes of Dental Research, Aging, and General Medical Sciences--and could you comment, please, on the ways in which the various Institutes have coordinated their efforts regarding bone disease research?

Answer: The Bone Diseases Program of NIAMDD maintains strong staff communications with other Institutes of NIH supporting related musculoskeletal disease research. Individual projects are discussed for scientific content and considered for exchange on mutual assignment among two or more Institutes. Several program initiatives by other Institutes, fluoride in bone and teeth and musculoskeletal disorders in the aged for instance, have been recognized as stimulants for research in the Bone Diseases Programs. The NIAMDD program also co-funds conferences related to two programs of NIDR: the Gordon Research Conference on Bone and Teeth and the International Biomaterials Conference. In addition, the Director of the NIAMDD Bone Diseases Program regularly consults with the FDA, and serves as a member of the FDA Orthopedic Advisory Panel.

BONE REGENERATION

Question: We are beginning to see articles in the press on regeneration of bone fracture with the aid of electrical stimulation. How widely used is this technique?

Answer: Until November, 1979, electrical stimulation devices for bone healing were used only in investigational research. Recently, office devices and their associated procedures have been certified by the FDA for clinical usage. The techniques include external electromagnetic coils, external direct current power pack with transcutaneous wires, and totally implanted direct current devices. While all three methods may be applied in cases of

non-union, only the electromagnetic coils are approved for pseudoarthrosis, a congenital disorder of children.

Question: How costly is bone regeneration using electricity?

Answer: Over 5,000 patients have been evaluated during the testing period. The costs to patients for these three devices range from about $1,000 for a one-time purchase to $1,800 for 4-months rental fee.

Question: Is this technique useful on disorders other than bone fractures (e.g. can it be used in soft tissue disorders)?

Answer: Research is progressing along two fronts: (1) understanding the basic mechanism of action in electric stimulation and (2) application of the methods to other bone injury and disease conditions. Other applications of electrical and electromagnetic stimulation include therapeutic trials in osteogenesis imperfecta, osteoporosis, early growth plate closure, and deep bone infections.

Question: What research results do you have from your orthopedics program concerning new methods of promoting bone healing and regeneration, such as electrical or electromagnetic stimulation?

Answer: The Bone Diseases Program supports research projects utilizing many approaches to improved bone healing and regeneration. The most basic scientific projects deal with the molecular biology of normal fracture healing. New advances in immunology and microvascular surgery provide encouragement for successful bone transplantation. Similar approaches are now being applied to early closure of the bone growth plate in children. Internal fixation devices with mechanical properties closer to those of bone now yield improved results in difficult fracture situations. Electrical stimulation devices are now clinically available for patients with non-union of bone fractures. The full role which such approaches will come to play in the management of bone diseases and injuries has not yet been fully assessed and will require further study of new applications.

Research is progressing along two fronts: understanding the basic mechanism of action of electric stimulation, and application of the methods to other bone injury and disease conditions. These were discussed fully by the experts in the field at a Workshop on Electrical Formulation of Bone supported by NIAMDD and the American Academy of Orthopaedic Surgeons held in Atlanta in March 1979.

KIDNEY DISEASE

Question: Last year funding for research in kidney disease increased by approximately 20.7 percent. How much is actually allotted to kidney disease research?

Answer: In 1980, $37.2 million has been allocated and in the 1981 budget, $40.5 million is requested for this research area.

Question: How has funding for renal disease fared over the past 10 years?

Answer: From 1970 through 1980, the funds for programs in kidney disease more than doubled. However, after adjustment for the effects of inflation the real growth is about 18%. Most of this real growth has taken place since 1977.

Question: What major advances can we point to in the past ten years in lengthening the lives of individuals with renal disease?

Answer: There have been major advances in technical areas, but relatively few in fundamental knowledge. The availability of chronic hemodialysis has been facilitated by the development of markedly improved means of blood access, primarily successful vascular fistulae and better indwelling cannulae; by more compact and efficient hemodialyzers; and improved water purification methods. Peritoneal dialysis has been improved and has expanded greatly with the development of better connecting devices and the introduction of continuous ambulatory peritoneal dialysis (CAPD) which utilizes plastic bags that are changed two or three times daily. Renal transplantation has benefited from improved techniques of surgery, anesthesia and postoperative care. Better methods of achieving immunosuppression, improvements in kidney preservation, and in tissue typing have resulted in better survival statistics. Identification of analgesic "abuse" as a cause of interstitial nephritis resulting in chronic renal failure with concomitant efforts to correct the "abuse" has saved lives in proportion to the ability to alter the patterns of use of this drug. Improved surgical techniques and postoperative care to correct anatomic abnormalities, primarily congenital, which cause urinary tract obstruction and secondary renal failure contribute to a decreased incidence of renal failure in this area. Antibiotics to treat different types of urinary tract infections help diminish progressive renal destruction by infection. A better understanding of the causes contributing to acute renal failure (ARF) has resulted in a decreasing mortality in the younger age groups. More aggressive treatment of hypertension at an earlier stage of the disease has diminished the development of severe renal complications.

Question: What is the usual age of onset of renal disease?

Answer: There is no single or average age of onset since there are a multiplicity of causes of renal diseases. Many renal diseases occur in the first decade of life, while others peak in the second or third decade. The occurrence in the older age groups (over 50-60 years) is less common. For instance, polycystic kidney disease, which is responsible for 9-10 percent of patients treated for end-stage renal disease (ESRD), is an inherited disease that is usually manifest by the third and fourth decades. Glomerulonephritis, which is responsible for fifty percent of patients treated for end-stage renal disease, can occur at any age, but commonly is evident between the second to fourth decades of life. The average age for evidence of end-stage renal disease is around the fourth and fifth decades. The average age of dialysis

patients currently is around 57 years.

Question: Last year the Subcommittee urged strong support for the kidney program. Does this current level of support represent your idea of compliance with the Subcommittee report language? What method are you using for the allocation of funds in FY 80? What is the current priority score for Kidney?

Answer: The Institute followed the guidance of the 1980 House and Senate Conference Report, as printed in the Congressional Record, and allocated the entire Institute's $35.5 million increase to regular research grants and among the various programs so as to achieve an overall Institute priority score payline of 210. We anticipate that the paylines for all of our programs, including kidney disease, will be roughly comparable and clustered around this objective. The Senate Subcommittee in 1980 emphasized funding for training stipend increases, arthritis, kidney disease, digestive diseases, and diabetes programs and all of these areas of emphasis are reflected in the FY 1980 allocation within the total funds available.

DIALYSIS - END-STAGE RENAL DISEASE

Question: Please summarize the state-of-the-art in dialysis?

Answer: Progress has been steady and consistent in dialysis. Improvements have been made in shortening treatment times, capability to control fluid balance, and control of acid-base balance. In the more advanced centers, techniques are now available to prescribe quantitatively dialysis to match the needs of the patient, avoiding under and over treatment. Industry has provided a variety of generally reliable and effective control devices and disposable devices. The nephrology community has expanded its capacity to meet overall patient needs, such that availability of facilities and trained medical personnel are no longer rate limiting. A variety of dialysis techniques are also available. Costs of dialysis therapy, while increasing to some degree, have been doing so at rates considerably below those prevalent in other segments of health care due to new efficiencies and higher volume operations.

Question: What advances have been made in machinery and conditions necessary for hemodialysis, peritoneal dialysis, and the newer portable techniques such as continuous ambulatory peritoneal dialysis (CAPD) and the "kidney-in-a-suitcase"?

Answer: The most striking recent advance in the techniques for maintenance therapies for chronic renal disease patients has been the development of Continuous Ambulatory Peritoneal Dialysis (CAPD). This technique permits patients to conduct dialysis at home without machinery. Sterile dialysate is supplied in plastic bags. The technique is new and the ultimate role it may play in the spectrum of therapies remains to be seen. Currently, it is being evaluated by a number of dialysis centers.

Portable dialysis delivery systems for conventional hemodialysis have undergone a number of improvements, but so far the "suitcase" kidney has been available only on a limited basis

from the industry. Improvements in control of salt composition in the dialysate recycling devices continue to be made. Automated intermittant peritoneal dialysis equipment has improved such that it now provides sterile dialysate in a highly reliable fashion. Such developments have led to improved acceptance of this maintenance technique.

Question: What is the average life expectancy of an individual after he/she has been diagnosed as having end-stage renal disease and receives dialysis?

Answer: With increasing use of dialysis and the increasing age of treatment of patients by dialysis, the figures are changing. Individual patients have lived 10-15 years after beginning hemodialysis. Mortality during the first year of dialysis is about 20 percent (if the first three months is included); but the year following the first three months of dialysis has a mortality of about 10 percent. Experienced centers now report a five year patient survival of approximately fifty percent. Maintenance dialysis has only been generally available for eight years so that long-term survival patterns of large populations are not yet clear.

KIDNEY TRANSPLANTATION

Question: What is the average life expectancy of an individual following kidney transplantation?

Answer: Life expectancy varies according to the expertise of the center. In the best centers, patients receiving kidneys from living related donors have a one year survival of 95 percent, while those receiving cadaveric kidneys have a 90 percent one year survival. After a patient survives two years with a kidney transplant, survival is somewhat less than that in the general population, with cancer, heart attacks, and complications of infections being the leading causes of death. Patients often go back onto dialysis after graft failure, a fact skewing distribution and interpretation of survival data.

Question: What percentage of kidney transplants are successful?

Answer: In the most experienced centers, kidney grafts from living related donors have a 75-80 percent two year survival, while that from cadaver grafts is 50-70 percent.

Question: At this point in our understanding of renal disease, should we place our efforts into improving the success rate of kidney transplants by refining kidney matches, enlarging the donor network, developing drugs and procedures to inhibit postoperative rejection rates, or would our research money be better spent in pursuing methods of preventing end-stage renal disease?

Answer: This not an either/or question. Because there are multiple diseases resulting in the final common pathway of end-stage renal disease (ESRD), one will not be able to prevent, arrest or cure all the diseases at one time. We will need to continue to improve our methods of treating end-stage renal disease

and its complications, while mounting an aggressive research program into the underlying causes of end-stage renal disease. This type of fundamental research will result in knowledge which can help to devise means for prevention, arrest, and/or cure of the underlying causes. Chronic renal failure, in approximate descending order of incidence, is caused by chronic glomerulonephritis, hypertension, diabetic nephropathy, genetic and/or congenital abnormalities, toxic or drug induced diseases, infections, and other less common causes. It is unlikely that the prevention or cure of all of these will be found simultaneously or rapidly, but certainly without a concentrated research effort, little progress can be made in this direction.

FUNDING FOR DIABETES RESEARCH

Question: The Administration's budget request provides for a $24 million increase for the National Institute of Arthritis, Metabolism, and Digestive Diseases over FY 1980 levels? How much of this increase will support diabetes research?

Answer: The Diabetes program is allocated $5.2 million of that increase.

Question: How much of this increase will support diabetes-related research?

Answer: All of the $5.2 million increase is allocated to the diabetes program; in addition, diabetes-related activities in other program areas continue to be significant but cannot be estimated until after specific research funding awards are made.

Question: How does NIH differentiate between diabetes and diabetes-related research? How do you determine how much goes to each?

Answer: There is a great deal of scientific interrelationship in our various programs, particularly between diabetes and endocrinology, metabolism, and nutrition. Those projects which have obvious primary applicability to diabetes are assigned originally to that program; other projects such as aspects of hormonal regulation may be assigned to endocrinology because of the general hormonal aspects which predominate but are also considered diabetes-related because of the applicability to insulin, for example. As the year progresses, based on well-defined review criteria, related projects may be selected for transfer to the diabetes portfolio, as indicated by relative program funding.

Question: At what priority score will the Administration's budget request enable NIAMDD to support diabetes research? How does this compare to FY 1980?

Answer: In 1980, the Diabetes program paid to a 90th percentile priority score level of about 250. In 1981, it is anticipated to be about 240, but it is very difficult to estimate individual programs precisely, since eventual funding is dependent upon both competing and non-competing dollar requirements and upon the number and quality of applications to be received.

DIABETES CLINICAL TRIAL

Question: Will NIAMDD have sufficient personnel in the diabetes program to conduct the clinical trial on the relationship of diabetes control and diabetes complications? Please describe your plans for this.

Answer: This clinical trial would be conducted under a research and development contract rather than by Institute staff. Existing staff will probably be able to absorb the additional workload of coordinating and administering such a contract.

DIABETES CENTERS

Question: What are your plans for new Diabetes Research and Training Centers under the budget request?

Answer: We will continue support of 8 existing centers but no new centers are planned under the budget request.

Question: How long will existing ones be funded?

Answer: Three of the existing centers will complete their original funding period and can compete for renewal in 1980 for several additional years. Four more current centers can next compete for renewal in 1982 and the eighth has just been renewed through fiscal year 1982.

EDUCATING DIABETES PATIENT

Question: The National Diabetes Mellitus Research and Education Act requires that diabetes research and training centers be established to, among other things, conduct research and disseminate information on the treatment of diabetes. The National Diabetes Advisory Board has consistently stated that diabetic patient education should be considered as treatment and that more needs to be known about how to most effectively educate patients and their families in the treatment of the disease. To what extent are DRTCs involved in patient education research?

Answer: As a general statement, it can be said that each of the DRTCs are involved in diabetic patient education research, the extent depending on the center's maturity, their stated goals and objectives, and the degree of existing activities at the time of establishment of the center.

One concept which was emphasized in the Report of the National Commission on Diabetes was the use of the team approach to the care and education of the diabetic patient. This approach is under study at all centers, in one it is a major focus while in others modifications are being developed for areas where assembling a team would not be feasible. In addition, there are research projects on such aspects of diabetes care and education research, funded through pilot and feasibility studies or from other sources, as compliance, use of home health aides, psychosocial and behavioral effects, etc.

Question: Do any of the centers have programs which specifically study the effectiveness of various diabetic patient education techniques? Do any of the centers plan such programs?

Answer: All centers are required to include plans for assessment of the effectiveness of patient education programs which they develop. The degree of sophistication of the assessment, which should include both metabolic and psychosocial status of the patients, varies with the state of development of the particular educational research program within the center. Generally, less sophisticated evaluation techniques are utilized during the development of patient education methodologies to facilitate on-going economically feasible evaluation. More rigorous evaluation techniques are used on fully developed programs which may have a relatively wider participation.

Question: How do the centers carry out their role of disseminating information on patient education and other treatment techniques?

Answer: The centers role in diabetic patient care and education is effected through development, validation, and testing of programs which can be exported; training and continuing education programs for the entire spectrum of health professionals involved in diabetic patient care and education (including training these professionals to train others); and once programs are developed and training of health professionals underway, developing outreach programs for practicing health professionals through cooperation, coordination and collaboration with relevant local, State and Federal agencies.

The absence of categorical focus on diabetes among many of the diverse public and private agencies involved in the health care system and its intrinsic pluralism represent challenges to the successful total development of the DRTC program, and thus far developments have been slow, particularly at the Federal level. There have been some important advances in this direction. DRTCs in geographical proximity to CDC State Diabetes Control Programs are developing cooperative and collaborative efforts. The DRTCs also will be involved in providing specialized training of health care personnel for the model diabetes care program of the Indian Health Service, providing opportunity for evaluation of programs in cultural and socioeconomic settings not available at the DRTCs.

DIABETES - EPIDEMIOLOGISTS

Question: Why is there a shortage of epidemiologists to carry out research in Diabetes Mellitus, and how long has this shortage been recognized?

Answer: It is well recognized that there is a general shortage of epidemiologists in the U.S. in all areas of biomedical research. This was documented in a report by the National Academy of Sciences which recommended that training opportunities be created to increase the supply of epidemiologists in research, industry, academic institutions, and regulatory agencies. The field of diabetes has never had more than a few epidemiologists

conducting research on diabetes. However, as our understanding of the clinical aspects of this heterogeneous disease has grown, the opportunities have become more evident for applying epidemiologic methods to research on the etiology and pathogenesis of diabetes.

Question: What specific actions has NIH taken to increase the supply of epidemiologists and to attract epidemiologists to Diabetes Mellitus research? To what extent have these actions been successful?

Answer: Several Institutes, most notably NHLBI and NCI, have vigorously encouraged the establishment of general epidemiology training programs at a number of U.S. schools of public health. In addition, the NIH has recently initiated an intramural epidemiology training program in collaboration with several other PHS agencies which will provide postdoctoral training in epidemiology. The NIAMDD has initiated discussions with several well-established diabetes research centers regarding their development of epidemiology training programs. In September, 1978, the NIH issued a program announcement requesting research grant applications in the area of the epidemiology of diabetes, this announcement has been reissued recently. Finally, the National Diabetes Data Group has achieved an international consensus on terminology, diagnostic criteria, and classification of the various types of diabetes, which will serve as a uniform basis for the conduct of clinical and epidemiologic research on diabetes.

As a result of these activities, the NIH now funds 16 research grants in the epidemiology of diabetes. Of these, four are being conducted by researchers who were not previously in the field of diabetes. The topics of these grants include the etiology and genetics of diabetes in specific, well-defined populations in the U.S. and abroad, causes of the cardiovascular complications of diabetes, pregnancy and diabetes, and the role of obesity in the development of diabetes. Several non-Caucasion populations are being examined for the causes and sequellae of diabetes, including Polynesians, Yemenite Jews, Oklahoma Indians, and Mexican Americans. These comparative studies, together with those being conducted by other countries, show great promise in unraveling the heterogeniety of the diabetes syndrome. Our intramural units associated with the Phoenix Indian Medical Center and the Gila River Indian Reservation in Arizona have pioneered in such studies and continue to conduct outstanding research in this field.

Question: Should additional actions be taken, and, if so, what do you believe should be done?

Answer: Only modest growth has been achieved in the number of research projects directed toward the epidemiology of diabetes. However, this discipline offers great promise in complementing the excellent basic and clinical research being conducted on diabetes. Epidemiologic investigations in other disease areas, such as cardiovascular diseases and cancer, have been particularly successful in advancing understanding of the etiology of these diseases and providing a scientific basis for preventive measures. It is highly likely that such approaches applied to diabetes will

meet with equal success.

The major research and training opportunities in epidemiology are located at the U.S. schools of public health. However, there is currently no involvement of these institutions in diabetes research and it will be important to generate new diabetes epidemiology expertise through training programs at these schools. In addition, continued efforts should be made to develop collaborations between established epidemiologists and diabetologists in order to increase the scope of epidemiologic research on the etiology and pathogenesis of diabetes.

INTRAMURAL RESEARCH ON BONE DISEASES

Question: Would you please tell us what the current situation is regarding intramural research on bone diseases?

Answer: The Institute continues to have major basic science programs in bone diseases. Unfortunately, we have been unable to establish a clinical orthopedic research program because of our inability to attract a program leader of the caliber expected of the NIH intramural scientific staff.

SUBCOMMITTEE RECESS

Senator SCHWEIKER. All right. The committee will stand in recess until 10 a.m. tomorrow, when we will continue the NIH hearings.

Thank you very much.

[Whereupon, at 4:04 p.m., Tuesday, February 5, the subcommittee was recessed, to reconvene at 10 a.m., Wednesday, February 6.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

WEDNESDAY, FEBRUARY 6, 1980

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. Richard S. Schweiker presiding.

Present: Senators Bayh, Schweiker, and Hatfield.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENTS OF:

DR. DONALD FREDRICKSON, DIRECTOR

EDWARD NICHOLAS, ACTING ASSOCIATE DIRECTOR FOR ADMINISTRATION

DR. RUTH KIRSCHSTEIN, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCE

DR. RICHARD KRAUSE, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DR. DONALD TOWER, DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

BUDGET REQUEST

Senator HATFIELD [presiding]. The subcommittee will come to order. Good morning.

Once again, I am sorry for the delay. I was unavoidably detained in my office.

This morning we will begin our third session of hearings on the President's budget request for NIH. Our first area this morning will be buildings and facility programs on the grounds of NIH. And before proceeding, I think it would be helpful for both the reporter and myself if each of you would state your name and the program that you are associated with.

Mr. Nicholas will present his testimony, which we will place in the record. And it has been understood that we will receive all of your printed statements, and then we will proceed. You will proceed to either summarize or highlight them.

Mr. Nicholas, would you officially, for the record, at this time present those who are accompanying you and your colleagues. Let's have each

person state their name for the recorder. The recorder is sitting down here. So speak up, if you will, with your name and your title or your area of expertise.

Mr. NICHOLAS. Ed Nicholas. I am Acting Associate Director for Administration. Mr. Osborne is with me, the OD Budget Officer.

Dr. DEVITA. I am the Acting Director of the National Cancer Institute.

Dr. LEVY. I am the Director of the National Heart, Lung, and Blood Institute.

Mr. ITTEILAG. I am Director of the Division of Budget Policy, and Management, DHHS.

Dr. SCOTT. Director of the National Institute of Dental Research.

Dr. WHEDON. Don Whedon, Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases.

Dr. KRETCHMER. I am Director of the National Institute of Child Health and Human Development.

Dr. BUTLER. I am Director of the National Institute on Aging.

Dr. CUMMINGS. I am Director of the National Library of Medicine.

Dr. FREDRICKSON. I am Director of NIH.

Dr. KIRSCHSTEIN. I am Director of the National Institute of General Medical Sciences.

Dr. KRAUSE. I am Director of the National Institute of Allergy and Infectious Diseases.

Dr. TOWER. Director of the National Institute of Neurological and Communicative Disorders and Stroke.

Dr. KUPFER. Director of the National Eye Institute.

Dr. RALL. Director of the National Institute of Environmental Health Sciences.

Dr. BECKER. Acting Director of the Fogarty International Center.

Dr. BOWERY. Director of the Division of Research Resources.

Senator HATFIELD. Any psychiatrists? [Laughter.]

Dr. Butler is a psychiatrist. [Laughter.]

Thank you very much.

Mr. Nicholas, you may proceed.

Mr. NICHOLAS. I submit my statement for the record. I would like to highlight a couple of items.

[The statement follows:]

Statement of Edward Nicholas

I would like to thank this committee for the opportunity 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 offices responsible for equal employment opportunity, program planning and evaluation, medical applications for research, public and scientific communication, protection from research risks, and (2) management support activities, including budget, accounting, personnel, management analysis and review, and contracts and grants.

Program Management

The Immediate Office of the Director includes principal associates of the Director and staff offices which provide assistance to the Director on program planning, policy development, and decision making, including the coordination of intramural and extramural research programs of the Bureaus, Institutes and Divisions.

Since most of the National Institutes of Health is located within the Bethesda, Maryland area, it is expeditious and economical to provide management support and program services on a consolidated basis. This appropriation provides support for the overall administrative management activities of the National Institutes of Health and provides a number of services to the individual Bureaus, Institutes, and Divisions. These services include the development of financial policies and procedures, 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 through all of the operating components of the National Institutes of Health.

The Office of the Director provides the overall leadership in the implementation of Congressionally mandated programs, such as the dissemination of research information, protection from research risks, Freedom of Information and Privacy Act requirements, as well as Executive Branch priorities in Civil rights compliance, and equal employment opportunity programs. Moreover, through the recently established Office of Medical Applications of Research, NIH will continue to translate the results of biomedical research and development into knowledge which can be effectively utilized in the practice of medicine and enhancement of public health.

Direct Operations

The direct operations activity of this appropriation provides for the direction, operation, and administration of NIH accounting functions and certain personnel activities. The accounting functions provided include financial analysis and reporting; auditing and proces-

sing of vouchers, payment of invoices, and the settlement of claims. Personnel services 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 $22,549,000 for 1981, an increase of $647,000 over the 1980 level of $21,902,000. The requested increase of $647,000 is comprised of mandatory items, including payments for centrally furnished services.

Buildings and Facilities

The Buildings and Facilities appropriation provides funds for design, construction, repair and improvement of buildings and supporting facilities for the National Institutes of Health.

The appropriation request of $11,750,000 in fiscal year 1981 is for the following:

Clinical Center Modernization

In FY 1981 we are requesting $7,000,000 for renovations to upgrade Clinical Center facilities which have been operational for 25 years. This project involves over fifty individual sub-projects of substantive scope which are necessary to bring the Clinical Center up to an effective functional and environmental level.

The Clinical Center, 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. The building must remain operational while the renovations and modernization are undertaken; therefore, the program is scheduled for implementation over a multiyear period.

Rehabilitation of Lab Buildings 2, 3, 4, 5, and 8

We are requesting $1,500,000 to begin the complete renovation, modernization and upgrading of research and support facilities at the National Institutes of Health which have been operational for 40 years. The timing for completion of all buildings is estimated to be about nine years.

These facilities 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 the needs of the handicapped, new life safety codes, energy conservation and central utility support services.

Repairs and Improvements - Plant

We are requesting $1,250,000 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; Hamilton, 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

A funding level of $2,000,000 is also requested 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.

Thank you. I shall be happy to respond to any questions you may have.

BUILDINGS AND FACILITIES BUDGET REQUEST

Mr. NICHOLAS. We have the repairs and improvements for plant and program, totaling $3,250,000. This is the ongoing regular maintenance, and preventive maintenance, of the over 97 buildings that are on the NIH campus for which we have maintenance responsibility.

We have also two renovation items. One is $7 million for clinical center modernization. This is the third phase of a multiyear program to upgrade the clinical center, which we will have to interface with our new ambulatory care research facility—$17 million.

And finally, $1,500,000 to begin the renovation of laboratory buildings 2, 3, 4, 5, and 8. These laboratory buildings are structurally sound buildings that were built about 40 years ago. The outside structure is sound, but the support systems inside must be completely renovated. We intend to start the program this year with a $1.5 million budget. And that program would be continuing through 1989.

The total building and facilities budget request, then, is $11,750,000.

REQUESTED REPROGRAMING FOR CLINICAL CENTER MODERNIZATION

Senator HATFIELD. Thank you, Mr. Nicholas.

Mr. Nicholas, as I understand the budget request this year, there are a number of millions of dollars that are being—that were originally appropriated for training, for grants, and for clinical trials to be transferred to the modernization program at the clinical center. In fact, I believe the total amount is over $7 million of that. Why didn't you just ask for new money instead of taking it from these high-priority areas?

Mr. NICHOLAS. For 1981 we are asking for $7 million in new money. We began the modernization program late in 1979. We are asking for a transfer for fiscal year 1980 of $7 million to be transferred from the Bureau's institutes and divisions that have clinical research programs and therefore utilize the clinical center. This money is coming mainly from intramural program funds.

Senator HATFIELD. My question is, as I understand the budget here, the National Cancer Institute is going to be asked to transfer $2.1 million; National Heart, Lung, and Blood, $1.1 million; National Institute of Arthritis, $1 million. I won't read all of them. The others are less than a million, but they include such groups as the Dental Research, the Allergy and Infectious Diseases, Child Health and Human Development, National Eye Institute.

61-400 O - 80 - 34

It seems to me these are very important programs, ongoing programs, priority programs. I would certainly be, for one, supportive of your request for this project under an out and out new money request. But to fund this remodeling program from transfers out of these high-priority items puzzles me.

Mr. NICHOLAS. Are you speaking fiscal year 1980?

Senator HATFIELD. I am referring to any time you do it. It is on page 11 of this 1980 budget.

Mr. NICHOLAS. Yes, sir; we are asking for new money for 1981.

Senator HATFIELD. I know, but what about 1980?

Mr. NICHOLAS. The program began in 1979 actually, with a reprograming of some $4 million—we are just catching up with the appropriation process in 1981. The transfer from the institutes is principally from intramural program plans, intramural being the program of the institute that gets the benefit of the use of the clinical research facilities.

Senator HATFIELD. What you are doing is putting a fee on each of these agencies that are using the facilities in order to improve it. That doesn't answer my question. My question is regarding the priority of those moneys that are coming from priority programs of these agencies. Why didn't NIH just ask for remodeling fund money in addition to whatever else you are asking for?

You could have asked for a supplemental.

Dr. FREDRICKSON. Mr. Chairman, we did ask for inclusion of that sum which we are discussing in the budget for 1980. It was not possible to include it in the 1980 budget at the time of its development. With the impending completion of the ambulatory care research facility we cannot delay further the beginning of modernization of the clinical center adjacent to it, and which must be tied into it.

[The information follows:]

This program has a threefold purpose: To integrate the activities in the clinical center with their functional counterparts in the new ambulatory care research facility now under construction; to upgrade patient care and medical support spaces to remove functional obsolescence and repair physical deterioration; and to satisfy the latest code requirements for the handicapped, for environmental health, and for the safety of the patients and the staff.

The individual projects would be scheduled to promote optimal interface between the clinical center and the ambulatory care research facility which will be completed in 1982.

The proposed plan provides a sequential pattern of renovation projects which will minimize the impact on patients and research projects.

Dr. FREDRICKSON. Therefore, we discussed carefully with these Institutes that are contributing, including two institutes of the ADAMHA, which expect to benefit from modernization. All agreed that we would present to the Congress a request for transfer of these funds.

Senator HATFIELD. These agency directors all have agreed?

Dr. FREDRICKSON. Yes, sir.

ALTERNATIVE UTILIZATION OF TRANSFERRED INTRAMURAL PROGRAM FUNDS

Senator HATFIELD. Then I would like, for the record, what they would have done with this money if you had not asked for its transfer in their programs. Was this excess money? Was this low-priority money? Was

this unnecessary appropriations for programs that were justified up here before this committee last year and the year before?

Dr. FREDRICKSON. I can answer that for the NIH in aggregate.

Senator HATFIELD. I would appreciate that, Doctor. But I would also like to get an answer from each one of these directors who have now willingly offered their program money for remodeling—I am getting some reaction from the program level. I would like to get from each of the programs affected just exactly what they would have used that money for.

Dr. FREDRICKSON. Very good, sir. You have before you a list of the eight NIH Institutes which are affected by the proposed transfer.

Senator HATFIELD. I have them here with the amount of money they contributed voluntarily. [Laughter.]

Dr. FREDRICKSON. Approximately $1.2 million of this proposal involves training funds. The largest portion involves redirection of research contracts funds and moneys for the operation of the intramural program, which depends heavily upon this facility. Support of research project grants has not been reduced.

Senator HATFIELD. I would like to proceed with the request that we have each director of each of the intramural programs, present to this committee in writing a response to my question: What would you have utilized this money for that you are now contributing for the remodeling project? I will make that a part of the record. I will not delay the proceedings this morning for that response. I think, perhaps, it would be better if it were in writing, anyway, when you have had a chance to sort of review and perhaps discuss with some of your own staff people.

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

BUILDINGS AND FACILITIES TRANSFER

Question: What do the Directors of the various Institutes --who stand to lose money because of the transfer, -- Cancer, Neurology and Allergy -- think of this proposal. Each program involved in this proposed transfer should state where the money will be used if it is not transferred.

Answer: Listed below are the responses of the Institutes involved in the transfer of funds to the Buildings and Facilities Account for the Clinical Center Modernization Project in 1980.

CANCER

The NCI recognizes and supports the need to modernize the Clinical Center. In the FY 1981 President's Budget the National Cancer Institute has included a transfer of $2.133 million to the Buildings and Facilities appropriation for its FY 1980 share of the cost of modernizing the Clinical Center. The source of these funds is proposed to come from direct operations activities. If these funds were available to the NCI for FY 1980, they would be used for direct operations and intramural research to help offset the impact of inflation on our in-house activities, including cancer communications, program evaluation and the cost of experimental animals and research supplies and materials in support of such research areas as prevention, biology and immunology research, drug development, and clinical studies.

NHLBI

The NHLBI agrees with the need to modernize the clinical center research facility. In 1980, $1,193,000 will be transferred to the B&F account to support this effort.

These funds, would be utilized in the areas from which they were initially transferred, within intramural research. They would be used to: purchase a fluorescent activated cell sorter for use in clinical hematology and preparation of space for its use. This could be accomplished in 1980, rather than delayed until 1981.

Funds would also be used to maintain the existing level of catheterization studies, exercise studies, echocardiography and radionuclide cineangiographics (a procedure developed here in 1976-77). It would permit the continued increase in the number of outpatients admitted, which have been increasing annually by 500.

DENTAL

The proposal to transfer funds in order to continue updating of facilities was agreed to by our Institute both because we realize the acuteness of the general need to modernize our research facilities and specifically because we are direct users of both the laboratory and clinical space in the Clinical Center, where renovation is essential to all activities.

The funds would otherwise be used to help cover increased operating cost for ongoing studies in the intramural program, especially in the areas of immunology and microbiology as related to periodontal disease. It is important that work with experimental animals, which is ever more expensive, be restored to levels more

commensurate with the demands of adequate and timely experimental design.

ARTHRITIS

The NIAMDD is totally supportive of the concept, modernization of the 1949 vintage clinical research facilities, and has no misgivings about sharing in the cost. We would, however, rather have absorbed this cost from the relatively large increase for research project grants provided in 1980, than from training funds as is the current plan.

If alternate funding were available for Clinical Center Modernization and this transfer were not necessary, the funds would be restored to the Research Training Programs.

NEUROLOGY

The NINCDS recognizes the importance of participating in funding of the Clinical Center modernization project since it will benefit the Institute's intramural program. The 1980 funds to be transferred from the Intramural Research program would be used to order equipment related to the NINCDS intramural Positron Emission Tomography research program and for research equipment to be utilized in the NINCDS laboratories in the Ambulatory Care Research Facility.

ALLERGY

The NIAID is in agreement with the need to modernize the Clinical Center and is supportive of this effort. The proposed transfer of $564,000 by the NIAID -- if not effected -- would be used to expand and pursue clinical trials in interferon and other antiviral substances.

CHILD HEALTH

The NICHD recognizes the need for and fully supports the concept of the Clinical Center modernization and the transfer of $236,000 of NICHD funds to the NIH Buildings and Facilities appropriation. If the transferred funds were available to the NICHD, the Research for Mothers and Children Program would use $137,000 for programs of research on high risk pregnancy and congenital defects. Population research would use $99,000 for support of clinical trials related to development of new and improved contraceptives.

EYE

It is generally accepted that upgrading physical facilities should be a top priority for any research institution, if required. The NEI supports the modernization proposal for the Clinical Center.

If the money were not transferred funds would be used to support 1 research and development contract and 4 trainees in one of the fields of vision research which we are currently emphasizing, for example, epidemiology.

In total, $933,000 will be transferred from ADAMHA intramural research funds to NIH to support the ADAMHA share of Clinical Center Modernization. Based on current and projected space in the Clinical Center, the mental health intramural research activity will contriubte $788,000 of the required amount and $145,000 will be transferred from alcohol intramural research funds.

The NIMH transfer necessitates deferral for one year of the acquisition of new and replacement laboratory equipment previously scheduled for purchase in 1980. A total of $2,258,000 had originally been budgeted for this purpose, with the result that acquisitions will be cut back by one third. The cutback will be prorated among all intramural research programs in order to minimize impact, and the 1981 budget includes a corresponding increase for equipment purchases. If the necessary funds are made available in 1981, the impact on ongoing NIMH research efforts will be minimal.

NIAAA would be required to forgo the purchase and replacement of equipment for the metabolism and preclinical studies programs. A number of experiments in brain metabolism , membrane biochemistry, and neurobehavior scheduled for 1980 would be delayed until 1981, when funds are expected to be made available for equipment purchases.

While this delay would certainly impede programs in investigating certain aspects of alcohol use and abuse, provision of the necessary funds in 1981 would permit research activities to proceed with a minimum of disruption.

RENOVATION OF OBSOLETE BUILDINGS

Senator HATFIELD. The thing I would also like to know is, it seems to me you have buildings that are 40 years old, you have buildings that are 25 years old. And any building in your field, they tell me, in the medical field, that buildings become obsolete probably sooner than buildings constructed for any other purpose.

Do you not have an ongoing review of projecting ahead for each building a time and a scope of remodeling and updating, so that you don't get caught in this situation where you come in here with this high priority now for remodeling that has been made at the sacrifice of transfers from programs?

Mr. NICHOLAS. Yes, sir, we do. It was as the result of that kind of a review that we identified the laboratory buildings 2, 3, 4, 5 and 8 as the next on our list of priority upgrading. Now this upgrading process for these buildings is a complicated business. All of the buildings are occupied and fully utilized by scientific personnel. So we need a musical chairs kind of operation to keep these programs going at the same time that we are remodeling. For that reason, we have the rehabilitation of these buildings scheduled over the period 1982 to 1989.

We will be coming in to you in subsequent years for additional moneys to continue this well-planned-out process. The $1.5 million that we are asking for today will start the process. But the total remodeling of these buildings into 1989 will require about $42 million in 1981 constant dollars.

Senator HATFIELD. Beginning 1981, it will be new money, a new money request?

Mr. NICHOLAS. That is correct. We are not reprograming any money for this project at all. I want the committee to understand, though, that this is just the beginning of a process which will ultimately end up with a request for a total of $42 million over a period of about 7 years.

Senator HATFIELD. I think you realize you go through the hoop preparing this budget in terms of the needs represented by your programs. The buildings are to facilitate the program. The program is the heart of the whole Institute, not the building. The building is merely a tool. And you go through the OMB and all of these other hoops. Then you come up here and those of us on the committee who support you, are committed to you programwise, and we make our battle on the committee against all of the other competition for resources and money and then go to the conference committees and make battle for programs and so forth.

It is really somewhat shocking to then find that we have such a flexible program budget that we can transfer moneys for remodeling purposes. It almost seems like we are reversing the priority.

I appreciate the important role of modern clinics and modern laboratories. But I am still reminded of Mark Hopkins. I know it is more than a teaching role. But I think sometimes in the fields of education and otherwise, we can get our priorities a little bit turned around between facility and program.

I want to give you every penny you can use on program and to get you proper housing for it. But I am really disturbed that these moneys that are really so tight in programs—we were led to believe they were tight, and we pled for them and bled for them. But now we find they are so flexible that we can transfer $3, $4, $6, $7 million out of them.

Maybe there was some fat in them. Maybe there was some change of program or reconfiguration or something that brought out this excess money, this fat in the budget that you had in programs before.

Anyway, we will get into that when we hear directly from the directors.

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

CLINICAL CENTER MODERNIZATION

Question: Last year our Committee agreed to a $842,000 reprogramming for the modernization of the Clinical Center at NIH, a long overdue step. What uses have been made of this $842,000 in connection with the project?

Answer: The total 1979 cost of the Clinical Center Modernization project was approximately $4.6 million. This initial phase was financed by the Committee-approved reprogramming of $842,000, from program funds already in the intramural program, and funds in the NIH Buildings and Facilities account.

Project Title	Actual Obligations	Remarks
Renovate Glassware/ Media Preparation Areas	$2,325,575	Design and work phases
Renovate 2 West Patient Care Unit	1,036,063	Design and work phases
Renovate Locker Area and Central Sterile Supply Area (Phase I)	752,943	Design and work phases
Renovate B1 Lobby and Concourse Area	209,528	Design phase only
Renovate 3D Corridor Laboratories	139,138	Design and work phases
Renovate 11D & N Research Module	43,378	Design and work phases
Procurement Servicing Costs	4,975	
Master Programming Contract	95,363	
	4,606,963 1/	

1/ Includes a total of $607,707 from the Buildings and Facilities appropriation to finance capital improvements elements of the work.

Question: How much do you plan to ask (for) in your Fiscal 1981 budget to continue this work?

Answer: The Fiscal 1981 budget includes a request of $7.0 million for the Clinical Center modernization project.

Question: At the time we agreed to the reprogramming, we said we expect to review, in a timely manner, each year's plan of work, and the funding related to it, before deciding whether to permit it to proceed. When will we have an opportunity to review the FY 81 plan of work?

Answer: The following is a list of projects proposed to be funded from the FY 81 appropriations. The work programmed essentially provides for renovation of space to accomodate much needed patient care units and support activities.

Project Title	Estimate	Remarks
Renovate NIDR Clinic/Labs	$1,450,000	Design and work phases
Renovate 10 East Patient Care Unit	950,000	Design and work phases
Renovate 12 West Patient Care Unit	850,000	Work phase only
Relocate Self-Service Store	300,000	Work phase only
Relocate Medical Records	220,000	Design and work phases
Laboratory Utilities Upgrading	1,400,000	Design and work phases
Laboratory Relocations - Post ACRF	200,000	Design phase only
Relocate Personnel/Nursing	180,000	Design and work phases
Renovate 10 West Patient Care Unit	90,000	Design phase only
Renovate 6 East Patient Care Unit	75,000	Design phase only
Renovate 3 East Patient Care Unit	130,000	Design phase only
Renovate 4 East Patient Care Unit	130,000	Design phase only
Renovate 1 B South Radiation Therapy Clinic	40,000	Design phase only
Design/Work Contingency	635,000	
Master Programming Contact	350,000	
	7,000,000	

BUDGET GROWTH

Question: The 1970's saw the budget for the Office of the Director more than double. Can you point out some specific changes during that time which you feel warrant such large increases?

Answer: The increase in the Office of the Director's budget is primarily due to annual mandatory pay raises, the increased workload in support services such as financial management, and the undertaking of several new initiatives. In the early 1970's, the Division of Management Survey and Review (internal audit) and the Division of Equal Opportunity were established. In recent years, the Director's Office has also introduced new initiatives to insure protection from research risks and to facilitate the transfer of pertinent biomedical research knowledge into the health care system. This has resulted in the creation of the Office for Protection from Research Risks and the Office for Medical Applications of Research.

POSITIONS

Question: For the record, list the number of people and programs in the Office of the Director from 1970 to your planned 1981 request.

Answer: A chronology of budgeted positions for the components of the Office of the Director is provided on TABLE I. Where possible, we have tried to make the figures comparable. The table indicates that there is a total increase of 49 positions from 1970 to 1981. As pointed out above, several new initiatives have been undertaken to deal with specific concerns, including internal audit, equal opportunity, protection from research risks, and transfer of biomedical research knowledge to the health care system. The additional positions have thus supported the following activities: the Division of Management Survey and Review, the Division of Equal Opportunity, the Office for Protection from Research Risks, and the Office for Medical Applications of Research (part of the Immediate Office of the Director).

LATE PAYMENTS

Question: In the past, late payments for goods or services rendered at the NIH was often a problem. Has this procurement purchasing and payment situation been resolved?

Answer: During FY 1979, entry and document flow of centralized purchasing and receiving was automated. Payments were partially automated. The number of vendor payments made in excess of 30 days was reduced from 50% to 10%. The extension of the automation to delegated procurement and receiving points along with implementation of an invoice entry system during FY 1980 should further improve our payment record.

Question: What is the time backlog for payment?

Answer: Ninety percent of vendor payments are being made within 30 days--ten percent of the payments require a longer period of time.

TABLE I

NATIONAL INSTITUTES OF HEALTH
Office of the Director
Number of Budgeted Positions by Program Office
1970 - 1981

	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981
Immediate Office of the Director	44	45	49	49	48	48	47	50	56	59	56	56
Division of Equal Opportunity	-	-	-	-	7	8	8	8	8	9	9	9
Office for Protection from Research Risks	-	-	-	-	-	15	15	15	15	15	15	15
Office of Communications	29	28	26	26	32	32	32	33	33	33	33	33
Office of Program Planning and Evaluation	53	52	51	51	48	48	48	43	43	43	43	43
Division of Financial Management	166	167	141	141	144	154	153	160	165	168	166	166
Division of Personnel Management	116	116	158	176	166	154	153	151	151	144	144	144
Division of Contracts and Grants	57	57	55	55	50	50	50	47	47	52	52	52
Division of Management Policy	37	26	23	23	24	28	28	29	20	20	20	20
Division of Management Survey and Review	-	12	11	11	12	12	12	11	11	13	13	13
TOTAL	502	503	514	532	531	549	546	547	549	556	551	551

COMPUTERS

Question: How many computers does NIH now have and what is the cost per year?

Answer: NIH has 72 central processing units currently on hand. Central processing units are elements of a computer system with the capability to decode, execute programmed instruction; and maintain the status of results as the program is run. The total cost of the purchased units was $3,567,056. The yearly rental fee for leased units is $4,476,000.

Question: Do you own them or are they leased?

Answer: NIH currently owns 68 central processing units and leases 4. The leased units are elements of large systems and are rented from GSA.

Question: Are you satisfied with the types you have?

Answer: NIH is generally satisfied with the types of hardware we have obtained from the commercial market.

EQUIPMENT

Question: Old and outdated equipment is becoming a problem nationwide as it relates to research. Is this also a problem in the various intramural programs?

Answer: Yes, the same problem related to equipment for the extramural community is applicable to the NIH intramural program. Equipment required for intramural research programs must be replaced for two reasons: it wears out and it becomes outdated by more sophisticated equipment. The combination of these two factors results in the relatively short lifetime of complex scientific equipment. With the rapid introduction of new technologies in the biomedical field, NIH has introduced equipment sharing programs which will permit optimum use of sophisticated equipment in a cost effective manner.

EXECUTIVE OFFICER

Question: NIH has been without an executive officer for several months now. When do you if ever plan to fill this position?

Answer: The Director, NIH, has every intention of filling this important position as expeditiously as possible. The request for authority to recruit for this position was forwarded to the Public Health Service on January 18, 1980. We expect to advertise this position as soon as authority to advertise is approved by the Public Health Service and the Secretary, DHHS.

Question: Why has it taken so long?

Answer: This position was first advertised from May 9 through June 8, 1979. As a result of this advertisement, eight highly qualified candidates were identified on July 12, 1979. Prior to filling this position, the Director, NIH, decided to review the

varied functions of the Associate Director for Administration. Based on this review, the decision was made to reorganize the functions, and the candidates were therefore not interviewed. The reorganization was approved by the Secretary, DHHS on November 9, 1979. As indicated above, the NIH, under the new Senior Executive Service procedures, submitted a recruitment plan for this position on January 18, 1980.

NIH ADVISORY COUNCILS

Question: In last year's hearings, we were concerned that advisory councils had few nurses, allied health, or other health professionals in their membership. Since then, you reported to us that four were nurses and few were allied health professionals---unbelievably low numbers considering their involvement in our health care system. Totally, how many people serve on your advisory councils?

Answer: As of December 31, 1979, there were 163 persons serving as active members of various NIH advisory councils. Of this number, approximately two-thirds are research scientists with remaining positions filled by lay persons who are active participants in health related issues.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF DR. RUTH KIRSCHSTEIN, DIRECTOR

BUDGET REQUEST

Senator HATFIELD. Dr. Ruth Kirschstein is the Director of the General Medical Sciences Institute, where the primary emphasis is basic research and training programs. Doctor, in fiscal 1980 you received $312 million. Your 1981 budget request is for nearly $332 million, one of the largest of all of the increases in the total NIH budget. We will put your statement in the record.

But before I begin any questions, would you like to make any further comments or summary?

[The statement follows:]

Statement of Dr. Ruth Kirschstein

I am honored to appear before you for the sixth time to present the programs of the National Institute of General Medical Sciences. This Institute, the "basic science" Institute, has had a distinguished record of supporting research of the highest quality. Evidence of this is the award by President Carter in January 1980 of the National Science Medal to Dr. Arthur Kornberg and Dr. Severo Ochoa who are current and former NIGMS grantees, respectively.

GENETICS

A primary focus of the NIGMS is the support of fundamental biomedical research in Genetics. Progress in this area over the past 25 years has been dramatic, as noted in a recent report to the Congress by the National Academy of Sciences. Research related to localizing and mapping specific genes on chromosomes has been supported by NIGMS, as has work on rapid DNA sequencing techniques, the significance of which was recognized this year in the presentation of the Lasker award to an NIGMS grantee, Dr. Walter Gilbert of Harvard University. Most of the genetics research using recombinant DNA techniques is supported by NIGMS. Of great importance is the very recent report by Dr. Gilbert and his colleagues that the genes of the virus of serum hepatitis or hepatitis B can be expressed in the common bacterium, Escherichia coli, and that the bacteria can produce hepatitis antigen. When this bacterial product is injected into rabbits, antibody to the hepatitis virus antigen is produced. The implication of this finding in relation to the possible future production of a hepatitis vaccine is enormous and it is anticipated that vaccines against other infectious diseases might be produced safely by these techniques in the future.

Encouraged by this Committee, NIGMS has begun to emphasize studies related to the complicated genetic aspect of common diseases such as diabetes and hypertension. For example, we have recently awarded a grant to the University of Utah for the development of a computerized data bank based on the careful genealogical records tracing the genetic relationship among Mormons combined with hospital records on the same population. These records can be used to study the development of common diseases in family groups and to look for markers which will trace inheritance of susceptibility to particular diseases. Such studies should lead to the identification of individuals susceptible to particular diseases as well as to a better understanding of the etiology of such diseases.

BURN AND TRAUMA RESEARCH

As one facet of its Physiology and Biomedical Engineering Program, for many years the Institute has emphasized support of basic biological studies related to the systemic response of the body to burns and other trauma. This is a difficult and demanding field of research, and it has suffered from a shortage of highly skilled investigators willing to devote the time, the painstaking efforts and the patience to such studies. Despite this shortage, progress has been made in reducing mortality after severe injury and burns, and the contributions of basic scientists in this area have been remarkable. For example, Dr. Richard Trelstad, an experimental cell biologist and pathologist at the Massachusetts General Hospital, is studying the basic mechanism of the formation of collagen, the protein which forms the essential element of the fibrous connective or supporting tissue

of the body. It is the collagen which, as healing occurs after injury or burn, holds the edges of wounds together and provides strength to the scar tissues. However, deposition of collagen may also distort the tissue and cause it to be less functional. In collaboration with Dr. John Burke, Director of the NIGMS supported Burn Research Center at Harvard Medical School, Dr. Trelstad is applying knowledge derived from studies of collagen formation to the task of learning how to control scarring after severe burn injury. It is believed that burned tissues release enzymes which remove the collagen and delay healing. Dr. Trelstad and his colleagues are now trying to determine whether immediate excision of burned skin will prevent the release of enzymes and the subsequent destruction of collagen leading to as little disfiguring scarring as possible.

Although such studies progress slowly, the support which the NIGMS has provided for burn and trauma research has been translated into markedly improved survival as well as the successful rehabilitation of many of the severely injured.

CELLULAR AND MOLECULAR BASIS OF DISEASE

The objective of the Cellular and Molecular Basis of Disease (CMBD) Program, the largest area of research support within NIGMS, is to gain the fullest knowledge about human cells to assist in the prevention and cure of diseases of man. Grantees of the CMBD Program use the techniques of many scientific disciplines such as biochemistry, physics and immunology and often study the components of diseased cells in order to elucidate cellular function. For example, in order to better understand the biochemical components of the nucleus of the cell, basic scientists are studying the cells and serums of patients with a so-called auto-immune disease called systemic lupus erythematosus which is of unknown etiology. In this disease, of which there are two forms, patients develop antibodies to the nuclear components of their own cells. In one form of the disease there is marked connective tissue involvement and in the other, severe kidney damage. At Yale University, a young medical scientist supported on an NIGMS research training grant, working along with a senior researcher, Dr. Joan Steitz, for the first time, has established the biochemical identity of several of the nuclear antigens, which are associated with the form of "lupus" having connective tissue involvement. Using the techniques of biochemistry and immunology, they believe that it should be possible to identify precisely and individually the other molecules against which these patients produce antibodies, to correlate these particular molecules with the various types of immune complexes that develop and with the symptoms of the disease and, finally, to devise methods to overcome the deposition of these complexes.

Other NIGMS grantees at Baylor College of Medicine in Houston, Texas, have been investigating approaches to preventing the pathologic changes in the kidney which occur in the second type of "lupus" as a result of the formation of immune complexes involving DNA. The usual treatment of "lupus" having kidney involvement is with non-specific immunosuppressive agents, such as cortisone. Dr. David Terman and his colleagues have developed an alternative approach which involves the removal of the immune complexes from the circulation of a patient with "lupus." This approach involves filtration and adsorption of these immune complexes by passing the patient's blood through a column filled with special adsorbing material and then returning the blood to the patient's circulation. Studies which were first carried out in dogs having a disease similar

to lupus were extended recently to the treatment of a patient by this adsorption and filtration system. Twenty-eight days after this procedure, not only was the patient markedly improved, but a microscopic study of tissue removed from her kidney showed considerable improvement in the pathologic findings. While this is a promising report on a single patient, additional studies are needed to confirm these findings.

PHARMACOLOGICAL SCIENCES

Studies involving immunologic phenomena are also important in the NIGMS Pharmacological Sciences Program, formerly called the Pharmacology-Toxicology Program. Investigations by Dr. John Oates, at the NIGMS supported Pharmacology Research Center at Vanderbilt University, involve the elucidation of the actions of a family of ubiquitous agents called prostaglandins. Many cells of the body produce various prostaglandins, including mast cells which play a key role in the inflammatory processes of the body. It has been shown that immunologic activation of mast cells in the lungs affects the production of metabolites of prostaglandins by these cells and this appears to be a factor in the development of allergic reactions. Studies by Dr. Oates and others of pharmacologically active chemicals which control the metabolism of the prostaglandins are essential to our understanding of the role of these humoral agents in allergic states such as asthma and to their cure and/or prevention. Furthermore, prostaglandins have been identified as important mediators in metabolic processes leading to diseases as diverse as arthritis and heart disease.

The Pharmacological Sciences Program also supports the development of synthetic methodology for producing new pharmacologically active chemicals. Dr. H. C. Brown of Purdue University, a grantee supported by NIGMS for many years, received the Nobel Prize in Chemistry this year for such studies.

RESEARCH TRAINING

The availability of a cadre of highly qualified research scientists is critical in assuring continued scientific progress.

NIGMS has a large research training program, designed to assure that future research scientists have had the best possible preparation. In particular, the Medical Scientist Training Program, which leads to the combined M.D.-Ph.D. degree, seems to be a way to assure that clinical researchers will be available in the years to come. It should be noted that the Committee on Research Manpower Needs of the National Academy of Sciences has emphasized the importance of the Medical Scientist Training Program in each of its annual reports. The NIGMS plans to increase the number of trainees in this program from the current level of 650 toward the 725 trainees recommended by the Academy committee.

MINORITY ACCESS TO RESEARCH CAREERS (MARC) PROGRAM

The other special NIGMS training program is the Minority Access to Research Careers (MARC) program. The MARC Honors Undergraduate Program now has twenty-two participating institutions, 16 have a significant Black student population; four, a significant number of Hispanic students; two, a significant number of Native American students; and one, predominantly Hawaiians in the student body.

Several schools have significant numbers of more than one minority group. The National Advisory General Medical Sciences Council evaluated this program at its February meeting, concluding that during the initial two and one-half years, a substantial foundation was laid that will undoubtedly have a positive impact on the number of well-trained minority biomedical research scientists in the country.

RESEARCH INSTRUMENTATION

In addition to research manpower, research instrumentation is critical. I would like to bring the Committee's attention, therefore, to a special initiative developed by NIGMS in FY 1979. In order to correct the serious lack, or in some cases, obsolescence, of sophisticated analytical instrumentation at many universities, the NIGMS announced a one-time only program of grants for purchase of instrumentation. The intent was to provide grantees with better access to modern, up-to-date instruments such as electron microscopes, nuclear magnetic resonance spectrometers, and cell sorters, on a shared basis. Access to such instrumentation is essential to continued scientific progress and its availability will insure the wide dissemination of new instrumental techniques particularly to new young investigators. The great need for such instrumentation was amply demonstrated by the fact that 212 applications were received despite a period of only two months between the announcement of the program and the receipt date for applications. Sixty-five instruments were awarded to 55 institutions in twenty-six states. We feel that the impact of this initiative will be felt throughout the biomedical research community for years as more and more research becomes dependent on the availability of such instrumentation.

Mr. Chairman, in order to continue the dramatic progress in basic biomedical research made in recent years in the programs discussed, the budget request for the National Institute of General Medical Sciences is $331,639,000, an increase of $19,011,000 over the 1980 estimate. I shall be pleased to try to answer any questions and to supply additional information as requested.

BASIC RESEARCH

Dr. KIRSCHSTEIN. Yes; I would like to highlight some of the activities of the Institute in the past years. As you indicated, the National Institute of General Medical Sciences is the basic science institute. The activities of our institute undergird the research done by all of the other categorical institutes.

We have a distinguished record of supporting research of the highest quality. Evidence of this is this year's award by President Carter in January 1980 of the National Science Medal to four current or past NIGMS grantees.

Senator HATFIELD. I was at that ceremony.

Dr. KIRSCHSTEIN. In addition, the Nobel Prize in chemistry went to Dr. Herbert Brown, who has been supported by NIGMS for many, many years.

Senator HATFIELD. Excellent.

61-400 O - 80 - 35

GENETICS

Dr. KIRSCHSTEIN. A primary focus of the Institute is the support of fundamental biomedical research in genetics, and progress in this area over the past 25 years has been absolutely dramatic. A recent report by the National Academy of Sciences has pointed this out. Some of the most exciting advances involve work in localizing and mapping specific genes on chromosomes, and on rapid DNA sequencing techniques, the significance of which was recognized this year by the award of the Lasker Prize to Dr. Walter Gilbert, who is a grantee of NIGMS.

The NIGMS supports most of the research using recombinant DNA techniques. For example, Dr. Gilbert just presented a recent report that the genes of the hepatitis virus can be introduced in the common bacteria, *E. coli*, and that these bacteria can then produce hepatitis antigens. The implications of this for future production of hepatitis vaccine are enormous.

TRAUMA AND BURN

The Institute has, for a long time, supported basic biological studies related to the systemic response of the body to burns and trauma. This, Mr. Chairman, is a very difficult and demanding field of research, and it has suffered from a shortage of highly skilled investigators who are willing to devote the time, the painstaking efforts, and the patience that is needed for such studies.

Despite this shortage, we have made progress. The contributions of basic scientists in this regard have been very remarkable. For example, a pathologist at the Massachusetts General Hospital is currently studying the basic mechanism of the formation of collagen. This is the material that holds tissues together as wounds heal, but it can also distort these tissues and prevent a limb, for example, from being totally functional at a later time.

This investigator is studying the possibility of excising burned tissue immediately after the injury occurs in order to prevent the release of enzymes which will allow spread of the injury and will cause destruction of the collagen, and perhaps prevent disfiguring scars.

CELLULAR AND MOLECULAR RESEARCH

In the basic cellular and molecular biology area, scientists often study the tissues or the cells from diseased individuals, in order to learn more about normal cells. For example, scientists are currently studying the biochemical components of the nucleus of the cell from individuals who have the disease systemic lupus erythematosus. They have discovered the actual biochemical identity of several of the nuclear antigens which are associated with this disease.

They hope to be able to correlate this biochemical identification with the symptoms of the disease and thereby devise methods of preventing the formation of the immune complexes that are laid down in this disease.

Another grantee of NIGMS is taking a different approach to the study of lupus erythematosus and has shown that it is possible to remove immune complexes from the circulation by passing the patient's

blood through an adsorbing column outside of the body. The column adsorbs the immune complexes and the blood then can be returned to the individual. This has been done on a single patient who showed improvement and it is obvious that additional studies will be needed.

PHARMACOLOGICAL SCIENCES

Investigators at a pharmacology research center are involved in studying ubiquitous agents called prostaglandins. These agents are produced by many cells including most cells which play a key role in the inflammatory processes of the body. It is these cells which, upon activation, seem to produce metabolites of prostaglandin, and this appears to be a factor in the development of allergic reactions.

TRAINING

In order to be able to continue such activities and the enormous progress that has been made and still needs to be made, the availability of a cadre of highly qualified research scientists is needed. And for this, a research training program is required.

MEDICAL SCIENTISTS TRAINING

Of particular interest are the two special programs in research training of the NIGMS: One is the medical scientist training program, which leads to a combined M.D.-Ph. D. degree. This assures, at least partially, that clinical researchers will be available in the years to come.

The National Academy of Sciences has emphasized the importance of this program and we hope to increase the number of trainees from the current level of 650 toward the 725 trainees recommended by the Academy.

MARC PROGRAM

The other program is the minority access to research careers program. The honors undergraduate part of this program now has 23 participating institutions. Sixteen have a significant black student population, four a significant population of Native American students, and one, Hawaiian student. This program has been underway for about 2½ years, and it has created a substantial foundation that will have a positive impact on the number of well-trained, minority biomedical research scientists in the country in the future.

BUDGET REQUEST

In order to continue this dramatic process, we would ask for a budget of $331,639,000, an increase of $19 million. I would be pleased to answer any questions.

GENETIC COUNSELING

Senator HATFIELD. Thank you very much, Dr. Kirschstein. That was an excellent summary. I would like to go into the subject of genetic screening, if I could, for a few minutes. I have some questions for you.

You are involved, are you not, in the matter of methods to improve the present screening techniques for genetic disease?

Dr. KIRSCHSTEIN. Our Institute is involved in research to improve such techniques. That's correct.

Senator HATFIELD. Are there guidelines presently, or do you contemplate drafting up guidelines for the genetic counselors to follow in counseling people with varied social, economic, religious, educational, ethnic backgrounds?

Dr. KIRSCHSTEIN. The Bureau of Community Health Services of the Health Services Administration—HSA—has the responsibility for that aspect of the program, sir.

Senator HATFIELD. Are you aware of what they are doing in terms of development along those lines?

Dr. KIRSCHSTEIN. I am aware in a general way. We work together on a report that is submitted to the Congress each year in response to the requirements of the Genetic Diseases Act. HSA has set up regional programs in order to give guidance, and does have guidelines for what should be in genetic counseling programs.

Senator HATFIELD. As you are aware, we have genetic information and counseling programs in the Health Services Administration as well?

Dr. KIRSCHSTEIN. Yes.

Senator HATFIELD. Do you work with them and correlate your activities with them?

Dr. KIRSCHSTEIN. Yes; up until about 1 year ago, there was an Interagency Public Health Service Genetics Coordinating Committee which initially began to coordinate these activities. I was chairman of the committee. As it became clear that the activities were being concentrated more and more in the Bureau of Community Health Services, that agency has been taking more responsibility for that program.

We, however, do participate and provide the portion of the annual report which is related to developmental aspects and research in regard to genetic diseases. I have the responsibility for preparing that part of the report.

HEREDITARY DISORDERS

Senator HATFIELD. Can you provide this committee with a list of those hereditary disorders that can be detected presently through prenatal screening?

Dr. KIRSCHSTEIN. Yes, sir.

[The information follows:]

HEREDITARY DISORDERS

The following genetic diseases can be diagnosed prenatally. They are divided into groups based on whether the defect is a metabolic, chromosomal, or congenital one.

METABOLIC DISORDERS

1. Adenosine deaminase
2. Alpha-thalassemia
3. Congenital erythropoietic porphyria
4. Hypophosphatasia
5. Lesch-Nyhan syndrome
6. Lysosomal acid phosphatase deficiency
7. Menkes' disease
8. Fabry's disease
9. Gaucher's disease
10. GM Gangliosidoses, including Tay-Sachs disease

11. Krabbe's disease
12. Metachromatic leukodystrophy
13. Mucolipidosis
14. Niemann-Pick's disease
15. Hurler syndrome
16. Hunter syndrome
17. Sanfillipo A disease
18. Maroteaux-Lamy syndrome
19. Galactosemia
20. Pompe's disease
21. Arginosuccinic aciduria
22. Citrullinemia
23. Cystinosis
24. Homocystinuria
25. Maple syrup urine disease
26. Methylmalonic acidemia
27. Proprionic acidemia
28. Xeroderma pigmentosa

Sex-linked disorders in which amniocentesis permits identification of males, thereby reducing the probability of an affected child since only males are affected:

1. Duchenne muscular dystrophy
2. Hemophilia
3. Severe combined immune deficiency
4. Pelizaeus-Merzbacher disease
5. Ocular albinism
6. X-linked blindness

Chromosomal anomalies.—All chromosomal anomalies are detectable prenatally.

1. Numerical anomalies
2. Chromosomal breakage syndromes: a. Ataxia-telangiectasia (or Louis-Bar syndrome); b. Bloom syndrome; c. Dyskeratosis congenita; d. Fanconi anemia

Hemoglobinopathies and other blood disorders diagnosed by fetoscopy or placental aspiration:

1. Alpha thalassemia
2. Beta thalassemia
3. Sickle cell disease
4. Hemophilia

Physical anomalies and other disorders diagnosed by fetoscopic observation, fetal skin biopsy, alpha-fetoprotein determination or ultrasonography.

1. Ellis-Van Creveld syndrome
2. Spina bifida
3. Congenital bullous icthyosiform
4. Erythroderma
5. Anencephaly
6. Encephalocele
7. Meningomyelocele (spina bifida)
8. Hydrocephaly
9. Perencephaly
10. Infantile polycystic kidney disease
11. Renal dysplasia
12. Renal agenesis
13. Hydronephrosis, megalureter, urethral obstruction
14. Thanatophoric dysplasia
15. Chondroectodermal dysplasia (Ellis-Van Creveld)
16. Roberts syndrome
17. Short limb skeletal dysplasia (not better defined)
18. Diaphragmatic hernia
19. Enteric cyst of thorax
20. Duodenal atresia; jejunal atresia
21. Omphalocele
22. Meconium ileus+ (cystic fibrosis)
23. Gastroschisis and malrototion
24. Lymphagiectasia
25. Ascites (isolated, without hydrops)

GENETIC SCREENING

Senator HATFIELD. Dr. Kretchmer, you are the Director of the National Institute of Child Health and Human Development.

Can you tell us what you are doing in this same area?

Dr. KRETCHMER. Yes; again, I would emphasize that we support research in genetics rather than the service aspects such as genetic counseling. We, too, were on that Interagency PHS Genetics Coordinating Committee that Dr. Kirschstein mentioned, and stayed in close conversation with the Health Services Administration. We did, this past year, sponsor a major conference on the problems of prenatal diagnosis, including genetic screening. We published the conference proceedings in book form.

This report discusses the possibilities and potentialities. The effort was to bring together a group of people from the various fields concerned with genetic screening and prenatal diagnosis to determine what areas were available for more research, what areas were available for service requirements, and what areas could be applied.

If you would like, I could provide the committee with a copy of the report.

Senator HATFIELD. We would appreciate that very much. Thank you.

[CLERK'S NOTE.—The report is in committee files.]

BASIC RESEARCH

Senator HATFIELD. Let me go back to basic research for a moment. It appears to me there has been a growing recognition in the country at large to the importance of the matter of basic research. It has been gaining front-page attention in the newspapers.

To what do you attribute this?

Dr. KIRSCHSTEIN. I think that this is because, first of all, many people have become cognizant of the fact that the work that has been going on for many years has uncovered important facts that are now beginning to have application.

In addition, scientists have begun to explain this in a way that we have not done in the past.

PUBLIC INFORMATION

Senator HATFIELD. You have a role in that, in the matter of public understanding, public communication?

Dr. KIRSCHSTEIN. Yes, sir. We have put out a number of booklets that we think are very important in this regard. Two of them, particularly—one called "The New Human Genetics" and the other called "Inside the Cell" are written by an excellent science writer who has a unique skill in presenting science to the public at large. The first booklet, aimed particularly at high school students, describes what genetic diseases are, how one can make diagnoses of such diseases, and in general the newest findings in genetics.

The other is a total description of the cell and of cell morphology. These booklets have been enormously popular. We have distributed 43,000 copies of the genetics booklet to high school students, and an

additional 50,000 are going along with the NIH traveling exhibit related to the Year of the Child.

About 100,000 copies of the "Inside the Cell" booklet have been distributed to date.

Senator HATFIELD. You have budgetary items in 1980 and 1981 for this kind of activity?

Dr. KIRSCHSTEIN. Yes.

Senator HATFIELD. How much are they?

Dr. KIRSCHSTEIN. This is actually not a very large sum of money because we can do this in a way that is relatively inexpensive. We pay the salary and the consultant fees for the individual who writes these booklets, and then they are printed through the Government Printing Office, so it is on the order of about $1 per copy. It would cost about $150,000 to $200,000 a year.

TRAUMA AND BURN

Senator HATFIELD. Dr. Kirschstein, as you may recall, in September there was a request to transfer funds from the burn program to other research. This was agreed to very reluctantly by Senator Magnuson, the chairman of the Appropriations Committee, and Senator Schweiker, the ranking minority member of the subcommittee.

As you know, they both—as well as others of us on the committee—feel very strongly about this program, the burn treatment centers especially.

However, it was approved, if you recall, on two conditions or contingencies—one, that we receive a report detailing what you were doing in this area, and No. 2, that $1.2 million of reprogramed funds would be added to the amount already estimated to be spent in fiscal 1980.

As you know, we received this report, the first part of this requirement, last Monday, which means that we did not have the time to review the report before this hearing.

I wonder if you at this time could highlight or briefly summarize that report to the committee and also, when following the second part of the directive of the committee, could you give us an analysis of expenditures—how much will we spend in 1981?

Dr. KIRSCHSTEIN. Yes, sir; the report was prepared by the staff of my Institute and was submitted some time ago, Senator. I have three copies of it here which we are pleased to submit to you.

Senator HATFIELD. Just for interest, when did it leave NIH?

Dr. KIRSCHSTEIN. I cannot tell you when it left NIH. It left my office well before Christmas.

Senator HATFIELD. Two and a half months to get out from Wisconsin Avenue to the Hill? We received it Monday. It left your office 2½ months ago?

Dr. KIRSCHSTEIN. That's correct.

Senator HATFIELD. Where has it been? Would you care to shed any light on this mystery of the 2½ months travel time between Bethesda and Washington?

Mr. ITTEILAG. First of all, I am not sure it is 2½ months. Maybe we need to check that. Senator, I think the basic explanation is that the

Department is responsible for preparing over 100 reports. The majority of them are due to the Congress in December and January, the very same time that all other important budget matters are occurring.

Each of these reports goes through a rather rigorous review process. Once it leaves Dr. Kirschstein's office, it is cleared by the Director of NIH. It is cleared by the Office of the Assistant Secretary for Health. Then it is reviewed by the Office of the Secretary, and finally it is submitted to the committee. And, therefore, it takes longer than otherwise would be reasonable for these reports to reach the committee.

I would say that over the period of the last couple of years, we have tried, and I think we have succeeded in meeting the deadlines of the committee and have been processing them faster, but there is room for improvement in this regard.

Senator HATFIELD. Would you please, for the record, give us sort of a Dick Tracy investigation of this particular report for the simple reason that I think the agency that you represent—you have 180,000 employees?

Mr. ITTEILAG. 150,000 employees.

Senator HATFIELD. I just might, for the record, say that 19 of the 34 reports that were due here on the Hill were 6 weeks or more—6 weeks or longer in terms of lateness, delay, and tardiness. I am interested in getting an analysis of the work procedures that create this problem for the Hill.

I know you have many responsibilities, and that would be one agency I would have no desire to get a work permit in. I appreciate the struggle that you have, but it seems like with 150,000 employees, we could maybe reallocate—reshift them around a bit to try to expedite this process up on the Hill.

These reports—we don't treat them lightly. They are very important to fulfill our appropriations responsibility. I know the view is—perhaps it is like many reports around Washington. There are long hours and effort put into them and nobody reads them, but we do. We do carefully review these reports, and this committee especially.

It is difficult when we have this long period of delay in getting the basic material upon which to make these judgments in these hearings.

Well, so much for the second lecture of the day. [Laughter.]

Would you proceed?

TRAUMA AND BURN RESEARCH REPORT

Dr. KIRSCHSTEIN. The report that we submitted is a status report concerning burn and trauma research. As I told you, in my opening statement, this is a very difficult and demanding field of research. It takes very highly skilled investigators, particularly highly trained surgeons who are not only trained in the care of patients—and this is intensive care for people who are severely traumatized or severely burned—but who are also trained in the techniques of research.

[The information follows:]

PROCESSING OF BURN CENTERS REPORT

Our investigation revealed that the burn treatment centers report was processed within the Department as follows:

Report submitted by Director, National Institute of General Medical Sciences (NIGMS) to Director, NIH, December 18, 1979.

Comments developed by NIH staff and returned to NIGMS, January 8, 1980.

Report resubmitted by Director, NIGMS, January 14, 1980.

Report provided by NIH to the Assistant Secretary for Health (ASH), January 21, 1980.

Report provided by ASH to the Secretary, HEW, January 24, 1980.

Report reviewed by Office of the Secretary, HEW, and submitted to Senate Appropriations Committee, January 28, 1980.

It is clear from this chronology that this report was processed expeditiously in both the Office of the Assistant Secretary for Health and the Office of the Secretary, HEW.

RESEARCH TRAINING

This is research that takes a great deal of time and painstaking efforts. These are very ill patients, and the research is very demanding. This area has suffered from a shortage of these highly skilled individuals.

The NIGMS efforts have been of several kinds, but one of the most important has been to try to get enough of these individuals interested in research training. So in recent years we have emphasized our research training program in this regard.

For the past 13 years, NIGMS has spent a total of $69 million in the area of burn and trauma research. For example, in 1977, we had 46 research project grants, and in 1979, 62, with a projected number of 70 research project grants for fiscal year 1981. Looking at the total program there has been a 51-percent growth in funding of this area since 1977.

The research centers portion of the program has had a 62-percent growth in funding since 1977, from $2.5 to $4.0 million. There are currently seven burn research centers, and in addition, five program project grants, which are really small research centers.

What has happened in this area as a result of research is that we have improved the survival rates in severely burned patients by as much as 50 percent. Nevertheless, severe trauma and burn injuries are still very serious problems.

Senator HATFIELD. If I may interject, I understand—correct me if I'm wrong—that trauma and burn injury is the leading cause of death of ages 1 to 44 in this country?

Dr. KIRSCHSTEIN. That is correct.

Senator HATFIELD. The leading cause of death?

Dr. KIRSCHSTEIN. Yes; it is a very serious problem, Senator. And the problem, I think, Senator, is that when an individual is severely injured or severely burned, there is total organ failure in the body. There is a total systemic bodily response that is very severe, and we do not know enough about that response. We are trying to get the needed information through basic studies at the cellular, biochemical, and physiological levels. But, there really is an enormous amount that is not known as yet. We need highly skilled investigators to obtain this knowledge.

The committee requested that we increase the appropriation in this

area in 1980 by the $1.2 million which we asked to have reprogramed out in 1979. We have actually increased it by $1.8 million.

Senator HATFIELD. Higher than the $1.2 million?

Dr. KIRSCHSTEIN. Right, for 1980. And we would propose to put a further $800,000 above the level for 1980 into this program in fiscal 1981. This is for the entire burn and trauma research program, and it includes a half million dollars in research training which, as I said, is a very important area.

Senator HATFIELD. We are all happy to hear that report, and I will make sure that Senator Magnuson and Senator Schweiker both receive it.

Dr. KIRSCHSTEIN. I did provide three copies for the record.

Senator HATFIELD. Very good. Thank you very much, Dr. Kirschstein.

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

RECOMBINANT DNA TECHNOLOGY/RISK ASSESSMENT

Question: What is your Institute's current involvement in recombinant DNA research?

Answer: The National Institute of General Medical Sciences supports more than one-half of the NIH funded studies involving the use of recombinant DNA technology. NIH support for such studies is $98 million, of which NIGMS contributes $35 million. The studies supported include those done under research grant support as well as those done under support for research training.

Question: Are you working cooperatively with other Institutes (such as the NIAID) in the area of risk assessment of the recombinant DNA technology?

Answer: Risk assessment is an area of concern to all of the Institutes of NIH. The primary responsibility for risk assessment concerned with recombinant DNA technology has been given to the National Institute of Allergy and Infectious Diseases, although other Institutes, including NIGMS, are involved. Preliminary risk assessment experiments have been completed, and the Recombinant DNA Molecule Advisory Committee has concluded that there is no evidence of risk for experiments conducted with the commonly utilized E. coli K-12 host-vector systems, and that, before further risk-assessment experiments are performed, a thorough examination of the need for them should be made. Accordingly, a conference devoted to "risk assessment" will be held in California in early April. Staff of NIGMS will participate and coordinate with NIAID in this regard. It should be noted that the Office of Recombinant DNA Activities (ORDA) was transferred from NIGMS to NIAID on October 1, 1979. This Office is responsible for the coordination and monitoring of all Federally approved research activities in this area.

Question: What will be the effect of the recent relaxing of guidelines on recombinant DNA research?

Answer: The major change in the Recombinant DNA Guidelines is the deletion of the requirement for registration with NIH of experiments using the host organism E. coli K-12 and an EK1 host-vector system. However, these experiments must still be registered with and approved by a local Institutional Biohazard Committee (IBC) and must be conducted under P-1 physical containment conditions. Since approximately 80 percent of the experiments using recombinant DNA technology now performed fall into this category, a major decrease in the documentation previously required will be effected by the guideline revision, and a major shift of responsibility and control to the local IBC will occur. These experiments will not be exempted from supervision; rather, the responsibility for their supervision is changed. Unnecessary red tape and administrative delays will be markedly decreased.

The actual effect of this revision of the guidelines on NIGMS programs will be very small. The number of recombinant DNA projects is growing rapidly, and this increase will continue, but mostly as a result of the recognition of the power of recombinant DNA technology as a research tool. A possible minor effect of the revisions may be to allow researchers at institutions lacking a P-3 containment

facility greater access to studies using recombinant techniques with mammalian DNA. This research previously required P-3 containment under some conditions. But, on the basis of recent risk assessment experiments, work with mammalian genes in E. coli K-12 is now classified as only requiring a P-1-EK1 containment level.

Question: Are these guidelines being universally followed by private sector researchers?

Answer: Researchers in the private sector are following these guidelines, to the best of our knowledge.

DISEASE PREVENTION

Question: What portion of your budget is used for research in the area of disease prevention?

Answer: A little over one percent of the NIGMS budget for fiscal year 1981 ($3.8 million) can be classified as directly related to disease prevention.

Question: Please specify for the Committee what you consider to be preventive health related research areas.

Answer: The NIGMS supports preventive research activities concerned with studies of the effects of anesthetics on chromosomes; the mechanism of development of malignant hyperthermia; and the development of methods both to detect carriers of genetic disease and for prenatal diagnosis. The Institute's mission is to support and foster the conduct of basic, undifferentiated research that undergirds the categorical missions of the other Institutes. As a result of this research, our understanding of the normal and abnormal biologic processes, which underlie all disease, is increased, allowing not only more precise diagnosis and more rational treatment, but making it possible to prevent a number of diseases. In this sense, the entire research budget of the Institute is dedicated to prevention of disease.

BASIC GENETIC RESEARCH

Question: What progress has been made in research relating to the diagnosis and treatment of hereditary diseases?

Answer: Substantial progress has been made in the past few years. Specifically,

A. Prenatal tests for sickle cell anemia and some types of thalassemias have been developed. These methods are unique in that they seek differences in the genes or DNA of the fetus from that of normal fetuses, rather than differences in proteins (such as hemoglobin) made in response to the particular genes. It is expected that the new principle on which these methods are based will have a bearing on the diagnosis of many genetic diseases.

B. There is now highly suggestive evidence about the nature of the basic defect responsible for Huntington's disease, a catastrophic neurological disease which usually manifests its first symptoms in middle life, and inexorably leads to tragic loss of mental and

physical function. The defect is probably due to an inability of the patient's cells to repair damaged DNA. This finding may lead to a test for presymptomatic victims of the disease which would permit the children of patients with the disease, who have a 50 percent chance of developing the disease themselves, to have the information that would permit them to better plan their lives, including the decision of whether to have children of their own.

C. In the past few years, a number of genetic diseases have yielded to therapy. Examples among older, well-established therapies are (1) the treatment of hemophilia with antihemophilic factors, (2) the treatment of certain genetic diseases, such as methylmalonic aciduria, with larger-than-normal doses of certain vitamins; and (3) Cooley's anemia, which has been treated for years with blood transfusion. The treatment, although life-saving, has posed problems of its own, in that massive blood transfusion can result in accumulation of excess iron. Recently, research in blood fractionation has permitted the transfusion of younger red blood cells, so that favorable results can be produced with fewer side effects, and transfusions are needed less often. More recently, also, some of the inherited immunodeficiency diseases (particularly adenosine deaminase deficiency) have been treated by bone marrow transplants from close relatives.

Question: Has basic research in the field of genetics yielded new insights into the problem of disorders not previously thought to have a genetic component?

Answer: Most of the things we now know about genetic disorders are the product of long years of painstaking basic research. In the past few years, such research has produced knowledge of a number of associations between inheritance and common diseases not previously realized. This is illustrated by information now available about the human HLA system and the relationship between genetics and cancer:

A. The Human Leukocyte Antigen (HLA) system is a complex of several human genes which seem to be responsible for some rejection of organ transplants. This is a genetic system in which there is much variation between individuals. Individuals with certain HLA types seem to be predisposed toward certain diseases, while others are predisposed toward other diseases. Some 40 such "disease associations" have been found, including some which link inheritance to arthritis, diabetes, psoriasis, hepatitis, and Hodgkin's disease.

Research geneticists feel that studies of such associations may provide insights into the genesis of a number of poorly understood common diseases. One hypothesis about these disease associations derives from the fact that the HLA system is related to genes controlling the human immune system. Some investigators hypothesize that many common diseases, such as some forms of diabetes, are causally related to previous infections. Thus, a predisposition to certain of these diseases may, in fact, be due to the relative inability of some individuals to combat certain infections. The development of such diseases in association with certain HLA types has thus led to hypotheses about the relationships between genetics, infection, and common diseases. The identification of highly susceptible subpopulations at risk for disease is considered a cornerstone of successful programs of prevention.

B. It is becoming more and more clear that there is a close relationship between genetics and cancer. The following is already known:

1. Most of the chemicals which produce genetic mutations in certain bacteria also produce cancers in experimental animals. This correlation is, in fact, the basis for the well-known Ames test for carcinogenic substances.

2. Certain types of chromosome rearrangements are associated with certain kinds of human cancers. The association of one such rearrangement (the "Philadelphia" chromosome) with chronic myelogenous leukemia is perhaps the best-known example. However, many genetic conditions which result in increased chromosome fragility (Fanconi and Bloom syndromes) or which result in impaired repair of damaged DNA (Xeroderma pigmentosa or ataxia telangiectasia) are associated with increased likelihood of the development of cancers.

Question: Genetic research is growing rapidly in this country and it seems to be gaining more and more front page attention.

To what do you attribute this?

Answer: This development can be attributed to a number of factors:

A. Up until the 1950s, geneticists observed the traits of parents and their children and made deductions related to inheritance based on these observations. Since then, genetics research has changed dramatically. It is now possible to isolate, characterize, and even synthesize genes or gene fragments, and methodology has been developed for transferring genetic material from one organism to another. The public has, understandably, focused on both the potential problems and the promise of medical insights, and relevance to the alleviation of human disease. Thus, the attention focused on genetics is due to the very successes of the geneticists. The increased ability to manipulate genes has resulted in concern, both by scientists and the general public, that such increased knowledge be used responsibly, for the good of mankind, and that it not be misapplied.

B. Our increasing knowledge of genetics and cell biology has led to the recognition that not only rare, single-gene defects, such as sickle cell anemia, Cooley's anemia, or Tay-Sachs disease, or chromosome defects (such as Trisomy 21, also known as Mongolism) are genetic, but that common diseases, such as diabetes or hypertension, may also have a genetic basis. Such diseases are, in part, also affected by life style. The public is clearly interested in knowing what contribution genetics has made compared to environment in regard to these diseases.

Question: Has your Institute become the lead program in this area?

Answer: The National Institute of General Medical Sciences is the lead Institute in genetics research. The basic research in genetics supported by NIGMS undergirds all of the programs of the categorical Institutes, which deal with specific genetic diseases. For

example, NIGMS supports a large part of the research efforts devoted to mapping the location of human genes on chromosomes, and grantees of the Institute have been largely responsible for much of the basic research which has led to recombinant DNA technology. The programs of the other Institutes are focused on diseases and medical problems which are either clearly genetic, such as sickle cell disease or Huntington's disease, or have a genetic component, such as diabetes.

As the "lead" Institute, NIGMS has the responsibility for coordinating the NIH section of the report to Congress required by the Genetics Diseases Act. In addition, the Institute has co-sponsored conferences on genetics and the genetic epidemiology of common diseases in conjunction with other Institutes. The recent funding of a workshop on the genetics of epilepsy in cooperation with the National Institute of Neurological and Communicative Disorders and Stroke is an example of the latter kind of activity.

Question: How much do you plan to spend on this in '80 and '81?

Answer: It is estimated that the NIGMS will spend $103 million on research and research training in genetics in FY 1980 and $111 million in FY 1981. Funds set aside solely for research grants total $93 million in FY 1980 and $100 million in FY 1981.

Question: What areas hold particular promise in the near future?

Answer: The following areas are particularly promising:

1. Regulation and control of gene expression and development in higher organisms, including man. This includes insights into the structure of genes, and how and why some genetic elements are transposed from one chromosomal site to another. It is expected that research in this area will lead to increased understanding of genetic processes as diverse as differentiation and development, and of the genetics of antibody production.

2. DNA synthesis, and repair of DNA damage. It is already apparent that defects in these processes can lead to genetic disease, and that malfunctions in DNA synthesis or DNA repair can also cause mutations and/or the development of malignant tumors.

3. New technologies, including methodologies which provide us with the capability to make human proteins in microorganisms, such as bacteria, and the ability to produce highly specific antibodies in cell culture. These technologies will continue to be improved, and the products produced will be increasingly used to devise new modes of therapy which will also depend on research leading toward more accurate delivery of drugs, proteins, and other substances to target organs or tissues.

GENETIC SCREENING

Question: Are you involved in research to improve upon current screening techniques for genetic disease?

Answer: Development and refinement of current screening techniques is supported by agencies more directly involved in the

delivery of genetic services, such as the Health Services Administration. However, the Genetic Mutant Cell Bank supported by NIGMS is a particularly crucial component for research in the area of developing new screening techniques. For example, cells derived from patients with Huntington's disease, which are grown and stored at this facility, have been used to develop information about the basic defect in this disease. Since the basic defects of many genetic diseases are, as yet, unknown, much of the research which will lead to new screening procedures is now aimed at learning about the fundamental lesions in these diseases.

Question: Are there any guidelines for genetic counselors to follow in counseling patients of varied social, ethnic, religious, educational, and economic backgrounds?

Answer: Yes. A large and growing body of literature exists on the topics of genetic screening and counseling. A selected and partially annotated bibliography, compiled by the Institute of Society, Ethics, and the Life Sciences of the Hastings Center lists several hundred relevant publications.

An article compiled by a group of clinicians and scientists and entitled "Ethical and Social Issues in Screening for Genetic Disease" (New England Journal of Medicine 286, 1129-1132, 1972) emphasized such factors as equal access to testing procedures, absence of compulsion, a well-defined procedure for obtaining informed consent, safeguards for protection of human subjects, provision of the counseling services which may be required after screening, and procedures for protection of privacy. In 1975, the National Academy of Sciences published a book, "Genetic Screening Programs, Principles and Research."

Question: As you may know, we have a genetic information and counseling program in the Health Services Administration.

How do you work with them?

Answer: The Health Services Administration developed a genetic information and counseling program with a National Clearinghouse for Human Genetic Diseases. NIGMS has collaborated with the Clearinghouse and provided it with pertinent publications developed by NIGMS and other organizations.

BURN RESEARCH

Question: Does your Institute cooperate with the NIDR or other Institutes in this research area?

Answer: Yes, the NIGMS does cooperate with other Institutes in the area of trauma and burn research. Such research is very broad and, while NIGMS has an organized program in this area, our efforts cut across the lines of responsibility of a number of the categorical Institutes.

Both the NIDR and the NIGMS support studies on the basic mechanisms underlying pain. Both of these Institutes are also interested in collagen metabolism, an important aspect in wound healing. Investigators supported by both Institutes have collaborated in this area.

NIGMS staff is aware of the NIDR-supported work on silphenyline, a skin-like synthetic pliable plastic being tested for use in the restoration of the maxillofacial area of the head. Other synthetic materials are being developed by NIGMS-supported investigators. For example, a group at the Massachusetts Institute of Technology are collaborating with scientists at the burn research center at Harvard University in the design of a bilayer membrane of silicone and collagen polymer which covers wounds and thus prevents fluid loss and infection. A method to lessen the scar formation must be developed before the material is tried out on burned patients.

The National Institute of Allergy and Infectious Diseases is particularly interested in the host defense mechanisms which break down during severe burn injury. The result is life-threatening infection. These studies overlap those supported by NIGMS. Also, the support of studies on wound healing of the National Institute of Arthritis, Metabolism, and Digestive Diseases overlap the NIGMS interest in the total body response to burn injuries.

Question: What efforts have been made to increase the public's awareness of burn treatment advances?

Answer: Both the staff of the NIGMS and investigators supported by the Institute have appeared on several television programs. In addition, many articles in lay journals have been prepared by burn researchers supported by NIGMS. As stated in the report recently submitted to the Committee, the Institute held a Consensus Development Conference on Supportive Therapy in Burn Care in November 1978. The Conference was open to the public. A closed circuit television feature on burn injuries has appeared in several exhibits for the public. The activities supported by the NIGMS burn research program were displayed as part of the NIH traveling exhibit prepared for the International Year of the Child. This exhibit was sent to state fairs and educational meetings, as well as to medical forums.

Question: How are health professionals informed of the latest advances in burn treatment?

Answer: Publications of the results of burn research appear in scientific journals and are presented at scientific meetings. In addition, the following activities were aimed particularly at health professionals:

In April 1978, the Institute, in conjunction with the Office of Communications, NIH, participated in three two-hour programs on burn injuries which were telecast live, via the Communications Technology Satellite (CTS), for the purpose of disseminating recent research advances to primary care physicians and paramedical personnel. The topics covered included emergency care and resuscitation, nutrition, and wound healing. The CTS linked Fairbanks, Alaska, to Seattle, Washington, and Bethesda, Maryland. In Alaska, the death rate from burns is higher than from any other cause. At Harborview Hospital in Seattle, case histories were presented for discussion by three burn researchers in Bethesda. These were followed by question and answer periods with live audiences in both Fairbanks and Seattle.

A 52-minute video tape of these broadcasts, tailored especially for the expert consultant and burn specialist, was prepared and

61-400 O - 80 - 36

presented at the Fifth International Congress on Burn Injuries held in Stockholm, Sweden, in June 1978.

In November 1978 the NIGMS, in cooperation with the American Burn Association, presented a Consensus Development Conference on Supportive Therapy in Burn Care. This conference was devoted to discussions of five major issues: fluid resuscitation, metabolism, infection, smoke inhalation, and excision. Ethical issues were also considered. Participants from 33 states and seven foreign countries debated the issue for two days. Consensus was reached on several of the issues.

The technical summary of the meeting was widely distributed to the scientific community, interested lay people, and members of the press. As a result, numerous articles appeared in medical journals, lay magazines, and newspapers.

The full proceedings of the conference were published in the November, 1979, issue of the Journal of Trauma. Periodically, the summary of the conference will be updated by former consensus participants. The first follow-up workshop will take place in the fall, 1980, and will have two major objectives: to determine whether the consensus recommendations reached at the Conference have been disseminated appropriately, and whether any new research in the five subject areas has affected the conclusions of the conferees.

At the eleventh annual meeting of the American Burn Association (ABA) held on March 14-18, 1979, the Institute presented a two-hour panel discussion based on the Consensus Conference to 2,000 attendees.

In December 1979, NIGMS staff spoke about the opportunities available for support of burn and trauma research and research training at the regional meeting of the International Society of Burn Injuries held in Denver, Colorado.

Five of the large research programs sponsored by NIGMS are directed by investigators who also participate in health care activities related to burn injuries which are supported by the Emergency Medical Services (EMS) program of the Health Services Administration (HSA). Institute staff will be visiting several of the EMS burn demonstration programs with staff of HSA in an attempt to further the collaborative efforts of the two agencies.

FUNDING BREAKDOWN

Question: In your professional scientific judgement are you pleased with your funding breakdowns.

Answer: In my professional scientific judgment, the funding breakdowns for the five NIGMS program areas are appropriate. Thus, the exciting scientific fields of genetics and cellular and molecular biology are emphasized, and two-thirds of the funds are allocated to them. The scientific progress made in these areas will have an important impact on pharmacology, burn and trauma research, anesthesiology, and biomedical engineering.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: Additional funds would primarily be used to support new studies in genetics, basic cell research, and pharmacology research.

As noted in our justification material, there has been a virtual explosion of exciting new findings in recent years, especially in genetics and our knowledge of the cell. This knowledge brings us a step closer to understanding a multitude of diseases and disorders, but also raises a host of new questions which will require many years and the work of many scientists to explore. The following areas are considered to be among the most promising, and would receive special emphasis, if funds beyond those requested in the President's Budget were made available:

1. Studies of the role of metals in protein function and the structure and function of such metallo-protein complexes. Studies of the structure and function of proteins are essential to expanding our knowledge of the metabolism of the human organism.

2. Studies of cell-cell interaction, cell regulation by calcium and the relationship of such regulation to that of other regulators of cell metabolism. Although calcium was recognized as a regulator of cellular function over 20 years ago, new findings are now revealing its great importance and mechanism of action, which is mediated by proteins that bond to it.

3. Studies to develop human polymorphic markers to identify individuals with genetic susceptibility to common diseases such as diabetes, hypertension, schizophrenia, and atherosclerosis. It has been shown that individuals with sickle cell disease can be identified in the womb, on the basis of the presence or absence of a particular restriction enzyme site in their DNA. This has led several groups of investigators to propose expanding this concept to the whole human genetic map.

4. Studies of pharmacologically active compounds tailored to specific activities, to determine how chemicals become active pharmacologically and how they reach and interact with cell receptors. This is important because, ideally, a drug should be synthesized to perform a particular action as needed, without causing damage to the cells or tissues of the patient.

National Institute of Allergy and Infectious Diseases

STATEMENT OF DR. RICHARD M. KRAUSE, DIRECTOR

BUDGET REQUEST

Senator Hatfield. Let's turn to allergy and infectious diseases. Dr. Richard M. Krause, Director of the National Institute of Allergy and Infectious Diseases is our next witness.

As Director of the Institute, you have a budget request of $228,412,000 for 1981, an increase of $12,925,000 over fiscal 1980. Again, I repeat that we will place the full statement in the record, and if you care to make any other comments before I begin questioning, Dr. Krause, I would be happy to hear from you now.

[The statement follows:]

STATEMENT OF DR. RICHARD M. KRAUSE

A year ago, I reviewed the outstanding research advances during the 1970's that have led to better methods to prevent and treat those diseases for which NIAID has responsibility. Since then, we have added to that list of accomplishments, and I shall mention some of these later. But my main purpose today is to describe a technologic revolution now at our doorstep that will have profound effects on medical practice. This ferment stems from recent progress in virology, bacteriology, and immunology. I shall cite three advances that have emerged from these disciplines.

The first is recombinant DNA technology. With this technique, bacteria can be "programmed" to produce medically useful substances by the selective introduction of genes from animal cells. It has opened up unanticipated opportunities to improve old vaccines and develop new ones, and to manufacture other substances, such as the antiviral agent interferon and hormones.

The second advance concerns a technique called hybridoma cell fusion, possibly the most exciting research development since the discovery of recombinant DNA technology. I mention this development here because it also will have great practical value for the future. Scientists are now creating versatile, replicating cell hybrids (double cells) by fusing a cancerous myeloma cell with a lymphocyte, a type of white blood cell that has been stimulated to make a particular antibody. The "hybrid" inherits the desired qualities of both parents: from the myeloma cell, the ability to multiply rapidly like bacteria in a test tube; and from the lymphocyte, the power to produce large quantities of a specific antibody. Bulk cultures of such hybrids will become a source of exquisitely specific antibodies. These products should facilitate the development of vaccines, enhance immunotherapy of infectious and malignant diseases, improve diagnostic tests, and serve as new probes to examine life processes.

The third advance concerns our increasing mastery of the immune system. In this area of research, there are emerging opportunities to treat several chronic diseases, such as asthma and lupus erythematosus. Novel methods are now being developed to alter the internal processes of the patient's immune system in order to reduce inflammation--the key destructive component in these diseases. Until now, we have had to "make do" with aspirin and cortisone derivatives--imperfect medicines at best--to suppress inflammation.

Before explaining how these advances are contributing to our program, I should mention the socioeconomic impact of allergies and infectious diseases.

During 1976, there were on the average 1,670 infections for each 1,000 Americans. In addition to common acute diseases--such as influenza, gonorrhea, and the common cold--infections are serious complicating factors in the management of certain underlying chronic diseases, including bronchitis, diabetes, cancer, cystic fibrosis, lupus erythematosus, and arthritis.

Recent health statistics also emphasize the financial burden caused by asthma and other immunologic disorders. In 1975, the direct cost of medical care for these diseases, including hospitalization, was $1.5 billion. Disability due to these diseases occurs at the very peak of an individual's learning capacity and producti-

vity. In adults, asthma alone accounts for at least 90 million days of restricted activity and absence from work.

A major but as yet unmeasured proportion of chronic diseases--such as rheumatoid arthritis, systemic lupus erythematosus, and probably juvenile diabetes--may be due to a complex interplay between infection and immunity. For this reason, the reported morbidity and mortality data cited above do not adequately reflect the health burden of infectious and immunologic diseases.

Infectious Diseases--Infectious diseases are caused by a large and diverse number of bacteria, viruses, and parasites, and this diversity complicates any strategy for treatment and prevention. Because a broad spectrum of knowledge is needed to combat such an array of pathogens, the strategy is to emphasize individual scientist-initiated research. Such research produces the new knowledge that is needed to overcome the obstacles to progress on diagnosis, treatment, and prevention. It is difficult to predict in advance specific accomplishments from any basic research program, but confidence in the future is supported by the successes of the past. For example, the three advances I cited earlier are outgrowths of basic research.

The NIAID has singled out viruses for special attention because they are collectively the most frequent cause of infectious diseases and indeed of all diseases in the United States. Futhermore, virus infections may trigger the occurrence of chronic diseases, such as lupus erythematosus and juvenile diabetes.

A virus infection may follow at least four different patterns, and once again diversity complicates any strategy for treatment and prevention. The most common pattern is a brief acute infection in which the affected cells are destroyed by the multiplication of virus. Examples include influenza and the common cold. A second pattern is a chronic infection in which the multiplication of virus within the cells persists for many months or years. This persistent process increases tissue destruction. An example is hepatitis B.

The third pattern is a latent infection. After the virus infects the cells by an acute process, it then goes undercover in a latent state, only to recur as an acute infection months or years later. An example is chickenpox. After the initial childhood illness, the virus becomes dormant, but later in life may be reactivated to cause shingles.

Finally, a fourth pattern of infection concerns the viruses that produce cancer. How this occurs remains to be fully explained. One surprising clue has emerged from research on mouse leukemia. NIAID intramural scientists have learned that two distinct mouse viruses, neither one of which alone causes cancer, undergo recombination to produce an entirely new virus that causes leukemia. While such animal experiments underscore the complexity of the cancer problem, they also reveal the importance of basic research on the relationship between cancer and viruses.

Because of the complexity of virus infections, research must be intensified on vaccines and antiviral drugs, including interferon. Vaccines remain the primary strategy for prevention. Recombinant DNA technology and hybridoma cell fusion will accelerate the pace of vaccine technology. One important example concerns influenza vaccine development. While the current killed vaccine is beneficial, the

requirement for yearly inoculation has hampered its usefulness. There are technical reasons to believe that a "live" attenuated flu vaccine would be more effective than the current vaccine. Recombinant DNA technology is being used by NIAID scientists to create an attenuated "master" influenza virus that will tame epidemic strains for use in a live vaccine.

Emphasis on viral infections has not diminished our sensitivity to new problems in bacterial infections, such as Legionnaire's disease and the rising tide of sexually transmitted diseases. A special study group on sexually transmitted diseases has developed recommendations on new research opportunities.

Recombinant DNA technology has presented new approaches to investigate antibiotic resistance among bacteria. Further research on this complex phenomenon is expected to have a very practical result--the development of methods to counteract antibiotic resistance in the common pathogenic bacteria.

At the urging of the Administration and Congress, between 1978 and 1980 the NIAID increased its investment in tropical diseases, including malaria, schistosomiasis, and the diarrheal diseases. NIAID scientists have just succeeded in growing a virus that causes infant diarrhea, a major cause of infant mortality throughout the world. This achievement is an essential first step in developing a vaccine. Using hybridoma cell cultures, research is also being pressed on possible vaccines against malaria in cooperation with other government agencies.

It should be apparent, from what I have said so far, that vaccine research receives top priority. More than eight vaccines for both viral and bacterial diseases are in various stages of development. Field studies are in progress to assess the efficacy of pneumococcal vaccines to prevent one form of middle ear infection in infants, a frequent cause of subsequent hearing loss. We also are evaluating a vaccine against hepatitis B. And a gonorrhea vaccine is in the initial phase of clinical testing.

The Immune System And Its Diseases--An intricate interplay of events regulates both the protective processes of the immune system as well as the destructive processes that lead to immunologic diseases and allergy. Taking a cue from recent basic research findings, scientists are extending their mastery over the immune system and are tailoring new forms of treatment for immunologic diseases. Indeed, Wegener's granulomatosis, a disease of the blood vessels, was usually fatal until a successful treatment was developed by NIAID intramural scientists.

Immunogenetics is a rapidly moving and volatile field, and advantage must be taken of new opportunities in clinical application that emerge from this basic research. One special area of immunogenetic research is concerned with histocompatibility antigens--those ubiquitous substances on the surface of all cells of the body that complicate and oftentimes thwart successful organ transplants. An individual's histocompatibility antigens are inherited. An important aspect of genetics research on these histocompatibility antigens concerns their selective association with certain diseases--such as juvenile diabetes and two forms of arthritis (ankylosing spondylitis and Reiter's syndrome). To put it another way, there is a high probability that these patients have certain characteristic histocompatibility antigens as cell surface compo-

nents. Further research may uncover the reasons for hereditary predisposition to these and other diseases in some individuals.

Our Advisory Council has reviewed the report of the Task Force on Asthma and the Other Allergic Diseases and has made recommendations in regard to research and training in several special areas, including asthma and hayfever, pediatric allergy, drug allergy, dermatologic allergies, occupational/environmental asthma, and related respiratory diseases (e.g., farmer's lung). The Task Force report called attention to the swift pace of allergy research and the opportunities for clinical investigation.

Basic research is clarifying the nature of allergic processes. It is known, for example, that particular antibodies, termed IgE, play a key role in allergy. These IgE antibodies to allergic substances (e.g., ragweed) attach to specific chemical receptors on the surface of mast cells, which are specialized cells in the tissues that resemble white blood cells. Mast cells congregate in the "target" organs where the allergic reactions most frequently occur--the nose, lungs, gastrointestinal tract, and skin. The binding of IgE antibodies to mast cells releases toxic chemicals into the tissues. This is followed by a cascade of chemical reactions, resulting in the signs and symptoms of allergy.

Clinical studies are underway to identify those critical points where allergy shots can block the allergic reaction before it begins, or where special drugs (e.g., cromolyn sodium and theophylline) can inhibit the release of damaging chemicals that come into play during the allergic process.

Recombinant DNA Research and Risk Assessment--Recombinant DNA technology is employed in research to examine medically important characteristics of microbes, such as virulence factors, antibiotic resistance, antigenic mutation, and genetics. In order to exploit safely the full potential of this new technology, risk assessment must be an ongoing process. The NIH Director has assigned to NIAID the responsibility for risk assessment of recombinant DNA research, and the Office of Recombinant DNA Research (ORDA) has been transferred to this Institute. A plan for risk assessment has been developed, reviewed by the HEW Recombinant DNA Advisory Committee, published, and is now being implemented.

Our intramural scientists are conducting risk assessment experiments. Results of this research, along with the general research experience of other investigators, have been used as the basis to revise the guidelines for biocontainment requirements for recombinant DNA experiments. These revised guidelines have expanded the use of this valuable new technology to a wide array of important biomedical research problems. Some of this research must be performed initially in high containment facilities operated by our intramural staff at Frederick, Maryland.

In conclusion, Mr. Chairman, our objective is to improve the treatment and prevention of allergic, immunologic, and infectious diseases, and I am optimistic that we will achieve this goal in the 1980's. Such expectations are the legacy of the new technologic revolution I have just described. The NIAID budget request for 1981 is $228,412,000, an increase of $12,644,000.

INTRODUCTORY REMARKS

Dr. KRAUSE. Senator, let me make a few comments. A year ago for this committee, I outlined some of the outstanding achievements of the 1970's in both the treatment and prevention of diseases for which NIAID has responsibility. I noted it was a decade studded with completed opportunities—prevention of disease, new vaccines, the development of a rubella vaccine that prevents birth defects, and a vaccine that prevents lethal meningitis in infants and children.

But in these few minutes I would like to move beyond these achievements of the past, and look ahead to the benefits of the scientific and technical revolution on which you have just commented, and which is now at our doorstep. This will have profound effects on the practice of medicine for the next 20 years.

ADVANCES FROM MICROBIOLOGY AND IMMUNOLOGY

To illustrate the potential benefits of this revolution, I will cite three advances—some of which have been referred to—which have grown out of various branches of microbiology and immunology.

The first advance Dr. Kirschstein mentioned—recombinant DNA technology. This is certainly going to open up unanticipated opportunities to develop new vaccines for serious disease, vaccines that 2 years ago we would not have dreamed would be possible, and to make important drugs such as interferon, which you have heard about.

The second advance is an immunological technique called hybridoma cell fusion. I must mention this because I think you will hear a great deal more about it, and it has already had space on the front page of the New York Times. Hybridoma cell fusion, to my mind at least, is possibly the most exciting advance since the development of recombinant DNA technology.

And what is it? With this technique, we can tailor make antibodies for use in clinical practice as well as research. For the first time since Pasteur, we can produce antibodies at will and in a predictable fashion. I mention this because it is going to have influence throughout the whole spectrum of biomedical science and in treatment used in medical practice.

The third advance concerns our mastery of the immune system—a system that has protective powers to mount an attack against invaders, but on the other hand a system which can unleash the destructive forces that contribute to many chronic diseases. And as we gain authority over this system, there are emerging opportunities to treat a diverse array of chronic diseases—as diverse as asthma on the one hand and lupus erythematosus on the other.

As a result of our mastery of this system, I believe we will develop new drugs and new procedures to reduce inflammation, in addition to drugs such as aspirin and cortisone—imperfect medicine at best for suppressing inflammation.

INFECTIONS

We have identified infections as the most frequent type of illness. And we have singled out virus infections particularly for special attention. We have done so for three reasons.

They are collectively the most frequent cause of infectious diseases. Second, there is no widely applicable wonder drug for the treatment of virus infections. And third, virus infections can trigger—at least we believe they can—the evidence is still incomplete—the occurrence of chronic diseases as diverse as lupus erythematosus and juvenile onset diabetes.

Now that is a catalog of misery, but optimism for the future again stems from the three advances that I spoke about in my initial remarks.

DISSEMINATION OF INFORMATION

Senator HATFIELD. How is that disseminated—that information?

Dr. KRAUSE. Through the scientific literature and through special seminars and meetings which the NIH holds and sponsors. It is disseminated in the popular press, and also it is disseminated, as Dr. Kirschstein noted, with publications that are particularly targeted at the high school and college level.

NEW VACCINE DEVELOPMENT

Now, in regard to vaccines, let me say that I cannot overemphasize that there are now novel approaches for developing new vaccines. This is a complete departure from everything we have been doing since the time of Pasteur. As a result, there is a possibility, as you heard, of a new hepatitis vaccine and an entirely new approach to the preparation of an influenza vaccine. I need not remind this committee of some of our recent past problems with influenza.

For the first time, a vaccine is on the horizon for malaria. I would not have thought 2 years ago that a vaccine was possible against a disease which affects 400 million people in the world today. I mentioned influenza, hepatitis, and malaria, because our own intramural scientists are very much involved in this new effort.

I have already mentioned the immune system, this complex apparatus over which we are gaining authority and this is giving us new opportunities. So I will not mention any more in that area.

BASIC/APPLIED RESEARCH

But let me take up one more point. We need a broad spectrum of knowledge to combat these many diseases. And you have already referred to that and the new awareness of the importance of basic research. And it is difficult, as you are well aware, to predict in advance the specific accomplishments from basic research—but our confidence in the future is supported by the success of the past. And the three examples I have cited are proof of that success.

But in addition to basic research, let me just say this: We also need applied research. Applied research includes the development of new drugs and vaccines and then clinical trials to test these for efficacy and acceptability for public use.

I ran across a quotation I thought I would share with you—there is no better description of basic research and applied research than this one formulated by the political scientist, De Toqueville, in his "Democ-

racy in America." He commented on basic research and applied research in a chapter amusingly entitled, "Why the Example of Americans Does Not Prove That a Democratic People Can Have No Aptitude or Taste for Science, Literature, and the Arts." [Laughter.]

De Toqueville said this: "The first aspect of science comprises the most theoretical principles and the most abstract conceptions, whose application is either unknown or very remote." The second—this was in 1832, he was 35 years old—"The second comprises general truths which, though still based in theory, lead directly and immediately to practical application."

But then he goes on and makes this important point: "Each of these different aspects of science can be studied apart, although reason and experience teach us that none of them can prosper for long if entirely separated from the other."

What he perceived as the relationship between basic and applied research in 1832 in the early years of this Republic, is as true today as it was when he examined American society 150 years ago.

We have just passed through what might be called Pasteur's century, a century that would see a complete break with a tradition of medical practice dating back 2,000 years to ancient Greece. And now we enter Pasteur's second century, with what I believe is a historical precedent for optimism. That expectation is the legacy of the technical revolution I have just described.

We are asking for an increase of $12,644,000. I would be glad to answer any questions.

RESEARCH TRAINING

Senator HATFIELD. Dr. Krause, as you know and other Directors of the programs of NIH, this committee puts a very high priority on training. How much was your training budget increased in fiscal 1980 over fiscal 1979?

Dr. KRAUSE. I would have to get out a different table, 1980 over 1979, or 1981 over 1980?

Senator HATFIELD. 1980 over 1979.

Dr. KRAUSE. $2 million. That was 1980 over 1979.

Senator HATFIELD. And then what is the projection of 1981 over 1980?

Dr. KRAUSE. It will be a decrease of $1.5 million.

Senator HATFIELD. So you are going the other direction?

Dr. KRAUSE. Yes.

Senator HATFIELD. Why?

Dr. KRAUSE. This is a generic question for the whole NIH, I think. And it is a matter of judgment on the allocation of resources for the various elements that must be maintained for a healthy research enterprise. And one can argue on various sides of the issue.

One argument is that at this juncture what is needed is the broadest possible support for individual investigators and for other research programs, so that they can take advantage of the science that I have just described to you.

Senator HATFIELD. You are saying this is an overall NIH policy that you are adjusting to within your Division?

Dr. KRAUSE. Dr. Fredrickson, I think it certainly reflects what all of the Institutes have done?

Dr. FREDRICKSON. The NIH has, through the Office of the Director, after a lengthy discussion with our several Institutes where we reached some consensus—certainly the administration, speaking after ourselves, has elected to place the highest priority this year on the maintenance of competing renewal and new investigator-initiated research project grants.

With the 1981 President's budget we will have the capacity to fund a reasonable number of research project grants. This emphasis has taken precedence over additions to the training budget in our development of the budget this year. We have had to put a lower priority on training funds than on the maintenance of grants.

Senator HATFIELD. Let's take a hypothetical situation. If no additional moneys can be given to your Institute, would you still feel that your emphasis upon research grants is correct, with the diminution of support of resources for training centers and intramural research?

Dr. FREDRICKSON. Mr. Chairman, in this fiscal year, yes, we would have to come to that conclusion. I would still feel the same.

Senator HATFIELD. You would. You know, I think I speak for most members of the committee, which has expressed itself to you before on this matter. I suppose because I come out of the field of education myself—that I come with a certain bias. But I believe that one could eventually find themselves without the opportunity to extend grants. If you don't continue a training program, who will do the research down the road, if there isn't an emphasis or a balance and a broad-based approach taken on this?

I think you put this continued emphasis on basic research grants to the detriment or to the neglect or to the imbalance to training, and eventually that faucet turns off, you know. I think De Toqueville could comment on that as well. [Laughter.]

Keeping the flow of qualified trained personnel to take advantage of the grant assistance is important.

Dr. FREDRICKSON. I cannot agree with you more. The availability of young trained investigators has to be maintained or there will be no one qualified to take those grants. The initiative on the part of the administration to establish some stability for research project grants must represent the first phase of a long-range planning effort.

It is quite clear that we will have to turn next to training. However, with budget requirements, double-digit inflation, and the other pressures on the system, we cannot correct all of our deficiencies in a single year.

Senator HATFIELD. But you started this trend last year of cutting back in terms of training. And it seems to me there ought to be some kind of a balance that you achieve, so that you are not swinging the pendulum from grants to training to some other emphasis. There ought to be some kind of—you talk about stabilizing grants. It seems to me it is important to stabilize the total program and the allocation to those various components that will sustain and maintain this program.

Dr. FREDRICKSON. That is true. Part of last year's cutback in the number of trainees was the result of having to increase stipend levels in order to provide adequate support to trainees and to maintain the attractiveness of the program.

Senator HATFIELD. I am informed that we gave you additional funds last year to maintain that level, so that you wouldn't have to sacrifice training.

Dr. FREDRICKSON. We had to approach last year's conference report in a crablike fashion, Mr. Chairman. [Laughter.]

There were conflicting desires on the part of the two Houses of Congress concerning the use of the additional funds. It was our desire to accommodate both, but we were unable to maintain training completely while simultaneously maintaining the desired number of grants.

Senator HATFIELD. I agree it is very appropriate that you remain sensitive to both Chambers, to the lower Chamber as well as to the upper Chamber. [Laughter.]

But I do feel that when you look at the simple final report, there was no reference in the conference report to this. We had expressed those views in our respective hearings and so forth. But in the conference, if I am not mistaken—correct me if I am wrong, staff—there was no instruction given to you in the final product of the two Houses resolving their differences. And we, in fact, specifically rejected language that would have given you instruction in the conference.

Dr. FREDRICKSON. Yes; we are aware that we were freed of that. I must take as much responsibility as anyone for attempting to interpret that conference language. I regret that we could not accommodate the Senate's desire for maintenance of the same level of training.

Senator HATFIELD. Again, I am aware of the constrictions that you come to this step in the process, budgetary process with, that you have already been hammered down by the OMB and so forth, and probably from HHS now. But Doctor, I hope you fully appreciate the fact that you are here in a very friendly environment. We want to have your professional judgment over and above whatever party politics that you are supposed to fall behind, or administration position.

We are asking you, really, to take off your administration hat and put on your professional hat. We have, as a legislative body, the right to ask you those questions. It is a difficult role for you to be here. You are in a dual role, I recognize that, as any agency head. And there has to be an overall administration policy.

As a former executive of a State, I operated in the same environment, the same framework. But, by the same token, I think the legislative branch has a right to invite and elicit from you your professional judgment, which may even be in conflict with what the administration position is, so that we can make an assessment of these needs of your agency.

We have the amending process, you know. We fly in the face of the administration all the time. That is one of our great sports up here. [Laughter.]

Dr. FREDRICKSON. I appreciate the description of our relationship and I highly value the opportunity for candor. Mr. Chairman, I commend

to you, if I may, the Department's health planning document that was just recently released yesterday. In the overview I have been able to express my view on health planning and priorities within the limited sphere of the activities included in this report.

Senator HATFIELD. Is there a training section in here?

Dr. FREDRICKSON. There is no initiative labeled training. However, discussion of training is not neglected in the description of what must come soon in the next phases of planning.

Senator HATFIELD. Would you underline those areas that have to do with training?

Dr. FREDRICKSON. I can do it very quickly, sir. [Laughter.]

It may seem a very small reference, sir, but it is an attempt to put into perspective a balance. It is difficult in 1 year to reshape completely the form of biomedical research support.

Senator HATFIELD. New scientists must be trained. [Laughter.]

Now, if a politician said that they would say that is so much rhetoric. I hope it has more meaning when a doctor says it.

Dr. FREDRICKSON. It does as far as I am concerned. [Laughter.]

Senator HATFIELD. New scientists must be trained. We must stop inflation. [Laughter.]

Dr. FREDRICKSON. Even in the face of inflation, it represents a central aspect of our——

Senator HATFIELD. I wonder if we could invite—maybe this is not an appropriate procedure, but I wonder if we could get a little more information on the composite judgment of all of the directors of your divisions here on the role of training and the use of training in relation to the other needs of their responsibilities.

I think it would be very helpful if we could. This committee, we may be laymen, off here in left field somewhere. We have sensed, at least in previous hearings and my own personal contact with you and your associates, that there is a great high priority on training in their own respective disciplines and specialties. So I wonder if we could get a brief memorandum, maybe half page, or if you could do it in eight words or something like that.

Dr. FREDRICKSON. I think that would be very valuable. We will be glad to provide that information.

[The information follows:]

THE ROLE OF RESEARCH TRAINING

It is the composite judgment of the NIH Directors that research training is of paramount importance in fulfilling their responsibilities. The research of the future will be only as good as the bright young people we train today. We must continue to assure the replenishment of a critical mass of scientists. NIH supports only a fraction of the individuals in research training, but it is the essential fraction that nurtures the Nation's most highly qualified and promising biomedical research trainees. Without support for them, tomorrow's resources will go unused and tomorrow's questions will remain unanswered.

IMMUNITY SYSTEM

Senator HATFIELD. I am going to submit, Dr. Krause, some other questions here for the record so that we can move on. If you will respond to them, it would be very helpful. Could we submit further

questions that I have not verbalized here today for the record, to which we would invite your response?

Dr. Krause, we have a lot of areas here we would like to get into, some more in your immunity system, sexually transmitted diseases, VD, interferon, diabetes. I have many, many. And I would like to invite you to respond.

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

TRAINING

Question: As you and the other Directors have seen by now, training is a high priority of this Committee. How much was your training budget increased in fiscal 1980 over the 1979 level?

Answer: The total training budget was increased by $1,738,000 in 1980 over 1979.

Question: What are your plans for training in the 1981 budget?

Answer: We will continue to support the 378 trainees awarded by grants in 1979 or earlier. In order to stabilize and maintain support for research project grants, we plan a one year moratorium on competing training grant awards in 1981. The $1.5 million decrease for training reflects this priority decision.

Question: If we were to assume that the largest portion of your budget increase is for research grants, would you agree with this apportionment?

Answer: A major goal of the National Institutes of Health is to stabilize funding of the science base. This involves several mechanisms of funding such as research project grants, center grants, training grants, and research and development contracts. Under the present fiscal constraints, certain choices must be made. Since research project grants make up the majority of the science base, this mechanism will receive priority for stabilization in 1981. Training is indeed important and an attempt to stabilize it will be made in the future.

SEXUALLY TRANSMITTED DISEASES

Question: On January 14-15 of this year, you convened a sexually transmitted diseases study group which recommended new areas of scientific investigation along with the budgetary needs to carry out this research. One recommendation called for the allocation of $13 million for herpes research. How do you plan to incorporate these recommendations into your budget request?

Answer: The Study Group rendered reports and recommendations in nine different areas related to sexually transmitted diseases. These were presented to the NIAID Advisory Council on February 1, 1980. A subcommittee of the Council will further review the funding requirements and priorities and make recommendations to the Institute at the May, 1980 Council meeting. The Council recommendations and priorities will be reflected in our FY 1982 budget request to the NIH. Study Group recommendations are for significant increases in funding of grants, contracts and training. There are overlaps, however, with the earlier recommendations of the Virology Task Force which must be resolved.

Question: Do you intend to increase the emphasis on venereal disease research, as recommended?

Answer: In fiscal year 1980 we expect to increase our funding of grants and contracts by $1.1 million over the FY 1979 level. We are also increasing support to intramural research. For fiscal year

61-400 O - 80 - 37

1981, we will make every effort to maintain the 1980 level in grants and intramural research but envision a decrease in contracts and training. One outcome of such study groups is more widespread awareness of the research opportunities in a problem area and an increased intellectual effort to solve them.

Question: What research coordination exists with other Institutes and how can this be improved?

Answer: There are two major areas of overlap with other NIH institutes -- herpes viruses and behavioral studies. Coordination in the herpes virus area with NCI and NIDR has been through a series of joint workshops and meetings. The NIAID will provide Study Group recommendations concerning behavioral research to the appropriate institutes but will not undertake the funding of such research.

More important has been the coordination with the Center for Disease Control (CDC) and the Bureau of Biologics/FDA (BoB). There is close coordination with the CDC, and CDC staff participated in the Study Group discussions. Vaccine studies are done with the collaboration of the BoB.

Question: Is there a possibility of trans-institute research projects?

Answer: To a very limited degree. This can be considered in field studies where there are opportunities for behavioral research. The National Institute of Mental Health or of Child Health and Human Development may wish to join in such projects. The latter may also wish to participate in studies on the effects of prophylactic and therapeutic hormonal treatment on susceptibility of the female to infection.

Question: Last year this Committee directed that increased funding be provided in the area of sexually transmitted disease research. We noted that we would look forward in fiscal 81 hearings to a report on the progress made in this area, which had previously received far too little attention. Please provide us with the report at this time.

Answer: The report was forwarded to the Congress through official channels in December.

Question: How have you cooperated with the Center for Disease Control (CDC) programs in this area?

Answer: We have cooperated through frequent meetings with the responsible CDC officials and seeking their involvement in NIAID research planning. Also through the development of an annual special report to the Congress that has summarized the activities of the CDC, the NIAID, and other agencies.

INTERFERON RESEARCH

Question: Bring us up to date on the status of research with interferon and your cooperation with the National Cancer Institute (NCI) in this regard.

Answer: Interferon continues to be a subject of intense interest in the international scientific community. The partially purified preparation of the several types of interferon available have a variety of effects at the cellular level. Efforts are to determine the differences between the interferons and the mechanisms that are involved in their effects on the cell. Antiviral activity is one such effect but the mechanism for interferon action to make a cell resistant to viral multiplication is still far from clear. Effects on cell multiplication form the basis of interest in antitumor activity but the mechanisms involved are still incompletely known.

Despite this lack of basic knowledge, clinical studies utilizing interferon made by human blood leukocytes (white blood cells) have progressed with promising results in some serious virus infections and with regression of some tumors. Supplies have been too inadequate and expensive for controlled clinical trials and the extent of benefits or range of activity is still to be determined.

The NIAID and NCI have had a long-term collaboration in interferon research, particularly in the possible use of inducers to stimulate secretion of these proteins. An NIAID intramural scientist developed an effective inducer that yielded high blood levels of interferon in cancer patients. Extensive toxicity testing is needed before clinical studies can go further. NCI is collaborating in such testing.

Question: Please describe the progress that has been made in Switzerland using the recombinant DNA molecule technique to aid in the production of interferon.

Answer: Biogen, an industrial company, has announced the successful cloning of the gene controlling interferon production in E.coli. Production levels are thus far below levels needed for commercial production. There are also chemical differences between this interferon and the human leukocyte interferon shown to have antiviral and antitumor activity in studies in man. Biogen reports the E. coli produced interferon has antiviral activity but quantitative data have not as yet been published. It is known that other groups are attempting similar cloning. Success is likely in the near future.

Question: What is the goal of this research in terms of treating viral infections?

Answer: The primary goal of the NIAID antiviral program including interferon has been to develop effective drugs for the treatment of severe and life-threatening virus infections. Only when inexpensive and nontoxic drugs are developed would these be thought of as applying to less severe infections such as the common cold or viral diarrhea.

Question: According to news reports, Biogen has made a major breakthrough in using recombinant DNA techniques to produce interferon. What are the implications of this advance for your research?

Answer: It is difficult at this stage to be sure of the

implications. The work that has been announced and verbally presented indicates that an interferon like protein has been produced through recombinant DNA technology. It is a larger molecule and apparently also has other chemical differences from human leukocyte interferon, the product that has been shown to have major antiviral activity and some antitumor activity. It also apparently cannot as yet be produced in sufficient quantities to be looked on as a source of interferon for clinical studies. We understand that further efforts to improve production, to make a product closer to leukocyte interferon, and to demonstrate the antiviral activity of the E. coli product are in progress.

If pure interferon can be produced in quantity by this process there will be many implications. Since most previous laboratory and clinical studies have been done using a partially purified interferon, much of this work would have to be repeated. If pure interferon does demonstrate high antiviral activity, there will be tremendous pressures for controlled clinical trials in order to move the product toward licensing and medical usage.

Question: How long will it be before this new interferon can be tested, in animals and humans, to find out whether it has the same properties as costly human interferon?

Answer: Apparently some of the tissue culture and animal work is going on now at Biogen or in laboratories closely associated with this organization. Production, as described, would not as yet permit clinical studies. How long it will take Biogen to solve some of its problems, or for one of the several known competitors to break through, is unknown.

VIROLOGY

Question: Have you expanded your Institute's virology research program, as directed last year?

Answer: Yes, in fiscal year 1980 we expect to spend over $4 million more on virologic research than in fiscal year 1979.

Question: What progress has been made in the development of antiviral drug compounds?

Answer: Progress has been slow but steady and we are well ahead of where we were five years ago. Adenine arabinoside or "Ara A" proved effective in the treatment of herpes encephalitis and is now licensed. Interferon has shown promise in the treatment of chronic hepatitis B infection and herpes zoster. Several compounds have been licensed for tropical use in viral conjunctivitis but interferon may be better if the results of preliminary studies are confirmed. Still other antiviral drugs, such as acyclovir and Ara T, have been made available by industry for cooperative, controlled clincal testing. Such trials require a long time since several medical centers are required to combine their efforts in amassing a sufficient number of patients to yield definitive results.

Question: How is our research progressing in finding drugs or other methods of treatment for viral diseases?

Answer: Our earlier efforts have been focused on drugs for treatment and vaccines for prevention. However, a new technological development has revived interest in an older and neglected form of treatment -- the use of specific antibody in treatment. Convalescent human sera containing high levels of antibody have long been used in treating certain life threatening infections, notably African and Bolivian Hemorrhage Fevers, and in the prevention of rabies. The limitation has always been in finding a serum donor with high antibody content and obtaining enough serum for practical use. Now with the development of the "hybridoma," a fused cell derived from a myeloma cell and an antibody producing lymphocyte, specific antibody can be produced in the test tube in large quantities. This opens up the need to develop and test such antibody against the more common and severe virus infections.

TB VACCINES

Question: A recent study found that two strains of BCG antituberculosis vaccine widely used in developing countries was ineffective. Are you aware of this study and do you have any comments on the results?

Answer: Yes, we are aware of the study. We have a high degree of interchange with India and have followed their results with interest. It is difficult to say at this time what the cause of the failure may have been and the results of the trial are under intensive review and analysis by the World Health Organization. We know that there are no standards for BCG vaccines, no recognized potency tests or other methods of determining whether a vaccine may be effective in man. As a result there is major variation between BCG vaccines made and used in different countries.

Question: What relevance would such a study have for the U.S. particularly since I understand we don't use BCG in this country?

Answer: Thus far the U.S. has had the good fortune to be able to control tuberculosis fairly effectively through early diagnosis, contact tracing and chemotherapy. BCG has not been used by health authorities because it takes away the most effective method for case finding and early diagnosis, a positive reaction to the tuberculin test. Among the poor and those in crowded dwellings, a highly effective BCG (or preferably other) vaccine could well be used. As the population grows the time may yet come when a vaccine would be more desirable than at present. The NIAID continues to support research on the tubercule bacillus and immunity in hope of finding a method to develop an effective inactivated vaccine. Recombinant DNA and hybridoma technology should speed up the research.

PNEUMONIA VACCINE

Question: Your Institute supported much of the research leading up to the development of new vaccines for pneumonia, which the FDA has approved. Of all the types of pneumonia in this country, what percentage could be prevented if the vaccine were used as recommended?

Answer: This question cannot be answered directly since the pneumonias are not reportable in the U.S. and etiologic studies are

not done in most hospitals. Viral pneumonia is common in very young children and during some influenza outbreaks. If one eliminates virus pneumonia and those caused on occasion by other organisms, the pneumococcus becomes the most common cause of bacterial pneumonia. The estimated incidence is 2.1 cases per 1,000 population or 150,000-300,000 cases per year, accounting for about two-thirds of all bacterial pneumonias. It occurs more frequently in men than in women, and three to four times more frequently in those over age 40 than in those younger than 40. The frequency is higher among blacks and American Indians than Caucasians. It is a particular threat to the immunocompromised patients, such as those with sickle cell anemia or those who have lost splenic function for other reasons. The overall mortality is estimated to be 5 to 10 percent with 13,000 to 66,000 deaths per year.

The pneumococcus also causes more than half of the bacterial otitis media infections in young children. Such infections occurring in the first six months of life tend to become chronic and are often complicated by meningitis. Otitis media is a significant cause of deafness in children and subsequent learning disabilities.

The licensed vaccine contains the strains causing about 70 to 80 percent of pneumococcal pneumonia in hospitalized patients in large city hospitals in this country and abroad. The vaccine should prevent infection and pneumonia caused by the 14 types in the vaccine with an efficacy of 70 to 80 percent. Otitis media in children is caused by different types of pneumococci and the experimental vaccine being used in current field trials for prevention of pneumococcal otitis media has a different formulation than the licensed vaccine. We anticipate results of these field trials before the end of this year.

INTERNATIONAL HEALTH

Question: What international health programs are supported by your Institute?

Answer: The NIAID supports research on a number of infectious and parasitic diseases of international health importance. Under the U.S.-Japanese Cooperative Medical Sciences Program it supports research on cholera and other diarrheal diseases, leprosy, tuberculosis, arbovirology, filariasis and schistosomiasis. In supporting the World Health Organization's Tropical Diseases Research Program it also supports research on malaria, trypanosomiasis, leishmaniasis and onchocerciasis. Support includes grants, contracts and intramural research and is targeted on methods for prevention and control.

Question: Do you cooperate with the WHO in this regard?

Answer: Yes. The WHO recognizes the NIAID research as being in support of its Tropical Diseases Research and Expanded Immunization Programs. NIAID staff and grantees have served on WHO expert panels and advisory committees. An NIAID staff member has been on loan to the WHO for the past three years assisting in the development of a peer review program for WHO grants. An international research fellowship program has been set up by the WHO, the Fogarty International Center and the NIAID. Further collaboration is

achieved by NIAID joint activities with the Center for Disease Control.

Question: How do you interact with the Fogarty International Center?

Answer: There is a close interaction. Reports on progress and activities in international research are provided the Fogarty International Center (FIC) annually for compilation and publication. International congress support is performed jointly with the FIC. All communications with the Office of International Health, the State Department and certain international groups are channelled through the FIC. The FIC also provides local currencies through the Special Foreign Currency Program to support a number of NIAID research agreements in Egypt and India.

RECOMBINANT DNA/RISK ASSESSMENT

Question: Just a few years ago, we were hearing all sorts of alarming reports on the possible dangers involved with recombinant DNA research. Within the last week, revised NIH Guidelines were published which lower the containment requirements for most DNA experiments. Do you really feel that such a relaxation of guidelines is safe and appropriate given our knowledge of this research at this time?

Answer: It must be recognized that most of the forecasts of dangers of recombinant DNA research were based on hypothetical situations. Also, that these involved possible infections by the products of such research and were postulated by scientists who were not themselves expert in infections.

The NIAID, working with the Recombinant DNA Advisory Committee (RAC), has held several workshops to address the risks that have been postulated in several scenarios. Intramural scientists have completed several key experiments, other experiments have been completed by contractors and grantees. The recent decision to lower the containment and filing requirements applied only to the weakened bacterial host E. coli K-12 and some of its specific vectors. Data accumulated over the past few years enabled the RAC to make this recommendation with confidence.

The plans to change the Guidelines were published twice for public comment and no serious scientific objections were raised. In fact, of the 185 letters received, 169 were in favor of the changes.

Question: What is your Institute's involvement in the area of recombinant DNA technology and risk assessment research?

Answer: The NIAID, along with the NIGMS, supported much of the basic research that brought this technology into being. Now that it is available it is being widely used by scientists supported by the NIH as a powerful tool for basic studies in cell biology and microbiology. The NIH in recognition that the possible hazards relate to infections has assigned responsiblity for risk assessment to the NIAID. This involved the transfer of the Office of Recombinant DNA Activities from the NIGMS to NIAID which includes responsibility for the operation of the Recombinant DNA Advisory

Committee (RAC). A subcommittee of the RAC has the specific responsibility for dealing with issues concerning risk assessment and the Institute works closely with this subcommittee. In response to Subcommittee recommendations the NIAID will sponsor a major conference on some aspects of risk assessment this spring. The NIAID also developed a plan for risk assessment that was approved by the Secretary, DHHS and published in the Federal Register. It is now seeking a distinguished scientist to lead risk assessment activities.

Since 1976 we have had contracts to develop safer host-vector systems and test them in simulated natural situations. These contracts have given us a new generation of host-vector systems with decreased capacity to survive or multiply outside laboratory conditions -- this is called increased biological containment.

Question: Are all of your facilities doing recombinant DNA research safe?

Answer: All experiments supported with Federal funding involving recombinant DNA technology must be carried out in compliance with NIH Guidelines. Insofar as can be determined all investigators are in compliance.

Physical containment is dependent on proper laboratory practices, use of specific containment devices, such as laminar flow safety hoods, and special laboratory design. Specifications for each level of containment, P1 to P4, are given explicitly in Guidelines to facilitate certification by the institution's biosafety committee.

Question: What is the status of private sector compliance with NIH Guidelines for recombinant DNA research?

Answer: The newest Guidelines specifically provide a mechanism for voluntary registration of projects planned by the "private sector." And we believe that the private sector will act in a responsible and cooperative fashion. Despite the short time period since the Guidelines were issued, several firms have filed Memos of Understanding and Agreement and the Pharmaceutical Manufacturers Association, speaking for its members, has formally agreed to comply.

IMMUNOLOGY / IMMUNOGENETICS / AUTOIMMUNITY

Question: This Committee noted the intention in last year's report that a portion of the fiscal 80 funding increase should go into the high priority area of immunology research. We expressed our desire that such research should be closely coordinated with both the National Eye Institute (NEI) and the National Institute of General Medical Sciences (NIGMS). Can you tell us how you have attempted to fulfill this request thus far during fiscal 80?

Answer: During the past year we have increased our effort in the three relevant areas of immunologic research.

	FY 1979	FY 1980
Autoimmunity	$ 8,651,000	$10,961,000
Immunology	25,718,000	27,261,000
Immunogenetics	3,207,000	3,527,000
Total	$37,576,000	$41,749,000

The first step in coordination with NEI was designed to stimulate interaction and collaborative efforts among research immunologists and investigators in opthalmology. In agreement with NEI we identified the need to introduce the eye community to the state of the art of modern day immunology and the applicability of emerging immunologic research data to ocular disorders; and at the same time to create an informed awareness among immunologists of the important problems in opthalmology for which their expertise was needed. The first project was to issue a request for research grant applications on "Immunologic Aspects of Ocular Disease" published in the NIH Guide for Grants and Contracts and circulated on a nationwide basis to biomedical scientists. Secondly, NIAID and NEI joined in planning a series of workshops to serve as a forum for meaningful discussions between immunology and vision researchers. The first in the series, "Immunogenetics and Transplantation Immunity," was held during December 1979 and was successful in identifying a number of potentially productive applications of recent advances in genetics and transplantation immunology to eye research. Two additional endeavors in this series are scheduled, "Autoimmune Phenomena and Ocular Disorders" on March 5-7 and "Infection, Inflammation and Allergy" on June 25-27, 1980.

Question: Do you feel research on the immune system should be a high priority?

Answer: We believe that understanding function and disorders of the immune system will increase our understanding of a number of well known diseases affecting almost every body organ. We also believe that this new knowledge will make possible improved diagnostic tests, better treatment and better methods of prevention of such diseases as lupus erythematosus, some forms of arthritis and vascular diseases, and some types of skin disease as well as for the better known allergic and immunological deficiency diseases. Accordingly, research on the immune system is among our highest of priorities.

Question: Please describe for the Subcommittee the area of research known as "Immunogenetics" and tell us what progress has been made in this relatively new field?

Answer: Immunogenetics is that branch of immunology which is concerned with the genetic factors that control the immune response and with the manner in which these factors are transmitted from generation to generation. These factors are studied at the molecular level in several ways: the way the genes are arranged on the chromosomes and expressed through specific metabolic processes, the way the protein products including antibodies of the genes are synthesized and arranged, the way these structures recognize foreign materials and are in turn recognized as self or foreign, the way in which such recognition determines the immune system's ability to resist infection, avoid reaction against one's own tissues while rejecting foreign tissues, and the way in which the genes control these functions are distributed and inherited among populations.

The ability to transplant organs and tissues such as hearts, kidneys and bone marrow to persons whose own organs no longer can support life is based on our recently acquired understanding of the genetics of the human histocompatibility system. It is now established, for example, that a kidney can be transplanted successfully between two related persons 90% of the time as determined one year after surgery. Such individuals need not be identical twins but must share the same major histocompatibility genes. In addition, improvements in the success rate are constantly being made even in the instances where such matching is not possible through the steady development of chemical and biological products which modify the rejection reaction of the immune system.

A remarkable development in recent years has been the discovery of the statistical association between certain genetically controlled histocompatibility antigens with susceptibility to certain diseases such as some types of arthritis and certain infections. Such genetic regulation of the immune response in both animals and man has been ascribed to genes of the major histocompatibility complex located in one specific region of one chromosome. It has been further found that for immune cells to recognize and destroy cells infected with certain viruses, they must not only recognize the viral antigens found on that cell as foreign but also recognize the antigens of the cell itself as being the same as their own.

Most dramatic have been recent advances in our understanding of the way components of the genes of the immune system are arranged on the chromosome of man in contrast to bacteria. Such knowledge is essential if genetic manipulation for the purpose of replacement of defective genes or of manufacture of the products needed to restore normal function is to be effective.

Question: Is your Institute working in close cooperation with the General Medical Sciences in this research area?

Answer: The National Institute of General Medical Sciences and the National Institute of Allergy and Infectious Diseases share responsiblity for support of research in genetics. The prime concern of the former is work on the molecular aspects of control and expression of gene function, while our primary concern is the manner in which the responses of man's immune system to challenge by foreign antigens are conditioned by one's genetic constitution. In addition, NIAID through its serum bank, supports research sponsored by NIGMS on cell surface proteins by providing histocompatibility testing (typing) sera to investigators.

NIAID's efforts complement NIGMS supported research on treatment of burn victims. A very recent major advance in this area has been brought about by the use of an immunosuppressant to delay rejection of transplanted foreign skin while small areas of the victim's own normal skin can expand sufficiently to permit its use in transplantation to the damaged areas. The temporary coverage of the burns with foreign skin prevents infection and fluid loss. Extensive burns that in the past were uniformly fatal now have only a 50% mortality rate. A key to this success is the manipulation of the immune system to prolong the life of the skin grafts, a manipulation that is the result of research sponsored by NIAID.

ALLERGIC RESPONSE

Question: What progress has been made in the area of allergic response research in the past year?

Answer: Researchers have been able to dissect and demonstrate the chemical and cellular basis of the allergic response. It has recently been shown that the overproduction of both total levels of allergic antibodies immunoglobulin E (IgE) and the IgE programmed to react with specific allergens results from a derangement of a complex balance of two types of interacting lymphocytes (white blood cells) called T and B cells. In turn, the ability to control the suppressing and/or enhancing effect of the T-cell products on the antibody producing B cells offers the potential of ameliorating the allergic response.

Progress has also been made in analyzing the receptors (receiving stations on cells) which allow the binding of IgE antibodies, potentially leading to development of specific drugs to block this binding and, thus, inhibit the allergic reaction. Other progress has involved the use of hybridoma technology to develop specific antibody that can be used to regulate these cell interactions and block reception sites.

Question: Does there appear to be some identifiable component of an allergic person's make-up that distinguishes him or her from the non-allergic person?

Answer: Allergic persons can be identified by the frequent occurrence of allergic symptoms among family members; the clustering of many allergic symptoms and sensitivities in an affected individual; and the tendency to form the blood protein, immunoglobin E or IgE, that is responsible for participation in allergic reactions. Such patients not only tend to possess the mechanism to develop high levels of IgE but also tend to form detectable IgE to specific allergenic agents upon natural exposure to otherwise harmless environmental substances such as ragweed.

Question: What about research to determine whether or not there is a genetic predisposition to allergy?

Answer: Several studies have clearly demonstrated that tendency to develop allergic disorders is inherited. Early studies suggested that the mode of inheritance could be simply explained the way Mendel originally described the inheritance patterns in short and tall pea plants. While the control of total blood levels of IgE, the protein responsible for allergies, may be explained in this way, other factors which ultimately determine whether allergic symptoms are expressed in a given individual are now thought to be governed by the actions of many genes and their products (polygenic inheritance pattern). This theory is currently under further investigation with encouraging insights emerging.

Question: What percentage of the population suffers from allergies of all sorts?

Answer: Fifteen percent have an allergy of some sort. Seven percent have hayfever and four percent have asthma but, at some point

in their lives, seven percent have had asthma.

Question: How many are severely debilitated by such allergies?

Answer: The following statistics indicate the severity:

Asthma

Incidence: 8.9 million sufferers (approximately 3 million children).

Mortality: 2,000-4,000 deaths per year (mostly adults).

Morbidity: 36 million days confined in bed per year.

Hayfever

Incidence: 14.7 million sufferers.

Morbidity: 6 million days in bed.

Other (Food, Skin, Occupational)

Incidence: 11.8 million sufferers.

Penicillin allergy

Incidence: 2% of all those receiving penicillin (70-80 million courses per year or about 1.5 million reactions annually).

Mortality: 400-800 deaths/year.

Morbidity: Hospitalization, extension of hospitalization, deprivation of needed antibiotic.

Insect sting allergy (bees, hornets, yellow jackets, wasps, fire ants, kissing bugs)

Incidence: 1 million at risk.

Mortality: 40 per year.

Morbidity: Change in life style for fear of exposure.

Eczema

Incidence: 1-2 million - mostly children.

Morbidity: 57% hindered in occupational activity up to 20% must change employment.

FOOD ALLERGY

Question: In general, is desensitization favored over simple avoidance of the offending food or class of foods in that type of allergic reaction?

Answer: In controlled studies, desensitization programs -

either through oral administration or injections -- have not been demonstrated to be effective. Avoidance is still the preferable and recommended most effective approach to management. There are encouraging reports of the successful treatment of some gastrointestinal disorders due to food allergy with sodium cromolyn, a drug well established for its use in asthma by the inhalational route.

Question: How many people are affected by food allergies?

Answer: The incidence of food allergy is unknown and difficult to evaluate because there is no reporting system and because diagnosis is not often accurate. Some general statements can be made, however: an unusually high incidence of sensitivity to cow's milk seems to occur within families; the estimate of the incidence of milk allergy in children is about 1%; and food allergy appears to be more common in children.

Question: How severe are they?

Answer: There is a spectrum of severity ranging from mild gastrointestinal upset and skin rashes to a rare case of life-threatening anaphylactic shock or closure of the airways.

DIABETES

Question: Your institute has been interested in the field of insulin allergy. What percentage of diabetics does this affect?

Answer: There are no good nationwide data on insulin allergy. Statistics developed by our intramural staff show that from 1 to 5% of the nearly 2 million diabetics who require insulin would develop some type of allergic or immunologic reaction severe enough to complicate treatment.

Question: Will advances in the use of recombinant DNA techniques to produce "human" insulin solve the problem?

Answer: It is premature to say that recombinant DNA techniques will produce insulin useful in treatment of diabetes that will be free of allergic complications. However, I am optimistic that such is the case and I would like to give you some idea of the status of this rapidly developing field. Insulin has two known polypeptide fragments - the A and B chains of amino acids. The exact sequence of these, like beads on a necklace, has been determined and replicas synthesized in the laboratory. The amino acid sequence determines the immunologic or allergenic specificity. For example, insulin from pig pancreas differs in one amino acid from human insulin.

Two different lines of E. coli bacteria have been instructed genetically by means of laboratory synthesized genes to produce the A or the B insulin chains respectively. The trick is to get the E. coli production turned on. One way is to attach the A and B chains to a normal bacterial product - in this case the enzyme B galactosidase. The instructed cell then starts producing the enzyme joined to either A or B chain. This foreign product is insoluble in the cells and forms microcrystals which can easily be separated from most of the other ruptured cell components. The crystalline enzyme - insulin chain can then be broken, the insulin chain further purified and concentrated and in a final step recombined with its opposite chain to form A + B insulin. Substantially this much has been

accomplished in the laboratory. But physiological activity of the E. coli produced A + B chain insulin has not, to my knowledge, been demonstrated as yet.

Commercial proprietary development of the process is underway in at least one concern. Many problems of optimal conditions for yield and purification must be worked out. And sufficient material must be produced in order to satisfy the FDA that the product is equivalent physiologically to insulin of animal origin and without safety problems.

Question: There have been news reports which suggest that diabetes may be caused by a virus. Would you please comment on this?

Answer: The recent resurgence of interest in the virus etiology of juvenile onset, insulin dependent diabetes, commonly called juvenile diabetes mellitus (JDM), stems from the fine work of Dr. Abner Notkins of the National Institute of Dental Research. Dr. Notkins has shown that a strain of Coxsackie virus isolated from a new case of juvenile diabetes has a trophism for the islet cells of the pancreas in tissue culture and can cause diabetes in the experimental animal. Other investigators are studying this virus and other viruses but so far there is no convincing evidence that any one virus can be incriminated. Epidemiologic evidence has associated mumps with juvenile diabetes and suggests that while some cases of diabetes are associated with a previous viral infection others do not seem to be.

Last September the NIAID convened a group of scientists to look at this question. Although the group noted the growing evidence implicating viruses in JDM, much work is necessary before there can be any certainty. New and more sensitive tests have to be developed to identify the presence of virus infection. Strains of viruses isolated from cases need to be rigorously studied in the way Dr. Notkins is pursuing the Coxsackie B4 strain. Case reporting and epidemiologic study for association with community occurrence of certain viruses is needed.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: I mentioned three fast moving areas at the beginning of the hearing. These were applications of recombinant DNA and hybridoma technology plus the growing promise of effective regulation of the immune system in diseases caused by abnormal function of this system.

Both recombinant DNA and hybridoma technology can be applied to the development of new and improved vaccines. Hybridoma technology opens up a whole new area of treatment of severe infections with highly specific antibody as well as antibody useful in immune regulation. Both drugs and antibodies will find a place in immune regulation and such research deserves a very high priority.

If interferon is indeed nearing production in E. coli cultures there will be great pressures for controlled clinical trials to determine its value in the treatment of virus infections so that it can be brought to public benefit as soon as possible. While some of

this will be done by industry, the government will have to perform its own studies to determine licensing needs and restrictions.

The reports of the Task Force on Virus Diseases and the Task Force on Asthma and Other Allergic Diseases are replete with descriptions of need and opportunities. The NIAID Advisory Council recommended at least a doubling of investment over a five year period in both areas but thus far the increase has been only about 10 to 15 percent.

The Study Group on Sexually Transmitted Diseases has also made recommendations to the Institute for major increases in investment in several different areas of basic and applied research, also training. NIAID Advisory Council recommendations regarding these investments will be available in May, 1980. In particular the Study Group thought that more emphasis should be given to the problem of herpes genitalis. They thought there was an urgent need to develop cooperative, controlled clinical trials on the treatment of herpes genitalis. This would involve contract research at an estimated cost of about $1 million per year.

Training also ranks high in the areas to be given more emphasis if funds were not a problem. The Institute and the Advisory Council have reviewed this problem and the Council has agreed that the number of postdoctoral trainees should be doubled over the FY 1978-79 levels. This number would provide only a minimum of the number required to replace researchers being lost from the active pool.

Many medical schools offer no program in allergy. With the rapid advances in this area, the Institute would like to initiate additional centers in such schools that can be staffed by scientists who have gained experience in the existing centers. These in turn can develop outreach programs to primary care physicians in their area, upgrading the whole practice and research effort.

COST TO ECONOMY

Question: Dr. Krause, how many people are affected each year by the types of diseases which your Institute studies?

Answer: Let me explain why this is a very difficult question to answer. There are well over 400 types or species of viruses, bacteria and parasites that cause clinically and economically significant infections of man. Although far too many people still die each year from infections, most infections do not result in death, but rather in morbidity. Infections usually cause illness that results in loss of work, absence from school, hospitalization, physician visits, and purchase of medications. Most of these illnesses are not reportable so one must depend then on estimates of morbidity based on population samples. These estimates are impressive:

- Over 300 million acute infections occurred in the U.S. in 1976 or about 148 for every 100 people
- 68% of all acute illnesses (whatever cause) were infections or allergies
- 10% of the deaths in children under six were due to infections or allergies

But to be somewhat more specific: in a typical year in the

United States the frequency of occurrence of various infectious and allergic diseases has been estimated as follows:

Disease Group	Number of Cases
Viral Respiratory (except ear)	217,048,000
Bacterial Respiratory (except ear)	14,093,000
Gastrointestinal	22,216,000
Eye and Ear	13,443,000
Genitourinary	4,865,000
All Other Infectious	26,706,000
(Infection Sub-Total)	(298,371,000)
Asthma	8,862,000
Hayfever	14,656,000
Other Allergies	11,759,000
(Allergy Sub-Total)	(35,277,000)
Total	333,648,000

The picture world-wide is more grim. The World Health Organization has estimated the total numbers of people infected as follows:

Schistosomiasis	200,000,000
Filariasis	250,000,000
Malaria	600,000,000

(150,000,000 new cases per year and, in Africa, about 1,000,000 children die yearly)

And, of course, our interests overlap with those of more categorical Institutes because a complex and poorly understood interplay between infection and the immune system may be a factor in the cause of many chronic diseases such as rheumatoid arthritis, various kidney disorders and diabetes.

Question: Do you have any idea of what the total societal costs of these diseases are?

Answer: Rather than attempt an overall figure I would prefer to illustrate the magnitude by a few examples from various estimates:

- Of some 588 million physician visits for all acute and chronic conditions, nearly 22% were for infections and another 9% for allergies and asthma (1976 data).

- Gonorrhea is the most commonly reported communicable disease in the country. About 1 million cases a year are reported, but the true incidence is approximately 2 million and the total cost to the U.S. in 1979 was approximately $1 billion. But no dollar figure can describe the personal tragedy of recurrent fallopian tube infection, infertility, surgical sterilization or the 40,000 fetal deaths associated with ectopic pregnancies.

- The annual cost of viral hepatitis is $650,000,000 (1970 data).

- An estimated 2 million patients acquire infections during hospitalization for other causes. On the average, these add 5 days to the hospital stay and $700 to the cost for a national annual cost of $1.5 billion.

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

STATEMENT OF DR. DONALD B. TOWER, DIRECTOR

BUDGET REQUEST

Senator HATFIELD. If we can then move on to the Institute of Neurological and Communicative Disorders and Stroke. Dr. Tower is our next witness.

As Director of the National Institute of Neurological and Communicative Disorders and Stroke, you have a budget request of $249,207,000 for 1981, an increase of $7.7 million over fiscal 1980. Dr. Tower, your full statement will be inserted into the record, and do you have any opening comments or summaries that you wish to offer at this time?

[The statement follows:]

61-400 O - 80 - 38

Statement of Dr. Donald B. Tower

It is a distinct pleasure for me to appear before this Committee and to report on progress made by the NINCDS and on our plans for the next fiscal year. There is a sense of excitement in the research community over powerful new techniques and extraordinary new insights that are advancing our understanding of the brain and its connections through spinal cord, peripheral nerves and muscles to the entire body. As reported to this Committee at last year's hearings, this mood has been captured in the reports to our National Advisory Council by the seven panels and two task forces charged with devising long-range research strategies for the next decade of NINCDS activities. Copies of the report have been provided to this Committee to aid in the understanding of resource allocation priorities and future planning. We have looked not only at the resources needed to take advantage of research opportunities in universities and other non-government laboratories but also at the needs of our own intramural laboratories and clinics. In addition, we have considered the very important needs for research training required to assure an adequate supply of future investigators.

I am pleased to report progress in several research areas of high priority; first, on the problems of stroke. Between 1950 and 1978 the age-adjusted mortality from strokes declined 50 percent from 88.8/100,000 population to 44.4/100,000, with most of the decrease in the past decade. This is the lowest stroke mortality rate ever reported by the National Center for Health Statistics and displaces strokes from the third leading cause of death in the U.S. to fourth, below deaths from trauma of all types. The decline in stroke mortality surely reflects improved detection and better management of risk factors like transient ischemic attacks and hypertension, earlier recognition and more effective treatment of acute stroke episodes, and the basic and clinical research of NINCDS-supported scientists which has undergirded these efforts.

In addition to 12 Stroke Clinical Research Centers NINCDS now supports three Comprehensive Stroke Centers at which the application of research findings, and of preventive, rehabilitative and educational measures can be evaluated in community settings. The multicenter evaluation of the neurosurgical extracranial-intracranial arterial by-pass to prevent stroke is in mid-course at 65 clinics in 20 states and 11 foreign countries. My recent visit under World Health Organization auspices to the People's Republic of China puts us in touch with their leading neurological centers where stroke is a number one problem.

In 1979 the NINCDS launched the positron emission tomography (PETT) research program. A total of seven new program project research grants were awarded to bring total funding in FY 1980 to about $9 million. The NINCDS intramural PETT program at Bethesda will be initiated this year to provide a joint facility for shared research with NIA, NIMH, NHLBI and NCI. One of the first problems being addressed by this technique is concerned with cerebral circulation and stroke.

Research on trauma to the nervous system continues at the NINCDS-supported Spinal Cord Injury and Head Injury Clinical Research Centers: notably, a study on the efficacy of very high doses of steroids to prevent destruction of the spinal cord immediately after injury, and the finding in head-injured children that brain

swelling is due to vascular congestion and not to excess edema fluid--an important distinction for proper treatment. Three Comprehensive CNS Trauma Centers have also been established to evaluate in community settings the effectiveness of the facilities and resources available, the incidence and types of injuries, and the outcomes of present methods of treatment of trauma to brain and spinal cord. These centers operate in close liaison with the Veterans Administration, the Rehabilitation Services Administration and the Emergency Medical Services.

Other research relevant to trauma deals with brain and spinal cord regeneration and with neural prostheses. The NINCDS-supported regeneration research program has quadrupled in the last five years, with FY 1981 funding expected to reach $8.5 million. Current emphasis is on the problems of eliciting functionally useful regrowth of severed spinal cord neurons and achieving effective reconnections of such neurons with target organs. Also, a neural prosthesis for the paralyzed urinary bladder is nearly perfected. The neurophysiological problems have been solved by segregating the nerves controlling bladder contraction and those controlling the outlet to the bladder. An electronically programmed sequence of stimulation of these nerves restores bladder control and voluntary function. The prosthesis works well in dogs and is ready for human application, once an electrode insulation problem is solved. Thus, we may expect shortly to see a very significant new approach to the serious problem of bladder management in paraplegic patients.

Implementation of recommendations of the Commissions on Epilepsy, Huntington's Disease, Multiple Sclerosis and Diabetes continues. NINCDS will shortly sponsor a consensus meeting on implications and therapeutic management of infantile febrile seizures. An urban center in the Comprehensive Epilepsy Program will be funded in FY 1980. Several new anticonvulsant drug candidates will shortly undergo chronic toxicity testing and clinical trials, as part of the ongoing anticonvulsant drug screening and development program. Huntington's disease (HD) "centers-without-walls" will be initiated in FY 1980, and clinical studies have been initiated at the HD focus on Lake Maracaibo in Venezuela. The recommended brain banks and HD patient registers are in operation. NINCDS-supported research on diabetic neuropathy has risen three-fold in the past five years, and an NINCDS neuroepidemiologist has developed a clinical protocol for a WHO-sponsored multicenter international trial of a new experimental drug for diabetic neuropathy. The NINCDS and NIAMDD will jointly sponsor in March a conference-workshop on neuroendocrinology to review the current status and trends in the field and to develop recommendations for additional research that will be the subject of an NINCDS program announcement for FY 1981.

Further examination of the foci of amyotrophic lateral sclerosis (ALS) and Parkinson-dementia in Guam, Japan and western New Guinea suggest an environmental variable involving a dietary calcium deficiency and/or disordered calcium metabolism together with abnormal deposits of heavy metals in bodily tissues including brain. Changes in the brains of such patients often resemble those seen in the dementias of the Alzheimer type, so the implications of such observations may be quite broad. A conference on Guam in early 1980 has planned the next steps in investigating these research leads.

For the communicative disorders one of the most puzzling and controversial childhood disorders is chronic secretory otitis

media, characterized by persisting fluid in the middle ear which may cause permanent impairment of hearing and interference with learning and speech and language development. The NINCDS has sponsored and published a workshop on otitis media and child development. Two contracts have been awarded to evaluate in clinical trials the use of decongestant drugs or tympanostomy tubes, respectively, in treatment of the disorder.

An X-ray microbeam tracking system should soon provide us with a much better understanding of the mechanisms and disorders of the articulations involved in speech production. This new technique is safe and non-invasive and permits sequential studies in patients of the various mouth and throat elements used in speech articulation. The NINCDS expects to award in FY 1980 a center grant to adapt this instrument to a variety of clinical studies and to provide cooperative facilities to be shared with other research groups. Other NINCDS-supported studies indicate that there are several speech and language areas on both sides of the brain, with obvious relevance to aphasia--the disturbances of central processing of speech and language associated with stroke, head injury or tumor.

The NINCDS has expanded its efforts in computerized information retrieval and abstracting services beyond existing systems available for epilepsy and stroke. Over the past three years our Communicative Disorders Program has developed and implemented with the NLM a computerized literature search system for specialists in the communicative disorders utilizing the NLM-MEDLINE data base. This information retrieval system has engendered a real sense of excitement among researchers in the communicative sciences and disorders. Now, working with the NLM the NINCDS has developed a comparable system for the basic neurosciences. This system provides search strategies for obtaining monthly printouts of citations in seven neuroscience research areas, as well as capabilities for obtaining abstracts and citation profiles tailored to individual needs. The neurosciences information system has been announced and demonstrated to the neuroscience research community and implementation continues. We believe these systems are highly cost-effective, provide versatility, and capitalize on existing facilities of the NLM and regional and local libraries.

Let me conclude with examples of future prospects from our intramural programs: Development of procedures for culturing brain tumor cells from patients and testing the individual response of such cells to anti-tumor agents; development of experimental primate models for herpes virus encephalitis, for papova virus-induced brain tumors, and for hydrocephalus induced by cytomegalovirus infection of the fetus; and development of a radically new technique for obtaining tissue cultures of mature neurons as developed from primordial embryonic brains from a variety of species. The last technique provides opportunities to study in specific types of mature neurons metabolic and functional characteristics, growth and trophic factors involved in maturation and differentiation, and interactions of such cells with neurotropic viruses. Already with this technique NINCDS scientists have discovered a specific antibody in the blood serum of patients with the atypical slow virus disorder, Creutzfeldt-Jakob disease.

Finally, there are the innovative studies by NINCDS intramural scientists on the neuroimmunological aspects of multiple sclerosis (MS). By use of the recently developed hybridoma or cell fusion technique, they have been able to produce highly specific antibody

to one of the proteins on the surface of the measles virus. This technique provides a powerful tool for studying the interactions of viruses with the nervous system and in particular the role of measles virus in MS. The same group of investigators has initiated studies on 30 pairs of twins, with MS in one of each pair, for some of the clinical answers to MS. Our scientists are finding evidence suggestive of a high rate of subclinical disease in the presumed normal twins and distinct differences in specific tests for immune responses to measles virus by each pair of twins. Such research exemplifies the extraordinary complexity of the MS problem which I have discussed with this Committee on previous occasions. In the broader sense these examples typify the mix of basic and clinical research approaches that are so necessary to an understanding of the nervous system and its disorders.

In conclusion, Mr. Chairman, the budget request for the National Institute of Neurological and Communicative Disorders and Stroke for 1981 is $249,807,000, an increase of $7,383,000 over the 1980 estimate. I shall be pleased to supply additional information as desired for the record and to answer any questions. Thank you.

LONG-RANGE RESEARCH STRATEGY

Dr. TOWER. I would like to highlight a few items. First, to emphasize the concern of the biomedical research community, the voluntary health agencies and the lay communities with whom we do business for the future, as exemplified in our long-range planning efforts.

I have sent to this committee copies of the summary of the NINCDS long-range research strategy. But in case you have not seen them, here they are, executive and general summaries of the whole proceeding. This represents the best efforts and the combined wisdom of the community and our staff with regard to where we should be going and how we should be allocating our resources over the next decade.

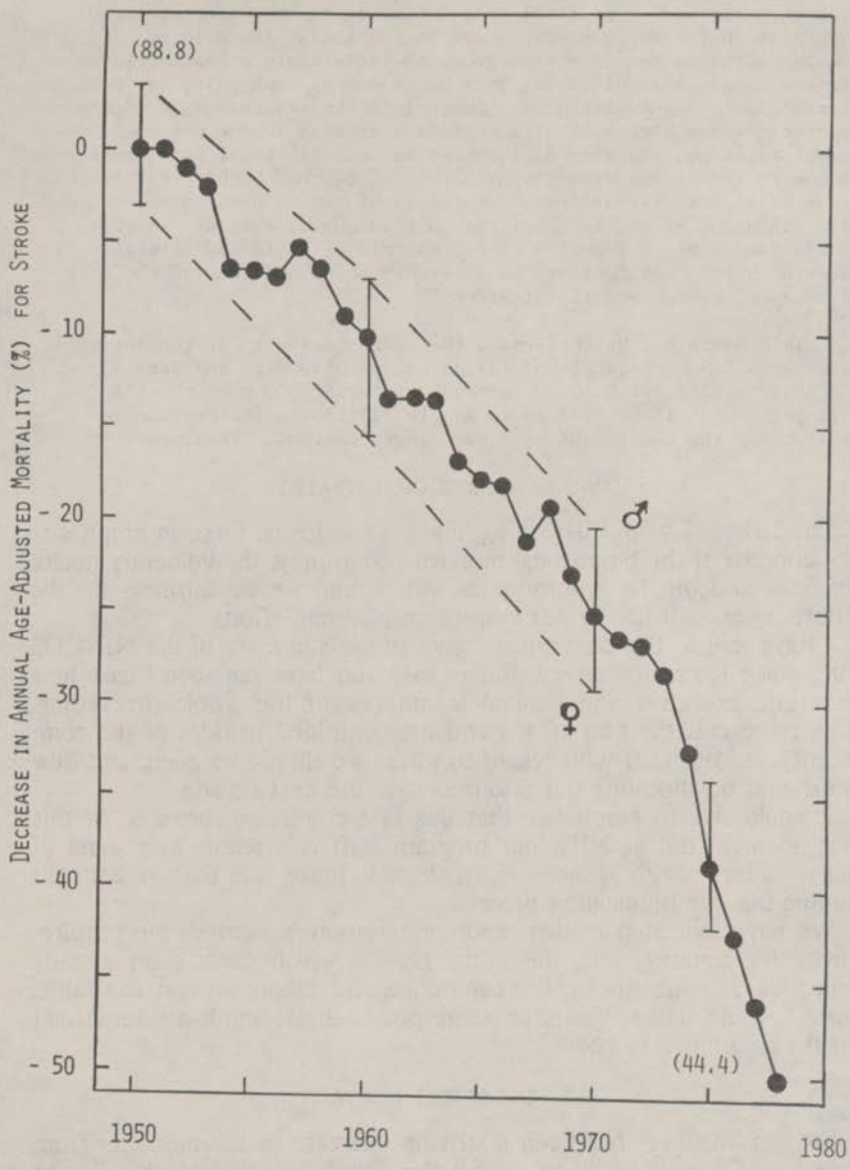
I would like to emphasize that this is a continuing process. At this very moment out at NIH, our program staff is meeting with some of the voluntary health agencies in an effort to make sure that we are continuing this communication process.

We have indicated in this report the resources needed, the requirements for training, and the other aspects which have been already expressed as concerns by the committee and others around the table. Now I would like to focus on some points that I think are important for the committee to know.

DECLINING STROKE MORTALITY

First of all, there has been a striking decrease in the mortality from stroke, and I would like to submit this graph, which I think tells the story much more impressively than any words that I can provide. The plot represents the age-adjusted percentage decreases for the period 1950 to 1978. The data come from the National Center for Health Statistics, and indicate that by 1978 there has been a 50-percent decrease in the mortality from stroke since 1950.

[The chart follows:]


(88.8)
0
- 10
- 20
- 30
- 40
- 50
DECREASE IN ANNUAL AGE-ADJUSTED MORTALITY (%) FOR STROKE
♂
♀
(44.4)
1950
1960
1970
1980

DROP IN CAUSES OF STROKE

Dr. TOWER. And for the first time since these statistics have been kept, stroke drops from the third leading cause of death to the fourth leading cause of death. Trauma, as you already indicated, now takes third place.

I think this impressive decline represents improved detection and management of the risk factors, like the transient ischemic attacks or little strokes and high blood pressure. And we certainly take due cognizance of the efforts of the National Heart, Lung, and Blood Institute in the latter situation.

The decline also reflects the earlier recognition and more effective treatment of the acute stroke situation.

I would like to point out that we cannot rest on our laurels here. There is still a great deal to do. We know now that at least one-half of the stroke patients do not have increased blood pressure. So there are other factors that we must uncover here.

One of the things that we think is most important to know is about the regulation of cardiovascular function that is exercised by the central nervous system, the mechanisms by which blood pressure is controlled or goes out of control, the mechanisms for the arrhythmias of the heart which occur from abnormalities of central nervous system function.

We are looking into new methods of treatment for the patients that I have mentioned, the one-half for whom treatment of blood pressure is not helpful, such as bringing new blood supply into the brain. As my submitted statement reports, we have now in progress in 65 clinics in many countries of the world, including the United States, Canada, a study to evaluate this procedure.

We have begun the collection of data in a data bank situation which will provide us with patient profiles to help improve management and treatment. Here is a little brochure outlining what this data bank approach entails. And finally, we would point to the promise that the positron emission tomography—PETT—program which we initiated last year is likely to bring to this area, since it will allow us to understand much better the interrelationships of blood supply and metabolism and function of nerve cells.

As one aspect of this PETT program, we propose to have such a facility at the NIH in Bethesda in which collaborations with other Institutes, such as Aging, Heart, Cancer, and Mental Health, have already been planned.

I would like to quote from the October 6 editorial from the medical journal Lancet the following:

> Among all imaging methods, positron emission tomography remains the clear leader. This development signals the advent of a new era in the neurosciences and probably in psychiatry, too.

This simply reinforces what we saw in this technique. We are looking forward to its contributing a great deal to our understanding of stroke and certainly many other disorders as well.

I would also like to emphasize the area of trauma. We have just had from our outside advisers a status report, and here is a copy of the report, on where we stand with trauma to the nervous system, both head injuries and spinal cord injuries, to tell us the current status and where we ought to be going.

Certainly, one of the current hotspots, so to speak, in neuroscience research is the studies on regeneration of the central nervous system, and here, I think, we have two major issues to address at the moment.

One is how to stimulate and maintain regrowth—the putting out of new fibers or axons from the nerve cells, and, second, how to guide these new fibers to reestablish the appropriate functional connections with the other nerve cells, the muscles, and other organs with which they interface. This is an extraordinarily complex problem.

Most of you are aware of the interest in the Soviet method of so-called enzyme therapy to reestablish connections in the severed spinal cord. Unfortunately, that turns out to be incorrect. The people whom we asked to reexamine in detail this Soviet claim have now published their reports and have demonstrated that indeed it does not work. The Soviet findings were the result of incomplete transections of the spinal cord, leaving intact nerve fibers and, therefore, those animals were still able to walk.

If you completely transect the cord, and demonstrate this by a very simple technique, then all of the enzyme therapy in the world will do nothing to restore function to such animals.

There are many other approaches that are emerging with regard to regeneration—for example, the use of organ cultures in which it is clear that there must be a symbiosis or cooperativity between various types of cells. Just the nerve cells alone cannot develop. They must have other types of cells, other relationships within the tissue, in order to make the appropriate growth and connections.

In addition, we are finding in the central nervous system that the use of fetal grafts taken from embryos and placed in appropriate parts of the brain experimentally will grow into and establish connections with the host brain tissue to restore not only the anatomy but also the function, including the elaboration of the chemical transmitters, the mediators of cell-to-cell communication.

These are indications on the horizon which we think will allow us to begin to solve some of the problems that are still confronting us in the area of central nervous system regeneration.

Another area which must not be overlooked in this context is the use and development of neural prostheses. The technological developments here are now really quite extraordinary. I brought with me one example.

[The information follows:]

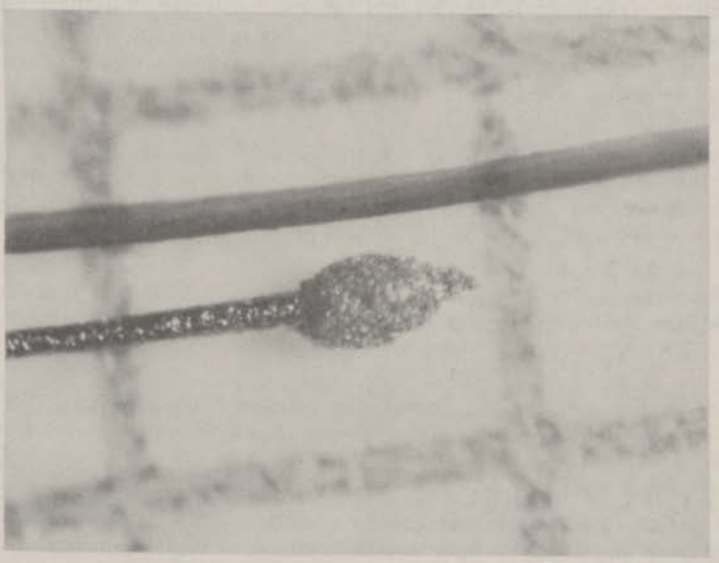
ULTRAMINIATURE CAPACITOR ELECTRODES FOR ACTIVATING NEURAL TISSUE

The ultraminiature capacitor electrode shown next to the human hair in the attached photomicrograph was fabricated under an NINCDS contract by Giner, Inc., in Waltham, Mass. After insertion into the brain, spinal cord, or a peripheral nerve, this

electrode is capable of exciting small populations of neurons without producing potentially toxic electrochemical reaction products that accompany neural tissue stimulation with conventional metal electrodes.

The electrodes are fabricated by mixing tantalum powder with glycerin to make a slurry. A tantalum wire, thinner than a human hair, is dipped into the slurry causing a drop to cling to the wire. The assembly is then heated to over 1,700° C. This results in fusion of the tantalum particles and disintegration of the glycerin. The matrix is then placed in an oxygen-rich environment to produce a very thin coating of an oxide of tantalum over its large sponge-like surface. This insulating surface prevents electrons from leaving the electrode to participate in chemical reactions and is the secret to the safety of the electrode. The thin oxide combined with the extensive surface area produces the equivalent of an electrical capacitor with the ability to store a large amount of electrical charge in a very small volume. This charge attracts and repels electrical ions in the neural tissue, and it is the movement of these ions that causes the excitation of the neural tissue.

The capacitor electrodes will be used in research and development of neural prostheses to replace hearing in the deaf, vision in the blind, and motion in the paralyzed.



(Grid squares have 1 mm. sides)

NEW ELECTRODE

Dr. TOWER. This is a new electrode which is smaller than a human hair, the dark line that you see in the photograph above the electrode. This type of electrode provides a much better way of recording from nerve cells and also stimulating nerve cells than we have ever had before. It gets around many of the technological problems. It is going to be useful in such things as bladder prostheses for the paralyzed bladder in paraplegics.

Now we are almost at the stage of human testing of the bladder prosthesis. It has been successfully tested in dogs, except for some minor electronic technical problems. We have solved the physiological problems, and we are going to be able to do the human trials over the next year.

Another thing which we are looking forward to that has not yet been

done, but for which the technology is there, is that on the end of such an electrode—not the end that sticks into the cell, but the other end—we can insert a microchip containing a computerized program. It no longer has to be separated from the electrode. We can put it all into the electrode, so it can be essentially inside the nervous system, and we hope by this means to be able not only to record chronically what is happening in a much better fashion over a time but also to be able to stimulate nerve cells in a sequential fashion to allow us to now bring in the normal brain circuitry that is there in a much more effective fashion. These are some of the highlights that I think one has to look for in this area.

NEUROENDOCRINOLOGY

Another area which is going to be extremely exciting and is already developing is the area that we call neuroendocrinology. That involves the shift in emphasis from the brain hormones acting on their peripheral body targets to their effects on the nervous system. We now know the latter action occurs—we now recognize that this is probably extraordinarily important in modulating the activity of the nervous system and, hence, human behavior.

In conjunction with the National Institute of Arthritis, Metabolic, and Digestive Diseases we are convening a conference next month, in March, to take a truly in-depth look at this whole area. One of the important aspects that will be touched upon is the area of the peptide neurotransmitters and neuromodulators.

Ten years ago, we knew about four chemical transmitters that accomplished the cell-to-cell communication in the central nervous system. Today there are over 30, and I am sure that we have not exhausted the list.

This implies, on the one hand, an extraordinary complexity in the biochemical circuitry of the brain, but it also tells us why and how we can be so versatile in what we do with our brain. It is the beginning of understanding of behavior and all that that implies, and some of the findings that are coming out already include an understanding of drug actions like the opiates and the tranquilizers, understanding of pain mechanisms, and the understanding of how the nervous system develops, matures, and ages—all of those things which go under the general rubric of behavior.

UNIQUE NEEDS FOR CLINICAL RESEARCH

I would like to conclude by emphasizing, especially for the nervous system, our need to combine basic and clinical research approaches in understanding the disorders of the nervous system. I have given an example in my submitted opening statement relevant to multiple sclerosis, which touches on the hybridoma technique that Dr. Krause told you about and on some studies on twins which get us into the niceties of the genetic problems.

These are certainly some of the areas that it will be necessary to understand before we will solve the problem of multiple sclerosis.

The essential point that I want to make here, Senator, is that so many

of the functions and disorders of the human nervous system have no experimental counterparts, so there is a very unique need for research on man and clinical investigations on such things as hearing, speech, pain, consciousness, memory, and a very long list I could go on with that will require research on man rather than on animals.

There is a unique need in the neurological and communicative disorders for clinical researchers and for some special disciplines in the basic research area. I think that is where and how the future answers must be sought.

Thank you.

SPINAL CORD INJURY AND REGENERATION

Senator HATFIELD. Dr. Tower, I always appreciate your comments in the area of spinal cord injury and regeneration, especially, since that happens to be one of my special interests, as you know.

The Washington Post on October 26, 1979, reported a special symposium at the Wilson Center of the Smithsonian Institution and the discussions that they centered around were restoration functions following spinal cord injuries. There was a general call from this workshop for a crash effort in this field of medical research.

How much was spent for this program in fiscal 1979 and how much was spent in fiscal 1980?

Dr. TOWER. Senator, in fiscal 1979, we spent for central nervous system regeneration, as a part of the spinal cord injury budget, $6.9 million. In 1980, the estimate—because we haven't finished the year yet—is for $7.7 million, and we are expecting in 1981 to up that to something over $8 million. It is a little hard to say exactly how much at the present time.

The total amount for spinal cord injury would be considerably higher than that, perhaps double those amounts, since we support the centers and other areas dealing with the acute problems of spinal cord injury as well as regeneration.

RESEARCH TRAINING

One of the difficulties, if I may pursue the business of the crash effort that you mentioned, is the need for more people trained in some of the specialized areas here. It takes time to generate trained researchers, so that the money can be adequately spent in the most effective ways with people who have been appropriately trained to deal with some of these very specialized areas.

Senator HATFIELD. Back to the training question. I had prepared a couple of questions for you on that subject. I have quotes here prepared for this committee—one by Dr. Goldstein of your Institute and one by you. I would like to quote them for the record.

First, Dr. Goldstein:

> The single most important unavailable resource at this time and for the future is skilled research personnel. An increase in the Institute's research training program would be required if this deficit is to be addressed.

That is Dr. Goldstein's quote.

Now, your quote:

A major problem for pursuing the research effort on spinal cord injury regeneration is the continuing lack of trained, skilled clinical and basic investigators. This can only be addressed by increased efforts of NINCDS research training programs.

And yet, Dr. Tower, in light of these two statements—and I don't think they were taken out of context—if they were, I would like to have a clarification—how can you possibly account for the reduction in training funds for spinal cord trauma by $153,000 for fiscal year 1980?

Dr. TOWER. I think it is more than that, Senator, but I don't know what figures you are looking at.

Senator HATFIELD. Let's take $1.8 million for all of NINCDS. Would that be a better figure?

Dr. TOWER. Yes, sir; definitely. You have heard the discussion before—Dr. Krause, Dr. Kirschstein, Dr. Fredrickson—and so I don't propose to plow over that ground again. I think the point has been made. Policy decisions have been made to support the individual investigator research grants, and I have no quarrel with that decision.

I think stabilization of research efforts in the community are a No. 1 priority. I have indicated that in our area we have some special needs, and many of these refer to areas of clinical investigation.

Now I think I can illuminate the situation a bit, because we really have two types of training mechanisms. One is that which appears under the training budget, as we have been discussing. In addition to that, we have those designated as "research career development awards," and in our case the teacher-investigator development awards. These latter two are budgeted with research grant funds and have been for a long while. Much of the work in clinical investigation that you and I are addressing right at this moment depends on the specialized training provided from these areas.

We propose to give emphasis here, so that while I will agree with you that there is a reduction—and if you like, I am not totally happy with that—in the training area, we are able to circumvent some of the problem by using these other funds, so that it is not a totally dismal picture, if you want to put it that way.

PRIORITY SETTING

Senator HATFIELD. How much flexibility is there within your organization as far as setting priorities within these various divisions headed by these gentlemen and lady?

By that, I mean if there is an overall budgetary policy that is to be established, I assume there is an input from each of the division people, each of the Institutes represented, and I suppose—I presume there is a general discussion, a specific discussion. But within that context and over and above that particular procedure, is there any flexibility as to Dr. Tower making, as an illustration—Dr. Tower making a judgment of how the money should be apportioned within his own Institute relating to training, relating to basic grants, relating to intramural research, relating to all of these things—such as you're saying to them, "We have to keep this budget within a 5-percent realm, but you apportion that adjustment within your own priorities," or is there a more centralized kind of policy that is formed so that all of the Institutes have to reflect the same kind of priority?

Dr. FREDRICKSON. The tradition has been, and remains, to give as much discretion to the Institutes as possible, Mr. Chairman. This discretion, however, is dealt with item by item as it appears in training, research grant items that you examine in your oversight. This is probably the first year in which we have undertaken an initiative and have presented to the Department certain priority items that represent decisions about total numbers of grants to be supported, modernization of facilities, and training. These have been presented by the Institutes of Health collectively to the Department. The purpose of this initiative is to attempt to develop a formula for possible stabilization of one aspect of the budget—and only one at this time—so you see an aggregate decision presented by the Institutes collectively from the Office of the Director.

Senator HATFIELD. You make very clear to these Directors your priorities, your concepts, your views, your hopes, your dreams, I suppose, in various meetings and contacts?

Dr. FREDRICKSON. I do. And they make very clear to me their ambitions and plans. We have a formal process that takes nearly 3 months, during which my staff and I meet with each Institute and Division. In fact, this year, members of the advisory councils also participated. This enabled us to learn from the Institutes' constituencies directly what they would like to do, where they feel they need the most money, and how they are affected by general NIH policies. The understandings reached in these meetings are summarized in lengthy memorandums.

This same planning process is utilized with regard to special issues, such as nutrition and diabetes, that involve a number of the Institutes.

BUDGET REQUEST FOR EACH INSTITUTE

Senator HATFIELD. Could you give this committee the information of how much these requests were, Institute by Institute, that you had in your initial budget request as presented to OMB? Or let's say HHS first, and then OMB?

Dr. FREDRICKSON. We can provide you with a chronological outline, by Institute, of the budget changes during the process.

Senator HATFIELD. Let's go back and get the pyramid built. I would like to get the figures submitted to you by the Directors of the Institutes first as the base. Then I would like to get the figures as you transmitted them after your processing within the Institute to the Department. Then I would like to get the figures that survived that to the OMB, so that I can make a comparison—this committee can make a comparison.

And could you do that in a table form, so I can just read across—put the Institutes down the lefthand side and I mean these various steps in the budgetary process across the top.

That is a formal request. So that clears you of any kind of difficulties.

Dr. FREDRICKSON. We will be glad to supply the information.

[The information follows:]

CHRONOLOGICAL DEVELOPMENT OF THE 1981 BUDGET (Comparable)
(Dollars in thousands)

Appropriation	1980 Comparable	1981 Institutes Forward Plan to NIH	1981 ZBB Estimate to PHS	1981 ZBB Estimate to Department	1981 Department Estimate to OMB	1981 President's Budget
Cancer	$1,000,802	$1,200,000	$1,047,000	$1,040,314	$1,015,657	$1,007,800
Direct Submission	-	-	-	-	(1,170,000)	-
Heart	527,806	642,160	570,000	564,490	550,091	548,399
Dental	68,734	79,750	74,000	73,300	70,724	70,451
Arthritis	341,939	499,744	360,000	358,135	366,202	365,711
Neurology	242,424	273,000	245,000	244,980	250,981	249,807
Allergy	215,768	260,000	235,000	224,940	229,516	228,412
General Medical Sciences	312,628	343,070	330,000	314,980	331,877	331,639
Child Health	209,602	251,000	236,000	234,893	218,175	217,531
Eye	112,968	133,002	118,000	114,940	116,815	116,562
Environmental Health	84,306	127,512	102,000	101,980	97,694	97,269
Aging	70,228	84,662	68,000	68,000	75,594	75,317
Research Resources	169,302	187,412	184,050	181,091	184,510	184,439
Fogarty Center	9,095	11,905	10,200	10,102	9,174	9,174
Library of Medicine	44,657	49,362	48,000	46,420	45,152	44,730
Office of the Director	21,902	27,000	23,500	22,780	22,719	22,549
Buildings and Facilities	10,480	33,050	24,000	25,013	13,250	11,750
TOTAL, NIH	3,442,641	4,202,629 1/	3,674,750 1/	3,626,358 1/	3,598,131	3,581,547

1/ Estimates based on 1980 President's Budget of $3,172,430.

SUBMITTED QUESTIONS

Senator HATFIELD. We have other questions, Dr. Tower, that I will submit to you for the record.

Dr. TOWER. Fine.

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

HEARING RESEARCH

Question: For the past two years, our Committee, especially Senator Schweiker, has directed you to expand your hearing research program, particularly in the area of sensorineural hearing loss. What have you done to accomplish this?

Answer: Selected measures have been implemented in the two year period. However, the requisite number of investigators needed to address some of the special areas of research necessary to understanding sensorineural hearing loss are not available. Examples of these areas are the biochemistry of the auditory mechanism and technological applications of signal processing in hearing aids for the moderately and severely hearing-impaired. The solution to this problem lies in the training of additional researchers in the clinical and basic aspects of the problems of hearing.

In the past two years, we have conducted a workshop to define the body of knowledge of the effects of noise on hearing which is a leading cause of sensorineural loss. An Institute-initiated contract will be awarded this month to provide further research direction in noise effects. Also, this year, we are conducting a workshop on signal processing in hearing aids in order to stimulate investigator-initiated research as well as Institute-initiated research contracts. The same mechanism is being used to explore tactile devices for the severely hearing-impaired and the very difficult problem of evaluating the prototype models.

Question: Has the proportion of funds going into the hearing program increased?

Answer: The following table indicates a relatively constant percentage of funds obligated in the hearing program since 1977.

Fiscal Year	Total NINCDS	Hearing and Equilibrium	Percent of Total NINCDS
1977	$154,594,000	$17,143,000	11.1
1978	177,312,000	20,827,000	11.8
1979	212,079,000	23,471,000	11.1
1980 estimate	242,424,000	26,910,000	11.1
1981 estimate	249,807,000	28,000,000	11.2

EFFECTS OF INFLATION

Question: Using examples, can you give us some idea of what direct effects inflation is having on your Institute?

Answer: In research grants, the average cost of Research Projects continues to increase yearly for all approvals including competing and noncompeting. In 1978 the average was $66,700 increasing to $78,900 in 1979. We estimate that it will increase to $81,900 in 1980 and $88,000 in 1981. Despite this increase, the 1981 budget will permit us to fund approximately the same number of Research Project grants as in 1980. The National Research Service Awards have been especially affected due to the stipend increases in 1980. These are the first increases in five years and raise the

costs per trainee 39 percent, from $13,740 in 1979 to $19,080 in 1980 and 1981. Stipend increases have been provided in 1980 and 1981 to offset the effects of inflation. In the Intramural Research Program, the cost of supplies and equipment is increasing at approximately the rate of inflation. In addition, as research advances, more complex and sophisticated equipment is needed which in itself is more expensive than previous less advanced equipment.

Question: Do you anticipate major priority changes and funding cutbacks as a result?

Answer: The Institute does not anticipate any major changes in scientific research priorities. The Intramural Research Program is particularly vulnerable to the effects of inflation on the resources available for laboratory supplies and complex scientific equipment. A delay in the purchase of such equipment will decrease the efficiency and increase the time required for prosecuting the research effort.

PROGRAM FUNDING BREAKDOWN

Question: In your professional scientific judgment are you pleased with your funding breakdown of your programs?

Answer: The FY 1981 budget breakdown reflects the anticipated distribution of Research Project grant applications for next year and the anticipated commitments for other extramural and direct operation activities.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: The following areas would receive priority if additional funds were provided:

(1) Research training with special emphasis in the areas of clinical research, spinal cord injury and hearing disorders; (2) intramural research with special emphasis in the areas of neurovirology, neuroimmunology, epilepsy, and clinical otolaryngology; and (3) extramural research (grant and contract) with special emphasis in areas of acute spinal cord injury and regeneration, deafness, drug development and clinical trials.

TRAINING PROGRAMS

Question: In two recent statements prepared for this Committee, one by Doctor Goldstein of your Institute and one by you, Dr. Tower, the following points are made:

"The single most important unavailable resource at this time and for the future is skilled research personnel. An increase in

61-400 O - 80 - 39

the NINCDS research training programs would be required if this deficit is to be addressed". (Goldstein)

And

"A major problem for pursuing the research effort on spinal cord injury and regeneration is the continuing lack of trained skilled clinical and basic investigators. This can only be addressed by increased efforts in the NINCDS research training program". (Tower)

How can you possibly account for the reduction in training funds by $153,000 from FY 1980?

Answer: This reduction in training in the Stroke and Nervous System Program reflects support of commitments in 1981, with no new awards being made. The NINCDS has proposed the distribution of resources among competing priorities, each of high merit. Within the funds available in the FY 1981 budget, stability of the investigator-initiated Research Project effort was given the first priority.

Question: Can you understand therefore why this Committee might feel the necessity to challenge the Institute's commitment to these areas in light of such proposed reductions?

Answer: Yes, the Institute can appreciate the Committee's concern about the impact of reduced research training on research areas of major importance. The 1981 training budget provides for meeting the present commitments in the program of National Research Service Awards.

STAFF RECRUITMENT

Question: In the past, Dr. Tower, you have complained that salary disparities between the private sector and the Government have resulted in problems with respect to personnel recruitment. Mention was made of the length of time needed (often up to 2 years) for candidates to be hired. Has there been improvement in this area over the past year?

Answer: The problems resulting from salary disparity have been somewhat reduced over the past year. The implementation of the Physicians Comparability Allowance has provided a means for supplementing physicians' salaries. For our most senior positions, the implementation of the Senior Executive Service with its bonus provisions for high-quality performance will further assist us in better compensating investigators. While these changes will not completely close the salary gap for all of our investigators, especially physicians, they have alleviated the situation.

Question: What could be done to expedite the hiring of staff?

Answer: In the past, the process for filling senior positions at the SES or super-grade level has been very lengthy. It has involved two major steps: developing a recruiting plan

and the actual recruitment and selection. Both steps have required clearances and approvals at various levels in the Department. We have been advised that the Department has developed a universal recruiting plan. Under this plan, no further approval would be required before implementing the search process unless a significant deviation from the plan is deemed necessary. Approval of the selected nominees for senior positions will remain at the Departmental level. This reduction in the search time should reduce the time required for senior level recruitments.

RESEARCH GRANT APPLICATIONS

Question: Can you give us a breakdown of the number of research grant applications you received in fiscal 1980, the range of recommended priority scores, what percentage of the grant applications you approved, and what percentage of these approved applications were funded?

Answer: Since fiscal year 1980 is less than half over, we only have data for the first two Advisory Council meetings for October and January. Of 843 Research Project applications received for October and January Councils, 658 or 78 percent were approved by the Study Sections and the Councils. Of those approved through the January, 1980 Council, 342 or 52 percent are being funded. The following table shows the range and distribution of approvals by priority score.

Priority Score	Number Approved
100-150	78
151-200	166
201-250	111
251-300	90
301-350	82
351-400	79
401-450	38
451-500	14
Total	658

The total estimate for fiscal 1980 Research Projects is 1,300 applications with 1,025 or 79% approved and 552 or 54% of the approvals funded.

GILLES DE LA TOURETTE'S SYNDROME

Question: There has been some interest expressed in a tragic disease known as La Tourette's Syndrome. Briefly describe this for us.

Answer: Gilles de la Tourette's syndrome affects children, usually between the ages of five and ten years, who develop tics of the hands, arms, or face, spreading to other parts of the body. The child demonstrates a combination of frequent repetitive facial grimaces, throwing out of the arms, contraction of the leg muscles, involuntary kicking, blinking, rubbing the face, thumb sucking, and hitting other parts of the body. There may also be compulsive repetitive noises like grunting or hiccuping, or explosive speech, sometimes obscene, or blasphemous.

Question: At what level and what kinds of research are you funding in this area?

Answer: In the area of research related to Tourette's syndrome, attention is directed to the possible role of neurotransmitters such as dopamine, serotonin, acetylcholine, etc., in the etiology and pathophysiology of the disorder. Investigations are supported to study the genetic and environmental factors which may cause this disorder. Since coordinated movement depends upon normal neuron to neuron and neuro-muscular interaction, disruption of this communication from any cause can result in an uncoordinated behavior. For this reason, NINCDS supports considerable research in this area as detailed below.

The NINCDS supports two projects directly related to Tourette's Syndrome in the amount of $129,687. In addition, we consider research in the areas listed below to be relevant to determining the cause(s) and expression of Tourette's syndrome.

Activity	Number of Projects	1979 Amount
Synaptogenesis and neurotransmission	32	$2,143,237
Axoplasmic flow	3	239,765
Drugs and Toxins	11	518,671
Genetic control of differentiation and function	10	714,954
Nutrition and central nervous system development	8	531,720
Total	64	4,148,347

Question: Do you coordinate your efforts with the National Institute of Mental Health?

Answer: Yes, in areas of mutual interest and responsiblity, the Institute's staff communicates regularly with the staff of the NIMH.

HUNTINGTON'S DISEASE

Question: Two years ago, the Huntington's Disease Commission made its report and we began funding research in the area of degenerative neurological disorders. What recommendations of the Commission have you not been able to fund because of budget limitations?

Answer: Implementation of all of the recommendations for which the NIH or the NINCDS has legislative authority are being implemented.

Centers Without Walls: Basic and clinical research Centers Without Walls were recommended by the Commission at a cost of 2 million dollars. Six applications have been received and are currently under scientific merit review.

Venezuela Project: A unique focus of Huntington's Disease (HD) families living in Venezuela could potentially shed light on the nature, treatment and prevention of HD. A research and development contract to study this HD focus is currently being negotiated.

Educational Materials: The NINCDS Office of Scientific and Health Reports had updated the basic information pamphlet on Huntington's disease (designed for lay people); materials for professional personnel are being developed.

Branch for the Neurological Disorders of Aging: Huntington's Disease, Parkinson's Disease, Alzheimer's Disease and others:

The Huntington's Disease Commission recommended the establishment of a Branch to foster research on Huntington's Disease and other neurological disorders of aging, and also to oversee the implementation of the Huntington's Disease Commission recommendations. One Health Science Administrator expert in this area was hired in September 1978.

Question: On the positive side, what kinds of steps have we taken to prevent, detect, or even cure this tragic illness?

Answer: The NINCDS supported 9 research grants directly relevant to Huntington's Disease (an increase of two grants over FY 1978) and two Teacher-Investigator Development Awards. This research is aimed at investigating abnormalities reported in skin fibroblast tissues, cell membranes, and neurotransmitters. A proposed animal model is under study. The Intramural Research Program is actively experimenting with new therapeutic agents and scientists at NINCDS and NCI have been collaborating on a new finding that cells from HD patients seem to be supersensitive to X-radiation.

The NINCDS has also funded research contracts and grants during FY 1979 which have great promise for future benefits. A Roster of Huntington's Disease patients and families was established at the University of Indiana to provide investigators with the patient volunteers and quality control information they need. A grant was made to the Hereditary Disease Foundation for a series of Interdisciplinary Workshops on Huntington's Disease to stimulate new research hypotheses and to recruit new talent to the field. The National Tissue Banks supported by NINCDS, NIMH, the Scottish Rite Foundation, Hereditary Disease Foundation and the Huntington's Chorea Foundation have provided investigators with brain tissue. NINCDS grants to investigators using the new technique of positron emission tomography (PET) to study brain metabolism in HD patients and those at risk will provide useful information for diagnosis of HD and understanding its etiology.

In addition the NINCDS supports an extensive body of basic genetic research relevant to neurologic disorders like HD.

Question: We continue to hear about the Venezuela project, could you please explain what this is and the implications of this project?

Answer: The focus of Huntington's Disease families around Lake Maracaibo in the state of Zulia, Venezuela, provide a unique research opportunity. The HD community is composed of over 200 patients and more than 1,000 relatives at risk, all of whom are descendants of a Spanish sailor who emigrated to Venezuela in 1860. A number of these patients have intermarried and produced children. With both parents ill with HD, these children have a 75% risk of developing HD and a 25% risk of inheriting two genes for the disease (instead of the usual one from a single affected parent). Children with two genes for HD (homozygotes) would have a "double dose" of the disease. Examing tissues from homozygotes may make the cause of the disorder more apparent since a double dose would make the defect much more obvious. The disease process could thus be studied at an earlier stage and hopefully a method of clinical intervention identified.

The Venezuelan HD community is also special because all members have inherited the same gene from the same ancestor. In the United States, the HD gene has come from different parts of the world and may vary from family to family. These variations may cause research results to cancel each other out and disguise a finding which may be valid for a particular family. The HD "family" in Venezuela is very large and concentrated in a small area so that tissue samples may be relatively easily obtained from large numbers of patients all of whom have the same HD gene.

Scientists will be looking at the Venezuelan HD for a "marker" for the HD gene, that is, some indication of which chromosome contains the HD gene. An added benefit is that in their search for the HD gene, investigators will be "mapping" chromosomes and discovering "landmarks" which can serve as markers for other genetic diseases. This search for the HD gene is fundamental basic research which has tremendous potential for the diagnosis, treatment and prevention of over 2300 hereditary disorders.

At present, the Venezuela Project is a collaborative effort between United States and Venezuelan investigators to collect tissues (blood and skin primarily) from particularly scientifically informative Huntington's Disease families in Venezuela. These tissues will be maintained in tissue banks in the United States (and Venezuela if possible) and will be available to investigators world wide.

Although many investigators will study the tissues immediately, banking these cells in federally supported tissue banks will provide an ongoing source of research material as new hypotheses are developed.

Question: For the record, would you provide us with a description of the progress being made to implement the recommendations of the Huntington's Disease Commission now and what is planned for FY 1981?

Answer: The Huntington's Disease Commission emphasized a generic and problem-oriented approach to the problems of neurologic and hereditary disorders rather than recommending programs exclusive to Huntington's disease.

The Huntington's Disease Commission proposed 27 general recommendations spanning areas of research, care, and medical and social services. Twenty-three are directed to the DHHS, with 19 addressed to the PHS, 14 of which apply to the NIH. NINCDS is designated as having primary or exclusive responsibility for 13 recommendations. Other NIH Institutes and Divisions involved are National Institute of General Medical Sciences, National Institute on Aging, and Division of Research Resources. Several recommendations are addressed to the Department of Labor, the Veterans Administration, and the Office of the President. Twenty-four of the recommendations could be implemented under existing law if funds are available.

The NIH activities in response to the Commission's recommendations are outlined below:

NINCDS

Over the past year, the NINCDS has continued to implement the recommendations. Plans have been made for further action in the next several months. Recommendations which have been implemented are the following:

1. Two National Tissue Banks: Established at McLean Hospital, Boston, under the auspices of Harvard University and at the Wadsworth VA Hospital, Los Angeles, for the collection and distribution of neural tissues from patients with Huntington's disease and certain other disorders. Joint sponsorship with the National Institute of Mental Health (NIMH) and private voluntaries.

2. Second International Symposium on Huntington's Disease in San Diego, California, November 16-18, 1978: This symposium brought together several hundred scientists from over a dozen countries to review the state of research on Huntington's disease. A summary has been published.

Recommendations for which implementation is planned or in progress:

1. Additional research on etiology, pathogenesis, detection (particularly presymptomatic detection) and treatment in Huntington's disease and increased research in the neurosciences and genetics: With the budget approved for the NINCDS by the Congress at $242 million and the allocation to the Neurological Disorders Program, this recommendation will be implemented in Fiscal Year 1980.

   Plans are to fund additional research grant applications in 1980 and to direct special attention to those with relevance in the area of neurosciences and genetics. The number of grants specifically related to Huntington's disease has increased from 7 to 9.

2. Centers Without Walls: The NINCDS has issued an announcement of Institute interest in supporting Centers Without Walls. Applications are under review for selection of the most scientifically meritorious for funding.

3. Venezuela Project: A contract is being awarded to the University of Zulia for collaborative research on a unique population of Huntington's disease. Long-range plans are being actively developed.

4. Research Roster for Patients and Families with Huntington's Disease: A contract was issued by the Extramural Program, NINCDS, to the Indiana University to establish and maintain a roster.

5. Interdisciplinary Workshops on Huntington's Disease and Related Disorders: A grant was awarded to the Hereditary Disease Foundation to conduct 4 workshops per year.

6. Neurogenetic Newsletter: This recommendation has not been implemented, although the grant for the Interdisciplinary Workshops may support some of the Newsletter functions.

7. Small Grants Program: The NINCDS is exploring with the NIH, mechanisms for initiation of such a program.

8. Funding for Research Training: NINCDS will fund meritorious applications for research training of individuals where such proposals have relevance to the neurosciences and to neurogenetic disorders.

9. Continuum of Care for Huntington's Disease Patients and Others with Chronic or Disabling Conditions: The data derived from the report of the Commission were used in the response to a Department initiative on long-term care requested by Dr. Faye Abdellah, Director of the Office of Long-Term Care in HCFA.

10. Branch within the NINCDS for Huntington's Disease and Related Disorders: To implement an expanded program in Disorders of Aging, the NINCDS has hired additional staff (an additional Health Scientist Administrator) to serve as a focal point for the implementation of the Commission's recommendations and to develop programs in the area of neurological disorders of aging. A second Health Scientist Administrator will be hired during Fiscal Year 1980.

11. Collaboration with NIMH on its Program of Continuing Education of Professional Personnel with attention to Huntington's disease, Alzheimer's disease and related dementias: The NINCDS and NIMH plan collaborative efforts.

NIGMS

The Commission recommended a budget increase for NIGMS to support increased research in the neurosciences and genetics. Particular emphasis was given by the Commission to research exploring mechanisms of autosomal dominant transmission. NIGMS currently supports a number of grants in these areas.

NIGMS has issued an Announcement in the NIH Guide to Grants and Contracts on the Development and Evaluation of New Therapies for Rare Genetic Diseases. The announcement was shared by NINCDS, NICHD, NEI, NIAMDD, and NHLBI. The Commission stressed the development of new drugs for small populations of patients and urged the creation of a Presidential Task Force on the problem. A committee has been formed within the FDA to consider the topic.

NIGMS also maintains a cell bank for human genetic disease which stores and distributes cell lines from patients with a variety of hereditary disorders including Huntington's disease.

NIA

The NIA supports ongoing research, primarily descriptive in nature, on changes in neural structure and function with age.

DRR

The DRR supports research on Huntington's disease and related disorders throughout its General Clinical Research Centers.

SPINAL CORD INJURY AND REGENERATION

Question: The Washington Post (Oct. 26, 1979) reported on a specially called symposium at the Wilson Center of the Smithsonian Institute. The discussions centered around restoration of function following spinal cord injuries. There was a call for a "crash effort" in this field of medical research. How much was spent on this in fiscal 1979 and fiscal 1980?

Answer: NINCDS funding for spinal cord injury and regeneration research was $13,144,000 in 1979 and it is estimated at $14,845,000 in 1980. This includes spinal cord regeneration research of $6,912,000 in 1979 and $7,700,000 estimated for 1980.

Question: Given the tremendous growth in your budget in the past 3 years, do you think that the Committee's intent has been followed in terms of adding new emphasis on this program?

Answer: In 1977 the NINCDS announced interest in stimulating research programs in the areas of CNS regeneration as well as the development of additional research training opportunities in these areas. The increase in total funding for spinal cord injury and regeneration research is noted in the following table:

Fiscal Year	Spinal Cord Regeneration	Other Spinal Cord	Total Spinal Cord
1976	$1,970,000	$4,220,000	$6,190,000
1977	3,150,000	5,488,000	8,638,000
1978	5,934,000	6,282,000	12,216,000
1979	6,912,000	6,232,000	13,144,000
1980 estimate	7,700,000	7,145,000	14,845,000
1981 estimate	8,500,000	8,007,000	16,507,000

In response to staff initiatives and to the program announcement, the level of effort for regeneration and spinal cord research has increased 140 percent from 1976 to 1980 while the Institute's budget has grown 67 percent during the same period.

Question: It has been said that only 7 percent of the spinal cord injuries (SCI) are due to the cord being severed and most of the rest are due to bruising of the cord. It has been said that the injuries due to bruising can often be helped by early enzyme therapy such as that being carried out by the Polenov Institute in Leningrad. What evidence do you have to prove or disprove the enzyme therapy theory?

Answer: The clinical use of early enzyme therapy was stimulated by the experimental animal study of Matinian et al. (Matinian LA, Andreasina AS: "Enzyme Therapy in Organic Lesions of the Spinal Cord." Akademia Nauk Armenian SSR, 1973, 94pp.) The same information was also presented by Professor Matinian at an NINCDS sponsored conference held in the U.S. in 1976.

On the basis of these reports a carefully controlled study was carried out under NINCDS contract by a U.S. investigator who repeated the Matinian experiments precisely, utilizing samples of the Russian enzymes; the report of this research has just been published (Guth et al. "Ineffectiveness of Enzyme Therapy on Regeneration in the Transected Spinal Cord of the Rat," J. Neurosurg. 52: 73-86, 1980).

The results of this study indicate that:

(1) Enzyme treatment did not facilitate nerve regeneration nor did it lead to functional restitution in rats with verified complete spinal cord transection;

(2) It was suggested that Dr. Matinian's reported findings were the result of incomplete spinal transection.

In addition, two independent investigators utilizing grant funds conducted experiments similar to, but not identical to, those of Professor Matinian. They also report a failure to confirm Professor Matinian's results and find the use of enzymes during either the acute or chronic phases of spinal cord injury to be without effect on experimental spinal cord injury.

Question: We have been told by advocates of and patients who were treated with enzymes that HEW officials have discredited the Polenov Institute's results based on exams NINCDS performed on U.S. citizens who were treated there. These same advocates and patients state, however, that no such post-therapy examinations were ever performed by U.S. officials. Can you please respond to this allegation?

Answer: Patients who have been treated at the Polenov Institute have not been examined by NINCDS physicians either before or after their visit to the Soviet Union. These patients were referred to the Polenov Institute through private channels and returned to the care of their private physicians. The "discredited"

results that were reported by the National Paraplegia Foundation were the failure of U.S. investigators to confirm the results of the animal experiments which were conducted in the Soviet Union and which were in part the basis for the clinical therapy being offered at the Polenov Institute.

Question: A bill has been introduced in this Congress which would obligate $16,000,000 for spinal cord research. Would such an increase in research in SCI be appropriate at this time?

Answer: If the proposed bill were to add to existing funds, such funds could not be wisely invested in research in a single fiscal year. A multi-year phasing in of such added funds would be more effective. If the proposed bill were to provide no additional funds but merely earmark $16 million of existing funds this could only be accomodated at the expense of other research in high-priority areas. At this time, additional funding for spinal cord research could be utilized effectively to train investigators in the difficult methods required for this area of research, to establish additional research groups and to develop more sophisticated research instrumentation. The regeneration research effort has moved so rapidly that the pool of skilled manpower available to this area has been nearly exhausted. There is an inevitable interval of time required for the training of additional investigators and the development of additional creative approaches.

Research into regeneration of the spinal cord shares many common areas with regeneration secondary to brain injury, and injury to other parts of the Central Nervous System. Most of the cell bodies of the neurons injured in the spinal cord are usually found in the brain, not the spinal cord. Thus, efficient utilization of funding should appropriately address the general problem of trauma to the Central Nervous System. The primary thrust at this time must continue to be basic research into a better understanding of the mechanisms and processes in primative nervous systems, complemented by subsequent translation of these observations into the more complex nervous systems of mammals and primates.

CONFERENCE

Question: A major conference was held in Las Vegas recently to discuss spinal cord research and regeneration.

We could not help but notice that there were people from all over the world on the agenda--but not one person from your Institute or NIH. Why?

Answer: No individuals from NINCDS or NIH were invited by its organizers to attend the Las Vegas meeting.

DMSO TREATMENT OF NERVOUS SYSTEM TRAUMA

Question: What indications do you have on the role of DMSO in treating Central Nervous System Trauma?

Answer: There are a few reports of the possible efficacy of dimethyl sulfoxide (DMSO) in the treatment of CNS Trauma; these are

reported primarily in the unrefereed literature. Although interesting, these reports do not constitute a useful and reliable body of scientific knowledge sufficient for making program decisions.

Question: Briefly, what type of "preliminary evaluation" is planned by the Institute?

Answer: In order to achieve a firmer scientific base, the NINCDS is exploring the development of a conference designed to analyze the current state of scientific information on DMSO and CNS trauma and to recommend future research directions.

AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Last year the Committee in its report recommended increased efforts in ALS or Lou Gehrig's disease research and treatment.

Question: What kind of progress are we making in this tragic disease?

Answer: To date, major research efforts have failed to uncover significant clues relating to the prevention, cause, or treatment of ALS. There is no firm evidence that factors such as microorganisms or altered immune responses are operative. However, toxic agents and metabolic abnormalities are also under study. Exploration of the fundamental processes involved must be continued before a "breakthrough" of clinical significance can be expected.

Question: How much do you plan to spend in Fiscal 1981 compared to 1980?

Answer: The estimated funding level for ALS research in 1980 is $2,980,000 and for 1981, $3,065,000. A program announcement will be issued to stimulate the submission of additional research project applications. In addition, the NINCDS has added a Medical Officer to its program staff to serve as the Institute's focus for sclerosing disorders.

MULTIPLE SCLEROSIS

Question: There are two major causative theories associated with multiple sclerosis: one focuses on the viral explanation, while the other centers around an aberrant immune response occurring in the body. Are data from research supporting one theory over the other?

Answer: The body of research data on multiple sclerosis does not favor one theory over another. The studies thus far suggest that an exogenous factor, possibly a virus or a defective virus, may initiate the MS process in a genetically predisposed individual. Whether or not clinical disease develops subsequently may depend upon an aberrant immune response.

Question: Is there evidence of a cause-and-effect relationship?

Answer: There is suggestive evidence of an interactive relationship between the viral and immune factors.

Question: Does your funding favor grant proposals directed toward one theory versus another?

Answer: No, the NINCDS provides roughly equal support for research investigating each of these theories.

Question: Dr. Tower, what is your Institute doing in this area?

Answer: The NINCDS supports research grants, research contracts, and intramural research on multiple sclerosis and related areas such as slow virus research. This research amounted to $13,935,000 in 1979 and is estimated at $14,850,000 in 1980 and $15,420,000 in 1981. The Institute has recruited a medical officer to serve as a program focus for research on multiple sclerosis.

Question: Will there be increases or decreases in the funding for MS research in Fiscal 1981?

Answer: The 1981 estimate for research specifically on multiple sclerosis is $13,430,000 an increase of $470,000 over the 1980 estimate of $12,960,000.

EPILEPSY

Question: For the record, would you provide us with a description of the progress being made to implement the recommendations of the Epilepsy Commission now and what is planned in 1981?

Answer: The following activities are being undertaken to implement the recommendations of the Epilepsy Commission. Numbers in parentheses refer to the specific Epilepsy Commission recommendations.

I. Prevention

Within "Prevention" many of the recommendations require advocacy with Congress (17, 24, 54) or state governments (16, 20, 21, 22, 23, 26). The Commission recommended that the Congress appropriate all funds authorized by the "Lead Based Paint Poisoning Prevention Act" (17). All states except one have legislation requiring immunization (16). Federal legislation currently is in place which imposes sanctions and offers incentives for enforcing the 55 m.p.h. speed limit (21, 26). Active or passive systems of restraint have been a topic of discussion by Congress (22). Several of the recommendations are dependent upon Congressional creation of the National Information Center on Epilepsy (NICE) (4, 8, 36, 41, 52) and the Office of Special Neurologic Impairments (OSNI) (6, 10, 13, 48). Efforts are being made to address these recommendations within the availability of current funding and staffing. The Public Health Service is developing an approach to assuring early and continuing health care supervision of high risk pregnant women and infants (12). The National Institute of Child Health and Human Development (NICHD) has completed dissemination of the summary from the Conference on Intervention Strategies for High Risk Infants and Young Children. Neurological Disorders Program (NDP) of NINCDS has an ongoing study on the prevention of epilepsy by better management of

head injury and these results will be published when completed (32). The Epilepsy Advisory Committee of NINCDS is routinely informed of all new studies in epilepsy (35). Standards for utilization of CAT standards were issued as part of the first set of National Guidelines for Health Planning in March of 1978 (49).

II. Research

The NINCDS Epilepsy Program Advisory Committee continues to monitor NINCDS extramural epilepsy programs (1). Ongoing surveillance of epilepsy incidence in the U.S. is actively being pursued by the NINCDS in cooperation with the National Center for Health Statistics and Bureau of the Census. Research grants and contracts have been awarded by NINCDS to support fundamental research on the pathophysiology of the epileptic discharge, neurochemistry of epilepsy, clinical studies, and prevention of seizures (4, 5, 6, 10, 12, 15, 16, 17, 21, 22, 27, 33, 34). Followup of the collaborative perinatal project is in process (11, 14, 19, 20).

NINCDS will fund a consensus conference on febrile convulsions in the Spring of 1980 (13), an international workshop on status epilepticus in the Fall of 1980 (7), and a workshop on genetics in epilepsy (3, 4).

Expansion of the Drug Development Program is underway (35, 36, 38). NINCDS has awarded 14 grants to stimulate development of new drugs. Early screening of new drugs has been gradually expanded by the contract mechanism. Clinical testing of new antiepileptic drugs continues. Of special interest is a controlled clinical trial of drugs in infantile spasms (68). The new antiepileptic drug, sodium valproate, (39) has been well received by the medical community and information on this drug has been widely disseminated to physicians by NINCDS (43).

Comprehensive Epilepsy Program funding continues (68) and establishment of an urban Comprehensive Epilepsy Program is expected in the Spring of 1980.

Epilepsy Abstracts and a method for computer based retrieval from this system continue (41, 43). NICHD will cooperate with NINCDS in responding to several Commission recommendations on problems of epilepsy and pregnancy (10, 12).

National Institute of Allergy and Infectious Diseases (NIAID) supports an ongoing research effort aimed at immunization against common causes of childhood meningitis (23).

National Institute of Dental Research (NIDR) continues to support research in phenytoin induced hyperplasia (44) and will shortly be publishing the report of a conference on antiepileptic drugs and gingival hyperplasia. NIDR continues to distribute their monograph entitled, "Dental Implications of Epilepsy."

Fogarty International Center will continue to support fellowships for foreign scientists in the United States. It will also seek to increase awards in neurosciences related to epilepsy and will support senior fellowships on epilepsy for U.S. investigators in foreign countries (59, 60, 61). Congressional action on this

year's budget will affect some of the Commission's budget recommendations (64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74).

III. Medical Services

The American Association of Clinical Chemists has adopted the quality control program for laboratories monitoring anticonvulsant blood levels (5), a recommendation which was originally targeted to the Center for Disease Control. The American EEG Society disseminates guidelines on the quality of EEG laboratory and interpretation of records (6). Discussions have begun on the development of medical standards for special groups of people with epilepsy (3).

IV. Social Adjustment and Mental Health

Despite the fact that the Commission found that possibly the least understood and most neglected aspects of epilepsy are the social, psychological, and behavioral problems that are so common, there has been relatively little activity in the area of implementation of these recommendations. Local voluntary groups have attempted to initiate implementation of some recommendations that have been faced with a lack of interest and funds (1, 5, 14).

V. Education and Employment

The Rehabilitation Services Administration (RSA) has been actively implementing recommendations. The RSA Commissioner designated persons with epilepsy as an underserved group in FY 1978 and established epilepsy as a priority in the special projects for Severely Disabled Individuals grant program. This was publicized in a Federal Register announcement and subsequently two projects were funded to expand and improve comprehensive rehabilitation services to persons severely handicapped by epilepsy (24). These projects will extend through FY 1980. RSA has worked closely with the Epilepsy Foundation of America to provide ongoing training and orientation of vocational, rehabilitation counsellors (25). The handicapped have been designated as a special target group under CETA (35). An amendment to the sex discrimination section of the Vocational Education Act includes the handicapped (23). The Epilepsy Foundation of America has been involved in public service announcements focusing on employment needs (52).

VI. Independence and Equality

The Center for Disease Control (CDC) requires FY 1980 State plans to assure participation of minority groups (5). A transmittal notice was sent to all regional offices instructing Developmental Disability Directors to take necessary action to assure minority representation on DD councils (6). NINCDS plans to fund an urban Comprehensive Epilepsy Program with special concern on the incidence of persons with developmental disabilities in minority groups (13). The Epilepsy Foundation of America has initiated action on a number of recommendations (1, 21, 27, 29, 32, 33, 43, 61). The Department of Transportation (DOT) has recently awarded a contract to develop a training package for bus drivers which will be disseminated to local transit authorities (44).

VII. Living Arrangements

The concept of "one system of care" in health planning is addressed in the draft, "National Health Planning Goals" (16). The Department of Housing and Urban Development (HUD) has assisted in the provision of service grants by Developmental Disabilities (DD) state agencies to local service providers (17). National Institute of Mental Health (NIMH) has developed technical assistance materials on deinstitutionalization (20) and developed two model programs in conjunction with DD. The Epilepsy Foundation is assisting its chapters in several areas (19, 44, 45). The Bureau of Prisons is working on medical treatment of prisoners with epilepsy (46) and discharge planning (48).

VIII. Public Information

The American Epilepsy Society's Committee on Education is actively improving and expanding its training efforts in the epilepsies (23). The nationwide voluntary health group concerned with epilepsy is expanding and improving its education program (1, 2, 3). Training opportunities for professionals continue within the NINCDS Comprehensive Epilepsy Programs (9). NINCDS will sponsor workshops on management of febrile convulsions in the Spring of 1980 and an international workshop on management of status epilepticus in the Fall of 1980 (20). An advanced nurse training program is funding an epilepsy nurse specialist training program through the Bureau of Health Manpower (30). RSA has awarded a short-term training grant of national scope to the Epilepsy Foundation of America for the conduct of special workshops on the rehabilitation of persons with epilepsy and for the preparation of training materials (43).

IX. Comprehensive Epilepsy System

The NINCDS is planning to initiate those portions of the National Information Center on Epilepsy which are appropriate expansions of their current activity (2).

Question: The FY 1980 appropriation for NINCDS contains support for the establishment of a sixth Comprehensive Epilepsy Center. Your statement on the FY 1981 Budget indicates that the center will be funded this year. When do you expect to announce the award?

Answer: We anticipate the award will be announced on June 1, 1980.

SUBCOMMITTEE RECESS

Senator HATFIELD. I want you to know that I am always inspired by these reports from your Department, your Institute, your agency. I think they are some of the most positive things that can be communicated from a central government today. There are times when I wish I could just reverse the budgetary amounts from Defense to NIH. [Laughter.]

I think we would gain more world prestige, influence and impact than from anything else by breaking through some of these great barriers that you are all working against.

Dr. FREDRICKSON. We are grateful for your comments, Mr. Chairman.

Senator HATFIELD. I appreciate each one of your programs and your efforts.

Thank you very much.

[Whereupon, at 11:55 a.m., Wednesday, February 6, the subcommittee was recessed, to reconvene at 2 p.m. this same day.]

61-400 O - 80 - 40

(AFTERNOON SESSION, 2 P.M., WEDNESDAY, FEBRUARY 6, 1980)

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. DONALD FREDRICKSON, DIRECTOR

SENIOR EXECUTIVE SERVICE

Senator SCHWEIKER [presiding]. The subcommittee will come to order.

As you will recall, Dr. Fredrickson, we interrupted our procedure yesterday about a rather disturbing letter that I put in the record. I understand that Mr. McFee is here today, and so we will proceed first to that and then go back to the regular funding.

Mr. McFee, we are most disturbed about HHS' response to the concerns we expressed about the long delays in hiring top-level scientists for NIH. In some cases, this process has consumed 2 years. Two years. Unbelievable. We have been prodding your Department on this matter since last May by letter to the Secretary and our committee report for fiscal year 1980.

In a January 4 letter to me, you said, in effect, that the problem is solved. You advised that NIH, through an interim delegation of authority from the Secretary, is "exempt from seeking prior approval from the Department before searching for candidates for highly specialized scientific positions." You also mentioned some staffing guidelines that had been discussed with NIH and then concluded as follows: "The delegation and the guidelines will reduce the time previously required to fill these positions."

That would be fine, but yesterday, during our first NIH hearing, we learned—and I heard from other authorities prior to that—that this apparently isn't so. Things apparently haven't changed; delays are still long.

How do you explain this discrepany?

Mr. MCFEE. Mr. Chairman, I am pleased to be able to be here to respond to your concerns.

Senator SCHWEIKER. I am surprised you're pleased to be here. But go ahead. [Laughter.]

Mr. MCFEE. The problems in recruitment and hiring of top-level people for the Department is not a new subject. In fact, the regulatory procedures that were in place prior to the Civil Service Reform Act did not uniquely impact on NIH. We've had similar problems that you described throughout the Department; in fact, even in my own office, it took me over 9 months to hire one of my top managers. And we have other examples under the old procedures where these problems were very prevalent within the Department.

It was for these reasons and others that the Department was a vigorous supporter of the SES concept which is part of the Civil Service Reform Act. And you will find that under these new procedures there

is considerable amount of delegation from the Office of Personnel Management, and the new rules have streamlined many of the cumbersome regulatory procedures.

And we have designed new procedures for operating under SES in the Department, and we have paid very particular attention to the unique problems of scientists at NIH. One of our very first actions which we took over a year ago was to have the Secretary approve the establishment of a subset of positions within the senior executive service, which we call the senior scientific service. These are scientists whose positions are principally established based upon their scientific knowledge and experience and not their managerial skills.

We were very sensitive that recruitment for these positions, evaluation for these positions, had to be tailored very specifically to the needs of NIH. We have approved a separate performance-evaluation system for these senior scientific positions which the scientists themselves helped to develop and which relies very heavily on peer review and evaluation of the research contribution made by the scientist peers.

I believe it was the establishment of this separate subset called the senior scientific service, and the development of a separate performance system, that was one of the reasons why 98.9 percent of the scientists at NIH chose to join the senior executive service.

Now, in designing new procedures for SES recruitment and promotion, we relied very heavily on the concept of delegating recruitment authority to NIH for these positions, as my letter informs you. The recruitment authority for the positions that was delegated covers approximately 65 percent of the NIH SES positions. NIH has 210 of the Department's 781 SES positions. They have, in fact, 26 percent of all of the SES positions for the Department.

In the next few weeks we will be issuing a universal search plan which will cover the remainder of those SES positions. The plan is developed; it's been sent out for comment by NIH and the other agencies. It lacks only the review and approval now of an executive resources management board, which we have established within the Department.

Once this plan goes out, as I mentioned, I believe, in the last paragraph of my letter to you, NIH will have recruitment authority for all of its positions, and this will produce a significant improvement in the overall process in time, compared to the old rules under the Civil Service—prior to the Civil Service Reform Act. I estimate that the delegation of recruitment authority will cut the overall hiring time from 3 to 4 months.

Now, in addition to that, the Secretary has also established executive resources boards in each of the major operating components. The Deputy Director of NIH is a member of the Public Health Service Executive Resources Board, and this Board is responsible for insuring that the selection procedures conform to the legal requirements of the Civil Service Reform Act in documenting the competition in filling these career jobs. Most of the scientific positions in the senior executive service are career reserved and must be filled by merit competition.

Now, prior to the delegation of the technical review qualifications, to the Executive Resources Board, this review was performed at least at three levels within the Department and finally had to be approved by the Civil Service Commission. I feel that this delegation will further reduce the processing time an additional 2 months.

HIRING TIME LAG

Although the Secretary has decided, for the time being, to retain final approval authority on SES appointments, we have greatly expedited the clearance time required at her level because of the reviews that have been delegated to various levels within the Department. In addition, the Office of Personnel Management, which still has to approve the final managerial qualifications of an individual prior to appointment to SES, has been expediting their review procedures, and we've actually had 1-day turnaround on some high-priority cases.

Senator SCHWEIKER. Where? One-day turnaround?

Mr. MCFEE. On clearance from the Office of Personnel Management.

Senator SCHWEIKER. You believe in the tooth fairy, too, I bet. Where is this?

Mr. MCFEE. What was the position?

Senator SCHWEIKER. What kind? Janitor?

Mr. MCFEE. It was an NIH scientific position.

Senator SCHWEIKER. What was it? What type?

Mr. MCFEE. Was it the audiology job, Dr. Fredrickson?

Dr. FREDRICKSON. It was a position in the Neurology Institute.

Senator SCHWEIKER. And when did this happen?

Mr. MCFEE. I happen to remember when it happened. It happened on the last day of September. We were concerned about the physician's bonus, and if we did not have the scientist on board by the end of the fiscal year we could not negotiate the physician's bonus contract. So, I happen to remember the day very well.

Now, in addition to this, I have written Director Campbell suggesting that, in the future, the OPM review of scientific positions be based upon a board that includes scientists to pass on these managerial positions.

In summary, its been only 6 months since we had SES operating, but I believe that we will find the personnel procedures have been reduced to a minimum and that we will continue to consult with NIH to assess any continuing problems and assist them in any way possible to attract and retain scientific managers.

Senator SCHWEIKER. Well, I am really impressed with that 1 day.

I would like to ask Dr. Tower what his time sequence was on that. It's hard for me to believe 1 day. What was the background of this particular position, Dr. Tower?

Dr. TOWER. Senator, this was a position for the Director of the communicative disorders program, which was vacated in April of 1978.

Senator SCHWEIKER. April of 1978?

Dr. TOWER. Yes, sir. We were in the process of search and recruitment since that date.

Senator SCHWEIKER. Since that date.

Dr. TOWER. Yes, sir. So, it's approximately 18 months altogether.

Senator SCHWEIKER. That's what I was afraid of.

That's exactly my point, Mr. McFee. Here is 1 day becoming 18 months.

I still didn't hear the answer to my question, which was why the discrepancy in this letter? You know, you say here in this letter: "As a result, she"—the Secretary—"has approved a delegation of recruitment authority to NIH on an interim basis until a final departmental plan for the senior executive service or another recruitment and appointment program is in place." I didn't hear you yet explain specifically why you said that when all the information we have contradicts that.

Mr. MCFEE. The delegations of authority for recruitment of scientific positions—not the managerial positions, but the strictly scientific positions—was given to NIH on October 15, as my letter said.

Senator SCHWEIKER. We had a lot of testimony yesterday, and I understand from a lot of sources that in terms of cancer, eye, aging, neurology, et cetera, it's just not happening. Now, you know, I am just not buying your story. I just have too many competent professional scientific people telling me, "It ain't so."

Now, where is the discrepancy here? Why is it we are still in the same kettle of fish and here 1 day became 18 months? How can we run a scientific managerial business here involving billions of dollars while delaying the hiring of top-level scientific personnel for 18 months? You can't hire anybody? I am sure you know from your 9-month experience what a frustration that was. You can't get high-caliber people to take that kind of punishment.

Now, where is the trouble here? Put it all on the table. I don't want it buried under some gobbledygook. Where's the trouble? You tell me one thing; everybody else tells me something else.

Mr. MCFEE. Let me clarify the 1-day statement. I was referring, when I mentioned the 1 day, to clearance at OPM level. It is the final step in the process before one is appointed to a senior executive service position.

Senator SCHWEIKER. But there was 18 months before it.

Mr. MCFEE. That is correct.

Senator SCHWEIKER. So, the complaint is the whole process, not what one particular step takes. The whole process. This case took 18 months. In some cases, it's taken 2 years, and an average, I am afraid, is 1 year.

Dr. FREDRICKSON. Mr. Chairman, let me interject a comment. I do not believe the 18 months referred to by Dr. Tower represents solely a delay in processing, as it includes the time spent by the Institute staff searching for eligible candidates. That time should be taken into account and the record should be clarified.

Senator SCHWEIKER. Dr. Tower, when was the person you actually had in mind for the job actually submitted?

Dr. TOWER. Senator, there is required by the Department—as far as I know, still required—approval for a search. When that has been approved, then a search committee is established, carries out the search, and then the candidates that are identified are subject to selection by

the selecting official—in this case, me. And that selection then has to be approved, as Mr. McFee has just recounted.

In this particular case, the approval of the search required approximately 1 year.

Senator SCHWEIKER. So, the point is, it wasn't a matter of you saying you had one guy in mind. You had to go back and get permission to even search for the one guy in mind in the first instance; is that what you're telling me?

Dr. TOWER. Yes, sir.

Senator SCHWEIKER. It took you 1 year to do that?

Dr. TOWER. Yes, sir.

Mr. MCFEE. Mr. Chairman, what he has described is the old procedures that, of course, this particular search was started under.

Senator SCHWEIKER. When did the new procedures go into effect? Nobody seems to know about them here. It must be a mystery.

Mr. MCFEE. All I can tell you, sir, is that authority was delegated to NIH on October 15.

Senator SCHWEIKER. On October 15 the authority was delegated.

Mr. MCFEE. In fact, there was an attachment to the letter I sent you, which was an actual copy of the delegation that I sent to Dr. Fredrickson.

Dr. FREDRICKSON. Mr. Chairman, may I interject one more comment?

Senator SCHWEIKER. I hope so.

Dr. FREDRICKSON. I think Mr. McFee and I can clarify this situation.

Senator SCHWEIKER. We sure need a lot of clarification on this whole procedure.

Dr. FREDRICKSON. I think the letter to which he refers in October did certainly delegate to NIH the authority to recruit without prior approval of the plan. However, this authority applied to recruitment of senior scientific personnel in the intramural program only and did not include managerial individuals who might also be scientists in the senior executive service.

Mr. MCFEE. That is correct.

Dr. FREDRICKSON. Doesn't some of the discrepancy hinge on that?

Mr. MCFEE. Correct.

Senator SCHWEIKER. Well, now, in the letter you advise me about the hiring of top-level scientists at the National Institutes of Health.

Mr. MCFEE. That covers 66 percent of all of the SES positions that NIH has.

Senator SCHWEIKER. Who doesn't it cover?

Mr. MCFEE. The remainder of them are bureau directors and people in managerial and supervisory positions. The delegation for recruitment authority on them will come in about 2 more weeks. Once that is out, NIH will have total recruitment authority for all of their senior-level positions. They will not have to come to us for prior approval, nor will they have to come to OPM as they did under the old rules.

Senator SCHWEIKER. You make it sound good, but the troops sure said it wasn't working that way. Where's the discrepancy?

Mr. McFee. I think the troops are remembering the old procedures, and because of the long delay in processing, some of the actions which are now being worked on were started under the old procedures.

Senator Schweiker. Why are we being slower on hiring for the top managerial posts? Is it because in many cases it is more difficult to get scientists for those posts than for some of the other scientific positions?

Mr. McFee. It has to do with the fact that the intramural or the scientific positions are what we call targeted search plans, in other words, we know in advance, because of the nature of the position, the scientific skills that we are looking for. And we know where these people are in the scientific community, and searching for those jobs is easier than the for positions of managerial skills, which need to have a number of disciplines or a number of scientific backgrounds.

Senator Schweiker. The first phase of this plan went into effect—you said what date, again?

Mr. McFee. Actually, I think Dr. Fredrickson got notice that the Secretary had made her decision a few weeks before. But I officially notified him on October 15.

Senator Schweiker. He had the power at that point, you're saying, to short circuit this whole procedure?

Mr. McFee. That is correct. For the intramural scientists.

Senator Schweiker. For the what?

Dr. Fredrickson. For the intramural scientific staff members.

Senator Schweiker. All right. Have we had any test cases on that yet, so far?

Dr. Fredrickson. Very few, Senator Schweiker, because we have hired very few bench scientists in the senior scientific service.

We have been recruiting and hiring more personnel in the senior executive service because they have been managerial scientists.

Senator Schweiker. You haven't been cleared on that yet; is that right?

Dr. Fredrickson. That is the group, the senior executive service group, to which Mr. McFee has referred as shortly to be freed from the same requirements.

Senator Schweiker. And when is shortly, again?

Mr. McFee. It will probably be within the next 2 or 3 weeks.

Senator Schweiker. Why didn't you tell me that in the letter, Mr. McFee?

Mr. McFee. I think I did, sir.

Senator Schweiker. Would you read me where you say you're telling me that in the letter?

Mr. McFee. The last paragraph.

Senator Schweiker. Yes; but you say, up in the first paragraph that Secretary Harris has asked you to respond to me about the hiring of top-level scientists. Well, top-level scientist means top-level scientist. And then you say, a review was recently concluded by the Secretary and as a result she has approved it.

So the implication there is it's all settled. Now you're saying the bottom paragraph is different?

Mr. McFee. The third paragraph speaks to specialized scientific positions. That is the term we used in the letter to you to mean the intramural positions. That is what was covered under the delegation of October 15. The last paragraph talks about a universal search plan for all of the other positions.

Senator Schweiker. And the other 37 percent, you say, will be freed up——

Mr. McFee. Be covered under the universal search——

Senator Schweiker. Will be freed up when?

Mr. McFee. I believe in 2 or 3 weeks.

Senator Schweiker. Now, when that's completed, how long should it take to clear someone through the procedural and administrative process—from the beginning to end? From the time we say, "Hey, I want this position filled," until you OK it all the way down the line?

Mr. McFee. Let me try to address that from our best guess because we really don't know. These are new procedures, but my best guess—if you exclude the time that it takes to find the individual, in other words, looking for the person, the paperwork, and the approval process will probably be reduced to 2 to 3 months.

Senator Schweiker. Wait a minute. Yes; but if we're talking 18 months or 2 years to begin with, that doesn't give me much help, unless I misunderstand your answer. These folks have been saying, "We have been taking 1 to 2 years to clear scientific jobs."

Now, if you're telling me we're going to beat it by 2 or 3 months, that's not much help.

Mr. McFee. I said it's only going to take 2 or 3 months.

Senator Schweiker. Total of 2 or 3 months.

Mr. McFee. One thing that isn't included in that 2 or 3 months is the time needed to find the individual and this varies, depending upon the position. And this is something that I have no control over at the Department level. That's the NIH experience. Maybe Dr. Fredrickson could comment on how long it takes to locate the individual once a search plan has been approved

SOLVING THE HIRING DELAY

Senator Schweiker. Dr. Fredrickson, you heard this testimony here. I'm still confused from yesterday and from other conversations I've had. Does this solve the problem, or doesn't it—assuming that last 2- or 3-month segment that he's talking about will come through in the way that he's explained it. Will that solve the problem that I have been critical of, and Chairman Magnuson has been critical of, do you think?

Dr. Fredrickson. I think, Mr. Chairman, it is going to help a great deal. We have enough difficulty already in locating individuals. The new procedures require advertising for certain positions. We have to find the candidates, interview them, and convince them to accept the positions. The time required for that process is very difficult to short circuit by any change in regulations.

But once we have the assurance that we do not have to wait for Department approval of recruitment for any of these senior executive service people, I think it will be of significant help.

Senator SCHWEIKER. Yesterday I thought you told me that, in essence, you didn't have this authority and it hadn't worked the way that I read the letter to you.

Dr. FREDRICKSON. Yes; I did tell you yesterday, Mr. Chairman, that, in our experience, the new SES system which is the total system we're talking about, had not yet proved to save very much time. One reason for that is that both the NIH and the Department are inexperienced with it. The second reason is that we have had practically all our experience in that 37-percent group that we're just talking about, for which the universal search plan will not be approved for another 2 weeks.

We have recruited very few of the 67-percent group into the senior scientific service, and, therefore, have had very little experience with the new system in that particular group.

Senator SCHWEIKER. Well, what I'm going to do is, I am going to ask several of the Institute Directors to give me the latest time frames that they have been operating with. We won't tie up the whole meeting here, but I am going to ask staff here to make a little survey of the last few that have gone through this system since the last deadline, and see just what the time frame has been in terms of this change, to see if there's some honest misunderstanding here or whether all of it applies to the so-called bench scientists, as you say.

I'll take it on or off the record, with or without videotapes—[laughter]—and maybe that will clear us up.

I want to ask Mr. McFee, you say this is going to be ready here when? This latest——

Mr. MCFEE. It is already prepared. It is actually—NIH people have reviewed it. Everyone has reviewed it. It lacks only an approval within the Department of a board that the Secretary has set up to review the procedures for the senior executive service.

That is the only thing that delays it—I mean the only thing that keeps it from being approved, is the scheduling of that meeting. The Board is chaired by the Under Secretary and actually has the Surgeon General on as a member. I don't think there will be any problems with approving it.

Senator SCHWEIKER. Well, let me do this. Would you convey to the Under Secretary, who is a good friend of mine, that if he can't do it in 2 weeks, could he please call me and let me know what the problem is as to why we are delaying it? I think he would be cooperative in that respect. I think that will at least give us some warning if there's a problem further.

Would you do that for me?

Mr. MCFEE. I will, sir.

Senator SCHWEIKER. Let us know. We did hear one report that this whole recommendation affecting this has, in fact, been sitting on the Secretary's desk since September; is that correct? That's why I am a little skeptical about the 2 weeks.

Mr. MCFEE. That is not correct, sir.

Senator SCHWEIKER. How long has this recommendation been kicking around that hasn't been acted on?

Mr. MCFEE. I believe it went to her on September 13, my records show me, and she made the decision——

Senator SCHWEIKER. You and I have difficulty communicating. That's exactly what I said.

Mr. MCFEE. She made the decision some time prior to October 15.

Senator SCHWEIKER. Of course she made a decision on the first part of it, of the bench scientist part, on October 15; is that correct?

Mr. MCFEE. That's correct.

Senator SCHWEIKER. The other part was also there from September but had not been acted upon; is that correct?

Mr. MCFEE. The package she acted on included the whole plan for recruitment and for selection of senior executive service.

Senator SCHWEIKER. Do I get the feeling from the Secretary that you're strongly dedicated to getting this problem solved?

Mr. MCFEE. Very much so.

Senator SCHWEIKER. Well, since you said you had a 9-month delay on your own, I suspect you have a lot of empathy for the problem. So I am sure you can assess it. But there does seem to be some misunderstanding here. There does seem to be some misinterpretation of facts on both sides, and we're going to try to get to the bottom of that.

But we will take your assurance that within 2 weeks, approximately, there is going to be a final go-ahead on it, and with the understanding that if there isn't, you would ask the Deputy Secretary or Under Secretary to give me a call, and let's see where we stand.

Mr. MCFEE. I will, sir.

Senator SCHWEIKER. And then, maybe about 30 or 45 days after that, Dr. Fredrickson, I wonder if you would give me a report on just how it's working.

Dr. FREDRICKSON. All right, we will do that.

Senator SCHWEIKER. After you get a chance to shake the bugs out of it.

Dr. FREDRICKSON. Yes, sir.

Senator SCHWEIKER. All right. Thank you, Mr. McFee, for coming here. I appreciate it. I appreciate your followup on it, too.

This afternoon we will conclude the committee's hearings on the fiscal 1981 budget request. We just have four accounts left, so we might as well begin with the Office of Director and then move to the Institute.

Mr. Nicholas, your statement will be put in the record. Do you have any comments?

[CLERK'S NOTE.—The statement is inserted earlier in the record.]

OFFICE OF THE DIRECTOR

Mr. NICHOLAS. Yes, Mr. Chairman, I just want to briefly mention that the appropriation for the Office of the Director is broken into two segments: One is program management, which is the overall management of the National Institutes of Health, the Director, and his associates; we have another category, direct operations. Under direct operations, we have lumped the services that can be performed for the various Institutes more effectively centrally. This is solely in the area of personnel management and financial management.

SENIOR EXECUTIVE RECRUITMENT

Senator SCHWEIKER. You heard this whole dialog here with Mr. McFee. Which category does the question that I was asking Mr. McFee come under?

Mr. NICHOLAS. The policy formulation for personnel administration is in the first category, and the day-to-day operation, the paper processing, is in the second category.

Senator SCHWEIKER. Let me just say that this committee's guidance on funding these departments may well rest on how well you respond to the concerns of the committee about whether we short circuited this procedure or not, because it seems to me that's a pretty good test of how we manage our people.

You see the point I'm making?

Mr. NICHOLAS. We have been working very hard in this area of senior executive recruitment. The universal search plan, as Mr. McFee mentioned, was, in fact, drafted at the National Institutes of Health as a method in an effort to help the Department break down this logjam.

1981 APPROPRIATION REQUEST

Senator SCHWEIKER. I'm sorry, do you have any other comments?

Mr. NICHOLAS. Simply that the appropriation request is $22,549,000, which is an increase of $647,000. This increase, by the way, is all mandatory, and all this is in mandatory items.

Senator SCHWEIKER. Old and outdated equipment, we have asked about on other occasions, has become a nationwide problem with universities' and nonprofit institutions' research.

My question is: What about equipment for intramural programs?

Mr. NICHOLAS. I wonder if Dr. Fredrickson might respond to that.

Dr. FREDRICKSON. Yesterday, Senator Schweiker, I mentioned the fact that we are trying to be as efficient as possible in the use of our equipment through an NIH system where we loan equipment to scientists, retrieve it, service it, and make it available to other scientists as well as we can. We certainly have the same problems with obsolescence of equipment as do other institutions. It remains an important item for us, too, in the operation of the intramural program.

Senator SCHWEIKER. I'm going to interrupt a minute. Senator Bayh has a couple of statements he would like to make, and I have some constituents I'd like to say hello to.

Senator BAYH. I just wanted to make an observation and ask consent of our witnesses, as well as the committee, to ask our very distinguished, illustrious panel here to respond to some questions in writing that I have. I apologize for not being able to be here earlier and spend all afternoon here. I have just been on the floor and I have another committee responsibility that I'm personally charged with.

But I must confess that I was distressed last year when we looked at the budget requests for the National Institutes of Health, and compared those to the cost-of-living inflation rate we had last year, and the problems this posed, not for starting new programs, but just for keeping up the same pace we were already making.

As I think all of you and my committee colleagues know, I offered an amendment at that time to say we are not going to start any new ventures, but we are just going to keep up with our primary existing research efforts.

And I was defeated on that.

We were then, as a fallback position, able to get some additional funding for cancer. And I think almost everybody knows I have personal reasons for being particularly sensitive about cancer. I must say I cannot imagine anyone experiencing less torment if a loved one is taken prematurely by some of the other killers that are wiping out millions of American citizens because we haven't found any answers. Our citizens think that our health research programs are in good hands. But, instead, this budget request is like sending an all-American soldier into battle with an empty gun or a rusty bayonet, for it doesn't provide the necessary resources for our research efforts.

I was concerned about that last year, and as I look at an inflation rate that is even worse this year than it was last year, I must suggest to you, gentlemen and ladies, that I am concerned this year.

As impolitic as it might be, considering the very legitimate concerns about spending and the need for a closer look at our budget and cutting out waste, I think we have to find out a little more, at least I have to find out a little more, specifically what these budget figures mean, compared to the cost-of-living inflation rates we are experiencing. We must look more closely into what we are asking you to do at the budget request's funding levels with today's costs, compared to what you did last year and the year before.

I don't want that to be interpreted as criticism of those of you involved in this panel. For it is most heartening, that we have made very substantial results.

And because of our expenditure of resources on health research, we have a lot of folks alive today that would have been dead 1 year ago, 10 years ago.

For many who are going to die this year or next, our efforts may be too late, but I want us to understand that if we don't make an honest effort in these areas where we are moving, even more are going to die that we might otherwise save.

Mr. Chairman, you have been very kind to let me get that out of my system. I would like to ask unanimous consent to submit questions to all witnesses and to have them respond.

Senator SCHWEIKER. Without objection, so ordered.

We appreciate your coming, Senator Bayh.

Senator BAYH. I must say, Senator, I appreciate the support and concern of my good friend and colleague from Pennsylvania. Last year I felt sort of like the Lone Ranger, but I had the support of my good friend from Pennsylvania, and that is not a unique occurrence.

Senator SCHWEIKER. Thank you. It was a good fight.

I appreciate it.

[CLERK'S NOTE.—The submitted questions are part of the relevant Institute's transcript questions for the record.]

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF DR. DAVID B. SCOTT, DIRECTOR

BUDGET REQUEST

Senator SCHWEIKER. Now we are going to turn to the National Institute of Dental Research.

Dr. David B. Scott is our next witness. Dr. Scott is Director of the National Institute of Dental Research, requesting a budget of $70,451,000. This is an increase of $2,083,000 over fiscal year 1980.

We will enter your full statement in the record. Would you care to make any comments before we begin?

[The statement follows:]

Statement of Dr. David B. Scott

The National Institute of Dental Research encompasses a broad field of activities and studies ranging from causes of dental and other oral diseases to the development and application of more effective therapeutic and preventive measures. In addition, many of our studies have broad application for an understanding of other acute and chronic diseases of concern to our citizens.

Dental Caries

Noteworthy advances have been made by our National Caries Program, which is specially targeted to prevent and control tooth decay. Progress continues toward developing a vaccine to prevent this disease. In recent animal and human studies, ingestion of an oral vaccine of killed streptococcus mutans, the principal bacteria suspected of causing tooth decay, led to the production of antibodies detectable in blood and saliva. Since the presence of antibodies implies protection against a disease, the principle of oral immunization for tooth decay appears feasible, and investigations will be intensified.

Another promising preventive approach has been developed--implantation into the mouth of mutant bacteria that do not cause tooth decay. These bacteria compete against decay-causing bacteria in the formation of dental plaque, and render it less decay-producing. Working with a competing mutant of streptococcus mutans, investigators reported a significantly lower rate of tooth decay in rats.

Intramural research on bacterial characteristics is yielding new and important information on how plaque forms and oral disease develops. We know now that some oral bacteria have surface receptors that interact with the surfaces of other cells to begin the accumulation of bacterial plaque. Understanding this mechanism may help us learn how to prevent plaque.

We are also beginning clinical trials of a device for the slow release into the mouth of fluorides or other agents to prevent tooth decay. This device has worked very well in dogs and has been tested to assure safety in humans. If clinical trials go well, the device could be of tremendous help, especially in non-fluoridated areas or for people with severe decay problems.

In our efforts to understand how the American diet influences the high rate of tooth decay in our country, we have worked out a testing system to screen common food items for their decay-causing potential. First, the acid-producing tendency of a test food is assessed in human subjects, by measuring the acid production in plaque on their teeth after the food is eaten normally. If the food produces a high level of acid, it is fed to animals, which receive all the rest of their dietary requirements by stomach tube. Any decay that develops can be directly attributed to the test food. Aside from their value in research, the results of these studies will offer information useful to both consumers and to food manufacturers.

Our 3-year school-based fluoride mouthrinse demonstration programs have been completed and continue to show good results, low cost, and ready public acceptance. In areas without community water fluoridation, these weekly programs of rinsing have prevented about 35% of new cavity development. Over 10 million U.S. children are now participating in similar programs, an almost six-fold increase since the demonstrations began.

As preventive programs are widely used throughout the country, we need a reliable way to measure their effects, as well as to identify segments of the population who need special attention. Last fall, we began a national survey of about 50,000 school children in kindergarten through 12th grade to learn the current dental health status of children in this country by age and geographic region. We intend to repeat the survey at regular intervals.

As part of a continuing review of our programs, we have just completed a year-long evaluation of the National Caries Program. A panel of outside experts concluded that the program has established a foundation of knowledge upon which future research programs can be built. Some changes were suggested, and we are considering their implementation.

Periodontal Diseases

Periodontal (gum) disease is the major cause of tooth loss in adults. As more and more Americans become aware of the importance of retaining their natural teeth, they become more and more disturbed at the unpleasantness, expense and all too frequent outcome of gum disease--loss of teeth.

Our investigators have been gaining a better understanding of the causes of periodontal disease. New evidence has strengthened the case against three pathogenic organisms. One organism has been found in large numbers in inflamed and infected periodontal pockets beside tooth roots in both humans and animals. In the laboratory, this organism has been discovered to produce an enzyme that destroys the fibers that hold the tooth in its socket, an agent that interferes with normal blood clotting, and several noxious agents that cause tissue destruction.

Another organism has been implicated in the highly destructive gum disease that afflicts children and adolescents. Large numbers of these bacteria have been found in the mouths of afflicted young people, and many of these patients have developed a specific protective antibody against it.

A third bacterium has recently been associated with the gingivitis that is common in pregnant women, apparently associated with the increase in certain hormones during pregnancy.

We are continuing our studies of the cellular and biochemical mechanisms involved in inflammation and tissue destruction.

Soft Tissue Diseases and Nutrition

Herpes simplex virus type I is a common human virus that causes painful recurrent lesions of the lips and mouth (fever blisters) and occasionally blindness and death. Recently, scientists have developed a new vaccine that has been effective in animals. The vaccine protected not only against lip infection and encephalitis, but also against latent viral infections of the facial nerves.

In the same studies, the investigators induced malignancies of the lip in mice by introducing the herpes virus. This is the first positive evidence of a relationship between the herpes I virus and cancer.

Craniofacial Anomalies

Craniofacial anomalies include birth defects, especially cleft palate or lip, malocclusion, and other acquired defects. Some human defects are caused by viruses and other infectious agents, and NIDR supports research on the effect of maternal viral infections during pregnancy on the developing baby. Recent evidence suggests that the mother's hormone level is important. In a study of hamsters, damage to

61-400 O - 80 - 41

offspring occurred only when the mother's progesterone reached a certain level.

Phenytoin (Dilantin), the anticonvulsive drug used widely to control grand mal epileptic seizures causes several hundred birth defects yearly in the offspring of treated mothers. Investigations have shown that cellular growth is often inhibited in the fetal nose, lip, and fingers resulting in clefting and short fingers. Recently, the Institute funded a workshop at the University of North Carolina which brought together various medical and dental researchers and practitioners to review the prevention and management of the side effects of phenytoin, including birth defects, gingival overgrowth, and some blood disorders.

Restorative Materials

Progress continues on developing new materials for dental restoration and improving other dental materials. The plastic filling materials now commonly used for restorations in the front teeth have been strengthened by aluminum oxide fibers so that they may soon be usable in back teeth. In animals tests, porous titanium and a porous plastic are being used as artificial tooth roots. Both appear to show promise either as free-standing teeth or as abutments for bridges. Studies also continue on the development of new plastics for prostheses used to replace facial tissues destroyed by accidents or disease and coloring techniques to match the patient's natural skin tones.

Pain and Behavioral Studies

Dental pain is not only troublesome but it also accounts for many people's avoiding necessary dental treatment. Animals studies in our intramural laboratories are giving us a much better understanding of the nerve circuits in the brain and spinal cord, the transmission and suppression of pain, and the body's own opiate-like substances.

Clinical studies have focused on pain assessment and control. After the extraction of impacted wisdom teeth, there is often an increased production of the brain's pain-suppressing chemicals (endorphins) and a reduced pain experience. We need to determine factors that control the release of these pain-relieving chemicals.

In the behavioral area, we are studying factors that may influence a child's perception of dental treatment. Early experiences often determine later attitudes and behaviors. In studying anxious and disruptive children undergoing dental treatment, investigators have found that neutral comments from the dentist reduce disruptive behavior more than positive reinforcement of "good" behavior or negative comments after disruptive behavior.

Progress in Other Biomedical Areas

As investigators pursue studies of dental and oral disease, they often uncover information that contributes valuable insight into other diseases. Studies of secretory activity by the salivary glands and pancreas, for instance, have helped investigators concerned with the prevention of diabetes immeasurably during the past year.

For the first time, a common respiratory virus (a variant of coxsackie B 4) was isolated from a child who died of acute onset diabetes mellitus. Injected into mice, the virus produced diabetes. This work supports the hypothesis that some cases of juvenile-onset diabetes are triggered by viruses. Studies are now underway to determine how important viruses are in the etiology of this serious disease of children and young adults.

Knowledge gained by NIDR scientists doing research on collagen, the chief connective tissue protein in the body, is the basis for a new method that ultimately may help pathologists diagnose the spread of even a few cancer cells from the breast to adjacent lymph nodes.

Dissemination of Information

The Institute continues to expand its information and education activities. Information for professional audiences on new developments in dental research is conveyed through "NIDR Research News" and "NIDR Abstracts." Exhibits, publications, articles, proceedings, and other means of disseminating information are used regularly to inform professional audiences and students of the health professions.

A campaign to inform children, parents, and educators of the dental problems associated with snacking on heavily sugared foods was initiated. One public service television spot was produced and widely aired across the country. Two more TV spots for children are in production and 12 radio spots directed to teenagers will soon begin production. A new pamphlet for children entitled, "Supersnack," explains how sugar damages teeth and lists alternative snacks that do not promote decay.

Efforts to promote alternative use of fluorides have continued through the year. Four films on fluoride mouthrinses, tablets, and drops for babies were produced this year and are now being promoted widely.

Budget Request

In conclusion, the budget request for the National Institute of Dental Research is $70,451,000, an increase of $1,717,000 over 1980. I shall be pleased to answer any questions or supply any additional information.

ORAL DISEASES

Dr. SCOTT. Yes, sir, Mr. Chairman. The message has come through strongly in yesterday's and today's testimony, that there is an air of optimism about biomedical science of the 1980's, about the surprising utility of the aggregate data that have built up during the 1970's, and the sense of their application for the next years.

This is especially the case with our Institute, as I will develop in the next couple of minutes.

We have consistently and, indeed, accurately stated over the years that we have had to play catchup ball to accumulate the basic information that must precede all of our successes in preventing or ameliorating oral disease. While I would be the last to say that this quest for basic knowledge has been in any sense fully satisfied, I would say we have reached a point almost across the board where we can begin to apply what we have learned in the test tube and the experimental animal to the human.

To those in our field, this is exciting. I would give you just a few examples of our progress.

CARIES PREVENTION

In the area of prevention of dental caries, tooth decay, the Nation's most prevalent chronic disease, we continue work on the effects of fluoride mouth rinses, tablets, and slow-release devices for children and initiate studes on the caries producing potential of a wide range of

foods through a combined human/animal assay. We are also conducting a large scale national survey of dental caries in children through high school age, to provide baseline data for comparison in future prevention studies.

PERIODONTAL DISEASE

In the area of periodontal disease, we are reassured of the validity of our decision 2 years ago to stimulate clinical research through the creation of three clinical periodontal research centers. Our premise that the basic data on hand could justify incursions into clinical research has been validated. Last week the directors of these three centers described their progess to our advisory council. They talked of studies which, in the human, are finally defining the various bacteria found in chronic periodontitis, and in juvenile periodontitis. They have identified over 200 species of bacteria in a well-defined group of patients, and they have found that these chronic diseases have very complex time and space relationships. Within the same individual, it is possible to have adjacent teeth that show, normal conditions, raging infection, an auto-immune destructive response, and repair, often going on at different rates. And these activities can switch on and off and back and forth.

This is leading the centers to the conclusion that very sophisticated patient control and tracking methods will be needed, and also has brought up the notion of tissue banks and cell banks representing various phases of the diseases, and making repetitive experiments possible.

HERPES

In the area of virology, the study of herpes infections, fever blisters, has moved into the human, as has the investigation of various other excursions of the herpes virus into facial nerve infection and encephalitis.

DIABETES

Along with these investigations comes the study of viruses as related to diabetes. It was mentioned yesterday that an important advance has been made by the unequivocal finding that a virus can cause diabetes. Our scientists have taken a virus, isolated from a child who died from acute onset diabetes, and shown that it could produce the disease in mice, that were genetically susceptible. This was direct proof of cause, and we have now started under contract, to find out if other viruses can also cause the disease.

Senator SCHWEIKER. I think this is good, and we did comment on it yesterday.

How did the Dental Institute come to get into this particular kind of——

Dr. SCOTT. I sensed yesterday that you might ask that. Our proposed answer to you is coming up. [Laughter.]

Senator SCHWEIKER. I'm not critical. I believe in cross-fertilization and interdisciplinary work. So, go ahead. Just about any answer will suffice this morning. [Laughter.]

Dr. SCOTT. After this direct evidence of cause, we are now starting a contract to find out if other viruses can also cause the disease.

Hopefully, this will go on to clarify the significance of viruses in diabetes causation.

All of this is pertinent to the other viral diseases in which we as a Dental Institute have an interest. Concomitantly, our interest in the pancreas is also easy to understand in light of our parallel studies of salivary glands which are very similar. The various glands often serve as good models each for the other.

CRANIOFACIAL MALFORMATIONS

Animal studies in the craniofacial area are now becoming involved in human aspects of malformation, especially as related to teratogenic drugs.

We are also beginning studies on the occurrence and treatment of acquired defects in the human, accidental and surgical.

IMPLANTS

You are aware from prior testimony, that we have been interested in implants as restorations. As an update on this we are presently leading into a series of clinical trials on the fate of various types of implants in the human.

PAIN CONTROL

Along still other lines, we continue to expand our clinical work on pain control, and we are pushing ahead in behavioral studies in the human, especially regarding acceptance of preventive methods and motivation for dental care.

Putting all this work in the human together, I hope I can convey to you our satisfaction that at last our dream of a clinical so-called applied translation of our research has finally begun to materialize. But let me reiterate quickly that there is still much basic research to be done, and remind the committee that our Institute remains almost the only source for research support in our field.

As you said, Mr. Chairman, our request is for $70,451,000.

DIABETES

Senator SCHWEIKER. On that diabetes sector, do you expect any other progress with this ongoing work that might be helpful in the diabetes area?

Dr. SCOTT. I think there's a good deal of relevant research going on primarily in relation to the position taken by viral infection in juvenile diabetes, and also the biology of the system. That is, the actual basic science part of it, which is not very well understood.

We go on in the study of diabetes, incidentally, to other ramifications such as periodontal disease.

PERIODONTAL DISEASE

Senator SCHWEIKER. Two out of every three Americans suffer from periodontal disease, since 25 million or more have lost all of their teeth as a result of those diseases.

Tell us what research is currently being done in order to avoid future toothless generations?

Dr. SCOTT. I don't think we will have entire toothless generations.

Senator SCHWEIKER. Well, people will get to live longer and thus be older, and periodontal being what it is, you may have if you don't meet the problem.

Dr. SCOTT. Actually, almost all of our work, except the efforts in restorative materials, is dedicated to the prevention of oral disease. We see that as the only salvation, rather than reparative methods following the onset of disease.

Senator SCHWEIKER. What progress are we making in periodontal work?

Dr. SCOTT. Periodontal research is only one aspect of our work toward better oral health.

As I mentioned, with our periodontal clinical centers we are now getting zeroed in on the immune response which you heard about yesterday and which was stressed this morning. The protective and destructive aspects of the immune response in disease are now recognized. We are beginning to sort out the different causes of this destructive process with an eye toward prevention. It may be a little premature to mention vaccine as a possibiltiy for enhancing the protective process at this point when I've just said there are several organisms involved. Right now, we have zeroed in on about three that seem to be the main culprits, and are examining their antibodies.

At the same time, knowing it is going to be a few years before the prevention problem is solved, we are conducting studies on interceptive methods which are far superior to what has been used already. Our knowledge of what actually happens with antibiotics, for example, has turned around quite considerably in the last couple of years, mainly through these centers. They have been able to gather together a special patient pool which they can recall consistently. With such a group they can really follow treatment methods better than they could before.

Incidentally, there is some evidence through national surveys that the edentulous rate has dropped off almost 10 percent in the last 10 years. That says that something positive seems to be happening as a result of our efforts in prevention to improve treatment methods, stimulation of acceptance of care, and also to third-party payment for care. Everything that is offered to the public now in the line of prevention and consciousness on the part of the public; all of these things are probably contributing to the drop in the rate of edentulousness.

SUBSTITUTE SWEETENERS

Senator SCHWEIKER. Your Institute has been conducting research in the hope of finding acceptable and noncarcinogenic substitute sweeteners. While many have been proposed, none of these reported in the past have yet been found to be acceptable, stable substitutes.

Where do we stand on it?

Dr. SCOTT. We stand about where we did last year with a series of basic studies going on, under contract, primarily to identify and——

Senator SCHWEIKER. Anything promising at all?

Dr. SCOTT. There are a few agents now which will go into toxicity testing, that may have some promise. There are many other ramifications to this problem, including considerations in food processing. So it's a bit early, I think, to say more than there are a few promising——

Senator SCHWEIKER. How long will it take to pursue a couple of them?

Dr. SCOTT. I should think before it is all said and done it must take 5 to 7 years, like almost any other substance that will have to meet regulatory requirements.

Senator SCHWEIKER. That much longer, yet?

Dr. SCOTT. I would think so.

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

DENTAL HEALTH OF OUR NATION

Question: Americans today appear more health-conscious than ever before. The "Caries and Periodontal Histories" of Americans would seem to provide an ideal indicator of the validity of this consensus. Has there, in fact, been a general improvement in the dental health of Americans?

Answer: We do not have sufficiently accurate nationwide data on dental caries to comment on changes in oral health status. For this reason, the National Caries Program is currently conducting a nationwide survey of a probability sample of about 60,000 children to establish patterns of caries prevalence by age and geographic region. We plan to repeat this survey at regular intervals to detect changes in the Dental health status of the population.

Data on the percentage of Americans of different age groups free of periodontal disease suggest an improvement from 1962 to 1971-74. For example, 61% of children, aged 6-11, were without such disease in 1962 compared to 86% in 1971-74. Even at the older age groups, about 10% of 65-74 year olds in 1962 were periodontally healthy compared to approximately 36% in 1971-74.

Similarly, the percentage of 65-74 year old people who were edentulous in 1957-58 was about 55% compared to 45% in 1971.

DENTAL HEALTH OF CHILDREN

Question: Advertising plays a large role in all of our lives, but the propaganda which is projected affects particularly the young in our society. An increasing number of advertisements appear yearly, promoting foods that are lacking in nutritional value, while each year, very few ads advocating good dental hygiene are viewed. What are the caries statistics of this generation vs. those of former ones? Have you taken a stand on T.V. advertising directed at children?

Answer: We continue to believe that frequent consumption of sugars, as in snack foods, is a major contributing factor to the high level of dental caries in this country. A representative of the NIDR testified to this effect at recent public hearings on T.V. advertising conducted by the FTC. We are, of course, opposed to efforts to persuade children to continue or to increase their consumption of snack foods containing sugars. During the past year, we have produced 3 television spot-films which urge children to avoid frequent use of sugar-containing snack foods.

We can assume that in areas that have adopted water fluoridation, dental disease, especially dental caries, has decreased during the past decade. However, we do not have adequate data to permit conclusions about the country as a whole. Much better data will become available this year as a result of our nationwide prevalence survey which is now in progress.

SEALANTS

Question: Reportedly, a plastic sealant material which protects tooth surfaces against decay is widely available, but only a few persons seem to be aware of this service. If such a service would provide insurance against decay, why aren't more

Americans taking advantages of this new treatment? Is it because of poor cost-effectiveness, poor publicity on the part of dentistry, etc.?

Answer: The use of sealants by practicing dentists appears to be steadily increasing as more and more favorable research reports have appeared and as dissemination of information has improved

However, for widespread public health use, sealants have poorer cost-effectiveness than, for example, fluorides. This is both because of the time per child required for application, and because most state dental practice laws require that sealants be applied by dentists or licensed auxiliaries, thus substantially increasing delivery costs.

FLUORIDE ISSUES

Question: You indicated last year that numerous requests had been received from communities regarding a previous two-year pilot program--nationwide demonstrations of school-based fluoride mouthrinsings--and that you anticipated providing such services to many of the 25 million children in non-fluoridated areas Please tell us the status of these pilot programs. What does the most recent data indicate?

Answer: According to data collected by the three major distributors of fluoride mouthrinses, more than 12 million children in non-fluoridated communities in the U.S. are currently enrolled in school-based, self-applied fluoride programs

We are continuing our efforts to inform and provide technical assistance to other communities which can benefit from these preventive programs. Four new films describing these programs were released during the past year.

Question: The controversy over fluoridation of public water supplies continues. Federal officials continue to claim that fluoridation is having a marked effect in reducing tooth decay, particularly in young people. Some, on the other hand, continue to claim that fluoridation is associated with an increased incidence of cancer or other diseases. Who is right? Is there any credence to these carcinogenic claims? What does the most recent data indicate?

Answer: The claim by organized opponents that fluoridation is associated with an increased incidence of cancer mortality has been investigated by scientists who are competent and respected in epidemiology and statistical analysis Independent studies or detailed reviews of the issue have now been published by workers at the National Cancer Institute, the National Heart, Lung, and Blood Institute, the Safe Drinking Water Committee of the National Academy of Sciences, the Center for Disease Control, the Department of National Health and Welfare of Canada, and the Royal Statistical Society, London, England. All concluded that there were no trends in cancer mortality in the U S . Canada, or England that could be related to the consumption of fluoridated drinking water Also, there have been no published scientific studies substantiating the original claim since it was formally published in 1977.

The most recent review of the relevant data, prepared in the form of an affidavit by an Associate Director of the NCI and subsequently published late in 1979 as part of the record of a court proceeding in New York City, further supports the conclusion that there is no hazard of cancer in the use of fluoridated water supplies. Concerning data on the effectiveness of fluoridation in preventing tooth decay, the most recently published U.S. study (school children in New Haven, Conn. in 1977) affirms that children using fluoridated water from birth can expect to have less than half the tooth decay that is experienced by children not using fluoridated water or fuoride supplements from birth. Similar benefits from water fluoridation were reported from Birmingham, England, in August 1979.

Question: You reported two years ago, some early results from animal tests, regarding a device that can be attached to a tooth and release precise amounts of fluoride or other preventive agents for up to six months. Have you to date begun human trials, and if so, would you comment on your findings?

Answer: The first human trial of an intraoral device for controlled, slow release of fluoride has just been completed. In this study, a small capsule-shaped device was cemented to the upper molar teeth of eleven adults, and the release of fluoride into the oral fluids was monitored daily for one month We observed consistently high fluoride levels in the saliva of the test subjects. The levels of fluoride reached in the dental plaque of these subjects are still being analyzed

The findings thus confirm those we have previously reported from animal experiments on the adaptation of controlled-release technology for intraoral use. A longer clinical trial will be started this year.

NON-CARIOGENIC SUBSTITUTE SWEETNER

Question: Your Institute has been conducting research in the hope of finding an acceptable non-cariogenic substitute sweetener. While many have been proposed, none of those reported in the past have been found to be acceptable, stable, substitutes Do you have any new evidence to report related to this concern, and if so, how far along in the toxicity testing stage are we.

Answer: At the moment, there is considerable interest in the protein, Talin, as a sugar substitute. We have determined that Talin is non-cariogenic, and it has been reported that the manufacturer plans to undertake extensive toxicology studies beginning this year

Two other promising sweeteners, Aspartame and Xylitol, are in various stages of the approval process by the FDA.

CARIES VACCINE

Question: Please review the current standing of the "Caries Vaccine" research involving the theory that specific antibodies against certain oral streptococci could be detected in the saliva of humans who had swallowed a vaccine made from killed organisms

Answer: Two years ago, one of our grantees reported increased levels of antibody against streptococcus mutans (bacteria believed

to be a primary agent in the cause of caries) when human volunteers swallowed capsules containing killed S Mutans cells During the past year, we have repeated this experiment twice in the laboratories of the National Caries Program Adult volunteers swallowed a vaccine capsule once each day for 5 consecutive days Both serum and salivary antibodies against S Mutans were detected and persisted during two month of observation In addition, the ability of S. Mutans bacteria to implant on the teeth was dramatically reduced in vaccinated individuals These experiments confirm the principle of vaccinating humans against caries, a preventive approach that has already been successful in laboratory animals. They also suggest that vaccination by the gastric route may be feasible. However, considerably more research is necessary to establish that point, to determine the most effective antigen and frequency of vaccination, and to investigate all questions regarding safety. Despite these very encouraging results achieved during the past year, we expect that full scale field trials of an anti-caries vaccine are at least several years away.

DIABETES

Question: Your Institute has been a leader in work on the association between viruses and development of juvenile-type diabetes. Has there been any new progress in this area?

Answer: Yes. Over the last two years we demonstrated that variants produced in culture of several common viruses that are widely disseminated in the human population could produce diabetes in mice. In addition, very recently we isolated a virus from the pancreas of a child who died of acute-onset diabetes and showed that this virus could produce diabetes when inoculated into genetically susceptible mice. Good animal models for virus-induced diabetes have now been developed but the degree to which viruses are a cause of juvenile-onset type diabetes in the human still remains to be determined.

Question: Have NIAMDD and the Allergy Institute been coordinating efforts with you?

Answer: Yes. Efforts are being coordinated through the NIH Diabetes Coordinating Committee. Also, a recent tangible result is the completion of a research paper on the effect of viruses on insulin receptors co-authored by scientists from both NIDR and NIAMDD. In this in vitro study we showed that certain viral infections could reduce the number of insulin receptors on the surface of cells, thereby offering one possible explanation for the increased insulin demand of diabetic children suffering from colds and other infections. This paper will be published shortly.

ORAL CANCER AND HERPES SIMPLEX VIRUS

Question: In your research in the area of oral cancer and cold sores, how do your activities differ from those of the National Institute on Allergy and Infectious Disease?

Answer: NIDR is interested primarily in the oral manifestations of herpes simplex virus, while NIAID is concerned, among other things, with the genital manifestations The herpes virus type that causes cold sores is different from the type associated with genital manifestations. Different models and

approaches are used by the NIDR and NIAID in their respective studies. Information is exchanged, however, on a continuing basis between the two Institutes.

Question: Is there an established link between the Herpes Simplex virus Type 1, which causes cold sores, and cancer?

Answer: At the present time there is no established link between herpes simplex virus type 1, and oral cancer, but an extensive epidemiologic study has not been carried out. In contrast, numerous studies have been carried out trying to link herpes simplex virus, type 2, and genital (cervical) cancer. This relationship also remains unclear.

Question: Are Herpes Simplex Type 1 and Genital Herpes the same virus?

Answer: Herpes simplex virus type 1, and herpes simplex virus, Type 2, are related but show major differences in their nucleic acids. Herpes simplex virus, Type 1, is the prime cause of oral lesions (fever blisters), while herpes simplex virus, Type 2, is the prime cause of genital lesions

Question: Have we made any advances in the treatment of Herpes Simplex?

Answer: There have been recent advances in the treatment of herpes encephalitis with antiviral drugs. This resulted from a multi-center study carried out throughout the United States and supported largely by NIAID. Thus far, while preventive methods are being intensively sought, the treatment of oral herpes remains symptomatic, with various new drugs under study.

Question: Does interferon play a role in the treatment of Herpes Simplex?

Answer: The capacity of interferon to remedy herpes simplex virus infection is under study at several universities, but it is too early to evaluate its efficacy One of the major problems is the lack of sufficient quantities of interferon for both experimental studies in animal and clinical trials. The recent preliminary report of the production of interferon by bacteria using DNA recombinant technology offers new hope in this area.

PAIN CONTROL

Question: The fiscal 1981 budget request for pain control and behavioral studies is $3 8 million. How do you coordinate your research into pain control with other institutes, such as the National Institute of Neurological and Communicative Disorders and Stroke, or with the National Institute of Mental Health?

Answer: The Interagency Committee on New Therapies for Pain and Discomfort was established in 1978. One of its major functions has been to coordinate research into the mechanisms of pain and its relief that presently is being conducted in various agencies. The committee has representation from six NIH institutes and from other agencies such as NIMH, NIDA, and FDA

In addition, NIDR will take the lead in coordinating pain control research programs at the NIH by establishing a pain clinic in the new Ambulatory Care Research Facility. Research scientists from NIDR, the Clinical Center and the National Institute of Neurological and Communicative Disorders and Stroke will collaborate.

BONE DISEASE

Question: Approximately a year or so ago we were told that your institute was then in the process of establishing an intramural orthopedic research program. Would you please tell us what the current situation is regarding intramural research on bone disease?

Answer: The NIDR has a long and continuing interest in bones and teeth. Several projects in the Intramural Research Program at the NIDR deal with mineralized tissue. One group studies the formation of calcium phosphate under biological conditions and in the presence of various trace elements. Among their findings is the observation that fluoride favors the formation of larger, more crystalline deposits in bone in part by converting an immature non-crystalline phase to crystals. Fluoride is used therapeutically in patients with osteoporosis, a condition of brittle bones associated with advanced age.

Another group is studying the induction of bone formation using implants of demineralized bone. This approach provides a useful model system for studying the effect of hormones, vitamins and drugs on bone formation. While this system is as yet experimental, identification of the inductive substance may make it possible later to promote bone formation in humans.

Question: What has your Institute been doing to support and stimulate new research on osteogenesis imperfecta, the brittle bone disease?

Answer: A new animal model for osteogenesis imperfecta is under study. Mice with this recessive condition are born with many fractures. It is possible that this model can be used to test diets and drugs for their ability to strengthen fragile bones.

Other studies are exploring the existence and release of factors that cause excessive bone resorption. These factors include prostaglandins and products of immunological reactions. Having an understanding of the basic mechanisms underlying the process of bone resorption may make it possible to inhibit it and thus strengthen bones damaged by periodontal disease, osteoporosis and oseteogenesis imperfecta.

Question: Could you explain how the bone diseases programs of your Institute relate to bone disease research supported through other Institutes of the NIH - such as the Aging, and General Medical Sciences - and could you comment, please, on the ways in which the various Institutes have coordinated their efforts regarding bone disease research?

Answer: NIDR is represented on the Intra-Agency Arthritis coordinating Committee on bone, arthritis, etc. NIDR also joined the NIAMDD and Clinical Center staff in organizing a one day

meeting on osteogenesis imperfecta and another meeting on osteoporosis. Excellent collaborations exist between NIDR and the other NIH institutes studying bone.

CRANIOFACIAL ANOMALIES

Question: In your research activities into Craniofacial Anomalies, you carry out scientific investigation in congenital disorders (for example, cleft lip/palate, malocclusion of the teeth and jaws) and of disfigurements acquired through accidents or surgical procedures. What are the major accomplishments you have achieved in the past five years?

Answer: With respect to cleft lip and palate, significant advances have been made in surgical procedures for habilitation of affected children. Through controlled clinical investigation, techniques have been developed which assure more normal growth patterns, improved speech and facial appearance.

Research directed at etiology and pathogenesis of cleft lip and palate have resulted in animal models contributing to understanding of the interaction between certain drugs and the individual genetic constitution. Among these drugs are dilantin, used in the treatment of epilepsy, and the steroid drugs, which have many uses. The effect of such drugs in causing cleft palate in offspring of treated pregnant mothers is being studied in the animal model systems, and related to the developmental sequences in the human.

In the area of malocclusion of the teeth and jaws, major advances have been made in understanding the fundamental mechanisms involved in bone remodeling and tooth movement in response to forces applied in orthodontic treatment. Considerable insight has been gained in how these forces are translated into messages to the cells responsible for the removal and redeposition of bone as the tooth is moved through it. Such information holds promise for future control of growth as well as improving treatment. In the clinical area, surgical treatment of severe tooth and jaw discrepancies is now almost routinely available, whereas a few years ago treatment was not common and results were often less than ideal.

Acquired craniofacial defects represent a relatively new area of emphasis at the NIDR. Accomplishments to date are primarily of an epidemiologic nature. These studies have begun to identify the magnitude of the problem and its public health consequences.

Question: What are the major areas of investigation still left unanswered?

Answer: Investigations still remain to be done on the etiology and pathogenesis of cleft lip and palate in humans, especially with respect to the role of the individual's genetic make-up in setting the scene for the production of defects by medication. The causes of malocclusion, the social and behavioral consequences of severe malocclusion, mechanisms of control of facial growth, and methods to utilize growth control in prevention and early treatment of dental-facial malrelations all need intensified study.

In the area of acquired defects some areas of investigation which remain include: basic mechanisms of tissue repair and wound healing, optimization of treatment methods, psychosocial consequences of severe traumatic or surgical disfigurement, and effects of trauma in children on subsequent growth and function.

NEW MATERIAL HOLDS PROMISE FOR RECONSTRUCTIVE SURGERY

Question: The recent discovery of a new material, silphenylene, reportedly holds great promise for the field of reconstructive dental surgery, where accident or disease has caused severe disfigurement. This material is said to feel and look like skin. Please tell us of the success of this material in clinical trials.

Answer: Although it was reported earlier that the new prosthetic material, silphenylene, appeared to hold great promise for the field of reconstructive dental surgery, subsequent studies did not bear out these favorable properties, including natural texture, colorability, tissue compatibility and adaptiveness to existing skin adhesive systems. Scientists had hoped to overcome its one drawback, a deficiency in tear strength, and then proceed to clinical trials. In attempts to improve the tear strength, the scientists made numerous chemical modifications in the silphenylene polymer, but these efforts were not successful. Therefore, clinical trials on silphenylene were not initiated.

The NIDR, however, has also supported investigations on other experimental materials for maxillofacial prostheses. One of these continues to show promise in both laboratory and clinical tests. This material, a chlorinated polyethylene polymer, is a low-cost substance with long term outdoor durability, and is suitable in strength, elasticity, wettability, colorability, stain resistance and in other respects for human use. Moreover, it has been shown to be nontoxic and nonmutagenic. During the past three years, investigators have conducted preliminary clinical trials on selected patients. After initial modifications in their preparatory procedures, they have fabricated new prostheses for 20 patients and some of these have been successful for up to two years. The investigators are currently planning an expanded clinical trial in collaboration with five other centers.

DISTRIBUTION OF FUNDS

Question: In your professional scientific judgement are you pleased with your funding breakdowns?

Answer: We are satisfied with the relative distribution of funds among our six categorical program areas. However, all areas suffer from the reduced resources available for training. Particularly critical is the need for investigators trained to conduct clinical research, oral epidemiology and behavioral/social research on oral health problems. Current funding for Intramural Research will sustain existing programs but it will be necessary to accomodate to the increasing costs of conducting biomedical research.

PROMISING AREAS OF RESEARCH

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: Given the high priority that NIDR ascribes to the prevention of dental caries, additional research funds could enhance our ability to explore the promise inherent in dietary and nutritional studies. Specifically, studies of the relationship of one food to another, mixtures of foods and sequence of eating different foods to determine differences in cariogenic potential of these foods constitute examples of research along these lines We feel it is important also to enhance the ability to transfer known preventive technologies for caries and other oral diseases to various user populations Additional funds would permit studies of the factors related to the awareness of and promotion of preventive methods, including identification of political and social barriers which prevent acceptance of these measures

Research in all of our areas of interest is now being done in the human, and it is evident that progress would be accelerated if a number of program projects or center-type operations were supported in which human clinical studies of various types could be initiated. Such environments, comprising appropriate staff, backup laboratories facilities and patients are not now readily available, and we feel that creation of a number of them would be feasible

Although we are expanding rapidly into clinical research, there is still need for basic research information Added support could be used effectively in our five Dental Research Institutes, at universities, and in our Intramural Program, which have remained at a relatively static level for some years Augmented research on fundamental microbial, immunological and biochemical mechanisms would enhance research in such promising areas as diabetes, pain control and behavioral studies, developmental defects of the head and face, bone disease, and oral ulcerative conditions.

A major need in all areas of dental research is the training of clinical researchers. Slowed progress in moving science advances to the stage of clinical testing can be directly attributable to the scarcity of manpower trained to conduct such research. It would be highly advantageous to develop postdoctoral training programs designed to attract and retain individuals with clinical (D.D.S.) doctorates.

National Heart, Lung, and Blood Institute

STATEMENT OF DR. ROBERT I. LEVY, DIRECTOR

BUDGET REQUEST

Senator Schweiker. Let's turn to the Heart, Lung, and Blood Institute. Dr. Robert I. Levy will be our next witness.

Dr. Levy is Director of the National Heart, Lung, and Blood Institute.

They are requesting a budget of $548,399,000. This is an increase of $20,717,000 over fiscal 1980.

A copy of your full statement will be inserted in the record. Would you care to make any comments or highlights before we begin our questions?

[The statement follows:]

61-400 O - 80 - 42

Statement of Dr. Robert I. Levy

It is a welcome opportunity for me to appear before you once again. This year I have some very good news to report. As we have discussed in the past, the National Heart, Lung, and Blood Institute has several multi-year clinical trials underway. It gives me particular pleasure to announce the conclusion of one which has extremely important implications for millions of Americans, the Five-Year Hypertension Detection and Follow-up Program.

High Blood Pressure

It is almost impossible to over-emphasize the magnitude of the public health problem caused by high blood pressure. Thirty five million Americans have definite high blood pressure, while an additional twenty five milion have so-called borderline hypertension. Hypertension is the major factor contributing to over a half-million strokes and 175,000 stroke deaths each year. It is a significant factor in the 1,250,000 heart attacks and 650,000 heart attack deaths that will occur this year. In addition to lives lost and disabled, this disease costs the nation more than $8 billion every year in medical care costs, lost productivity, and lost wages.

In 1972, half the Americans with high blood pressure did not know they had this disease and physicians were not aggressively taking advantage of the knowledge we had at that time in treating their hypertensive patients. We had a major public and professional education challenge. In 1972 we also knew that there were still several unanswered questions regarding the treatment of hypertension. We did not have evidence of the benefit of treatment in the community setting, in women, minorities, and the young; most importantly, we did not know whether treatment was beneficial in individuals with so-called "mild" hypertension - those with a diastolic blood pressure between 90 and 104 mm Hg. So in 1972, we launched two major efforts--The National High Blood Pressure Education Program (NHBPEP), to inform the public and the health care professional about the facts and opportunities on hand so as to stimulate awareness and aggressive treatment of high blood pressure and the Hypertension Detection and Follow-up Program (HDFP), to gain additional facts and resolve unsettled issues regarding the treatment of the disease.

We have many times discussed the merits of the NHBPEP. Since its initiation, patient visits for detection and treatment of high blood pressure have steadily climbed. The public is now more aware and understanding of high blood pressure and its implications. Most significantly, however, as is the bottom line for any prevention program -- our progress in controlling high blood pressure is temporally associated with a dramatic decline in death rates from cardiovascular disease, particularly stroke. From 1972 through 1978, we have witnessed a 31.7 percent decrease in stroke deaths is this country.

The HDFP was initiated at the same time to find answers to questions that are as pertinent today as they were in 1972. Is a systematic vigorous approach to treatment effective in reducing mortality in a community setting? Can a substantial proportion of hypertensives be brought under and kept under medical management? Is antihypertensive therapy equally effective in the young and old, men and women, whites and blacks? Can morbidity and mortality from heart attack be decreased by anti-hypertensive therapy? And finally,

do the benefits of treatment exceed possible toxicities, especially in the case of patients with so-called "mild" hypertension? I am happy to announce the messages resulting from this trial are clear. People with high blood pressure who undergo systematic care will live considerably longer than those who receive no care or routine care. In fact, with systematic care, it may be possible to reduce premature death among hypertensives by an additional 17 percent and in mild hypertensives by 20 percent. Treatment was effective for all groups independent of age, sex, or race, and it was clear that the benefits of treament for the "mild" hypertensives far outweighed the possible toxic effects. Thus, this trial has given us the evidence that it is possible to save the lives of tens of thousands of Americans each year who are now probably dying at an earlier age than they should. The HDFP will have a final cost of almost 70 million dollars. If we apply the lessons learned from it, we will see a return well into the billions of dollars each year as the morbidity and mortality associated with hypertension decreases.

It is important to realize, however, that despite the success of this trial and the opportunities it presents for saving additional lives and reducing economic costs, diseases of the heart, lung, and blood remain the Nation's most serious health problem. Cardiovascular diseases, though sharply on the decline, still constitute the leading cause of death in the United States. Diseases of the blood are a major economic burden and diseases of the lung continue to rise. Chronic obstructive lung disease (COLD), which includes emphysema, asthma, and chronic bronchitis, was the eighth leading cause of death in 1968. In 1976, it ranked sixth.

Lung Diseases

The high prevalence of COLD and the morbidity associated with it have been a challenge to the Institute and the research community. It is now known that emphysema, a disease characterized by loss of lung elasticity and breakdown of alveolar walls, results from an imbalance between a protease (elastase) that breaks down the elastin network of the lung, and a protease inhibitor (alpha-1-antitrypsin) that blocks the action of elastase. Considerable progress has been made in elucidating the mechanisms by which proteases and anti-proteases act, but with each advance new complexities are revealed that are capturing the interest of researchers.

While the Institute is making great strides in investigating the underlying dysfunction associated with emphysema, we are also examining better treatment methodologies for the thousands already affected.

Therapy for both emphysema and chronic bronchitis can at present only relieve symptoms, and even widely used modalities are still of unproven efficacy. In previous reports to this committee the establishment of a clinical study to evaluate the long term efficacy of nocturnal (12-hour) oxygen administration was noted. This clinical trial has now entered its final stage. The 12-month study period has been completed and baseline data are undergoing analysis. Another clinical trial, discussed previously, a collaborative study of the efficacy of intermittent positive pressure breathing (IPPB) is still in the recruitment phase and will continue for another two years.

Blood Diseases

In the past few years, of all the cellular components of the blood, the red cell has been most thoroughly studied. Recently, emphasis has been given to the genetic regulation aspects of both sickle cell disease and thalassemia, including Cooley's anemia.

A recent investigation has shown that as a result of treatment with a drug called phenylhydrazine, a previously undescribed chicken alpha-globin gene has been "turned-on". This exciting finding may provide a model system in which to study the molecular events involved in globin gene switching and provide a future mode for treatment for some red cell disorders.

Another major advance in the blood area lies with the further development and effective early clinical testing of artificial blood substitutes. Fluorocarbons with oxygen carrying capacity that hold the promise of emergency availability for accident victims or surgical patients unable or unwilling to receive whole blood or red blood cells.

Unanswered Questions

As described above, in the past year the Institute has seen some major advances toward diagnosis, treatment, and prevention of heart, lung, and blood diseases. It is clear that yesterday's research is today's more effective medical treatment. But many questions remain.

Last year, I told you about a meeting to examine the cause of the precipitous decline in heart disease mortality observed over the past ten years. The meeting was to examine this decline and the question, was the decline real? What were its causes? The conclusions were that the decline is clearly real. The major cause is uncertain, but it is clear that both primary prevention and improved treatment played a role. It is difficult, however, to assign qualitative values since, although the death decline is real, we don't know what has happened to the number of heart attacks. Until we know both the trends in morbidity (number of heart attacks) and mortality (number of heart attack deaths) we won't be sure of the role of prevention versus treatment.

What was clear at the conference was that major advances have occurred in our understanding and treatment of coronary artery disease over the last 30 years. The advances made possible through basic and clinical research include: the diagnosis of the asymptomatic at-risk individual through the identification of cardiovascular risk factors; earlier diagnosis of asymptomatic coronary artery disease through non-invasive techniques; improved concepts of coronary care; the ability to control heart rhythm; and medical and surgical treatments not even dreamed of 30 years ago. But each of these advances has brought new problems, new questions.

Questions remain about the use of some current widely used therapies for coronary heart disease such as beta adrenergic blockers, diuretics, vasodilators, digitalis, anticoagulants, and surgery. It is clear that coronary artery bypass surgery relieves angina and appears to improve cardiovascular function, but what is its effect on longevity and in what cases? Until the role of bypass surgery is clarified, it remains unclear how many of the 70,000-80,000 procedures at a cost of over $1 billion per year should be done. Furthermore, the effectiveness and role of new procedures to dilate diseased coronary arteries

without surgery, like percutaneous transluminal coronary angioplasty, which I discussed with you last year, need definition.

Human Resources

The Institute must respond to the need for highly trained physicians to maintain the health of our research programs. Two years ago, NHLBI established the "Special Emphasis Research Career Award; Diabetes Mellitus; Cardiovascular; Metabolic and Endocrinologic Aspects" in order to encourage physicians to develop research interest in the cardiovascular aspects of diabetes. Last year, we initiated the Preventive Cardiology Academic Award to encourage development of quality preventive cardiology curriculum that will attract outstanding students to both preventive cardiology research and practice. This year, NHLBI established the Clinical Investigator Award, a program to encourage newly trained clinicians to develop clinical and basic research interests and skills in areas of cardiovascular, pulmonary, and blood disease research. These three new programs complement our ongoing career development program and institutional and individual fellowships, all designed to develop independent biomedical researchers so greatly needed if we are to continue the progress against heart, lung, and blood diseases started in the seventies.

Prevention, Education, and Technology Transfer

The National Heart, Lung, and Blood Institute is strongly committed to the goal of bringing the findings of heart, lung, and blood research to bear on the practice of medicine in the community setting.

Continuing education for physicians and other health care professionals to assist them in keeping abreast of rapidly developing techniques for the detection, management, and treatment of heart, lung, and blood diseases and for managing our blood resources is the focus of several studies.

Other studies have focused on improving patient education so as to improve a patient's own involvement in health care. One such study involves the development of an index that provides an individual with an assessment of his or her personal risk of developing chronic obstructive lung disease. The "Foods for Health" program initiated last year with Giant Foods to assess the effects of nutrition education on consumer food habits is now being evaluated to measure the feasibility and impact of communicating health information at the point of purchase.

Strategy

While the National Heart, Lung, and Blood Institute through its Program Plan addresses specific scientific goals and individual program areas, there is an overriding strategy that lends direction and momentum to the National Program as a whole. The program strategy employed for each of the disease-related mandates of the NHLBI consists of an ordered sequence: acquisition of new knowledge, testing and evaluation of promising hypotheses, and dissemination of new and existing knowledge. The Institute's strategy is aimed at maximizing the beneficial effects of research findings on clinical practice and on the health-related behavior of the American public.

In conclusion, Mr. Chairman, I have provided some recent accomplishments, discussed some of the issues, and outlined our strategy aimed toward the ultimate prevention of heart, lung, and blood diseases. We have chosen just a few examples of our progress and I would be happy to supply additional information for the record.

The proposed budget for the National Heart, Lung, and Blood Institute for fiscal year 1981 is $548,399,000, an increase of $20,593,000.

Dr. LEVY. Mr. Chairman, I am delighted to be here once again. I am pleased to submit my full opening statement for the record.

Let me highlight in my brief statement just 1 of the Institute's 20 program activities, but one of great importance to the Institute and the Nation, our hypertension program.

Previously we have talked about the magnitude of hypertension, the fact that more than 35 million Americans have blood pressures higher than 160/95; another 25 million have blood pressures between 140/90 and 160/95, so-called borderline high blood pressure.

Hypertension is the major factor involved in the 500,000 strokes and 175,000 stroke-related deaths that occur each year. High blood pressure is also a major factor in the 1.25 million heart attack deaths which occur each year.

High blood pressure costs the Nation over $8 billion each year in lost wages and productivity.

Twenty-five years ago, hypertension was only diagnosed when symptoms occurred, when the clinical complications of high blood pressure like heart attacks, stroke, renal or heart failure occurred. Physicians looked for esoteric secondary causes of hypertension like adrenal and kidney tumors, and renal vascular disease. There was only one effective therapy then—the rice diet. The available drugs were either ineffective or had serious side effects.

Through research over the past three decades, we have learned about the basic complexity of blood pressure control in man. We have learned about the involvement of the central nervous system—our conscious and unconscious brain, of the autonomic nervous system, of the heart, the kidneys, the vessels themselves and their intrinsic contractility, of bodymade hormones, kallikrein-kinin systems, bradykinin, prostaglandins, renin and angiotensin I and II, and of the importance of salt and water balance and nutrition.

By 1972 it was clear that control of hypertension was very complex. It was clear that in over 90 percent of hypertensives we didn't know the primary cause. We called the hypertension essential to hide in part our ignorance. Still, we had made advances. By understanding the involvement of the many different systems in blood pressure control we had developed a host of different drugs which worked by different mechanisms to safely lower blood pressure.

Some, like diuretics, helped the body get rid of excess salt and water. Others, like alphamethyldopa, act on the central nervous system. Others act on heart action or affect vessel reactivity. Still others, like most recently developed oligopeptides, competitively inhibit the conversion of angiotensin I to angiotensin II and thereby block the formation of angiotension II, the most potent body made vessel constrictor.

By 1972 we not only knew that several different drugs were safe and effective, but through controlled clinical trials we also had shown that treatment of moderate and severe high blood pressure—with diastolic levels above 105 millimeters of mercury—prevented stroke, renal failure, and heart failure.

In 1972, while continuing to seek the basic cause of hypertension, we already knew that we had effective medicine available. We also had information available which revealed that 50 percent of overt hypertensives were not even aware they had hypertension, and that physicians and patients alike were not taking advantage of the available opportunities and need to treat hypertension.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM

Therefore, in 1972, we started two programs: The first, the national high blood pressure education program, I have highlighted in the past and will not highlight now, except to say that the striking figures that you saw this morning about the downturn in stroke mortality rates is temporally related to the implementation of this program. Over three-quarters of the decline in stroke deaths that Dr. Tower talked about have occurred in the past 8 years. In that period we have seen an over 30-percent decline in stroke deaths, over 5 percent per year.

HYPERTENSION AND DETECTION FOLLOWUP PROGRAM TRIAL

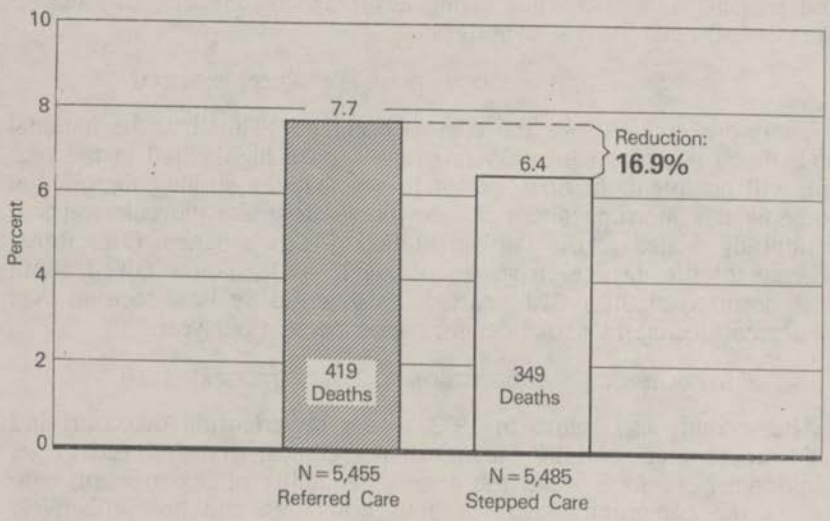
The second, also begun in 1972, is the hypertension detection and followup program—HDFP—a multicenter clinical trial designed to get additional facts, facts about the general reliability of hypertension control in the community setting; about how long and how effectively blood pressure control could be maintained in the community; about the effectiveness of blood pressure control in younger subjects, women, blacks, and of most importance since there are over 40 million Americans in this group, the value of treating so-called mild hypertension—individuals with levels of diastolic pressure between 90 and 105 millimeters of mercury.

When the trial ended this past summer these same questions were just as important as they were in 1972. The answers were of great importance to the Institute and the Nation.

[The charts follow:]

Hypertension Detection and Follow-up Program

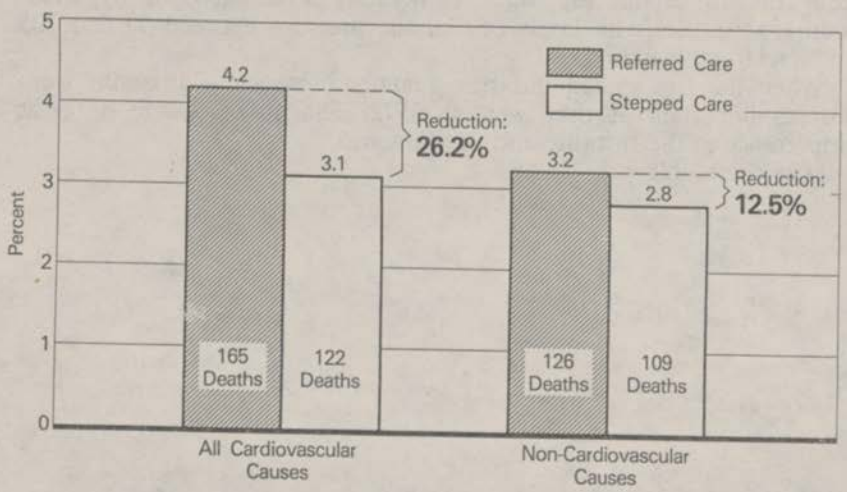
5-Year Mortality Rates from All Causes



Hypertension Detection and Follow-up Program

5-Year Mortality Rate by Cause

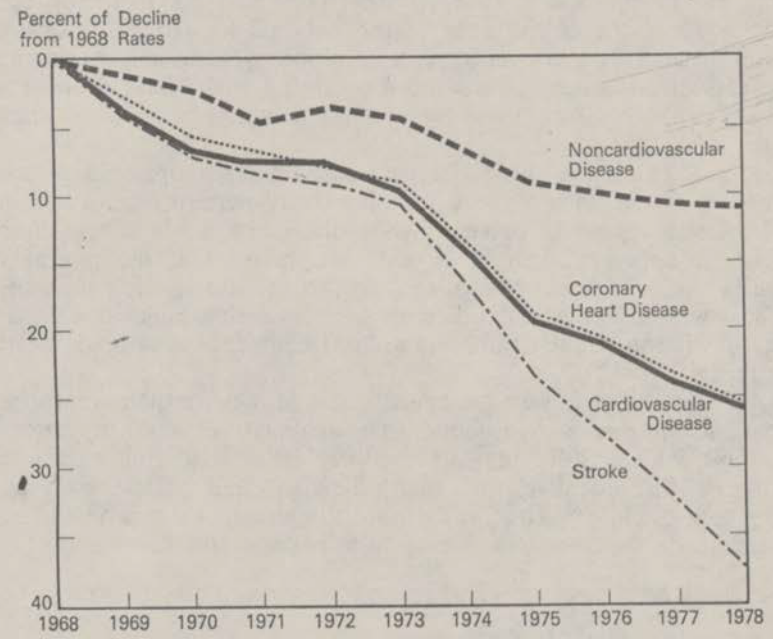
Participants with Mild Hypertension, DBP 90-104



JACKET NO. 58-E91 ILLUS. NO. 94

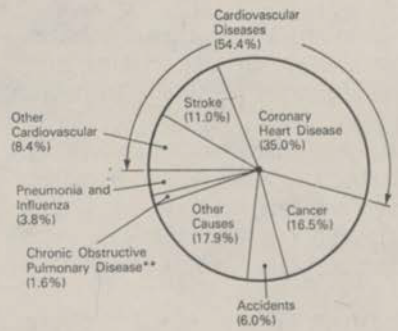
SIZE 26% x 38 PERCENTAGE 44.5%

Trends in Cardiovascular Disease and Noncardiovascular Disease: Decline by Age-Adjusted Death Rates, 1968-1978

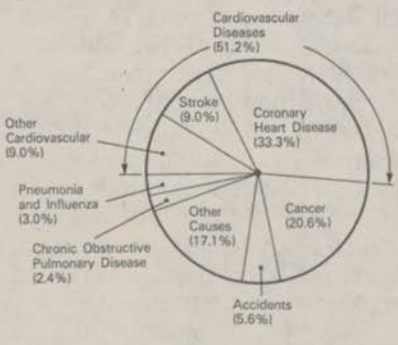


Deaths by Cause and Percentage of Total Deaths

1968



1978*



Cause	Number of Deaths 1968	1978
Cardiovascular Diseases		
Coronary Heart Disease	674,747	641,140
Stroke	211,390	172,520
Other	162,176	172,125
Cardiovascular Subtotal	1,048,313	985,785
Cancer	318,547	396,060
Accidents	114,864	107,930
Pneumonia and Influenza	73,492	58,290
Chronic Obstructive Pulmonary Disease	30,390	46,582
Other Causes	344,476	329,953
Non-Cardiovascular Subtotal	881,769	938,215
Total All Causes	1,930,082	1,924,000

*Based on Provisional Data
**Coded in 1968 as Bronchitis and Emphysema

Sources: National Center for Health Statistics and National Heart, Lung, and Blood Institute Estimates: Percentages Do Not Add to 100% Due to Rounding

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM

Dr. LEVY. I will place some figures in the record, but let me summarize and say that these studies show that people in a community setting can be put on, and will stay on effective treatment. In fact, probably because of the concurrence of the national high blood pressure eduction program, we saw an increase in blood pressure control during the 5 years of this study. This is the first clinical trial I have ever been associated with in which there were more patients dropping in than dropping out of treatment.

These studies further show that in a community setting, a vigorous systematic-care approach reduces mortality by 17 percent overall and in mild hypertensives by 20 percent. When one looks at life tables, these benefits are apparent even at 1 year. We found that the mortality decline in the mild hypertensive was most impressive in the cardiovascular area with a 26-percent decline in overall cardiovascular death, 45-percent decline in stroke death, and a 46-percent decline in acute heart attack death.

Finally, this study showed the effectiveness of hypertension control in women and in blacks. We found that treatment of mild hypertensives—those with diastolic pressures between 90 and 105 millimeters of mercury—is cost effective, and that physicians and patients can no longer watch blood pressures in the mild range without recommending some treatment, for treatment of even mild hypertension saves lives.

HYPERTENSION DETECTION AND FOLLOWUP PROGRAM CONCLUSIONS

Four closing points, Mr. Chairman.

First, the hypertension detection and followup program would not have been possible without the preceding years of basic and clinical research, drug development, and the willingness of this committee to provide the Institute with the resources and the flexibility to undertake and support this trial whose aggregate cost since 1971 is over $65 million.

Second, if the public and health professionals act on these messages, which we will disseminate, we should be able to save the Nation hundreds of thousands of additional lives and billions of dollars in health care costs and disability in the next few years.

Third, the results of this trial emphasize the importance of more aggressive basic research to learn the true cause or causes of hypertension, its etiology and pathophysiology. Today we can save, prolong, and improve the quality of the lives of up to 60 million Americans with pharmacological and nutritional treatment, but treatment that is required for a lifetime.

Tomorrow, by knowing the cause or causes of high blood pressure, we could prevent it from occurring at all, and thereby have an even better and more cost-effective solution.

Finally, point No. 4, Mr. Chairman, let me emphasize that because of the conclusion of the hypertension detection and followup program, this year I have related only the exciting advances in 1 of the Institute's 20 programs. There are important and exciting developments in each of the other program areas of heart, lung, and blood diseases.

Our budget for 1981 is $548,399,000,

I would be pleased to answer questions and provide additional information for the record.

TRAINING AWARDS

Senator SCHWEIKER. How many new individual or institutional training grant awards do you plan to make next year, Dr. Levy?

Dr. LEVY. In fiscal 1981 we will not be making any new individual or institutional fellowship awards.

RESEARCH GRANT AWARDS

Senator SCHWEIKER. Does this mean the number of future basic research grant awards in your research files is adequate?

Or, does it mean that that's all the money will permit us to do?

Dr. LEVY. I would have to say that means that is all the money will permit us to do.

I hope in years to come it will be different.

Senator SCHWEIKER. Because, as you point out, with the gains we made, we had to have money for the clinical trials to make them productive. And now we are saying we don't have money for clinical work to enable us to realize some of these things in the future that we found in the past with this kind of a budget.

Is that right?

Dr. LEVY. That's correct, Mr. Chairman.

FUNDING FOR COMPETING RESEARCH PROJECT GRANTS

Senator SCHWEIKER. Your budget shows that you will be funding approximately 20 percent of competing research project grants in fiscal 1981.

What percent did you fund in the last several years? How does that compare?

Dr. LEVY. It's less than in previous years. In fiscal 1979 we funded 942 competing research project grants. That represented 44 percent of the new and competing grants.

Senator SCHWEIKER. Forty-four percent?

Dr. LEVY. Yes, Mr. Chairman; 942 competing research project grants, 44 percent of those eligible for award.

Senator SCHWEIKER. For which year?

Dr. LEVY. 1979.

Senator SCHWEIKER. What will that be this year, 20 percent? For 1981?

Dr. LEVY. In 1981, it will be 601, or 20 percent of competing.

Senator SCHWEIKER. What's the 1980 figure beginning in 1979?

Dr. LEVY. In 1980 the figure was 596, or 25 percent of eligible competing research project grants.

Senator SCHWEIKER. We've dropped from 44 to 25 to 20 percent?

Dr. LEVY. That's correct, Senator.

ALTERNATIVE TREATMENTS OF HYPERTENSION

Senator SCHWEIKER. Since the fiscal 1981 increase that you propose for the Heart Institute does not include an increase in intramural research, there is some concern that this will deprive the Institute of flexibility in pursuing promising leads. One area involves finding alternative courses of treatment for victims of mild hypertension, who were the focus of the Institute's recent landmark report on hypertension.

I'm informed that unless alternatives can be developed, the prime or only course of treatment is to put victims on regular antihypertensive drugs for the rest of their lives.

What's your reaction to that?

Dr. LEVY. Yes. I highlighted that briefly at the end of my opening statement.

We now know that it is beneficial to treat hypertension; we have the evidence that 40 to 60 million Americans should be on treatment. I would not be very comfortable however, thinking that these 40 to 60 million Americans would be on drug treatment for a lifetime.

We have to seek alternatives to drug treatment, we have to look at behavioral and other approaches such as nutritional treatment. We must seek ways to prevent hypertension from occurring at all.

Senator SCHWEIKER. Does that mean that we should be eating less salt?

Dr. LEVY. That may mean that we have to eat less salt.

Senator SCHWEIKER. Should we be labeling sodium in all diets?

Dr. LEVY. We think it would be helpful for the consumer to know how much salt or sodium is in the food.

Senator SCHWEIKER. We are going to have a hearing on that in my health committee very shortly, this month, on that very issue.

What else should we be doing to change that, from the behavioral standpoint?

Dr. LEVY. We hope that we will find ways to combine behavioral and pharmacological treatment to lessen or obviate the need for pharmacological treatment. We would hope that techniques like biofeedback and other behavioral approaches might, in the long run, be able to reduce our requirements or needs for drugs.

PROGRAM BALANCE

Senator SCHWEIKER. Well, as I read your budget then, we are focusing purely on research to the exclusion of grants in training. Is this a good balanced program to do it that way?

Dr. LEVY. That's a difficult question to answer, Senator, in view of the fiscal restraints. This is one way to present the program.

Senator SCHWEIKER. Well, is this the way that you submitted it to the budget people?

Are these the recommendations that you made to the Director of NIH?

Dr. LEVY. No; they are not, Senator.

BUDGET STRATEGY

Senator SCHWEIKER. Well, what would your recommendations have been?

Dr. LEVY. Mr. Chairman, our research strategy has, for the last several years, certainly entailed focusing on the research project grant as a prime objective—acquisition of new knowledge, since there certainly is more knowledge that we don't have that we need in order to totally prevent disease.

But, our strategy has also included a focus on knowledge validation through clinical trials and other means and on knowledge translation and dissemination of research results to the community as well as the further development and training of research investigators.

This year we could only establish as a first priority the focus on research grants.

Senator SCHWEIKER. All right.

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

CHRONIC OBSTRUCTIVE LUNG DISEASE

Question: Almost one and a half million Americans are known to have chronic lung disease, and the cost is enormous in terms of human suffering, lost productivity, and medical expense. What is your Institute doing to prevent this malady, to arrest progression of the disease, to develop better therapy and to improve the quality of life of those who are affected with chronic lung disease?

Answer: Chronic bronchitis and emphysema, two major contributors to the progressively debilitating, generally irreversible condition known as chronic obstructive lung disease (COLD), continues to be a serious health problem in this country. The increase in reported incidence in the last decade is due in part to improvements in techniques for its detection, but there is also a real increase because of greater environmental and occupational exposure to agents implicated in the pathogenesis of chronic obstructive lung disease. A particularly difficult problem is that chronic obstructive lung disease develops so insidiously that many victims are unaware of their condition until symptoms appear, but by this time irreversible lung damage has occured. For this reason, great emphasis is being placed on early detection of structural, physiologic, and biochemical abnormalities which precede the development of more symptomatic, relatively irreversible disease.

Among all known risks, cigarette smoking continues to be a prime target of investigations to determine mechanisms by which it induces its adverse effects and how it interacts with other predisposing factors--host and environmental. The Institute supports numerous studies designed to establish how cigarette smoke produces its adverse pulmonary changes and interacts with other environmental factors by reducing clearance of inhaled dusts from the lung. Nearing completion is the initial phase of a program to develop an index of an individual's risk of developing chronic obstructive lung disease. The index will take into account such variables as age, sex, socioeconomic status, smoking and drinking habits, exposure to airborne pollutants, and genetic and familial factors. The index should enable practicing physicians to assess an individual's risk of chronic obstructive lung disease and to recommend appropriate interventions. It is also hoped that individual knowledge of risk might encourage the patient to adhere to suggested changes in behavior as therapeutic regimens that can prevent or arrest the disease processes.

Therapy for chronic lung disease can at present only relieve symptoms and even widely used modalities are still of unproved efficacy. The Institute has undertaken two clinical trials, one to evaluate the efficacy of 12 hour (nocturnal) compared with continuous, 24 hour, oxygen administration in a home care setting. Another is to establish the efficacy of intermittent positive pressure breathing (IPPB) as a therapy for the ambulatory chronic lung patient. Both trials are still underway. Results from these collaborative studies are expected to have an enormous impact on the home care and treatment practice for the chronic lung patient.

Important new contributions are being made to alleviate discomfort experienced by patients with chronic lung disease by teaching

them to condition their ventilatory muscles through exercise training. These procedures are possible because of the knowledge gained over the years on the role of the diaphragm, and respiratory and ventilatory muscles in the breathing process. Initial studies of exercise training in emphysema patients are indeed encouraging. In addition to relieving discomfort, there appears to be an increase in the mean expiratory flow rates in the subjects.

EMPHYSEMA

Question: What major advances have we seen in the past 5 years in both decreasing the incidence of emphysema and improving the quality of life for patients who have the disease?

Answer: It is generally believed that emphysema, a disease characterized by loss of lung elasticity and breakdown of alveolar walls, results from an imbalance between protease (elastase) that breaks down the elastin network of the lung and a protease inhibitor (alpha-1-antitrypsin) that blocks the action of elastase. Although there has been no decrease in the incidence of emphysema in the last five years--in fact the incidence has increased--the success in elucidating the role of protease-antiprotease interactions has been such that researchers are turning to the possibility of developing synthetic inhibitors to use for replacement therapy for individuals genetically deficient in alpha-1-antitrypsin. At the same time, basic investigators are moving into new areas of exploration that involve other antiprotease (such as alpha-2macroglobulin) and other agents (such as free radical oxidants) that may have a role in development of emphysema in persons who are not genetically deficient in alpha-1-antitrypsin. Furthermore, there is considerable hope that methods for early detection of the disease may soon be developed by measurement of elastin breakdown fragments in the urine.

The Institute is conducting clinical trials (one on oxygen therapy, the other on intermittent positive pressure breathing) designed to test the efficacy of two modes of treatment for patients with chronic bronchitis and emphysema. As part of the protocol of these trials, the investigators are collecting information on the quality of life in an attempt to establish the effect of the treatment regimens on the physical and emotional status of these patients and to quantitate the possible benefits of therapy.

CAUSES OF CHRONIC LUNG DISEASE

Question: Is chronic lung disease thought to be congenital in nature or is it the result of environmental hazards, or both?

Answer: Chronic obstructive lung disease appears to be a multifactorial disease suspected to result from an interaction between external factors such as smoking, infection, and inhaled irritants. However, one genetic form of emphysema is known to be inherited. When, as is the case in approximately one in 2,000 people, there is a homozygous (ZZ phenotype) genetic deficiency of alpha-1-antitrypsin, the lack of the protease inhibitor appears to predispose the persons to emphysema. In these individuals, the progressive development of emphysema occurs at an early age and the downhill course appears to be particularly rapid for those who smoke. However, it is currently

thought that this genetic deficiency accounts for less than 5% of the emphysema cases in this country.

LUNG DISEASE MORTALITY AND RESEARCH

Mortality from lung disease remains high, yet emphasis on research in this area remains relatively low.

Question: What is being done to increase research emphasis on this subject in accordance with our recommendations last year?

Answer: Mortality from lung disease does remain high--and appears to be on the increase. Deaths from chronic obstructive lung disease alone increased from 11.6 to 14.0 per 100,000 between 1968 and 1976, an increase of 20.7 percent. The most striking increase (62.5 percent) occurred in white females, for whom the death rate increased from 3.9 to 6.5 per 100,000. During this same time period, death rates for heart disease and stroke fell from 19.3 and 27.9 percent, respectively. In absolute numbers, deaths from chronic obstructive lung disease increased by 13,517, which was exceeded only by an absolute increase of 58,765 for all cancer deaths. The high incidence of lung disease in females is consistent with the increasing number of women who smoke cigarettes (Surgeon General's Report on Women and Smoking, 1980).

The Institute remains aware of the important problems that must be solved before the trend of increased mortality from lung disease can be reversed. It should, however, be noted that reduction in the mortality from chronic lung diseases that are at present irreversible by the time they become symptomatic (for example, emphysema and chronic bronchitis) will depend on early diagnosis as prevention. On the other hand, for acute lung disorders like adult respiratory distress syndrome (ARDS), reduced mortality can be anticipated as studies of various treatment modalities lead to improved survival. At the same time, research is focusing on the processes that account for the acute lung injury that results in ARDS. These studies should result ultimately in the prevention of ARDS and its attendant high mortality, as has already been achieved for neonatal respiratory distress syndrome. A variety of approaches are being undertaken, these include basic research efforts designed to elucidate the causes of lung damage at the cellular and molecular level; epidemiologic studies to assess relative contributions of various risk factors; clinical studies designed to develop new methods for diagnosis and treatment and to evaluate the efficacy of existing treatment modalities; and educational programs to help the practicing physician, and other health professionals as well as patients and their families, to understand and manage lung disorders.

By encouraging research efforts through this entire spectrum, the Institute is confident that knowledge can be gained that will lead to a reduction in mortality and an alleviation of the many years of suffering caused by these debilitating diseases. We can already report success in one major lung disease--neonatal respiratory distress syndrome. Infant mortality from respiratory disorders have been dramatically reduced by a combined approach of basic and clinical research findings that have led to improvements in obstetrical care, fetal monitoring, early recognition of respiratory

distress, and improved treatment of critically ill premature or low birthweight neonates. In fact, data on infants below one year of age indicate a remarkable decline of 42 percent between 1968 and 1976 in total deaths from neonatal respiratory diseases. Of course, the NHLBI has worked closely with many institutes, for example the NICHD, NIAID, and NIAMDD on problems related to pediatric pulmonary disorders. It is anticipated that close collaboration will continue with all NIH institutes in problem areas of mutual interest.

PUBLIC EDUCATION

An estimated 60 million Americans have definite or mild hypertension, a major risk factor for heart attack and stroke. Each day, some 3,400 Americans suffer heart attacks--more than two every minute. Strokes attack some 1,600 people each day. Four of the 10 leading causes of death in this country--heart disease, stroke, respiratory disorders and arteriosclerosis--fall within the responsibility of the National Heart, Lung, and Blood Institute.

We understand that education can play a major role in the prevention of these diseases. The National Institutes of Health asks for millions of dollars every year to communicate their health messages across the nation. One place we would like to see this message delivered is in the Nation's schools. Yet very few models have been developed in this area.

The Office of Education has direct access to the public schools through State Education Departments.

SCHOOL CURRICULUM AND HEALTH

Question: Wouldn't it be appropriate to include the School Health Office in the Office of Education for planning and implementing dollars earmarked for health education? Do you have any interagency agreement or cooperative arrangements with the Office of Education concerning school health?

Answer: Educating school children about positive health practices regarding cardiovascular diseases is very much a concern of the Institute. We regard effective school health curriculum as highly desirable as a means of preventing disease and enhancing the quality of life.

School curriculums must deal comprehensively with all health concerns. Within the Department of Health and Human Services, the Office of Health Information and Health Promotion in the Office of the Assistant Secretary for Health and the Bureau of Health Education in the Center for Disease Control have the lead in this crucial area and work quite closely with the Office of Comprehensive School Health in the new Department of Education. Within NHLBI, we have recently created a full-time position within our Health Education Branch to be concerned primarily with school health and to serve as a liaison to these offices. We feel we can bring up-to-date knowledge in the area of heart, lung and blood diseases to the many activities underway.

61-400 O - 80 - 43

Through research support, we are also encouraging the development of effective school curriculum, particularly as it effects children at high risk. For example, both NHLBI and the National Cancer Institute are supporting the American Health Foundation which has developed the "Know Your Body" program for schools. The project we are supporting will test the effectiveness of intervening in those cases where school children are at more than average risk because of nutritional problems, high blood pressure, smoking, or obesity.

This fall, together with the American College of Cardiology, we will be sponsoring a conference on the role of the physician in disease prevention. One of the principal topics will be the physician and adolescent practice and school health.

Reducing disease through intervention activities in the community, the workplace and the school setting has been receiving increasing attention at NHLBI. We will be working more and more closely with other health education agencies to help make school curriculums as effective as possbible as one means of preventing disease.

HYPERTENSION STUDY

The Committee has received a report from a group of distinguished citizens concerned with hypertension.

It was in general a good report, but some important questions were raised.

Question: First, would you summarize your findings on this hypertension study that was just completed?

Answer: The Hypertension Detection and Follow-up Program (HDFP) followed over 10,000 patients for 5 years. Patients were randomly divided into two treatment groups, Referred Care (RC) which received whatever treatment was considered appropriate by their usual source of care, and Stepped Care (SC) which received free care in special clinics that followed a specific drug use protocol aimed at a specific goal blood pressure lowering. The SC groups had a 17 percent lower mortality experience over the five year period than did the RC group. In those with mild hypertension (diastolic pressures between 90-105 mm Hg) mortality was reduced by 20 percent and there were 45 percent fewer stroke deaths and 46 percent fewer heart attack deaths. This happened in spite of steadily improving control success of the RC group, due in part to our national hypertension education efforts.

The findings are dramatic and positive. The care given the SC group not only lowers overall mortality, but also demonstrates that:

1. treating even mild hypertension has an impact on reducing death, and

2. black people benefited even more than whites at all blood pressure levels.

It is important to remember that this was not a placebo trial, not a comparison of no care versus good care. Thus, the fact that

some groups showed little benefit (white women for example) means that these groups were already well treated in the community and does not mean they should not be treated.

The results also do not mean that community care (referred care) was bad. Community practitioners clearly and steadily improved the care of their patients throughout the course of the study. Much of the success in the SC group derived from treating mild hypertension and from seeking goal blood pressures lower than the community practitioner should have been using during the trial because, until the trial was done, the benefits of such treatment could not be known.

Question: Is there any better understanding of the dramatic differences in rates of hypertension between blacks and whites?

Answer: Regarding the cause of higher hypertension prevalence among blacks compared to whites, no, we have no further insights. The cause of most hypertension remains unknown in all races. We continue to increase our understanding of the physiologic processes which regulate blood pressure but, as yet, we usually cannot tell clinically, in a given individual, which of these many processes has gone awry or what pathology caused the process to go awry.

The recently completed Hypertension Detection and Follow-up Program does provide an important finding regarding effect rather than cause. Contrary to past popular belief, hypertension among blacks responds readily to treatment and such treatment results in striking declines in mortality.

The Institute has recently initiated a clinical study to better assess the role of sodium (salt) as a potential cause of hypertension. Because a high sodium content is characteristic of many traditional black diets, the question is an important one for black Americans.

HYPERTENSION: CAUSE OF STROKE

Question: Is hypertension still the number one cause of stroke?

Answer: Hypertension remains the major risk factor for stroke. It is estimated that 75 to 80 percent of our nations stroke victims have borderline or overt hypertension. Although it is very reasonable to assume from available data that the nations' rapid progress in controlling hypertension has markedly contributed to the recent striking declines in stroke deaths, we really cannot be completely sure. Fewer stroke deaths could mean either fewer strokes (prevention), or better post-stroke care or both. Unfortunately, there are no national data allowing a confident estimate of the incidence or number of strokes occurring in the United States each year. We expect, as hypertension control continues to improve, that hypertension will decline as a cause of stroke. At present, without better incidence data, we cannot be positive that hypertension control deserves all the credit.

COOPERATION WITH HSA'S HYPERTENSION PROGRAM

Question: What, specifically, is your Institute doing to work with the Health Services Administration's hypertension program?

Answer: The NHLBI is doing many things:

1. we support, in seven states, demonstration programs to develop improved state-wide hypertension control program management systems;

2. we supply technical assistance to many of the grantees of the HSA at both the state and local level;

3. we provide educational materials to the grantees of the HSA;

4. we provide technical assistance to HSA staff to assist development of appropriate regulations and guidelines, and assist in reviewing proposals received by HSA under these regulations and guidelines;

5. we and HSA draw mutually on each other's staffs for planning and participation in such meetings as:

   a. State hypertension programs - December 13, 1979

   b. Interagency Working Group on the Training of Physicians in Patient Education (TOPPE) - meets quarterly,

   c. Rural Health Planning Advisory Committee - meets quarterly,

   d. National Conferences on High Blood Pressure Control-- held annually, this year in March,

   e. National High Blood Pressure Education Program Coordinating Committee -- meets quarterly;

6. we are jointly planning with HSA a major national conference to assist Native Americans in developing improved hypertension control programs;

7. we are exploring with HSA a jointly funded series of research/demonstration projects aimed at improving hypertension control in predominately black communities.

Question: How can this coordination be improved?

Answer: In all candor, given the large numbers of cross-attended meetings now taking place, the limited number of staff available and the limited hours of a workday, it probably cannot be dramatically improved. This does not mean we are unmindful of Congressional interest in this issue. Rather than seeking a quantitative increase, we will continue to seek a qualitative improvement, meaning better identification of major issues of mutual interest and more timely interaction on those issues. Such a goal rests not with

administrative structure, but almost wholly with staff creativity. Both the director for the NHLBI and administrator of the H.S.A. will seek every means to encourage these immeasurable but important relationships.

HYPERTENSION: EDUCATIONAL TECHNIQUES

Question: Dr. Levy, What new educational techniques have you developed, other than pamphlets, to help the American public better understand the dangers of hypertension:

Answer: We are exploring many avenues. To cite just a few:

1. To improve television, radio, and print materials we are developing with the National Cancer Institute a pretesting system to help assure that the final product will be seen and understood, before we invest thousands of dollars on production.

2. We have just finished a pilot series of television production on hypertension. These programs, designed to be inexpensively produced by local television stations for use in existing health topic programs, have been enthusiastically received in Petersburg and Fredericksburg, Va; Charlotte, NC; Baltimore, Md, and Pittsburgh, Pa. After meeting in March with representatives of these stations for a final critique, we expect to market the programs nationally.

3. We continue to place or stimulate development of in-depth, information articles in popular newstand magazines, including those with special ethnic interests. Using the Readers Guide to Periodical Literature as a rough measure, the number of items available to the public has steadily increased each year.

4. We inaugurated this past year an ongoing effort to place large sized advertising posters in major airports across the U.S.

5. Allegheny Airlines, recently renamed U.S. Air, will shortly begin carrying Institute sponsored health messages, especially messages related to diet, in their air travelers magazine.

6. We have and will continue to produce a variety of mass media public service announcements. This year, in addition to our previous mix of announcements, we have added another important target group--friends and relatives of hypertension sufferers-encouraging them to understand the problems of and give support to the hypertensive patient.

These are some examples of mass media efforts. We also do more education aimed at health professionals who directly counsel hypertension patients in cities and rural areas; in the workplace; in private and in public supported health care setting; in dental,

podiatric and optometric offices; in pharmacies; and in any other place we can imagine that a person with hypertension might come in contact with a trained health professional.

DEALING WITH MILD HYPERTENSION

Question: We have recently heard that your clinical trial on hypertension indicated that a specific treatment of mild hypertension has the potential of saving thousands of lives. This trial involved thousands of individuals and cost millions of dollars but the outcome indicates that it was well worth the investment in terms of lives saved and cost to the economy. Does the Institute have more clinical trials of this type planned for this year?

Answer: You are referring to the results from the Hypertension Detection and Follow-up Program. We strongly concur that the outcome is worth the investment and feel that such expenditures are a critical component of the Institute's research strategy. Our overall portfolio of clinical trials consumes approximately fifteen percent of the Institute's annual budget. One of the key decision factors in initiating a clinical trial is the potential impact of that trial on health care. We carefully consider this impact measured in both terms of mortality, morbidity, and economic cost in a structured decision making process which requires that all feasibility studies and preliminary tests be undertaken before resources are committed to the conduct of the trial.

The Institute has underway a large portfolio of clinical trials similar to the Hypertension Detection and Follow-up Program in their potential impact on the Nation's health. In addition, we have a number of clinical trials planned for the future. We feel strongly that clinical trials are the key to expediting the development of new knowledge and the validation of existing knowledge.

ONGOING CLINICAL TRIALS

The following paragraphs briefly summarize some of the clinical trials we have underway. None of these clinical trials are scheduled to be completed this year.

- The Coronary Primary Prevention Trial (CPPT) - Purpose: To determine whether the reduction of cholesterol by drug therapy will significantly lower the atherosclerotic coronary heart disease rate in a group of hypercholesterolemic, but otherwise healthy men. The 3,810 subjects included in this trial, are being followed for seven years in twelve clinics. The trial is scheduled for completion in 1983.

- Multiple Risk Factor Intervention Trial (MRFIT) - Purpose: To determine for men at high risk of death from coronary heart disease whether a special intervention program simultaneously lowering serum cholesterol, blood pressure and eliminating cigarette smoking, results in a significant reduction in coronary heart disease mortality. This, our largest clinical trial, is following 12,866 subjects for six years. The trial is expected to be completed in 1982.

Both of the above trials are aimed at the primary prevention of coronary heart disease. The potential benefits to be derived from these trials are tremendous. Indeed, if the death rate from arteriosclerosis is lowered by as little as one percent, the annual cost reduction due to cardiovascular disease could amount to over 500 million dollars.

- The Coronary Artery Surgery Study (CASS) - Purpose: To compare coronary artery surgery with medical management in patients with coronary artery disease and to maintain a registry on all patients undergoing coronary arteriography whether these patients are operatively or medically managed. This trial of approximately 800 patients, will extend until 1986.

Coronary artery surgery and its prior diagnostic procedures represent substantial costs in both monetary and manpower terms. We estimate that the average cost of each coronary artery surgery is about $15,000 and that some 100,000 such procedures are performed annually. This trial will provide reliable and quantitative information on the effect of coronary artery surgery on patient morbidity and mortality.

- The Beta-Blocker Heart Attack Trial (BHAT) - Purpose: To determine whether the administration of beta-blocking drugs in patients who have suffered a myocardial infarction will result in mortality reduction. A total of 4,200 patients will participate in this clinical trial which is scheduled to conclude in 1982.

- A Multi-Center Investigation of the Limitation of Infarct Size (MILIS) - Purpose: To test therapeutic interventions to limit the ultimate size of an acute myocardial infarction. By limiting the infarction size, the patient's immediate and long-term prognoses should be considerably enhanced. Approximately 1,500 patients, both male and female under age 75 will be included in this study, which is expected to conclude in 1983.

Both BHAT and MILIS deal with therapies to improve a patient's prognosis following heart attack. Each year, we estimate that over 1,250,000 people suffer heart attacks and that some 60% succumb to these attacks. A reduction in mortality would expand our human resources, and significantly reduce our health care costs.

- Neonatal Respiratory Distress Syndrome (NRDS) - Purpose: To determine the effect of corticosteriods on the incidence of neonatal respiratory distress syndrome. This trial, on approximately 800 subjects, is scheduled for completion in 1981.

Neonatal distress syndrome is one of the leading causes of disability and death in the newborn. In the United States approximately 10% of all infants are premature, and each year, about 50,000 cases of neonatal distress syndrome occur. Hospital cost average about $5,000 per patient with an average stay of 23 days. If this trial yields positive results this toll will be reduced through prenatal treatment.

- Intermittent Positive Pressure Breathing (IPPB) - Purpose: To evaluate the efficacy of long-term intermittent positive pressure breathing treatment for patients with chronic obstructive pulmonary disease. The clinical trial involves 1000 patients and is scheduled to conclude in 1981.

Intermittent positive pressure breathing is a widespread adjunct therapy for in-hospital and home patients with chronic obstructive pulmonary disease. Its efficacy, however, has yet to be determined. We have conservatively estimated that the annual cost of the therapy at home could exceed $30 million per year. This trial will determine the effectiveness of this expensive unproven treatment for ambulatory patients.

FUTURE CLINICAL TRIALS

The above represent our largest clinical trials now underway. We have several trials projected.

- Systolic Hypertension in the Elderly - Purpose: To determine whether treatment of isolated systolic hypertension in 4,200 patients 60 years of age or older randomized to treatment and control will reduce the incidence of stroke. Secondary aims are to evaluate the effect of treatment on total mortality, fatal and non-fatal myocardial infarction, congestive heart failure and renal insufficiency, and cognitive impairment and psychiatric morbidity. The expected duration is six years.

We estimate that as many as 15,000,000 of our citizens 60 years of age and older have hypertension. Hypertension treatment in the elderly is widely recommended based on extrapolations from HDFP and other trials; yet we have not as yet validated its efficacy in the elderly especially those with isolated systolic hypertension. Its benefits in reducing stroke and heart disease morbidity and mortality may be great, but such treatment needs to be validated to determine if the benefits warrant the treatment costs and possible side effects.

- Validation of Non-Invasive Assessment of Large Vessel Atherosclerosis - Purpose: The progress that has been made in non-invasive techniques to assess large vessel atherosclerosis could significantly enhance the likelihood of safe, inexpensive, early detection of progressive atherosclerosis. This trial will validate the new techniques against the existing invasive methods, a necessary step before widespread application of the techniques. The expected duration is five years.

Atherosclerosis is the basis for 85% of the nearly 1,000,000 cardiovascular disease deaths incurred each year in the United States. Noninvasive techniques for atherosclerosis detection could enhance early detection of the disease and thereby encourage early treatment. Even small changes in cardiovascular death rates could yield dramatic changes in health care costs, in increased length of life, and in our productivity.

- Percutaneous Transluminal Coronary Angioplasty (PTCA) - Purpose: To evaluate the effect on morbidity and mortality of PTCA therapy on patients with advanced coronary artery disease. PTCA may be a feasible, less costly alternative than coronary artery surgery in selected patients and a more effective therapy than nonsurgical management. The expected duration is five years.

PTCA may be a feasible, less costly treatment alternative than coronary artery surgery in selected patients and a more effective therapy than nonsurgical management of atherosclerosis. At less than $1,000 per treatment it has some potential but must be carefully validated before widespread use is undertaken.

- Platelet Active Drugs and Myocardial Infarction - Purpose: Recent clinical trials indicate that the first year following myocardial infarction, and in particular the first three months, may be a critical period in which administration of platelet active drugs may be most effective in prevention of sudden death. This trial will evaluate the effect of various platelet active drugs (aspirin, Persantin, Anturane) on mortality and morbidity during the first three months following myocardial infarction. The expected duration is three to five years.

Each year some 500,000 patients survive a heart attack but face at least a two-fold increase in risk of cardiovascular death.

- Effect of Dietary Modification in Blood Pressure Control - Purpose: To determine whether an intervention of sodium intake restriction plus potassium intake elevation and an intervention of weight loss reduces the need for drug therapy. Approximately 700 male and female currently controlled hypertensives and 240 patients with uncontrolled blood pressure will be included in the study. The expected duration is four years.

Hypertension control now relies primarily on drug treatment which may range in cost from $60 to over $600 annually, depending on the prescribed regimen. This trial could reduce the need for drug therapy for the Nation's over 35,000,000 hypertensives and thereby reduce both potential drug side effects and our health care costs.

The above trials are illustrative of those now underway or projected. The full portfolio of NHLBI clinical trials is aimed at testing therapies that can be effective in fighting some of our Nation's major health problems.

SLOWING OF CARDIOVASCULAR RESEARCH?

Question: It is said that heart research is in danger of being slowed because of a reduction in the number of physicians entering cardiovascular research. Your Institute has had a good track record of supporting clinical researchers in the seventies. Will you continue in the eighties?

Answer: The NHLBI has been successful throughout the seventies in attracting new researchers into the cardiovascular research field. In 1980 the NHLBI will continue its support of research training. These efforts have been given special staff attention and the total number of trainees supported was 1,438 in 1979 (approximately 850 in heart research). This number is not as large as it may seem when one considers the growth of NHLBI mandates, lung diseases, blood diseases and blood resources, covering newer and larger areas of investigation, since 1972, when there were also 1,369 trainees (all then essentially in heart research).

A special problem is the dearth of physician investigators in the training program. Where there were 630 medical doctors in the 1972 training programs, there were only 295 medical doctors in the 1979 programs. This represents a severe research-manpower shortage. The Institute has initiated several training and manpower development programs to reverse the downward trend in physician-researchers.

Question: What kind of programs are available through NHLBI to continue to bring young physicians into cardiovasular research?

Answer: The most recent development is the Clinical Investigator Award. The new clinical investigator award program, scheduled to begin in 1980, is intended to encourage newly trained clinicians in cardiovascular, pulmonary, or blood diseases and blood resources and to increase the pool of physician investigators in these areas.

It is hoped that these awards will provide the opportunity for promising, clinically trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award, made to a suitable institution, will enable candidates to undertake up to five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the NIH Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background very early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

Another program, the National Pulmonary Faculty Training Program, strengthens pulmonary medical faculties by training junior faculty members at specialized medical centers. The first recipients were selected for training in 1976, and last year trainees were supported at six national training centers.

Another award program in the area of lung diseases is the Pulmonary Academic Award Program. This program encourages medical students to pursue studies in respiratory medicine and diseases. A large portion of the program is devoted to providing senior staff for pulmonary disease curriculum development and research, and the program also supports students at 45 medical schools throughout the country.

The Institute's major new training program in the cardiovascular area is the Preventive Cardiology Academic Award begun in July 1979. By supporting a specialized faculty member in an educational institution, it is intended to:

- Encourage the development of high quality preventive cardiology curricula that will attract outstanding students to preventive cardiology research and medical practice;
- Develop superior faculty who have a major commitment to and possess educational skills for teaching research and practice of preventive cardiology; and
- Develop institutional ability to strengthen continuously the improved preventive cardiology curriculum with local funds subsequent to the award.

FLEXIBILITY OF NHLBI FUNDING

If the FY 81 increase you propose for the Heart Institute all goes to competing research grants, there is some concern this will deprive the Institute of flexibility in pursuing promising leads.

One particular area involves finding alternative courses of treatment for victims of mild hypertension who were the focus of the Institute's recent landmark report on hypertension. I am informed that unless alternatives can be developed, the prime or only course of treatment is to put victims on regular anti-hypertensive drugs for the rest of their lives.

Question: What are your comments about this?

Answer: Your information is correct. The results of our recent report on the Hypertension Detection and Follow-Up Program (HDFP) are simultaneously exciting and troublesome. The HDFP clearly showed the value of treating high blood pressure, especially in the range of what formerly had been called mild hypertension. We found that through the control of blood pressure levels with a drug treatment regimen, we could significantly lower mortality. However, at the same time the positive and exciting results of the HDFP raise the concern-provoking specter of placing 60,000,000 or more Americans on antihypertensive medications for the rest of their lives.

Question: How will the Heart Institute be able to investigate alternatives in such areas a "biofeedback" and salt and weight control if it does not have sufficient funding to do the job?

Answer: We know that in carefully controlled situations with small numbers of patients that weight reduction, salt restriction and biofeedback techniques have all been shown to be efficacious in reducing blood pressure levels. However, we have no information on the extent to which these techniques would be effective in larger populations, especially in a community setting, in replacing drugs in either the initial reduction of blood pressure or, perhaps more importantly, in maintaining normal levels of blood pressure for those patients initially controlled with drugs.

We are currently funding some early efforts to address these important questions. Given the magnitude of the societal impact of this work, especially with the results of HDFP now available to the community, we and our advisors feel that it is important to move as rapidly as possible in this area of research.

BLOOD SUBSTITUTES

Question: We have recently heard that an artificial blood substitute has been given to patients both in the United States and in Japan. What is this substitute, and what role has the NHLBI played in the development of blood substitutes?

Answer: This blood substitute is a mixture of fluorocarbons, substances which have a high carrying power for oxygen and carbon dioxide and are compatible with blood. The specific blood substitute used clinically recently is a mixture of fluorodecaline and fluoropropylamine known as Flourosol A. Early research with these two fluorocarbons was supported by Institute funds, but more recent commercial development has been done through the commercial sector. The Institute is supporting further development and testing of a number of other fluorocarbons, and several of these are show promise for further advanced tests.

HEMOPHILIA RESEARCH

Question: Hemophiliacs now must use a "clotting factor" derived from blood, which can be very costly. Is there any research being done at NIH toward the development of a less expensive therapy, for example, by using recombinant DNA technology to synthesize the factor?

Answer: The technology, employed by the plasma fractionation industry today to separate the clotting factor used by hemophilia patients from human plasma, produces only modest yields of the product. Only 20-25% of the amount theoretically available is recovered. The NHLBI is supporting research on new, sophisticated protein separation techniques to isolate this, and other, clotting factors. It is hoped that the improved technology will increase the yields of this important blood product and that costs to the patient can be reduced significantly.

The Institute also is supporting numerous studies to isolate other products from plasma that may be therapeutically useful. By increasing the number of clinically useful products from a unit of plasma, costs of all products, including clotting factor, may be reduced.

Due to the lack of an adequate means to identify messenger RNA for the antihemophilia factor, the use of recombinant DNA technology to produce this clotting material is still a decade or more away from being a feasible production alternative.

DIABETES AND CARDIOVASCULAR DISEASE

Question: Diabetes is a dread disease that affects millions of Americans. I understand that the great majority of diabetics,

however, succumb to cardiovascular disease. Is the National Heart, Lung, and Blood Institute supporting research to investigate this diabetes-cardiovascular disease correlation?

Answer: Recent surveys indicate that the risk of cardiovascular events are two to five times higher for the diabetic individual, at any age, than the non-diabetic and that there is a positive correlation between atherosclerosis and diabetes-related phenomena such as elevated triglyceride levels, obesity, and hypertension. There is, thus, no doubt that diabetes greatly accelerates and exacerbates the "killer process" atherosclerosis and its dreadful clinical sequella heart attack, stroke, sudden death, gangrene, etc. While the National Heart, Lung, and Blood Institute does not have a direct programmatic focus on diabetes, it does support investigations that are diabetes related. The cardiovascular consequences and metabolic effects of diabetes are studied as aspects of NHLBI-supported investigations focused on atherosclerosis, hypertension, coronary heart disease, peripheral vessel disease, arrhythmias, heart failure, shock, thrombosis, and 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.

Among the specific diabetes-arteriosclerosis activities of the Institute in the last fiscal year were:

o The support of individual research projects specifically addressing cardiovascular disease as it relates to diabetes. These applications arose from specific requests by the National Heart, Lung, and Blood Institute for research applications in fiscal years 1976 and 1977 and remain from the original 48 projects funded.

o The initiation and funding, in conjunction with NIAMDD, of the Special Emphasis Research Career Award (SERCA) in Diabetes Mellitus: Cardiovascular, Metabolic, and Endocrinologic Aspects. This five year, nonrenewable award is intended to encourage qualified individuals in the early stages of their postgraduate medical and scientific careers to develop research interests and skills in the metabolic, endocrinologic and cardiovascular aspects of diabetes mellitus.

o Data Collection in Clinical Pathology and Morbid Anatomy, "the Honolulu Study" was designed to assess coronary heart disease (CHD) mortality and morbidity among 2,500 Japanese men in Hawaii to see whether their rates were intermediate between the low levels in Japan and the high levels on the U.S. mainland. The major aspects of this study include a series of examinations of the type used in the Framingham study and lipoprotein phenotyping; diabetes is one of the factors being studied.

o Epidemiological studies of coronary heart disease "the Puerto Rico Study". This is a prospective epidemiological study which began in 1965 to investigate coronary heart disease mortality and morbidity in a cohort of 2,567 rural and 6,190 urban men. The major effort of this study is a series of Framingham-type examinations at 2-3 year intervals. Diabetes is one of the factors under investigation.

o Multiple Risk Factor Intervention Trial for the Prevention of Coronary Heart Disease (MRFIT). This trial initiated in 1972 for an anticipated duration of 10 years, aims at determining whether a significant reduction in mortality from coronary heart disease (CHD) will result from a special intervention program designed to simultaneously lower serum cholesterol, lower blood pressure and achieve smoking cessation. Individuals with glucose intolerance are included in the study group.

o Beta-Blocker Heart Attack Trial (BHAT). Survivors of a documented myocardial infarction are recognized as having a high risk of dying relative to the general population. This clinical trial aims to determine whether the regular administration of propranolol, a blocker of sympathetic nervous activity , i.e., a beta-blocker, to individuals who have had at least one documented myocardial infarction will result in a significant reduction of mortality from all causes during the follow-up period. Glucose intolerant individuals are included in the study.

o The Lipid Research Clinics (LRC): Prevalence Study. One of the programs concerning dyslipidemia, lipid diseases, operating under the umbrella of the LRC, collects data on glucose intolerant individuals. This is an internationally-based study of the prevalence of dyslipidemias in defined populations. The large numbers and more defined methodology aim to enhance detection of dietary influences on lipid transport diseases where they exist.

o Vascular manifestations of diabetes are being studied in a large population of Oklahoma Indians as part of multi-national cooperative research program sponsored by the World Health Organization. The aim of the study, one of 14 being carried out throughout the world, is to determine the magnitude and characteristics of the differences among populations in susceptibiltiy to microvascular and macrovascular lesions.

o Quarter Century Study of Glucose Intolerance. This study will determine the prevalence and 25-year incidence of cardiovascular disease manifestations by race in women first diagnosed as exhibiting normal or abnormal carbohydrate tolerance tests in association with pregnancy. It is expected to characterize the source of the expected high rates for cardiovascular disease among diabetic women, as contrasted with the low rates, at least among white, nondiabetic women.

o Microcirculation in Patients with Diabetes Mellitus. The changes in the distribution, number and patterns in the microvessels of the conjunctiva for nondiabetic individuals and patients with diabetes mellitus is being studied.

o Blood Glucose, Hemoglobin A_1, and Diabetic Vascular Disease. This program is a prospective five year evaluation of the effects of glucose control in juvenile onset diabetic (JOD) patients on the development of microvascular disease and the classical risk factors that lead to macrovascular disease.

o Long-term Study of Diabetic Vascular Disease. This project is investigating the incidence of peripheral atherosclerosis,

extracranial arterial disease and peripheral neuropathy in selected subgroups of patients with diabetes mellitus. A five year prospective study of diabetic vascular disease is being carried out using noninvasive testing techniques.

o NHLBI is cooperating with NEI in the support of cardiovascular studies within a collaborative primary prevention trial entitled "Early Treatment for Diabetic Retinopathy Study" (ETDRS).

o To further examine the diabetes-atherogenic correlation and to raise the question of how and why diabetes potentiates atherosclerosis, the NHLBI is cosponsoring with the Juvenile Diabetes Foundation a conference entitled "Atheriosclerosis Diabetes" to be held this March. This conference will begin with a session that details the established facts which indicate an association between diabetes and atherosclerosis. After the opening session, we will hear from experts in basic research fields relevant to diabetes and atherosclerosis as they discuss general theories on the formation of athermatous lesions and speculate on how diabetes exacerbates and accelerates the process. It is from these discussions that we should be able to realize new insights into, and establish new research directions toward, a better understanding of the "diabetes--atherogenic connection".

Question: How much is in your new budget for this kind of research?

Answer: The fiscal year 1981 budget will allow NHLBI to continue its present commitments in diabetes research.

Question: Are you missing any opportunities in this field?

Answer: The budget will allow us to address some very significant problems in the area of diabetes. However, in the future we would also like to pursue the high priority programs listed below.

- Studies of the effect of diabetes on platelet composition and function and on Thromboxane A_2 and Prostacycline production.
- Studies of the effect of diabetes on the cerebral vasculature;
- studies to examine the pathogenetic enhancement of placque formation in atherosclerosis by diabetes;
- studies on the contribution of diabetes to congestive heart failure;
- investigations on the effect of diabetes on major mechanisms involved in the development of hypertension;
- a program of small supplementary grants to add diabetic variables to existing programs in cardiovascular disease;
- studies of the effect of glucose and insulin on lung development and surfactant production;
- investigations on the effect of hemoglobin glycosolation on hemoglobin function;
- studies on the interrelationships of obesity and glucose intolerance and hypertension.

LUNG DISEASE AND CIGARETTE SMOKE

Question: It has been said time and again that those suffering from chronic lung disease should not smoke. What effect does the cigarette smoke from others have on either nonsmokers or individuals with chronic lung disorders?

Answer: There is a growing body of medical research which demonstrates the harmful effects of cigarette smoke from others (side-stream smoke) to non-smokers and individuals with chronic lung diseases.

Infants and children are particularly sensitive and, therefore, harmful effects from side-stream smoke are seen earlier and are more obvious in children than adults. It has been shown that cigarette smoking by parents has a measurable effect on the pulmonary function of their children which is independent of any direct use of cigarettes by the children. For example, pulmonary function measurements of young school children and teenagers indicate a decrease in the breathing capacity if the child is from a home where even one parent smoked; pulmonary function was decreased even more if the child was from a home where both parents smoked cigarettes. It has also been shown that infants whose mothers smoke are more likely to be admitted to hospitals with bronchitis or pneumonia than are infants whose mothers do not smoke. Another study showed that the chances of pneumonia or bronchitis developing in an infant are almost doubled if both parents smoke. In addition, asthmatic children whose parents smoke often show improvement when their parents cease smoking. Other studies showed that the frequency of respiratory symptoms in children is directly proportional to the amount of tobacco smoke in the child's development.

Allergic and asthmatic persons can be affected by tobacco smoke in at least two ways. The smoke can irritate the respiratory system and it can act as an allergen stimulate in the production of IgE antibody (IgE antibody levels are a specific sign for the development of allergies).

These findings have important implications for the future health of young people because long-term epidemiologic studies suggest that children with respiratory problems have a significantly increased risk of developing a chronic lung disorder as an adult.

A study soon to be reported in a major medical journal provides startling data on the pulmonary function tests of non-smokers exposed to cigarette smoking in a working environment. Both men and women non-smokers who work along side of individuals who smoke had pulmonary function scores reduced to a level of those reported for light smokers. Individuals who are non-smokers and work in a smoke-free environment consistently scored better in the tests of pulmonary function. The authors of the study conclude that chronic exposure to tobacco smoke in the working environment is deleterious to the non-smoker and produces significant reduction in measurements of small airways function.

The National Heart, Lung, and Blood Institute will continue to monitor the results from these and other studies to learn more

about the impact the cigarette smoker has on the respiratory health of the non-smoker.

Question: Do you feel the federal government should play a stronger role in barring smoking in public places to protect the non-smoker and the chronic lung patient?

Answer: Many states have already passed restrictive legislation to protect the non-smoker from cigarette smoke exposure both in the work environment and in public places such as food markets, restaurants and other public buildings. Furthermore, the federal government has taken steps to require non-smoking sections in public transportation; airplanes, trains and buses. The National Heart, Lung, and Blood Institute is committed to continue to provide as much data as possible on the effects of exposure to cigarette smoking on those who choose not to smoke, especially those who already have chronic lung disease or cardiovascular disease, so that state and federal agencies with regulatory functions have access to sufficient data to make appropriate decisions that may ultimately have an impact on the health of the individual who does not smoke cigarettes.

Question: How do you coordinate your anti-smoking campaign efforts with those of CDC's Bureau of Health Education or those of the Office of the Assistant Secretary for Health (OASH)?

Answer: Coordination of the Institute's anti-smoking efforts are conducted in several ways. The Institute has a congressional mandate to coordinate the Federal Government's research on heart, lung and blood diseases. This coordination is accomplished through the Interagency Technical Committee (IATC). The IATC parent body has developed a Working Group on Smoking and Heart, Lung, and Blood Diseases. Both the CDC's Bureau of Health Education, as well as the Assistant Secretary's Office of Smoking and Health have representative members on this Working Group. The Working Group regularly meets to exchange information on current research activities, program plans and evaluation procedures. The IATC Working Group on Smoking and Heart, Lung and Blood Diseases is not only sharing program data, but has taken a pro-active role and is helping other Federal agencies with their smoking and health activities. Through the IATC Working Group, NASA will be given technical assistance to improve their physicians continuing education program and the Office of Personnel Management has been given technical assistance to help them develop model smoking policies and guidelines for Federal employees. The Institute also is a member of the Office of Smoking and the Workplace, and the Office of Smoking and Health's Ad Hoc Committee on Smoking Information and Education. Further, the Institute has sent representatives to the Office of Smoking and Health's Working Group to Implement Section 403 of Public Law 95622. In addition, the Office of Smoking and Health and the NHLBI are both members of the National Institutes of Health Ad Hoc Committee on Behavioral Sciences Research and Smoking. The NHLBI staff have reviewed the Office of Smoking and Health's latest public service films and posters and have provided a critique for that staff. The Office of Smoking and Health has also used the Health Message Testing Service program jointly sponsored by NHLBI and the National Cancer Institute. Finally, it should be noted that these solid lines of communication between the NHLBI staff and the Office of Smoking and Health resulted in a common

61-400 O - 80 - 44

need to collect additional information on the prevalence of smoking. Through an interagency transfer of funds agreement, the NHLBI will partially support a survey to be conducted by the National Center for Health Statistics for the Office of Smoking and Health. Both agencies will be able to immediately use the results of this survey.

HEPATITIS

Substantial progress has been made in testing for viral hepatitis transmitted by blood transfusion; but it has now been discovered that a new form of hepatitis, referred to as "non-A, non-B hepatitis" for which there is no available test, is proving to be a continued hazard in blood transfusion.

Question: How long have we been aware of the new form of hepatitis?

Answer: Despite suggestive evidence from studies dating back over a decade, the existence of more than two human hepatitis viruses has only recently gained acceptance. With phasing out of the use of HBsAG-positive donor blood in the United States, the non-A, non-B hepatitis agent has become the source of nine-tenths of all cases of post-transfusion hepatitis. The existence of a transmissible non-A, non-B hepatitis agent in man has been substantiated by the results of retrospective and prospective epidemiological studies, and by the successful infection 18 months ago of chimpanzees with serum from human beings with the disease. Today, the reality of non-A, non-B hepatitis is firmly established in an epidemiological and clinical sense.

Question: How are we progressing in developing a test to identify the existence of this hazard in donor blood?

Answer: Control of non-A, non-B hepatitis remains a problem. Several investigations of post-transfusion hepatitis indicate that the frequency of both type B and non-A, non-B hepatitis can be reduced by eliminating commercial blood donors. Additionally, other studies suggest that screening donor blood samples for serum alanine aminotranferase, a liver enzyme, may help eliminate some of the risk. However, until a specific serologic method is found to detect the non-A, non-B hepatitis agent (or agents), progress in eliminating the risk of hepatitis associated with the administration of blood or blood products will be slow. The recent transmission of non-A, non-B hepatitis from humans to chimpanzees provides an excellent tool for further understanding of the disease and enhances the prospect for the development of sensitive and specific serologic markers to control post-transfusion non-A, non-B hepatitis. The NHLBI is supporting several projects aimed at developing such diagnostic methods as well as a number of other studies related to generating a better understanding of the pathophysiology of the disease.

Question: A few years ago there was talk about moving to an all-volunteer blood donor system. It was felt that such a system would cause a significant decrease in the incidence of viral hepatitis. What is the status of this suggestion?

Answer: An all-volunteer blood donor system was targeted as a major goal of the National Blood Policy promulgated by DHEW in 1973. There has been impressive progress toward this goal. Currently it is estimated that only about 3% of blood donations come from paid donors, as compared to between 20-30% a decade ago. The change has come about as the result of many factors, including recognition of the hazard of the high hepatitis carrier rate in commercial donors. The requirement that blood must be labeled as to its origin (volunteer or paid), issued by the Bureau of Biologics, FDA, has discouraged physicians from using paid blood. There has been a significant change in public attitudes regarding payment for blood. Both the Council of Community Blood Banks and the American Association of Blood Banks defined an all-volunteer system as their goal, a system always employed by the American National Red Cross as a supplier of about 50% of the national blood transfusion needs.

Question: Would an all-volunteer donor system significantly decrease the hazard of "non-A, non-B hepatitis?"

Answer: Yes, an all-volunteer system would decrease (and already has decreased) the risk of transfusion-transmitted non-A, non-B hepatitis, since epidemiological studies supported by NHLBI had shown that this form of hepatitis, like Hepatitis B, is carried significantly more often by paid than by volunteer donors.

Question: What role should the Federal government play in fostering a change to an all-volunteer blood donor system?

Answer: We believe that the regulatory actions of the Bureau of Biologics, combined with the change in public attitudes regarding paid donors, which the American Blood Commisssion and other organizations have fostered, suffice to achieve a system that for all practical purposes is an all-volunteer system. There are a few pockets where donors are paid for reasons unique to certain communities, but these have an excellent record in terms of the safety of the blood they draw, and their existence would not seem to warrant Federal legislation.

DIET AND HEALTH

Question: The Surgeon General, in his report "Healthy People" suggested that there was a link between diet and cardiovascular disease. As a result, he advised the American people to reduce their consumption of saturated fat, cholesterol, and sodium. What is your opinion?

Answer: There is little doubt that far too many Americans have diets that are unnecessarily high in fats and sodium and this can lead to serious health problems. The Surgeon General's report was a step forward in alerting the public to these dangers.

Question: What have you done to educate the public regarding the dangers associated with a high fat, cholesterol, and sodium diet?

Answer: The question that is frequently asked of NHLBI is whether or not lowering cholesterol levels will prevent heart attacks.

We do not have the answer to that question as yet, and so we have not made a recommendation to the general public regarding desirable cholesterol levels as a means of preventing coronary disease.

We have, however, taken steps to communicate to the public the dangers of excessive sodium, particularly as it relates to high blood pressure. That message is conveyed in a variety of forms to both health professionals and the public as part of our ongoing National High Blood Pressure Education Program.

We are also actively involved in providing dietary advice to the patient with hypercholesterolemia. NHLBI has already distributed more than 7-million copies of the highly-regarded publication, Dietary Management of Hyperlipoproteinemia.

We do have several nutritional education activities underway for the general public which deal with the cholesterol question and contain advice based on what has been established as scientific fact.

For the health professional, we are sponsoring along with the American Heart Association a series of workshops on nutrition counseling. At the conclusion of these workshops, we will have a "package" containing guidelines, materials, and videotapes to allow similar workshops to be put on by AHA chapters throughout the country. AHA is also going to distribute through its network the "Foods for Health" program developed jointly by the NHBLI and Giant Foods Inc. This brings information to the consumer at the point of purchase--the grocery store. AHA has already distributed another pilot project of NHLBI--"Food for Thought"--a game designed to be played in the cafeteria setting, again to influence decisions at the point of purchase.

A new publication--Heart Attacks--will be widely promoted in magazines, newspapers and radio and television. It, too, will provide guidance and understanding to the public regarding all risk factors, including cholesterol.

COORDINATING COMMITTEES

Question: How effective are your many coordinating committees in lessening duplication of research efforts within NHLBI and NIH at large?

Answer: Coordinating committees at the Institute, NIH, and Interagency levels have been and continue to be an important mechanism for promoting communication, exchange of information, and collaboration that minimize unnecessary duplication of research support. This is particularly true in areas of concern in health and disease research that cut across NIH Institute and other agency missions such as diabetes, cystic fibrosis, environmental illnesses, genetic diseases, toxicology, epidemiology, etc.

Furthermore, in providing leadership for the National Program on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources, the NHLBI exercises its major responsiblity for coordinating those aspects of all Federal biomedical/health programs related to

cardiovascular, pulmonary and blood diseases and blood resources through various formal and informal mechanisms, including the Interagency Technical Committee (IATC) on Heart, Lung, and Blood Diseases.

Almost 50 Federal organizations conduct or support programs related to the National Program that includes basic and applied biomedical research, clinical research and clinical trials, health services research and delivery, health care financing, as well as the evaluation and regulation of these activities. Thus, the National Program encompasses not only the research supported by the NHLBI but also the relevant research efforts of other NIH Institutes, many components of DHEW, and parts of other Federal departments and agencies.

The role of committees in coordination of this diverse involvement has significant benefits for the Program, as well as for the individual Institutes and other Federal agencies contributing to it. Through the activities of these committees research areas that warrant greater emphasis are identified; the roles of various agencies in pursuing these new thrusts are delinated; unnecessary duplication of effort is avoided; and available resources are used more effectively and efficiently as a result of joint sponsorship and support through various mechanisms including interagency agreements to fund research in areas of mutual need and interest.

In view of the vastness and complexity of the National Program and the number of agencies involved in supporting related efforts, the NHLBI provides the leadership for and participates in a variety of formal and informal coordinating committees whose activities and effectiveness are typified by the IATC.

Since its establishment in 1972, the IATC has evolved into a forum through which interagency cooperation and involvement within the National Program has been fostered. The IATC plays an important role in National Program coordination through the exchange of programmatic information, the provision of technical expertise, and the promotion of interagency collaboration that lessen duplication of research effort and support while maximizing the benefits obtained. For example, to determine the scope of Federal support of research relevant to the National Program, the NHLBI, in conjunction with the IATC, developed an inventory of federally supported research related to cardiovascular, pulmonary, and blood diseases and blood resources. The data in this report are updated as needed as a basis for maintaining an annual review and tracking of the total Federal committment in the National Program, broadening awareness of the research supported, and promoting future collaborative efforts that maximize the utilization of federal resources and the information obtained concerning diseases of national importance and relevance to various governmental agencies.

DIET AND HEART DISEASE

Question: The Public Health Service Act directs the Institute to appoint an Assistant Director for Prevention, Education, and Control who has the responsibility to conduct a public information program placing special emphasis on "Dissemination of Information

Regarding Diety and Nutrition...and Other Factors Affecting the Prevention of Arteriosclerosis and Other Cardiovascular Diseases..." (Public Health Service Act, Section 413 (D)). What have you done to carry out this mandate?

Answer: Prevention, education, and control has the highest priority in the Institute. During the past year, we recruited a new Director of the Office of Prevention, Education, and Control to strengthen and improve the information/education arm of NHLBI. This office is comprised of two major components: the Health Education Branch and the Public Inquiries and Reports Branch. OPEC activities are very much a part of the biomedical research spectrum at the NHLBI. Its key role is to hasten the progression of new knowledge so that individuals and health professionals can put it to beneficial use.

Perhaps, the most visible activity of the Office of Prevention, Education, and Control is the coordination of the National High Blood Pressure Education Program. Administered by Health Education Branch, this program has been credited with doing a superb job in educating both the public and the medical profession on the dangers, detection, treatment and control of high blood pressure. However, it does more than simply disseminate information. It provides guidance and direction to a vast network of agencies and organizations in the private and the public sectors. It has also served as a catalyst stimulating high blood pressure control projects in communities and in organizations with large numbers of employees.

Mass media campaigns, publication distribution, technical assistance to others who want to initiate educational or intervention efforts, and coordination and cooperation with a wide range of other groups involved in disease prevention and health promotion are some of the activities and functions of the Office of Prevention, Education and Control.

Question: How strong is the link between cardiovascular disease and diet?

Answer: The link between diet and heart disease is based largely on epidemiological evidence and animal studies. The all-important question of whether lowering cholesterol levels actually prevents heart attacks has not been answered to the satisfaction of the Institute or to the eminent scientists who sit on our advisory bodies. We have an ambitious clinical trial underway now which hopefully will provide us with definitive data regarding this important issue. Should the answer firmly establish that lowering blood cholesterol to a certain level helps prevent heart attacks, no one will be more aggressive than the NHLBI in conveying the related messages to the American public. The Institute's experience with the National High Blood Pressure Education Program puts us in a unique position to do just that.

Question: Who do you feel should be carrying out these educational activities: NHLBI or some other entity within HHS?

Answer: We feel that the Institute is appropriately responsible for the full biomedical research spectrum in diet and heart disease,

i.e., knowledge development, knowledge validation, and knowledge translation. Location of the continuum in one organizational unit insures timely, accurate and precise information flow. In the area of heart disease and diet, we have several activities underway. We have just completed a year-long nutrition education project in cooperation with Giant Foods Inc. in the Washington, D.C. area. That effort included a series of "Eaters' Almanacs" which provided some basic dietary advice, suggested recipes, and other information related to heart disease. The project was designed to demonstrate the value of nutrition guidance at the point of purchase. We are now working with the American Heart Association which intends to adapt this program and make it available to its chapters throughout the country. The AHA has already adopted another pilot project of NHLBI dealing with nutrition. This one, entitled "Food for Health," is directed at people in a cafeteria setting.

Together with the American Heart Association, we are also sponsoring workshops on nutrition counseling for nutrition practitioners. The objective is to disseminate up-to-date information on effective nutrition counseling skills to these practitioners at the local level in as cost-effective a manner as possible. After an initial series of workshops have been completed, a model workshop "package" including materials and videotapes will be put together for widescale distribution.

Continued distribution of the Dietary Management of Hyperlipoproteinemia takes place in response to growing numbers of request. Four-hundred thousand copies of this popular publication were distributed in 1979; more than 7-million since it was first published. This series was selected as a model by the General Accounting Office for effectively transmitting health education and information to patients.

CORONARY ARTERY BYPASS SURGERY

Question: What is the status of the clinical trial, initiated in 1973, to evaluate the long-term benefits of coronary artery bypass surgery?

Answer: The patient recruitment phase of the study was completed in May 1979. The 24,968 patients who had undergone coronary angiography in the 15 participating institutions have had complete data entered into the study files. They are undergoing follow-up through May 1983, whether they received bypass surgery, medical treatment, or were found to have no disease at all. Of these patients, 780 who met specific clinical, coronary angiographic, and other criteria agreed to participate in a randomized study comparing medical and surgical management for their disease. They will be followed even more closely. We are very satisfied with the continued acquisition of data. For example, among our randomized patients we have continued follow-up data as to survival in the 780. The data of this study, as all of our long-term medical trials, is under regular review by a Data Monitoring and Policy Advisory Committee. While we cannot say anything about the outcome in the randomized patients, we can report some of the outcomes from the broader registry. Indeed, several reports have been published from this registry including one which characterizes the safety and complications of the coronary angiography

diagnostic procedures, and another very provocative one discussing the limitations and incremental information to be derived from the diagnostic exercise tolerance test performed on persons undergoing coronary angiography. The primary goals of the study - a comparison of the long-term outcome of surgical and medical management of coronary heart disease - promise to be very rewarding.

Question: Are the benefits, in fact, tangible and worth the cost of the operation?

Answer: The coronary artery surgery study discussed above is designed to provide us more meaningful answers to this question. This will be through the results of the randomized study of 780 patients which can serve as benchmarks and the correlated studies on the 24,188 additional patients characterized in an almost identical fashion at the outset.

Based upon what is known today, it is safe to say that the coronary bypass surgery is of unequivocal benefit to those persons who have angina pectoris truly unresponsive to intensive medical management. We also have the results of the Veterans Administration randomized trial which show that in patients with substantial narrowing of the left main coronary artery, statistically significant increase in life expectancy can be expected through surgery - and our data confirmed this. While there is an increasing body of opinion and some inconclulsive evidence that longevity may be improved in patients with three vessel disease, this is not based upon firm fact, and the Coronary Artery Surgery Study does not yet provide data to help resolve this issue. However, this and the possible role of this therapy in less severe disease are among the topics of investigation.

There is no question that in approximately 85% of patients undergoing coronary bypass surgery, there is subsequent substantial decrease or disappearance of angina pectoris. What is not clear is to what extent this is associated with improved life expectancy. Furthermore, while there is a physiological basis why there should be decreased angina pectaoris, such angina pectoris sometimes diminishes or disappears in patients who have relatively unsuccessful operations. Thus, we are left with a quandry of the possibility that in some patients the benefit may be from something other than a direct physiological effect. No doubt for many, many patients the surgery is of substantial tangible benefit. We suspect that there are others in whom it is now being done in whom further evidence will show that it is probably not of major importance. It is the goal of the Coronary Artery Surgery Study to shed further light upon these issues.

ARTIFICIAL HEART PROGRAM

Question: What is the status of research in artificial (including nuclear powered) hearts?

Answer: The major focus of research in the targeted "artificial heart" area is the development of a longterm fully implantable pump to assist or replace the function of the left ventricle--but not require the removal of the diseased heart. Such an assist or booster

pump has been validated for shortterm (up to two weeks) clinical use after very extensive bench and animal studies. We have limited its use to those patients who are undergoing open heart surgery with the heart lung machine and who for unrecognizable reasons cannot be weaned off the heart lung machine by any known pharmacological or other technique.

The major effort in the program, however, is the development of long-term devices which can be fully implanted and functioning for periods of at least two years, allowing the patient normal activities and ambulation. The major components of such systems--the pumps, engines, control systems, and energy transmission devices--are in advanced development stages. In view of the need to have unusually long-term reliability in miniature units without any servicing whatever in the adverse 100% humidity and salty environment of the human body, these developments are no small task. We look forward to animal tests of complete systems within the next two or three years. The validation for human use will require substantial further effort.

The major thrust of these developments has been on electrically powered engines. However, one approach uses a heat machine, and the heat could come either from electrical energy or from nuclear energy. Any electrical pump would require a recharging of the system one to three times a day, whereas with nuclear energy source, there would be no need for recharging for a decade. All of the systems under development must or could be powered electrically.

Through the grant program of the Institute, there is some research in total artificial hearts. Here the natural heart would be replaced by a totally mechanical unit. This is a much smaller effort in terms of resources, but it borrows heavily from the developments of the target program. Most of the major developments in materials, pumps, engines, energy systems, control systems, and manufacturing processes are applicable to both assist devices and total cardiac replacement units.

Question: Is this research being funded per NHLBI?

Answer: Yes, in 1979 the Institute spent $10.329 million in this area through targeted or contract support and about $2.2 million through its regular grants programs. An additional $4.7 million was spent on grants in the closely related biocompatible materials program, much of this is on fundamental processes dealing with clotting and foreign materials in the body.

Question: How much has been expended by National Heart, Lung, and Blood Institute on this research to date?

Answer: The targeted program was begun in 1964 and since that date approximately $135 million have been involved. When the program was in its early growth stage and the "crash program" mood was prevalent, the program grew quickly from 4 to 8 million dollars per year and represented as much as 5% of the Institute' annual budget. In recent years it has grown little in current dollars and shrunk in constant dollars so that it has represented a substantially lesser fraction of the Institute's efforts; it now comprises less than 2% of the Institute's budget.

Question: Should this research effort be continued?

Answer: The primary thrust of heart research in the Institute is in the direction of prevention and secondly in areas of therapy which can be very widely applied. Unfortunately even when we are optimistic, we cannot foresee complete success in these goals; thus the situation in which a long-term left ventricular assist or a total artificial heart device would be useful will continue to exist. The developments are now going forward in a very satisfactory fashion. When our Cardiology Advisory Committee examined this program in detail several years ago, they recommended a continuation of the program and they have continued to look at it in a systematic fashion. Currently the National Heart, Lung, and Blood Advisory Council will be looking at it in detail as well, reviewing its overall goals, accomplishments, prospects for success and directions. We feel this kind of review is necessary whenever the Institute is undertaking a substantial effort in an area in which the broad scientific community does not have extensive familiarity.

Question: Is this another example of an expensive biomedical technology which ultimately will benefit a few?

Answer: The immediate major goal of the "artificial heart" left ventricular assist device program is the development of a totally implantable device with at least a two year useful life which would take persons who are totally incapacitated or perhaps moribund and allow them normal activities. The next stage would take this to devices with at least a five year period of reliability. Undoubtly such units would be "expensive" in comparison to some medical therapies and technologies, but no more expensive than others. If the projected goals of two and then five year effectiveness and reliability are achieved, they would probably compare favorably with a number of quite widely practiced medical technologies in terms of years of added life and improved quality of life per dollar invested. Until development is further along, it is impossible to state with certainty that these goals will be achieved, or to calculate the "cost benefit." The estimates of need for such a device vary and undoubtly will be influenced by the actual success of the technological development in terms of its period of reliability and degree of effectiveness. However estimates range from 10,000 to as many as 60,000 or more patients a year.

Question: In other words are the prospects for breakthrough in this field great enough to justify continued funding?

Answer: There has been progressive and substantial developments in this area. Unfortunately the need continues and we foresee that the need will remain. Our current investment in this are--about 2% of Institute's resources--represents a reasonable allocation when we weigh need, opportunity, and likelihood of success. We have examined these issues on a regular basis with aid of our advisory apparatus. We have done this recently and we are about to do it again through the National Heart, Lung, and Blood Advisory Council.

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: The NHLBI, as part of its program planning and analysis activities, develops in concert with the scientific community a prioritized list of potential research projects. It is from this list that new initiatives are identified and funded. Each year the planning process identifies many more initiatives than can actually be undertaken due to budget constraints. The National Program Plan addresses specific scientific goals and individual program areas. In order to meet these goals, the Institute utilizes a program strategy that lends direction and momentum to the National Program as a whole. The program strategy employed for each of the disease-related mandates of the NHLBI consists of an ordered sequence: acquisition of new knowledge (science base), testing and evaluation of promising hypotheses (application), and dissemination of new and existing knowledge (transfer). While the new areas of research are grouped by science base (the majority of the activity at NIH), clinical application, and transfer activities, often an initiative will overlap two or more categories. Selected initiatives that await adequate funding are presented below:

HEART AND VASCULAR DISEASES

Science Base Activities

The Role of Salt and Water in the Pathogenesis of Hypertension: to encourage and support research that will increase our understanding of the basic mechanisms whereby excess sodium intake participates in elevation of blood pressure.

Blood Platelets and Atherosclerosis: to study the functional and structural effects of dietary modification on platelet-arterial wall interaction. The role of arterial wall prostacycline and platelet thromboxane and their inhibitors will be actively explored.

Community Surveillance System for Cardiovascular and Other Chronic Diseases: to establish a surveillance system to monitor, in 10 geographically circumscribed communities representing regionally different parts of the United States, possible concurrent trends in the incidence of first and recurrent myocardial infarctions, stroke, and other chronic diseases like diabetes.

Longitudinal Studies of Coronary Heart Disease Risk Factors in the Young: to measure changes in risk factors (e.g., blood lipids and lipoproteins, blood pressure, adiposity, blood sugar) that have been associated with the development of coronary heart disease in cohorts of males and females newborn to 30 years of age.

Migration and Culture Change in Relation to Coronary Heart Disease: to study CHD morbidity and mortality in population groups that currently are undergoing rapid social change.

Studies on Efficacy of Combinations of Biobehavioral and Pharmocologic Treatments of Essential Hypertension: to promote and

encourage clinical research projects dealing with evaluation of combinations of pharmacologic and non-pharmacologic therapies in the treatment of patients with diagnosed essential hypertension.

Animal Models for Study of the Pathogenesis of Cardiomyopathies: to study several models of cardiomyopathy in experimental animals and to evaluate the pathogenetic mechanisms of these conditions.

Expansion of Specialized Centers of Research in Arteriosclerosis: to continue to study hyperlipidemia and vascular diseases, including animal and tissue studies and basic laboratory investigations.

Smoking and Heart Disease: to learn more about the mechanisms by which smoking influences the development, pathogenesis, and manifestations of cardiovascular disease.

Feasibility of the Development of Markers to be Used as Adherence Measures in Clinical Trials of Pharmacologic Agents: to develop safe, stable and non-interfering, non-radioactive substances which can be added to pharmacologic agents which may be used in clinical drug trials or therapeutic intervention trials to assess patient adherence to the drug regimen.

Clinical Application Activities

Clinical Trial of Hypertension in the Aging: to launch a clinical trial, jointly with NIA, to determine the effectiveness of treating systolic hypertension commonly found in older persons. The potential impact from such a trial is now considered to be of major significance.

Cardiovascular Disease (CVD) Nutrition Research Unit for the Study of Nutrition and Heart and Vascular Disease: to establish close interaction and collaboration between investigators in CVD and nutrition, to offer a broad range of research training activities oriented toward human nutrition in health and disease.

Small Blood Vessel Prosthesis: to conduct a program for the research, development, and evaluation of small vessel prostheses for use in pediatric patients with congenital heart disease and adult populations with peripheral vascular or coronary artery disease.

Transfer Activities

Behavioral Studies of Prevention Techniques: to build our understanding of methods of changing risk-prone cardiovascular disease behavior from the nutritional and behavioral data base developed through the Institute's clinical trials.

Studies on the Influence of Psychosocial Stressors in Smoking Cessation and Maintenance of Cessation: to obtain data to clarify the role of psychosocial stressors in smoking recidivism.

Targeted Smoking Cessation for Cariovascular High Risk Groups: to develop targeted smoking cessation programs specifically for populations of smokers who are at special risk for cardiovascular

disease as a result of the combination of smoking and other exacerbating risk factors.

LUNG DISEASES

Science Base Activities

Immune Complexes in the Pathogenesis of Pulmonary Fibrosis: to encourage studies on the formation and significance of antigen-antibody complexes in interstitial pulmonary disease in order to determine whether immune complexes represent an initiation, an unimportant consequence, or a contributing factor in chronic pulmonary injury in man and experimental animals.

Vascular Basement Membranes in Interstitial and Vascular Diseases of the Lung: to determine the structural and functional properties of the vascular basement membrane in interstitial and vascular lung diseases.

Expansion of Specialized Centers of Research in: Fibrotic and Immunologic Diseases, Cystic Fibrosis, Chronic Obstructive Lung Diseases, and Pediatric Pulmonary Diseases: to conduct basic, applied, and clinical research projects for chronic airways, pediatric pulmonary, fibrotic and immunologic pulmonary and pulmonary vascular diseases.

Cell-to-Cell Interaction in the Developing Lung: to conduct fundamental studies to define the interactions between lung cells in developing lungs; and to determine the contribution of interstitial cells to lung development.

Studies of Neuro-Histopathologic Changes in Obstructive Airways Diseases: to support fundamental studies directed at elucidating the morphologic features of the sensory and motor innervation of the airways during development, health and disease and at correlating the morphological information with their physiologic function.

Immune Responses in the Lung: to encourage research to define immune responses within the lung; to identify agents known to produce lung disease, particularly fibrotic and/or granulomatous lung disease.

Characterization of Periciliary Fluid in Mammalian Airways: to isolate and characterize the aqueous environment (periciliary fluid) between the mucous and epithelial surface and to establish how this fluid influences the mucociliary clearance process in health and disease.

Clinical Application Activities

Prevention of Pulmonary Emphysema in Patients with Alpha-1-Anti-Trypsin Deficiency: to develop and test synthetic low molecular weight elastase inhibitors for the treatment of patients with the genetic deficiency of alpha-1 anti-trypsin.

BLOOD DISEASES AND BLOOD RESOURCES

Science Base Activities

Dietary Lipids and Hemostasis: to investigate the role of dietary lipids in hemostatis and thrombosis with regard to platelet lipids, and to determine if there are any changes in the functional activity of platelets.

Deep Vein Thrombosis: to conduct a cooperative study of laboratory methods for determining patients at high risk to deep vein thrombosis.

Cardiac Function in Sickle Cell Disease: to evaluate cardiac function and the nature, prevalence, and incidence of cardiac impairment in patients with sickle cell diasese as a special study within the Cooperative Investigation of the Clinical Course of Sickle Cell Disease.

Clinical Application Activities

Modified Hemoglobin: to test various forms of modified hemoglobin as a blood replacement preparation.

Factor VIII Preparation: to improve methods of harvesting, preparing and, eventually, using Factor VIII. Particular emphasis would be on the development of methods to ensure that the cryoprecipitate produced by hospital and community blood centers would not be wasted.

Donor-Recipient Compatibility in Platelet Transfusion Therapy: to determine which patterns of platelet transfusions are most clinically beneficial and most cost-effective and to assure optimal transfusion therapy for patients requiring long-term platelet support.

Leukapheresis Donor Safety Study: to conduct a multifaceted study of the effect of leukapheresis on repeat donors in order to develop guidelines that assure donor safety and assist in donor selection and care. These data are necessary as a prelude to licensure for the product.

Transfer Activities

Sterile Connecting Device for Blood Bags: to demonstrate and evaluate the most promising existing types of docking devices in terms of potential uses, acceptability to the user communities, cost-effectiveness, and safety and efficacy.

RESEARCH AND TRAINING PROGRAMS IN HYPERTENSION

Question: Can you tell us how the research and training programs in hypertension are progressing in accordance with last year's funding levels?

Answer: The hypertension program within the Institute is a multifaceted one. It encompasses not only biomedical research and

training, but also prevention and education programs for the public. The NHLBI currently supports more than 200 research projects concerned with etiology, pathogenesis, prevention, diagnosis, and treatment of high blood pressure. Closely related subjects, such as kidney disorders and renal physiology, also are under study.

Principal research areas in the hypertension program include:

- The search for causes of essential hypertension and identification of genetic and environmental factors that increase susceptibility to the disease or aggravate its clinical course. Without such knowledge, cures or effective means of prevention are unlikely.

- Evaluation of drugs and other therapeutic procedures for blood pressure control and assessment of the effects of these measures in reducing illness and death from hypertension and hypertension-associated cardiovascular disorders.

- The role of the nervous system, hormones, and other biologically active substances in the regulation of blood pressure.

- Diagnosis and treatment of hypertension secondary to kidney disorders, endocrine disturbances, and certain tumors.

- Comparison of surgical and medical treatment in the management of renovascular hypertension.

- Isolation, purification, and characterization of renin and studies on the role of renin-angiotensin-aldosterone system in the development of hypertensive vascular disease.

- The kidney mechanisms operative in maintaining fluid and electrolyte balance, and disturbances in these mechanisms that may underlie or result from hypertension.

- The identification and typing of hypertensive patients, using endocrine profiles related to electorolyte metabolism.

- Identification of innovative methods of educating professionals and the general public about all aspects of hypertension.

In the clinical treatment of hypertension, some cases of secondary hypertension can be cured by eliminating the underlying cause (for example, removal of a diseased kidney or adrenal tumor). And essential hypertension, if mild, often can be controlled by curbing salt intake or by weight loss in obese subjects. However, the vast majority of hypertensives must take medication, usually for the remainder of their lives, to achieve and maintain the desired blood pressure levels. In this regard, new drugs continue to be developed and old drugs are found to have new applications in the management of hypertension. For example, propranolol--a drug originally evaluated primarily for the relief of angina pectoris and for the prevention or treatment of heart rhythm disturbances--has proved to be an effective antihypertensive drug as well.

The Institute currently is supporting a number of large-scale clinical trials evaluating measures to avert or delay the onset of crippling or potentially lethal manifestations among persons at high risk by timely interventions against modifiable factors known to increase vulnerability to premature arteriosclerosis. As high blood pressure is a potent factor increasing risk of coronary heart disease and stroke, the value of blood-pressure control measures is being evaluated in two primary prevention trials. The Hypertension Detection and Follow-up Program, whose clinical and evaluation phases have been completed, is described elsewhere in these hearings. The Multiple Risk Factor Intervention Trial involves subjects at heightened risk of coronary heart disease (CHD) because of various combinations of elevated blood pressure, elevated blood cholesterol, and/or cigarette smoking. It is hoped that systematic modification of the factors over a 6-year period will produce substantial reductions in that risk and will be reflected in lowered CHD mortality rates. The clinical course of this study continues in 1981.

In 1977 the Institute initiated large-scale state-wide demonstration projects in hypertension education, screening, and control throughout the states of California, Connecticut, Maryland, and South Carolina. Similar projects have since been funded in Georgia, Maine, and Michigan. The goals of these projects are to provide expansion and effective coordination of ongoing education, screening, and treatment activities so as to avoid needless duplication or fragmentation of effort while insuring the availability of effective methods of hypertension detection and control, not only to communities throughout the state but to rural areas as well. It is also hoped that the experience of these states may provide encouragement and possible models for other states desiring to undertake similar programs.

The Institute also is funding demonstration projects concerned with hypertension detection and control in the work setting at four Ford plants in Southeastern Michigan, five Westinghouse plants around the U.S., and among Maryland state employees in Baltimore. Pilot evaluation studies of hypertension control in communities with a high incidence of the disease have been initiated in Detroit; Berkeley, California; and also in rural areas of North Carolina, Georgia, and Kentucky.

The Institute is aware of the timely interest the Committee has taken in its hypertension education programs. Coordinated by NHLBI, the National High Blood Pressure Education Program (NHBPEP), since its inception in 1972, has carried out a wide range of activities concerned with alerting health professionals and the general public to the wide prevalence of hypertension, the dangers that uncontrolled hypertension poses to the victim's health and life, and the benefits of early detection and adequate treatment. The program enjoys the support and cooperation of numerous federal agencies, 150 or more national organizations, and virtually all state health departments. Its success has been reflected in sharp decreases in the numbers of hypertensives unaware of their disease, by dramatic increases in patient visits for hypertension and in prescriptions written for blood-pressure drugs, and by substantial increases in the numbers of hypertensive patients whose blood pressure is under adequate control.

In 1980 the Institute has received more training resources. This is allowing for additional competing new and renewal awards and for a much needed increase in stipend levels for these young investigators. The NHLBI currently has 18 training programs primarily concerned with hypertension, and others of which hypertension training is a part. Assessing 1979 data, it was found that the Institute is supporting 100 postdoctoral trainees in the high blood pressure area; of these 30 hold MD degrees and 70 are Ph.D.s. There has been a progressive increase in the number of trainees in high blood pressure since 1976. The Minority Hypertension Research Development Seminar Program, also announced in 1976, is designed to encourage the recruitment and development of minority investigators in specialized areas of research, prevention, control, and education related to hypertension. This is accomplished by establishing Hypertension Training Centers in university medical schools with strong, well-established hypertension research training programs. These centers develop summer research training opportunities in cooperation with minority schools for minority school faculty members or graduate students. The program now costs approximately $700,000 and consists of 17 centers cooperating with 53 minority institutions with over 150 training slots currently available.

In conclusion, although current knowledge allows neither prevention nor cure of essential hypertension, research over many years has yielded a large body of information about blood pressure control mechanisms and some of the derangements that occur. It has yielded effective means for identifying potentially curable secondary forms of high blood pressure and for searching out the few persons most likely to benfit from surgery or other definitive therapy. It has led to the development of many drugs that are very useful for controlling high blood pressure of all degress of severity and agreement that such drugs can prevent complications and save and prolong lives. Of particular importance is the recent demonstration of the importance of controlling even the "mild" hypertensive.

Continued research may yield even safer, more effective drugs or, preferably, preventive measures that may eliminate high blood pressure and its consequences as major causes of illness, disability, and death in the United States and around the world. In the meantime, ongoing public and professional education activities of the National High Blood Pressure Education Program continue to foster increased application of our current knowledge that is so valuable for the control of hypertension, so that growing numbers of hypertensives will become aware of their disorder and motivated to adhere to prescribed treatment regimens. The budget increase for 1981 is 3.9% for all high blood pressure programs.

Question: How are you interacting with the American Red Cross, Health Services Administration, and state and regional programs in this regard?

Answer: The Red Cross has set hypertension control as a priority and is an active participant on our National High Blood Pressure Education Program Coordinating Committee. We provide technical assistance both to its national headquarters staff and to its chapters involved in local control efforts.

61-400 O - 80 - 45

The Institute's interactions with the Health Services Administration have already been detailed in answer to a previous question. In terms of states, as I just mentioned, we support a variety of hypertension control demonstration projects. We provide continuous and extensive technical assistance to the states and, in addition, we sponsor annually a national conference on high blood pressure control and High Blood Pressure Month in May, both of which elicit highly active state participation.

Question: Do you feel there are some tangible results from public education programs?

Answer: I believe there is no doubt that public education has produced not only tangible, but impressive results. In 1973 we performed a survey of public knowledge about high blood pressure to help plan educational activities. We repeated that survey in 1979. The findings show clear and striking changes in the public's understanding of high blood pressure. In 1979, 73 percent of the public, compared with 63 percent in 1973, believe hypertension is a serious condition. Between 1973 and 1979 the percent of the public having their blood pressure checked within the last 12 months increased from 73 percent to 83 percent. Nearly twice as many people now know what a normal blood pressure is. Forty percent more people understand that hypertension does not have reliable symptoms. More people believe there is effective treatment for hypertension. Greater numbers of people are following their therapy.

Looking at other data, although our analysis is not yet complete, it appears that stroke death rates are measurably lower over time in communities having active education programs compared with those that do not.

In short, we believe that public education does work and has worked. We are pleased with these results, but have no inclination to rest on our laurels. More education needs to be accomplished, and we intend to pursue this activity vigorously.

PERCENTAGE INCREASE IN NHLBI 1981 BUDGET

Question: What percent increase is the Administration's budget request for the Heart Institute for FY 1981 over FY 1980?

Answer: The 1980 adjusted budget authority of $527,806,000 increases to an Administration budget of $548,399,000 in 1981, an increase of 3.9%.

Question: How does this compare with the budget request sent to the OMB by the Heart Institute?

Answer: In its 1981 Forward Plan review within the NIH, the Institute's request was $642,160,000. In turn, the NIH allocation for the NHLBI was $570,000,000. The Departmental request sent to the OMB for the NHLBI was $550,091,000, an increase of 4.2% over 1980.

PERCENT OF APPROVED GRANTS FUNDED

Question: If the budget request for Heart is sustained, what percent of approved grants can be funded?

Answer: The NHLBI has estimated it would be able to fund 20% of approved competing research project grants at the 1981 budget request.

Question: Is this not the lowest percentage in Heart Institute history?

Answer: The Institute anticipates that the number of approved applications for competing research projects will increase in 1981 due to continued growth in the number of approved applications received each year by NHLBI--an increase which has averaged 12% over the past 10 years, as well as an increase in approved applications carried-over from 1980.

Because the budget will support approximately the same number of competing projects as in 1980 the percentage funded will decline. If estimates are accurate, the rate of approvals funded would be approximately 20% which is lower than in previous years.

RESEARCH TRAINING FUNDS

Question: In research training funds, how many new awards or new renewals can be given under the Administration's budget request?

Answer: No new or competing research training or fellowship awards can be made at the Administration's budget request. However, the noncompeting commitments made prior to 1981 can be funded.

Question: If the budget request is sustained for research training funds, what will have been the trend in funding research training grants for the last 3 years, most particularly for new positions or new renewals?

Answer: NHLBI funding for 1979, 1980, and 1981 for research training is summarized on the following table. NRSA training was funded under a continuing resolution in 1979 which prevented the awarding of many meritorious, new or renewal applications in that year. The training budget in 1980 therefore represents the funding of many highly qualified applications which were not funded in 1979, as well as stipend and institutional allowance increases. The total number of trainees supported, especially in the cardiovascular area, is then closer to the figures of former years.

National Heart, Lung, and Blood Institute

National Research Service Awards (NRSA)
(amounts in thousands)

	1979			1980[2/]			1981[2/]		
	No.	FTE[1/]	Amount	No.	FTE[1/]	Amount	No.	FTE[1/]	Amount
Individual NRSA									
Noncompeting.....	89	89	$1,258	93	93	$2,046	210	210	$4,305
Competing									
New.....	80	80	1,182	184	184	3,600	--	--	--
Renewal.....	3	3	50	--	--	--	--	--	--
Supplemental.....	(8)	--	6	--	--	--	--	--	--
Subtotal competing	83	83	1,238	184	184	3,600	--	--	--
Subtotal individual...	172	172	2,496	277	277	5,646	210	210	4,305
Institutional NRSA									
Noncompeting.....	215	1,177	17,528	163	843	16,208	253	1,306	26,724
Competing									
New.....	21	87	1,258	88	350	7,158	--	--	--
Renewal.....	--	--	--	40	208	4,256	--	--	--
Supplemental.....	(2)	2	28	--	--	--	--	--	--
Subtotal competing	21	89	1,286	128	558	11,414	--	--	--
Subtotal institutional	236	1,266	18,814	291	1,401	27,622	253	1,306	26,724
Total training, NHLBI	408	1,438	21,310	568	1,678	33,268	463	1,516	31,029

1/ Full-time equivalents
2/ Includes stipend increases

NUMBER OF APPROVED GRANTS FUNDED

Question: The administration is stressing stabilizing investigator initiated grants. What will be the number of such grants which the Heart Institute can fund under the FY 1981 budget request?

Answer: The NHLBI has estimated it would be able to fund 601 competing research project grants at the 1981 budget request.

Question: What has been the average number which the Heart Institute has funded over the last 3 years?

Answer: Over the past three years the NHLBI has funded 729 grants in 1977, 759 grants in 1978, and 942 grants in 1979 for an average of 810 competing research project grants per year.

Question: What amount of funds would be needed to restore investigator initiated grants to this average of the last 3 years?

Answer: In order to fund 810 competing research project grants in 1981, the Institute would need an additional $33,400,000.

PROBLEMS IN HEART DISEASE RESEARCH AND TREATMENT

Question: What are the primary problems now in heart disease research and treatment?

Answer: Very briefly, the causes and prevention of arterio sclerosis and treatment to retard its progression; the mechanisms of and susceptibility for high blood pressure, its possible nonpharmacological therapy and fine tuning the indications for treatment; in coronary heart disease the recognition of those who will develop the disease, procedures to prevent sudden cardiac death, therapy to reduce heart damage in association of heart attack, the management of angina pectoris and the role of coronary bypass surgery; in peripheral vascular diseases the development of arterial protheses for smaller vessels; for cardiomyopathies - inflammatory and degenerative disorders of the heart muscle - putting them into perspective as to their importance and understanding their causes; for heart disease in general, better diagnostic and quantitative methods with attention to their indications and limitations.

PROMISING AREAS

Question: What are now the most promising areas of heart research and heart treatment development?

Answer: It is difficult to be both inclusive and brief.

In the area of atherogenesis, the possible contributory role of platelets - "thrombo atherogenesis" - and the possible interruption of this phenomenon with drugs are new and exciting areas of research.

Studies of factors effecting arterial wall metabolism, interaction with vascular reactants and the effect of injury and mitogens on arterial wall cells. Clarifying the role of diet, both in those

with specific lipid disorders and in the general population, is of major importance. The "lipid hypothesis" is in the process of assessment. Methods of recognizing and quantifying subclinical atherosclerosis are under active and promising development.

In hypertension, the whole question of the causes of elevated blood pressure is evolving. The identification of persons susceptible, perhaps by their genetic and metabolic makeup, and the possible role of salt are among important current topics. The great value of the control of blood pressure by drugs has been shown, but the possible value of nonpharmacological therapy as a contributory, or in some cases a primary, role has to be developed. Fine-tuning the indications for treatment, for example, in the elderly with systolic hypertension in warranted.

For coronary heart disease, the recognition of those who are susceptible is of great importance. An understanding of the precipitants of acute cardiac events is necessary. The role of coronary artery spasms, a new concept of recent years, is evolving. Therapy designed to reduce the amount of heart muscle subject to irreversible damage in the course of heart attack is being evaluated with a goal of reducing the amount of irreversibly damaged heart muscle and therefore the amount of ultimate heart impairment. Chronic therapy, to prevent recurrence of heart attack or to prevent sudden cardiac death in those at heightened risk through drugs which interfere with platelet aggregation and through drugs which tend to stabilize the rhythm of the heart, is under study. The results are awaited. New drugs are being assessed with apparent increasing effectiveness and less toxicity for the chronic management of rhythm disturbances. Drugs which will enhance the effective force of the heart beat in the damaged heart are under promising clinical investigation. A more precise definition of the indication for coronary artery bypass surgery and the assessment of its long term results is in progress and the results are badly needed. Alternatives for coronary bypass surgery - instrumental techniques such as the percutaneous transluminal coronary angioplasty and better pharmacological control of angina pectoris - are the topic of active investigation. The instrumentation to permit more accurate assessment of the severity of disease and the effects of therapy, be it on the heart and coronary anatomy, on the heart muscle and its integrity, on its electrical properties, or on the release of chemical substances from the heart muscle, are under development.

Cardiomyopathies - primary disorders of the heart muscle--are recognized with increasing frequency and they are the topic of increasing investigation. Their onset may be associated with a mild viral infection with completely inapparent reasons or they may develop gradually as progressive degeneration or as a progressive overgrowth of heart muscle. The causes of these conditions remain obscure and their recognition and prevention represent important topics of current research.

For congenital heart disease, the whole area of developmental biology, the different behavior of fetal, neonatal, infant, and adult tissues to their environment and to drugs and the effects of all this upon the normal and abnormal development of the cardiovascular system are topics of active research and great importance.

The prevention of congenital heart disease through an understanding of developmental biology and what may interfere therewith is of high importance. Methods of therapy particularly suited to the neonate with congenital heart disease are of special interest.

For peripheral vascular diseases, the developments of vascular surgery are being extended to involve smaller and smaller vessels, but this requires the development of prosthetic grafts of correspondingly smaller diameter with appropriate long-term ability to remain open and free of clot. Improved developments for the noninvasive detection and quantification of lesions of the arterial tree are also of great importance.

Diagnostic and quantitative methods of relevance to all facets of cardiovascular disease are the topics of important development. These include more informative, complete, and precise "noninvasive" techniques from lower x-ray doses to echocardiographic techniques, radioisotopic methods, enzyme methods, electrocardiogram mapping methods, radioimmunological methods, continuous rhythm monitoring techniques, and the use of stress as well as rest measures of several of these tests. Determining the indications, limitations, and optimal utilization of these technologies - and the recognition of when they are not needed - are important topics of research.

As more is learned about which people are at risk and what people should do, so education and development programs must be developed. Behavioral research and communication, in general and specifically as they relate to diseases of the heart and vascular system, are also important current topics of research.

HEART DISEASE RESEARCH FUNDING

Question: How will a budget increase of less than 4%, the increase proposed in the budget request which represents a decrease in real funds in the face of an inflation rate of 13% or more in 1979 and a projected one of 11% in 1980, affect our heart research effort?

Answer: In the discussion of research, it is important to emphasize that we will be funding 601 essential new and competing research project grants, approximately the same number as in 1980. Furthermore, all research centers and other research programs will be funded at the 1980 level. This is possible in part, because research training is being held to the commitment base level. This means that no new research training grants or fellowships will be made in 1981. Naturally our peer review groups will assign the highest priority to those grants that have the greatest chance of success. Those that are more speculative, or of lessor merit will be less likely to be funded.

Question: When one factors out the funds for lung and blood programs in the Heart Institute budget request, how much will be left for heart research and heart programs?

Answer: Almost 33% of the National Heart, Lung, and Blood Institute programs go towards lung and blood activities, leaving essentially 67% to the heart and vascular diseases areas. In 1981,

it is estimated that $317.162 million will be spent in extramural grants and contracts, and approximately $32.083 million will be spent in the intramural program. Prorating the other costs of the Institute, two-thirds to heart and vascular adds up to a grand total of $370.850 million which includes not only the research grants, contracts, and training programs of the Institute, but also its direct operations and program management costs.

Question: The proposed funding for heart research and heart programs represents approximately how much per death due to heart disease?

Answer: There are just under one million deaths due to heart and vascular diseases in the United Staates annually. Thus, this $370.850 million represents about $370 per death. It represents $9.25 per person in the United States who now has heart or vascular disease. Even more significantly, of the more than 220 million Americans now living, if the current mortality rate were to prevail, a little more than half will die of heart and vascular diseases. Thus, for each American now living who will die of heart or vascular disease, about $3.25 is being spent annually for research in the prevention and better treatment of the disease with which he or she will become afflicted and from which he or she will die.

DIET AND CARDIOVASCULAR DISEASE

Question: Many reports have been published in the past ten years on heart disease which emphasize the importance of low cholesterol diet to prevent heart disorders. These reports include the recent report by the Surgeon General, Healthy People, and the National Heart, Lung, and Blood Institute's Task Force on Arteriosclerosis. Yet, NHLBI has made little effort to launch a strong publicity campaign to inform the public of the importance of a low fat and salt diet to lowering the risk of cardiovascular disease. Why is this the case? What information does NHLBI feel to be necessary before it agrees with others who have conducted studies on the importance of diet to cardiovascular diseases?

Answer: NHLBI has invested a considerable portion of its resources into the question of diet and cardiovascular disease. In the message it conveys to the public and health professionals via mass media, publications, journal articles, conferences, etc., it frequently addresses this concern of diet and heart disease. We impart our messages on the basis of what is established as scientific fact and are candid about what is still uncertain. The potential dangers of excess salt intake as it relates to high blood pressure, for example, plays a prominent part in our National High Blood Pressure Education Program. We also disseminate the fact that calories do count and that dietary fat is both a source of excess calories and, if of animal origin, a source of cholesterol. We further verify that saturated fats and dietary cholesterol elevate the level of cholesterol in the blood and that diets low in fat and cholesterol will lower the blood cholesterol level. The message we cannot convey at this time because we feel it has not been established as scientific fact is that lowering the serum cholesterol to a certain level will help prevent a heart attack.

The position of the NHLBI and its scientific advisory groups is that the evidence available regarding cholesterol lowering and heart disease is not adequate to serve as the basis for an educational campaign aimed at the general public similar, for example, to that of the National High Blood Pressure Education Program.

Studies supported by us have provided epidemiological evidence, as well as evidence based on animal studies, suggesting the link between cholesterol and heart disease. However, we feel that the extent of this linkage is still not clear and that the evidence is not consistent enough nor convincing enough to warrant definitive dietary recommendations to the general public to prevent heart disease.

NHLBI is supporting clinical trials seeking to validate several research hypotheses and findings bearing on the relationships between nutrition and heart disease. Should we obtain sufficient definitive evidence of such a linkage, we would be most aggressive in launching an education campaign. To do so prematurely, however, could both mislead the public and damage the credibility needed to convince people that the nutritional changes we encourage are indeed essential to their good health.

NATIONAL CANCER INSTITUTE

STATEMENT OF DR. VINCENT DEVITA, JR., ACTING DIRECTOR

BUDGET REQUEST

Senator SCHWEIKER. We are going to turn to National Cancer Institute, Dr. Vincent DeVita, Jr., the Acting Director of the National Cancer Institute will be our next witness.

Dr. DeVita is the Acting Director of the National Cancer Institute.

You have submitted a budget request of $1,007,800,000. This represents an increase of $6,998,000 over fiscal 1980.

We will insert your full statement in the record. Do you have any comments you would care to make.

[The statement follows:]

CURRICULUM VITAE

Name: Vincent T. DeVita, Jr., M.D.

Date & Place of Birth: March 7, 1935; Bronx, New York

Education:

1957 - B.S. (Chemistry) College of William and Mary, Williamsburg, Virginia

1961 - M.D. (With distinction) George Washington School of Medicine, Washington, D.C.

Positions Held:

1961-62: Internship, University of Michigan Medical Center, Ann Arbor, Michigan

1962-63: Residency in Medicine, George Washington University Medical service, District of Columbia General Hospital, Washington, D.C.

1963-65: Clinical Associate, Laboratory of Chemical Pharmacology, National Cancer Institute, Bethesda, Maryland

1965-66: Senior Residency in Medicine, Yale-New Haven Medical Center, New Haven, Connecticut

1966-68: Senior Investigator, Solid Tumor Service, Medicine Branch, National Cancer Institute, Bethesda, Maryland

1968-71: Head, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institute of Health

1971-74: Chief, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1974- : Director, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1975 Clinical Director, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1980 - Acting Director, National Cancer Institute, National Cancer Program, National Institutes of Health, Bethesda, Maryland

Academic Appointments:

Associate Professor of Medicine, George Washington University School of Medicine, Washington, D. C., 1971-75
Professor of Medicine, George Washington University School of Medicine, Washington, D.C., 1975

Editorial Boards:

Associate Editor, Journal of the National Cancer Institute, Bethesda, Maryland, 1968-74
Scientific Editor, Cancer Chemotherapy Reports, National Cancer Institute, 1970-74
Advisory Editor, Journal of Radiation Oncology, Biology, and Physics, 1975 -
Associate Editor, Editorial Advisory Board, Cancer Research, 1976-79
Member, Board of Medical/Scientific Consultants, Cancer Nursing, 1977-
Member, Board of Scientific Council, "Cancer Chemotherapy and Pharmacology", 1977-
Associate Editor, Cancer Clinical Trials, 1977-
Member, Editorial Board, Amer. Federation of Clinical Oncologic Soc., 1977-
Member, Editorial Board, American College of Physicians A.C.P. Audio Cassette Program, 1979-1980

Member, Editorial Board, Seminars in Oncology.
Associate Editor, The American Journal of Medicine, 1978-1981

Committees and other Offices:

Councilman, Assembly of Scientists of the National Cancer Institute, National Institutes of Health, 1968-70
Chairman, Program Committee, American Society of Clinical Oncology, Inc., 1972
Clinical Research Committee, NCI
Board of Directors, American Society of Clinical Oncology, 1973-76
American College of Surgeons Commission on Cancer, Committee on Patient Care and Research, 1975-78
Advisory Committee on Clinical Investigations II - Chemotherapy and Hematology, American Cancer Society, Inc., 1975-76
Publications Committee, American Society of Hematology, 1975-
WHO Expert Advisory Panel member, 1976
Board of Directors, American Association Cancer Research, 1976-79
Lasker Award Jury, 1976-
President, American Society of Clinical Oncology, 1977-78
Chairman, Committee of the French-American Agreement, 1976-
Chairman, Special Membership Committee, American Association for Cancer Research, 1978-79
Member, Panel of Consultants on Clinical Oncology International Union Against Cancer, 1979-82

Specialty Board Certification:

Diplomate of the National Board of Medical Examiners, 1961
Diplomate of the American Board of Internal Medicine, 1968
Diplomate in the Subspecialty of Hematology, American Board of Internal Medicine, 1972
Diplomate in the Subspecialty of Medical Oncology, American Board of Internal Medicine, 1973
Recertification, American Board of Internal Medicine, 1974

Professional Societies:

Fellow, American College of Physicians
American Medical Association
American Society of Hematology
American Society of Clinical Oncology
American Association for Cancer Research
American Federation for Clinical Research
American Society for Clinical Investigation, elected May, 1972
Society of Surgical Oncology (Ewing Society)

Honors and Awards:

Alpha Omega Alpha Medical Honor Society
Smith-Reed-Russell Medical Honor Society
Tobacco Research Industry Fellowship, Mount Desert Island Biological Laboratory, Bar Harbor, Maine, 1959
Award by the Government of Peru, "Oren del Sol en el Grando de Official", 1970
Visiting Professor of Medicine, Stanford University School of Medicine, July, 1972
Albert and Mary Lasker Medical Research Award, November 16, 1972
First Annual Clowes Lecture, Roswell Park Memorial Institute, October, 1973
DHEW Superior Service Award, 1975
Esther Langer Award, June 1976
Alumni Medallion, College of William and Mary, October 1976
Jeffrey Gottlieb Award, November 1976
Karnofsky Lecture, ASCO Meeting, May 1979

Martial Status: Married, two children

Present Address: 9925 Julliard Drive
Bethesda, Maryland 20014

STATEMENT OF DR. VINCENT DEVITA, JR.

I am pleased to have this opportunity to present the budget of the National Cancer Institute and to discuss our accomplishments of the past year and our plans for the coming year in cancer research.

Cancer, as it expresses itself clinically, must be regarded as a complex of many related diseases. It actually appears as more than 100 different diseases. Cancer also has many different causes. Chemicals, viruses, and radiation all have been implicated as inducers of the cancer process. At the cellular or molecular level there very well may be a single, common mechanism, some sort of switch, for the disease. Such a switch may trigger a cell to become cancerous no matter which body organ or causative agent is involved. But at this point, a central mechanism remains elusive. The NCI will continue in 1981 its strong commitment to support investigators who are pursuing studies in fundamental cancer research.

Despite our lack of understanding cancer's most basic mechanism, much can be done. It is obvious that the environment plays a major role in cancer causation, and this presents opportunities for cancer prevention.

Environmental factors associated with cancer include not only chemicals found in the air, water, and workplace, but also factors associated with our society and culture, such as tobacco, alcohol consumption, dietary habits, sexual and child-bearing patterns, and perhaps even stress. For example, nearly 1,200,000 new cases of cancer, including the most common skin cancers, are expected to occur this year. Of these new cases, most of the 400,000 skin cancers are associated with excess exposure to the sun and ultraviolet light; 125,000 are attributable to tobacco use; and some computations have suggested well over 50,000 may be associated with occupational exposure to cancer causing agents; and others suggest that perhaps as many as 100,000 are associated with as yet unidentified dietary factors. Prevention efforts could help for many of these.

Reorganization Focuses on Prevention

A major reorganization of the National Cancer Institute has been proposed to improve, among other things, coordination in prevention research, chemical testing and related activities. We have arranged funding priorities to give greater emphasis to prevention activities. A new division will incorporate cancer control, centers, and training and education activities. This division will devote a major portion of its budget to applied prevention.

The Institute's smoking and nutrition programs illustrate further how the reorganization has emphasized prevention activities. Both have been made Institute-wide programs. The new Smoking, Cancer and Health program emphasizes prevention activities rather than development of a less hazardous cigarette. Coordination of the Diet, Nutrition and Cancer Program was discussed before this committee last year. The potential for prevention of cancer by dietary means continues to receive NCI's strong support. Last October, the NCI issued simple, prudent, interim dietary principles that may minimize one's cancer risk.

Occupational Factors

The NCI collaborates with the National Institute for Occupational Safety and Health to explore opportunities for cancer prevention in the workplace. Altogether 68 projects are in progress; some 30 of these concern specific industries, such as beryllium, paint trades and pesticide formulation.

Epidemiologists in our intramural program continue to pursue leads on occupational and other factors that appear associated with cancer, using clues generated from the survey of cancer death rates for the period 1950 to 1969 in all continental U.S. counties. This survey indicated a higher cancer rate among male residents of 39 counties where the primary industry was petroleum manufacture.

Through the Oil, Chemical and Atomic Workers Union, NCI scientists gained access to employee health records at 5 specific plants in Texas. They found increased frequencies of cancer of the brain and central nervous system in a large petroleum refinery where most of the employees are production workers. In another plant that also produces sulfuric acid, the scientists found increased frequencies of stomach, skin and kidney cancers. In a third refinery, the number of brain and lung cancer deaths observed was greater than expected. No excesses of cancer were found in the other two plants.

NCI epidemiologists are now examining workers' records in detail for clues to a common workplace exposure that may account for the increase in cancers.

Low-Level Radiation

Concerns about the effects of low-level radiation were heightened by the accident at the Three Mile Island nuclear plant. The NCI led a committee to assess the need for followup studies of the health effects on the off-site populations resulting from the releases of radioactive material during the accident.

NCI epidemiologists initiated a new intramural program to examine the risk of cancer in populations exposed to ionizing radiation, especially at low dose levels. The NCI group also collaborates with other government agencies involved in radiation research.

Testing Chemicals

The NCI continues its program of animal testing for carcinogenicity of suspected environmental chemicals. Functioning now as part of the HEW National Toxicology Program, the program will initiate about 75 tests in 1980, and plans to increase that number in 1981.

When properly performed, tests on laboratory animals are reliable predictors of cancer-causing potential in man. The artificial sweeteners provide an excellent example. Results of the recently-completed NCI/FDA epidemiological study on 9,000 Americans are consistent with earlier animal studies showing the artificial sweeteners to be weak carcinogens and enhancers of the carcinogenic action of other chemicals. This epidemiological study used our existing SEER (Surveillance, Epidemiology and End Results) Program to help identify the nearly 3,000 bladder cancer patients who participated.

Activities to Increase Survival of Cancer Patients

Detection of cancer at its earliest stages--a time when it is most treatable--is one effective way to increase the survival of cancer patients. Mass screening of asymptomatic women with the Pap test has contributed to the reduced mortality from uterine-cervical cancer. Opportunities to do the same for breast cancer using mammography and physical examination appear promising for women over age 50. Because of the exposure to low-level radiation associated with mammography, the NCI will be supporting clinical trials to determine its usefulness for women aged 40 to 49 and to determine the optimal frequency of screening for women of all ages.

Four years ago, scientists in England discovered a powerful research tool that holds great promise for the early detection and possibly the treatment of cancer. The British scientists created "hybridomas" by causing antibody-producing spleen cells from mice to fuse with cells that grow continuously in tissue culture. Such hybrid cells secrete large quantities of a single kind of antibody, which is called monoclonal antibody.

This technology is being used in fundamental research funded by NCI to understand the mechanisms of cancer causation. But it also may allow us to take advantage of unique antigens that occur on cancer cells to detect cancer at a stage earlier than ever before. Because the body's immune system is exquisitely sensitive, this technology enables us to label cancer cells anywhere in the body. Scientists have already demonstrated that monoclonal antibodies labeled with radioactive iodine can be used to test for the presence of cancer cells in mice. Hybridoma technology also holds promise for cancer therapy. About half of the pending grant applications in NCI's Immunology Program include work with hybridomas and/or monoclonal antibodies.

Successful treatment of cancer is cure. We define cure in a very strict way. A patient is considered cured if he or she remains free of disease and has the same life-expectancy as a person who never had the disease. Of the more than one million Americans who develop cancer this year, 58 percent can expect to be cured of their disease using currently available techniques. Even if one subtracts the 400,000 patients with the easily curable skin cancers and in situ cancers of the uterine cervix from the total, approximately 41 percent of patients with serious cancers can still be cured by using one or more of the three main approaches to treatment: surgery, radiotherapy and chemotherapy.

The National Cancer Institute has been in the forefront of anticancer drug development since 1955 when Congress appropriated funds for such a program. Aclacinomycin A is a second cousin to the very active drug Adriamycin, but the analogue is devoid of the troublesome side-effects of hair loss and cardiotoxicity. It came from Japan and is one of the drugs that was put into clinical trials this year. A major effort of the NCI program is development of drugs like Aclacinomycin A that are analogues of active drugs but have less toxicity. We term these "second generation" anticancer drugs.

In the NCI's continuing search for improved forms of treatment, three U.S. medical insitutions were awarded support for construction of neutron generators and for clinical trials on 3,000 cancer patients to evaluate this promising new high-energy form of radiotherapy.

Neutrons have an advantage over conventional X-rays because their effect is less dependent on oxygen, thus offering a possibility of activity against large tumors that have oxygen-deficient regions.

New Program

This year the NCI has launched a program to explore the use of substances that we call "biological response modifiers." These are substances, such as interferon, many of which are made by the body and in some way may alter its response to cancer. Because of the nature of these substances and their action on the host rather than the tumor, they may be less toxic than conventional chemotherapy. NCI plans to purchase enough interferon to treat 400 cancer patients. This resource will allow investigators to evaluate whether the positive clinical findings that have been reported for a few patients can be confirmed.

Cancer Centers

With the beginning of a new decade, we have many new leads to pursue. Passage of the National Cancer Act in the beginning of the 1970's increased our freedom of funding and brought us far in the development of new ideas. The cancer centers, for example, mandated by that Act, have developed into an enormously important national resource. We have recognized 21 comprehensive centers that conduct the full spectrum of research, treatment, and community outreach activities. Another 41 are specialized centers to conduct clinical and non-clinical research. More than 90 percent of the U.S. population now live within 200 miles of a comprehensive or clinical cancer center.

Appropriations Request

Mr. Chairman, the request for the National Cancer Institute for fiscal year 1981 totals $1,007,800,000. This is an increase of $6,998,000. The new request includes $313,545,000 for Cause and Prevention Research; $57,796,000 for Detection and Diagnosis Research; $318,418,000 for Treatment Research; $142,832,000 for Cancer Biology; $68,371,000 for Cancer Centers Support; $37,790,000 for Research Manpower Development; $3,941,000 for Construction; and $65,107,000 for Cancer Control.

I shall be pleased to answer questions and supply additional information desired for the record.

Mr. Chairman, this concludes my statement.

MORTALITY AND MORBIDITY

Dr. DeVita. Yes, Mr. Chairman. I would like to highlight a few points of the program.

I think I only need to remind the committee of the magnitude of the cancer problems in the country to highlight the Institute's budget.

61-400 O - 80 - 46

The death and morbidity from cancer costs the American people about $30 billion a year in medical care costs. I am pleased to say that there has been some progress as shown in our mortality data figures.

We are beginning to see a downturn in mortality from cancer below the age 55.

Disease specific mortality data comparing 1960 to 1963 with 1970 to 1973 also show an increase in survival in some of the more common cancers which we hope will be translated on a nationwide basis very shortly. We are very encouraged with that last piece of information.

BUDGET CATEGORIES

Our budget is divided in four thrusts. I would like to make just a few comments in each of the four areas: Biology, cause and prevention, detection and diagnosis, and treatment.

First, my colleague Dr. Kirschstein covered some important areas in biology that also pertain to cancer; new techniques, such as DNA sequencing, DNA splicing, DNA recombinant research all of which are applicable to understanding the genes that control growth. Much study in this area is going on in the cancer program.

The current budget that will stabilize research projects, will allow us to fund the high-priority research in this area.

We divide our cause and prevention thrust into three areas; discovery of causes of cancer, mechanisms of action, and application.

There are some good leads in the etiology of cancer that we believe are worth emphasizing and that require further work, for example, smoking and cancer. About 125,000 cases of cancer a year in this country are related to smoking. Also, occupational causes of cancer are known in areas that can be approached.

We estimate as many as 100,000 cases of cancer a year in this country may be related to overconsumption of some constituents of our diet.

And, radiation exposure is another area warranting further investigation.

Senator SCHWEIKER. I see we have no smokers at the table right now.

Dr. DEVITA. That's right.

EPIDEMIOLOGY

At the human level in epidemiology we have a program which is concerned with looking at environmental causes of cancer. I am pleased to say a great deal of progress has been made in this area.

As you probably have heard, in previous years, maps were developed by the Institute showing clusters of certain kinds of cancer. These have been followed up and there is a good bit of research going on in this area.

Between 1977 and 1980 we actually doubled the resources in the field studies and statistics area, so we feel we have given priority to this particular program dealing with chemical causes of cancer.

NATIONAL TOXICOLOGY PROGRAM

Dr. Rall yesterday related the development of the national toxicology program.

In the 1981 budget, the Institute contributes an increase of $20 million to the growth of the national toxicology program.

PROMOTERS

In the area of mechanisms of action, we are excited by some new work on cancer promoters. These are to be distinguished from chemicals that are initiators of the cancer process.

There is some evidence that promoters play a very significant role in the etiology of cancer. For example, cigarette smoke may contain a significant number of promoters; colon cancer, may be related to promoters. in our diet; bile salts in the diet may serve as promoters.

The significance of promoters is that removal can lead to a rapid downturn of the incidence of a particular cancer.

Senator SCHWEIKER. The industrial chemicals we call carcinogens, are they promoters or initiators?

Dr. DEVITA. We are not sure in each case. Many are initiators. Many potent carcinogens we know are initiators. There is evidence that if you get an initiator in low enough doses in some experimental animals——

Senator SCHWEIKER. The TCE we were talking about yesterday, is that an initiator?

Dr. DEVITA. I really don't know. An initiator in a low enough dose may not cause a cancer unless combined with a promoter at a later stage in the development of the process.

Our problem, of course, is how to identify promoters, and there is much research going on to develop tests to identify promoters.

PREVENTION

In the area of application of prevention opportunities, we have made some strides. We have recently reorganized the Institute so that we have a new division which will concern itself with the applied part of prevention. This division will combine the control, centers, education, and organ site programs. We hope by more efficient use of all these resources, to bring their efforts to bear on areas such as smoking and health, asbestos and radiation.

The budget in these combined programs in 1981 should allow us to proceed quite effectively in these areas.

TREATMENT

Finally, in the treatment area, some new initiatives that have been started over the last couple of years will be maintained. For example, two new medically dedicated neutron generators will be initiated in 1981; and the radiosensitizer program will continue. Research for second-generation anticancer drugs will continue and there are promising results.

For example, we have a new drug, aclacinomycin, which is related to the very commonly used drug, adriamycin, used in breast cancer. This drug doesn't cause heart damage or hair loss, like the parent compound. We are quite encouraged that if we look we can find these kinds of compounds.

The drug development program turned out 15 new compounds this year, and filed 8 new investigational drug applications—IND's—with the Food and Drug Administration.

Finally, in clinical trials we support—unlike some of our other institutes, a multitude of different diseases are the clinical expression of cancer—we support 732 clinical trials involving 36,000 patients.

I am sure you have heard about the results in sarcomas, breast cancers, and some of the other tumors.

I'd be glad to respond to your questions in these areas if you have them.

The budget in the clinical trials area will allow us to maintain these programs at the current level.

In detection and diagnosis, the discussion earlier today about hybridoma methodology is the newest and most exciting area of research in detection and diagnosis——

Senator SCHWEIKER. With your budget, how can you maintain 732——

Dr. DEVITA. A lot of these studies turn over on an annual basis. We will have a lesser number of protocols but we will be able to maintain high-priority protocols. It will mean that some of the groups that do these studies will have to——

Senator SCHWEIKER. Will you be undertaking new ones or not?

Dr. DEVITA. Yes.

Senator SCHWEIKER. Because of the phasing out?

Dr. DEVITA. Because rollover of protocols will occur.

Mr. Chairman, our budget is $1,007,800,000, an increase of $6,998,000.

I'd be happy to answer any questions.

RESEARCH RESULTS

Senator SCHWEIKER. We hear a lot of negative talk about big spending of our cancer program, and the inability of finding a cure for cancer.

Obviously, we must be doing some things right.

What would you say in summary, do you feel we are getting our fair share of returns for the investment we are making in cancer in terms of the most interesting, promising results of research?

Dr. DEVITA. I tried to highlight some of these points in this statement. I would be happy to reiterate what Dr. Levy said in terms of clinical trials.

They can be looked on as an annuity in a sense, because, for example, our clinical trials in breast cancer have cost us $10 million since 1972. But we estimate that the results will show a 100-percent increase in survival of certain groups of premenopausal women. Those treated with chemotherapy can return about $80 million to the economy.

These kinds of results of clinical trials make it worthwhile to do the clinical trials research.

The explosion in biologic information that's come along in the areas mentioned by my colleagues and reiterated by me also hold a great deal of promise.

We have started a new program, the biological response modifiers program, which will look at natural materials. We are in the process of purchasing interferon, one of these natural materials. You have heard, I am sure, about the reports that some of the new technology has already led to the production of interferon in bacterial systems. They promise to make this material available very cheaply.

Interferon may be a potential tool for treating cancer; it certainly is a very important tool for viral diseases.

These kinds of things highlight what can happen in cancer research.

INTERFERON

Senator SCHWEIKER. Following up on interferon, in last year's committee report, we requested that a study be given Congress about interferon.

This was finally received last month, 6 weeks late. Furthermore, it addressed neither the points our report requested, nor the question of an adequate funding level for interferon research.

Finally, it was poorly written and not at all informative.

Because of this, for the first time in memory, Chairman Magnuson and several members of the committee returned this study to the Secretary and asked that she try again.

What position are you now taking on the importance of interferon research?

Why did you do so poorly the first time out?

Dr. DEVITA. Mr. Chairman, last year a subcommittee of the Division of Cancer Treatment's Board of Scientific Counselors spent a good deal of time developing a plan for the new biologics program. This work culminated in October with a final review of the board and preparation of a two-volume set of the plan for the biological response modifiers program.

In that report there are plans for the purchase of interferon, which are reaching fruition this month.

The report you received followed the final review at the board meeting, in the latter part of October.

The document that summarized the very lengthy report was probably not in enough detail, so that the committee had only a brief summary, or the choice of reading a rather lengthy report, which was probably too much to digest.

Senator SCHWEIKER. Out of the increase—this is from our Senate report, Doctor. Out of the increase which the committee has provided, a substantial portion is to be used in this area. Now, we ended up, I guess, with $13 million out of $63 million.

We have trouble reconciling that with "substantial"—and we're also disturbed at the brevity of the report and the description of the program that we got.

Dr. DEVITA. Mr. Chairman, I do want to emphasize, in fairness to the people who put that report together that it was not a brief report. It was a very detailed one. The error was that you were submitted a too detailed report. We gave a very high priority to the biologics program, and interferon was the top priority of the biological materials.

Senator SCHWEIKER. Well, should we be putting more than $13 million of $1 billion budget into interferon?

Dr. DEVITA. We advertised for competition, for institutions to prepare interferon for clinical trials. We were uncertain at that time what the cost would be to find out whether interferon was useful in cancer. We now know, roughly—it is still not quite firm—that $8 to $9 million will purchase enough interferon to test in 450 patients.

Four hundred and fifty patients should allow us to find the answers to the question of whether any further research should be initiated in interferon, and that money is available within the $13.5 million. An additional $2 million for more clinical testing of interferon to support the clinical trials will also be required.

INTERFERON PROMOTION

Senator SCHWEIKER. Well, we recently read, of course, that Swiss and Finnish scientists have been able to make a substance close in nature to human interferon by advanced biological techniques. Have you studied their results and what do you think of them? Have you cranked this into your equation of spending?

Dr. DEVITA. Yes; we have. We reconvened the committee that made the report on the biologics program and invited Dr. Gilbert to come and make a presentation. Unfortunately, he became ill. But we were able to receive information from him.

His information suggests that his findings right now are preliminary in the sense that pure interferon may not be available for 2 or 3 years. And since this material——

Senator SCHWEIKER. Two to 3 years? This is not what their news accounts say.

Dr. DEVITA. They're making it in very small amounts. They're not making it in quantity. One other point——

Senator SCHWEIKER. I read accounts that said clearly that it was within the year that a substantial amount of this material would be available.

Dr. DEVITA. The material they make is minus the sugar part of interferon. Right at the moment, there isn't any information whether interferon, minus the sugar, will work as well as the full drug.

The conclusion of the committee review of this particular point, Mr. Chairman, was that the NCI should go ahead and purchase the cruder interferon and not wait, and then purchase pure interferon when it becomes available.

I should stress, Mr. Chairman, that we would obviously prefer to purchase pure rather than crude interferon. It's a matter of whether we wait 1, 2, or 3 years, or whatever it takes to do this, and not do any clinical studies, or we proceed with the current material.

Senator SCHWEIKER. Here's an article from Victor Cohn, the health writer of the Washington Post, saying that these bacterial factory scientists said they should soon begin to produce the first substantial quantities of interferon-like substance.

That doesn't sound like 2 or 3 years to me. Vic Cohn is pretty knowledgeable about that.

Dr. DEVITA. I hope that's correct, and we're prepared to purchase

pure interferon as soon as it's available. The real question facing us is whether we should delay purchase of the crude material. It would mean, at the very least, if that article is correct, that we not purchase crude interferon for a year and delay clinical trials for a year.

Our decision is to go ahead with the clinical trials with the crude material and be ready to purchase the pure material as it becomes available. There are many, many companies now working on it.

Senator SCHWEIKER. Another one was just about to announce the same thing. So it's a matter of everybody racing to get it.

Dr. DEVITA. It may come surprisingly fast.

Senator SCHWEIKER. Dr. Levy, did you have a comment?

Dr. LEVY. Just one, Mr. Chairman. Right now white cells are the major source of the interferon that is used. And because our Institute is interested in blood separation procedures our advisory council has recommended that during fiscal year 1980 we find a better way of processing leukocyte—white cell—interferon in larger batches. When we heard about this information, we, too, thought perhaps we didn't have to process white cells any more. Perhaps it wasn't going to be necessary. So we sent inquiries to Europe and other places, and we obtained exactly the same information that Dr. DeVita has; that this is not totally like human interferon, the carbohydrate residue is not there and that it will take a good deal of time before large amounts can be made and it can be shown that it acts exactly like white-cell interferon. And even then, we'll need the white-cell interferon to test against this new material.

So this is an area that has great promise for the future, but not for today.

Mr. NICHOLAS. Mr. Chairman, quantities that are substantial for a biochemist to use in assays and studies are different from those that are substantial for therapists. I think that may be one of the discrepancies in that article of Vic Cohn's.

Dr. DEVITA. We have some purification work of our own going on. Dr. Anfinson of the National Institute of Arthritis, Metabolism, and Digestive Diseases has been working with interferon supplied by the Cancer Institute at a cost to us of $400,000 a year. He is making considerable progress.

INTERFERON COST

Senator SCHWEIKER. Coming back a minute to my original question, is $13 million enough to be spending on interferon?

Dr. DEVITA. We can buy enough to do the trials on 450 patients and support the actual clinical trials, which cost an additional $2 million. We should be able to get an answer within that level.

Senator SCHWEIKER. Should we be spending more?

Dr. DEVITA. If it works on these 450 patients as well as we hope it will work, we undoubtedly will need to spend more. At this point in time, I don't know that answer. I don't know what direction we'll take a year from now. The 450 patients are more than we normally need in what we call a phase II study to determine whether a chemical agent has effectiveness against a whole variety of cancers. In this case, we plan to test interferon against a dozen types of cancer.

COORDINATION WITH NIAID

Senator SCHWEIKER. Also, our report asks you to tell us what they were doing to coordinate the efforts with the Allergy Institute. The report stated to us one meeting was held between the Institutes. You know, with this kind of a technological breakthrough, don't we need to do more than one——

Dr. DEVITA. Dr. Galasso, who is in charge of this program in the Allergy Institute, has been working very closely with us, almost on a daily basis. He has been on all the review committees that review procurements for interferon. So we have had many more than one meeting.

Senator SCHWEIKER. Does he want to comment on it?

Dr. DEVITA. Yes; Dr. Galasso, who was in charge of this program in the other Institute, has worked almost on a daily basis on this.

Senator SCHWEIKER. The report didn't say that, I guess. The report said one meeting.

Dr. DEVITA. The work has really transpired since the October board meeting. The work has been hot and heavy since then. We're working very closely.

Senator SCHWEIKER. Dr. Krause, you want to comment on this?

Dr. KRAUSE. One or two comments. First, although making of interferon by recombinant DNA is a fantastic breakthrough, there is still a long way to go until this technology can be the source of the material. We don't really know what the material is that we obtain from the white-blood cells, and we must know that before we can really be sure that the bacteria are producing the same substance which is so active from the white cells.

So I would support the notion that we must continue to obtain material from white-blood cells as well as pursue the possibility that interferon can be made by recombinant DNA.

Second, I would say this: Interferon was initially described as an antiviral substance, and the effort to determine its antiviral capacity parallels, but not entirely, the effort to determine whether it has antitumor power. And those two efforts must be pursued together. But also, in the end they have different objectives and we must not lose sight of that as we focus on the possible beneficial effects of interferon. The two programs can reinforce each other, but their final objectives are certainly not the same.

Senator SCHWEIKER. I know it's new ground, no question. But it seems like when you got $1 billion to spend you can afford a little bit for new ground.

What is the Allergy Institute spending?

Dr. KRAUSE. In 1980, we expect to spend $3.6 million. Last year we spent $3.1 million. We have spent, since our program started in 1968, about $12 to $13 million.

We started the interferon program in 1968. It was discovered in 1959.

ROLE OF FAT IN CANCER

Senator SCHWEIKER. Last year the NCI issued a report recommending,

among other things, Americans reduce fat consumption as a means of avoiding cancer. This announcement, or announcements of this kind, stirred up some controversy. Dr. Samuel Epstein, professor of environmental health at the University of Illinois, is quoted as saying: "There's not a scrap of evidence that fat causes cancer; there's more evidence cancer is caused by the GNP," presumably meaning that chemicals and carcinogens are spewed in the air.

My question is, What is your comment?

Dr. DeVita. Dr. Upton gave his recommendations for a prudent diet for Americans, which was to reduce the amount of fat, refined carbohydrate, alcohol, and increase fiber, basically doing everything in moderation. This has been expanded now by a new set of recommendations by NIH with the Department of Agriculture.

The statement that there's not a shred of evidence that cancer of the colon is related to fat is not correct. There's a good deal of evidence that people who migrate from areas where their fat intake is very low to areas where the fat intake is very high have a much increased incidence in colon cancer. The question is: Is this the only factor? The answer is probably, No. Colon cancer is probably tied into fiber in the diet as well.

At the moment we can only just make a general suggestion, since it seems to be relatively harmless, to reduce the amount of fat in the diet. This would be a prudent thing to do.

Senator Schweiker. I think that's a wise course.

There's also this controversy that even unsaturated fat sends cancer charts zooming, it's just as dangerous to eat unsaturated fat as saturated fat. Do you have a reaction on that?

Dr. DeVita. Data showed that the incidence of cancer of the colon in rodents is somewhat less with saturated fats than unsaturated fats. And that's worrisome, because we would recommend the reverse in reference to heart disease. So one has to be a bit careful about being too specific in recommending that Americans make the choice between getting cancer of the colon or heart disease.

It's vague enough for us to say that while it is prudent to eat less fat, don't ask us to be more specific than that at the present time, because the data just aren't there. There's some very extraordinary information coming along in colon cancer, though. And I believe we'll know more from further epidemiological studies.

Senator Schweiker. In what respects extraordinary?

Dr. DeVita. People from the northeast part of the United States have a high incidence of colon cancer. When they migrate to the South, where the incidence is less, these people also adopt the incidence of colon cancer in the South. And this occurs in a relatively short span of time. This indicates that maybe some promoter is involved.

These bits of information, though, Mr. Chairman, will give us some leads in research.

Senator Schweiker. Let's get the regional proportional rate there. They have a lot of skin cancer down in the Sunbelt. [Laughter.]

Thank you very much.

ACHIEVEMENTS

There's one thing I didn't do that I think we should do. I think, you know, when we do make significant advances and reach some very desirable goals, that we ought to compliment people. And I must say, after looking at those charts just a few minutes ago, I should comment for the record that they are very impressive—the reductions that we see in stroke and cardiovascular diseases.

I know you commented on these in your opening statement. I think it's a little more dramatic to see it in a chart. And I also think we ought to show it on the record, because since we do spend an awful lot of Government money here to buy medical research, it's often good to be able to point to some things that we're doing right to bring that down.

I hope in our funding effort we don't lose sight of the kind of investment that we make to bring this down. It seems to me when you can show reductions of 20, 30, 40 percent in the coronary, cardiovascular, and stroke areas, it's a very, very significant achievement. I think we should not only commend the Institutes that have been following this very closely and NIH, but also let the people whose money we're spending know that there are some successes and some very good cost-benefit ratios. And I think we should learn from that, you know, where some of these moneys should be invested for the coming year in terms of budgeting allocation.

STROKE AND THE PILL

I did have one other question for Dr. Tower.

Dr. Tower, there's some controversy among your Institutes which was covered earlier. But I heard some controversy on the pill and stroke. Where do we stand on this controversy in terms of the pill and stroke, and how much of a problem is that, really, as you see it?

Dr. TOWER. Sir, it is clearly a problem. We have taken the view that, as far as stroke is concerned, we would recommend that preferably women would minimize or avoid the pill, if possible. But there are many facets to this, so I don't think we can just make an out-and-out statement. It is not as major a factor as some other things.

Senator SCHWEIKER. I was going to say, could you put it in some perspective? How big a risk or little a risk is it? Because I think that's the one thing we tend to lose sight of.

Dr. TOWER. My expert tells me about a 5-percent increase in the risk in women of the age when the pill is most likely to be taken.

Senator SCHWEIKER. About a 5-percent increase?

Dr. TOWER. Yes; 5-percent increase in risk.

Senator SCHWEIKER. Does the Heart Institute want to comment on this at all?

Dr. LEVY. There's no doubt that it does increase risk. Stroke incidence is very low in that group to start with. So that you've got to weigh that against the other risks.

Senator SCHWEIKER. Say that again? Stroke is very low?

Dr. LEVY. The incidence of stroke is very low in women between ages of 20 and 45. So increasing stroke risk by 5 or 10 or 15 percent does not significantly increase the number of strokes.

Senator SCHWEIKER. Maybe I should ask another question, then. Does that carry over? In other words, suppose you have a woman who takes the pill when she is in this low-risk period of 20 to 40 years of age, and then she stops the pill. Is there any kind of cumulative effect that carries the risk with her when she is off the pill, approaching the stroke age? Or does the risk then go back to normal because she's no longer taking the pill? Do we know the answer to that question?

Dr. TOWER. I don't think we really have adequate data on that, Senator. Dr. Levy, do you have any thoughts on that?

Dr. LEVY. With cardiovascular disease, from some of the English studies there's the suggestion that the risk of heart attack and other diseases is increased for a period of time after a woman comes off the contraceptive medicine. Again, I would say that the risk of heart attack in women at this age is low. But there is a carryover. Some risk continues after the woman stops taking the contraceptive medicine.

We do not know, however, how long this increased risk is maintained.

ORAL CONTRACEPTIVES AND ASSOCIATED RISK

Senator SCHWEIKER. How about the Child Health Institute, population research? Any further information?

Dr. KRETCHMER. We have a study in California from which these data on the effect of the pill on the incidence of stroke and of heart attack were derived. There is, as Dr. Tower and Dr. Levy said, an increased risk with the pill. But this risk is considerably magnified if a woman smokes, and takes the pill.

From the data we have, it appears that even when the woman stops taking the pill, the risk for stroke remains about five times that of women who have never used the pill. There is still a lot of data to be analyzed. While it is true that statistically, few young women on the pill have heart attacks or strokes, there is increased risk to certain individuals.

Senator SCHWEIKER. You're telling us they got to make a choice what they want to do, right? [Laughter.]

Dr. Levy?

Dr. LEVY. Just to add to what Dr. Kretchmer said, it's not only true for smoking; it's true for the other risk factors. So if a hypertensive woman uses contraceptives, the risk is skyrocketed. If a woman with hypercholesterolemia uses contraceptives, the risk is increased tremendously.

So it's clearly in the high-risk women that contraceptives are most concerning.

Senator SCHWEIKER. Well, all right. I think that helps put it in perspective, because I think sometimes we do overblow in the media some of these risks, and we ought to put them in perspective.

Well, we have some questions that we will submit for the record.

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

POSITIVE SIGNS

Question: Hearings tend to dwell on the negative aspects of programs but you must be doing something about which NCI can brag. What is it?

Answer:

- The death rate from cancer for Americans under the age of 55, where cancer is the commonest cause of death and has the greatest social and economic impact, is decreasing and under the age of 30 has fallen precipitously as shown in figure 1 due to our success in treating certain forms of cancer. We now can expect to cure half of all children with cancer using modern treatments. Figure 2 shows how multimodality treatment (using surgery, radiation therapy and chemotherapy together) has increased survival for children with solid tumors. We are beginning to see the success of a similar approach in treating some of the more common adult cancers: malignant melanoma, small cell lung cancer, soft tissue sarcomas, testicular cancers, gastric cancers, and even tumors originating in the brain. Important clinical trials are underway in other common cancers of adults.

- We have taken the lead in improving the outlook for women with breast cancer -- the major site of cancer and the major cause of cancer death among women. Recent data from two clinical trials sponsored by the NCI (one conducted in Italy, the other here in the United States) have shown a 57 percent increase in survival of premenopausal women with breast cancer who received anticancer drugs following mastectomy. Data from several studies now indicate that the larger group of postmenopausal women can also benefit from such therapy.

- Through breast self-examination and other early detection procedures fostered by the Institute, women are being diagnosed when their cancers are small.

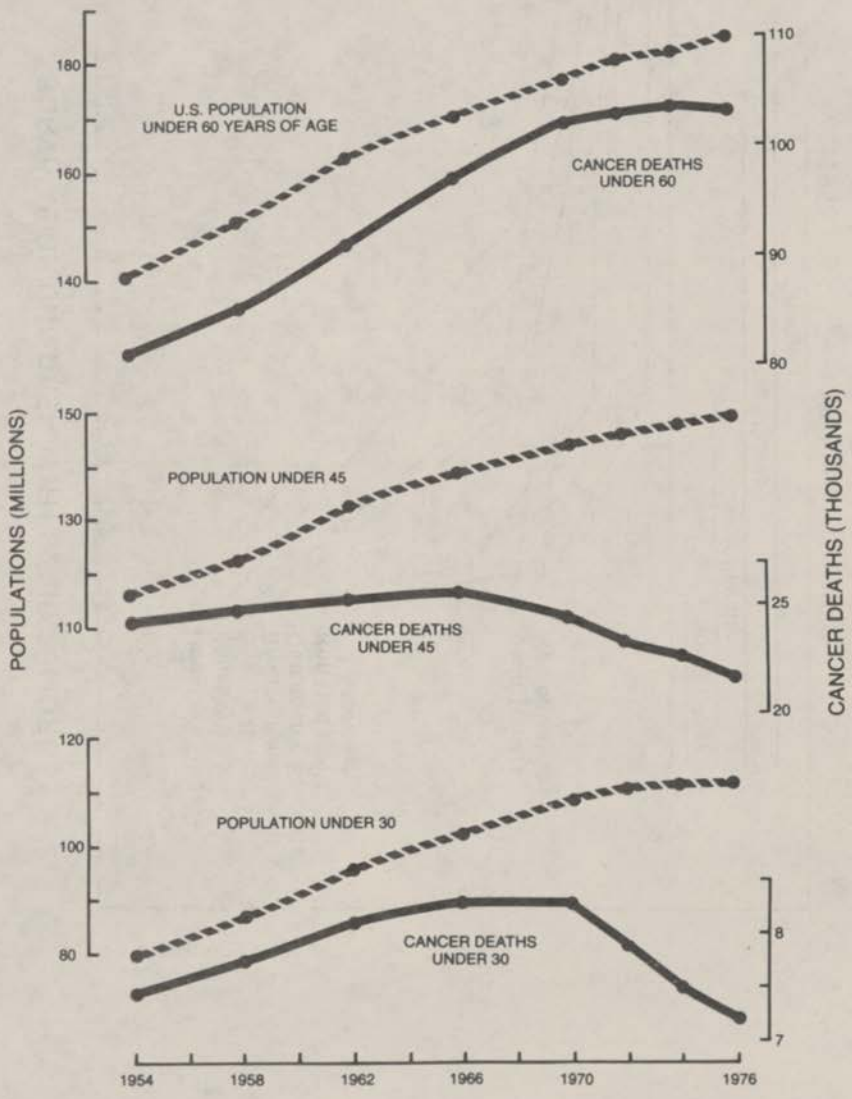
- Last summer, NCI sponsored a consensus meeting where experts in the treatment of breast cancer agreed that patients with small tumors could be treated by a simple operation that would remove the breast but leave the chest wall muscles intact. Fully 85 percent of the 108,000 women diagnosed with breast cancer this year could benefit from this less mutilating surgical procedure. NCI continues to sponsor trials to explore even less radical surgery as well as the use of radiation therapy as primary treatment for this disease.

- Through these studies, we have learned an enormous amount about the biology of breast cancer. The presence of estrogen receptors in breast tissue and the microscopic characteristics of the tumor will allow us to fine tune the treatment of breast cancer.

- We have supported on our own and now in conjunction with NIEHS, NIOSH and FDA, a carcinogenesis testing program. While this program has been controversial it was started anew in 1972 in response to a national need. Over 100 widely used chemicals have been identified as carcinogens for animals. The number represents 40 percent of the 251 chemicals tested in that program. This information provides new opportunities for cancer prevention, particularly in the workplace.

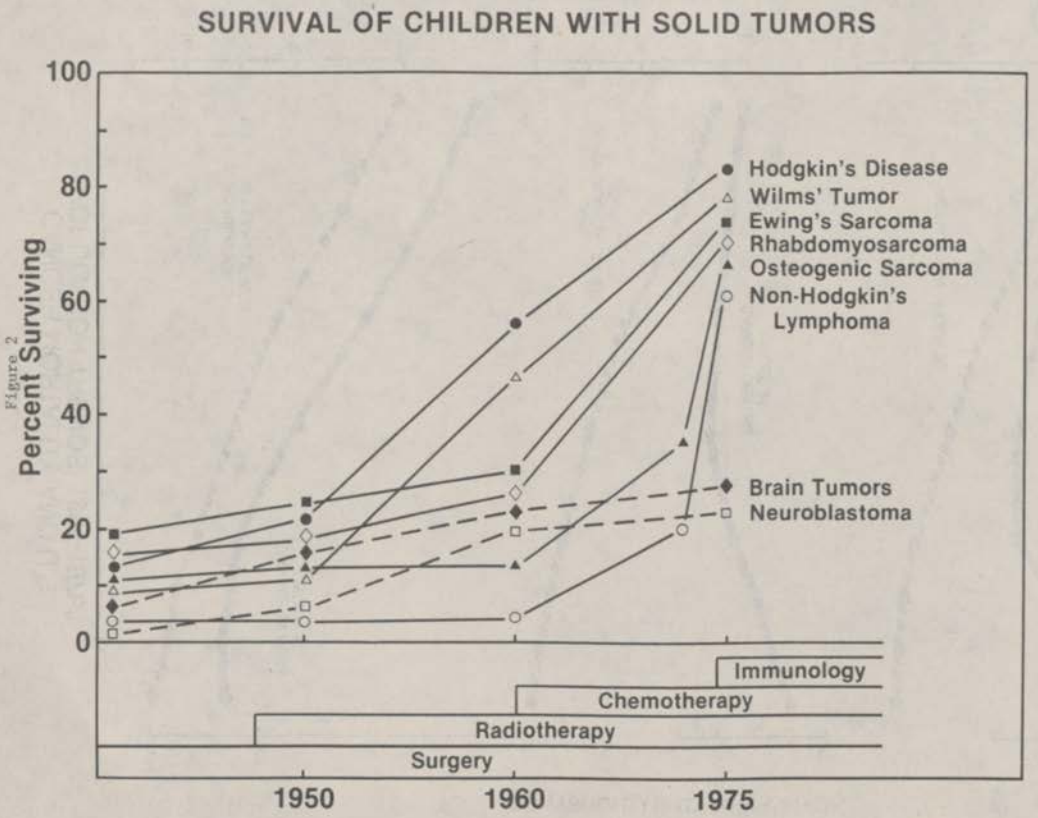
FIGURE 1

CANCER MORTALITY AND U.S. POPULATION TRENDS: 1954-1976*



*SOURCE OF DATA: U.S. PUBLIC HEALTH SERVICE STATISTICS

Figure 2


SURVIVAL OF CHILDREN WITH SOLID TUMORS
Percent Surviving
100
80
60
40
20
0
1950
1960
1975
Hodgkin's Disease
Wilms' Tumor
Ewing's Sarcoma
Rhabdomyosarcoma
Osteogenic Sarcoma
Non-Hodgkin's Lymphoma
Brain Tumors
Neuroblastoma
Immunology
Chemotherapy
Radiotherapy
Surgery

- The opportunity for the most immediate impact on cancer prevention comes from epidemiology studies. An intramural epidemiology program has provided excellent documentation that occupational and other factors are involved in cancer causation through clues generated from the survey of cancer death rates for the period 1950 to 1969 in all continental U.S. countries.

  This survey indicated a higher cancer rate among male residents of 39 counties where the primary industry was petroleum manufacture. Through the Oil, Chemical and Atomic Workers Union, NCI scientists gained access to employee health records and identified higher cancer rates among workers at three of five specific plants. NCI epidemiologists are now examining workers' records in detail for clues to a common workplace exposure that may account for the increase in cancers. In turn, industry can use this kind of information to develop substitutes for these carcinogens or to initiate more effective safety measures that will limit a worker's exposure.

- The SEER (Surveillance, Epidemiology and End Results) Program collects current basic data on cancer incidence, mortality, and survival from five metropolitan areas, five states and the Commonwealth of Puerto Rico. This program is widely recognized as a valuable source of statistics for both scientists and health planners. For example, the SEER data base was used to identify the 3,000 bladder cancer patients who participated in the NCI-FDA epidemiological study on the artificial sweeteners saccharin and cyclamate.

- Last year we took the lead in issuing "prudent interim dietary principles" to the American people. These were and remain based only on suggestive evidence. The principles are consistent with those recently issued jointly by the Departments of Agriculture and Health and Human Services.

- NCI has been a dominant force in anticancer drug development in this country. The Institute has participated in the pre- and post-marketing clinical trials of all 20 anticancer drugs that became commercially available since 1955. Fully 12 of these drugs were developed under direct NCI sponsorship. Included are Adriamycin and Platinol, two of the most active anticancer drugs, and the nitrosoureas, the only drugs on the market active against brain tumors. Another 60 drugs are now in various stages of clinical trials sponsored by NCI.

- At the present time, more than 90% of the people of the United States are within 200 miles of a cancer center including the 21 comprehensive centers.

- Twenty-one Cancer Information Services (CIS) have been established with NCI support. They are located throughout the United States and are affiliated with the Comprehensive Cancer Centers and with local divisions of the American Cancer Society. Cancer patients and concerned others can call the CIS offices in their area toll-free to receive support, understanding and the latest information on cancer and local resources.

- The International Cancer Research Data Bank Program (ICRDB) promotes worldwide exchange of information among cancer scientists. The ICRDB Program is operating an on-line computer information retrieval system called CANCERLINE. It links the computer system at the National Library of Medicine in Bethesda with terminals in more than 1,200 locations in the United States and in several countries throughout the world. CANCERLINE contains over 200,000 abstracts of scientific papers published in the field of cancer and also contains information on more than 20,000 current cancer research projects and clinical cancer therapy protocols.

- Bilateral international collaborations in cancer have been established with the governments of the U.S.S.R., Japan, Poland, Egypt, West Germany, France, Italy, Hungary, and the People's Republic of China. In addition, we have other cooperative programs in more than 20 countries. We expect these international activities to continue fostering exchange of scientific information that could benefit the American people as well as peoples throughout the world.

Question: How far have we come in the past decade in cancer research?

Answer: Since 1971, the National Cancer Program has encouraged and coordinated balanced programs in cancer prevention, treatment, and basic research. In addition, we have fostered cooperation of a network of community and national resources to conduct research and provide the best possible care and support of cancer patients. Accomplishments derived from this program provide direct and definitive benefit to patients through advances in diagnosis, treatment, and rehabilitation and to prospective patients through advances in detection of risk and prevention. Some specific accomplishments of the Program have been discussed in the response to the last question. Most of the recent data on successful treatment of the common solid tumors of adults such as breast cancer, sarcomas, histiocytic lymphoma and ovarian cancer well as limb sparing surgery and more refined use of x-irradiation were developed since 1971.

Question: What can we look to in the 80's?

Answer:

- In the 1980's we hope to see a downturn in the incidence and mortality of some common cancers due to the application of the results of epidemiologic research on cancer causes in cigarette smoke, diet, and cancer due to chemical exposure. Many of these cancer causing factors serve as promoters not initiators of carcinogenesis. When promoters are removed, incidence can drop quickly as was shown when a decrease in the post-menopausal use of estrogens was followed by a decrease in incidence of cancer of the lining of the uterus. There is already good evidence that there are promoters in cigarette smoke since exposure does not lead irreversibly to lung cancer. Promoters are suspected to play a role in the common cancer of the colon since migration from the north to the south of the United States decreases the incidence of the tumor in a relatively short time span.

- In vitro systems will probably replace animals for the initial screening of chemicals for carcinogenicity. These test-tube systems will be much less expensive and will provide answers within a few weeks rather than a few years. Simpler systems will allow scientists to survey the large number of environmental chemicals and to identify those that might increase a person's risk of cancer.

- The application of two new technologies, gene splicing and the use of hybridomas to produce monoclonal antibodies, discovered in the 1970's, will allow us to unravel some of the mysteries of the cancer cell in this coming decade.

  Four years ago, British scientists created hybridomas by causing antibody-producing spleen cells from mice to fuse with cells that grow continuously in tissue culture. Such hybrid cells secrete large quantities of a single kind of antibody, which is called monoclonal antibody. This technology may allow us to take advantage of unique antigens that occur on cancer cells. About half of the pending grant applications in NCI's Immunology Program include work with hybridomas and/or monoclonal antibodies.

- The techniques of gene splicing or recombinant DNA allow single genes from higher organisms like humans to be separated and inserted into bacteria, where they are reproduced as though they were bacterial genes. Because bacteria reproduce so quickly, many copies of the gene and its protein product can be created. These techniques were recently used by a team of scientists to produce human interferon. Gene splicing is also an important tool for exploring the genetics of cancer cells.

- Anticancer drugs that are less toxic to normal cells than conventional chemotherapy agents will be developed. Currently, two avenues are being explored: second generation drugs and biological response modifiers. Second generation drugs are chemical cousins of conventional anticancer drugs but have fewer side effects. Aclacinomycin A is an analogue of the very active drug Adriamycin. Unlike Adriamycin, it causes neither hair loss nor damage to heart muscles. Aclacinomycin A is in clinical trials in the United States. Biological response modifiers are substances, such as interferon, many of which are made by the body and in some way may alter its response to cancer. Because of the nature of these substances and their action on the host rather than the tumor, they may be less toxic than conventional chemotherapy

- Development of particle therapy for the treatment of cancer is a project of the 1980's. This is a high energy form of radiation therapy that appears to be more selective in killing cancer cells and sparing normal cells. Three facilities for neutron therapy, one form of particle therapy, will be supported with NCI funds during the 1980's.

61-400 O - 80 - 47

RESEARCH OPPORTUNITIES

Question: What promising areas of research would you like to be able to pursue if you were not constrained by budget limitations?

Answer: The National Cancer Program is a well-balanced effort in which no promising area of research is being totally ignored. However, promising areas which could be pursued include:

Chemoprevention studies -- seeking to identify new classes of agents, to explore the mechanisms through which they exert their effects and to determine the type of cells and tissues most susceptible to their actions.

Biological response modifiers -- the studies of interferon typify this field. As in the closely related area of chemoprevention much remains to be done in identifying substances of possible significance, their methods of action and possible synergism with other modalities of treatment.

Recombinant DNA -- additional efforts to exploit recombinant DNA technology in characterizing or producing biological material in studies that might have implications for prevention, detection, or treatment.

Nutrition -- studies to be conducted at laboratory and clinical levels could include identification of the role of trace elements and vitamins, epidemiologic surveys of the role of diet in populations with certain forms of cancer, certain patterns of cancer occurrence, and the contribution of dietary factors to response to cancer therapy.

Detection and diagnosis -- the occurrence of biological markers in various forms of treated and untreated cancer bears increased scrutiny.

Cancer treatment -- the search for development and trial of agents with more acceptable levels of toxicity, the clinical studies of mixed modalities of treatment, and the increased exploration of the uses and effects of new forms of radiation therapy.

Control activities -- expansion of outreach activities as well as new prevention activities, primarily in the areas of industrial carcinogenesis and smoking.

Resource support -- support of the above areas is linked to providing the appropriate manpower and facilities. Indirect support of these promising areas could also be accomplished by modernization and upgrading of facilities for biohazard containment, and by training additional biomedical researchers.

These few examples illustrate the great importance of pushing ahead as rapidly as possible in both exploring the basic biology of the cancer cell and the development and application of this fundamental knowledge to the specific problems of the cancer patient and the person at risk to cancer.

PRIORITIES

Question: Given the tight budgetary situation, what do you plan to do with the increase which has been requested for fiscal year 1981?

Answer: The primary areas of emphasis in the 1981 President's Budget request for the National Cancer Institute are stabilization of the science base through funding of competing research projects at the same level as in 1980. Emphasis will be given to prevention research, especially applied prevention, and most especially carcinogenesis testing through an increase of $20 million to NCI's contribution to the National Toxicology Program. These increases are reflected in expansion of the physical and chemical carcinogenesis research program and the nutrition research program. Further, the 1981 budget request will sustain the ongoing research efforts in the areas of preclinical and clinical treatment research, immunology, tumor biology, diagnostic research and epidemiology.

The program increases can only be partially supported by the $6.998 million increase in the 1981 budget request; reductions to areas such as resource development and control activities help to support increases to high priority areas mentioned above. The only resource area that will be sustained at the current level is the Cancer Centers Support Program. Further, some expansion of individual projects will be supported through funds that become available through the termination of ongoing projects; such as applied prevention carried out through the Cancer Control Program.

Question: What impact has inflation had on your programs?

Answer: For 1980 the biomedical inflation factor is projected to be at about 11%. Actually, in areas where use of chemical solvents and petrochemical products is heavy, this factor is higher. Assuming this trend will continue into 1981, there is an immediate decrease in purchasing power affecting the cost of research including the costs of laboratory supplies, raw materials for drug development, drugs for clinical trials, experimental animals, and the cost of carcinogenesis testing. Over the past few years, inflation has resulted in a net decrease in purchasing power for all of biomedical research.

Question: What areas require financial help to properly carry out your mission?

Answer: The 1981 President's Budget will permit the Institute to support the highest quality research, control and support activities. It is a question of judgment to determine the level required to properly carry out our mission. Most of the research areas supported by the NCI have the science base available for increased exploitation and could utilize financial help to properly carry out the science including: basic research, particularly relating to recombinant DNA technology; applied research such as studies concerning chemoprevention or biologic markers; and clinical trials, particularly relating to biological response modifiers.

Resource development areas in support of research that could utilize additional support in 1981 include: Cancer Centers which require additional funds in order to be supported at the levels recommended by peer review; construction, since requirements for biohazard containment and upgrading of animal research facilities should meet minimum animal welfare requirements; and training of predoctoral and postdoctoral fellows. Intramural research in 1981 shows an increase of 2.2%. Additional funds would be required to carry out badly needed upgrading of inhouse facilities and to support ongoing research efforts that form the core of support for a strong extramural program.

CHANGE FROM 1980 TO 1981

Question: What percent increase in funds does the Administration's Budget request for FY 1981 over FY 1980?

Answer: The Administration request for FY 1981 of $1,007,800,000 represents an increase of 0.7% over the FY 1980 level of $1,000,802,000.

Question: This is in reality a substantial cutback in funds with a 13% + inflation rate in 1979 and a projected inflation rate of 11% for 1980. How will the Cancer Institute be able to sustain the same level of effort in FY 1981 as in FY 1980 under these funding circumstances?

Answer: The FY 1981 budget request includes significant increases for some areas of the budget such as research projects and NCI's contribution to the National Toxicology Program. These increases are made possible through reduced funding to other areas such as manpower development, construction, cancer control, and certain research areas including clinical trials and other research grant programs. The Cancer Centers support program as a whole will remain at the same level as in 1980; however, those core grants with sufficient priority scores to be funded will receive about the same level of funding as in 1980. This means that NCI will be able to fund about 4 fewer core grants than in 1980.

In any particular research program, some projects will be funded with modest increases to offset inflationary pressures. The funds to support these increases will be made available from the phasing out of projects that have reached the end of their project period in FY 1981.

FUNDING BREAKDOWN

Question: In your professional judgement are you pleased with your funding breakdowns?

Answer: The NCI budget is broken out in terms of a program structure which in the case of research identifies a number of broad programs, e.g., cancer biology and cause and prevention which in turn encompass several activities such as epidemiology, nutrition and immunology, etc. These programs relate to the entire spectrum of neoplastic diseases. Other broad elements of our program structure, i.e., control and resource development are in like fashion subdivided into readily identifiable program areas.

NCI also identifies high priority research areas such as the National Toxicology Program, nutrition and interferon research that fall across research programs. Money is allocated to these disease areas and other programs according to our estimation of where the greatest potential lies for scientific breakthroughs in terms of existing leads and the viability of rapid and accurate research results.

For example, under the current funding levels for 1981, we have developed a budget which reduces the level of effort in research manpower training, centers support and control activities to preserve investigator initiated research and carcinogenesis testing efforts in the National Toxicology Program.

We are satisfied with the funding breakdowns in this budget since the classification used serves both as an analytic and planning tool, which facilitates the task of assigning resources to scientific and other programmatic efforts on the basis of identified needs, priorities, limitations, and the likelihood of progress. We are also satisfied that the allocation of resources among the budget categories will help the goals of the National Cancer Program.

EXPECTATIONS TOO GREAT

Question: There are many people who believe that the potential of the war on cancer was oversold to the public--that public expectations cannot be realized. What is your comment on this?

Answer: The launching of the National Cancer Program--the "War on Cancer"--stuck a responsive chord among the American people. Although the Institute has steadfastly played down the idea that cancer could quickly be conquered, the climate in which the program was initiated and which accompanied its initial growth spurt raised the hopes of many Americans who were led to believe that the problems of cancer, like the problem of placing a man on the moon, could yield to a substantial infusion of funds and be rapidly solved.

These expectations have been frustrated by the reality—not completely understood by the public--that the extraordinarily complex theoretical and practical problems posed by cancer yield only slowly to intensive efforts bridging a wide spectrum of research, development, and application initiatives. Yet the accomplishments of the Program lead me to believe firmly that public expectations can be met, perhaps not as quickly as we all desire, but met nevertheless.

Question: Do you believe the public is aware of what has been accomplished--or do you need to do a better job of informing?

Answer: In general, I do not believe that the public is fully aware of program accomplishments and what these achievements mean in terms of its hopes and expectations. The public is not a homogenous assembly of people. There are significant differences in interest and education among segments of the public. Moreover, public access to information varies widely. Unfortunately, most people are not exposed to comprehensive accounts of cancer progress and problems, but rather are distracted by accounts of impending "breakthroughs" on the one hand and the seeming pervasiveness of potential cancer causing substances on the other.

Although our ability to reach and inform the public about cancer has increased dramatically, the NCI and the media both will continue to inform and educate the public. More than ever these efforts must accurately represent the facts of a very complex problem and in doing so must be keyed to the needs of the many segments of a very diverse public.

INTERFERON

Question: Some very encouraging news was recently announced regarding Interferon. Could you explain what this development means in the development and testing of Interferon, and exactly what the National Cancer Institute is doing in this area? I would point out that the report recently submitted by NIH to the Senate Appropriations Committee in response to this same question has been rejected by the Committee as unresponsive and unsatisfactory, a most unusual occurrence.

Answer: Human leukocyte interferon, the material that has been used for the majority of current clinical studies has been until now produced from human blood collected in blood banks. The material has therefore been very scarce and expensive, in addition to which it is very impure. Recent reports suggest that it may be possible in the near future to produce interferon on a commercial scale with recombinant DNA techniques, which should solve these problems. Biogen, a Swiss pharmaceutical firm, working in collaboration with Dr. Cantell of the Finnish Red Cross and Dr. Walter Gilbert of Harvard, recently announced that a small quantity of a material very similar to natural leukocyte interferon has been produced through recombinant DNA techniques utilizing the bacterium E. coli. Although the yield was exceedingly small, the material is slightly different from natural leukocyte interferon (it contains only the protein portion of the molecule, not the sugar portion) and it has thus far been tested only in culture, there is great optimism that it will be possible to develop this material into a biologically active commercial preparation in the foreseeable future. Many other pharmaceutical companies are also working on this general problem and great strides are being made, although this is the first report of success in producing the material through this means.

The National Cancer Institute has been in the process of awarding contracts for the production of leukocyte, lymphoblastoid and fibroblast interferons, utilizing conventional production techniques. In view of this new development, National Cancer Institute staff recently asked the Subcommittee on Biological Response Modifiers of the Division of Cancer Treatment's Board of Scientific Counselors to review this new development in order to determine whether a change in direction should be taken at this time. Dr. Gilbert had been invited to participate in those discussions, but unfortunately could not attend. He did discuss the progress of the work with National Cancer Institute staff, however. Although Dr. Gilbert indicated that it should be possible within a vear to develop the interferon process to the point of application, both he and the Subcommittee agreed that such material would probably not be available in quantity for a significant period of time, and they, therefore, recommended that we proceed with the procurement contracts as planned. These contracts, which should be awarded during February and March 1980, will provide interferon for clinical trials during FY 1981. The National Cancer Institute will keep in close touch with Dr. Gilbert and others who are working on this new approach to interferon production and will be prepared to move quickly to obtain the larger quantities of interferon that may be possible utilizing this new technology.

INTERFERON--A NEW WONDER DRUG?

Question: Recently we have read that Swiss and Finnish scientists have been able to make a substance close in nature to human interferon. Have you studied their results and what do you think of them?

Answer: The results reported by the Swiss firm, Biogen, are very encouraging in that they have been able to produce, through recombinant DNA techniques, a molecule very close in chemical structure to natural leukocyte interferon. It is somewhat different in that it possesses only the protein component of natural interferon, not the sugar portion. Testing has been very limited because of the very small quantity available, but there is every reason to hope that this material, or later materials made by these techniques, will be biologically equivalent to natural interferon. NCI asked a group of its advisors to reassess its plans to purchase crude interferon in light of these discoveries. They recommended that NCI proceed with the purchase of the crude interferon in view of the uncertainty surrounding the early results with DNA recombinant technology.

Question: Do their efforts represent a quantum jump in technology that makes our efforts cumbersome by comparison -- or even obsolete?

Answer: Recombinant DNA technology represents a very substantial improvement in facilitating the production of many natural materials that are now available only through very costly and difficult extraction procedures. These techniques are being applied to a wide variety of important materials besides interferon, such as insulin and other hormones.

Question: When will we know whether the Swiss and Finnish have been able to make human interferon?

Answer: Dr. Walter Gilbert of Harvard University, who is affiliated with the Swiss firm, Biogen, has indicated that large-scale production of the material should be possible in about one year although it will probably require several years to develop to the point of clinical application. During the coming year, it should be possible to develop additional biological data to determine if this material is equivalent to natural interferon.

Question: What do you believe you can spend in fiscal years 1980 and 1981 to develop adequate supplies of interferon?

Answer: Production of interferon for clinical trials is expected to cost $6-9 million during fiscal year 1980. Since later production will depend on the progress of these trials and costs may be altered significantly through the techniques discussed above, costs for future years cannot be estimated at this time.

Question: What are you doing to coordinate your efforts with the American Cancer Society which is conducting its own clinical tests of interferon?

Answer: The National Cancer Institute is in frequent communication with the American Cancer Society and the investigators

carrying out the interferon clinical tests, and is fully informed of the ongoing work. National Cancer Institute trials will serve to amplify and extend those trials, and will likely include many of the same investigators.

Question: Do you have any concern that interferon is being oversold as a new "Wonder Drug"?

Answer: The National Cancer Institute is very concerned about overoptimism regarding interferon, as it is with any drug that receives such a large amount of publicity. It is therefore essential that adequate and well-controlled clinical trials be carried out as soon as possible, and the National Cancer Institute is proceeding in that direction expeditiously.

ACCESS TO CENTERS

Question: I am concerned that too many people still lack access to Cancer Centers. How widespread is this problem and what are you doing about it? Are you satisfied with the quality of information exchange among cancer centers, hospitals and private practitioners? Can it be improved? Have you thought about the possibility of encouraging a voluntary setting up of areas of regional responsibility for care and referral?

Answer: At the present time, more than 90% of the people of the United States are within 200 miles of a clinical or comprehensive cancer center. The current information exchange among centers, hospitals and private practitioners has been improved during the recent past. We are continually trying to improve our efforts in information dissemination. We have considered fostering the development of regional activities that would improve the utilization of existing resources and facilitate those clinical investigations so important to future progress in the prevention, diagnosis, and treatment of cancer. One aspect of regional activities will be the improved communication and consultation between private practitioners, community hospitals, community cancer centers and university cancer centers. We expect this to lead to increasing partnership between community physicians and oncologists at cancer centers and the consequence should be improved quality of care in the communities and increased numbers of patients participating in clinical oncology research programs of relevance to prevention, detection and treatment.

Question: Under the Administration's budget request for cancer centers for the same amount in FY 1981 as FY 1980, how many of our 66 cancer centers will have to close?

Answer: In FY 1980, the National Cancer Institute estimates that a total of 65 core grants will be awarded and one exploratory project. It is important to point out that for most of our cancer centers, the core grants awarded by the National Cancer Institute represent only a portion of the funds involved in the center. Thus, the decision to terminate a core grant is not equivalent to the decision to close a center. It is estimated that with the same level budget for cancer centers in 1981 as in 1980 four core grants will go unfunded.

Question: Under last year's funding for cancer centers, how many centers were scheduled to close? If some centers were not actually closed, how much in cuts were the centers in total forced to suffer to prevent the closing of some? Is there any less need for these centers?

Answer: To our knowledge, no cancer center will actually close because most of the research support comes from sources other than the core grants. In 1980, two core grants to cancer centers went unfunded. In order to keep the number of unfunded grants this low, center core grants were funded at less than fully recommended levels and received the same amount they were awarded in FY 1979 plus 50% of any peer review recommended increase. This amounted to reductions of approximately $1.6 million below the amounts recommended by peer review for these competing renewal core grants.

The need for cancer centers has not decreased. If anything, we anticipate a larger role for at least some of these centers as we attempt to improve patient access, clinical research activities and physician education through regionalization.

Question: The National Cancer Institute is planning on closing four centers. Would you please specify which centers you intend to close and how you intend to carry on the research or services provided by those centers? Please specify the dollar amount expected to be saved for each of the four centers.

Answer: The National Cancer Institute estimates that by funding competing renewal core grants at about the same level as in 1980, four core grants will go unfunded in 1981. This does not necessarily mean the closing of these centers, but does mean that the support provided by the cancer center core grant will not be available. If the center wishes to continue the same level of research activity, it will have to find other sources of support.

The National Cancer Institute cannot identify the specific centers that will lose their core grants. The determination will be made following peer review, and the four grant proposals receiving the lowest priority score will be phased out.

Even though it is not possible to specify the exact core grants and their dollar amounts, it is estimated that the four unfunded grants in 1981 represent approximately $1.2 million assuming that if they were paid, they would be paid at about the same level as in 1980. However, since these grants will receive some phase out support estimated at $500,000, the net savings in 1981 is about $700,000.

NEW TRAINING AWARDS

Question: How many new training awards or new renewals of training awards will the Cancer Institute be able to grant under the Administration's FY 1981 budget request?

Answer: There will be no new or renewal training awards in FY 1981. The Administration budget will support 130 individual fellowship awards and 132 institutional training awards (supporting 1,138 full-time equivalents) in FY 1981. These levels compare to 210 individual fellowship awards and 157 institutional training awards (supporting 1,345 full-time equivalents) in FY 1980.

STABILIZATION OF GRANTS

Question: The Administration is stressing that this budget request would stabilize the number of the very important investigator initiated grants. What is the average number of such grants which the Cancer Institute has been able to fund for the past 3 years?

Answer: For the past three years, the National Cancer Institute has funded an average of 841 competing research projects per year.

Question: How many will NCI be able to fund under the Administration's budget request? What percent decrease is this in the number of grants?

Answer: NCI will be able to fund 734 competing research projects which represents a 12.7% decrease from the average number funded over the past three years.

Question: How much would be needed to restore the Institute's number of grants to the 3 year average?

Answer: It would take approximately $14.9 million to fund an additional 107 competing research projects, bringing the total of competing funded to the 3 year average of 841 grants at a total cost of $105.7 million.

CANCER CONTROL REDUCTIONS

Question: What substantive facts or developments since only last year justify a $5 million cut in Cancer Control?

Answer: The National Cancer Institute has proposed a reorganization that, when approved by the Secretary, DHHS, will place cancer control, cancer centers and education in a new division. During the reorganization, the Cancer Control Program will be restructured with an increased emphasis on applied prevention. The phasing down of old programs and the orderly initiation of new ones is consistent with a transient drop in the Cancer Control budget.

In addition, peer review of the community based cancer programs has led to the recommendation that some existing programs should be eliminated, and that new programs should not be initiated until the experience with existing programs has been thoroughly evaluated. Implementation of these recommendations will transiently decrease the budgetary needs for cancer control in FY 1981.

STRENGTHENING CANCER CONTROL

Question: There has been a great deal of concern over your Cancer Control Program. What steps are you taking to beef-up this effort in community programs as well as educational programs for professional and lay persons?

Answer: The Cancer Control Program is in the midst of a reorganization which, when approved by the Secretary, DHHS, will place cancer control, cancer centers and education all within the same division in the Institute. This should permit more effective development of educational efforts for professional and lay persons and, by emphasizing a regional approach, facilitate interactions between community programs and cancer center programs. Applied prevention will receive major emphasis in these programs.

Within the past year the Cancer Control Program has initiated an effort to develop and field test curricula for medical students, residents and nurses in areas of relevance to cancer prevention. Information dissemination as well as professional and lay education has been continued and strengthened through the Cancer Information Services of cancer centers. A new community program concerning oncology in community hospitals will be initiated at the end of FY 1980 and the beginning of FY 1981.

SMOKING AND CANCER INCIDENCE

Question: The Surgeon General's very disturbing report on smoking and women recently came out. We are increasingly confronted by the environmental damages to us in the form of cancer. Could you give us some picture or projections of the cancer incidence statistics we are probably facing in the future?

Answer: The lung is the site most affected by cigarette smoking and data show that the incidence of lung cancer from 1969 through 1977 has been increasing at about 1.5 percent per year for white males and 8 percent per year for white females. The corresponding changes for blacks are 4 percent and 6 percent. There seems to be some evidence that the incidence and mortality for lung cancer is beginning to level off for males but is still increasing at a rapid rate for females. Lung cancer has now displaced colon cancer as the second most prevalent cancer in women, next to breast. Not only is lung cancer going up, but cancer of the larynx, esophagus, and bladder as well. At one time there were 10 deaths among men from larynx cancer for each death among women. In about 15 years this has changed to 7 to 1.

It is quite likely that the slowing down of the increase in lung cancer incidence and mortality among males is a reflection of lowered smoking rate among older men, and possibly the lower tar and nicotine in modern cigarettes. It may also reflect improvements in the work environment. While similar factors may impact on females, the effect may not show up in trend data for several years. The increase in lung cancer incidence and mortality began much later among women. The increase now occurring among women parallels those that occurred among men in the 1950's and 1960's. It may be another few years, therefore, before these increases begin to slow down in women.

Question: What specific things are you doing to disseminate information on smoking to teenagers and pregnant women? What impact have you had?

Answer: Activities are being funded to determine effects of peer pressure on smoking prevention and cessation. As part of these

efforts films are being developed to provide teenagers with information about the short- and long-term consequences of smoking and also to provide them with mechanisms to withstand peer pressure to begin smoking. The impact of these films will be assessed after they have been produced.

Within several of the community based cancer programs, efforts are directed toward educating elementary and high school students about the cancer risks associated with smoking. The information disseminated to teenage women includes warnings about the increased risk of fetal problems in mothers who smoke. It is too soon to evaluate the specific impact of any of these programs.

Two publications are also being distributed: Smoking and Health: An Annotated Bibliography, School Edition, which lists current educational materials available for young adults; and Smoking Programs for Youth, written for educators, school administrators, and concerned parents, describing ways in which smoking prevention programs can be established in schools. It reviews a variety of school programs designed to prevent smoking among youth and methods to assist young people who wish to quit. These materials are actively promoted to teachers, librarians, prinicipals, parents, and community groups.

NCI has cooperated with the Office of Smoking and Health (OSH) in the development of the 1980 Surgeon General's Report on the Health Effects of Smoking in Women. The report stresses smoking effects on teenage and pregnant women. As follow up to the reports, OSH and NCI are developing a series of short media spots, posters and brochures to disseminate information to these target groups.

NCI has produced the Helping Smokers Quit Kit for use by physicians. This package of materials supplies tools to counsel smoking patients who want to quit. The package has been strongly promoted to physicians, including obstetricians and gynecologists. The kit includes humorous waiting room posters, take home materials for smokers, and information on counseling the smoking patient. To date, 90,000 kits have been distributed upon request, providing enough materials for 4-5 million smokers. In addition, efforts are coordinated with other programs, including OSH, whose efforts are directed toward smoking effects in pregnant women.

Question: There has been a steady trend toward smoking cigarettes with lower tar and nicotine content. Is there any correlation between this shift and a change in morbidity and mortality due to cancer?

Answer: Data have shown that the low-tar cigarettes now represent one-third of the cigarette market compared to two percent of the market in 1967. Studies on the contents of some of these cigarettes imply that smoking them may reduce mortality risks substantially below that for the pre-1960 cigarette. But we know of no data that would now permit one to determine the impact of smoking low-tar and nicotine cigarettes on changes in morbidity and mortality

At a recent NCI sponsored workshop on fat and cancer, experts agreed that sound dietary recommendations depend heavily on quality research endeavors which will allow closer comparison of results among investigators. Efforts continue within NCI to stimulate these activities in the research community.

Question: Your proposed 33% cut in fat intake is challenged on grounds that it's taken from the recommended diet to cut heart disease. Is that true? How did you arrive at a one-third cutback? What is your comment on the claim that animal fat consumption has dropped while the cancer rate has gone up?

Answer: Epidemiology and animal studies suggest that there is a relationship between the high dietary intake of fat and the incidence of certain cancers most notably colon and breast cancer. While the evidence is preliminary, NCI determined that it was prudent to suggest a series of dietary principles at the hearings before the Senate Nutrition Subcommittee on October 2, 1979. Among these principles is a recommendation that total dietary fat intake be reduced. While NCI did not propose a specific reduction in its statement on dietary principles, it was conceded during questioning that perhaps a decrease from the current level of 40% to 30% would be consistent with the intent of the NCI dietary principles. It is to be pointed out that there is no evidence available to allow NCI to select a specific level of fat intake. To develop the information base further, NCI held a workshop on "The Role of Fats in Cancer" in December 1979. The conference recommendations are being finalized and will provide NCI a research strategy for the future to further define this matter. The evidence on fats from specific sources such as animal fat and cancer rates remains controversial. NCI's positions on reduction of total fats is consistent with the current state of knowledge and will be further refined and improved as additional studies are completed.

DIET AND CANCER

Question: The Senate Subcommittee on Nutrition has asked the GAO to examine problems with the peer review system at NCI. One problem cited is that a lack of clinical nutritionists sitting on panels reviewing nutrition research proposals could bias grants away from this field.

Answer: The NCI is responsible for review of program project applications (P01's), core support applications (P30's) and control activity applications (R18's) involving clinical nutrition. In all such cases, consultants with appropriate training and experience are sought to participate in the review. In any case where clinical nutrition is the major thrust of an application it is reviewed by an ad hoc or special review committee of appropriate experts who make the recommendation which goes to the National Cancer Advisory Board for final action. In cases where clinical nutrition is not the major thrust of the application, consultants are invited to sit with the committee to provide advice. Such consultants do not vote on the recommendations. NIH and NCI have requested suggestions for expert reviewers to serve on review and advisory groups. Our experience indicates that good research is recognized and approved when appropriate experts are involved in the review.

In the case of regular grant applications (ROl's) the Division of Research Grants, NIH, bears responsibility for the review. Applications are assigned to study sections with experts most familiar with the subject matter of the application. When there is no standing study section with the expertise, either a special study section could be convened or mail reviews would be sought from appropriate experts to round out the expertise resident in the study section.

Question: Is the Institute seeking out more qualified peers for these panels?

Answer: NCI routinely seeks highly qualified peer reviewers for each of the reviews for which it is responsible. This is true of clinical nutrition as for any field. The same may be said for the Division of Research Grants.

It does appear that there are fewer scientists who specialize in clinical nutrition than is desirable to carry out research and review of research in this field. Therefore a balance is sought of scientists and clinicians who have expertise both in nutrition and in oncology.

VITAMIN C

Question: The suggestion has been made that ascorbic acid (Vitamin C) greatly improves the lives of terminal cancer patients. What research has the Institute done to prove or disprove this theory? What activities have been carried out by the Institute in the area of dietary and vitamin deficiencies and cancer?

Answer: It has been suggested that vitamins A and C can reduce the risk of certain cancers. Vitamin A may play a role in maintaining normal epithelium structure and may inhibit the development of already initiated tumors. Vitamin C may react with and deactivate certain active compounds, such as nitrites, and prevent the formation of potential carcinogens, such as nitrosamines. In the human body, vitamin C also helps to protect vitamin A from destruction.

Environmental Epidemiology

To test whether vitamin A and C intake are inversely associated with certain cancers, the Environmental Epidemiology Branch of the National Cancer Institute has initiated several research projects. For example, case-control interview studies of lung cancer in high-risk areas (New Jersey and the Gulf coast of Texas) will include detailed dietary questionnaires. Analysis of the results should indicate which micronutrients (including vitamins) or which classes of fruits and vegetables, if any, are associated with reduced rates of lung cancer.

A case-control interview study of lung, pancreas, and stomach cancers presently underway in southern Louisiana also involves a detailed dietary component, including an evaluation of vitamin C intake.

Based on the observations that colorectal cancer mortality is lower in the southern U.S. than in the Northeast, and that Northerners who retire in Florida soon acquire the reduced risk of the Florida natives, a case-control interview study with both dietary and

biochemical components is being launched in Florida to ascertain the cause of the reduced risk and to see whether it might be associated with consumption of more fresh fruits and vegetables.

Data from the Health and Nutrition Examination Study (HANES), conducted by the National Center for Health Statistics, is being analyzed to see what regional differences in micronutrient intake do exist in the U.S. and whether they correlate with the regional differences in cancer mortality.

Participants in HANES are being followed up so that cancer morbidity and mortality data can be collected on these individuals for whom we already have extensive dietary data prior to onset of disease.

A case-control interview study in two Nebraska counties with exceptionally high rates of colorectal cancer has suggested a role of high-fat consumption, but not protection due to micronutrients such as Vitamins A and C.

Clinical Treatment Research

Interest in the possible activity of ascorbic acid (Vitamin C) as an antitumor agent has been generated in recent years by Dr. Linus Pauling. In collaboration with Dr. Pauling, Dr. Ewan Cameron has carried out clinical studies in Scotland on the use of Vitamin C in the treatment of terminal cancer patients. Dr. Cameron reported an increased survival of breast cancer and other patients treated with Vitamin C. Because of interest generated by these studies, the National Cancer Institute asked Dr. Charles Moertel and his associates at the Mayo Clinic to evaluate the utility of Vitamin C clinically. The studies at the Mayo Clinic were not intended to duplicate those studies, since the use of vitamin C to treat previously untreated breast cancer patients could not ethically be done in the United States, because of the existence of other effective therapies.

Unfortunately, the results from the Mayo clinic did not demonstrate activity of Vitamin C. To our knowledge, there has been no confirmation of the reports from Dr. Cameron. Consideration is currently being given to the initiation of clinical studies in untreated patients in situations where such treatment can be ethically utilized. Although such trials would not duplicate Dr. Cameron's work directly, they would be somewhat closer to the type of situation in which he reported activity. Until such time as controlled clinical studies demonstrate the utility of Vitamin C, however, we must still consider its activity to be unproven.

Nutrition

The Nutrition effort at NCI encourages research designed to investigate the possible role of these substances as factors in the carcinogenesis process, or its inhibition.

Investigation of deficiencies of a single dietary component in long-term animal studies are often difficult to interpret because widespread physiological disturbances resulting from the deficiency affect the study although they may not be cancer related. More typically, research in this area involves the use of several levels of a vitamin, mineral, etc., with or without the administration of known

carcinogens in well characterized animal populations in which their cancer incidence has been thoroughly studied. Examples of such studies currently in progress include those with selenium, zinc and vitamins A, C and E as well as dietary fiber. In human population studies, normal dietary intake of these substances is being examined in relation to possible effects on the subsequent development of cancer.

A recently initiated long-term study will examine the effects of dietary restriction, leading to undernutrition, not malnutrition, on immune responsiveness and development of cancer. Another examines physical activity levels in relation to levels of nutrient intake and cancer development.

HIGH RISK FACTORS

Question: Under the level funding requested for FY 1981 for Detection and Diagnosis identifying high risk factors in high risk populations, how will we be able to sustain the same level of effort as FY 1980? Is there any less need for this effort?

Answer: In the area of Detection and Diagnosis research, several projects to detect cancer in high risk populations are being carried out for cancer of the lung, bowel and endometrium. This research can be sustained in FY 1981 at the same level of effort as that of FY 1980, through the completion of ongoing projects in FY 1981. There is a continual need to extend efforts to further identify the high risk factors in high risk populations. The increasing emphasis on epidemiology and the requirement for complete, up-to-date data draw attention to the need to sustain this area of research.

CONTRACTING PROCEDURES

Question: Last year the Committee, along with GAO, found that you were delegating a great deal of your testing of compounds to a large contractor who then turned around and subcontracted the work out at a great cost. What is the rationale behind such contracting and subcontracting?

Answer: The Institute initiated a large number of long-term bioassays of chemicals in the late 1960s and early 1970s. Because highly specialized facilities and personnel were needed to conduct these tests, NCI entered into contracts with a number of firms to perform these tests. By 1975 it became apparent that these individual contracts were not executed and monitored properly in that test processes were truncated to the extent that contractors could complete in vivo tests, but other contractors would supply pathology services, and there was a lack of clarity on responsibility for writing final reports of the test results. When this problem was fully recognized, there was a shortage of NCI staff positions available to bring the test results to completion in the form of final reports. Consequently, a new competitive contract was inititated with Tracor-Jitco under which that firm would share overall responsibility with NCI staff for management of the complete testing procedure, from chemical selection through actual testing, pathologic analysis, and preparation of final reports. Tracor-Jitco assumed responsibility for sub-contracting these separate steps. Meanwhile, Congressional action

led to the allocation of additional personnel slots to the Testing Program in FY 1977.

Tracor-Jitco then concentrated on clearing the backlog of tests initiated before 1976, and on handling current testing needs, while NCI concentrated on filling the newly provided positions so as to enable direct management of future testing contracts. This overall procedure was very successful as a means for clearing the backlog of some 200 tests which had been in process since 1968. With the acquisition of additional staff, and the creation of the National Toxicology Program, the Tracor-Jitco contract/subcontract mechanism will be phased-out and NCI-NTP staff will directly manage testing contractors.

Question: What has been done to tighten up your grant and contract procedures? Detail for us what action was and is being taken to bring such procedures under control.

Answer: Several concurrent actions have been taken to improve grant and contract procedures. The major step is the reorganization of the Institute which was initiated in January 1978. Under this reorganization NCI changed from a plan under which a single division handled virtually all grant programs, to one under which each programmatic division manages the grants related to its program. As a result, each programmatic division has continuing cognizance of research being performed by grantees and is, therefore, less inclined to develop contracts addressing the same or similiar research needs. Secondly, under the new organization all peer review of grants and contracts is managed by a single division, thereby separating responsibility for review procedures from responsibility for program management. This step further insures the objectivity of review and evaluation procedures.

Over the past two years massive re-training programs have been undertaken under which all NCI Contracting Officers will become certified on technical contract management policies and procedures, and all Institute Project Officers will be fully apprised of their responsibilities. The latter policy requires that Project Officers receive 40 classroom hours of training in order to continue in that role.

Steps have also been taken to improve expenditure patterns throughout the fiscal year and reduce spending for grants and contracts in the last quarter.

Institute management has also taken steps to insure that contracts are regularly recompeted and the selection of initial contractors on a non-competitive basis has been significantly reduced.

Finally, a policy has been established under which Project Officers must submit, for supervisory review, a semi-annual progress report on each contract under their responsibility. These reports identify progress, shortcomings, and corrective actions taken or required.

61-400 O - 80 - 48

PROGRAM SUPPORT

Question: Please provide information on expenditures for travel for FY 79, FY 80, FY 81?

Answer:

FY 79	$3,652,000
FY 80	3,724,000
FY 81	4,300,000

Question: How many conferences/retreats do you intend to hold in FY 80 and FY 81?

Answer: The National Cancer Institute (NCI) plans to sponsor approximately 51 conferences during FY 1980 and approximately 50 conferences in FY 1981. These conferences cover the topics of cause, prevention, treatment, biology, diagnosis, and control relating to cancer. Conferences in FY 1981 are proposed for such areas as mammary cell transformation, viral chemical interactions, smoking, low-level radiation, occupational carcinogenesis, nutrition, and professional education.

Question: What portion of your budget will be spent on training?

Answer: In FY 1981, $155,000 or 0.02% of the budget will be spent on training of NCI employees to keep the employees abreast of developments in their fields.

SUBCOMMITTEE RECESS

Senator SCHWEIKER. This completes the series of questions on NIH, and the committee will stand in recess until 10 a.m. tomorrow, when we will hear testimony from the Alcohol, Drug Abuse, and Mental Health Administration.

[Whereupon, at 3:45 p.m., Wednesday, February 6, the subcommittee was recessed, to reconvene at 10 a.m., Thursday, February 7.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

THURSDAY, FEBRUARY 7, 1980

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. Quentin N. Burdick presiding.

Present: Senators Burdick, Schmitt, and Schweiker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF GERALD L. KLERMAN, ADMINISTRATOR

ACCOMPANIED BY:
JOHN R. DELUCA, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
WILLIAM POLLIN, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE
HERBERT PARDES, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH
WILFORD FORBUSH, DEPUTY ASSISTANT SECRETARY, POLICY COORDINATION
DAVID E. JOHNSON, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
CHARLES MILLER, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS
WILLIAM H. DOBBS, ACTING SUPERINTENDENT, SAINT ELIZABETHS HOSPITAL

BUDGET REQUEST

Senator BURDICK. Our hearing this morning will focus on the President's budget request for the Alcohol, Drug Abuse, and Mental Health Administration. Dr. Klerman is the Administrator, and with him as principal witnesses are Mr. DeLuca, Director of the National Institute on Alcohol Abuse and Alcoholism; Dr. Pollin, Director of the National Institute on Drug Abuse; and Dr. Pardes, Director of the National Institute of Mental Health.

Gentlemen, I would once again like to extend to you the subcommittee's welcome.

The mission of the ADAMHA is to prevent, control, and treat alco-

holism, drug abuse, and mental illness primarily through research, training, and service programs. ADAMHA also provides technical assistance to States and communities in their alcohol, drug abuse, and mental health programs, and has the major Federal responsibility for educating the public on these problems.

Saint Elizabeths Hospital is the only Public Health Service hospital devoted exclusively to the care and treatment of the mentally ill.

The President has requested $1,163,396,000 for the ADAMHA in his fiscal 1981 budget—an increase of $135,748,000 over the previous year. For Saint Elizabeths Hospital, the President has requested $97,706,000, including construction, for fiscal 1981. This is an increase of $12,622,000 from last year.

The subcommittee has numerous questions to ask you gentlemen, but before we begin our questions, would you, Dr. Klerman, please introduce your associates and then proceed with your opening statement.

Dr. KLERMAN. Thank you, Mr. Chairman.

As you have indicated, I am accompanied by the Directors of the three ADAMHA Institutes. On my immediate right is Dr. Pollin, Director of the National Institute on Drug Abuse, and on my immediate left is Dr. Pardes, Director of the National Institute of Mental Health, and on his left is Mr. DeLuca, Director of the National Institute on Alcohol Abuse and Alcoholism.

In addition, we are accompanied by three officials of the Department: Mr. Charles Miller, who is a Deputy Assistant Secretary for Health Operations. Next to him is Mr. Wilford Forbush, who is in the Office of the Assistant Secretary for Management and Budget.

We are prepared to answer questions that you may ask of us.

I will submit for the record a complete statement, but if you agree, I will make a few introductory comments.

[The statement follows:]

Statement of Gerald L. Klerman

It is a pleasure to appear before the Subcommittee to discuss the President's budget request for alcoholism, drug abuse, and mental health activities in 1980 and 1981. The Directors of the three Institutes comprising our agency are with me.

Mr. Chairman, I am pleased to be able to report to the Subcommittee that we are making significant progress in our efforts to understand, and ultimately to treat or prevent alcoholism, drug abuse problems, and the mental illnesses. To cite only one important advance, knowledge of the brain's functioning is being greatly expanded through studies of the recently discovered naturally occurring chemicals in the brain and their possible implications for addiction, control of pain, and treating mental illness. This research frontier holds genuine promise for making significant inroads against major afflictions such as depression, schizophrenia, narcotic addiction, and other health problems.

Mr. Chairman, we have two budget requests before you today--a supplemental appropriation request for 1980, and the regular appropriation request for 1981. The supplemental budget for 1980 is necessary so that we can move ahead immediately to implement two important initiatives: new community and State mental health programs, as provided in the proposed Mental Health Systems Act, and a major Departmental initiative to reduce and prevent alcohol problems.

The combined total of the supplemental is $65 million, including $50.4 million for the mental health initiative and $14.6 for the alcohol effort. I will describe the programmatic content of these programs in a moment, but a particular point should be made to highlight the need for a supplemental.

As you are aware, the Mental Health Systems Act is currently before the Congress. The full Senate Committee on Labor and Human Resources has begun consideration of the bill. The House Subcommittee on Health and the Environment has had hearings and plans to mark-up the bill either this week or next. By proposing funding for the pending legislation at this time, we hope the processes can run on parallel channels so that we will be able to initiate this important new program as soon as possible.

With regard to the alcoholism initiative, the Subcommittee may remember that this proposal was part of the 1980 President's Budget. However, since authorizing legislation was not available at the time the budget was considered by the Congress, the alcoholism programs were continued at the 1979 level under the continuing resolution. Because the initiative represents an increase over our 1979 level of effort, a supplemental is required to fund the service portion at the level originally proposed in the 1980 President's Budget.

I would like, Mr. Chairman, to proceed by discussing the 1980 and 1981 budget requests in terms of their programmatic content.

Funding is provided in the 1980 supplemental to initiate four new and innovative community programs recommended by the President's Commission on Mental Health. These mechanisms are designed to create a more flexible approach to building service delivery networks for meeting the mental health needs of populations and geographic areas currently unserved or underserved. The four new grant programs are:

Initiation grants to support discrete mental health services for priority population groups identified by the Commission including children and youth, the aged, minorities, the poor, and rural populations.

Development grants to support community projects committed to eventually becoming a comprehensive program for an entire mental health service area.

Linkage grants to make mental health services available in ambulatory health care centers, and,

Preparation grants to assist communities in assessing local mental health needs and designing appropriate service programs to meet the needs.

We share the conviction of the President's Commission on Mental Health that these new approaches will enable the Nation to make dramatic progress in bringing mental health care to segments of the population which have been underserved. The 1980 supplemental budget contains $12 million for these four new grant programs.

Our supplemental also includes $38 million or over half of the total monies for project grants to the States to promote a Federal-State partnership in the development and provision of mental health services. Specific efforts in this area include:

- $25 million to improve the care the Nation offers to its chronically mentally ill citizens, a group singled out by the President's Commission on Mental Health as requiring our highest priority attention. These monies would be used for major expansion of a successful pilot program, known as the Community Support Program, which has assisted the States in planning, development, and implementation of deinstitutionalization programs for this population. The funds would be used not only to expand projects in the 20 States where they already have shown their usefulness, but also to inaugurate a similar program in all other States.

-- $7 million for important new efforts on behalf of children with serious and persistent mental and emotional disabilities, and $6 million for activities to prevent mental and emotional illness.

Turning to the other major program area addressed by the supplemental request, we would devote $15 million to fulfilling the Department's commitment to strengthening its activities related to alcohol problems in our society today.

The special alcoholism initiative includes intensified prevention and service activities directed at alcohol problems among young people and women, investigation of alcohol related fetal defects, development of model programs to deal with alcohol-related family violence, expansion of occupational alcoholism demonstration projects, and development of a model employee assistance program

for the Department itself. The initiative was formally announced in May of 1979 and has already generated a substanital number of applications.

More specifically, we would be able to fund 12 more specialized programs to deal with the alcohol problems of youth, providing service to some 2,000 youngsters, and 18 additional specialized programs for women alcohol abusers, affecting about 5,000 persons.

Ten grants would be made to regions, States, or communities to develop specific model programs for dealing with alcohol-related domestic violence, and $1.5 million would go for projects to demonstrate innovative approaches for reaching employed persons with alcohol problems in a variety of work settings.

Finally, $1.2 million would be used to establish a Department-wide model employee assistance program, as mandated by the Congress, to identify, assist, counsel, and refer employees with job-impairing personal problems resulting from alcohol or drug abuse.

Mr. Chairman, I have devoted this amount of time to discussing the 1980 supplemental request because the programs it would support are two of the highest priority areas in the President's Budget request for fiscal 1981. A further increase of $20 million in 1981 is requested to strengthen and expand programs under the Mental Health Systems Act, and an additional $15 million increase is requested to advance the alcoholism initiative. The mental health increase will allow us to more than triple funding support for the new community grant aspect of the services program; in alcoholism it will permit the program to increase the funds available for new and competing awards by 13 percent over 1980.

Prevention and research activities are the focus of our other two priorities in the 1981 budget. Prevention activities are particularly highlighted in the drug abuse program where, in line with the newly enacted drug abuse authorizing legislation, 10 percent of total drug abuse community service funds requested for 1981 will be used for primary prevention and intervention purposes. These dollars would be used to support evaluation grants to learn which drug abuse prevention strategies work best, contracts to support new family and school prevention initiatives, and projects to promote technology transfer so that effective action can be taken to stop drug problems before they start.

In both the mental health and the alcohol initiatives, prevention activities figure prominently. The 1981 budget request before you will allow prevention efforts to increase by 10 percent in mental health and 32 percent in the alcohol program over the 1980 level of effort.

With regard to research, it has been our longtime priority to maintain a strong research program to uncover the causes of and develop effective treatment for alcoholism, drug abuse, and the mental illnesses. In 1979 and 1980 increases were provided for research in recognition of its importance as underscored by the President's Commission on Mental Health. The 1981 request maintains

this momentum by providing a $25 million, or a 12 percent increase over 1980.

With 1981 funds, the mental health program would give special emphasis to studying the problems and needs of the priority populations mentioned before, as well as to continuing investigations of major mental illnesses such as schizophrenia; the drug abuse program would focus on drug abuse treatment methods and basic research activities such as those concerned with endorphins, the naturally occurring opiate-like brain chemicals; and, the alcoholism program will give special attention to identification of the genetic factors associated with alcohol consumption and to the methods for early identification and treatment of persons with alcohol-related problems.

Mr. Chairman, in summary the budget documents before you request a 1980 supplemental of $64,987,000 and a 1981 budget of $1,163,396,000 for the Alcohol, Drug Abuse, and Mental Health Administration. Assuming the supplemental, this is an increase in 1981 of $68.0 million over the 1980 level. This includes increases of $25.0 million for research and $27.2 million for community programs and a decrease of $2.4 million for training programs.

Mr. Chairman, I will be pleased to answer any questions you or the other members of the Commmittee may have.

ADAMHA SUPPLEMENTAL REQUEST

Dr. KIERMAN. As you have indicated, we are here to discuss with you the request submitted by the President as part of the 1981 budget. The budget request is in two parts. First, is our request for a supplemental to the fiscal year 1980 budget of $65 million. Second, the main topic of discussion, is our fiscal year 1981 budget request which is for a total of $1,163,396,000.

We feel that the supplemental requires some degree of explanation. It comprises two main components: $50 million to implement the President's mental health initiatives, and $15 million for new efforts in alcoholism.

Both of these budget requests were in the President's fiscal year 1980 budget submitted to the Congress last year. The reason we are coming in for a supplemental request has to do with the fact that the authorizing legislation for these two items had not been passed at the time Congress acted on the 1980 appropriation.

In the case of the $50 million for mental health, we anticipate that the Congress will act very shortly on the Mental Health Systems Act submitted by the President as the major piece of legislation to implement the recommendations of the President's Commission on Mental Health which Mr. Carter called into being in 1977. The $50 million would enable us over the next 2 years to implement the new programs authorized by the Mental Health Systems Act.

The other main item in the supplement is $15 million for increased efforts in alcoholism. This had been recommended by the President in the regular submission of the 1980 budget, but because the authorizing legislation for the alcoholism programs was not passed in time for this

committee to consider support the funds are not included in the appropriation. Therefore, we require a supplemental appropriation for fiscal year 1980 in order to put into effect these programs.

ADAMHA ACCOMPLISHMENTS

Those are the main purposes of the supplement. As for the 1981 budget, this allows the programs in alcohol, drug abuse, and mental health to continue their momentum and to capitalize on some recent encouraging developments in these fields.

Let me say a few words about these developments and then, perhaps, each of the Institute Directors can amplify.

We are encouraged by signs of progress in each of these fields and by indications that the Federal efforts over the past decades are having significant impact.

In the field of alcoholism, for example, there is evidence of greater public awareness of the problems of alcoholism. This is reflected in a slowing down of national per capita consumption indicating that the American public, and in particular the adult members, is moderating its alcohol intake as part of a general concern with health promotion. One result of this decreasing consumption is a decrease in the death rate from cirrhosis of the liver which is one of the adverse consequences of excess alcohol consumption. The statistics indicate about a 10-percent reduction in the death rate from cirrhosis of the liver, over the past few years. This is the first time we have been able to document a decrease following a period of rise for about three decades.

There are encouraging signs that people are coming into treatment, and that the Federal dollars in alcoholism are being matched by contributions from the private sector, industry, and also by the States and local communities.

Similarly, in the field of drug abuse, there are indications that the heroin problem has plateaued over the past few years. There has been perhaps a 10- to 15-percent decrease in heroin use as measured by heroin use indices, such as death due to overdose and emergency room visits. We, however, have some caution about the heroin problem since there are indications that in Western Europe there has been an increase in the use of heroin and an increase in supply. Even this morning's newspaper indicated increased law enforcement efforts to intercept illicit supplies of heroin.

In the field of mental health there have been a number of very significant research breakthroughs on the relationship between the developing brain and behavior, which indicate that the investment in research that this committee and the Congress have encouraged through the years has resulted in a growth of capability in both the Federal laboratories and universities for high-quality research in biomedical and behavioral areas.

This research payoff is also reflected in a further decrease in patient residence in large public mental hospitals and in increasing effectiveness of various types of treatment, although here we have some problems with deinstitutionalization and insuring a better quality of life for patients discharged into the community.

These, then, are some of my general comments. And I would appreciate the opportunity for the individual Institute Directors to amplify from their perspectives, Mr. Chairman.

I would first call upon Mr. DeLuca, who is head of the National Institute on Alcohol Abuse and Alcoholism.

ALCOHOLISM INITIATIVES

Mr. DeLuca. Thank you, Dr. Klerman.

Senator, let me take one moment to briefly highlight the initiatives which are the focal point of both the 1980 supplemental request and the 1981 budget request.

There are, throughout this Department, extensive efforts to increase access to care for women and young people, two population groups which have not had adequate services. We are anxious to increase our information efforts to the American public with respect to the relationship between excessive consumption of alcohol during pregnancy and birth defects, sometimes referred to as the fetal alcohol syndrome. We are prepared, if these requests are favorably reviewed, to enhance our prevention efforts. We also will be devoting substantial resources in both fiscal years to increasing early identification programs in the workplace, both in private and public organizations. We consider these budget requests critical to the continuation of the Federal efforts with respect to this most important public health problem.

Senator Burdick. Suppose somebody were to ask me what we do with this money. What do you do?

Mr. DeLuca. Well, we do a number of things with this money.

Senator Burdick. Specifically, what do you do?

Mr. DeLuca. We make grants available to community and nonprofit organizations to develop treatment and rehabilitation services. The majority of these grant applications are devoted to new treatment services and increasing access to care. We would hope that through these projects we would be able to demonstrate new treatment services for women, as I mentioned earlier, and new treatment services for young people.

PROGRAM APPLICATIONS

Senator Burdick. What form do these programs take when you give them to the localities?

Mr. DeLuca. What we do is announce through formal grant guidelines the kinds of program applications that we would like to see—types, formats.

Senator Burdick. Give an example.

Mr. DeLuca. For example, the Institute published a program announcement to invite grant applications for programs in 1981 which would have a treatment service directed specifically to women's needs. And we have received an overwhelming number of applications.

Senator Burdick. Who makes an application?

Mr. DeLuca. The application could come from a hospital, from a community organization, from an existing treatment program which wanted to add on an additional component for women.

These applications are then reviewed by the Institute's dual review system consisting of an initial peer review for technical merit by experts in the field and a secondary review by our National Advisory Council. The grants reviewed must be recommended by both bodies in order to be eligible for consideration based on program priorities and fund availability.

ALCOHOLISM SUPPLEMENTAL

Senator BURDICK. Well, granting that we approved the supplemental, the 1981 budget won't be substantially larger at all than 1980, if we include the supplemental for 1980.

Mr. DELUCA. The supplemental request is for $14.6 million. The 1981 budget request would continue the commitment to those programs and requests an additional $15 million.

Senator BURDICK. Over the 1980 budget?

Mr. DELUCA. That's correct.

Senator BURDICK. Including the supplemental?

Mr. DELUCA. That's correct.

Senator BURDICK. That's just for alcoholism?

Mr. DELUCA. Yes.

Senator BURDICK. Can you speak to the other programs?

Mr. DELUCA. Only very cautiously.

Senator BURDICK. I'd like to hear from the rest of the programs.

Dr. KLERMAN. I'd like to introduce Dr. William Pollin, who is the Director of the National Institute on Drug Abuse.

DRUG ABUSE REQUEST

Dr. POLLIN. Mr. Chairman, I would like to summarize the situation with regard to the drug abuse problem. After a period of explosive growth in this country of this problem and a parallel explosive growth in the development of a whole new national treatment system, we now come upon a period of plateau. Our budget request reflects that plateau in that the total budget request is essentially a level-budget request.

The program levels within this level request reflect the significant advances which were made in research into understanding the basic mechanisms related to drug abuse and the mechanisms responsible for it. And we are requesting an additional $4 million for research in 1981 to take advantage of those breakthroughs which were made in the past 2 years.

We are also requesting an increase in funds to be used for prevention. We believe that now that a national treatment program has been set in place, prevention has a larger role to play in our overall program.

Senator BURDICK. Your budget for 1980 was $274,220,000 and the supplemental asked for $527,000 and this year you're asking for $274,414,000. So actually the 1981 budget is going to be $587,000 less than the 1980 budget.

Dr. POLLIN. We don't have a request for a programmatic supplemental.

Senator BURDICK. You are asking for a supplemental.

Dr. POLLIN. For pay increases but not in terms of new programmatic initiatives.

Senator BURDICK. But the 1981 budget would be $447,000 less than the 1980 budget?

Dr. POLLIN. That's right.

Senator BURDICK. Do you think that will affect the program any?

Dr. POLLIN. I think we will be able to increase managerial efficiency by transferring funds in the directions I have indicated.

Senator BURDICK. Mental health is next?

Dr. KLERMAN. I'd like to introduce Dr. Herbert Pardes, who is the Director of NIMH.

MENTAL HEALTH REQUEST SUMMARY

Dr. PARDES. Mr. Chairman, the administration budget on mental health reflects many of the developing initiatives and recommendations that came out of the President's Commission on Mental Health.

We have a recommendation to the Congress for a major alteration of the services which you see reflected in both our supplemental request and our 1981 budget.

In addition, as Dr. Klerman indicated, the research field in ADAMHA generally, and particularly in mental health is, in my view, one of the most exciting areas of research. We are seeing a tremendous amount of knowledge forthcoming in a variety of areas so that the support secured from the Congress is having an enormous amount of payoff.

You see, also, within the budget a basically level budget in training which constitutes our efforts to meet the critical priorities and yet be as economically efficient and effective as possible.

Finally, I would draw to your attention that in the last year we have been successful in having Saint Elizabeths Hospital's programs reaccredited in three phases. One was the adult program, one was the child program, and the third was the alcohol program.

I would say we are moving rather actively to bring that hospital back to the kind of level of quality that it had in past years.

PRIORITY SCORES

Senator BURDICK. In the NIH we have attempted to insure that all research programs are funded at a level of 200 or more. Do you use similar scoring systems at ADAMHA?

Dr. KLERMAN. Yes, ADAMHA research and training grants undergo a dual review. Grant applications are reviewed, first, by initial review groups, peer experts, and consultants, and then are voted upon by the appropriate national advisory council.

In the priority score area, the current practice would indicate that 90 percent of the awards in mental health, drug abuse, and alcoholism will be at a priority score of about 220 to 240 or lower. A lower number means a higher grade, so scores in the 100 range are considered of higher merit than those of 250 or 300.

Senator BURDICK. Do all of the institutions now have a core program on which to build a sound grant and contract program?

Senator BURDICK. If each Director told you he could fill the positions, would you allow it?

Dr. KLERMAN. Well, we always have the opportunity to improve the quality of our programs if resources become available. I'd have to ask Mr. Miller. [Laughter.]

Mr. MILLER. Mr. Chairman, the employment ceiling authorized by the administration is less than those numbers.

Senator BURDICK. That isn't a very persuasive argument. Just because it hasn't been, isn't very persuasive. Does it always have to be that way?

Mr. MILLER. Even if we were authorized to fill all budgeted positions, it would be difficult to get close to 97 percent, to the ceiling that is established. So there is probably a fractional difference there.

TREATMENT PROGRAM LINKAGES

Senator BURDICK. We will ask this question later and see if there has been any progress.

The field of mental health, drug abuse, and alcohol treatment are said to be similar by many people, involving as they do the daily prevention and treatment activity. If so, facilities separated and often within walking distance of themselves are a waste of resources. What is your feeling on sharing the programs in the in-service programs?

Dr. KLERMAN. I am not sure whether you are referring to research or treatment programs.

Senator BURDICK. Treatment.

Dr. KLERMAN. At the local level we encourage local commmunities to link various programs in alcoholism, drug abuse, and mental health with each other and with the general health care system. We have requested authorization for special linkage grants to link mental health grants with general health grants.

At the State level we are encouraging the States to submit combined State plans for either drug abuse and alcoholism or for drug abuse, alcoholism, and mental health.

In fact, at the present time I understand that some 40 State authorities have combined drug and alcohol administrative units. Last year we received 8 combined plans for alcohol, drug abuse, and mental health, and 24 States submitted combined State alcohol and drug abuse plans. We are working to speed the review process.

At the Federal level we have a number of programs in research and training and elsewhere in which the three Institutes cooperate and share review or program areas.

We constantly review the various program areas looking for opportunities for sharing. For example, we have recently reviewed our prevention area and identified the adolescent area as one in which common programs for alcoholism, drug abuse, and mental health would be useful.

Senator BURDICK. That partially answers the next question.

I understand that in many cities you still have separate facilities that could be operated under one system.

Dr. KLERMAN. Well, that is true. However, we are limited in what we can do for various reasons. One is that, currently, each of the programs

operate under a separate authorizing legislation. We do encourage cooperative efforts. But the basic statutes under which the programs operate, with their separate authorities, mandate separate review of applications and independent program development and policy. That is by congressional statute per the authorizing committees.

Senator BURDICK. That doesn't prevent them from living together.

Dr. KLERMAN. Well, they can live together in the same building, and we make every effort to develop cooperative programs. At the community level we leave it to the community to determine how many specialized services are needed and how many coordinated services are sought. One important aspect of this is the community mental health center program which offers alcohol and drug abuse programs along with mental health services.

FREESTANDING VERSUS COMPREHENSIVE TREATMENT PROGRAMS

Senator BURDICK. Do you look forward to bringing more and more of these facilities together?

Dr. KLERMAN. I think I have to answer that in a complicated way. In some areas I think we can do more together; as I say, in the area of adolescence and, perhaps, some prevention and research. But studies have shown that for some specialized treatment, such as in the heroin area or some aspect of alcoholism, the best results are obtained through separate programs. But perhaps you can hear information on this from Dr. Pollin and Mr. DeLuca.

Senator BURDICK. All right.

Dr. POLLIN. Mr. Chairman, we have conducted a study comparing treatment effectiveness of drug abuse treatment programs which are freestanding programs, those which are separately defined programs within a community mental health center, and those which are just part of an overall community mental health center. The results showed clearly that both treatment retention and treatment success are significantly greater in the freestanding treatment programs than the others.

Senator BURDICK. Why?

Dr. POLLIN. First, I think that there are specialized differences among clients entering the different treatment programs. Second, I think there are specialized skills and approaches to treatment.

We all are working toward the goal of identifying precisely those cases where linkages and intercommunication can be effective among the ADAMHA programs. But clearly there remain areas where specialized categorical programs are generally more effective.

Senator BURDICK. I'm sure you are familiar, in a general way, with the 1981 budget proposal sent down by the administration. You've got a pretty tight situation in the programs. Is this one place where you would have one building instead of three, maybe, for some of these programs?

Dr. POLLIN. I think one building instead of three and greater coordination in many areas is undoubtedly very desirable. I am merely trying to point out that there are specific areas where specialization can be shown in the long run to be more cost effective. I don't think it's an either/or situation.

RESEARCH PRIORITIES

Senator BURDICK. In the area of mental health research, what program priority will be given to research this year?

Dr. KLERMAN. Dr. Pardes.

Dr. PARDES. We are expanding our research efforts in several areas, Mr. Chairman. These include increased support for research on the major mental illnesses, epidemiological research, service delivery research, and also more basic research into the causes of psychiatric disorders. We are also stimulating more efforts in the evaluation of treatment strategies or treatment procedures in mental health, and also making a heavy focus on research on the special population—minorities, elderly, and children.

Senator BURDICK. Children, minorities, and the elderly are served by the mental health system, as you indicated in your testimony last year. What steps have been taken to aggressively include these groups since last year?

Dr. PARDES. We are doing this across the board. We take them one area at a time. First, we have increased our levels of research support relating to those populations. Second, the Mental Health Systems Act we are recommending to Congress identifies or includes those populations as populations of special need, and allows us to set up specialized service programs identified for those populations.

Third, we redirected our entire clinical training efforts so populations such as minorities, elderly, and children are prime priorities for our teaching profession and personnel programs.

Finally, in developing prevention programs, we are also highlighting those populations as key populations for our program.

Dr. KLERMAN. I might amplify, Mr. Chairman, that in two of the areas you mentioned, Congress has requested special reports. The House committee requested a report on our efforts and accomplishments in the area of the mental health needs of the aging, and a special report has been sent to the Congress.

In addition, this committee requested of us a report on progress made in improving the number and diversity of professionals that come from minority backgrounds. This has been a major effort, not only at NIMH but also in NIDA and NIAAA. And we have submitted a detailed report on those efforts to your committee.

Dr. PARDES. Mr. Chairman, if I could add one other thing to the comment I made, the administration has also made recommendations to the Congress which we think would represent improvements in the reimbursement of mental health services for several of those priority populations.

Dr. KLERMAN. There is before the Congress a modification of medicare which would make more equitable the financing of the mental health services for the elderly, comparable to the financing of general health services. In addition, the child health insurance program has passed the House and is now before the Senate, and the administration supports those efforts as improving the availability of mental health and developmental disability services for children.

USE OF NEW CMHC FUNDS

Senator BURDICK. Looking at the fiscal expenditures provided by ADAMHA, it has come to our attention that the $35 million allocation for startup cost for mental health centers has been spent on two different programs as well. I speak of the $28 million your budget shows was spent on community mental health services—$1.5 million to a new State monitoring program, and $5.5 million to various continuing cost categories.

How do you explain this transfer of appropriated money when this committee has not been requested for a reallocation of the 1980 funds for mental health startup costs.

Dr. PARDES. There are several factors involved here, Mr. Chairman. First, by virtue of some of the budgetary developments of 1979, we were able to put money into new starts which had continuation cost obligations in 1980. That had some impact on the number of dollars available for new operations in 1980.

Second, we are, in fact, in the process of asking the Congress for approval of a $1.5 million allocation to a program for State monitoring. That is in the spirit of our trying to more tightly and effectively administer this nationwide program.

Third, and most significant, continuation costs from the preexisting centers have gone up much higher than was expected by virtue of inflation.

In essence, with regard to that situation, we found ourselves with a choice of either underfunding existing centers as opposed to creating new ones, and it was our impression we were creating a greater difficulty by jeopardizing existing centers and so tried to have some continuation cost responsibility. If you look at the total amount between new expenditures and continuation costs, that still amounts to the same amount that Congress has recommended.

Senator BURDICK. Well, I am advised by the staff that we provided $35 million for a certain program and it hasn't been spent for that program.

Dr. PARDES. Let me go back over it.

The dollars which you would be recommending in 1980 for new grants by virtue of our ability to start some new in 1979 have continuation costs built into 1980. In other words, we have almost done what you wanted—a little bit ahead of time—by virtue of our being able to save some dollars or to utilize dollars most effectively.

Second, we are formally making a request to you, which will be forthcoming from the Department shortly, regarding the use of $1.5 million for State monitoring activities. That would account for some of the reduction.

Finally, as I mentioned, we have the problem of the inflation rate impacting on continuation costs. While the $35 million for new operations is reduced, the total amount available for new awards and continuations remains the same, except for the $1.5 million.

Senator BURDICK. I don't want to belabor this, but maybe you could give us a further report before we conclude these hearings.

Dr. PARDES. Certainly.

Senator BURDICK. Our own language specifically says, "startup cost for new health centers."

Dr. PARDES. I'd be happy to give you a full statement on that. Is that what you want?

UNDERSERVED AREAS

Senator BURDICK. Yes; if you don't have the material in the next question, you can supply it for the record, too.

How many community mental health centers are located in rural areas and urban centers?

Dr. PARDES. We will supply that.

Senator BURDICK. Do you feel there is a disparity of service between rural and urban areas? You can answer that now if you wish.

Dr. PARDES. A disparity? We are attempting to provide services throughout the country where they are in short supply. I think there are underserved areas in both the urban and rural areas.

Senator BURDICK. Do you feel there is a disparity at the present time, that there is less attention paid to rural areas, for example, than should be?

Dr. KLERMAN. I think evidence does indicate there are significant unserved areas in the country. Rural areas are generally underserved medically, and also in mental health and alcoholism. We are making efforts to direct more resources, more programs, and more personnel into rural areas, along with other underserved medical areas. But the basic thrust is correct. Many rural areas are medically unserved.

Dr. PARDES. If you'd like a breakdown of the proportion of the centers in kinds of population centers, I can give it to you now.

Some 14 percent of the community mental health centers exist in cities over 500,000 population, some 48 percent in cities from 25,000 to 500,000, and some 38 percent in cities of less than 25,000.

Senator BURDICK. Of course, you haven't got the rural population yet in cities of 25,000.

Dr. PARDES. This means less than 25,000. I think the point is there are obviously areas in the country in need, and we are making those areas of need our highest priority for establishing more mental health services.

Senator BURDICK. I know we give you so much money, and I understand your problem, too. But keep on thinking about it, will you, the underserved areas.

Dr. PARDES. In my mind it is one of the prime features, both of our systems act and our programs.

CMHC BACKLOG

Senator BURDICK. Do you have any specific plans for startup costs for new centers?

Dr. PARDES. I am not sure what you mean.

Senator BURDICK. Do you have any plans? Are there any community centers that are on the drawing board?

Dr. PARDES. Oh, yes. There are applications which we have in, and some of them have already been reviewed and are awaiting funding.

61-400 O - 80 - 49

Also, it is our understanding that beyond those applications that are already in, there are some 63 communities which are at some stage of planning to introduce yet additional proposals for starting of services.

Senator BURDICK. Sixty-three?

Dr. PARDES. In addition to those already having come as applications.

RETURN OF PATIENTS TO THE COMMUNITY

Senator BURDICK. Have community mental health centers made substantial efforts to insure that persons discharged from mental hospitals have access to community mental health services and support services?

Dr. PARDES. The community mental health centers have played a substantial role both in terms of people being discharged from institutions and those who otherwise might have gone to institutions. I might say the community mental health programs have been an important factor in moving our services system toward giving a much higher proportion of our services in the ambulatory setting versus the inpatient setting. If you look at 1975 through 1977, whereas we were once giving services on a 3-to-1 ratio, inpatient versus outpatient, that has totally been reversed.

If one looks at the diagnostic groups seen in CMHC's, something like 45 percent of the patients are described as having most severe mental disorders. These are people who in the past, I think, spent much more time in hospitals than they do in our more advanced system today.

Dr. KLERMAN. I might add, Mr. Chairman, that the problem of patients discharged into the community was highlighted by the President's Commission on Mental Health, and in response to one of their recommendations the Department has just set up a special work group to develop a long-term plan for the chronically mentally ill.

Dr. Richmond and I are cochairmen of that planning effort. One section is devoted to reviewing funding mechanisms, particularly through reimbursement programs in titles 18 and 19. Dr. Pardes is heading the other work group on service needs. The evidence thus far indicates that in addition to treatment services, these patients need access to housing, to vocational rehabilitation, and often to disability assistance. We are reviewing the programs both within HEW and other parts of the Federal Government for possible recommendations for change.

COMMUNITY SUPPORT PROGRAM

Senator BURDICK. As of right now, what support services are available to these people who are discharged in State hospitals?

Dr. KLERMAN. NIMH has recently begun a special program to help the States, the community support program. I think Dr. Pardes has described that. In addition, these patients are eligible for SSI and medicaid, but that varies from State to State. There is, we must acknowledge, considerable variation across the States in these programs.

Dr. PARDES. As Dr. Klerman mentioned, we see the community mental health centers as giving the specialized mental health treatment for such people. But in addition, it is well-recognized that in order for them to function optimally outside of an institution, one has to attend

to a variety of their needs, including housing, work, social relationships, et cetera. Therefore, the NIMH recently set up a community support program which offers such people help in terms of attending to a variety of needs. That program is already operative in some 20 States.

Senator BURDICK. Who administers it?

Dr. PARDES. That is administered by NIMH. We work with the various States.

Senator BURDICK. For example, in North Dakota, do you have a program like that?

Dr. PARDES. I'm not sure. I'd have to check.

Senator BURDICK. Would you set up an office in these various States? How do you administer it?

Dr. PARDES. The State decides what kind of office it will set up. Really it's their initiative to tell us how they'd like to set it up.

One of the nice features about this program is that many of the States have become so enthused about the concept that they have brought major match money in to enlarge it.

The second thing is, many of the concepts of that program formed the foundation of much of our thinking in the Mental Health Systems Act.

Senator BURDICK. What happens if there is no mental health center in the area the patient is going to?

Dr. PARDES. Then they utilize available mental health practitioners or sometimes use the general health sector.

MENTAL HEALTH NEEDS ASSESSMENT

Dr. KLERMAN. I might add to that, Mr. Chairman, that under statute each State, in order to be eligible for CMHC funds, must designate a single State authority which must furnish to us an assessment of needs in the State. This includes an identification of exactly what you mention—if there are areas not served by mental health centers or by existing professionals or clinics, what efforts the States are making to fill those needs—particularly for children or the chronically mentally ill. We review those plans with the States each year to help define where the high-priority gaps are.

I don't know the situation in your State, but there is a State mental health authority which does provide this kind of annual update of its needs assessment.

DEINSTITUTIONALIZATION

Senator BURDICK. Well, based upon the knowledge that I have, this is a very important period in a patient's life we are talking about right now.

Dr. PARDES. Absolutely.

Senator BURDICK. So you are thinking about it?

Dr. PARDES. We are not only thinking about it, Senator, but the Mental Health Systems Act attacks this as one of the central issues. The national plan that Dr. Klerman identified is struggling not only with the

short-term situation with regard to these patients' problems, but also to have a plan for the future.

Dr. KLERMAN. With respect to that, some $25 million of our supplemental request, which is also incorporated in the 1981 budget request, would make moneys available to the States for development of plans and programs exactly in the area you identified; namely, in the assistance of patients who are leaving hospitals and community placement. One of the main features, if not the largest single dollar component, of the supplemental request in mental health is to provide moneys to the States to help them be more effective in assisting the chronically mentally ill who are being discharged from public hospitals.

Many States report to us, as they did to the President's Commission, that while they have been successful in reducing the population in the large public institutions, there has not yet been the development of community treatment and support programs to meet all the needs of the patients.

Again this varies from State to State, and we hope under this new program, for which we are requesting funds in the supplemental budget, to go through a State-by-State review with the State authorities as to what the needs might be. And I imagine in a rural community State like yours, the needs might be very different than in a city like Philadelphia or New York.

Senator BURDICK. You are talking about the supplemental 1980 funds?

Dr. KLERMAN. Yes, which is also incorporated in the 1981 Presidential request.

Senator BURDICK. In North Dakota, the impact of rapid energy development is putting tremendous pressure on the resources of the mental health centers. We have real boomtowns in which there is no traditional social support structure for people to fall back on. These boomtowns are common wherever rapid development occurs in rural areas. What is even worse in North Dakota is that centers already established had to cut back because they couldn't afford the outreach workers.

Is ADAMHA sensitive to this kind of need, or are you responsible for it, or do you know about it?

DISTRESS GRANTS

Dr. KLERMAN. I don't know the situation specifically in that community, but we have a category of grants called distress grants which are specifically designed to provide fiscal flexibility to individual centers such as the one you indicate. Inflationary costs largely contributed to by energy, are part of the considerations that Dr. Pardes indicated were behind our not being able to put as much money into new starts because of the need to continue the existing costs from previously established centers.

Dr. PARDES. I am intimately familiar with that kind of situation, Senator, inasmuch as I not long ago visited that same kind of situation in Gunnison, Colo., the same kind of boomtown problem. I think you are speaking to the problem here of the financial strength of centers generally.

As Dr. Klerman mentioned, we have a distress grant program to help out community mental health centers as their Federal money starts to reduce in other categories.

However, one of the positive things is that if you look at the programs across the country, we are getting three non-Federal dollars for every dollar of Federal money invested. In other words, the centers are actively looking for other resources to strengthen their functions.

In addition, the Systems Act provides for several services for ongoing support, services that typically have not been reimbursed or have not been reimbursable.

Senator BURDICK. Under the category of distress, we find in the 1980 budget authority $12,010,000. The estimate for 1981 is $9,435,000. So the distress money is going down.

Dr. PARDES. Yes; but remember, we are anticipating the implementation of the Mental Health Systems Act which has different funding mechanisms which would afford some help to the centers in financial difficulty.

Senator BURDICK. Over and above this figure here?

Dr. PARDES. Yes; one category of grants within the Mental Health Systems Act would offer them money for a variety of services and give them money to draw upon. The distress grant money has not been continued in the Systems Act because we are trying to have a more flexible set of financial mechanisms so we can put such funds where we need to and think the priorities are.

TRANQUILIZER ABUSE

Senator BURDICK. In the fall of 1979, a Senate subcommittee was told that valium abuse threatens public health. One witness called valium the No. 1 drug problem in the United States today, exclusive of alcohol. Another witness testified that the combined dependency on alcohol and tranquilizers is now the No. 1 public health problem in the Nation.

What special efforts are you making to tackle the problem of tranquilizer abuse? And part 2 of the question is: Are there any of the fiscal year 1981 funds appropriated for tranquilizer use research?

Dr. KLERMAN. My answer to that would be, Yes. This is a matter that has concerned not only ADAMHA, but the Public Health Service in general, since drugs that have the potential for abuse as may occur with valium, is a concern also shared with the Food and Drug Administration.

Dr. Richmond, the Surgeon General, sent out an advisory to all practicing physicians in the fall of this year advising them of the potential dangers of combining these categories of drugs. Particularly in individuals who may abuse alcohol. Almost all of the deaths and adverse effects occur due to the combination of these drugs with alcohol.

In addition, the Surgeon General has announced a special program, operation sleep, which is an attempt to educate physicians, pharmacists, and the general public about the various types of sleep disturbance and the best means to deal with hypnotic drugs, including the tranquilizers.

Most recently, Secretary Harris has asked Dr. Richmond to develop a position paper with regard to the problems of prescription drugs as they may impact upon women.

The overall death rate from barbiturates and from sedative drugs has been reduced dramatically in the past few years. The prescription rate for valium and other minor tranquilizers is down about 10 percent over the past few years. The FDA is developing a series of what it calls patient package inserts to inform patients about the proper use and dangers of various categories of drugs. Minor tranquilizers is one of the first three categories selected by the FDA.

This is a general problem that the Public Health Service is concerned about.

Now, more specifically with regard to alcoholism and drug abuse, this is an area where there has been good cooperation. Dr. Pollin and I were discussing just yesterday and today the circumstances under which valium is of danger and what is the best way to put this problem into perspective. Dr. Pollin?

VALIUM ABUSE

Dr. POLLIN. Yes; we have found that the great majority of individuals who are addicted to valium are either individuals who had prior addictive problems, as with alcohol in most instances, or have difficulties because of the combined use of the drug with other substances. Though the rate of the problem with valium is very low compared to all other psychoactive substances, nevertheless the huge number of prescriptions nationwide makes it a problem deserving of special attention. It has received that special attention both in regard to an increase in treatment services and also with respect to substantial advances in research which help us understand the mechanism and action of the drug, and which offer hope of developing specific antagonisms to counteract the problem.

Senator BURDICK. Excuse me. Can that substance be acquired without a prescription?

Dr. KLERMAN. No; it not only requires a prescription, but the minor tranquilizers are in schedule 4 of the FDA and DEA scheduling. The law requires that the Department of Justice, upon recommendation from the Public Health Service and HEW, schedule drugs of potential dependence. The judgment has been made that this class of drugs has such potential that they occur in what is called schedule 4, which limits prescription refills to five in a 6-month period by physicians.

Our research indicates that something like 70 to 80 percent of all prescriptions for psychoactive drugs are written by general physicians and interns. They are not written by psychiatrists or mental health specialists. Thus, in our training area we are devoting special efforts in the mental health and alcoholism programs to develop special curriculums for family doctors and medical students, part of which will be the proper use of these drugs and their indications and contraindications.

Second, there has been some very dramatic research on how these drugs affect the brain. We now know there are receptors in the brain for benzodiazepines, and they are receptive to a substance called GABA. There has been mapping of those parts of the brain where this

substance occurs. This research has been supported by NIMH and NIDA and has been conducted in both the universities and the intramural laboratories of the Federal agencies.

So we feel we have a combination of knowledge about the clinical problems as well as more basic knowledge of the way in which the brain, so to say, processes and uses these drugs.

Senator BURDICK. You say you have regulations where this prescription is limited to five in 4 months or something like that?

Dr. KLERMAN. Five in 6 months.

PHYSICIAN PRESCRIPTIONS

Senator BURDICK. Well, just being a suspicious character, what would prevent a user from going to doctor A and getting a prescription and going to doctor B, doctor C, and doctor D? How do you cross-check all of this?

Dr. KLERMAN. Unfortunately, I don't think we have any statutory authority at the Federal level for that. The responsibility for that rests with the local States. There is, to my knowledge, nothing in the existing statute that prevents that from occurring. However, the pharmacists of this country in particular, as well as physicians, are increasingly sensitive to that occurrence. But I would have to acknowledge that there are instances where patients may do that, and there are even instances where individual physicians do not follow the Federal guidelines. That has occurred with certain prominent rock singers and elsewhere.

Senator BURDICK. In most cities there is more than one pharmacy.

Dr. KLERMAN. We have no way to check it. You identify a serious problem.

Dr. PARDES. I think there are two sides of the general question of drug dispensing by general practitioners, and I would augment Dr. Klerman's comments that we are trying to educate general practitioners in the appropriate use of medications and also in psychotherapeutic techniques which sometimes can be as effective in relieving some of the psychological problems.

AVAILABILITY OF METHADONE INFORMATION

Senator BURDICK. Just a few questions about heroin and marihuana. Regarding heroin and other drug-sponsored research, it has come to our attention that an individual searching for information on methadone treatment was referred to your clearinghouse. His efforts produced a long series of delays, denial of available information, and finally the researcher was informed that it existed but was not available to the public.

Haven't we put thousands of dollars into the methadone program for research, and why wasn't that information available in the clearinghouse?

Dr. POLLIN. I am not familiar with the situation you have described, nor does your description suggest to me what the precise problem may have been in that situation. Was this an individual looking for information on treatment programs or a researcher looking for inf. rmation with regard to it?

Senator BURDICK. Both.

Dr. POLLIN. If I had whatever information would enable me to identify this particular case, I would be very glad to review it and supply an answer in detail.

I might say, in general, that there have been problems in the past with respect to responses prepared by the clearinghouse mail contractor. We have become aware of this in the past year, and I think now have corrected that particular problem. Overall, I believe our record, both in terms of response to the public and to researchers in requesting information, has been more than adequate. I would certainly like to investigate this further.

TRAINING PROGRAMS

Senator SCHMITT. Gentlemen, I am glad to be here. I am sorry I was late and missed the prepared testimony.

One question many people put to me and many others is how you achieve the goals of your programs, and particularly the outreach goals, without training personnel. As we look at your budget information, area training is either held constant in terms of dollars or goes down—with one minor exception.

Since the early 1970's there has been a decrease in real dollars of some 29 percent in training funds, particularly in mental health.

How are we going to carry out these grandiose plans of the President when we are apparently not going to have the trained personnel to do it?

Dr. KLERMAN. Senator, you have hit upon a very difficult and complex problem. It is true that the budget presented by the administration does not request any new funds in the area of clinical training. The reason for this is complex. One consideration is, particularly in the field of drug abuse and mental health, that we have gone through a period of very rapid expansion of the total personnel and human resources available mostly stimulated by Federal funds since the Korean war period. There have been dramatic increases in the number of psychiatrists, psychologists, nurses, social service workers, and counselors. And while part of our judgment is that there may be serious shortages in distribution and in certain subgroups, the administration's judgment is that, overall, the supply of professional personnel is available.

In certain of the specialties, particularly social work and psychology, the so-called marketplace mechanisms are, in our judgment, operating to attract an increasing number of talented young people into these fields, as witnessed by the number of people in the master's and doctoral programs. It is our judgment that additional Federal moneys are not needed to stimulate personnel overall.

We do acknowledge there is a shortage in one of the fields—psychiatry. We are not at this moment prepared to give an absolute number of the shortage in that area, although that is being worked on in the Health Resources Administration. With regard to the serious distribution problems of professionals in rural areas and in serving certain populations such as the aged, children, and minorities, efforts have been made to redirect Federal funds in order to target personnel and human resources needs toward these areas.

REPORT ON PERSONNEL SHORTAGES

Senator SCHMITT. Don't you owe us a report on the details of that?

Dr. KLERMAN. We have submitted a report on the details of the minority professionals as was requested in writing. We were requested to be prepared to discuss the types of questions that you have just generated. But we were not, as I recall, requested to have a specific written report except in the area of minority personnel.

Senator SCHMITT. We will look into that, but it was my memory that the final report asked for a more comprehensive report. We will check that.

Dr. KLERMAN. Our understanding is that the only written report that was required was on our efforts to meet the needs of minority personnel, and we have submitted that report. We are prepared to discuss the general problems, but my recollection is that we were told it would be brought up in verbal questions.

Senator SCHMITT. You might refer to Senate Report 96-247, the bottom of page 72 and top of page 73, where I think there is a request for a report.

I think it is very important that we have that. The APA has indicated a shortfall of some 10,000 psychiatrists—that is referenced here. And the committee is getting conflicting stories here. You are saying we are approaching saturation, by implication, or soon will be, whereas others are indicating a shortfall that is considerable.

We don't, basically, have the information. It is a maldistribution, but where is that? How do we target it?

PERSONNEL SHORTAGES

Dr. KLERMAN. Let me respond that we do agree there is a shortage of psychiatrists. That has been referred to the Graduate Medical Education Medical Advisory Group which advises the Department, and it is undertaking a systematic study of the quantitative aspects. The Department, at this moment, has not sufficiently analyzed the problem to give a detailed number or to say whether we agree or do not agree with the estimate of 10,000.

However, the evidence that we have is that there is a shortage of psychiatrists, particularly as reflected in the fact that the percentage of medical students electing to come into this field has decreased. And there are a number of efforts made in concert between NIMH and the Health Resources Administration, between Dr. Foley, who is the Administrator of that agency, and Dr. Pardes, to mobilize the Public Health Service resources to correct that.

We are also reviewing the personnel needs in the other professions as to whether or not efforts are currently sufficient. As I mentioned, our judgment is that the overall supply of mental health professionals is adequate but there are serious problems of distribution. One has to do with geographic distribution, particularly a lack of mental health professionals in rural and mountain areas and also in certain inner-city areas.

There are also certain kinds of institutional maldistributions, particu-

larly in some of the public institutions like the State hospitals and the veterans hospitals which are heavily dependent upon foreign medical graduates. That supply of medical personnel will no longer be available, and that is a distribution problem of magnitude. It is potentially serious, not only in medicine, but surgery and pediatrics, particularly in the cities like New York and San Francisco where the municipal hospitals have been heavily dependent on foreign graduates.

We also have a problem in terms of insufficient professionals for children, for the aged, and also, as I have indicated, of minority background. Each of the Institute Directors is prepared to discuss in detail the special personnel and human resources needs since there are important differences between mental health and alcoholism and drug abuse that do not lend themselves easily to an overall summary statement by myself.

Senator SCHMITT. Well, I would like to have Dr. Pardes comment. Let me quote to you again from the record:

> The committee directs the agency to review its planning to determine where changes should be made to deal with the shortage of mental health professionals. In the fiscal 1981 hearings, the agency should be prepared to show how the shortfall can be reduced or eliminated over the next 5 years and the amount of money necessary to do that.

Are you prepared to do that?

Dr. PARDES. Senator Schmitt, our understanding was that the committee wanted us to be prepared to respond to the committee during the hearings, and I'd like to make a few comments.

Senator SCHMITT. Well, you can read it any way you want. I think we expected to have specific information on how it is to be eliminated over the next 5 years. The committee needs information.

Mr. MILLER. We are not satisfied with our own numbers yet.

Senator SCHMITT. When will you be satisfied?

Mr. MILLER. Shortly; but it is very difficult to assess.

Senator SCHMITT. Well, what kind of recommendations were you given from the outside for this year's budget? Did you explore that with the nonadministration people?

MENTAL HEALTH TRAINING PROGRAMS

Dr. PARDES. I would like to comment on some things that we have done because the training area is a complicated one. First of all, I think you would see by the fact that the Federal Government or the administration recommends a continued support of mental health training programs that we recognize there are major problems in the training of manpower area. I think it is a question of where one places one's priorities, and we see as one of the preeminent priorities the kind of training that individuals within the various disciplines have. As a result, the NIMH has redirected its entire program to focus particularly on the shortage in terms of geriatric mental health professionals, child mental health professionals, minority specialists, and so forth.

Senator SCHMITT. And that redirection means you can get by with 922 fewer students this year than last?

Mr. MILLER. I think, as Dr. Klerman indicated, in some of the mental

health areas our feeling is that we are doing better in terms of the total number of people, and the most glaring needs are in the area of particular kinds of work within the mental health field—minority, geriatric, et cetera.

Senator SCHMITT. What basis does the committee have to evaluate that? We haven't gotten the information we requested.

Dr. KLERMAN. As Mr. Miller has indicated, the Department is not yet prepared.

Senator SCHMITT. Like in many other areas of administration policy, we are not going to be able to develop the capability to deal with it; is that correct?

Mr. MILLER. Senator, before you markup we will supply the data. But I'd like to emphasize that once you get the data it doesn't necessarily follow that it is a Federal responsibility to make it up.

Senator SCHMITT. We are not going to overfund you, but we'd like to know the scope of the problem and where the maldistribution may be.

Mr. MILLER. Before you mark up we will provide you with the information that is implied by last year's report.

Senator SCHMITT. Lack of this information makes it very difficult for us.

Thank you, Mr. Chairman. I personally believe we've got to have this information. And as I said before, we are staring at a policy that says, "Let's move forward," and staring at a budget that says, "Let's stand still or go backward."

PSYCHIATRY SHORTAGES

Dr. PARDES. I'd like to emphasize that there have been several things we have done. I understand your questions about the budget, but there are other things the Department has done to try to address what Dr. Klerman identified as some of the problems.

They include collaborating with HRA, which recently sent out a statement to all medical and osteopathic students around the country indicating psychiatry is one of the specialties most needed by the National Health Service Corps.

Also, we are supporting a conference of academicians and service providers to look at the array of problems around this shortage area. And also we took the initiative in amending the technical language which limited deferral of service for specialty training to 3 years. In other words, psychiatric residents would have had to break their training in order to fulfill service requirements from medical school. The recommendation to change this has been approved by the Congress, so we have removed one of the disincentives of people going into psychiatry.

Dr. KLERMAN. In addition we are requesting authority for a payback provision so that those individuals who receive clinical training supported by ADAMHA funds will have an obligation to provide service. We do have such a payback provision in the Research Training Act which has proven quite successful.

We hope this will provide an administrative vehicle by which we can help motivate new trainees in the mental health professions to go into some of the underserved areas geographically and otherwise.

We also have a very good cooperative relationship with the National Health Service Corps, as that Corps increases, to include psychologists and psychiatrists and other mental health personnel to go to underserved areas.

But your point that we have not supplied you with this quantitative data that you have requested is accurate, and as Mr. Miller said we will have that for the committee shortly.

Senator SCHMITT. Is your budget based on this legislation?

Dr. KLERMAN. There are no budgetary requests with regard to the payback provisions in our budget. There are budgetary requests for the National Health Service Corps.

MENTAL HEALTH SYSTEMS ACT

Senator SCHMITT. Can you provide the committee with details on how much of your budget is based on unenacted legislation?

Dr. KLERMAN. Oh, yes, the supplement to the budget for 1980 is contingent on the expected passage of the Mental Health Systems Act which we hope Congress will pass shortly. And that is about $50 million in the supplemental budget. Also, our mental health services budget for 1981 assumes the Systems Act. That total request is about $368 million.

Senator SCHMITT. Is that the only unenacted legislation on which you base your request?

Dr. KLERMAN. Yes.

Senator SCHMITT. What would you recommend to the committee if this legislation fails to be enacted by the time we markup the bill?

Dr. KLERMAN. Well, the administration position is that the Systems Act represents a major opportunity for systems reform.

Senator SCHMITT. But it isn't enacted.

Dr. KLERMAN. And the other alternative would be to do what the committee did in previous years, to make funds available for new starts under existing authority under the Community Mental Health Act.

Senator SCHMITT. That would be your recommendation?

Dr. KLERMAN. We have not discussed it in the Department.

Senator SCHMITT. You ought to start discussing it, because when we get to markup I think you know the sentiments of this committee, certainly its chairman, that it is not appropriate to appropriate funds for programs not authorized.

Dr. KLERMAN. Well, we will discuss that.

Senator BURDICK. The authorization isn't out of subcommittee yet.

Dr. KLERMAN. I'd like to say the Department's request for the supplement is based on our expectation, hope, and understanding that the Congress will act on the President's bill very shortly.

Dr. PARDES. Our understanding is that the subcommittee has basically gotten close to the language it wants in the Senate. The House subcommittee is marking up today, and our best impressions from contact with the staff and such is that we feel very optimistic that that legislation will pass shortly.

Senator BURDICK. Shortly? What do you mean by "shortly"?

Dr. KLERMAN. Within the next few weeks.

Mr. MILLER. Senator, the appropriation language that we have proposed in this bill has a proviso in the language which would make the 1980 supplemental appropriation contingent on the passage of the bill. So we are asking the Appropriations Committee if it is necessary to act first.

MENTAL HEALTH TRAINING

Senator SCHMITT. Could you provide for the record what your professional recommendations were to the administration prior to the final budget on training?

Dr. KLERMAN. Yes.

[The information follows:]

National Institute of Mental Health Agency Request—Training by type of award

	1980 estimate		Fiscal year 1981 President's budget		Fiscal year 1981 Agency request	
	No.	Budget authority	No.	Budget authority	No.	Budget authority
Clinical training:						
Grants:						
Noncompeting	811	$57,015,000	782	$53,991,000	782	$53,991,000
Competing	42	2,764,000	54	4,046,000	54	4,046,000
New	189	11,884,000	174	12,112,000	483	35,943,000
Supplemental	( )		(44)	1,514,000	(44)	1,514,000
Total, Clin. Trng	1,042	71,663,000	1,010	71,663,000	1,319	95,494,000
Research training:						
Grants:						
Noncompeting	145	14,547,000	125	13,216,000	125	13,216,000
Competing	4	458,000	11	1,211,000	11	1,211,000
New	16	1,375,000	20	1,863,000	102	9,470,000
Supplemental	( )		(11)	90,000	(11)	90,000
Subtotal	165	16,380,000	156	16,380,000	238	23,987,000
Fellowships:						
Predoctoral:						
Noncompeting	33	246,000	22	220,000	22	220,000
New/competing	31	348,000	37	374,000	60	606,000
Subtotal	64	594,000	59	594,000	82	826,000
Postdoctoral:						
Noncompeting	37	657,000	31	527,000	31	527,000
New/competing	55	1,060,000	70	1,190,000	138	2,351,000
Subtotal	92	1,717,000	101	1,717,000	169	2,878,000
Subtotal, F'll'wship	156	2,311,000	160	2,311,000	251	3,704,000
Total, Res. Trng	321	18,691,000	316	18,691,000	489	27,691,000
Total, Training	1,363	90,354,000	1,326	90,354,000	1,808	123,185,000

Clinical training program distribution

	1979 actual		1980 estimate		1981 estimate	
	No.	Amount	No.	Amount	No.	Amount
Total program:						
Mental health manpower R. & D.:						
Training	34	$3,136,000	27	$3,000,000	34	$4,000,000
Manpower	67	6,967,000	66	6,700,000	90	9,030,000
State manpower development	39	6,015,000	39	6,000,000	34	7,000,000
M. H. service education:						
Psychiatry	531	23,745,000	468	23,300,000	622	31,444,000
Nursing	89	8,097,000	83	7,863,000	101	10,600,000
Social work	146	11,165,000	137	10,900,000	163	14,690,000
Psychology	202	10,195,000	175	9,900,000	218	13,340,000
Paraprofessional	28	2,253,000	25	2,200,000	28	2,960,000
Multi- and other disciplines	37	2,690,000	22	1,800,000	29	2,430,000
Total	1,173	74,263,000	1,042	71,663,000	1,319	95,494,000
New/competing:						
Mental health manpower R. & D.:						
Training	11	531,000	3	380,000	22	2,709,000
Manpower	20	2,805,000	19	1,813,000	47	4,964,000
State manpower development	17	2,985,000	2	382,000	3	1,581,000
M. H. service education:						
Psychiatry	135	6,156,000	155	7,534,000	262	13,572,000
Nursing	45	4,350,000	8	1,206,000	34	4,029,000
Social work	54	5,443,000	21	1,737,000	46	5,303,000
Psychology	88	4,954,000	17	1,090,000	88	6,062,000
Paraprofessional	16	842,000	3	294,000	13	1,388,000
Multi- and other disciplines	1	75,000	3	212,000	22	1,895,000
Total	387	28,141,000	231	14,648,000	537	41,503,000

Mr. MILLER. We supply that to the committee every year.

Senator BURDICK. I didn't quite understand you. Did you say you were recommending that we pass an appropriation subject to the authorization?

Mr. MILLER. Contingent upon the passage.

Senator BURDICK. You have a chairman who doesn't look very kindly on that.

Mr. MILLER. I have about 10 years of awareness of that. [Laughter.]

Senator SCHMITT. Thank you, gentlemen.

ALCOHOLISM PROGRAMS

Senator BURDICK. We have a few more questions here before we adjourn.

In your testimony last year—this has to do with alcoholism research—you said there were 10 million adults and 3.3 million youth problem drinkers. This is a three- or four-part question, so listen care-

fully. Have your programs reduced these statistics? Part of your 1980 goals were targeting of programs of alcohol abuse among women, the fetal alcohol syndrome. What programs is NIAAA implementing for this specific problem? Has a safe level of drinking been determined for pregnant women?

ALCOHOLISM CONSUMPTION

Mr. DeLuca. Let me begin by answering that those basic national figures continue to represent what the Institute feels is the most accurate measurement of the incidence and prevalence of alcoholism and alcohol abuse. We estimate there are approximately 10 million adult problem drinkers in the United States and 3.3 million young people who have problems in their use of alcohol. I do want to clarify for you that does not mean there are 3.3 million young people who are alcoholics, but we do estimate that an increasing number of young people are experiencing problems when they use alcohol.

I think one of the reasons why the administration has requested an enhancement of the Institute's budget, both in 1980 and in 1981, is that we feel and continue to feel that we have yet to meet the need, as expressed by these numbers. Although, as Dr. Klerman mentioned in his opening statement, there are some overall indicators which suggest improvement—the leveling off of the curve of per capita consumption and other health statistics of related diseases associated with alcoholism—the actual public health problem of alcohol abuse seems to continue to be of major concern.

With respect to the second part of that question, we are continuing a number of activities to insure that both physicians and the general public are informed about the relationship of excessive consumption of alcohol to birth defects. We are expending substantial resources in trying to refine our knowledge in the sense of fine-tuning specific understanding of where and when during a pregnancy the unborn infant could be damaged. We really do not know that. We are suggesting at this point, however, that there is enough research to conclude that the risk of damage to the unborn baby is substantial enough that the best clinical advice that could be offered to women who are pregnant is not to drink during that period of time. Our information and literature do contain what we consider to be the best pragmatic judgment on drinking while pregnant as we pursue a more detailed understanding of the effect alcohol has on unborn babies.

I must confess, Mr. Chairman, I do not remember the third part.

Senator Burdick. The safe level of drinking for pregnant women. You can't give a safe level?

Mr. DeLuca. We can give a safe level, which is not to drink.

Senator Burdick. That would be a safe level for everybody.

Mr. DeLuca. That would be.

Senator Burdick. Somebody asked me, "What are we going to do about these kids in high school? What are we going to do about these youth drinkers? And how are you doing it?"

Mr. DeLuca. We are already funding a number of demonstration programs to test new ways of reducing alcohol problems among young people. As the health care delivery system is learning more and more about that problem. We want to expand demonstration programs targeted to youth. A large part of the increase in of the budget requests, $6.4 million in 1980 and $6.6 million in 1981, is directed at just that.

We are anxious to work with national youth organizations. Part of the Department's initiative is an attempt to fund organizations like the Boy Scouts or other basic organizations that work with young people so they can begin to carry important messages about the most appropriate use of alcohol.

We are also very concerned about highway accidents. Alcohol-related deaths are the leading cause of death for young people from the ages of 15 to 24. So again, part of the proposed departmental initiative is to try to fund highway safety programs aimed at youth. We are trying to do that through school systems, through education, and through treatment demonstration programs as well. We are now replicating three exemplary youth education projects. Originally funded as demonstration projects, and testing their suitability in a number of sites across the country.

Senator Burdick. Well, I will give you a hypothetical. Say I am going to attend a PTA meeting in Fargo, N. Dak., at the high school. What is this alcohol program all about? What are you doing to stop drinking in high school? What can I tell them?

Mr. DeLuca. Through various programs, we have produced or funded the development of educational materials on the misuse of alcohol available upon request. Alcohol is a legally available, socially accepted drug in our society. We have to make a distinction that what we are telling young people is not a message of prohibition, because that message doesn't exist in our society. What we are really trying to convey is that you can have problems if you misuse alcohol.

Senator Burdick. Wait a minute. It is illegal under a certain age in most States, so it is not legal for those people.

Mr. DeLuca. Whether it is legal or illegal from our perspective, young people are drinking and somehow gaining access to alcohol. We are addressing this issue through our public media campaigns and demonstration prevention projects are very concerned about young people who would break the law and obtain alcohol. We are getting some very good cooperation from the State alcohol beverage control agencies, and working cooperatively in trying to stress the legal drinking age and the rights and problems associated with it.

But we are trying to be very specific about the messages we convey to young people in the hopes that they listen closely to areas which are of concern to them—the driver's license, for example. We hope by telling them there are real risks involved in excessive consumption, such as specific problems of coordination, et cetera, that exist in states of intoxication, that we can get them to listen and begin to use alcohol more responsibly.

Senator Burdick. I am sure you are hopeful, but I am at that

meeting now. What can I say your Department can do about it in Fargo, N. Dak.?

Mr. DeLuca. We can accept a grant application from that school system, or any interested community organization. In fact, we are anxious to do so. We are looking for high-quality demonstration programs in local communities. We have technical assistance capacity.

PUBLIC INFORMATION

Senator Burdick. Do you have enough film, literature, and the like?

Mr. DeLuca. We have a national clearinghouse that responds to thousands of school inquiries for alcohol information around the country. It produces educational material and works with selected national organizations serving youth. Information can be sent very easily on inquiry or request from our national clearinghouse.

We also are going to initiate a public media campaign with funds contained in our continuing resolution for 1980. The contract is in the final stages of implementation. We expect to have an impact through this multimedia campaign which would disseminate information on alcohol abuse through TV, print media, and posters. In fact, we consider this one of the most important and effective ways to inform the public and to reach young people.

Senator Burdick. Then the main weapon you've got is publicity.

Mr. DeLuca. Yes; the most important weapon, if you want to use that term, is to try to inform and educate people about the risks associated with the misuse of alcohol and hope that individuals understand the risks involved with excessive drinking.

HEW DRUG AND ALCOHOL EDUCATION PROGRAM

Dr. Klerman. Mr. Chairman, I might add that there is a special program for school populations that is in the now HEW, soon to become the Department of Education. There is a program on alcohol and drug education which is about to be transferred from HEW to the new Department of Education. It develops curriculums and programs for school-based programs and alert school superintendents and State school boards as to the availability of technical assistance, films, and programs.

Senator Burdick. Who coordinates that program?

Dr. Klerman. Well, right now within HEW it is jointly coordinated by the Public Health Service and the Office of Education. Coordinative mechanisms for when it goes to the new Department of Education will have to be worked on.

There is a Federal Interagency Committee on Alcoholism, of which Dr. DeLuca is the chairperson, which includes representation from all the Federal agencies that have alcoholism concerns, including the Department of Defense, the Veterans' Administration.

Senator Burdick. Who is the individual who is in charge of this coordination in your shop?

Mr. DeLuca. In the Federal Interagency Committee on Alcoholism? In my capacity as Director of the Institute, I chair that committee.

Senator Burdick. But who is the key person?

61-400 O - 80 - 50

Mr. DeLuca. Dr. Helen Nowlis is in charge of the alcohol and drug abuse program.

Senator Burdick. And coordinates the program?

Dr. Klerman. She is in the Department. In my capacity it is my responsibility to coordinate activities between agencies in the Department.

Senator Burdick. Can you, for the record, give us more examples of what you have been doing in this coordination?

Mr. DeLuca. When Dr. Nowlis and I develop our programs we consult to assure that no duplication occurs. I feel very confident that our efforts are complementary.

Dr. Nowlis' programs are demonstrating with a specific number of schools to obtain valuable information which can benefit NIAAA programs as well as their own.

FEDERAL ACTIVITIES

Senator Burdick. The restraining thing is that those of us representing people always have to come up with some answers. We can wring our hands about the problem and the percentages, but then they ask the tough question: "What are we doing?"

Mr. DeLuca. We are trying to move as quickly as we can. When we talk about young people, extensive use of alcohol, and the public health problems that extend from that, Senator, you are addressing one of the most difficult questions: What role the Federal Government should play in changing that behavior, and how we can best assist parents and concerned adults about that behavior. I think one reason we are spending as much time as we are on prevention, both at NIAAA and jointly with NIDA and NIMH, is that we are extremely anxious to get answers to those questions. I think that our budget requests indicate extensive and serious planning in the development of new strategies to address young people's problems associated with the misuse of alcohol.

Dr. Klerman. I would have to add, Mr. Chairman, that you identify an area where we are not as successful as we would like to be. Evidence of Dr. Richmond has shown that the adult members of this country are modifying their behaviors. We are eating less and drinking less and jogging more, and cardiovascular diseases and other diseases are down for adults.

We have not been as successful in reaching young people and teenagers with regard to cigarette smoking, use of alcohol and drugs, and risk-taking behavior. And pregnancy is a matter of concern. And I must say the techniques we now use, while we are trying hard, are not as successful as you and your constituencies feel they should be.

Senator Burdick. Gentlemen, I must say you all have a tough problem. There is no pat and easy answer, I understand that.

[The statement for St. Elizabeths Hospital follows; and the following questions were not asked at the hearing but were submitted to the Department for response subsequent to the hearing:]

Statement of William H. Dobbs

Mr. Chairman and members of the Committee, it is a pleasure to have the opportunity to appear before you to present the 1981 operating and construction and renovation budget requests for Saint Elizabeths Hospital.

When we appeared before this Committee last year, we reported on a variety of activities which were then underway to revitalize the hospital. Thanks to the efforts of an extraordinarily dedicated hospital staff, I am pleased to say that substantial progress has been made in most areas.

RESTORATION OF ACCREDITATION

First, and foremost, as I am sure you are aware by now, Saint Elizabeths Hospital has been accredited by the Joint Commission on Accreditation of Hospitals. During the last year, the Hospital received and successfully satisfied three separate groups of surveyors representing the Joint Commission. The Adult Psychiatric Programs, the Alcoholism Programs, and the Child and Adolescent Programs all have been designated as the recipients of one year accreditation. The Area D Community Mental Health Center was surveyed two years ago and received a two year certification. Thus, for the first time since 1975, the institution has regained accredited status as a health care facility. With accreditation and the prestige that it holds for the Hospital, there is a renewed commitment and sense of responsibility among the staff to assure that the one year status is translated into a full two year accreditation when the next survey is consummated in June of this year. It is our feeling that the Hospital is on the way up and has achieved a level of excellence which will assure the continuing availability of high quality services to our constituent community.

OUTPLACEMENT OF PATIENTS

Another area of substantial accomplishment relates to the final submission of a joint plan by the District of Columbia Government and HEW for implementation of the Dixon Plan. The Dixon Plan is an outgrowth of the Dixon vs. Harris lawsuit, which successfully has resulted in the submission of a joint formal planning effort to deinstitutionalize several hundred Saint Elizabeths Hospital patients in the least restrictive environment possible. The management and staff of Saint Elizabeths Hospital have worked tirelessly to forge a reasonable and realistic working agreement with the District of Columbia.

With the agreement having been signed, staff is now working to assure the availability of needed resources in which patients can be outplaced into quality residential living facilities with appropriate and timely follow up by the clinical staff. In order to fully comply with the spirit, intent and requirements of the Dixon vs. Harris lawsuit, members of the Hospital staff have met with several nursing home administrators in areas surrounding the District, and quality nursing care beds are being made available to make up for the relative shortage of bed capacity which currently exists in the District of Columbia.

CONSTRUCTION

An integral part of the success of our efforts is represented in the ongoing SEH construction program. As you are aware, Congress appropriated $52.2 million in 1978 for the continuation of improvements to maintain the accreditation of Saint Elizabeths Hospital. Indeed, the accreditation of the institution by the Joint Commission on Accreditation of Hospitals is in major part predicated on the successful completion of the construction effort. The construction program continues to move ahead. We are currently in the process of evaluating the impact of inflation, as well as some additional requirements articulated by the Joint Commission on Accreditation of Hospitals during their survey last year.

MANAGEMENT IMPROVEMENTS

With respect to the management of the Hospital, we have noted some significant improvements during the last 12 months. A major concern had been the degree of use of overtime by staff. The implementation of strict management practices and accountability standards during the first quarter of this fiscal year has resulted in a 60% decline in the use of overtime, over the same period last year.

With respect to the administrative costs of operating the institution, there has been a major decrease in the use of tax dollars to provide administrative services during the first quarter of this fiscal year. The funds which heretofore have been used for administrative services are now being reprogrammed and directed for use in the area of clinical services. This is resulting in more staff time being directed toward patient care and less tax dollars being spent to defray administrative costs. We are now reviewing a proposed reorganization for the Hospital and its Division of Administration. The reorganization will further provide the kind of supervision and direct staff involvement with our clinicians to ensure the availability of top quality management and supervision and a further increase in direct patient services.

All of this, I believe, is leading toward a much better managed institution which provides the kind of services which are so necessary to develop the full potential of our patients. There must be a delicate balance drawn between the quality of administration and the availability of patient services. If either suffers in relation to the other, the entire Hospital can tilt away from the excellence toward which we are all striving.

REVISION OF BUDGET ACTIVITY STRUCTURE

For several years, there has been a steady decline in the hospital's inpatient load, accompanied by a complementary increase in the level of activity devoted to outpatient care, day care, and outplacement efforts. In order to display these efforts more clearly, the 1981 budget request reflects a new activity structure which allocates resources among these various areas of effort, as well as for training, research, and program support.

DISCONTINUANCE OF INDEFINITE APPROPRIATION

Since 1964, the hospital has operated with an indefinite appropriation. Under this arrangement, Congress established a total ceiling for expenditures each fiscal year, and provided that

the budget authority share would be automatically adjusted to make up the difference between the total budget and the level of reimbursements received for inpatient care. This financing mechanism was established during a period when reimbursements for inpatient care constituted over 70 percent of the hospital's budget, and when unexpected variances in reimbursement income could cause serious disruptions in program operations. During the past 16 years, the inpatient load has declined by nearly two thirds, and reimbursements now constitute only 20 percent of hospital income. Accordingly, the proposed 1981 appropriation language has been modified to establish a maximum ceiling on both budget authority and expenditures.

SUMMARY

The 1981 operating budget totals $120,528,000, representing an increase of $8,124,000 over the 1980 level. Of the $120,528,000 total requested, $24,322,000 represents anticipated reimbursements - principally from the District of Columbia. The remaining $96,206,000 represents the budget authority we are requesting for 1981. The additional funds are all that are needed to cover mandatory operating costs and salary increases. Clinical care at the hospital will be strengthened and administration streamlined through various anticipated management improvements, including a reduction of 139 positions.

The 1981 construction and renovation budget includes a request for $1,500,000 in new budget authority. These funds will be used for upkeep and general improvement of the physical plant, to prevent further deterioration.

Finally, the Administration plans to work closely with the Government of the District of Columbia in the year ahead, to create a public corporation to assume responsibility for management of the hospital in the future.

ADAMHA POSITION ON INCREASED STIPENDS

Question: Last year this Committee increased training stipends in the National Institutes of Health to $15,000. However, researchers in ADAMHA were not affected by this change. Furthermore, the Committee did not receive a request from ADAMHA to increase stipends for their investigators similarly. What is the agency's position on this issue?

Answer: In July, 1979, ADAMHA participated with the National Institutes of Health and the Health Resources Administration in making a joint request to the Assistant Secretary for Health to increase trainee stipend levels. Annual stipend levels were approved at the level of $5,040 for predoctoral and $13,380 to $17,040 for postdoctoral students. These stipend levels apply to clinical as well as research training programs of ADAMHA.

The stipend increases, which ADAMHA strongly supports, are being implemented in FY 1980 within appropriation levels. The intended consideration of a PHS wide increase in stipends was mentioned to the Subcommittee on Labor and HEW Appropriations by the Director, NIH in testimony he presented in February, 1979. We believe that adjustments in stipend levels should be made regularly to reflect the ever increasing costs of living.

ADAMHA PEER REVIEW SYSTEM

Question: What is the status of the proposal for the reorganization of the peer review system for grants and contracts?

Answer: The ADAMHA peer review system for grants and contracts was reorganized in 1979 to separate management of the review process from the management of programs. On the basis of wide consultation, a decision was made to accomplish this objective by creating a centralized review office within each Institute. These review offices are organizationally separate from, and operate independently of, the Institute program components. This change provides for more independence for the review process, and hopefully, will facilitate more consistent implementation of review policies.

The Director of each Institute's review office has responsibility for developing Institute review policies, and ensuring the quality, accountability and integrity of the review process. The staff of each review office includes Executive Secretaries and grants assistants for the review committees, as well as other necessary support and managerial staff. As under the old system, review staff coordinate the review of applications by groups of principally non-Federal experts in the relevant professions, disciplines, and fields of activity. Operations under the new, centralized review arrangements began with applications reviewed in May, 1979.

The Office of the Administrator, ADAMHA, continues to provide policy guidance concerning the peer review process, assist in the orientation of review staff and committee members, and evaluate the operation of the review process.

As part of the reorganization of peer review, the structure of ADAMHA's initial review groups was revamped. The number of IRG's within ADAMHA was reduced from 32 to 28. NIMH has 20 initial review groups, NIAAA has 5, and NIDA has 3.

ALCOHOLISM FUNDING DISTRIBUTION

Question: In general, what proportion of budgeted alcoholism funds is allocated to treatment, prevention, and research?

Answer: Of the total funds available in 1980, we estimated that 51 percent will be obligated for treatment, 8 percent for prevention, and 12 percent for research.

FY 1981 INCREASES IN ALCOHOLISM FUNDING

Question: What are the changes in this allocation in the Fiscal 81 Budget from last year?

Answer: The proportion of funds obligated for each of these areas will increase in 1981: treatment to 52 percent, prevention to 10 percent, and research to 13 percent of the total.

FY 1981 ALCOHOLISM RESEARCH

Question: The fiscal 81 budget request is $25,168,000 million -- 3 million more than last year.

What portion of the research appropriations request is planned for research in the following areas:

(A) teenage and youth alcoholism;
(B) impact of alcoholism on families;
(C) fetal alcohol syndrome;
(D) the effectiveness of occupational alcoholism programs;
(E) impact of lowering the legal drinking age on alcohol-related traffic fatalities; and
(F) alcoholism and the elderly.

Answer: The 1981 Request includes funds for research pertaining to teenage and youth alcoholism ($1.5 million); impact of alcoholism on families ($.6 million); Fetal Alcohol Syndrome ($.9 million); occupational alcoholism programs ($.4 million); and alcoholism and the elderly ($.2 million). Although no research is planned into the impact of lowering the legal drinking age, the budget for community programs includes $.3 million for demonstration projects related to the impact of alcohol beverage control laws. The research division does collect data that would allow the Institute to analyze national traffic mortality experience by State for the period 1970 to 1977.

YOUTH ALCOHOLISM PROGRAMS

Question: Referring to educational programs, do you have any of the following types of programs in mind addressing youth alcoholism? Counseling? Detoxification? Vocational or Referral? Legal Assistance?

Answer: Our youth treatment programs provide, or arrange for, all of these services. The treatment programs work in cooperation with available community-based resources such as social services agencies, schools, hospitals, law enforcement agencies, Community Mental Health Centers, and vocational and legal aid services.

OCCUPATIONAL ALCOHOLISM PROGRAMS

Question: Does the Alcohol, Drug Abuse and Mental Health Administration address the needs of employed alcoholics or maintenance of the recovered alcoholic?

Answer: Yes. The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) has addressed the needs of employed alcoholics since the inception of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in 1971. This has been done primarily through the NIAAA's occupational alcoholism project grant program.

Occupational grants have been awarded to provide consultation and program development as well as identification, referral, and counseling services to alcoholic employees in a wide assortment of work forces in each State. The number of occupational programs in industry grew from about 500 in 1973 to 2,400 in 1977 and to 4,500 in 1979. Not all of these receive Federal assistance.

Employee assistance programs include support services for the recovering alcoholic and all NIAAA funded treatment programs are required to make arrangments for clients' after-care in order to support recovery through self-help groups such as Alcoholics Anonymous, Women for Sobriety, or other organizations.

Currently three contracts are underway to study employed alcoholic women and to design and implement whatever special techniques may be necessary to assist them.

FUNDING LEVELS FOR OCCUPATIONAL ALCOHOLISM PROGRAMS

Question: How much are you planning to spend on this area in fiscal 1981 as compared to previous years?

Answer: In fiscal year 1981 the National Institute on Alcohol Abuse and Alcoholism (NIAAA) plans to spend $6,938,000 in the area of occupational programming. This compares with $4,938,000 in fiscal year 1980 and $3,849,000 in fiscal year 1979. In addition, three related contracts are supported for $500,000 in 1980 and $535,000 in 1981.

ECONOMIC COST OF ALCOHOLISM

Question: In terms of numbers of work days lost and loss of productivity, what is your estimate on the cost of alcoholism?

Answer: The cost of goods and services of lost production associated with alcohol misuse was estimated to be $19.6 billion for 1975, the most recent year for which data are available. This estimate includes three components: lost market production among men, $15.5 billion; lost military production, $0.4 billion; and lost future production from excess mortality, $3.8 billion. The lost production is associated with absenteeism, tardiness, accidents, worker friction and lowered productivity generally.

The lost market production among men of $15.5 billion is equivalent to 1.2 million full-time employee years based on estimates

of average annual wages and salaries and wage supplements for all domestic industries. The estimate of lost market production is considered to be conservative because it does not encompass workers under 21 or over 59 years of age or working women. Women were not included in this calculation because sufficient data were not available at the time of the study.

EFFECTIVE METHODS OF ALCOHOL ABUSE PREVENTION

Question: Have any effective methods of alcohol abuse prevention been identified?

Answer: The answer to this question is yes, but it must be qualified and should be clearly understood.

The Division of Prevention seeks to develop strategies and analyze policies for reducing the negative consequences of drinking. This approach requires that alcohol-related problems first be defined and then measured over time, both in the individuals targeted for impact and the involved communities. Such longitudinal measurement techniques are difficult to conceptualize and very difficult to conduct.

Therefore, the measurement of the effectiveness of prevention programs must often rely on assumptions such as:

- information about alcohol and its actions on the body will lead the individual to make better decisions regarding alcohol use;
- alcohol-specific education programs impart certain skills which decrease the risk of alcohol abuse; and
- programs of alternatives deter alcohol abuse by increasing self esteem and modifying use of leisure time constructively.

The Division of Prevention has been instrumental in developing alcohol education curricula which have been demonstrated to measurably increase knowledge about alcohol and its effects on the body, as well as methods of teaching alcohol-specific affective educational skills, and alternative programs that increase self esteem and occupy leisure time. Whether these measures are also indicative of changes in behavior that decrease the long-term incidence of alcohol-related problems in an area that needs more investigation, but preliminary evidence suggests they do.

Little research has been done in this country to test the effects of availability of alcohol on consumption of alcohol. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is particularly interested at the present time in an analysis of data in communities that are changing laws and regulations that might impact on drinking patterns.

Such changes might involve upward or downward movement in drinking age, pricing and/or taxation policies, zoning changes, regulation changes in production, distribution and consumption of alcohol. These are "naturally occurring" events that could produce significant results.

Other areas of interest would be studies examining changes in beverage alcohol advertising, labeling, and other changes of a regulatory nature. NIAAA is also interested in comparative studies which examine the effects of different laws and regulations on comparable population groups and/or similar geographic areas.

One of the main efforts by the Division of Prevention, NIAAA, is in the area of evaluation. Analysis is being done through the grants program to determine the long-term effectiveness of prevention programs and the consequences of "natural experiments" where changes in alcohol-related laws or policies impact on the drinking practices of the community involved.

FY 1981 TRAINING SUPPORT DECREASE

Question: Does this affect any of your training programs implemented last year?

Answer: The budget request for clinical training contains sufficient funds to make awards to all training grants for which we have a 1981 commitment. Research training funds will permit, in addition to covering our commitments, support for 5 new training grants and 11 new fellowships.

ALTERNATIVE FUNDING SOURCES FOR ALCOHOLISM TRAINING

Question: Are you developing alternative fund resources to support training programs?

Answer: We expect that the State Manpower Development Program will stimulate increased attention to and support for the continued development of human resources. This program is intended to improve the overall management of the manpower resources within the States and to expand the capacity of the States to plan and to provide training in response to the specific needs of the treatment service delivery systems within the States.

ALCOHOLISM HEALTH PROFESSIONAL NEED

Question: What is the health professional need in the area of alcoholism treatment?

Answer: The need is for all health care professionals, including physicians, nurses, counselors and social workers, who come into contact with alcoholic persons, to be knowledgeable about the most effective ways of treating those persons. There is a need to provide access to services for National Institute on Alcohol Abuse and Alcoholism (NIAAA) targeted populations such as minorities, women, youth and the elderly, as well as to improve services to persons currently being treated.

Access to and improvement of services depends not only upon the number of treatment personnel but upon issues such as the distribution, accessibility, utilization and effectiveness of treatment personnel as well as their training.

FUNDING FOR PREDOCTORAL RESEARCH TRAINING GRANTS ON ALCOHOLISM

Question: If encouraging alcoholism research is a high National Institute of Alcohol Abuse priority, why have predoctoral research training grants been cut by 50% from $829,000 to $478,000 for Fiscal 81?

Answer: The FY 1981 budget shows an overall increase in support for research training grants from $948,000 to $1,027,000. These grants are for the support of both predoctoral and postdoctoral research trainees. The $478,000 represents only the continuation costs in 1981 of awards made in prior years; once again, this figure includes both pre- and postdoctoral support. In general, however, the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) is increasing support for postdoctoral trainees. The trend toward more postdoctoral awards is a result of ADAMHA's implementation of National Academy of Science/National Research Council recommendations on the relative need for predoctoral and postdoctoral researchers in the behavioral sciences.

FUNDING FOR PREDOCTORAL MINORITY ALCOHOLISM TRAINING

Question: Where in the budget are the minority predoctoral support training programs you state you are funding for Fiscal 81?

Answer: The funds for the minority predoctoral research training programs are contained in the budget line item "new research training grants," $359,000 in 1981. The exact amount to be spent for this purpose will depend on the number and quality of applications received by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and approved by the appropriate review committees.

ALCOHOLISM PROGRAM EVALUATIONS

Question: Does the collection of Alcoholism Program activities data aid your program evaluation?

Answer: Data from the National Alcoholism Program Information System (NAPIS) are used extensively for program evaluation and for monitoring purposes. Evaluations using the data were conducted for Alcoholism Treatment Centers, the Problem Drinking Drivers Program, and the the Public Inebriate and the American Indian and Occupational Programs. Actions were taken as a result of those evaluations to improve effectiveness of the programs and to minimize costs. Program policy and guidelines have been revised based on the evaluation results.

Another example of program data use is the ongoing tracking of special treatment populations and program performance through the Operations Management System (OMS) established by the Secretary, Department of Health and Human Services (DHHS).

INTRAMURAL CAPABILITY FOR DATA COLLECTION

Question: Is there any intramural capability for this data collection, or must it be let on contract as it is proposed for Fiscal '81?

Answer: The data collection is performed by individual contracts. Data are edited and processed under contract, using Department of Health and Human Services (DHHS) computers. Several States are collecting compatible data. In those instances States perform the editing and place the data on computer tape which is submitted to the National Institute on Alcohol Abuse and Alcoholism (NIAAA) contractor. There are no other means available for processing of the data other than with contractor assistance.

THIRD PARTY PAYMENTS FOR ALCOHOLISM TREATMENT

Question: What is the extent of third-party payments of alcoholism treatment?

Answer: Health insurance coverage for alcoholism has historically been limited in nature and scope, and has lagged behind benefits for the care of primarily physical illnesses. As a result, third-party reimbursement to providers of alcoholism services has been limited, and persons in need have not had access to a full array of benefit coverage that would include a continuum of care from emergency services to aftercare.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)-supported alcoholism treatment programs for 1978 received 26 percent of their income from all third-party reimbursement services; this percentage included 3.2 percent from private insurance, and 7.0 percent from Medicaid and Medicare. Preliminary data from the 1979 National Drug and Alcoholism Treatment Utilization Survey report 32 percent of all funding for alcoholism treatment is derived from third-party payments (nationally).

There is an increasing role being played by the Nation's labor unions and management in seeking the expansion of insurance coverage for alcoholism. For example, in 1972, few firms provided comprehensive coverage for alcoholism (125 of the Fortune 500 companies had employee alcoholism programs). By 1977, increasing numbers of companies began to provide alcoholism coverage (250 of Fortune 500 by this date had implemented alcoholism programs). Large unions such as UAW offered comprehensive alcoholism coverage to their 1-1/4 million members.

Since 1978, 25 States have passed some form of legislation either mandating such coverage or requiring the offering of such coverage. Similar legislation is currently pending in several States.

In both Medicaid and Medicare, there is a limited amount of coverage available for alcoholism. Generally, these limitations relate to the scope of services in these two programs, the eligibility restrictions that cannot be met by many alcoholism providers, and in Medicaid the option left to the States in providing specific services for alcoholism. A survey done in 1976 of Medicaid plans showed that

less than 1/3 of the States reimburse for care at an alcoholism treatment center or from an alcoholism counselor; only approximately six States paid for treatment costs at a halfway house or similar facilities.

A survey of Medicare discharges from acute care hospitals by the Health Care Financing Administration (HCFA) indicates that the utilization is lower than would be predicted by the estimate of Medicare. While there has been a gradual increase in the availability of comprehensive alcoholism coverage among the 69 Blue Cross plans, a study completed by the Blue Cross Association in 1977-78 showed a non-uniform, low level of coverage for comprehensive alcoholism rehabilitation services. For example, although 93 percent of the plans cover hospital detoxification, 13 percent cover only these services; inpatient services were covered in a freestanding alcoholism facility by over 33 percent of the plans, and outpatient services in a freestanding facility were covered by only 4 percent.

ALCOHOLISM INSURANCE INITIATIVE

Question: Are you working on increasing this through an insurance initiative?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) accords the highest priority to the development and expansion of health insurance coverage. It has developed a variety of activities designed to provide a sound program approach to the development of such insurance coverage in all insurance sectors.

The Institute is now implementing a health insurance initiative which has been included as part of the fiscal year 1981 Budget Request. This initiative includes such areas as technical assistance materials for the planning and implementation of broad-based health insurance coverage for alcoholism treatment and working with the Health Care Financing Administration (HCFA) on implementing a $1 million demonstration program to show the feasibility of providing expanded alcoholism services through Medicaid and Medicare. We are also collaborating with HCFA in implementing policy changes in Medicare and Medicaid that will assure provision of alcoholism services in a more effective and less expensive manner.

FY 1980 SUPPLEMENTAL FUNDING FOR ALCOHOLISM

Question: Your fiscal 80 Supplemental requests $14 million additional funding for Community Alcohol Programs. As this appears to be a delayed fiscal 80 request due to a lack of authorizing legislation, for what purpose are you, in effect, doubling your fiscal 81 request?

Answer: The 1980 supplemental of $14.6 million enables the Institute to implement the Department's initiative on alcohol abuse and alcoholism.

The 1981 Request provides $15.0 million for continuation support for those programs and provides an additional $15.5 million to expand the programs in the initiative areas, including $4.8 million for new programs directed to prevention of the Fetal Alcohol Syndrome and to prevention of alcohol abuse among women and youth; $2.0 million for

new occupational programs; and $8.7 million for new treatment programs for women and youth.

In addition the FY 1981 request will allow for new evaluation projects to assess the effectiveness of Institute programs, as well as for new projects directed to increasing health insurance coverage for alcoholism.

ALCOHOLISM RESEARCH ON MORTALITY DATA

Question: It is my understanding that the death rate from cirrhosis of the liver has decreased over the past few years.

Is there evidence which suggests that other diseases caused or associated with alcoholism have also decreased?

Answer: Mortality data for other causes of death related to alcohol dependence (i.e., alcoholism and alcoholic psychosis) show no clear trend either up or down, at least through 1977, the most recent year for which data are available.

COMMUNITY PREVENTION BRANCH

Question: How many staff are assigned to this branch and what specific activities are being performed?

Answer: There are two professional and one support staff members assigned to the Community Prevention Branch. The branch supports demonstration grants aimed at testing the effectiveness of community-based prevention programs and strategies. Examples of such grant projects include:

- o Alcoholism Prevention in Small Rural Communities which, through data collection and analysis, will provide information on the extent of various alcohol problems and projected social and economic costs, as arguments to persuade target communities to develop and evaluate prevention strategies and policies.

- o Prevention Program for Reducing Excessive Drinking in Spanish-Speaking Communities explores the impact of a culturally relevant mass-media alcohol abuse prevention campaign on the prevalence of alcohol problems in several Spanish-speaking communities.

- o Impact of Two Approaches to Primary Alcohol Problem Prevention compares the effectiveness of a media-only alcoholism prevention approach to a combined media and community task force prevention approach.

Through such demonstration projects, the Community Prevention Branch is gaining knowledge about prevention strategies and techniques that can be used by different kinds of communities in different parts of the country to develop effective and efficient alcohol problem prevention programs.

The Community Prevention Branch also started a State Prevention Coordinator program by funding a position in each applicant State to coordinate the alcohol problem prevention activities of that State. When the seed funding by the Community Prevention Branch was terminated, almost all the participating States retained the position with

State funds. The effects of the State Prevention Coordinator program has been to greatly increase the development of alcohol problem prevention programming at the State and community levels.

Question: Wouldn't the resources devoted to these efforts be more appropriately directed toward the achievement of more tangible and attainable alcoholism prevention goals?

Answer: The strategy of the Division of Prevention which includes the Community Prevention Branch, is to explore methods to decrease the prevalence of specifically defined alcohol-related problems. Examples of alcohol-related problems that are possible targets for intervention are:

- o chronic illness or disability resulting from prolonged, excessive drinking;
- o acute health problems related to a specific drinking bout;
- o injuries, death, and property loss caused by accidents and crimes related to drinking;
- o failure of the chronic, excessive drinker to fulfill his or her role in the family or on the job; and
- o mental problems, such as depression and anxiety, related to drinking.

Through its demonstration grant program, the Division of Prevention provides support for projects aimed at testing the effectiveness of strategies for: modifying the individual's knowledge about the effects of alcohol, the attitudes that influence drinking patterns, and the drinking behavior itself; the regulation, distribution, and/or availability of beverage alcohol; and informal social and environmental influences such as drinking norms and customs.

At this time, the Division is particularly interested in and actively soliciting grant applications for the study of the effects of availability of alcohol on drinking patterns and consumption. The Division is particularly interested in an examination and analysis of data in communities that are changing laws and regulations that might impact on drinking patterns. Such changes might involve upward or downward movement in the drinking age, changes in pricing and/or taxation policies, zoning changes, and regulatory changes in the production, distribution, and consumption of alcohol. Other areas of Division interest that will provide useful knowledge to community prevention efforts will include studies examining changes in beverage alcohol advertising, labeling, and other changes of a regulatory nature.

STATE ENACTMENT OF UNIFORM ALCOHOLISM AND INTOXICATION ACT

Question: How many States have passed the Uniform Alcoholism and Intoxication Act which decriminalizes public drunkenness charges?

Answer: Legislation has been enacted in 33 States as well as in Puerto Rico and the Virgin Islands. It is anticipated that a total of 40 States and territories will have enacted and implemented legislation by 1981.

FUNDING FOR UNIFORM ALCOHOLISM AND INTOXICATION ACT

Question: What portion of the Project Grants and Contracts request is earmarked for these States?

Answer: Of those forty States and territories, 24 will receive Uniform Act grant awards in 1981 totaling $7.9 million.

FUNDING FOR UNIFORM ACT GRANTS

Question: Why have these Uniform Act funds been decreased by $4 million for fiscal 81?

Answer: The law authorizing Uniform Act grants provides that no State may receive more than six such grants. It also provides that no grant may exceed $150,000 plus 20 percent of a State's formula grant for that year. Sixteen States will receive their sixth and final Uniform Act grant in FY 1980. The FY 1981 budget includes $7.9 million for Uniform Act grants to 24 States - 19 which are currently receiving such a grant and 5 which would receive one for the first time. The net effect of these changes plus the proposed reduction in formula grant funds is a decrease of $4 million for Uniform Act grants between fiscal 1980 and 1981.

SERVICES PROVIDED BY UNIFORM ACT GRANTS

Question: As opposed to jailing intoxicated individuals, what alternative care and referral services do these project grants develop and/or support?

Answer: Detoxification units, sobering up stations, and reimbursement for use of beds as needed in nursing and private homes, hospitals, and other lodging facilities are some examples of alternative care provided by funds from Uniform Act grants. Emergency service patrols often provide transportation when police refer individuals for treatment rather than incarceration. Services provided under the program vary from State to State according to particular needs in order to assure a continuum of coordinated care.

ALCOHOLISM DOMESTIC VIOLENCE PROGRAMS

Question: What is the reason behind the small amount of funding devoted to Community programs dealing with Alcohol and Domestic Violence? ($400,000 for fiscal 81)?

Answer: In both 1980 and 1981, the $400,000 budgeted specifically for domestic violence will fund pilot programs to provide liaison between community alcoholism services and the social services agencies which deal with domestic violence cases. The purpose is to coordinate the referral of domestic violence cases to the appropriate agencies and to provide technical assistance to the alcoholism programs, as well as to the social services agencies, on the handling of alcohol-related domestic violence. In 1981, an additional $150,000 is requested for evaluation of these pilot programs and any future expansion of the program will depend upon the assessment of its effectiveness.

Additionally, $8.7 million is budgeted in FY 1981 for 67 new treatment programs which focus on services to women and youth. It is anticipated that many of the new programs will deal also with alcohol and domestic violence issues.

The relationship between alcoholism and alcohol abuse and domestic violence is well known in general and particularly by alcoholism treatment personnel. The Institute's ongoing treatment and rehabilitation programs serve both alcoholic persons and persons without a primary alcohol problem but is associated in some way with a person who has an alcohol problem. The latter group is frequently the victims of an alcoholic's destructive behavior. In calendar year 1978, the National Alcohol Program Information System (NAPIS) showed that 21,000 of the program contacts were in this latter category. Many programs assist the victims of alcohol-related violence by intervening with the entire family. A treatment program affects the victims of domestic violence by treating the alcoholic and by helping the family cope constructively with the alcoholic person's behavior.

STATE FORMULA GRANT FUNDING

Question: What will the effect of cutting State formula grants back $6 million have on prevention and treatment activities on the local level?

Answer: This decrease should be offset by the considerably increased funding for prevention, treatment and rehabilitation services within the project grants and contracts portion of the budget. Support to the States through the State and Local Alcoholism Services Demonstration Program of $9.8 million should directly promote greater State involvement in these efforts.

EFFECT OF STATE FORMULA GRANT REDUCTION

Question: Will Community programs become over-burdened or underfunded due to State grant cut-backs?

Answer: The increased State and local involvement in the planning and implementation of prevention and treatment programs should enable the community-based programs to continue to operate effectively. We do not anticipate that these programs will be overburdened or underfunded.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM/LAW ENFORCEMENT ASSISTANCE ADMINISTRATION INTERACTION

Question: The committee has received reports that in excess of 80 percent of those individuals incarcerated in our nation's prisons were judged to have serious alcoholism or drug abuse problems prior to their convictions. Accordingly, we would appreciate learning whether you have been working closely with state prison authorities to address this matter, or whether this is a problem that should be addressed solely by LEAA.

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has been active in this area but significant additional research, demonstrations and services are needed. This is an issue which should continue to be addressed jointly by the NIAAA, Law Enforcement Assistance Administration (LEAA) and State prison authorities.

As the Committee is aware, NIAAA alcoholism treatment funds cannot be obligated to other Federal agencies for services which should be performed under their own authorities and appropriations. Health

61-400 O - 80 - 51

care and rehabilitation activities, including alcoholism treatment, for prisoners in Federal penitentiaries are under the authority of Federal law enforcement officials.

NIAAA currently funds three grants which provide alcoholism treatment to State prison inmates in Connecticut, Utah, and North Carolina. The Institute also helped to start a prison alcoholism treatment program in Mississippi State Prison; it has become a part of the ongoing prison rehabilitation program and no longer requires Institute funds.

ALCOHOLISM AMONG NATIVE AMERICAN PACIFIC ISLANDERS

Question: The committee has recently become concerned about the extent to which Native American Pacific Islanders (NAPI), and especially American Samoans have been exhibiting alcoholism problems, expecially in Hawaii and California. Accordingly, we would appreciate learning whether this matter has come to the attention of your administration, and if so, what special initiatives you are planning in response to this need?

Answer: Yes, there is increasing concern for the alcoholism problems among the Pacific Islanders. The Institute participated in a recent ADAMHA consultation with Asian Americans and Pacific Islanders to discuss the alcoholism, drug abuse, and mental health problems of those populations. One of the issues addressed at that 3-day meeting was the need for increased alcoholism services for the Pacific Islanders. Further consultations are scheduled in Guam and Hawaii later this month. NIAAA will attempt to assess the needs and develop ways to make our programs more responsive to those needs.

ALCOHOLISM AMONG ALASKA NATIVES

Question: Alcoholism continues to be the most critical health problem facing Indians and Alaskan Natives. Last month, a study conducted by the University of Pennsylvania reported that 72% of the adult Eskimos in Barrow, Alaska are alcoholics.

In the past, NIAAA has supported innovative programs in Alaska to deal with this situation. Do you have any recommendations to deal with this pressing problem in the Arctic?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) continues to support alcoholism treatment programs in Alaska for the benefit of Alaskan Native people. At the current time we are supporting 6 projects in the treatment areas totalling approximately $1.0 million and a related training project for $.1 million. In addition, Alaska receives a Uniform Act grant, formula grant, prevention and additional training funds which may be used to support Alaskan Natives projects.

The Institute's immediate concern is that quality grant applications be developed by Alaskan Native villages, organizations, and institutions that will be competitive with applications by other potential grantees. Staff of NIAAA's Indian Desk have personally traveled to Alaska within the last year to provide technical assistance directly to organizations expressing interest in developing proposals for Alaskan Native people. In addition, close contact has been established with the Alaska State Alcoholism Authority to enlist the expertise of that office in assisting Native villages,

groups, and organizations to compete effectively for Institute project grants.

NEW INDIAN PROJECTS

Question: In the 1978 Labor-HEW Appropriation bill, language was inserted directing NIAAA to maintain funding at least at the FY 77 level for Indian programs. Please submit a report on all new Indian projects funded from FY 78 through FY 80.

Answer: The language directing the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to fund Indian programs at the FY 1977 level was not located in the 1978 Labor-HEW Appropriation Bill, but in the 1978 Senate Report. However, in an attempt to be responsive we have given special consideration to the Indian programs, along with other Congressional priorities, in allocating our available resources. In FY 1978 and FY 1979, 22 percent of new treatment grants were Indian programs. The level of support for Indian treatment was $14.8 million in FY 1977. Projects funded by the NIAAA and projects transferred to the Indian Health Service (IHS) total $19.4 million in FY 1980. Therefore, it is evident that we are supporting and increasing this crucial effort. Specifically with regard to new programs in FY 1978 and FY 1979, NIAAA funded 15 new grants totalling $1.8 million. The target population is 115,000 native Americans in urban and rural settings. Seven of the fifteen programs focus on services to women and youth. The beneficiaries receive treatment services in a wide range of settings. The types of service are family, individual and group counseling; half-way and quarterway houses; drop-in centers, outreach; transportation; home visits and home counseling; emergency shelters for alcoholics and the children of alcoholics; 24 hour hotline; and community education.

RELATIONSHIP BETWEEN NIAAA AND INDIAN HEALTH SERVICE

Question: There has been confusion over the relationship between NIAAA and the Indian Health Service regarding services provided to Indians and Alaskan Natives. Please outline the specific duties of each to clarify this relationship.

Answer: The relationship between the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Indian Health Service (IHS) regarding the provision of services to American Indians and Alaskan Natives is delineated in a Memorandum of Agreement Between the National Institute on Alcohol Abuse and Alcholism and the Indian Health Service signed on May 5, 1978.

The central concept of this Memorandum of Agreement involves the transfer of NIAAA American Indian/Alaskan Native alcoholism treatment programs to IHS for long-term funding support. Provisions of this agreement provide that these Institute supported projects be transferred to IHS at the conclusion of their sixth year of NIAAA support. This transfer pertains only to Indian alcoholism treatment programs, and does not concern Institute supported alcoholism research, prevention or training programs serving Indian people.

Specifically, the duties and responsibilities of NIAAA and IHS according to the Memorandum of Agreement are as follows: the NIAAA will maintain its Indian Desk to serve as the focus of leadership within the Institute concerning American Indian and Alaskan Native alcoholism activities; NIAAA is committed to fund new American Indian/Alaskan Native alcoholism programs as funding is available; NIAAA

agrees to accept new project grant applications from Indian alcoholism projects transferred to the IHS. Such applications must offer distinctly different services than those for which the project was originally funded. NIAAA will require that new applications from transferred Indian alcoholism programs serving Federally recognized tribal reservations must have the sanction of the appropriate tribal government prior to funding; and programs transferred to the IHS may continue to utilize NIAAA assistance in the areas of training, research and prevention to include the National Clearinghouse and the National Center on Alcohol Education.

The Office of Alcoholism established in the Office of the Director, IHS, will direct and coordinate the activities of the phased transfer and the alcoholism initiative within the Indian Health Service through the IHS Area Alcoholism Coordinators. IHS Area Alcoholism Coordinators will be identified to serve each of the ten IHS Offices. These individuals will work with the IHS Office of Alcoholism, and the NIAAA Indian Desk. The specific responsibilities of the Area Coordinators will include the monitoring of transferred alcoholism programs, and the provision of technical assistance to transferred programs.

FY 1981 FUNDING FOR INDIAN DESK ACTIVITIES

Question: How much is included in the 81 budget for Indian Desk activities? How will this be divided between ongoing and new programs?

Answer: The 1981 Request includes $5.9 million for American Indian and Alaskan Native community alcoholism treatment programs. We estimate that $3.9 million will be needed to honor the Institute's continuation commitments. The budget reflects $2 million for new American Indian and Alaskan Native programs which will emphasize services to women and youth.

FUNDS FOR NEWLY AUTHORIZED PROGRAMS

Question: Most of your supplemental requests are for uninitiated or unauthorized programs. Would it be correct to surmise that the core ADAMHA programs are within fiscal 1980 budget appropriations?

Answer: Although the 1980 appropriation provides for the majority of ADAMHA programs through the continuing resolution, it does not include sufficient funds to carry out two much needed service initiatives originally proposed in the President's budget. The budget requested funds to expand alcoholism service programs and to initiate a series of new mental health service programs. Authorizing legislation for the alcoholism service programs was not yet enacted when 1980 funds were appropriated. Similarly, Congress had not completed action on the proposed new Mental Health Systems Act. These two efforts are expected to become an integral part of our overall strategy for providing services targeted to those most in need of them.

Question: It is noticed for example, that you are not requesting additional funds for the drug abuse programs. Are we correct in assuming these supplemental requests are not essential to ADAMHA authorized programs and services?

Answer: Congress acted upon all of the drug abuse programs except for the services component which, due to the lack of author-

izing legislation, was funded under a continuing resolution at the 1979 level. No supplemental is requested for drug abuse services since the amount currently available is the same as the President's budget request.

As stated above, the alcohol and mental health program increases were included originally in the 1980 budget but were not considered by the Congress. Our supplemental request now is to enable funding of these programs at the initially proposed level. We included these increases when submitting the 1980 budget due to our belief that a need exists for these services which can and should be met by increased Federal funding. Authorization now exists for the alcoholism service programs, and current Congressional activities would indicate that enactment of the Mental Health Systems Act is likely this session. Additional funds at this time will enable us to initiate expeditiously mental health and alcoholism services essential to promoting and ensuring the health of those persons who need those services most.

HEROIN TRENDS

Question: Has the 20 percent drop in heroin addiction since 1975 continued?

Answer: It appears that the decline has ended; however, current heroin indicators are contradictory. There are some signs that there may be increased heroin use during the next year.

After reaching an all-time low of 40 percent during the first quarter of 1979, the percentage of drug treatment program admissions reporting a primary problem of heroin abuse rose to 42 percent in the second. Future trends in this indicator are not clear since heroin admissions declined to 41 percent of the total in the third quarter.

Indicators of heroin availability are not as mixed. Retail heroin purity rose from 3.5 percent in the first and second quarters of 1979, to 3.7 percent in the third, and to 3.8 percent in the fourth. This moderate increase at the national level is consistent with anecdotal reports by local officials, particularly in the Northeast, of increased heroin availability. In the past, increased availability of the drug has been followed by increased heroin-related morbidity and mortality.

METHADONE USE

Question: Has it been replaced with increased addiction to methadone?

Answer: Available data do not suggest this. The Drug Abuse Warning Network (DAWN) system, which looks at emergency room episodes and medical examiner reports, indicates a general decline in methadone abuse since 1976. For example, emergency room mentions citing methadone have fallen from 652 in the second quarter of 1976, to 325 in the third quarter of 1979. Medical examiner reports citing methadone have fallen from 109 in the second quarter of 1976, to 64 in the first quarter of 1979.

Question: What is the recidivism rate for methadone-treated heroin addicts?

Answer: The longitudinal followup of methadone maintenance clients in the Drug Abuse Reporting Program (DARP) has determined that 41 percent of methadone-maintenance clients reentered treatment during the first year after discharge, and an additional 18 percent reentered treatment during the subsequent two years.

DEVELOPMENT OF LAAM

Question: What is the status of research in testing the drug LAAM, a narcotic analgesic similar to methadone, but requiring less frequent administration?

Answer: The contract for LAAM development, which NIDA had with Medical Research Applications, Inc., (MRA) was terminated for the convenience of the Government on September 11, 1979. NIDA took over responsibility for the care of all patients maintained on LAAM as of that date. No new patients have been added, but those patients who wish may continue to be maintained on LAAM indefinitely. Before the termination of the contract, MRA submitted a New Drug Application (NDA) for the marketing of LAAM in males. The NDA application is currently being reviewed by the Food and Drug Administration. The Government's future position regarding further development of LAAM is still under discussion, and no decision has been reached. However, MRA has been asked to give NIDA all of the data and the entire NDA application which were produced under the contract. MRA has not as yet complied.

DATA AVAILABILITY FROM CONTRACTORS

Question: Have there been problems with data availability and/or exclusivity in research contracts awarded to outside researchers devoted to NIDA projects?

Answer: There has been only one contract where data availability has been a problem. NIDA's claim to the data, which it exercised under a specific termination clause, has been disputed by the contractor. The Institute is working to resolve this disagreement; however, a final agreement has not yet been reached. The data in question concerns clinical testing of the investigational new drug alpha acetyl methadol (LAAM).

MARIHUANA USE

Question: Concerned citizens are actively protesting increases in the numbers of school-age children smoking marihuana. Has your program focused on this problem and, if so, how?

Answer: The Institute is greatly concerned about the increased number of youth who are smoking marihuana. Frankly, we are pleased to see so many concerned citizens actively protesting the use of the drug.

We have recently been more vigorous in our warnings concerning the health hazards of marihuana. We feel this is related to the most recent change in trends: more negative public attitudes and the first decrease in five years in daily use by high school seniors.

In terms of treatment of the marihuana abuser, NIDA must limit treatment resources to serve those with the greatest clinical need. Often greatest clinical need translates to caring for heroin abuse and/or polydrug abusers who are deeply entrenched in the drug culture.

We have been working with the Community Mental Health Centers (CMHCs) in an attempt to broaden treatment facilities. In these facilities, it is often more feasible to care for clients who respond to early intervention and treatment. Currently, NIDA spends $18.3 million for treatment slots in CMHCs. These funds provide for numerous treatment modalities, including more than 8,000 outpatient drug-free treatment slots; a large portion of which serve marihuana abusers.

Most of NIDA's programs relating to youth and marihuana fall into what is categorized as prevention; however, much of the prevention work is not drug specific. Some activities have, however, focused on parents and communities regarding marihuana use. For example, NIDA has recently published a book, "Parents, Peers, and Pot," which describes a successful experience in one community to decrease marihuana use by the young. We are also developing a film to provide general information about marihuana use and give parental tips on how to work with the children to discourage use of the drug. Also, a recent conference was sponsored for representatives of Children Action Groups, e.g., YMCA, MWCA, PTA, etc., in which they shared experiences of strengthening and developing strategies for use of communities in marihuana prevention activities.

Question: What is the status of State legislative programs to allow the use of marihuana in the treatment of glaucoma and cancer patients?

Answer: As you know, the use of marihuana for purposes of medical treatment is still in the preliminary stages. Before marihuana can be used for glaucoma and cancer patients, investigative new drugs (IND) permits have to be issued by FDA. As of November 13, 1979, four States had received approval of such permits; however, only New Mexico, Washington, and Illinois had actually been provided the drug and were carrying out treatment. Louisiana is now in the process of organizing its program and should soon be submitting an application for the IND. FDA reports that three other States are in less advanced stages of submitting IND applications, i.e., California, Florida, and Oregon. Other States have eased legislation or policy restricting the use of marihuana in the treatment of glaucoma and cancer, however, their status on IND applications is not precise. These States are: Arizona, Alabama, Georgia, Illinois, Iowa, District of Columbia, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, North Carolina, New York, Texas, Virginia, and West Virginia.

Question: What is your feeling regarding a Federal marihuana decriminalization law?

Answer: The use of marihuana is illegal. I feel that it is not a benign drug and constitutes, especially for our teenage population, a clear and present public health hazard of considerable significance. Therefore, I feel that any steps taken by the Federal Government with regard to legal changes that apply to marihuana must be considered from the point of view of their ultimate impact upon increasing or decreasing levels of usage in this country.

I favor the use of Federal law enforcement resources to reduce the availability of the drug. This is done most effectively by placing Federal law enforcement priority on high level trafficking organizations--those able to move the largest quantities of marihuana.

Empirically, the history of the past 15 years demonstrates that the use of criminal sanctions against the possession of small amounts

of marihuana for personal use has been an ineffective deterrent, given that during the same period of time we have seen an explosive increase in the incidence and prevalence of use of this drug. I can, therefore, understand the rationale of efforts to remove Federal prison sentences for such offenses and their replacement by the imposition of fines. However, I support such initiatives only to the extent that they are proposed in the context of a wider comprehensive program which simultaneously is directed at the goal of discouraging and decreasing marihuana use, particularly by young people, and offers some significant and realistic hope of achieving this goal. In the interim, I would urge serious consideration for various citation diversion proposals which have been introduced into the Congress.

I am greatly concerned that decriminalization has become a symbol, a symbol that bears little resemblance to reality. Far too many view decriminalization as the first step toward legalization and an indirect admission that marihuana is not so bad a drug after all. I believe that we must find ways of discouraging marihuana use; ways that work without creating their own harmful side effects. Current Federal criminal sanctions against the possession of small quantities of marihuana meet neither criterion and should, therefore, be carefully reviewed. Any modifications must meet the test of discouraging marihuana use. Well-intentioned efforts may have unintended effects. I believe that we can communicate an accurate message about marihuana to the American public, and I welcome the challenge to do so.

ANTI-SMOKING PROGRAMS

Question: Recently-released data suggest that the rate of lung cancer among women has risen so dramatically that in three years it may overtake breast cancer as the leading cause of cancer-related deaths among women. What research efforts are being made regarding nicotine dependence?

Answer: NIDA's research on cigarette smoking is centered around three aspects of the problem: (1) initiation, (2) maintenance, and (3) treatment. In all these areas, both pharmacological and behavioral factors are studied. The goal of the program is to clarify the relative importance of the various determinants of smoking behavior in order to design the best treatment strategy for those who smoke and the best prevention program for those most likely to start.

Current or recent efforts include investigations of:

(1) The relevance of the social role of women on smoking behavior;

(2) The relevance of parental smoking habits on the smoking behavior of children;

(3) Ways of refining procedures to measure smoking behavior (e.g., simply counting the number of cigarettes a person smokes is not a good measure of how much the person smokes since the amount of nicotine in different brands of cigarettes varies);

(4) The role of nicotine in smoking behavior;

(5) The effects of smoking, particularly in combination with other drugs, on human performance and mood;

(6) The possible existence of nicotine receptors in the brain;

(7) The effects of aggression on nicotine intake, and vice versa;

(8) The use of nicotine gum as a replacement for cigarettes;

(9) The effects of health messages and economic incentives for inducing the smoking of lower tar-nicotine cigarettes; and

(10) The causes of relapse after smoking cessation.

Question: Particularly for pregnant women, what are your program objectives for education and prevention of drug abuse with tobacco?

Answer: NIDA has not been mandated in its authorizing legislation to conduct tobacco smoking prevention programs and, therefore, has not developed programs for pregnant women. NIDA's research program, however, has initiated a study of the effects of tobacco smoking on pregnant women.

Question: Do you have the authority to fully address nicotine dependence and include it under the umbrella of drug abuse research and treatment carried out by NIDA?

Answer: NIDA has been directed by the Assistant Secretary for Health to conduct a broad research initiative into the phenomenon of nicotine dependence and its relation to tobacco smoking behavior. As mentioned above, NIDA has not been mandated to conduct tobacco smoking prevention or treatment programs.

Question: What types of innovative smoking-prevention programs are you involved in?

Answer: For the reasons mentioned above, NIDA has not as yet developed specific smoking-prevention programs. However, there is reason to believe that a number of NIDA's more generic drug abuse prevention initiatives help to prevent tobacco smoking, particularly in youth.

Question: Are your anti-smoking efforts coordinated with those of the Assistant Secretary of Health to avoid duplication?

Answer: Yes, NIDA's anti-smoking responsibilities have been mandated by the Assistant Secretary for Health in a manner to avoid overlapping with the responsibility of the Office of Smoking and Health and other PHS agencies involved in this avenue of research. There is continuing coordination to prevent duplication.

RELOCATION OF THE ADDICTION RESEARCH CENTER

Question: Last September, our Committee agreed to a reprogramming of $400,000 to permit NIDA to initiate an architectural design contract to assess the cost of renovating a building to house an Addiction Research Center. What progress have you made toward letting the contract and getting started on architectural design?

Answer: The contract for architectural and engineering design of the proposed new research building for the Addiction Research Center was let at the end of FY 1979 and is on target. Assuming NIDA obtains Congressional approval for new facilities' funds, we expect

to let a construction contract in the first quarter of FY 1981 for renovation of Building "C" on the campus of the Baltimore City Hospital.

Question: What is the status of your plans to lease the building from the Baltimore City Hospital?

Answer: A lease has already been signed which has an effective occupancy date of January 1, 1981. On this date, we could begin renovation.

Question: Are you asking for the estimated $5 million in renovation costs in the FY 1980 budget?

Answer: We are requesting $4.7 million in the FY 1981 budget for renovation of Building "C" at the Baltimore City Hospital.

TRAINING OF DRUG ABUSE WORKERS

Question: What are the States' training programs doing to address the need for adequately trained personnel in drug abuse programming?

Answer: As part of their development under the National Training System and the State Training Support Program Guidelines, all States carry out a regular assessment of training needs along with identification of internal resources. In addition to existing State resources, the State training programs are using the resources of the National Training System to secure additional training of trainers, course manuals, technical assistance, and specialized services. The goal of building State training capacity is being met through the training and certification of instructors/trainers. During fiscal 1979, more than 32,000 individuals were trained by more than 800 State-based trainers. This number increases annually as State capacity becomes the primary focus of delivery of training to drug abuse program personnel.

Question: What is NIDA's role in coordinating personnel training programs nationwide?

Answer: NIDA's role in coordinating training programs nationwide has resulted in the building of the National Training System (NTS). The NTS includes component parts such as the National Drug Abuse Center for Training and Resource Development, five Regional Support Centers, 52 State Training Support Programs, a Career Teacher network, and scores of grantee and contractor participants. Cooperation with other Federal agencies in the Federal Agency Manpower and Training Group and directly through supportive services to the Bureau of Prisons, Veterans Administration, Department of Defense, and Law Enforcement Assistance Administration/Treatment Alternatives to Street Crime, has further expanded the drug abuse training programs beyond NIDA's immediate purview. Several programs and many course materials are cooperatively managed by both NIDA and NIAAA to assure completeness and avoid duplication.

Question: Fiscal 1981 training requests are down from last year's levels, except in research training. Why is this?

Answer: One portion of the drug abuse clinical training program, the Developmental Grants program, is being phased down. This program was originally established to meet an urgent need for increased numbers of skilled drug abuse treatment workers in the shortest possible

time. Developmental Grants were awarded to community-based training programs to support what was in effect on-site training of treatment workers. The major advantage of this program was that it made use of existing training resources, thus avoiding the delays that would have resulted had the Federal Government attempted to establish new training programs.

NIDA's long-term training strategy, however, has been to meet the nation's drug abuse treatment training needs by encouraging the States to provide or support training through their own programs; restricting the Federal role to the provision of technical and financial support to the States' efforts. This policy has been successful. In 1971, the States supported only about 10 percent of the costs of training treatment workers. In 1979, the States supported approximately 50 percent of these costs.

As a result of the increased efforts by the States in the provision of training, the relative stabilization of the drug abuse treatment network, and the existence of a large pool of skilled drug abuse treatment workers, we now believe that the Developmental Grants program can be phased down without adverse consequences. Future Developmental Grant awards will be made only to meet unexpected urgent training needs for drug abuse workers with particular skills which cannot be met through existing State or local training programs.

Question: Will this curtail your program improvement and implementation efforts?

Answer: No, the remaining major portions of the National Training System (NTS), and in particular the National Drug Abuse Training Center, the Regional Resource Support Centers, and the State Training Support Program, will be supported at FY 1980 funding levels.

THIRD-PARTY PAYMENTS FOR SERVICES

Question: What is the extent of third-party payments for drug abuse treatment services?

Answer: NIDA has expended considerable effort to assist the States and programs in their ability to garner third-party dollars. During the past five years, the proportion of third-party funds have increased from less than 1 percent to the current 16.7 percent.

TARGETED DRUG ABUSE TREATMENT SERVICES

Question: Are your current treatment programs meeting the needs of target populations?

Answer: Yes, we have increased our efforts to meet the special needs of women, youth, and minorities, particularly American Indians. For example, our strong encouragement of States to develop programs for American Indians has resulted in a significant increase in the number of admissions to treatment by this targeted group during the last fiscal year. To expand upon this initiative, NIDA has developed a contractual arrangement with an American Indian association to facilitate the relationship between the Single State Drug Abuse Agencies and the American Indian tribes. This arrangement is designed

to assist the States in recognizing the special needs of American Indians and to target additional treatment services to this special population group.

INFLATIONARY COSTS OF TREATMENT

Question: How has the rise of inflation affected your service delivery and budgets?

Answer: To date, there has not been a visable change in the delivery of services. For fiscal 1980 and 1981, the budgets do not propose increased funding for treatment services to meet the rise in inflation. However, the Institute does plan to provide for some inflationary increases in the treatment services network by reducing the overall number of treatment slots receiving partial funding support from the National Institute on Drug Abuse. These adjustments will be made as individual Statewide Services Grants are negotiated in fiscal 1980 and 1981.

REDUCTION IN DRUG ABUSE FORMULA GRANTS

Question: The grants to States budget request is down five million from fiscal 1980. You state that this cut in formula grant money will most likely result in decreased State prevention activities. How will the proposed increases in NIDA's direct prevention programs offset this reduction?

Answer: NIDA's request for formula grant funds for FY 1981 is $4,098,000 less than was appropriated in FY 1980. We do believe that this decrease will most likely result in decreased State prevention activities supported with formula grant funds. However, we believe that this decrease will be more than offset by increases in NIDA's direct prevention program in both FY 1980 and FY 1981. As directed by the Congress in NIDA's reauthorizing legislation, funds used for prevention and early intervention will increase from approximately 3.9 percent of the funds obligated for community programs in FY 1979, to at least 7 percent in FY 1980, and at least 10 percent in FY 1981.

The largest increase in prevention funds will be made available to Single State Agencies for drug abuse prevention. For example, funds for State prevention coordinators will be increased from the $2,681,000 obligated in FY 1979, to $3,925,000 in FY 1980, and $5,000,000 in FY 1981. Increases will also occur in funds used to support community-based prevention service demonstration programs, including Channel One site. In reviewing applications for these funds, special consideration will be given to applications for prevention programs which serve women, the elderly, and individuals under the age of 18. Special consideration will also be given to programs which are located in occupational and educational settings.

The remainder of the increased prevention funds will be used to strengthen technical assistance efforts for State and local communities and to expand the prevention grants program. The purpose of the prevention grants program is to identify those prevention models that have the greatest potential to reduce the incidence and prevalence of drug abuse among youth, and to replicate and validate these "high promise" prevention models, including strategies for parenting and families. The Institute will give greatest attention to proposals which are designed to produce reliable information about effective methods for and outcomes of a successful prevention strategy and programs that emphasize evaluation of drug abuse prevention strategies and assess program impact on drug-using behavior.

DISSEMINATION OF RESEARCH FINDINGS

Question: Regarding methadone and other drug-abuse sponsored research, we have a particular complaint to question you on. It has come to our attention that an individual searching for information on methadone treatment and maintenance was referred to your information clearinghouse. His efforts produced a long series of delays, a denial of available information, and finally a notice that informed this researcher that methadone-related material did exist but was not available to the public. How accessible to the public are research findings? Could you briefly describe the procedures followed and indicate the time needed to disseminate such information?

Answer: NIDA has a policy of making our research findings available to the public and the research community in a number of ways:

1. We produce three major publications series that cover research findings in the treatment services area and in the basic and applied research of our Research Division. These are described below.

   a. Services Research Series - This series is issued by the Services Research Branch of the Division of Resource Development. Its primary purpose is to provide reports to the drug abuse treatment community on the service delivery and policy-oriented findings of long-term demonstration projects. The series includes state-of-the-art studies, innovative treatment management and financing techniques, and treatment outcome studies. The Branch decides the value of the findings and publishes those that can increase the knowledge of the service field. After the research report is submitted to the project officer, and approved, the material is edited and formatted for printing. It takes about six months until it is available and disseminated to the field.

   b. Research Monograph Series - This series is prepared by the Division of Research to provide critical reviews of research problem areas and techniques, the content of state-of-the-art conferences, integrative research reviews, and reports of significant original research. An Editorial Advisory Board of important researchers in the field advises the Editor on topics and content of the series. Most of the monographs are developed by field researchers who write chapters on their own research. Individual monographs take approximately 8-10 months before they are ready to distribute.

   c. Research Issues Series - This series deals with the theoretical and research literature on the social and behavioral implications of drug abuse. It is primarily composed of a series of Resource Handbooks and Reference Summaries. The Handbooks cover original research and research tools that provide needed assistance to drug researchers in areas that have previously received little attention. The summaries present abstracts of selected research studies that represent the most up-to-date

information on the topics. A peer group of investigators reviews the studies for inclusion in the bibliographies. It takes about 8-10 months to produce these for distribution.

2. Another way NIDA-supported scientists communicate their research results is by submitting the material to privately published scientific journals. Because of the thousands of articles submitted each year, these articles can take well over a year to find their way into literature.

3. NIDA also published public information pieces on the latest findings on topics of general interest. These pamphlets usually take from six to eight months to write, clear, format, and publish for distribution.

4. Final project reports of grants and contracts are placed in the NIDA Resource Center, which is part of the Clearinghouse, so that they can be accessible for review. These reports can be used in the Resource Center or can be borrowed via the Interlibrary Loan system.

With over 150 publications produced each year, NIDA has an extensive publishing program which is geared to provide the lay and professional public with the latest information about the drug problem.

MENTAL HEALTH TRAINING

Question: I have authorized a bill to encourage medical schools to incorporate geriatric education in their curricula. This was supported by the President's Commission on Mental Health because of their specific concern about mental health and the elderly. Is ADAMHA doing anything to promote the training of geriatric psychiatrists or to promote the development of this field in the other mental health professions?

Answer: Yes, it is. The Center for Studies of the Mental Health of the Aging in NIMH has been funded for several years now, and awards grants for the education of geriatric psychiatrists and for the development of model programs to train a wide variety of caregivers on the special mental health needs of the elderly. In addition, training specifically directed toward work with the aged is one of the major priorities of our redirected clinical training program. This means that we are attempting to incorporate geriatric curricula in the educational programs of all mental health disciplines, as well as encouraging the production of specialists in this area. It is estimated that approximately $2.8 million will be awarded in 1980 in clinical training grants targeted on the mental health needs of the elderly, and $3.1 million is projected for 1981.

Question: Last year, the Committee directed the National Institute on Mental Health to review its planning to determine where changes should be made to deal with the shortage of mental health professionals. What recommendations are you prepared to make as a result of this review? What is being done regarding an expected 13,500 psychiatric professional shortfall that NIMH projected for 1980?

Answer: A detailed report on this subject is now being prepared and will be given to the Committee before the mark-up of the budget.

This report will identify the various areas of need for mental health professionals, the skills needed both now and in the future, and the steps proposed to meet these needs.

RESEARCH TRAINING BUDGET

Question: The Coalition for Health Funding's recommendation for the National Institute for Mental Health fiscal 81 budget states that "without adequate support for research training, which should be $29,737,000...we stand to lose a generation of researchers." Would you explain and elaborate on this please, in light of the unchanged budget allocations in your fiscal 81 training research monies?

Answer: The proposed research training budget is similar to our clinical training request, in the sense that it is proposing a re-direction of existing resources to achieve its goals. In 1981, although the total funding level does not change, the level of funds available for new and competing awards increases by 46 percent, from $3,241,000 in 1980 to $4,728,000 in 1981. This amount will enable the Institute to increase opportunities for the development of minority researchers, and increase support for researchers who will study mental health service system issues. Thus, we feel that the total level of funding is quite sufficient to meet our commitments, provide an adequate level of new starts, and permit the Institute to begin new programs in a number of priority areas.

FINANCIAL DISTRESS

Question: After eight years from startup, if a community mental health center is not financially self-supporting, it then qualifies for "Financial Distress" grants to maintain service while continuing to seek other sources of funding. The fiscal 81 budget requests continuation monies of approximately $7 million and new distress grants of another $7 million. Are the numbers of community mental health centers requiring financial assistance increasing?

Answer: The fiscal 81 budget requests $9.4 million for continuing financial distress grants but has no request for new financial distress grants. Under the proposed Mental Health Systems Act the financial distress grant mechanism would be phased out. Terminated CMHCs in serious need of further assistance could apply for limited maintenance grants for support of non-revenue producing services. As of October 1, 1979, 325 CMHCs had terminated basic support and were eligible to apply for financial distress grants. However, to date only 75, or 23 percent, of these CMHCs have been awarded financial distress grants. Of the 75 financial distress grants awarded to date, four have already terminated and 17 more will terminate in 1980. The percentage of CMHCs terminating support, that need financial distress assistance does not seem to be increasing. The number of such CMHCs needing some form of assistance will increase as the number terminating support increases. As mentioned above, we expect that the assistance provided through the proposed maintenance grant program will be sufficient to meet their needs.

Question: What is the average length of time a community mental health center is supported on financial distress grants?

Answer: Financial distress grants may be awarded for no more than five one-year periods following termination of a staffing (or operations) grant received by the center. Eligibility for five years of funding was authorized in 1978, the previous maximum time being three years, and no center has yet completed five years of funding. We estimate that 17 CMHCs will complete their fifth and final year in 1980. Of the 75 financial distress grants awarded to date, four have terminated early, having completed just one or two years of support.

ALTERNATIVE FUNDING SOURCES

Question: What are the alternative funding sources available to a community mental health center?

Answer: Other than a grant under the CMHC Act the following funding sources apply: local fund raising; county or city mill tax; philanthrophy; investment other than Federal grant funds; contracts to provide service to organizations; fee for service first party; private insurance; Title XIX; Title XX; various Federal programs for veterans, military, personnel, children and others; and State support.

FINANCIAL VIABILITY OF CMHC's

Question: How many community mental health centers fail entirely to become self sufficient?

Answer: Only one CMHC has failed to the extent that it has terminated all services and closed its doors. A number of other centers have been threatened with termination, but at least to this date they have been able to work out their financial problems. We estimate that up to 30 percent of the centers have severe problems.

TECHNICAL ASSISTANCE

Question: Do you or the appropriate regional office provide any technical assistance to community mental health centers in financial distress to help them better manage their fiscal affairs?

Answer: Since fiscal year 1976 the NIMH and the regional offices have jointly provided technical assistance, supported by the two percent technical assistance fund, in the form of on-site consultation, workshops, seminars and five-day intensive courses in fiscal and administrative management to centers in financial distress. In addition the NIMH produced and distributed A Manual of Third Party Funding Sources for Community Mental Health Centers to all centers.

Question: If not, do you think it would be helpful?

Answer: The answer to the previous question indicates that the NIMH has provided considerable technical assistance to community mental health centers in financial distress. An evaluation study of the Two Percent Technical Assistance Program conducted by the Organization for Applied Science in Society (OASIS) found that the technical assistance provided to CMHCs through that program has been very helpful.

EFFECT OF BOOM TOWN ECONOMY

Question: In North Dakota, the impact of rapid energy development is putting tremendous pressure on the resources of the mental health centers. We have real "boom towns" in which there is no traditional social support structure for people to fall back on. These "boom towns" are common wherever rapid development occurs in a rural area. What's even worse in North Dakota is that the center is responsible for the energy development area is already in financial distress, has had to cut back on staff and cannot afford any outreach workers. Is ADAMHA sensitive to this unique kind of need and are you doing anything to respond to it?

Answer: The NIMH is keenly aware and has shown its concerns for the mental health problems of energy impacted "boom towns" and their surrounding areas. In 1977 it published The Impact of New Boomtowns: The Lessons of Gillette and the Powder River Basin" (ADM 77-514). This is a report on the Wyoming Human Services Project sponsored by NIMH and the University of Wyoming School of Social Work to meet human service needs in energy impacted communities.

The Division of ADAMHA Programs in the PHS Denver Regional Office has been closely monitoring the development of energy impacted areas in that region. They have supported technical assistance projects to help CMHCs affected by these developments. These projects are primarily in Wyoming and Montana. North Dakota is only now beginning to be affected. There are eight catchment areas in the State, five of which have federally funded CMHCs. Among the federally funded CMHCs, it is anticipated that Memorial Mental Health and Retardation Center at Mandan is the one most likely to be affected. However, the two catchment areas that are likely to be impacted to a greater degree than Mandan by energy development projects are at Willistan and at Dickison. They do not have federally funded CMHCs. Their mental health services are provided through the State's Human Service Agency and funded primarily through Title XX payments. They have not submitted an application for CMHC grant support.

The Division of ADAMHA Programs is continuing to provide workshops and instructions, supported by TA funds, to the entire region on how to manage mental health services in energy impacted areas and find fiscal alternatives to support the needed services.

CSP PRIORITIES

Question: Last year the President's Commission on Mental Health found that 15 percent of the population seeks some form of mental health care during the course of the year. In what service areas have you directed your fiscal 1981 budget priorities within the Community Support budget activity?

Answer: At the community support level the 1981 budget recognizes the great investment of past years in the Community Mental Health Centers Program (CMHC) that has led to the funding of 763 CMHCs by the close of FY '79. With some 50 percent of the population now having access to services provided by established CMHCs, it is of the greatest importance to provide necessary and continued financial support consistent with the objectives of the CMHC grant mechanisms. Therefore 86 percent of the proposed budget is earmarked for the continued funding over a phase-out period for pre-

sently operating CMHCs. The remaining 14 percent of the budget is available for services targeted to high need underserved groups, for new comprehensive community programs, for linking mental health and health programming, for support of certain essential but not revenue producing activities, and for community planning.

Within the State Support budget activity for 1981 the major priority is on planning for and implementing services for the chronically mentally ill, both adults and severely mentally ill children, with 88 percent of the budget. These activities too will impact in major ways on the development and improved coordination of services in the communities. The remaining 12 percent of the State support activity funds is focused on preventive activities.

ALLOCATION OF BUDGET-INPATIENT VS. OUTPATIENT

Question: What proportion has been allocated for inpatient care versus outpatient community mental health services?

Answer: With respect to the proposed 1981 budget, no portion is specifically set aside for inpatient or outpatient care or for any other service modality per se. Grant applications reflect service needs and describe programs that are designed to meet the mental health needs of a given mental health service area. Maximum flexibility for program design and budgeting are thus maintained.

On the basis of past experience with the Community Mental Health Centers (CMHC) Program it can be stated with confidence that a relatively small portion of any funded application would be in support of an inpatient service. In FY 1977, for example, 12.5 percent of the CMHC case load received services in an inpatient unit while 81 percent of the case load was handled in an outpatient program and 6.5 percent was assigned to a partial hospitalization service.

DEINSTITUTIONALIZATION

Question: What kinds of controls do you impose to insure that adequate alternative community resources are available to deinstitutionalized individuals once they return to the community?

Answer: Federally funded community mental health centers are required to provide assistance to the courts and other public agencies in screening people being considered for referral to public mental health facilities, and to arrange for alternative treatment for such individuals wherever possible. These screening activities are designed to prevent inappropriate hospitalization and to link people with appropriate alternative community resources.

In addition, community mental health centers are required to provide followup care to persons discharged from public mental health facilities. NIMH guidelines for followup care emphasize that centers should attempt to link discharged patients to whatever community services they may need to readapt to community life.

These requirements, as well as other requirements regarding deinstitutionalization, are monitored by the regional offices as part of their overall monitoring of federally funded community mental health centers. In the case of State performance contracts, State mental health agencies will assume these monitoring responsibilities.

COMMUNITY SUPPORT PROGRAM

Question: What are the current community support program pilot projects doing to improve state and local mental health agency services for the chronically ill?

Answer: The NIMH Community Support Program is now entering its third year of operation. The following major accomplishments can be reported over the last year.

Responsibilities for assisting the mentally disabled in the community have been clarified at both State and local levels in the 20 CSP contract States. In these States, mental health agencies have assumed leadership in advocating with other health, housing, and human service agencies to meet the needs of the mentally ill. In a number of States, interagency agreements have been developed, discharge planning and policies have been improved, and other such steps have been taken to clarify responsibility for the mentally disabled in the community.

Improved models for local service delivery are being developed and tested in fifteen local demonstration sites. These local sites are testing a variety of ways in which a broad range of services needed by the chronically mentally ill can be organized, developed, financed, and coordinated. In these sites, specific improvements in client services have been made, impacting on a total of 2,250 individual clients in the demonstration areas.

State legislative and policy changes have been instituted in CSP States to improve services to the chronically mentally ill. Some of these include development of an adult protective services bill in Maryland; development of standards for licensing for levels of residential programs in Minnesota; development of guidelines for outpatient and aftercare in Massachusetts.

Stimulated by the CSP contracts, many States have increased State funding for community services for the chronically mentally ill. For example, special State appropriations in CSP States include: $350,000 in South Dakota; $909,631 in Minnesota; $7.3 million in Florida; and $28.2 million in New York State.

These are just a few examples of the progress being made in the funded CSP States. NIMH continues to receive indications of intense interest in the Community Support Program from non-contract States. We hope to be able to work with more States in the future, providing that sufficient funds become available.

Question: How successful are community support program projects in coordinating federal, state and local resources?

Answer: Coordination of all these diverse resources is a complex task, requiring specific initiatives at Federal, State, local, and client levels.

At the State level, a number of CSP States have established cabinet level task forces, committees, or other mechanisms to identify problems in service coordination and delivery affecting the client population and to develop solutions. NIMH is currently collaborating with the Office of the Assistant Secretary for Planning and Evaluation, HEW, in designing methodologies to evaluate

the impact of these coordination efforts. By June, 1980, we will have recommendations based on this project. Meanwhile, our impressions, and the narrative information provided by CSP States, lead us to believe that the program is substantially increasing the level of awareness, attention, and priority to the needs of the chronically mentally ill in the participating States.

At the local level, the Community Support Program includes 15 different demonstrations of alternative ways to organize, finance, coordinate, and support services to the chronically mentally ill. States are in the process of evaluating these demonstrations and using them as a basis for program planning and evaluation elsewhere in the State. For example, in Florida, the local demonstration focuses on Fellowship House in Miami, a "psychosocial rehabilitation center" which provides daytime activities, transitional employment, alternative living arrangements, and other such services to the population. Florida is financing four other local demonstration projects with $7.6 million special State appropriation, using the NIMH-assisted demonstration project in Miami as a model.

Another local impact of CSP is clarification of roles and responsibilities for meeting the needs of former mental patients in the community. Staff of CSP projects have organized local communities, helped identify sources of funding, provided technical assistance, and encouraged development of new opportunities for clients in a number of States. As an example, in Maryland, State CSP staff have already assisted in the establishment of new psychosocial rehabilitation programs in four counties. These programs, which will be supported from a combination of SSI entitlements to individuals, vocational rehabilitation, State and local social service, and other such resources, are starting to offer meaningful daytime activities, real work opportunities, and dignified living arrangements in shared apartments to former patients who might otherwise have been left to fend for themselves.

Question: Would this coordination of funds more effectively address the needs of the chronically mentally ill?

Answer: Yes, we are convinced that more effective coordination of the resources that are already in the system is critical for this population. As an example, many of the chronically mentally ill are eligible for Supplemental Security Income (SSI) income assistance. Too often, no mechanism exists to help discharged mental patients find appropriate living arrangements. Consequently, Federal SSI funds are often spent by former patients to pay for their room and board in sub-standard boarding rooms or single room occupancy hotels.

With a minimal investment of staff time, these same income payments could be used to enable former patients to live in shared apartments with other former patients. Often, these clients do not have the initiative or skills needed to find their own roommates, to locate apartments, or to negotiate leases with the landlords. However, if an agency provides a staff member to assist in this process, two or three clients can share the rent in a much more dignified and independent living arrangement than they would otherwise have available to them.

This is just one example of how currently available resources could be better organized to improve opportunities for the chronically mentally ill. We believe that to some extent, staff already in the mental health system can be redirected to work in different ways

and to do the community organization and advocacy that is necessary to make better use of currently available resources. These are the kinds of activities that are taking place at State and local levels through the Community Support Program.

CHRONICALLY MENTALLY ILL PROGRAM

Question: The FY 80 Appropriation to State Community Support Programs was $7.6 million. For Fiscal 81, you are requesting 38 million. Would you give us the details and justification for so large an increase?

Answer: Although the current 1980 appropriation for the Community Support Programs is $7.6 million, we are requesting a supplemental of $25 million for this program to expand it into a national program. With the supplemental, the 1980 request is intended to achieve four basic purposes.

First, we plan to continue to expand the service development and improvement activities of the 19 States and the District of Columbia that are currently participating in the Community Support Program. These States are in various stages of developing comprehensive interagency strategies to improve services to adult chronically mentally disabled persons who are capable of living in the community with adequate rehabilitation and support services.

Funds requested for expansion would enable these States to refine their State level activities, to improve collaboration with other State agencies, to provide technical assistance to localities, and to engage in other State level functions to benefit the population that is capable of living in the community.

In addition, the existing projects need local service development and improvement funds to implement their strategies. These funds would be used, for example, to improve services to the chronically mentally disabled in areas heavily impacted by deinstitutionalization, and to initiate local demonstration projects illustrating how to organize and finance community support systems.

Additional resources would also be allocated to the current projects to enable these States to expand their strategy development activities to plan for service improvements for those persons so disabled that they need skilled or semi-skilled nursing care. Current activities are limited to persons who are capable of living in the community.

In order to achieve these purposes, it will be necessary to increase the budgets of the currently participating States to an average of approximately $900,000 per State.

Second, we plan to set aside approximately $2,600,000 for interagency collaborative projects of national significance. These projects will be designed to demonstrate various approaches to linking Federal programs to benefit the mentally disabled in the community. Collaboration will continue with the Department of Housing and Urban Development, the Rehabilitation Services Administration, and the Health Care and Financing Administration.

Third, we plan to set aside approximately $1 million for a national technical assistance program to disseminate information across States on effective methods for organizing, financing, and monitoring the quality of services to the chronically mentally ill.

Fourth, we plan to expand the Community Support Program to approximately 34 additional States and Territories, with initial projects being funded at an average of approximately $300,000 per State. This amount would allow all States to engage in initial State level interagency planning and strategy development, and to begin implementing limited local demonstration and service improvement projects.

Our 1981 request of $33 million is intended to continue the State programs initiated in 1980 enabling continued Statewide strategy development and increasing numbers of local service development and improvement projects.

THIRD PARTY PAYMENTS

Question: What is the extent of third-party payments for mental health treatment services?

Answer: Third-party payments for mental health treatment services are made by both the government and by private insurers. Public payments for mental health are provided for individuals entitled to benefits under such programs as Medicare and Medicaid. The private sector provides various coverages to individuals and groups under a variety of subscriber arrangements. Regardless of the source of third-party payments, the amount, duration and scope of mental health coverage does not approach coverage for general health care and is not reimbursed on the basis of true cost.

Presently, CMHCs are not considered Medicare providers of services. That is, unless CMHCs are operated by a general hospital (only 15 percent of centers are) reimbursement on the basis of cost is not permitted under Medicare. In CMHCs generally, only the services of physicians are reimbursed. This reimbursement is on a fee basis and is limited to a net of only $250 per patient annually. Reimbursement for inpatient psychiatric facility care is limited to 190 days in a patient's lifetime.

Similarly, a center's ability to collect Medicaid reimbursement is severely limited. For example, only those CMHCs directly operated by a hospital can be reimbursed for outpatient mental health services. Otherwise, CMHCs can be reimbursed only if they meet State-by-State criteria for "clinic" services (only 14 States specifically identify CMHCs as reimbursable clinical entities). Further, Medicaid rate structures differ from State to State. The most prevalent rates are the per diem flat rate and the per service rate. Regardless of the structure used, all fail to cover the costs of outpatient care. Mental health inpatient facilities and Skilled Nursing facilities cannot be reimbursed for mental health services to those between the ages of 21 and 64.

As for private insurers, virtually all of them offer mental health coverage. However, the coverages vary widely, stress inpatient mental health benefits (albeit limited as compared to general

health benefits) rather than outpatient mental health care, and provide more extensive coverage to groups than to individuals. Limits on days of treatment and unrealistic deductibles and co-payments abound for mental health.

Data from our latest survey indicate that 23% of center revenues are from third party payments. This percentage has been steadily increasing over the years: from 8% in 1969 to 20% in 1974 to the current amount. Much of this growth is due to increasing Medicaid reimbursements.

Question: What has been done to extend third-party payments to mental health centers -- particularly those in financial distress?

Answer: Improving the ability of CMHCs to collect third-party payments is recognized as a chief priority by the NIMH-RO Technical Assistance Committee, especially for those centers which have "graduated" from federal grant support and/or those in financial distress.

Among the methods used to assist CMHCs in the collection of third-party payments are:

Center to Center Assistance - Those centers which have developed outstanding third-party programs constitute the best reservoir of talent to help others who have problems in that area, and are called upon to serve as procedural models.

Training Consultants and Trainers - Applying the rationale for center to center assistance, individuals with recognized third-party potential are selected for additional training to expand the available pool of those qualified to assist CMHCs in third-party matters.

Training Key CMHC Staff - Intensive training of key CMHC staff enables them to enhance their program management skills as well as enabling them to become in-service trainers within their own centers.

Development of Resource Material - Provisions are made for the preparation of manuals, guidelines and other materials relevant to the improvement of third-party payments. Some examples include: the "Working manual of third-party funding sources for CMHCs"; "Multiple Source Funding"; "Cost Finding and Rate Setting for CMHCs"; the "Title XX Handbook"; "The Design of MIS for Mental Health Organizations"; "Resources for CMH Program Evaluation"; etc.

Professional Expert Assistance - Experts provide either direct consultation or instruction thru courses and workshops. The NIMH Staff College has played a major role in providing structured 3rd party payment programs via experts.

Organizational Consulting Assistance - Contracts with organizations or agencies to provide technical assistance in 3rd-party issues continues to be a useful supplementary procedure.

Additionally, as part of a broader strategy, NIMH staff continue to seek improvements in the policies, regulations, and legisla-

tion which perpetuate reimbursement restrictions on the effective delivery of mental health services.

HOSPITAL RENOVATION

Question: Saint Elizabeth's Hospital is the only public Health service hospital devoted exclusively to the care of the mentally ill. In 1978 the Committee appropriated $54,210,000 million for the renovation of Saint Elizabeth's Hospital. How has the renovation progressed and what major improvements have been made in the facility?

Answer: The SEH Construction Program is moving ahead. We are currently initiating an extensive renovation program in John Howard Pavilion. This houses the Hospital's forensic programs, and the renovations represent a major expenditure of funds for this project which will total $7.0 million. There are eight contract packages in all. All of the construction packages will be under way and/or completed during the next two fiscal years.

Question: For Fiscal 1981 the Hospital is requesting $1,500,000 for construction and renovation. What improvements will the requested $1,500,000 be utilized for?

Answer: The request is intended to meet ongoing repair and improvement requirements of the hospital, which develop as part of the normal aging process. The $1,500,000 request includes $500,000 for work on steam tunnels; $200,000 for roof replacement; $250,000 for demolition of obsolete buildings; $150,000 for expansion of an electric feeder line; $200,000 to replace a central fire alarm network; and $200,000 for upkeep of roads.

ACCREDITATION

Question: Will Fiscal 81 funds be used to fulfill the terms of reaccreditation granted by the Joint Commission on Accreditation of Hospitals in August of 1979?

Answer: The $1.5 million in our construction request for improvements is intended primarily to forestall deterioration in the physical plant which might lead to future accreditation problems.

EFFECT OF IMPROVEMENTS

Question: Will these improvements maintain Saint Elizabeth's Hospital in good condition after the past efforts made to repair extensive deterioration?

Answer: If the improvements are continued as part of a regular annual program of maintenance, they should forestall deterioration. The past deterioration of the hospital resulted, in large measure, from prolonged periods without appropriate resources for maintenance and repair.

STAFF REALLOCATION

Question: To improve the manpower efficacy at Saint Elizabeth's Hospital, an internal reallocation of staff was recommended by the Report by the Assistant Secretary for Management and Budget/OS. Has a staff reallocation been accomplished?

Answer: There are approximately 250 positions which are being reallocated over a two to three year period primarily from two Hospital divisions - the Division of Administration and the Division of Medical/Surgical Support Programs. The reallocation also is taking into account an intensive emphasis on the Upward Mobility Program of the Hospital which provides professional and paraprofessional opportunities to our line level staff members.

Question: Has this involved retraining current employees or the replacement of staff?

Answer: There is an emphasis on reassignment and retraining of displaced staff members. To date, no terminations or Reduction in Force procedures have been initiated as a result of the overall transfer of staff.

Question: Specifically, the Report states Saint Elizabeth's is understaffed in areas such as direct patient care while overstaffed in areas such as administration and support functions. Has this imbalance been corrected?

Answer: To some extent, yes. As mentioned above, a large number of the reallocated staff will be transferred from the Division of Administration. Also, within each of the Hospital's clinical divisions there are certain imbalances in the assignment of staff and this also is being addressed as a followup to the original reassignment of staff members.

Question: Is the Fiscal 81 transfer of 30 positions to direct patient care sufficient?

Answer: While more needs to be done, we feel comfortable with a recent reallocation of staff that was undertaken to provide a greater degree of flexibility in our patient services commitments. This staff allocation is assuring the availability of some positions which are needed by Hospital clinical staff and this in turn is furthering a pattern and philosophy of treatment which emphasizes the patient care components of our service mission.

PATIENT LOAD

Question: Regarding the use and patient load at Saint Elizabeth's Hospital have studies been made on the patient to occupancy available ratio, and other such "user" ratios, to determine if Hospital space is being fully utilized?

Answer: Yes, in fact these studies have been expanded to include such factors as cost per patient day and manpower utiliza-

tion. In particular, SEH is examining the cost of operating the medical services segment of the Division of Medical and Surgical Services to determine if this, like surgical services, can be better provided at a lower cost through contract, perhaps with Georgetown University or some other teaching hospital. SEH is also examining the costs of housekeeping and building maintenance. The hospital is also studying other factors of its operation. For example, the use of overtime as a result of absentism is being assessed. The Hospital has completed its manpower utilization study in the Administrative Division and as a result has been able to reallocate positions into Direct Patient Care without an increase in total positions.

COST PER PATIENT

Question: Is the total cost per patient ratio at Saint Elizabeth's comparable to that of other public service hospitals or other psychiatric hospitals?

Answer: We estimate that Saint Elizabeths ranks somewhere in the upper third of public mental health facilities, in terms of cost per patient treated. Several factors contribute to this. First, it is one of the few "State" hospitals to be located in a large urban area, where the cost of treating patients tends to be higher. Second, by virtue of its location and Federal status, Saint Elizabeths has a large forensic program. Because of the special security needs for treatment of patients referred under criminal proceedings, this program tends to drive up the average treatment cost. Third - and this is why we can only estimate the hospital's ranking in terms of patient costs - Saint Elizabeths has a fully self-contained budget, which reflects every aspect of its operating cost. Many State and other public institutions receive at least part of their support services from State and local governments. As a result, some of their costs are buried in the budgets of other State and local agencies.

OUTPATIENT PROGRAM

Question: Saint Elizabeth's Hospital is implementing a new outpatient program and several community care projects. In its move to promote more outpatient treatment, will the patients at Saint Elizabeth's run the risk of being "bumped" into the community without adequate treatment and aftercare?

Answer: Of immediate concern is the fact that we will be responsible for reducing our inpatient bed capacity from a current level of 2,100 patients to a level of at least 1,800 patients by December 31, 1981. In fulfilling that mission, we have found it most difficult to outplace patients in the District of Columbia. Therefore, we are working quite closely with the Medicaid Certification Authority of the District of Columbia to obtain certification of appropriate residential facilities and nursing homes in Maryland, Virginia, and other surrounding areas, which have quality beds at a reasonable cost. Additionally, to insure that patients in the community receive needed treatment, Saint Elizabeths Hospital is reallocating resources to expand its outpatient, day care, outplacement and staff training activities. These resources will be used to assess the living arrangements of patients residing off the

Hospital grounds, adequacy of follow-up care for discharged patients and of the quality of care provided to outpatients not yet discharged.

CONTRACTUAL SERVICES

Question: What percentage of services performed for Saint Elizabeth's are let out on contract?

Answer: For FY-1981, the Hospital is projecting an expenditure of $7.7 million dollars in contractual services, representing 6.5 percent of the FY-81 operating budget. During FY-1980, 3 percent of the budget was spent for contractual services.

The increase is due to a planned increase in the use of contracts for services currently provided inhouse. Some medical services are expected to be provided under contract, as will a number of housekeeping functions, such as carpentry, metal working and welding. The Hospital is also examining the possibility of employing contracts in dietary services and other housekeeping areas.

FUTURE ACCREDITATION

Question: What is Saint Elizabeth's standing in receiving accreditation from the Joint Committee on Accreditation of Hospitals after the current one-year accreditation is over?

Answer: The Hospital received a one year accreditation essentially because we were not in compliance with the life safety code requirements of the National Fire Protection Association. The current construction program is designed to correct that problem, and we are optimistic about future reaccreditation. Compliance with life safety code requirements and fire safety standards are the most significant steps being taken to improve the Hospital's status with respect to the JCAH effort.

PUBLIC CORPORATION PROPOSAL

Question: Out of the President's Budget speech to the Press for Fiscal 81 regarding Saint Elizabeth's Hospital, has come a proposal to create a Public Corporation to administer and fund Saint Elizabeth's. First of all, what is the status of an earlier proposal that the District of Columbia assume the funding and administration responsibilities for Saint Elizabeth's Hospital?

Answer: The most recent proposal that the District of Columbia assume funding and administration responsibility for Saint Elizabeths Hospital was in the form of decision proposals from the "Congressional-District Government-Executive Branch Task Force", chaired by Vice President Walter Mondale. The Task Force statement of September 21, 1977 included the following proposal:

"St. Elizabeth's Hospital - Supports HEW's efforts to reach an agreement with the District and the Congress for Transfer of SEH to the District based on the following concepts.

1. Transfer of an accredited hospital to the District by 1982;

2. Outplacement of patients consistent with outstanding court order to place 800-1000 SEH inpatients in long-term nursing homes in the community;

3. Management and financial responsibility for SEH transferred to the District within five years;

4. Phase-out of Federal financial support;

5. Federal assistance in renovation and construction costs to achieve accreditation."

Since issuance of the Task Force statement, several major events have occurred pertaining to St. Elizabeths as a component of the system of mental health care for the District of Columbia:

1. The Hospital has received accreditation certification from the Joint Commission of the Accreditation of Hospitals (JCAH);

2. A major construction-renovation program has started on the Hospital grounds to meet current facility requirements and;

3. Intensive collaboration between the District of Columbia and HEW has resulted in the submission of plan to the U.S. District Court for the District of Columbia for placement (deinstitutionalization) of patients in the community who no longer require long-term psychiatric care and treatment.

Analysis of these events and the overall progress toward a high quality comprehensive mental health delivery system for the District has resulted in the policy determination not to pursue transfer of St. Elizabeths to the District. Consequently, the President's Fiscal Year 1981 Budget states: "Legislation will be submitted to establish a public corporation - accountable to the Secretary of the Department of Health and Human Services and the Mayor of the District of Columbia to manage the Hospital."

Question: What is the exact nature of funding under this new Public Corporation Proposal?

Answer: Details relating to the funding structure will be worked out during the coming year. A working committee has been established including both Department and D.C. staff to formulate recommendations regarding funding under the corporation proposal.

Question: How do the proposed federal shares of funding, either 35 or 45% matching money to District local taxes, effect the overall federal budget appropriation for Saint Elizabeth's?

Answer: The relationship of the Federal share of the payment to Saint Elizabeths and the proposed Federal match for District revenues is in the process of being negotiated. Under the new corporate structure, the hospital would be funded from both District and Federal funds; however, we have still to resolve the questions of the size of the Federal share, and whether the Federal payment would be considered part of the overall Federal matching payment to the District.

Question: Who would administer the Public Corporation?

Answer: Administration of the public corporation is one of the critical issues to be addressed by the HEW/DC negotiating teams being formed to develop specifications for the public corporation. After agreement is reached on this and other matters, legislation will then be drafted for submission to Congress.

Question: What is the time period under consideration for the study and evaluation of this proposal?

Answer: The time period for study and evaluation of the proposal is geared to creation of the independent corporation not later than October 1, 1981 (beginning of FY 82). In order to achieve this it will be necessary to submit legislation to Congress as early as possible during Fiscal Year 1980 for legislative deliberations. A joint HEW/D.C. Task Force is being formed to reach agreement on critical issues and development of a legislative proposal to establish the independent corporation to administer St. Elizabeths.

SERVICES SUPPLEMENTAL

Question: Why are you requesting 49 million in supplemental funds for general mental health programs under the as yet unauthorized Mental Health Systems Act?

Answer: Based upon the rate of progress to date, we are optimistic that a Systems Act could be enacted prior to July 1, 1980. This would provide sufficient time to spend the funds this year. It should also be noted that the proposed appropriation language in the supplemental provides that funds would become available only in the event of enactment of the legislation. We are proposing a supplemental now, in order to make it possible to move ahead with implementation of the new programs as quickly as possible. We feel that the existing national need for programs of the type proposed lend some urgency to the request.

Question: How specifically would these funds be used to initiate authorized new programs, providing the Act was authorized?

Answer: The proposed supplemental of $49,812,000 would be used to initiate seven new programs under the Systems Act. Of this request, $1,000,000 would support seven initiation grants, to provide mental health services to previously underserved population groups; $2,228,000 would provide four development grants to activate community mental health services, much in the same manner as under the present Operations grant program; $7,584,000 would be used to provide 152 linkage grants, to provide for the development of mental health services in ambulatory health care centers; $1,000,000 would support 20 Preparation grants, whose purpose would be to prepare communities for the provision of local mental health services; $25,000,000 is requested for 38 projects designed specifically to improve the accessibility and availability of mental services to chronically mentally ill; $7,000,000 would be required to support 21 projects to develop State and local treatment systems geared to the mental health needs of children; and $6,000,000 would support 26 projects relating to the prevention of mental illness.

RESEARCH ACCOMPLISHMENTS

Question: Many of your fiscal 1981 research goals are identical to those of fiscal 1980, e.g., studying the hereditary aspects of schzophrenia. Can you enumerate for us the accomplishments of fiscal 1980 within your stated research goals?

Answer: Uncovering knowledge about mental illness is a continuous process, based on the incremental advances made by investigators from the mental health sciences. Promising areas that attract scientific attention may remain of high interest for several years, as investigators pursue lines of attack that may shed light on the causes of mental illness and new therapeutic and preventive strategies. From this vantage point, it is to be expected that research goals and interests will be fairly stable and not shift precipitously from year to year.

In 1980, the Institute will continue to pursue the goal of fostering exchange between basic and clinical research by funding an eleventh Clinical Research Center at the University of North Carolina. In addition, the planning of an overall research strategy in the area of treatment assessment research will go forward and a major collaborative study in the comparative treatment of depression will be launched. A new research program in Health Service Systems Research will receive modest funding. Initial data from the three newly established (1978 - 1979) Epidemiologic Catchment Area sites will be analyzed. Other emphasis areas include studies of the adjustment problems of Viet Nam Veterans; the initial research funding of the new prevention program; and the funding of projects both in the intramural and extramural programs, on the treatment of schizophrenia through hemodialysis.

Some recent research advances to be noted include the development of a self-contained noninvasive device which continuously measures the rate of an individual's spontaneous motor activity. This instrument is the first continuous, nonsubjective measure of motor activity and will have significant applications in the study of depression, mania, hyperactivity, insomnia, hormone and neurological disorders. Also, the first assay capable of measuring minute amounts of melatonin present in the blood has been developed. The assay counts individual molecules with a gas chromotograph-mass Spectograph. Melatonin is a hormone product of the pineal gland which is thought to regulate sexual and reproductive function, as well as daily and seasonal rhythms, all of which are disturbed in depressive illness. In a series of epidemiologic studies, it has been found that tardive dyskinesia is more likely to develop (1) if there have been many discontinuations of drug treatment (neuroleptics); (2) if the individual has low platelet monoamine oxidase activity and high plasma dopamine-beta-hydroxylase activity; or (3) if the individual has high blood levels of neuroleptic drugs. The latter finding suggests that people who are prone to tardive dyskinesia may metabolize neuroleptics differently than people who do not have high concentrations; this may ultimately allow prediction of those individuals who are prone to this disease.

A significant advance in basic research during the last year has taken place in brain grafts. A major effort has focused on making a model for Parkinson's disease in the rat. These studies have now been expanded to the monkey and attempts to make grafts of the adrenal gland from the same animal have begun. (The advantage of the adrenal gland is that it might dedifferentiate from its normal role in making epinephrine to making dopamine. Thus, if this technique were ever to be applied to humans, it might be done as an autotransplant.)

FY 1981 RESEARCH NEEDS

Questions: Do the continued research goals from fiscal 1980 warrant an increase in appropriations from fiscal 1980 levels of $145.3 million to your fiscal 1981 request of $162.9 million?

Answer: The overall research strategy of the NIMH is motivated by the need to simultaneously perform three research functions within the wide range of categories and topics that comprise the study of mental health and mental illness.

The first function is the development and maintenance of a national research capacity that is commensurate with the burden of mental illness and emotional disorders found in society. An appreciation of the fact that the mental health sciences are still in the early stages of exploration and are relatively underdeveloped in comparison to other biomedical specialties is fundamental to an understanding of the quantity and consistency of resources required to build an adequate scientific base for mental health research.

The second research function is the support of special initiatives in areas where public policy, public need, or the requirements of research progress dictate a particular emphasis or concentration of resources. Thus the area of treatment assessment research, which is currently a high priority Congressional concern, should consume an increasing proportion of resources in order to develop the kinds and quality of information required both by the field and by the makers of social policy. Similarly, the Institute's research endeavors in rape and prevention began as modest program initiatives responding to widespread policy and social concerns; however, increased resources are required to productively maintain these initiatives beyond their beginning stages. Other examples of special initiatives designed to be particularly responsive to public policy or public health needs are: The ECA program; the MH Service System Research Program; the important Clinical Research Center Program; research on Viet Nam veterans; treatment of schizophrenics by hemodialysis; and drug research which seeks simultaneously to develop longer acting psychoactive compounds, and to identify the consequences of long-term neuroleptic drug administration.

The third research function of an overall research strategy requires generous support for burdgeoning research areas which show an ability to develop far beyond the availability of the resources required to sustain such growth. Ten, fifteen, and twenty years ago, drug research was such an area. Today, the study of the brain and its endogenous substances shows unbridled promise for discoveries relating to the causes as well as to the treatment of mental illness.

The requirements of building and maintaining a national research capacity do not diminish; rewarding initiatives in prevention or treatment assessment research require a stable base of support as well

as the promise of growth and expansion; and the boom in brain science research must not be excessively restricted from fulfilling the tremendous potential which has been shown.

Question: For what reasons or purposes?

Answer: Of the $17.7 million increase requested in 1981, $2.3 million will be used for studies of the major mental illnesses, principally schizophrenia and depression; $1.9 million is requested for research in services delivery, including the assessment of the effectiveness of treatment methods; $3.7 million is targeted for additional research into the mental health problems of underserved population groups, including minorities, children and the elderly; $2.0 million is requested to expand new initiatives relating to prevention of mental illness; $3.1 million will provide for strengthening of ongoing projects and new research efforts relating to neurological and behavioral disorders; $1.7 million is requested for increased research into the causes and effects of rape; $1.7 million relates to social problems, including crime and delinquency and the special problems of urban areas; and $1.3 million will be used to strengthen several areas, including the epidemiology of mental illness, neurosis and personality disorders, and the mental health impact of life change events.

BRAIN CHEMISTRY STUDIES

Question: Brain chemistry studies have been a high priority with the National Institute of Mental Health in the past. Have funds devoted in Fiscal 1980 produced results which fiscal 1981 projects will build upon?

Answer: All research supported by NIMH contributes to some degree to expanding the base of scientific knowledge in the area of mental health. As expected, some results are of a more significant or immediate nature and can be more readily built upon to address areas of current concern. For example, building on a method pioneered by an intramural research program scientist, Dr. Louis Sokoloff, for mapping brain function using audioradiographic techniques, methods are now available for scanning the intact human brain using positron emission transverse tomography. With new and sophisticated apparatus now on the market, investigators will be able to have a direct look at the human brain at work seeing, hearing, feeling, caught in an epileptic seizure, or responding to drugs. Knowledge thus gained will be useful not only in understanding brain function but in devising new and improved therapies for central nervous disorders.

Studies of the newly discovered brain peptides are currently having a profound impact on our understanding of the biological basis for mental health and disease. It has become evident that individual peptides serve multiple functions and that the brain contains virtually every peptide found in peripheral tissues. The possibility that peptides function as neurotransmitters or neuromodulators is now generally accepted to be the case. Such a hypothesis, developed from evidence that peptides have electrophysiological, neuropharacological and behavioral effects, has enourmous implications for endocrinology, neurology and psychiatry and will be studied further.

Question: Would you detail for us a few of these projects: for example, work done on endomorphin and neurotransmitters for treatment of mental illness?

Answer: The role of neuropeptides in neurologic and psychiatric disorders is ripe for exploitation. Early reports that opioid blocking agents were effective in schizophrenia have not been confirmed. Elevated levels of beta-endorphins have been reported in the cerebrospinal fluid of patients with schizophrenia but confirmation is required. Longitudinal studies with repeated administration of beta-endorphin are needed to further clarify the relationship of this chemical to schizophrenia (J. Barchas, M.D., POl 23861, Ca.). Several ongoing studies are designed to clarify interrelationships between abberations in neurotransmitter and neuroendocrine systems in depression. These studies aim to illuminate the relationships of these biologic systems to etiology as well as define appropriate biochemical markers predictive of treatment response. Release of endogenous opioid substances appear to account, at least in part, for the effectiveness of acupuncture and of analgesia induced by electrical stimulation of certain central nervous system sites. Reduced levels of other peptides have been reported in postmortem brain tissue from patients with Huntington's disease. While all of these observations must be considered preliminary, they point up the need to learn more about peptide function in the brain.

PRIMARY CARE MENTAL HEALTH TRAINING

Question: We understand strong criticism has been registered from professional associations regarding on-going National Institute of Mental Health programs which train primary care physicians to diagnose, treat, or where appropriate, refer patients to qualified mental health professionals for treatment. This criticism appears to be related to the quality of such training, and the effectiveness of devoting resources to manpower in short supply in most underserved areas, e.g., physicians. Your fiscal 1981 priorities include continuation of this program to meet the needs of underserved populations. Is this a large chunk of the request training funds?

Answer: Current studies indicate that approximately 60 percent of the people with emotional illness are seen by general health practitioners, and for the majority this is the only care they receive. Other studies have shown that these physicians often do not recognize emotional disorders, and do not provide adequate treatment. To improve this situation NIMH has devoted an increasing amount of its resources to programs which train primary care physicians to diagnose, treat, and where appropriate refer patients with mental illness. We believe that the primary care physicians can and must treat the more routine mental health problems as part of their function of giving care to the whole patient. We want to help them do a better job, and to work together with mental health specialists in this area. In our 1980 budget, $17.0 million, or 23.7 percent of the total, will be spent in developing curricula or programs for primary care physicians. In 1981, we propose to spend $17.6 million, or 24.6 percent of the total.

Question: How will you address the effectiveness and manpower shortage questions raised under this physician training program?

61-400 O - 80 - 53

Answer: All of the programs NIMH supports for the training of primary care practitioners in mental health skills and knowledge must contain an evaluation plan in order to be funded. Some of these measure increases in knowledge about mental illness or changes in attitudes toward emotionally ill patients. Others, using video tape or chart reviews, show changes in behavior after training. We are now beginning career follow-up studies of physicians who have had this type of education.

We realize that primary care physicians are in short supply and are often over-worked. Nonetheless, a large percentage of their patients have emotional problems and expect help from these physicians. We hope to teach them to do this work more effectively, and also to collaborate more closely with mental health specialists on difficult cases.

Question: Can you document the application and effectiveness of such trained physicians once in the field?

Answer: The program is relatively new, so that there are not many primary care physicians who have received mental health training now in the field. We do have some studies showing that this training does improve the physician's ability to recognize emotional disorders and to interview patients in a more sensitive manner. One recent study has demonstrated that when general physicians use a mental health screening questionnaire, and treat the problems which it uncovers, the patient returns to a normal physical and emotional condition more rapidly than if such a questionnaire is not used.

NIMH is now planning a series of career follow-up studies of a sample of primary care physicians in its training program, and is also embarking on an evaluation of its overall effort to give mental health skills and knowledge to general health practitioners.

DECLINE IN TRAINING SUPPORT

Question: Over the past few years, appropriations for mental health training in ADAMHA have steadily increased. For example, in FY 1978, it was $86.8 million and in FY 1979 $92.9 million. At the same time that this area has seen increased appropriations, the number of awards for psychiatric nurses has dramatically declined from 1,092 in FY 1977 to 890 in FY 1979. Can you explain why this has happened?

Answer: The psychiatric nursing education program has changed its focus from undergraduate training to a greater emphasis on master's and doctoral degree programs. This has resulted in fewer undergraduate stipends being awarded. For example, in 1977 134 undergraduate stipends were awarded, while in FY 1979 44 undergraduate stipends were awarded. However, because graduate stipends are paid at a higher level than undergraduate, fewer graduate stipends can be awarded than undergraduate stipends. That is, the shift in emphasis is not a one-to-one change. In addition, because the institutional and teaching costs associated with graduate awards are higher than those associated with undergraduate awards, the decline in the total number of awards is accelerated.

PSYCHIATRIC TRAINING

Question: How much money has ADAMHA invested in psychiatric training in both institutional support and individual support over the last five years?

Answer: For the five fiscal years 1976 thru 1980, NIMH has invested a total $116,478,000 in psychiatric training. Of the $116,478,000, $22,635,000 has been provided in individual trainee support. The remaining $93,843,000 is institutional support.

Question: How many trainees did this support?

Answer: The $22,635,000 provided in individual psychiatric student support over the five years supported training of 4,634 pre-doctoral trainees and 1,579 post-doctoral, for a total of 6,213 trainees.

CLINICAL PSYCHOLOGIST TRAINING

Question: How much money did you invest in training clinical psychologists?

Answer: For the five fiscal years 1976 through 1980, NIMH has invested a total of $49,986,000. Of this, $28,111,000 has been provided in individual trainees support. The remaining $21,875,000 is institutional support.

Question: How many trainees did this support?

Answer: The $28,111,000 provided in individual psychology student support has provided training for 7,170 pre-doctoral trainees and 273 post-doctoral trainees, or a total of 7,443 students.

MENTAL HEALTH PERSONNEL

Question: How many trained personnel are available in each of the core mental health professions - psychiatry, psychology, nursing, and social work.

Answer: We estimate that there are at this time approximately 29,000 psychiatrists; 25,000 doctoral level health service providers in psychology; 26,000 master's level psychiatric social workers, and 6,000 master's level psychiatric nurses. It should be emphasized that many of these professionals spend part or all of their time in teaching, research, and administration as well as in the provision of mental health services.

PSYCHIATRIC SOCIAL WORKER TRAINING

Question: How much money did you invest in training psychiatric social workers?

Answer: For the fiscal years 1976 through 1980, NIMH has invested $53,182,000 in Social Worker training. Of this $41,291,000 has been provided in institutional support and the remaining $11,891,000 in individual trainee support.

Question: How many trainees did this support?

Answer: The $11,891,000 provided in individual Social Work trainee support has provided training for 3,570 pre-doctoral students and 9 post-doctoral students, or a total of 3,579 trainees.

PSYCHIATRIC NURSE TRAINING

Question: How much money did your agency invest in training psychiatric nurses?

Answer: For the five fiscal years 1976 through 1980, NIMH has invested $42,068,000 in psychiatric nurse training. Of this, $24,798,000 has been provided in institutional support and the remaining $17,270,000 in individual trainee support.

Question: How many trainees did this support?

Answer: The $17,270,000 provided in individual psychiatric nurse trainee support has provided training for 4,783 students. Of this, 4,770 are pre-doctoral trainees and 13 are post-doctoral.

STUDENTS ENTERING PSYCHIATRIC TRAINING

Question: Can you supply us with the number of graduates of American medical schools who have gone into a psychiatrist residency each year for the past five years?

Answer: Definite data on this subject are not available, as data from the American Medical Association, our usual source, have not been published for the last three years. Published data show the numbers of first year psychiatry residents who were graduates of American and Canadian medical schools dropped steadily from 1,051 in 1970 to 952 in 1974 and 842 in 1976. We estimate the comparable numbers to be 746 in 1978 and 717 in 1979, on the basis of the total number of first year psychiatry residents and a declining proportion of foreign medical graduates.

PROJECTIONS OF NEED - MENTAL HEALTH PERSONNEL

Question: What are your agencies' projections of the needed number of mental health personnel in each of the four core areas and how were these projections based?

Answer: Projections of need can be done in several ways. The simplest is that of establishing an optimal professional to population ratio and measuring the shortfall. This method, however, is not sensitive to problems of geographical maldistribution, staffing of public facilities, service to special age groups, subspecialty areas, or racial/ethnic characteristics of the professional. All of these areas are of prime importance in the delivery of services and are priorities of the NIMH clinical training program.

We are now preparing a detailed report which will identify specific areas of need in a future service delivery system, and describe what NIMH plans to do to meet these needs. This report will be submitted to the Committee prior to the budget mark-up, as requested.

PROGRAM AUTHORIZATION

Question: What step is the Administration undertaking to insure re-authorization of the community mental health center program prior to Congressional mark-up of the President's budget - probably in late May?

Answer: The Administration is working with the authorization committees of the House and Senate, as they consider and mark-up the proposed Mental Health Systems Act, H.R. 4156 and S. 1177 respectively, to include in that legislation a reauthorization of the Community Mental Health Centers Act until such time as the Mental Health Systems Act goes into effect.

MEDICARE REIMBURSEMENTS

Question: Is the National Institute of Mental Health currently working with the Health Care Financing Administration on ways to standardize medicare payments for partial hospitalization under existing law?

Answer: NIMH, together with HCFA and the Office of the Assistant Secretary for Planning and Evaluation, is engaged in a planned demonstration of the impact of reasonable cost reimbursement for mental health services to Medicare beneficiaries in non-hospital based CMHC partial hospitalization units and in free standing programs of partial hospitalization. All non-inpatient mental health care to Medicare beneficiaries in these facilities is now reimbursed on the basis of the usual and customary charge/fee which is highly variable. Reimbursement on a reasonable cost basis is an approach to standardizing payments for services covered under the Medicare program.

MEDICARE PROVIDER STATUS

Question: What effect would the enactment of legislation granting Medicare provider status to Community Mental Health Centers have on the appropriations request for operations and staffing grants to Community Mental Health Centers?

Answer: During the grant period, community mental health centers are required by P.L. 94-63 to maximize their third-party resources, with an aim towards self-sufficiency via expanded third-party payments (including Medicare). Operations/staffing grants are awarded to successful applicants on a declining schedule for an eight-year period. The diminishing percentage of grant support is calculated on the basis of the amount by which the grantees' projected costs of operation for a given year exceed the total of State and local funds and any fees, premiums, and third-party reimbursements which the grantee may reasonably expect to collect during the year.

It should be noted that as a center improves its third-party collections, the absolute dollar amount of Federal support may remain relatively constant over a period of years while the percentage of such support relative to the center's total budget may be diminishing. An additional consideration is the fact that the federally funded CMHCs are not necessarily limited to one grant, or even to one class of grants.

Assuming some basically supported centers qualify as Medicare providers sometime during fiscal year 1980, the request for continuation support by these grantees would be based partially on an estimate of Medicare income. Because of the nature of operations/staffing grants as a deficit financing mechanism, on a center-by-center basis, an increase in the amount of Medicare reimbursement may result in a corresponding decrease in the amount requested from grant funds. This correspondence will not result necessarily in a dollar-for-dollar situation.

The relationship of Medicare provider status to total NIMH appropriations for CMHCs cannot be drawn readily, however. The NIMH

CMHC grants program is one that is not only growing, but is in a constant state of transition. The nature of fiscal support to individual grantees results in a continual flow of participating centers from "new start" to "operational" to "graduate" status. The very nature of the program therefore obviates the validity of comparisons between provider status and total appropriations, for anything beyond a case-by-case situation.

ALLOCATION OF CMHC FUNDS

Question: What criteria are used for allocating mental health care -- particularly community mental health center funds -- from region to region?

Answer: The Regional allocation of Community Mental Health Center funds is basically a two step process. First, funds are allocated to cover the continuation costs of all previously funded projects having an entitlement for support during the budget year. Second, the remaining funds are allocated for new projects. The criteria for distributing the funds for new projects may vary. In a normal year, assuming that the backlog of approved but unpaid grant applications equals or exceeds the available funds, the resources would be prorated on the basis of the relative backlogs in each Region. Every Region would receive sufficient funds to support at least one project, assuming that it has applications on hand. When the backlog exceeds the funds available to a Region, that Region generally makes the determination as to which projects are paid. The Regions are assisted in this decision by general guidance from the Central Office. For example, we might designate programs in rural, poverty, or inner-city areas as having a higher priority.

EMPLOYEE PROTECTION DURING HOSPITAL CLOSURES

Question: Exactly what types of protections are provided to employees who have lost their jobs through hospital closures?

Answer: The process by which State mental hospitals close tends to limit the adverse effects upon employees. Phase down and closure usually occurs over a period of several years. During this period many non-critical positions are left vacant as normal attrition takes place. It is also common for a State to provide an early retirement plan for employees with lengthy service in the State system as an option when facilities close.

Nonetheless, safeguards do exist through State civil service systems which provide basic protection to all employees. Reemployment benefits are provided to employees under these systems based on a variety of factors including length of service, veteran status, grade, previous performance and other factors. For personal reasons some employees whose positions are terminated, choose not to relocate to another area where their job skills and civil service status offer them reemployment benefits. These employees receive only the benefits provided by their own States' civil service system as they are placed out of work. It should be noted that these protections are generally much greater than those received by private sector workers who are adversely affected by closings or relocation of job sites.

Question : How are these employee protections assured?

Answer: The State civil service systems are established in law and employee rights are protected by the legal process. Due

process and contract provisions govern all of the States civil service laws. In addition, in many States, unions provide an important contribution in assuring that employee rights are protected.

Question: Through what specific authority are employee protections funded?

Answer: Employees protections are generally funded through the States' own operations budgets. It is a normal part of operations of government to support a civil service system which includes employee protections.

Question: What level of support did employee protections receive in fiscal years 1979 and 1980?

Answer: There is no allocation of Federal mental health or other funds to pay the cost of implementing employee protections. The States may use a portion of their mental health formula grants for such activities if they so desire. However, the largest portion of State support for employee protection is through the State operating budget which includes its civil service system.

Question: What effect has the change in 314(g) and the establishment of 314(g) - State Mental Health Grants - had in the provisions of employee protections?

Answer: Section 314(g) requires that in order to receive 314(g) funds, State mental authorities must develop and implement a State plan for deinstitutionalizing persons with mental health problems which includes arrangements, as determined by the Department, to protect employees of State institutions. The form and content of the guidelines and regulations to implement these requirements are under consideration in the Department.

PREVENTION

Question: What specific prevention goals are to be achieved?

Answer: Specific prevention goals will be achieved through project grants to State agencies for a variety of purposes. These include: developing local prevention and promotion programs by strengthening the capacity of States. For example, States may collect and disseminate information about local prevention activities that can be developed such as mutual aid support groups for bereaved persons; school and community-based parent education skill building-activities; community based stress management workshops and self-help groups for single parents. Other activities would include: assisting States to train mental health and other personnel in the application of preventive measures; expanding mental health information and education programs; and developing joint prevention programs by collaborating with other State and local human services agencies. These programs include those focused on individual efforts and those directed toward system and institutional change. The latter could include modifying the visiting policies for families in pediatric wards and working with schools to increase teacher sensitivity regarding normal and abnormal developmental processes among children.

Emphasis will be placed on building such prevention efforts into the mainstream of State and local mental health programs--particularly those in community mental health centers.

Question: Will prevention activities continue to be primarily in research and planning in FY 81?

Answer: During FY 1981, prevention activities will be primarily in research and, with the new initiatives under the Mental Health Systems Act, in State level mental health prevention demonstration projects and, through the State program, assistance to local communities to develop a variety of preventive/promotion approaches.

Research will include new projects such as research about high risk factors for depression and will include continuation funding for projects begun in FY 80. The two major research announcements for FY 80 emphasized the development and evaluation of intervention models to prevent harmful psychological impact on children of severely disturbed parents or children involved in marital disruption. In FY 81, special attention will be given to information exchange among the various projects funded.

In addition, FY 81 training plans include assessment of current prevention components of training programs and the development of a knowledge-base concerning prevention curricula and training experiences. These activities will be carried on in collaboration with the research and academic communities.

Question: When will this activity yield concrete program activities in prevention?

Answer: Preliminary research results for projects funded in FY 80 will be available late in FY 81. In addition, information from contract activities in FY 80 will be available in areas such as: high risk factors among women for depression, improving the competence of teenage parents, and research regarding the mental health diagnostic skills of primary care physicians.

State level activities would be expanded in FY 81 under the Mental Health Systems Act. At present, less than ten States have full-time employees assigned to the area of prevention. It is anticipated that under the Mental Health Systems Act, 23 prevention projects will be awarded to States.

At the community level, it is anticipated that 65 communities will be receiving "maintenance grants" in FY 81. Many of these grants to assist communities in defraying the cost of indirect (non-reimbursable) services will significantly involve the support of preventive activities.

In addition, the NIMH Office of Prevention will continue to collaborate with other components of PHS and DHEW in the initiation and development of prevention activities.

MENTAL HEALTH GRANTS TO STATES

Question: This year, the National Institute of Mental Health is requesting the full authorized ceiling levels under 314(g) funds for grants to States for Mental Health Planning. What specifically will the requested $12.1 million be used for in health planning?

Answer: Section 314(g) provides funds to support both the planning for and the provision of mental health.

The 314(g) program provides funds to assist the States "in meeting the cost of carrying out the functions under Title XV of (the Public Health Service Act) and under section 237 of the Community Mental Health Centers Act and, after September 30, 1979, in meeting the cost of providing mental health services." The functions of the State mental health authorities under Title XV and section 237 relate to planning. However, the largest portion of funds for which the States use their 314 allotments is to support the provision of services at the community level.

The State mental health authorities' responsibility for planning are spelled out in the recent amendments to the Health Planning and Resources Development Act, P.L. 96-79. Under these amendments, State mental health authorities are required to participate in the development of the mental health provisions of the State health plan. Some States may choose to use their grants for this purpose. However, since the old section 314(d) grant required that 70% of each State's allotment for services in communities, each State has a number of community service programs which are dependent on the formula grant for support and which can be expected to take the bulk of the formula grant funds. We do not anticipate that a very large portion of the formula grant funds will be used to support activities in planning at the State level.

MENTAL HEALTH FORMULA GRANTS BUDGET REQUEST

Question: Why was there no budget request for 314(g) last year and were Mental Health activities still able to be carried out under the 314(d) authority?

Answer: The Administration did request funds in 1980 under a consolidated grant proposal, but no action was taken by Congress. Congress, however, added $16 million to the $52 million requested by the Administration for the 314(d) program to a total appropriated amount of $68 million. At the time the Congress took the action adding the $16 million to the amount the Administration had requested, it also indicated in the language of the Committee reports that these funds could indeed be used to support mental health activities. This being the case, the Assistant Secretary for Health notified the State Governors that 314(d) funds can be used for mental health activities during FY 1980.

COMMUNITY SUPPORT PROGRAM

Question: What are the program priorities you will use in awarding among States the $33.5 million requested for State Community Support Programs in Fiscal 1981?

Answer: The funds requested for continuation and expansion of existing State contracts will be awarded on the basis of a review of each State's past performance in implementing CSP contract requirements. All States that are making satisfactory progress will have an opportunity to continue their State level activities on

behalf of the population capable of living in the community, and to expand their strategy development activities to include the population in need of skilled or semi-skilled nursing care.

Local service development and demonstration funds for the currently participating States will be awarded based on review and assessment of each State's program development strategy. Some States with urban areas highly impacted by deinstitutionalization, for example, are likely to request local service improvement funds targeted to those urban areas. Some States without any viable examples of effective community support systems are likely to request resources to develop local demonstration projects that can serve as an example for other parts of the State. Some States that have identified specific service gaps, for example, a need for rehabilitation clubs for former mental patients, may request local service development resources for start up costs for such programs.

Each State will be required to justify how it is effectively using State mental health money, resources of "mainstream" Federal programs such as vocational rehabilitation, Supplemental Security Income, HUD programs, and other such programs, and how it is linking these funds with local resources. CSP funding will be targeted to provide the "glue" and to maximize the effective use of all other available resources.

MOST IN NEED PROGRAM

Question: Would you specifically outline the objectives of the Most in Need Program for children and the results of this program so far?

Answer: The "Most in Need" (MIN) Program is a proposed initiative directed towards providing support for improvement in the system of services relating to children and youth with serious problems. Such improvement requires change in how the agencies comprising the human service system in a community interact. Since such change is expected to be difficult on the basis of experience with similar efforts over the past decade, the program is envisioned as a developmental program, one that would allow communities to plan and implement change strategies over three years, with continuing evaluation to enable further insight into how such changes can best be made and what kind of changes that do occur have positive impact on most in need children, their families and the workers who serve them.

There are several program objectives. The first is to demonstrate the efficacy of strategies for service system change in terms of qualitative and quantitative improvement in the delivery of services to the young people who are most in need of those services. A qualitative improvement in service delivery is one that results in:

1. a reduction in the severity or frequency of clinical symptoms or signs in a significant number of most in need children;

2. an increase in a youngster's coping ability or function in the context of his/her environment -- school, family, community;

3. a more comprehensive view, and treatment of the child by the system, as a whole;

4. a more humanistic approach to the child by the system, one that promotes the child's self-esteem, self-worth and sense of personhood;

5. the incorporation of a long-term as well as short-term approach to the problems of a child;

6. the inclusion of the child's family in the development of plans, solutions, and support to the child, and in receiving assistance in meeting its internal problems and coping with its external stresses; and

7. an increased sense of interaction and integration, of being part of a team, among service providers in the system.

A quantitative improvment in service delivery is one that reflects:

1. more services available to the child and his family appropriate to their needs;

2. greater efficiency in the provision of services by the system as a whole;

3. more children being effectively reached by services; and

4. fewer children getting "lost" in the system, falling between cracks, or winding up in long-term residential facilities with a hopeless outlook.

Another objective is to facilitate cooperation between community agencies and State government, so that a community-based service system may have greater access to information and assistance available at the State level, and, conversely, a State may acquire, through community demonstrations, information and ideas that it may use in carrying out its mandates in the provision of human services. Remaining objectives are to provide a context for the provision of technical assistance in the areas of service systems, systems change, and children and youth service and treatment models; and to acquire meaningful data on children and youth, their problems, their needs, and the resources that exist to meet their needs.

Question: Has an evaluation of the cost-effectiveness of this program been conducted and with what results?

Answer: No evaluation has been conducted. The Most in Need (MIN) Program is basically in the proposal stage at this point, awaiting appropriations. A small-scale project for Native American children has recently been initiated, to test out ideas and help design evaluation strategies. The effectiveness of the program would be measured in terms of change in the interactions among

human service agencies -- how they share information, exchange resources, make joint decisions, improve referrals, etc.; and evaluation of satisfaction with services among families with seriously disturbed children; and measure of long-term changes in the expected level of health of the child.

STATE MENTAL HEALTH PREVENTION PROGRAMS

Question: State mental health prevention programs are recommended for funding at less than the levels allocated in the fiscal 1980 budget; please specify the justification behind this decrease given the overall priority of prevention programs.

Answer: The 1981 budget includes support for all 23 State prevention programs initiated in 1980 at a level slightly higher than the previous year's amount. The decrease reflected in the budget represents termination of 3 related technical assistance and national collaborative projects conducted during initial start-up of the prevention program.

MENTAL HEALTH POSITIONS

Question: Would you more fully explain the creation of 10 new positions to "increase efforts to eliminate fraud, waste and abuse in de-centralized service grant programs"?

Answer: Decentralized service grant programs account for over half of the total Institute budget, and a substantial number of the grantees are relatively new to the task of administering a large and complex service operation. Even if the efforts of the additional NIMH staff result in an annual savings of only one-fifth of one percent of the program costs, the cost effectiveness of their efforts will have offset the additional salary costs. We also feel that the presence of a group of individuals, whose specific mission is to identify fraud, waste, and abuse, will act as a deterrent to such problems throughout the CMHC system. In general CMHC's have not been wasteful - and certainly not fraudulent. However, they need consultation and technical assistance with respect to planning, management and evaluation in order to minimize the potential for fraud, waste, and abuse.

We would not have staff specifically identified as "fraud abuse hunters"; rather they would aggressively pursue the TA and Consultation (which GAO keeps pointing out is needed more) in order to eliminate and reduce such problems before they start.

Question: You are requesting 16 new positions to handle anticipated work loads under the proposed Mental Health Systems Act program. Are these professional or support staff?

Answer: The positions represent a mix of professional, technical, and clerical employees. The distribution takes account of the fact that the workload of the Institute will be affected at all levels, not only requiring in a demand for increased analytical and technical assistance capability, but also generating greater clerical support needs.

Question: Will you be duplicating existing administrative capability?

Answer: We will be increasing our capability to administer programs, but not duplicating it. The position request takes account of the fact that some existing staff will become available as the previously authorized service programs reach the end of their authorized periods of support and are replaced by new programs authorized by the Mental Health Systems Act.

SERVICE NEEDS OF THE ELDERLY

Question: Why are CMHCs underserving the older populations? What is ADAMHA doing to correct this problem? Finally, why haven't the statistics on population served by CMHCs been analyzed for years subsequent to 1976?

Answer: The underservicing of the elderly in the CMHCs Program is an issue with multiple contributing factors. Service providers and consumers possess attitudes which inhibit the responsive and adequate delivery of services. Staff are frequently unfamiliar with and insensitive to the special needs of the elderly, while the elderly frequently possess a negative and resistant attitude towards being identified as requiring mental health services. Further obstacles are created by inadequate health insurance coverage, poor transportation systems, expensive comprehensive assessment outreach programs, training deficiencies of staff, and the lack of planning for improved service delivery.

ADAMHA through the CMHC service system is currently undertaking a series of service initiatives specifically targeted to improving the delivery of mental health services to the elderly. These include: expanding service integration and coordination of public and private agencies with centers; developing and evaluating various CMHC demonstration research service projects to examine alternatives to institutionalization for the aged, such as the Community Support Program; designing and expanding training support programs to increase the supply of competent personnel with geriatric mental health training while simultaneously increasing the sensitivity and familiarity of service professionals and the general public; expanding the dissemination of information on therapeutic intervention, treatment choice, and effectiveness to practitioners in CMHCs; and increasing the awareness of residents of the CMHC catchment areas of the nature of mental health problems and the range of services available to the elderly. Further attention is being directed at analyzing utilization rates of the elderly at CMHCs annually, expanding the focus on annual site visits to monitor the level and extent of geriatric service delivery and in reviews of annual grant applications for continuation funds.

Utilization rate data for the elderly in the CMHCs program are annually by the Division of Biometry and Epidemiology of the National Institute of Mental Health. Delays in the reporting of data are due to the time required for data collection, verification and subsequent analysis from the many reporting units.

Question: The Administration's proposal for improving mental health service delivery includes special emphasis on the needs of the elderly. Since older Americans are supposedly a target population in the existing program, why should we expect the new initiative to be any more successful than previous efforts?

Answer: The Systems Act provides for the funding of service grants targeted toward specific population groups including the elderly. We anticipate that there will be initiation awards focusing specifically on the service needs of the elderly, increasing our effectiveness in meeting the needs of this group. Additionally, with the proposed development grants program, priority is to be given to identified population groups, including the elderly.

It should also be noted that service provision depends upon having a number of trained personnel available. Through the clinical training program redirection we anticipate increased numbers of service personnel trained in meeting the specific needs of the elderly.

GERIATRIC MEDICINE

Question: In 1978, the Institute of Medicine made a report on its study of geriatric training needs in the nation's health profession education programs. Rather than developing only geriatric "specialist", the Institute recommended that study of geriatric medicine be incorporated in the training of health professionals on an on-going basis and that such training include the study of "normal" aging and work with a variety of older persons, not just the hopelessly ill and the dying. How does the Administration's health manpower proposal plan to address these needs?

Answer: The National Institute of Mental Health agrees with the recommendations of the Institute of Medicine. The President's Commission on Mental Health also states that mental health specialists should receive training to work with the elderly, and NIMH is implementing these recommendations. Education in recognizing and treating the special mental health needs of the aged is one of our major clinical training priorities. Our budget calls for approximately $3 million in 1980 or 1981 to be spent on developing curricula and training students in all the mental health disciplines in the area of geriatric mental health. Much of this focus is on outpatient and preventive work, to maintain the elderly in their communities and forestall debilitating depression and degeneration of functioning.

Question: How much of your research and training dollars are being directed to the special needs of the elderly? What do you see as the top priority need for research in this area?

Answer: The special needs of the elderly have been recognized in determining ADAMHA research and training priorities. In FY 1978 and 1979, a NIDA demonstration project designed to study drug misuse among the elderly was launched in Houston, Texas. The outcome of this effort will assist in establishing policy priorities in the future. NIDA also launched a major prevention effort in FY 1979. This program was designed to provide educational material to older citizens aimed at helping them better manage their drug-taking requirements. Several States have used the educational material to develop elderly programs of their own, e.g., Michigan.

NIDA's addiction Research Center (ARC) has been working towards a collaborative effort with the Gerontology Research Center (the intramural component of the National Institute on Aging) towards investigating problems common to both Institutes' objectives. Studies under consideration include the relation of changes in the biological disposition of drugs with age, a long-term longitudinal study of people looking at all aspects of their behavior, including drug use and abuse, the endocrinological changes in the elderly as they may relate to drug misuse, an investigation of the nutritional needs of old people and how they may relate to possible drug abuse, and, finally, studies of the treatment of chronic pain in the elderly.

In addition, the extramural program is in the process of developing new program announcements for FY 1981 to stimulate research with the elderly. This will include studies of the patterns of drug abuse among the elderly, studies of drug interactions among the elderly, and studies of how disease conditions associated with the elderly such as renal insufficiency may interact with their drug use and abuse. We are currently looking at how drugs may be particularly deleterious to the motor activities of the elderly such as their driving performance.

In FY 1979 NIMH spent $6.6 million on research in aging, of which $1.5 million was for intramural research; $2.8 million for clinical/services training; and $230,000 for research training. Of this, the NIMH Center for Studies of the Mental Health of the Aging spent $2.2 million for research, $285,000 for clinical training, and $100,000 for research training.

NIAAA has directed $136,000 of its FY 80 research funds to the special needs of the elderly. Collaborative efforts are underway with the Office of Human Development Services in the development of nutrition programs for the elderly. A study is also planned on alcohol usage among the aged in rural communities.

Question: How are research efforts and service delivery by the NIMH, NIAAA, and NIDA coordinated with the National Institute on Aging and the Administration on Aging to insure a consistent effort and effective programs?

Answer: There are continuing efforts by staff members in all three agencies to maintain open communications regarding completion of relevant studies and review of new grant applications. Over the last several years the National Institute on Drug Abuse has engaged in numerous activities with respect to drugs and the elderly. Each of these efforts involved some coordination with the Administration on Aging (AoA) and the National Institute on Aging (NIA). Program initiatives included:

- A NIDA-sponsored conference on drugs and the elderly; invitees included officials from the NIA and AoA.

- NIDA supplementation on an AoA grant to conduct research on drug use patterns by the elderly. The final report was shared with AoA.

- NIA and AoA participation in a review of four NIDA reports, including: a review of program efforts directed toward the elderly who are experiencing problems with drugs; an annotated bibliography and a list of researchers in the field; a report on medical implications of inappropriate drug usage by the elderly; and a

summary of existing knowledge on drug use patterns by the elderly. The final report was disseminated to the two agencies.

- NIDA participation in the AoA-sponsored Older Americans Health Fair Day - May 1979 - in the following manner:

  -- State drug abuse agencies assisted State Agency on Aging s in planning and organizing Health Fair Day activities.

  -- Drug abuse staff presented and discussed the NIDA-developed Elder-Ed film and other prevention materials at the Health Fair Day.

NIAAA coordinates its service delivery with the AoA through review of AoA plans and other information exchange. Generally, the Administration on Aging, which provides no alcoholism service funds, supports social service systems while NIAAA funds health-related alcoholism treatment services. With respect to research, the Ad Hoc Interagency Committee on Research in Aging of which the Institute on Aging is the lead agency, seeks to coordinate research efforts throughout the Federal Government. NIAAA is represented on this committee.

The mandate given the NIMH by the Congreee is to conduct a program of research, training, and services for the prevention and treatment of mental illness and for the maintenance and improvement of the mental health of the Nation. Since persons 65 years of age and older now constitute approximately ten percent of the population and display the highest incidence of new cases of psychopathology, it follows that a significant portion of the NIMH effort should be directed toward the mental health problems and eeds of this age group. The basic focus of NIMH efforts must be on mental health. When applied to this age group the essential considerations are the manner in which aging affects mental health and the influence of mental health upon aging.

NIMH staff together with NIA staff serve on the Interdepartmental Task Force on Research in Aging which is conducted under the auspices of the AoA and is advisory to the Commissioner on Aging. A considerable array of formal and informal relationships also exists between the NIMH Center for Studies of the Mental Health of the Aging and the National Institute on Aging. Research applications of interest to both organizations are dually assigned. On occasion, projects with dual assignments, approved by the primary Institute but for which sufficient funds are not available, have been transferred to the secondary Institute for funding consideration.

Since 1974, staff of the NIMH Center for Studies of the Mental Health of the Aging have served on the Interagency Committee on Research in Aging. This Committee, chaired by the Director, NIA, and in conjunction with the National Advisory Council on Aging, helps define the research goals of the NIA and meets regularly for purposes of coordination and consultation.

Under the terms of a 1978 Interagency Agreement between AoA and NIMH a wide variety of collaborative activities have been undertaken. In research, staff of the Center for Studies of the Mental Health of the Aging consult on the development of the yearly AoA Research and Development Strategy, help frame research initiatives, and serve on AoA review committees. In the past the two agencies have jointly supported projects of mutual interest. In service delivery, the two

agencies have collaborated on joint training of aging and mental health service providers. Through a series of regional workshops, administrators of Area Agencies on Aging, Community Mental Health Centers, State Units on Aging, State Departments of Mental Health, regional and central office staff have been trained in collaborative program development. State-level followup is now being planned through 2% technical assistance. In addition, in FY 1980 the NIMH will publish a resource manual for CMHC directors -- this manual will include Older Americans Act programs as possible sources for collaborative efforts.

Question: The legislation signed early this year to reauthorize alcohol and drug abuse prevention and treatment programs put special emphasis on the elderly because of their unique patterns of substance misuse and need for specialized treatment programs. What steps are being taken to carry out the new law in research and services to older Americans? What are your goals for FY 80 and FY 81, for the number of elderly people to be treated in these programs?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is (1) preparing a special notice to the field to announce the continuing interest of the Institute in receiving grant applications directed towards the alcoholism treatment needs of the aged; and (2) analyzing the two currently funded alcoholism treatment programs for the aged with a view to disseminating findings from these projects to other programs that serve aged clients or may do so in the future.

It is expected that as a result of the increasing awareness of the alcoholism treatment needs of the aged the total number of elderly people presently being treated by NIAAA funded programs, approximately 8,800 in 1978, will increase. Information to date on alcoholism problems and treatment among the aged indicate that the treatment needs of the aged can be integrated into ongoing treatment programs and that the aged in general need more support services such as transportation than do younger clients.

NIDA is now in the process of establishing goals for the elderly. It must be kept in mind that less than 5% of NIDA funded treatment slots are currently used to treat people over the age of 44, and the number of patients aged 65 or older is less than 0.3%. The major goal of the future is to document the special needs of the elderly and to respond to these needs through prevention, education, and out-patient services.

A task force is being formed within NIDA which will be charged with the responsibility of developing recommendations to meet the new legislative mandate. As a minimum States will be directed to expand their services to the elderly; annual State Plans will be given special review to assure that the special emphasis is given to the elderly; priority will be given to additional demonstration projects; and technical asssistance will be made available to State agencies and treatment programs.

FACILITIES CONSOLIDATION

Question: "It has been argued that patients themselves prefer not to share facilities and would not, even if given no other choice. Is this an example of professionally-defined need, or do you have research to support this claim?"

61-400 O - 80 - 54

Answer: Historically, the alcohol, drug abuse and mental health treatment systems have developed from different philosophies. An early and continuing form of treatment for alcoholics included self-help. People with alcohol problems usually viewed themselves not as criminals but rather as victims of a disease over which they had no control. Professional people working with alcoholic persons brought with them their many professional skills which gradually united with the self-help movement to produce the existing systems of alcoholism treatment. However, in recent years in some facilities it has been possible to treat both alcoholics and drug abusers. Some preliminary findings suggest that when professionals view themselves as capable of treating both types of patients and want to do so it can be done without decreasing quality of care.

The basic concept of the Community Mental Health Centers Act is to assure availability of a comprehensive array of treatment and services to all persons in a defined area. It is not uncommon for some services of a CMHC to be provided in other facilities. However, such instances of separately provided services reflect the unique needs and resources of a particular area; they are not dictated by Federal policy.

If alcoholism and drug abuse services are not already available in the CMHC catchment area under other auspices, the CMHC is required to provide them. These services, like other required services, may be provided either through the main facilities of the center or through affiliation with other service providers in the area.

To our knowledge, there has been no study which clearly documents clinical contraindications in sharing facilities for the treatment of alcohol abuse, drug abuse and mental illness. There are, however, studies of combined treatment of alcohol and drug abuse. One study suggested that within a properly structured environment, treatment is feasible and patients do well. Another similar study revealed less favorable results. Neither study was comprehensive enough to recommend major changes in programs.

Question: Would public education programs, focused on eliminating the social stigmas associated with these diseases, further the likelihood of patient acceptance of shared treatment facilities?

Answer: There have been many efforts on the part of the ADAMHA to conduct public education programs, especially using the mass media, to convey information on health-related topics. Evaluations of the effects of these efforts on alcohol-related problems have not been conclusive. Campaigns conducted by NIAAA between 1971-1975 and evaluated by nationwide interview surveys did indicate some changes in the desired direction in attitudes and knowledge. It does not necessarily follow, however, that a public education campaign alone could impact significantly on issues as ingrained and complex as social stigmas associated with alcoholism, drug abuse and mental illness and patient acceptance of shared treatment facilities. Within all ADAMHA Institutes there is an increased emphasis on public education to reduce stigma against mentally ill or drug or alcohol abusing individuals. One goal of activities in this area is to increase tolerance by the general public of behaviors which are perceived as "different." One possible benefit would be increased willingness on the part of the general population to accept services in settings where health and behavioral treatments are provided to a broad range of persons.

Overall, we believe that properly structured education programs could do much toward lessening social stigma associated with alcohol, drug abuse and mental illness.

Question: In summary, has ADAMHA considered in any detail the consolidation of alcohol, drug abuse and mental health facilities and capital cost-related funds?

Answer: During the past few years there have been many successful attempts in the collaboration of alcohol, drug abuse and mental health treatment, research and prevention programs. However, the question of consolidated facilities is difficult to address because three separate service systems have emerged over the years. The mental health system is one in which services are provided to geographically defined catchment areas with direct Federal funds to Community Mental Health Centers (CMHCs). Alcohol services are also directly funded; however, the Federal share is relatively small in proportion to the total amount of dollars expended. With drug abuse, there is a cost sharing approach in which the Federal Government pays a prescribed portion of the treatment costs indirectly through a Single State Agency network. Each of the three components has a rather clearly defined constituency which has grown from three different funding mechanisms.

The CMHC Act authorizes funding for facility construction, but no funds have been appropriated for construction since 1966. Therefore, ADAMHA does not have any direct control over capital investments. Nonetheless, efficient use of Federal resources is encouraged in achieving a comprehensive program. Such efficiencies may include co-location where possible and appropriate. However, co-location of services within the same facility cannot be expected to automatically produce increased efficiency in the use of funds and other resources.

SUBCOMMITTEE RECESS

Senator BURDICK. Well, thank you, gentlemen.

The committee will be in recess until 2 o'clock when we hear testimony from the Health Resources Administration.

[Whereupon, at 11:45 a.m., Thursday, February 7, the subcommittee was recessed, to reconvene at 2 p.m., Thursday, February 7.]

(AFTERNOON SESSION, 2 P.M., THURSDAY, FEBRUARY 7, 1980)

HEALTH RESOURCES ADMINISTRATION

STATEMENT OF DR. HENRY A. FOLEY, ADMINISTRATOR

ACCOMPANIED BY:

DR. JULIUS RICHMOND, ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL
DR. JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT
DR. COLIN C. RORRIE, JR., DIRECTOR, BUREAU OF HEALTH PLANNING
DR. FLORENCE B. FIORI, DIRECTOR, BUREAU OF HEALTH FACILITIES FINANCING, COMPLIANCE AND CONVERSION
DR. DANIEL F. WHITESIDE, DIRECTOR, BUREAU OF HEALTH MANPOWER
WILFORD FORBUSH, DEPUTY ASSISTANT SECRETARY, POLICY COORDINATION

BUDGET REQUEST

Senator SCHWEIKER [presiding]. The Labor-HEW Appropriations Subcommittee will please come to order.

At today's hearings we will hear from witnesses from the Health Resources Administration. Dr. Henry A. Foley, Administrator of HRA, will be the lead witness.

Dr. Foley, I bid you and your colleagues welcome to the subcommittee and I am glad to welcome Dr. Richmond as well. We appreciate your getting here, too, Doctor.

The mission of HRA is to identify the health resources of this country and strengthen their supply, distribution, and utilization for the benefit of the Nation and its health. To this end, HRA administers a wide range of important programs. These include health planning, assistance to medical, nursing, and other health professional schools. The agency concerns itself with increasing the supply of trained professionals in the field of family medicine and primary care practice.

The budget request for HRA for fiscal year 1981 is $529,692,000, a decrease of about $100 million from the budget for fiscal 1980. That decrease is due largely to the administration's proposal to rescind funds Congress provided for medical capitation grants.

We seem to be going over the same battles year after year. The subcommittee has many questions to ask you and your associates, Dr. Foley, but before we ask these questions, would you please introduce your colleagues and go ahead with your opening statement.

Dr. FOLEY. Thank you, Senator.

As you are aware, Dr. Richmond is here to my left, the Surgeon General of the United States. Dr. Whiteside, Director of the Bureau of Health Manpower is to his left. To my right is Dr. James A. Walsh,

Associate Administrator for Operations and Management; Dr. Colin C. Rorrie, Jr., Director, Bureau of Health Planning; Dr. Florence B. Fiori, Director, Bureau of Health Facilities; and to her right is Mr. Wilford Forbush, Deputy Assistant Secretary for Policy Coordination.

Senator, would you like me to read my statement for the record?

Senator SCHWEIKER. We will put your whole statement in the record, but there may be some parts of it you might want to highlight or emphasize particularly.

[The statement follows:]

STATEMENT OF DR. HENRY A. FOLEY

I am pleased to appear before the Committee today to present a proposed budget for the Health Resources Administration in Fiscal Year 1981 amounting to $529,692,000 and 1063 positions. These funds will enable the Agency to continue development of a national health planning capacity geared to promoting equal access to quality health care at a reasonable cost, and promotion of innovative strategies and targeted development of manpower, facilities, and other resources required for an effective health care system. More specifically, the request includes funds to continue implementation of the National Health Planning and Resources Development Act (as amended by Public Law 96-79 which revised and strengthened the Act and extended it through Fiscal 1982), and a proposed Health Professions Educational Assistance Act that will be submitted for Congressional action early in 1980 to replace the present manpower authorities scheduled to expire at the end of the current fiscal year.

Health Planning

In October 1979, the health planning legislation was extended for an additional three years and amended to improve the functioning of the program. Major changes in the legislation include: (1) changing the designation and planning cycles so that health planning agencies operate on a three-year rather than an annual cycle; (2) requiring coordination of State Health Plans with other planning, particularly in the areas of mental health, drug abuse, and alcoholism; (3) strengthening the role of the Governors; (4) revising the certificate of need program to exempt projects of certain large health maintenance organizations from review; and (5) highlighting the role of competition in the allocation of health services.

The health planning agencies have been moving to full designation, meaning that they are assuming the full range of functions required of them by the legislation. Major focus has been on implementing acceptable certificate of need programs, and developing Health Systems Plans and State Health Plans.

At present, 199 of the 204 local health planning agencies are fully designated. Two more are operating under conditional designation and are expected to receive full designation this year. The remaining three are agencies that were non-renewed because of serious management problems, and new agencies will be established in those areas during the current fiscal year.

Capital expenditure reviews by the agencies are having an impact on the rate of increase of health care costs. During the first six months of calendar year 1979, capital expenditures for which we have data were $2.4 billion. Projected for the year, the total 1979 level would reach $4.8 billion. This is a significant decrease from the prior year levels of expenditures of $5.2 billion, particularly if inflation is taken into account since these are not constant dollars.

Now that the agencies have organized and most have developed health plans, the program emphasis in 1981 will shift increasingly toward implementation and evaluation activities, with particular focus on the review and determination of the appropriateness of

given types of service, and on the review and approval of proposed uses of Federal health funds. Agencies also will need to balance cost containment efforts with maintenance of access to health services for underserved populations.

The budget request for health planning activites is $170,649,000 and 272 positions.

Health Facilities

The Bureau of Health Facilities Financing, Compliance and Conversion was created to promote the effective and efficient utilization of existing health facilities; and cost containment to include the conversion or closure of unnecessary beds.

It will focus its resources on five major goals: (1) to directly promote hospital cost containment by financing the discontinuance or conversion of unnecessary beds; (2) to assist in developing Department policy on health facility capital formation in order to reduce unnecessary beds and inefficient utilization of facilities; (3) to assure that facilities which received Federal funding provide a reasonable volume of free care to persons unable to pay; (4) to actively monitor some $3 billion in outstanding facilities' loans and loan guarantees in order to minimize default; and (5) to direct a program promoting energy conservation and cost savings by health facilities. The Bureau also will monitor about $1.5 billion of outstanding Health Professions and Nursing loans and grants to ensure compliance with Federal requirements.

The budget request for this Bureau is $19,045,000 and 156 positions.

Health Professions Education

The Health Professions Educational Assistance Act of 1976 and the Nurse Training Amendments of 1979 expire at the end of the 1980 fiscal year. The Administration will submit proposed legislation early in 1980 to enable a thorough exploration of the most effective way to channel Federal assistance so it will have an impact on priority problems.

Both the 1981 budget and the legislative proposal are designed to address five major objectives: (1) remove incentives for unwarranted growth in the aggregate supply of health professionals; (2) promote the increased supply of primary care professionals relative to other types of specialists; (3) assure the availability of health professionals in underserved areas; (4) continue to promote minority participation in the health professions; and (5) promote national health care priorities through special projects.

Consistent with the objective of removing incentives for unwarranted growth in supply of health professions, we would eliminate such growth-stimulating programs as capitation grants, construction grants, and start-up assistance; but would provide short term financial distress assistance to institutions experiencing financial difficulties under such a proposal.

Evidence indicates a need for continued Federal aid for primary care training, especially in family medicine, and our budget reflects this objective with increases for the family medicine and primary care training programs.

The major effort 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. Another program directed at this objective of making health professionals available in underserved areas is the Area Health Education Center (AHEC) program, which would be continued. This program addresses problems of geographic distribution and overspecialization of health professionals by fostering changes in the pattern of education and the educational environment. Funds are provided to medical and osteopathic schools or to universities for remote site training of medical and other health professionals in rural or other medically underserved areas.

It appears that an effective way to promote the participation of minorities is to maintain the scholarship program for first-year health professions students of exceptional financial need and to continue the program of educational assistance to disadvantaged students. These help students from disadvantaged backgrounds get into health professions schools, and to complete successfully their education and training.

Health professions special projects would focus on national priority areas such as public health and health administration training, with special consideration given to biostatistics and epidemiology, cost containment, health administration and health planning, environmental and occupational health, nutrition, and health education counseling. In the nursing area, priorities would include projects to improve the distribution of nurses by geographic areas, increase nursing education opportunities for persons from disadvantaged backgrounds, developing innovative techniques to meet the needs of such high risk groups as the elderly, children, and pregnant women; and to provide training to enhance clinical skills, concentrating on primary care and the needs of the high-risk target groups mentioned above.

The 1981 request for health professions education activities is $325,662,000 and 417 positions.

Program Management

The program management activity request for $14,336,000 and 218 positions provides funds for the HRA Administrator and his office and staff personnel. Included within this activity is funding for budget and fiscal direction, as well as agency-wide planning and evaluation, policy coordination, legislative liaison, personnel, and procurement functions. It also supports the leasing of the Federal Center Building in Hyattsville through payments to the General Services Administration as well as other operational costs for the facilities.

Supplemental, 1980

The Health Resources Administration also is requesting a supplemental appropriation to its fiscal year 1980 budget. The amount requested, $2,400,000, is to provide needed financial assistance to four health professions educational institutions that provide training for disadvantaged and minority students.

Financial Distress grants, are awarded to assist health professions schools meet the cost of operations if they are in serious financial distress, to meet accreditation requirements, and to carry out appropriate operational, managerial, and financial reforms to correct financial deficiencies of the institution.

Applications have been received delineating critical deficits at the four institutions which train disadvantaged and minority students. The amounts requested for each school are:

Meharry Medical School	$1,200,000
Meharry Dental School	400,000
Tuskegee Institute School of Veterinary Medicine	600,000
Xavier University School of Pharmacy	200,000
Total	$2,400,000

The grant application and review process continues with national advisory council action scheduled for the week of January 28 to February 1.

A level of funding significantly less than the amounts requested would seriously jeopardize the continuation of the educational programs at these institutions.

Rescission, 1980

Also in connection with the 1980 budget, we are proposing to rescind $97,768,000 for two health manpower programs - Health Professions Student Loans and Capitation to schools of the Health Professions, other than schools of Public Health. Continued Federal assistance for these programs is no longer required; we are now directing our limited resources to programs addressing the Nation's higher priority goals of improving the geographic and specialty distribution of health professionals.

Health Professions Capitation

Health Professions Capitation Grants provide Federal financial support to health professions schools on a formula basis, with certain conditions required. The program has been successful in meeting its original objectives - to expand the enrollment of health professionals and to stabilize the financial status of the health professions schools. Since 1963, the first-year enrollment in medical and osteopathic schools, for example, has grown from 9,200 to the current level of 17,500 and the number of physicians in active practice has increased over the past 10 years by 34 percent.

There is, however, a continuing need to attract these health professionals to areas not now adequately served. Accordingly, the Administration is directing health professions education funding to those programs that create a better geographic and specialty distribution among the professionals being trained.

Because these capitation grants, which support undergraduate medical training, have not proven to be an effective way of influencing specialty or geographic maldistribution problems, we are asking for a rescission of $81,268,000 for this program in the fiscal year 1980 budget.

Health Professions Student Loans

The proposed rescission for Health Professions Student Loans is based on the premise that students receiving Federal aid should agree to serve in a medically underserved area, thus contributing to correcting the national imbalance of health personnel.

The health professions student loan program authorizes long-term, seven percent interest loans to certain health professions students (MOD/VOPP). Since 1965, this program has assisted approximately 332,000 students. However, these loans do not require a service payback. Other programs, such as the National Health Service Corps Scholarship, are relied upon to alleviate specialty or geographic maldistribution. Students not selected for the National Health Service Corps Scholarship program have access to the Health Education Assistance Loan program, and the National Direct Student Loan program administered by the Department of Education and loan funds will continue to be available from the revolving funds previously established in the health professions schools.

We are requesting a rescission of $16,500,000 in this program.

Thank you for the opportunity to appear before you today, and I will be pleased to answer any questions you may have.

HEALTH PLANNING

Dr. FOLEY. I'd like to briefly highlight several points in the budget itself.

First of all, as you have mentioned, we have a budget of $529,692,000 for 1981 which would cover also 1,063 positions in the central office and regional offices of the country for the program activities under the administration of the Health Resources Administration.

The first important program is clearly the health planning legislation which you have graciously supported and reauthorized in the past session of Congress. That program now is at a stage where over 95 percent of the local health systems agencies are fully designated.

Senator SCHWEIKER. Ninety-five percent?

Dr. FOLEY. Ninety-five percent. There are now, I believe, 199 HSA's and they have been fully designated. Two are operating under conditional designation and three were not renewed and we are now developing new agencies in those areas.

At this point, Senator, the health systems agencies and the State health planning agencies are in a position to carry forth the command of Congress to review and approve Federal grants, on an areawide basis

within their areas and States, and also administer appropriateness review as well.

The program has been relatively successful this past year at checking the growth of capital expenditures. We have had a holding of capital formation to $4.8 billion nationally, which represents a significant decrease compared to $5.2 billion the year before and taking into account inflation. So capital expenditure reviews are having an impact in this particular area.

We have moved the program emphasis—you may be interested in this—to much more of a performance direction in the field. We are coming forth with performance outcome measures for the health systems agencies consistent with what was passed in the last act of Congress.

HEALTH FACILITIES

The second major area is the program of the Bureau of Health Facilities. We are focusing here on several areas, particularly to insure that the loans which the Federal Government has guaranteed under the Hill-Burton Act and section 242 of the Housing and Urban Development Act are safeguarded.

In the second area we are trying to insure that the Hill-Burton free-care assurances are, in fact, implemented by the hospitals that took on this responsibility. That program is targeted through the use of scarce personnel. They are using targeted approaches and working collaboratively with the Office of Civil Rights of HEW and the Health Care Financing Administration to assure that this program is effective.

We have also been concerned about the question of energy conservation within hospitals and that program has been effectively mounted. We have been holding regional conferences around the country on that.

The Bureau of Health Facilities program contains a budget of $19,045,000 and covers 156 positions in the regional offices and central office.

HEALTH PROFESSIONS EDUCATION

We will come forward with a proposal from the administration that will be submitted close to March 1—proposed legislation on the part of the administration covering the health professions area. We recognize that there are several proposals that have already been introduced on the Hill, including your own, Senator. But our proposal has items that basically move in the direction of trying to target the Federal resources in terms of the kinds of specialties, particularly in the area of primary care—first, by increasing the supply of primary care professionals and, second, by targeting the positions of those health professionals to underserved areas.

We will continue to support minority participation in the health professions and also try to come forth with a special project rather than formula approach. We will also continue short-term financial distress assistance which is indicated for those institutions that are experiencing financial difficulties.

We continue the basic support of the area health education centers program which our own studies in the Department have indicated is an

effective approach, and we have recently received the Carnegie Commission's report on the program which also reinforces that. I suggest that, perhaps, both we, the administration, and the Hill will want to consider more flexibility in the administration of this program. It is a program where the dollars have been well spent. We are receiving good cooperation from the States and from the medical schools in basically decentralizing medical education and health profession education.

Senator SCHWEIKER. Dr. Foley, I understand from testimony the other day that there is a report in HEW about health professionals and about assessment of where our country is going in the next 5 or 10 years. I just wonder when the committee might benefit from this report in doing its own work. I recognize there are policy decisions that have to be made in HHS before the report is released, but I just would like to ask when we might have a look at it, since it would be very helpful to us to have some insight into it.

[Discussion off the record.]

Senator SCHWEIKER. I might amend that by saying I think this report also addresses biomedical research issues. What is this report about?

Dr. FOLEY. We have a couple of reports, Senator. The first one is the report that will be coming from the Graduate Medical Education National Advisory Committee established 3 years ago at the request of the Appropriations Committee in the House. There is an interim report of that committee which the Congress and staff should have and if they don't we will bring that up to you. It came out last spring.

MEDICAL SPECIALTIES

But there is a second report which has not been totally completed. It is due to the Department for review on April 1, due also up here by September. This is the second report of the Graduate Medical Education National Advisory Committee. It looks at a proposed number range of specialists in the country by the 23 major specialty areas in the physician population: How many surgeons do we need? What number of internists do we need? What number of psychiatrists do we need? It uses basically what is called the requirements model which considers the procedures that doctors basically have to use to diagnose and treat patients with certain types of illness.

That report will again indicate the numbers that will be appropriate up to the year 1990, since any change we would suggest would affect the educational programs for at least 10 years, given the time frame it takes to put a medical student through graduate training.

Second, we will look at questions of distribution in the country and, third, at the type of financing that might be appropriate in terms of categorical types of funding and/or reimbursement from the Federal Government and States, for training costs. Finally, we will actually look at the content of the medical schools themselves in terms of influencing the direction of how students are being trained in the field.

The information is discussed in public sessions held on a regular basis. The issues are debated by the professionals first.

RAND CORP. STUDY

In addition, there has recently been a study produced by the Rand Corp. that looks at the distributional effects of the increased production of physicians from 1960 to 1977 in eight specialty areas, including general medicine.

We found that because of increased production we are seeing a 14-percent net increase in the number of physicians practicing in towns of 50,000 or less. They are practicing in areas that did not have a large number of physicians before. Those areas now have a 14-percent real increase when we consider general practitioners who have left practice, retired, or died. So we are seeing physicians moving, in terms of the market phenomenon in some areas of the country.

For a specific example, because of growth in the whole area, we see physicians between here and Frederick, Md., who might not have been there in as great a number in 1960.

The GMENAC report also contains data like this, and I think will be very helpful.

In addition, at the request of this Congress, a contract for the Institute of Medicine is being executed in the area of nursing. And that particular agreement has been signed off by Dr. Handler at the Institute of Medicine, and we will sign our detailed contract with them this Friday. That is a phased approach. The IOM will be basically looking at the whole field of nursing for the next 6 months and carrying out further reviews over the next 2 years.

Senator SCHWEIKER. Does HHS agree with the range? Or how close are we to it?

Dr. FOLEY. At this point we are carefully examining the Rand study. We have had some discussions with the analysts who did the study, and our conclusion will be in terms of that report.

Senator SCHWEIKER. When?

Dr. FOLEY. I think we will be in a position to do that in the late spring, in April.

Dr. RICHMOND. I think, Senator, it is rather interesting to observe that some of the problems we are now encountering and having to think through are really born of rather considerable successes. We have increased our capacity to produce many more health professionals in a way that we really hadn't quite anticipated, and——

Senator SCHWEIKER. Like the Hill-Burton program?

Dr. RICHMOND. Yes, indeed. We in this country have always been coming from behind and not had an experience in dealing with oversupplies. That is one example.

In health manpower, while we can't say for certain we are going to be in an oversupply, I think we can say that we have, in terms of total numbers, adequacy. And therein lies the interest in the Rand report. I think what they are indicating is that health personnel will move out into reasonably affluent communities and into communities that are fairly well populated; that is, when one thinks of the size communities that they were studying.

We remain concerned about remote rural areas where there are concentrations, particularly of very poor people, as well as in urban areas

where there are high concentrations, and which have not been attractive to health professionals.

And we are, fortunately, I think, for this country, in a very important transitional period of having been successful and now having to make some new accommodations.

Senator SCHWEIKER. I will ask Dr. Foley if he has any other highlights.

Dr. FOLEY. Let me just move on briefly to a couple of items.

We have focused, in terms of the program management—and those figures are indicated in the document. But we should indicate here that we have made a basic choice within the agency itself that perhaps is not often seen from the outside, and that is to go with more support where we can, given the scarce resources that we have allocated to our program levels—and we have been thinning out, basically, the Office of the Administrator, cutting my staff size, so that the program chiefs could run their particular programs.

SUPPLEMENTAL REQUESTED FOR FINANCIAL DISTRESS

We are requesting a supplemental to cover the financially distressed schools. That request is $2.4 million, particularly focused on Meharry, Tuskegee, and Xavier Universities. We have the proposals reviewed by the National Health Professionals Advisory Council. They have indicated that in one school much tougher requirements by the Department in terms of funds are necessary.

Senator SCHWEIKER. Is that Meharry?

Dr. FOLEY. That is Meharry. And we have had a task force under the leadership of the Undersecretary and Dr. Richmond to look into those conditions in Meharry over the last 2 weeks. We intend to allocate those funds conditionally on the implementation of the specific management steps that are necessary.

RESCISSION REQUESTED

We are proposing, as we have indicated, a rescission in this 1980 budget of $97,768,000 for two health manpower programs—health professions student loans and capitation to schools of the health professions, other than schools of public health. We had made our position clear in the administration that in the area of schools of public health it was critical that this type of institutional support be continued because of the nature of how these students graduate and go into, primarily, areas of public service and also areas of high priority for the administration, such as occupational safety and health. That position was accepted by the administration last week, and so the President will be sending up a revised amendment to his budget that was published last Monday.

I have been advised this morning, Senator, that that should be up to this committee of the Congress by next week from the President's budget office.

We are requesting rescission of $16,500,000 in the health professions student loan program.

Senator, I'd be glad to entertain any questions or comments concerning this.

EFFORTS OF PLANNING AGENCIES

Senator SCHWEIKER. All right. On health planning and resources development, the Health Resources Administration is responsible for developing health planning capabilities in order to make decisions crucial for an effective national health care system. The Health Planning and Resources Development Act, the legislative act founding this program, is in its sixth year of authorization. In this network, HSA's health planning and development agencies have been developed for the purpose of improving health services and containing costs.

In fiscal year 1980, health systems agencies were credited with implementing capital savings of over $1.8 billion to influence the number and type of capital investments made for health facilities. To what extent have the agencies continued their planning efforts?

Dr. FOLEY. Specifically, I'd better ask Dr. Rorrie, Director of that Bureau.

Dr. RORRIE. While there has been a focus on the regulatory activities in that particular area of the planning program, they have continued to expand their activities beyond that. The HSA's are continuing to work with the States to produce State health plans.

Senator SCHWEIKER. I supported the administration in that request. I thought it was a good approach.

Dr. FOLEY. We were very pleased with it.

Dr. RORRIE. The HSA's have continued to work on development of plans.

In addition, there has been a concern which has been increasing in many parts of the country over access to care. We have seen over the last 3 years the figures on areas of the country that are medically underserved as far as health personnel are concerned and have indicated in our testimony that over a thousand National Health Service Corps personnel were placed through efforts of the planning agencies.

CAPITAL FORMATION

Senator SCHWEIKER. The figure of $4.8 billion—how accurate is it and what is it composed of?

Dr. FOLEY. Well, Senator, we now have a data system which collects from the States basic data on what they are approving or disapproving in the area of certificates-of-need. This system has been in effect since June of this past year, and what we have is some very exact data on many of the States, but not all yet. And so we have what we think is the best estimate at this point from the data that is coming forth from those States.

Also, what is not indicated in that particular savings, is the fact that because of the more mature development in the HSA's, a lot of applications are not even submitted to the HSA's as they were in the past, because there is much more prior discussion with the HSA's on what is appropriate for their particular community. They lay out what resources are available, what, in fact, may be the services that are necessary. And

as they improve that process over the next couple of years with the appropriate review, I think we will see a tendency for less application—"more careful," maybe, is a better way of phrasing it—a more careful decision made on the part of hospitals and long-term care facilities to apply for either renovation or expansion or actual new construction because of the tighter requirements in the local planning areas.

NEED FOR STATE ACTION

Senator SCHWEIKER. Maybe you mentioned this—I don't recall hearing it. Have all 57 State health planning agencies been fully designated as of this date?

Dr. FOLEY. No; they have not.

Dr. RORRIE. We have 37 fully designated. The other 20 are pending approval.

Senator SCHWEIKER. When do we expect to have the other 20 completed?

Dr. RORRIE. Well, according to the new legislative amendment you passed with the renewal, all States will have to have satisfactory programs on or about January of 1981.

Senator SCHWEIKER. Will we meet that goal?

Dr. RORRIE. Yes.

Dr. FOLEY. Senator, if the State legislatures stay in session long enough this year to consider the certificate-of-need requirements and pass that through their respective legislatures, they will, in fact, meet that deadline. If there are any legislatures that are in their off-year and have not, it is going to be difficult to try to get the Governors to call special sessions for this one area.

So we are monitoring the problem on a State-by-State basis through Dr. Rorrie's office and offering technical assistance to each State. The major problems are in such States as California that do not have an acceptable certificate-of-need program and have 10 percent of the total health care provided in the country. And we are trying very carefully with the legislature there and the Governor to encourage them to meet the October 1 deadline so we will not have to report back to you and Congress that they are not going to meet that date. There is a very serious concern about this area, and we hope the State legislatures can meet the deadline that is set.

ANNUAL IMPLEMENTATION PLAN

Senator SCHWEIKER. How is the implementation plan reviewed, and how does that affect the health systems agencies' designation guides?

Dr. RORRIE. The annual implementation plan will remain a 1-year plan. That will not change as a result of the legislation. There will be increasing focus on that implementation plan. It is reviewed along with the health systems plan as well as the agency performance of all functions. The AIP will have increasing attention focused on it in line with congressional intent to focus on implementation of plan priorities.

61-400 O - 80 - 55

MEMBERSHIP ON HSA BOARDS

Senator SCHWEIKER. Amendments to the health planning law which were passed last year now require that HSA boards include handicapped individuals among the broad spectrum of representatives. The intent of this legislative change was to insure that the boards represent these people in the health services area. The Congress was very specific in saying a quota system would not be established.

What problems do the HSA boards have in complying with this mandate?

Dr. FOLEY. Senator, you have either an election or selection process in each of the HSA's, depending on the methods they have chosen. And as the HSA's have various seats come up for renewal or vacancy, given the fact the law requires they not be self-perpetuating boards, you then have the HSA members, as well as the staff of the HSA's, involved in trying to meet the requirement of getting these other types of handicapped and other population types to fill those slots. So as the slots become vacant, basically they have experienced consumers in those population groups who try to fill those vacancies.

I think the problem we face in the planning process is the attempt to get full participation and, at the same time, some enlightened participation on the part of consumers and providers so that we have a situation where you have to involve some of the consumers and providers in training on what the act is all about, what its purposes are.

That's going on and is encouraged through the regional offices and centers for health planning—there are now four centers that basically provide this kind of technical assistance to the HSA's.

I think we are showing progress. We have also had some reversals. We have had allegations of stacked elections, voting processes, such as we see historically in general politics.

Senator SCHWEIKER. That is not unique, I will have to say that.

Dr. FOLEY. We have directed the agencies that clearly they have to conduct themselves with the utmost integrity in regard to democratic principles, and we have indicated to them that we are looking over their shoulder where we find these allegations of abuse.

I do think there have been some gains in the country in regard to meeting the broadly representative requirement of the statute. Where we have seen any tendencies for overkill, we have cautioned and directed HSA's not to have a quota system because of the intent of Congress.

HOSPITAL CONVERSION PROGRAM

Senator SCHWEIKER. On the hospital conversion program, the health planning amendments passed last October authorized $30 million for fiscal year 1980 for a hospital closure or conversion program. This year you want $10 million. This also was another program that I strongly supported and advocated.

Now that the administration's hospital cost-containment program has been defeated in the House, how much emphasis will the administration place on closure or conversion as an alternative way to cut hospital costs?

Dr. FOLEY. We are going to place a great deal of emphasis on this program even though the resources are relatively modest for the effort. We are requesting less than $10 million from Congress for the program itself to try a demonstration, but we are linking with the Health Care Financing Administration to try to assure that some projects leading to discontinuation be much more directed to ambulatory care. That process is consistent with going through the State health planning agencies.

So we will try not only to use the resources of $9-plus million, but also to be sure that any activities that HCFA gets involved in will also move in that direction.

The prime example is clearly the case of Brooklyn Jewish Hospital, in which the conditions that were put on the use of medicare/medicaid funds in cooperation with the State of New York enhanced the ambulatory care in the community for that particular area.

Senator SCHWEIKER. I was going to say: How many hospitals do we have to bail out?

Dr. FOLEY. Well, Senator, we do have a task force chaired by Undersecretary Stark which is looking at the problem of financially troubled hospitals in both urban and rural areas. We recognize continually in the case of public-supported hospitals, not just in the New York City area but other parts of the country, particularly, for example, on the west coast where you have had the impact of proposition 13 and other tax measures in that State, that hospitals are beginning to feel a tremendous financial pressure in regard to payment for services of populations that are legal and populations that are illegal, the illegal aliens among them. And the Undersecretary's intention is for the Department to come forth with a set of proposals to the administration and at a certain point in time there will be more discussion. We will be coming back for oversight hearings to the Congress.

We recognize that in the private sector we have seen a number of bankruptcies over the past several years. Some of those may be quite appropriate. It may be that we do not want to take away the incentive and to reduce competition in the whole health planning process.

DEMONSTRATION APPROACH IN HOSPITAL CONVERSION

Senator SCHWEIKER. There is a very broad policy question here that you have articulated well. It gives us all a multifaceted approach to the problem because of its complications.

Let me follow up this other point. How long do you think it's going to take to get this program off the ground, and what can you really do with $10 million? As you say, it is a modest authorization, which I acknowledge. On the other hand, what can you do and how long will it take us to do something with the $10 million?

Dr. FOLEY. Well, although we did not request it this year given our budget constraints in fiscal year 1980, we have had staff developing approaches to the planning, State planning particularly, for demonstrations. And they are prepared so when grant requests come in through the State planning agencies, there are criteria to review against.

Clearly we have some States that are further ahead in what they visualize—and there has been debate on that for 2 years now in Congress and the administration. At least two States, Michigan and New York State, do have proposals at the moment to see what, in a demonstration way, with other resources, can be done.

Senator SCHWEIKER. Will this money cover both of them or not?

Dr. FOLEY. We think it could cover demonstration areas, yes.

Senator SCHWEIKER. Well, I realize the amount of money we are talking is on the demonstration level.

Dr. FOLEY. I am not going to suggest to you that what we asked $50 million for we can accomplish with $10 million; but we can accomplish something with $10 million, some type of preplanning.

Dr. RICHMOND. Senator, if I might be permitted, it is important, I think, to indicate that since 40 percent of our total health expenditures go to hospital care, if we can properly make any reductions in those expenditures, this would be desirable. And I think this comes back to your theory about bailing out hospitals. In fact, we really don't have any authority to bail out hospitals, and what we are looking toward is really appropriate, high-quality health services for the people in need. In a number of situations like the Brooklyn Jewish situation and the Bedford-Stuyvesant proposal, what we are moving toward is the development of more ambulatory care facilities, which is what this population probably needs to a much greater extent than hospital beds.

And these are the directions that we are going in, trying to provide appropriate ambulatory care and conserving hospital beds wherever we can.

Senator SCHWEIKER. Well, now, you did ask for $30 million last year, so my question obviously is: Why didn't you ask for $30 million this year? Is there any consistency of need there?

Dr. RICHMOND. Senator, since $30 million wasn't accepted last time, I think it's appropriate to go in the direction of demonstrations to see if we can't demonstrate to the Congress with modest funds that we can be effective. We do think that in the long run, as I think you suggested, that this will be very cost effective. If, indeed, we don't do a disservice to the health care people in those communities, we certainly can effect greater economies by moving in this direction.

HILL-BURTON PROVISIONS ON FREE CARE

Senator SCHWEIKER. A number of hospitals, as you may know, are complaining about requirements that they provide charity care in return for receiving Hill-Burton and certain other Federal funds.

New regulations provide for Federal monitoring of compliance. Although they eliminate the old policy of providing an open door to all patients unable to pay, they do set dollar levels of compliance for each hospital that has received Federal assistance. How much charity care do you estimate these hospitals should provide?

Dr. FOLEY. Dr. Fiori, what is that figure in this fiscal year?

Dr. FIORI. In fiscal 1980 it is approximately $435 million.

Dr. FOLEY. Senator, if I might address the question more fully, as you might be aware, we did have open hearings on the Hill-Burton assurances, which was probably one of the best kept secrets in the history of the Federal Government. In almost 30 years it was not forced on the facilities. I think you have covered this in some of your oversight hearings in the past. We feel very strongly that program needs to be conducted. We recognize that this situation exists, and we have been successful in a lawsuit around that issue, at least so far.

Our concern, however, is a measured approach to that. Hospitals did, in fact, sign agreements with the Federal Government, legal documents, where it was freely stated they would provide free care. Now, 10 years later, these hospitals are saying, "We didn't really mean that," or, "We thought the Federal Government didn't mean it." The courts have told the executive branch, "You did mean that."

We think, in fact, most hospitals can meet that responsibility and should meet that responsibility. So we are going to try to target our staff toward those cases where there is serious offense, where a hospital has consistently refused to provide that free care as in a case we had on national television just several months ago in which a Mexican family was denied care in a hospital in the Southwest which did have the responsibility for free-care assurance. There had been longstanding reports about that hospital, but no action from the Federal Government.

In our review we had the public hearings and saw some hospitals that had been extremely honorable in meeting their responsibilities in contrast to others that did not.

If there is a situation where other payment sources are not covering adequately some type of cross-subsidization for this care——

FREE CARE AND HOSPITAL BANKRUPTCY

Senator SCHWEIKER. That is my next question. Is it true that some hospitals could go bankrupt in complying with that regulation?

Dr. FOLEY. If some hospitals have overexpanded and have been using their sinking funds to pay for their principal, for which they have been basically reimbursed for by third-party reimbursement, it is possible.

Senator SCHWEIKER. How does that apply to the New York case?

Dr. FOLEY. We have a third of our portfolio in the New York regional area, heavily in New York City. It is Dr. Fiori's challenge to monitor those particular loans. We had seen earlier that some of the hospitals were not effectively putting aside funds to pay for their principal and putting themselves in a postion of great risk. We are monitoring that very closely. Dr. Fiori might want to be more specific.

Dr. FIORI. In response to your question, I think there are two provisions in the regulation, one of which is related to the fact that those hospitals that feel they are financially unable to meet their obligation do have the option of expressing that to us.

Also, in terms of that limitation with regard to their financial capacity, the regulation makes provision for them to carry a deficit over to the next fiscal year. In other words, they can extend the period of time over which that obligation must be met.

Senator SCHWEIKER. And how do we monitor this? You said there is a mechanism here, but how do we look at it each year for each hospital? What is the monitoring technique?

Dr. FOLEY. There are several approaches that we use. One is, if a hospital has had a series of complaints against it, we are required to investigate that situation. Theoretically we are investigating just one complaint, but given the staff resources that we have, we, in fact, look at a specific hospital or group of hospitals and there might be a set of accusations, not over just 1 year but a couple of years.

Senator SCHWEIKER. On a pattern basis.

Dr. FOLEY. That's right. If we cannot respond within a set period of time, the person can go directly to the court for redress against that hospital. So if we can't administratively be responsible, we have set up in our regulation—what is it?

Dr. FIORI. Six months.

Dr. FOLEY. Six months. Then they must go to court.

AUTHORITY OF HSA'S

Senator SCHWEIKER. Last August, HEW issued implementing regulations which give HSA's authority to approve or disapprove the use of specified HEW health funds within the Nation's health service areas. However, the regulations, in a kind of catch-22 manner, permit HEW to override HSA disapproval of an application for HEW funds.

How much real authority are you giving the HSA's if you can override a decision any time you wish?

Dr. FOLEY. We have a committee composed of the PHS agencies, which has yet to be activated, by which we could look at the questions of: If HSA's are consistently being overruled and think they are covered by the regulation, is there due process for the HSA's, and what are the reasons for their being overruled? So there is appropriate feedback.

We recognize that we need to improve the approach we have in this area so the agencies don't feel they are being discredited by arbitrary and capricious actions. It is very clear from Dr. Richmond's instructions that the PHS agencies should be able to give the reasons for any overruling of an HSA, and the reasons should be fairly substantive for that to happen.

We are moving on this and gaining experience.

MEDICAL SCHOOL CAPITATION

Senator SCHWEIKER. In fiscal 1980, Congress provided $87.7 million for medical school capitation, yet a few months later you come up here requesting a rescission of $81.2 million. How do the schools that were to get these funds make up for their loss?

Dr. FOLEY. We are talking, Senator, of funds the schools would have received next school year, beginning September of this year, 1980. We would expect that the schools could entertain other possible alternatives. Some schools will go to their State budget committees to ask for the difference. A few schools will go to their endowment funds. Other

schools may well raise their tuition fee cost for the students. A fourth possibility, which is often not entertained by bureaucracies at the Federal level or at the congressional level or certainly at the medical schools, would be greater economy moves on the part of the deans and chairmen of departments to see if they can, in fact, move their faculty onto part time. They can, in fact, also have their faculty basically be paid through the service dollar and provide more hospital care by their faculty.

That has been the pattern, and we could provide for the record a report on what these options are and how effective they have been. We do know, in terms of our discussions last year, that several States did go to their State budget committees. In some cases they were received well, and in some cases they were not.

CHANGE IN RESCISSION REQUEST

Senator SCHWEIKER. Why did you decide to reverse field and not ask for a rescission of $6.4 million in public health capitation funds?

Dr. FOLEY. The Department did not reverse its field, but it was felt that OMB made a mistake in the process, and that is how they characterize it.

Senator SCHWEIKER. OMB made a mistake.

Dr. FOLEY. In this area I think they agreed with us that the reason we presented was valid. The schools of public health do, in fact, produce some of our key health professionals. Almost 85 percent of the professionals at State and county levels who provide public health services come from schools of public health, and so OMB agreed to that position.

Senator SCHWEIKER. We have two votes back to back, so I think, with your understanding, we will recess for about 10 minutes.

[A brief recess was taken.]

Senator SCHWEIKER. The subcommittee will reconvene. I apologize for the interruption.

INCREASE IN NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM

On the one hand, you propose to cut back help to medical schools, and on the other hand you propose a substantial increase in the National Health Service Corps program which would lead to increasing the ranks of doctors. Aren't you being in some way inconsistent?

Dr. FOLEY. Senator, no; we are not. We are requesting that those students who are already in the slots in medical school or who go into the slots—some of that number would, in fact, be directed toward service in underserved areas. So we are not requesting a total aggregate increase of number of positions. We are saying that within the pool of physicians that we know we have the capacity to train in medical schools, a portion of those can choose the scholarship approach, so when they get through with their undergraduate training and 2 or 3 years of graduate training they can serve in underserved populations.

Senator SCHWEIKER. The Health Professions Educational Assistance Act does expire at the end of 1980. When do you intend to submit a proposal specifically for this health assistance legislation?

Dr. FOLEY. Senator, we expect to submit a proposal to the Congress around March 1, preferably before March 1.

Senator SCHWEIKER. The National Health Service Corps scholarship budget has grown very rapidly over the past several years. You are now asking for an increase of $8 million. Do you expect the program to continue to grow at that fast a rate?

Dr. FOLEY. Senator, we are requesting for this upcoming fiscal year, 1981, an appropriation to cover—Dr. Whiteside, how many scholarships?

Dr. WHITESIDE. For 1981?

Dr. FOLEY. Yes.

Dr. WHITESIDE. We will have about 6,700.

Dr. FOLEY. To cover 6,700 scholarships. The number of new scholarships in that area is a little under 2,000. And that is all we are considering at this point in time. The Administration has under advisement what will be the increase in the upcoming years. There is some discussion about what that should be, and we are not in a position yet to give you what the numbers would be and whether that would be an increase, a holding constant—which is the tendency at the moment—or a decrease, but we will report that to you later on in this session of Congress.

Senator SCHWEIKER. Do you have any figures for 1985 and 1990 in these projections?

Dr. FOLEY. We had figures, Senator, but again I must reiterate that the Department and the administration have under consideration whether or not they want to go to an increasing number in that particular area, an increasing number of scholarships. And we are not prepared at this point to discuss anything beyond fiscal year 1981.

RECIPIENTS OF CORPS SCHOLARSHIPS

Senator SCHWEIKER. What is the percent of scholarship recipients who stay in an underserved area once their service obligation ends?

Dr. FOLEY. Dr. Whiteside.

Dr. WHITESIDE. In terms of the scholarship recipients, we really have not had sufficient experience to be able to answer that question. As of September 30, 1979, we had only 238 scholarship recipients who have fulfilled their service in this area.

Senator SCHWEIKER. Is this just the first year's class now? Where are we in terms of who has gone through the pipeline and is out? Because this has been going on for 7 years now. This is the first year out, or not?

Dr. WHITESIDE. No; they have been out long enough to complete at least 2 years of service. We have given awards to 11,446 individuals. Now, most of those are still in school. About 6,400 of them are still in school. We have about 2,500 who are in deferment status.

Senator SCHWEIKER. What status?

Dr. WHITESIDE. Deferment status. And there are about 1,100 who are currently on active duty.

Senator SCHWEIKER. OK. How many are all the way through, then? The 238?

Dr. WHITESIDE. The 238.

Senator SCHWEIKER. And of those 238, how many are staying in the area?

Dr. WHITESIDE. I have asked the National Health Service Corps to provide us that figure but I don't have it yet. But I will be happy to give it to you.

Senator SCHWEIKER. All right, will you submit it to us for the record.

[The information follows:]

NUMBER OF NHSC SCHOLARSHIP OBLIGEES REMAINING IN HEALTH MANPOWER SHORTAGE AREAS

National Health Service Corps (NHSC) scholarship recipents may fulfill their service obligations in the NHSC field program, in Indian Health Service facilities, or in Federal Bureau of Prisons facilities. A formal tracking system exists only for those obligees who serve with the NHSC field program. During fiscal years 1977, 1978, and 1979, 142 scholarship recipients completed their service obligation in the Corps for at least 1 year; 17 went into private practice in health manpower shortage areas; and 109 left the shortage areas upon completion of their service obligation. Comparable information is not available for those obligees who served in Indian Health Service or Federal Bureau of Prisons facilities.

CORPS SCHOLARSHIP RECIPIENTS STAYING IN UNDERSERVED AREAS

Dr. FOLEY. We have been told by our counterpart in the Health Services Administration that they have over 20 percent now and they see it increasing each year.

Senator SCHWEIKER. I know their projections are much higher than that. The first figures out are low, but they project much higher—I'm not sure on what basis. They are optimistic, and I hope they're right.

Will most awards be made to new recipients or to support students continuing in the program?

Dr. FOLEY. There will be both. You will have students who will choose in their second, third, or fourth year to accept scholarship, and we also have students who would choose in their first year as well. We don't know what percentage the split will be.

ADEQUACY OF SUPPLY OF NURSES

Senator SCHWEIKER. The administration has indicated in the past many times it considers current and future supplies of nurses to be adequate to meet the Nation's health care needs. Is this still the situation? And, if so, how does the Administration make this determination?

Dr. FOLEY. Senator, we have estimated that the number of nurses over the last 10 years has increased from approximately 722,000 to over 1,100,000. We have a current estimate for this year that there will be 1,152,000 nurses in the country, a ratio of 520 nurses to every 100,000 population.

I think the concern that you have here in the Congress and that we have, perhaps, is of a mutual nature, but not in terms of shortage. It is in terms of vacancies that are seen in hospitals in this country. And I think it would be foolish on our part not to recognize that those

vacancies do, in fact, occur. But it is the nature of what is going on both in the fields of nursing and hospital care in this country.

We have seen in the field of nursing that nursing salaries have not, in a real sense, grown since 1972. They have kept up with inflation but they have not had the same kind of increases that they had from the period 1965 through 1972. A lot of nurses have said, and surveys have indicated, that 57 percent of them have left the field because of wage dissatisfaction. We are also seeing strikes, such as the one in New York City around wages, where there is a tremendous pressure to raise the wages of nurses to keep them attracted to the hospital care setting, to acute care and intensive care wards, and also keep nurses on the swing shifts.

The second factor is that we have a morale problem in the hospitals themselves, in which the nurses oftentimes feel that they have not been appropriately respected—I am not saying in every hospital but in enough to make it disturbing. We are concerned, not only in terms of the morale but, as indicated, in the economic incentives. What we are seeing is that nurses are not staying in the field. We have nurses who, after we educate them, come out and practice for a couple of years, 2 or 3 years, and then leave the work force. They do not, in many cases, return to that work force, particularly if they are in their childbearing years. They stay out and take other jobs.

Let me be specific. We are finding examples in this country—recently I was in the Southeast—where it is more attractive for a nurse, an RN, not to practice as a nurse but to become a waitress in a hotel where she will make greater wages than she would in a particular hospital setting. The salaries are not competitive.

On top of that, we have a different phenomenon happening in the hospitals. While we have had vacancy rates increasing for RN's, at the same time we have been increasing the number of LPN's and orderlies in the hospital. We have seen these groups grow approximately—I believe the figure is from 500,000 to 1 million in the past 10 years.

So we have had a change in the work force that is providing services in the hospital. And we recognize that we are having significant vacancies and, more importantly, we are having a tremendous turnover rate. And that will not be solved by the production of more nurses. That will be solved by the field of nursing and the hospitals figuring out a way to attract and hold the nurses.

California this past year had a turnover rate in their hospitals of 48 percent of all their nurses who left for some other hospital or left the field for some other job. What we are concerned about, and I think what Congressmen were concerned about last year, was that a study be done of what the field of nursing can do about this; second, what is Government's appropriate role, and third, what is the appropriate role of hospitals, both in terms of salary and psychological incentives to keep nurses in practice.

HOSPITAL NURSE SHORTAGE

Senator SCHWEIKER. Dr. Foley, I really have trouble with the administration's analysis of the nursing program. In my work I visit quite a

few hospitals for one reason or another and I haven't been to one hospital in the last year or two that hasn't told me they have a nursing shortage.

Now, you mention the vacancies, but I can't see for the life of me how the administration can come back and say year after year that there is no shortage and this isn't a problem per se when every hospital I go to tells me there is one—they show me the want ads. They are offering bonuses of $100 to tip them off where a nurse is, and if they bring the nurse in there's a $300 bonus—like a bounty hunt.

I can't believe there isn't a nursing shortage in this country. I have never seen the Federal Government so insistent on something that just doesn't agree with what is happening at the grassroots.

Dr. FOLEY. Senator Schweiker, I say I recognize there are significant vacancy rates occurring in the hospitals. But that is not solved by an added production of nurses who leave the field.

Senator SCHWEIKER. You did say that, and I am trying to reconcile that with saying there is no shortage. How can we say there is no shortage if there are significant vacancies around? Maybe I'm not hearing you right and there is trouble with terminology. I know there are vacancies because people have lectured me as a person responsible for health shortages, "What are you doing about our nurses and how can you be so dumb as to not see there is a shortage?"

And I am using their words.

Dr. FOLEY. How do you produce so many nurses who leave the field? And how do you have enough so that the attrition rate is not significant?

Senator SCHWEIKER. Explain to me how you differentiate between the shortages you say do exist and the supply—you say there are plenty. I am mixed up with what you are telling me. It is like two different answers.

Dr. FOLEY. If we were constantly producing soldiers, for example, and not sending them into any kind of military duty, never sending them to the front, we'd say we have something wrong with our system. It is not going to help us by adding more numbers of soldiers who are going to go off to the sidelines and not go into battle.

We have the same problem with nursing. We produce more and more at a couple of levels, diploma levels, RN–BS, and multiple community colleges that have 2- and 3-year programs. We are not suffering from lack of production. We are just not holding them in the hospital setting once they are produced.

And I am suggesting to you it is not only a wage phenomenon but a psychological phenomenon. It is difficult work; nurses are oftentimes not respected; nurses work horrendous hours. And we still keep adding and adding as if, if we add 200,000, the vacancies would disappear.

I am suggesting that even if we produce 200,000 more, the vacancies will occur, because after they are out for 2 years they find alternative jobs that pay much more money, that are much more decent in terms of living. Why should someone have to go on a swing shift and be paid $11,000 in Florida when she can work 8 hours as a waitress and make $14,000.

Senator SCHWEIKER. I concur with your analysis of the shortage problem, and maybe we should be talking about the shortage problem and not the other problem, because by saying the supply is adequate and the numbers are OK we convey the impression that everything is OK.

Dr. FOLEY. Senator, I think that terminology has probably not been helpful to a really intelligent discussion of what is happening in nursing.

Senator SCHWEIKER. It sure hasn't, because they laugh at the administration's health policy in nursing. There isn't a hospital I go to that doesn't laugh at it and wonder what is wrong.

Dr. FOLEY. We have been supportive of your direction to have the Institute of Medicine study this particular area, because, if the terminology that has been used is only accurate to a few people who understand what they are talking about, it doesn't communicate to everyone.

ASPECTS OF THE NURSING SHORTAGE PROBLEM

Senator SCHWEIKER. I understand some of what you are saying here today, but it is difficult to send those two messages out simultaneously and think people will understand your point. I think your point on why the vacancies are occurring is quite valid because, as I said, I just met with the Pennsylvania hospital people this week—and they produce 10 percent of the country's nurse supply. That's probably 40 percent above Pennsylvania's quota in terms of our population. But that is now going down. We are no longer going to be able to do that, and part of that is because the diploma schools are dropping out and the baccalaureate schools are not picking up the difference. For a while they did, but they are not any more.

So you are going to be caught with a double-whammy here, the vacancy problem caused by the pay and the rise in other emoluments for other occupations where they get better pay. I completely concur with your analysis that pay is one of the major aspects of the problem.

But when you look at the figures in Pennsylvania where they have been producing 10 percent, they are doing just the opposite. They are not going to produce the number in place any more that you say for x years we have been doing. That is now dropping. And that is what is so scary—because, in addition to the shortage problem that you did speak of, we are now, at least in Pennsylvania, dropping in terms of the sheer numbers of input besides, this is going to make the matter worse.

And unfortunately, part of the problem is that there is a fight going on in the profession between baccalaureate degree people and diploma people. I don't want to get into that fight because that is another day and another battle. But that is going to make the problem even worse, because by looking down our nose and shunning the diploma nurse, we are creating an even worse problem, in my judgment.

Dr. FOLEY. Senator, I share that with you. I think the terminology that has been used is inappropriate. When they talk about "shortage," they look at numbers and supply and demand, but not necessarily at vacancies. And when people translate the vacancies out there as shortage, that is terminology a layman might use.

Senator SCHWEIKER. Not just a layman. A vacancy would mean a shortage to me.

Dr. FOLEY. But not necessarily to an economist, and they write statements about this. I think we need new terminologies to address the issue of what is happening in the field of nursing. But what I am suggesting to you is that increased production of more nurses, given what we are producing now, will not solve that problem.

Senator SCHWEIKER. I'd probably concede that, except that production is, in fact, declining.

Dr. FOLEY. Of the RN's.

Senator SCHWEIKER. Of the RN's. They are dipping now, where for some years they'd been going up. So in addition to the financial problem, which I think you analyzed quite correctly, you have this other fact now, that even the input is dipping. It is no longer even holding its own, in Pennsylvania anyway.

NURSE PRODUCTION VERSUS SUBSTITUTION

Dr. FOLEY. We have seen that. It is somewhere in the 5- or 10-percent range this year in entering classes at the undergraduate level. There is a decrease; we recognize that. All we are suggesting to you, though—or at least I think it's quite possible—is that hospitals are basically involved in a substitution process, too. When you expand the number we have in this country over the last 10 years, some hospitals are choosing to use an LPN because that is where they think they can hope to use them instead of RN's whether they come through the diploma program or B.S. programs.

The other problem we have is that we train nurses 4 years in some schools who never see a patient, take their exams, and then go out and find out what nursing really is all about, which is a contrast to the old diploma programs. And they go into intensive care units where they are really technicians dealing with parts of bodies—there's a whole person there, clearly, but it is a different kind of work; it is very difficult. If they go onto a ward situation, they suddenly find out that what they were trained to do is not, in fact, what they are doing.

And we talk to nurses who say, "What can we do, together, about that? What can we do as nursing faculty so that nurses have role models that know how to practice nursing? And is that attractive enough to them?"

And can we increase the number of males becoming nurses, as well? We seem to have done well in getting a third of the classes for physicians to be women. Can we reverse it for nurses? Except for that little bulge after Vietnam of picking up nurses who were orderlies, we haven't seen that increase in males. I suggest it is because males, as well as females, are wising up.

Senator SCHWEIKER. We will have to draft male nurses; right? That's the answer. [Laughter.]

NURSING PROGRAM DECREASES

You do say in your backup statement something that elaborates on what you are telling me, that the distribution of nurses, retention of trained nurses, is a serious problem. I am not going to argue with that.

But what disturbs me as I go through the backup book is that when we come to the budget for nursing special projects, there is a $5 million cut there, which relates to the distribution situation. And then we go to nursing loans, and there is a $13 million cut, which is going to redirect the scholarships, supposedly. Then you go to scholarships and there is a $9 million cut.

So let's assume that your definition, economically, is quite technically accurate, although I think it's confusing. But let's assume it is accurate. Are we then doing the right thing—$5 million cut in nursing projects, $13 million cut in nursing loans, and a $9 million cut in scholarships, a $13 million cut in nursing professional traineeships. I don't understand it.

Dr. FOLEY. Senator, can I reverse the order, if I might?

Senator SCHWEIKER. Sure.

Dr. FOLEY. Let's take the scholarships first. There the narrative is addressing the question of the use of the National Health Service Corps scholarships for nurses so that the nurses would be—at least they should be—placed in service areas. It says "scholarships," doesn't it? It is supposed to be the National Health Service Corps scholarships basically.

What we are suggesting in the area of scholarships and loans, is that normal educational scholarships and loans for nursing students, would come out of the Department of Education.

Senator SCHWEIKER. We have some different understanding here. It is pure scholarships there.

Dr. FOLEY. I am addressing the rationale. We are saying, basically, that with the nursing scholarships a student has one of two options for loan programs, either go to the Department of Education for programs that are there, or come to the National Health Service Corps scholarship program for a service commitment. But these particular program directions we had before, which were of a specific categorical nature in nursing as such, we are not supporting.

Senator SCHWEIKER. For all the elaboration you gave me on the shortages and the shift in the profession, we are still cutting an awful lot out.

Dr. FOLEY. Well, we are cutting out, in our specific categorical support at the graduate-level, programs for nurses through the Health Resources Administration. We are saying that in those programs in the Department of Education that are open to all students, they can compete for those scholarships. The reason for the cut in special projects is simply, frankly, a budgetary decision, given the priorities.

Senator SCHWEIKER. All right, now we are getting down to it. If you had said that in the first place I'd have understood. [Laughter.]

Dr. FOLEY. The difference is spelled out in the terms of the rationale for loans and scholarships. This would be the special projects. The special projects amount is a decision. Within the resources we have and the priorities we have, we could not support it at a level that others might find desirable, but this is a sum we think is realistic, that we can spend well, and, given the other types of priorities and service programs, this is the budget we have.

NURSE RECRUITMENT BONUSES

Senator SCHWEIKER. You start adding up how many hospitals are offering a $100 bounty and a $300 bounty to someone for whispering who the next nurse is and I wonder what that costs in resources. We talk about cost containment, saving, and all that, and you cut all this out here, and the end result is to have the system spend $100 or $300, saying, "Hey, if you can tell me where the next nurse is coming from, you'll get a $300 bonus," which is what they are offering.

I have to believe there is a terrific cost impact there that is built into the whole system, that we are paying for as third-party payers. I wonder if you have any knowledge of what that is running.

I was astounded when I heard of these bonuses. If you recommend a nurse there and she is accepted, you get a $300 bonus.

Dr. FOLEY. I would rather see the hospitals raise the salaries for the nurses and use the newspapers, et cetera, to attract those nurses. It is a concern when you start to see that 10,000 nurses now are nurse recruiters. That isn't what they were trained to do. That is basically an administrative position.

So I really think the question is: Why that particular mechanism? Why not hit the real issue straight on, which is not to hold nurses' salaries to 3- to 4-percent increases when they are at such a pitifully low level now—which some hospitals have done—but make their cuts for cost containment in other parts of the hospital.

Senator SCHWEIKER. In our cost containment figures and the savings we envision from cost containment, can we put a 25-percent increase in nurses' salaries into effect? Could we really put that into the balance sheet of all the money we are going to save in cost containment?

Dr. FOLEY. I don't think we have done it in the Congress or Administration's discussions, nor the voluntary effort.

NURSE SALARIES

Senator SCHWEIKER. No; we talked about all this voluntary saving, but here's a case where somebody is going to have to spend some money, whether it's the Government or the private sector, or probably both. Because I think your analysis about salary is probably right; I won't argue that. What would we project the nurse salary ought to be roughly? I know it's a regional thing.

Dr. FOLEY. It is regional. The average for the country is about $13,000. What we have seen since 1972 is that the salary level for the beginning nurse has been increased by many hospitals, but it has not been increased for the experienced nurse whom we want to hold on to. One State close to your own is considering raising the salary—currently it's $16,000 and they are going to raise it to $19,000 and go to $21,000. So you're talking about a fairly significant percentage increase in that area.

We do know in some other countries they had similar problems. Israel recently raised its nurses' salaries—and they must have been incredibly low—and they had the same problem of turnover—70-percent real dollars above inflation. It is a very significant increase and they

have now found, 6 months later, that they are holding their nurses in the hospitals. I think we have to wrestle with that in the Institute of Medicine's study that we will be a part of.

Senator SCHWEIKER. When are we going to have that study?

Dr. FOLEY. Well, we will have it over the next 2 years.

Senator SCHWEIKER. How is that being financed?

Dr. FOLEY. It is being financed by a reprograming of funds to the tune of $750,000 to conduct this study.

Dr. Walsh?

Dr. WALSH. From nursing capitation.

Senator SCHWEIKER. We don't have any reprograming?

Dr. FOLEY. The request has not reached you yet. Dr. Richmond has signed off on it.

Senator SCHWEIKER. You can't blame us for holding up on it again.

Dr. FOLEY. No, I'd like to but I can't. [Laughter.]

ADVANCED NURSE TRAINING

Senator SCHWEIKER. Following on here, on advanced nurse training, recent reports indicate there is a strong effort underway to train more nurses at the graduate level but that there is a long wait for admission to graduate programs. And in light of that, how do we justify the Administration's budget request of zero for the advanced nurse training program?

Dr. FOLEY. Well, we expect that the schools will seek out other resources to support their faculty for advanced nurse training so that, basically, the faculty teachers will be trained nurses in these particular areas and will also train the nurses who want to go into research in that area. It is really not a question of the Federal Government any more, but what other sources of funding become available.

NURSING RESEARCH

Senator SCHWEIKER. And you also zeroed the nursing research—the Administration again is requesting no funds for nursing research.

Dr. FOLEY. The Administration here is taking the position, Senator, that nursing research, the items that are researched under this category, legitimate items that they are, are not necessarily categorical in nature. That is to say, they are not categorical to nursing. They are issues of how one, for example, would treat a long-term-care patient, a chronically ill patient, and that that research should be conducted under the National Institutes of Health, that the research protocol should go to them.

Senator SCHWEIKER. Let me say they are not doing anything either. We have virtually zero money there in terms of nursing research.

Dr. FOLEY. Senator, the nature of the research itself isn't nurse research. It is research that is going to affect the delivery of health care services, part of which nurses might provide or part of which doctors might provide or which they might provide together in teams. And if you will look at what we have funded under that title over the last years, that has been the area. What we are concerned about is that

there be nurses placed on the review committees at the National Institutes of Health—and Dr. Fredrickson has taken steps to do that—so their applications will receive due consideration in that situation.

Senator SCHWEIKER. I hope we have done something. Staff says that out of several thousand people we have placed four nurses in that review process.

Dr. FOLEY. We have taken a tiny step. [Laughter.]

We could take a much greater stride. I think Dr. Fredrickson would like to do that, frankly.

We are not dodging this issue. There is a legitimate concern that research items, particularly in regard to patient care, ought to be directed to the National Institutes of Health or the National Center for Health Services Research.

Senator SCHWEIKER. I am glad you took the step. You are honest in saying it was a tiny step. The thing is, you pointed very eloquently to the economic factor with regard to nurse professionals, and I think you're right. I have just got to believe that the prestige and status that we give nurses today is another part of the same thing. And it just seems to me here is one area the Government could be very helpful in to give the nursing profession prestige and status.

So I hope you will take a few more tiny steps, maybe even a big step. But I think you are going in the right direction.

Up to now nothing had been done, so I have to give you some credit for that.

Dr. RICHMOND. I would just add, Senator, that recently the pool from which to draw for people who review grant applications in this kind of research, and even who submit them, has been relatively small. We are gratified that this pool is growing. It is more realistic with regard to various study sections.

NURSE-ANESTHETIST PROGRAM

Senator SCHWEIKER. I notice that the new program for nurse-anesthetists is one of the very few nursing programs that you do plan to continue. I'd just like to know what rationale is behind this program in view of the fact we are and zeroing out almost every other nurse program we've got. Why should we invest in this program?

Dr. FOLEY. I'd like to ask Dr. Whiteside to respond to that. [Laughter.]

Senator SCHWEIKER. All right, Doctor, you heard the signal.

Dr. WHITESIDE. Let's see if I can get the boss in trouble. [Laughter.]

The current supply of nurse-anesthetists in this country is about 15,000 currently active, and our estimate of the number that might be reasonably employed and used in hospitals to deliver anesthesia would be someplace between 22,000 and 25,000.

Senator SCHWEIKER. What is the number?

Dr. WHITESIDE. Between 22,000 and 25,000.

Senator SCHWEIKER. The present supply is 50,000?

Dr. WHITESIDE. 15,000.

Senator SCHWEIKER. And give me the next figure.

Dr. WHITESIDE. Between 22,000 to 25,000.

Senator SCHWEIKER. Go ahead.

61-400 O - 80 - 56

Dr. WHITESIDE. Since there's a clear need for that kind of person, particularly in small hospitals around the country, it seems to us that to begin to train some of those people to perform those functions is a reasonable thing.

Senator SCHWEIKER. Well, is this the same argument, though, that Dr. Foley was making? Is it because we are not paying these people enough and they are leaving? Why should we input them and train them if we are not paying them enough? He made the point very eloquently on the other cases.

NURSE-ANESTHETIST SALARIES

Dr. WHITESIDE. The nurse-anesthetist is considerably better paid than a nurse, their annual earnings range from $16,000 to $20,000.

Dr. RICHMOND. I think, Senator, there is another kind of problem. Over recent decades we have moved rather heavily into the position of nurse-anesthetists, and I think there is the growing recognition that to move in that direction predominantly—I think this is an effort to make an accommodation to what the need seems to be—we really need to train more nurse-anesthetists.

Senator SCHWEIKER. Is there any other health professional who substitutes for the nurse in these kinds of situations?

Dr. WHITESIDE. You could have an anesthesiologist—a physician especially trained in anesthesiology.

Senator SCHWEIKER. But, of course, he is a much higher paid person.

Dr. WHITESIDE. Yes, indeed.

Dr. RICHMOND. That is one of the points, Senator, that we have gone in the direction of turning out more physician-anesthetists, and we think that that is a rather costly direction to go, and if we can train nurse-anesthetists, particularly to work with physician-anesthesiologists, we can do that. It is very difficult to recruit physician-anesthetists.

Senator SCHWEIKER. I see your point. I wish we'd apply it to the other points about input. In other words, if I can see it there, I think we ought to apply it to the other ones, too. Because training nurses, you know, just lets a doctor go that far with his regular health care delivery aside from the anesthesia.

NURSE-PRACTITIONERS

Dr. RICHMOND. But the companion piece in the budget, Senator, is a modest increase in the training for nurse-practitioners. So we are trying to target this where we think there is a very important service.

Senator SCHWEIKER. Dr. Richmond, what progress are we making with nurse-practitioners? Do you have any figures on that?

Dr. RICHMOND. Do you have the numbers?

Senator SCHWEIKER. I think that is a very relevant question.

Dr. WHITESIDE. We have a supply of 16,000 trained nurse-practitioners.

Senator SCHWEIKER. Do we have any projection of what, theoretically, we could do to make the system more efficient or what potential there is to utilize resources better?

Dr. WHITESIDE. Yes; in the second report to Congress that was done

on nursing there was an estimate made that by 1982—and this is a very wide range—between 27,000 and 57,000 nurse-practitioners could be employed in this country.

Senator SCHWEIKER. Do they save money in terms of cost in the system? Do we have an estimate on what we are saving?

Dr. FOLEY. Senator, we find that oftentimes the nurse-practitioner, in contrast to the physician-extender, practices in areas where there are no physicians, but they have monthly supervision by a physician who will come in. And many of these nurse-practitioners have been recruited.

NURSE-PRACTITIONER COMPARED WITH PHYSICIAN-EXTENDER

Senator SCHWEIKER. Explain to me why the nurse-practitioner practices and a physician-extender doesn't. Did you say that?

Dr. FOLEY. Yes.

Senator SCHWEIKER. Do they have to work more directly under the direction of a physician, or what is the reason?

Dr. FOLEY. No, the nurse-practitioner does have more flexibility on delivering health care service than the physician-extender because of their training, the quality of difference in training. But the critical difference is that States have different licensing acts which allow reimbursement for nurse-practitioners in solo practice but with supervision of a physician, even if it is at a distance, whereas in the case of physician-extenders there is much more restriction on that.

And our studies show that the physician-extender is often used as part of a team in the doctor's office, helping out in delivering services, but it doesn't necessarily result in cost savings. It results, perhaps, in better care. Whereas the nurse-practitioner has much more flexibility to practice solo, and the State licensing acts allow for that and allow reimbursement for that.

We have under our own medicare-medicaid statute allowed for reimbursement of nurse-practitioners in rural clinics if the States have a law licensing them.

Senator SCHWEIKER. Wouldn't a nurse-practitioner allow physicians to see more patients per hour, for example?

Dr. FOLEY. Yes.

Senator SCHWEIKER. You could save money there.

Dr. FOLEY. Not necessarily. But it is more of a team use of that position.

Senator SCHWEIKER. All right. We do have some more questions for the record and we will submit them. We thank your witnesses, including Dr. Richmond as well as Dr. Foley and the others.

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

REDUCING COSTS AND EFFECTIVE RESOURCE UTILIZATION

Question: What has been the impact of these agencies in reducing costs and inducing effective resource utilization?

Answer: Perhaps the most visible and dramatic impact of the program has been in the area of reducing excess capital expenditures. Total capital expenditure approvals were estimated to be about $4.7 billion for 1979 - a significant decrease from the level of $5.2 billion for the previous year, particularly in view of inflation.

Also dramatic has been the reduction in the level of increase of hospital beds. Estimates that the net increase in hospital beds for 1979 will total 3,800 are far below net increases in previous years of more than 10,000 beds annually.

Control of capital expenditure investment, however, is only one aspect of planning agency functions. Some 96 percent of the local agencies' first year plans include other types of cost containment goals and objectives which are designed to promote a shift in third party reimbursement toward less costly health care alternatives; the development of multi-institutional arrangements for sharing services; and the regionalization of services. For example:

- The number of ICHSA Area hospitals with established formal multi-institutional sharing and/or contracting arrangements for administrative services should be increased from the current level of 3 (15 percent) to 20 (100 percent). - Illinois Central HSA

- A regionally stratified and integrated system of care for the delivery of highly specialized hospital services ... which links the hospitals providing only basic services with those of increasing complexity, thus minimizing costs and enhancing quality of care provided. - Southwest Washington HSA

REDUCTION OF OVER-BEDDING AND EXCESS SERVICES

Question: To what extent do Health Systems Agencies and State Health Planning and Development Agencies effect reduction in over-bedding and excess services in health institutions? Have you any statistics on these demonstration projects to date?

Answer: State Health Planning and Development Agencies (SHPDAs) and Health Systems Agencies (HSAs) are actively pursuing strategies that promote the Administration's policy of health care cost containment. Working with business and community leaders, health care providers and legislators, they are helping promulgate programs to contain costs. The processes of certificate of need negotiation and disapproval are constraining capital investments in new facilities and services, while other actions of the agencies are rationalizing the allocation and utilization of resources by promoting such things as mergers, closures and sharing of services. For example:

- The State of Michigan is implementing its bed reduction legislation that calls for the elimination of 3,800 beds (10 percent of its acute care bed supply). A unique "Coalition on Health Care Costs," comprised of the big four auto makers, UAW, Blue Cross/Blue Shield and the legislative and executive branches of State government made this legislative mandate possible. The process on the local level will be conducted by the HSAs with full public participation and by June 1980 the SHCC, with this local HSA input, will have adopted an institution-specific hospital bed reduction plan. After that date no certificate of needs will be issued that are inconsistent with this plan and in the meantime, a moratorium on certificate of needs is expected in all over-bedded areas.

- The Finger Lakes HSA is participating in an experimental pilot project, Maxicap, whose purpose is the development of a prospective payment methodology for hospitals which will take into account estimates of the need for services as established by the HSA. The project, now in Phase II, is of national significance since it has the potential of demonstrating improvement in cost-effectiveness of hospital services by linking their reimbursement with community need.

- The Newark, New Jersey HSA adopted a Pediatric Service Plan based on the Federal guidelines and a staff needs assessment study. The HSA has since negotiated the closure of 32 pediatric beds with closure of another 22 beds expected in the near future. A perinatal services plan, in conjunction with State regulations, set the framework for a regional perinatal care network. After many discussions three underutilized units totalling 31 beds have been closed and two other planned closures would eliminate another 40 excess beds.

- The Puget Sound HSA was instrumental in bringing about the merger of three major Seattle hospitals - Swedish, Doctors and Seattle General. The merger eliminates 160 excess beds and reduces the community's health care costs by about $1.5 million a year by preventing duplicative construction; consolidating obstetrical services at one hospital; and through consolidating of staffing, administration, physical plant, purchasing, etc.

ALTERNATIVES TO INPATIENT CARE

Question: What alternatives to inpatient care are the agencies promoting--and are they reasonably successful in reducing costs after implementation? For example, alternative uses of ambulatory and long-term care?

Answer: Health Systems Agencies (HSAs) have included in their Health Systems Plans goals calling for the development of primary care services, the development of Health Maintenance Organizations (HMOs) and other types of prepaid group practices as well as alternatives to institutional care for the mentally ill and for our elderly.

Many HSAs have undertaken initiatives in these areas. For example:

- Orange County, California lacks accessible primary care for its sizable concentration of Indochinese refugees and large number of undocumented immigrants. One initiative the HSA has undertaken is the implementation of a special Annual Implementation Plan (AIP) priority establishing the Santa Ana Health Care Authority, a citywide authority whose goals are the development of a primary care network to serve the needs of the barrio and other underserved populations. The same AIP priority also calls for creation of a self-insurance benefit program for local employers, and the establishment of a prepaid health insurance plan for city residents and employees.

- The Southeast Michigan HSA supported and gave technical assistance to the Black-Polish Alliance Council in its efforts to get outpatient services in two Detroit areas. As a result of the HSA enlisting various community organizations, support of this project has culminated in a Federally-funded HMO.

- Some State agencies and HSAs are undertaking joint initiatives to shift resources towards community-based mental health programs. In Massachusetts, for example, the Statewide Health Coordinating Council (SHCC) and the HSAs across the State have been supporting the joint goal of the State Department of Mental Health and the SHPDA to shift mental health resources toward community-based programs. The planning agencies have supported State legislation to shift budget monies towards local programs; have worked with local government, agencies and communities to reduce resistance to community-based care, and have been working with these same groups to assure that local and regional programs are available for the deinstitutionalized patient.

Home health services and other alternatives to institutional care, and expanded housing, transportation, and other services are among the broad areas addressed by HSA plan goals and objectives; and most agencies have goals and objectives in several such areas related to care for the elderly. HSAs are also undertaking initiatives to promote the development and funding of alternatives to institutional care. For example:

- In Broome County, New York, the interstate NY-Penn HSA is playing a pivotal role in the development of a home health care project. The agency provided major technical assistance during the development of a Federal funding assistance application and facilitated the development of a community-based board to sponsor the project.

- The Bergen-Passaic HSA developed a congregate living program as an alternative setting for the frail elderly. An option on a facility to be converted for group living has been

obtained and the HSA is presently screening sponsors to manage the project. The agency is also working with a community group to establish and obtain Bergen County funding of a similar facility for multiple-handicapped persons.

HSAs are also promoting cost containment by shifting third-party reimbursement from traditional health care delivery models towards alternative care programs. For example, one HSP goal states:

- o Third-party payors should be encouraged to cover additional outpatient services as a means of containing costs by reducing inpatient stays, especially in the areas of substance abuse, mental illness, and rehabilitation. - HSA for Summit Portage County (Akron, Ohio)

GOVERNING BOARDS: REPRESENTATIVENESS

Question: When is a group actively solicited for representation?

Answer: Many agencies use an appointment process to select their governing boards. Such a process frequently involves the identification of a specific organization or group in the community which is designated to provide a representative to the board. Such groups are usually provider or consumer associations such as the local medical society or hospital association and the local labor council or association of retired citizens. In addition, because of the statutory requirement that a board be broadly representative of the principal social, economic, linquistic, handicapped and racial populations of the health service area, an HSA frequently will stipulate that a seat on its board be reserved for a member or representative of a specific population group.

Boards are further required to include public elected officials and other representatives of units of general purpose local government and most HSAs have made a concerted effort to ensure that these representatives are members of their boards.

Question: What steps are taken if a board is clearly heavily favoring one group or another?

Answer: The health planning law requires that all governing boards must have a consumer majority of at least 51%. The percentage may not exceed 60%. Any board which is found not to have a consumer majority is considered to be in serious violation of the statute and immediate corrective action is required. Failure of an agency to initiate this corrective action would result in a notification to the agency by the Department that its designation agreement must be terminated.

Besides the requirement for a numerical majority of consumers on an HSA board, the statute contains several other provisions which are intended to enhance the effective participation of consumers in the planning process. A frequently cited reason for provider domination of the planning process is the disparity in knowledge

between consumers and providers. The amendments to the planning law emphasized the need to increase staff support to governing body members, especially consumer members. The Department had strongly endorsed the establishment of a staff liaison for board members in a directive to the planning agencies prior to the legislative amendments. With the necessary authority enacted, the Department will enforce the designation of a staff person in each HSA who is responsible for this function.

HSAs are also strongly encouraged to have a training and orientation plan for board members designed to address in particular the specific issues in their health service area. In addition, in recently redirecting the overall technical assistance efforts of the Centers for Health Planning, the Department has requested that the Centers are to give increased emphasis to developing materials that will assist HSAs in meeting their training responsibilities.

The new mandate that at least one-half of the members of a governing body must be selected by a method other than by the existing members of the governing body is expected to result in boards which are representative of their communities and which have greater accountability to the groups which individual members represent.

Agency activities with respect to ensuring the effective participation of consumers in the business of the HSA and in ensuring that board education and training activities are conducted by HSAs are closely monitored by the regional offices of the Department. Appropriate corrective action is required by the agency and technical assistance is provided by the Department or its agents when deficiencies are identified in this area.

Question: Will the 1979 requirements in the makeup and representation of HSAs impose a serious burden on these agencies as some have charged?

Answer: The amendments added an additional population group, the handicapped, to be represented on an HSA's governing body. The other groups to be represented, which are unchanged from the previous requirements, are economic, social, racial and linguistic groups. The additional representation requirement will pose the same types of issues which have arisen in response to the broadly representative requirement. These issues consist of questions on accountability and what adequate representation on an HSA's governing body is for any particular population group.

The amendments also introduce a requirement for the selection of governing body members. They provide that not more than one-half of the governing body may be selected by the governing body itself. This will require that some HSAs change their selection procedures through modification of their bylaws. We expect that HSAs will be able to implement this requirement effectively. Again, however, the issues of accountability and representation will continue to be debated in the community.

HEALTH CARE COSTS SAVINGS

Question: What is the estimated national saving in health care costs due to the health planning program created by the Health Planning and Resources Development Act?

Answer: Capital expenditure reviews by the agencies are having an impact on the rate of increase of health care costs. During the first six months of calendar year 1979, capital expenditures for which we have data were $2.4 billion. Projected for the year, the total 1979 level would reach $4.8 billion. This is a significant decrease from the prior year levels of expenditures of $5.2 billion, particularly if inflation is taken into account since these are not constant dollars.

Question: Do you collect your own data now or still use that of the professional interest group, the American Health Planning Association?

Answer: The Bureau collected aggregate data from January through June, 1979, which reflected the impact of the agencies. The final report of this six months data is available to the Committee. In July, 1979, the Bureau began to collect impact data which includes each project considered by the agencies. Periodic reports will be prepared from this data and made available to the Committee.

DESIGNATION OF PLANNING AGENCIES

Question: Has completion of the designation process taken longer than expected? Why is this?

Answer: The Congress authorized a period of 36 months for the Health Systems Agencies (HSAs) to attain full designation status. To date 198 of the 204 HSAs have completed the process and received full designation status.

Currently only 37 of the State Health Planning and Development Agencies (SHPDAs) have attained full designation status. The process has proven longer than anticipated. The primary obstacles in completing the process are: inability of the State to enact a Certificate of Need program which meets Federal requirements; and the absence of a Statewide Health Coordinating Council (SHCC).

Question: What criteria are used in awarding designation to SHPDAs and are they similar in every case?

Answer: The following three major uniformly applied criterions are used in determining the designation of SHPDAs.

1. Adoption of a State Health Plan which meets the requirements of the Act, implementing regulations and State Health Plan Guidelines as issued by the Bureau in August 1978.

2. Establishment of Certificate of Need program which is satisfactory to the Secretary.

3. The establishment of a Statewide Health Coordinating Council (SHCC) which meets the requirments of section 1524 of the Act.

IMPACT OF PLANNING AGENCIES ON DELIVERY OF HEALTH CARE

Question: Dr. Foley, at the time the President signed the new health planning law last year, you said that various analyses showed that the decisions of the health planning agencies "are having significant and growing impact on the delivery of health care in America." What specific decisions and accomplishments can you cite to back up such a statement?

Answer: Local Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) specifically are supporting the Administration's cost containment efforts by helping to hold down capital expenditures by hospitals and reduce the unnecessary duplication of expensive health care facilities and services. They also are reinforcing and promoting other Administration health priorities and initiatives.

Primary Care: Beyond cost control, three-fourths of the Health Systems Agencies have included goals calling for increased accessibility and availability of primary care services for underserved populations. For example:

- The Miami, Florida HSA was instrumental in the establishment of Community Health of Southern Dade, Inc., a primary care center with an operating budget now in excess of $6 million annually. Most of the indigent and migrant farm workers in southern Dade County receive care through this center or its satellite, Martin Luther King Clinica Campecina.

HSAs have helped place more than 1,000 National Health Service Corps personnel in areas where they are needed, and they also have been instrumental in facilitating the development of health manpower residency programs and working to assure the availability of rural health facilities and services.

Maternal and Child Health: Nearly all, 96 percent, of the Health Systems Plans (HSPs) contain goals and objectives which focus on such priority areas as reducing infant mortality, improving both perinatal and pediatric services; and providing education regarding all aspects of natality.

Some HSAs have undertaken initiatives to attack the high infant mortality rates of their communities. For example:

- In developing its HSP the West Central Illinois HSA uncovered information that the highest infant mortality rate in Illinois existed in a ghetto area in central Springfield. The HSA working with the community and the city's health department worked to obtain increased City Council funding to establish a special nurse practitioner program for these neighborhoods. The additional funds have been granted and

in 1979, several minority nurse practitioners began providing intensive neighborhood maternal and child health services.

Health Maintenance Organization (HMO) Development: HSAs and, in a few instances, State agencies are taking actions and bringing about results that promote the development of HMOs. HSAs have also fostered the spread and strengthening of HMOs and in other ways stimulated and assisted with HMO development. For example:

- An Annual Implementation Plan (AIP) objective of the Orange County HSA was realized with the recent purchase of Canyon General Hospital by the Kaiser-Permanente HMO. The agency intervened to help persuade the hospital it was in the community's interest to allow the HMO to acquire existing beds thus saving $15-$25 million in construction costs, and avoiding both a lapse in services and the building of 200 new beds in this populous southern California county which has excess beds and low occupancy rates.

- By acting as a catalyst and providing technical assistance, the Southeastern Massachusetts HSA initiated the development of an HMO which will serve some 18-20,000 people in the Middleboro area; and the Western Massachusetts HSA served as a catalyst for a four hospital consortium to develop an HMO in the Springfield area.

Disease Prevention and Health Promotion: Ninety-six percent of the HSAs also include disease prevention and health promotion in their plans, and these touch on almost every aspect of life - from improving water quality to eliminating safety hazards in work places. HSAs have been supporting actions to increase immunization levels, too, and have sponsored health fairs and other activities to provide education about and screening for potential health problems. For example:

- The Phoenix, Arizona HSA has been working with the major employers, Motorola Corp. and General Electric Company, in its health service area to identify the population-at-risk in their plants. Following identification of the health problems the HSA helped the industries design special health education programs to meet the needs of their at-risk populations.

- Over the past year the HSA in Maumee, Ohio has been working with city, county and State governments to increase immunization levels for children. One of the heavily populated counties, for instance, had immunization levels below 65 percent. This county and every county in the health service area now has at least 95 percent compliance with child immunization standards.

- The Central Indiana HSA, for the second consecutive year, joined Blue Cross and Blue Shield in sponsoring the Central Indiana Health Fair. Held in downtown Indianapolis, the fair drew over 35,000 participants and nearly 100 exhibitors

offered informational presentations and free health tests for diabetes, cancer, sickle cell anemia, hypertension, vision and hearing.

Question: How will the new law affect the effort to expand the nation's system of Community Mental Health Centers and HMOs?

Answer: In regard to Community Mental Health Centers, the new legislation will compel health planning agencies to examine all mental services being provided in their areas and determine the adequacy of these services in terms of accessibility, availability, acceptability, cost, quality and continuity. If mental health services are lacking or inadequate, the HSA will work with the community, both consumers and providers to encourage that mental health services are brought up to standard in the area, including adequate Community Mental Health Centers.

The new amendments clearly recognize HMO's as a viable alternative in the delivery of health care. In order to foster establishing such programs, the Congress exempted from review certain HMO's, combinations of HMO's, and health care facilities controlled or leased by HMOs.

EXPANDING THE PLANNING PROCESS

Question: We often hear talk of drawing Federal Hospitals, namely the VA and DOD facilities, into the health planning process that all civilian hospitals participate in. Are you aware of any studies that have explored the advantages and disadvantages of such action? If so, what do they recommend? If there has not been such a study, do you suggest that we direct HEW to conduct one?

Answer: A six month study of the U.S. Public Health Service Hospitals conducted by an Ad Hoc Advisory Committee appointed by the Secretary, HEW in 1978, took into account the function of the PHS hospitals within the planning framework of the communities in which they are located. Based upon the Report of the Committee, the Secretary concluded that the same guidelines, planning standards, and cost containment measures established for the non-Federal sector through the health planning process will apply to the PHS hospitals.

The Academy of Sciences and the GAO have conducted studies which address the negative and positive aspects of the inclusion of the VA and DOD facilities into the health planning process. Both studies concluded that the VA and DOD facilities should be subject to the same process as facilities in the non-Federal sector. Implementation of these findings would require Congressional action or the Establishment of Interdepartmental Agreements. Potential for effecting such agreements is not good since neither the VA or DOD concur with the findings.

PERFORMANCE EVALUATION

Question: What measure of performance evaluation does the Health Resources Administration apply to Health Systems Agencies and State Health Planning and Development Agencies?

Answer: During the past year we have progressed markedly in the development of a more comprehensive and coordinated reporting system. In designing these efforts, we have been careful not to place unnecessary or duplication reporting burdens on the agencies. In fact, most of these activities require no further reporting systems by agencies. Among the new steps taken in this regard have been:

- The institution of a formal Performance Evaluation Program (PEP), initially with contractor assistance, designed to measure the impact of the health planning program with respect to specific, selected health system objectives, such as those expressed in agencies' HSPs and SHPs, Section 1501 priorities, and the National Health Planning Guidelines and goals.

- The development of measurable program objectives that will provide Congress and others as well as the program's managers with a better basis for assessing progress (and problems). It is anticipated that a preliminary or initial set of measurable objectives based on selected National Health Planning guidelines and goals, will be in place, with baseline data established for those, some time this year.

- Near completion of a set of outcome-oriented HSA performance standards to be used in assessing the performance of individual agencies. These also should be implemented this year.

- Establishment of a comprehensive tracking system to provide early warning on agencies with problems which may offset the designation decisions. This system, coupled with our interest in providing rapid and effective technical assistance, should help us improve agency performance.

- Establishment of AGPLAN - a computerized system for collecting information on the types of goals and objectives which agencies are including in their Health Systems Plans.

FUNDING CHANGES

Question: Will the changes in funding levels authorized under the 1979 Amendments provide real assistance to large HSAs serving sparsely populated areas, especially considering the increased costs of travel in such regions?

Answer: We hope to implement the discretionary funding authority by issuing final regulations as soon as possible. These regulations will describe the manner by which we will distribute these funds for this first year. Initially, we will hope to

distribute $1.7 million of discretionary funds to HSAs serving (1) large geographic areas; (2) interstate health service areas, and/or (3) large medically underserved populations. An estimated 122 HSAs would be eligible for these discretionary funds under one or more of these categories.

With regard to HSAs serving large geographic areas, these additional funds are intended to help defray high travel expenses, the costs of stationing staff in subareas and other "distance related" expenses associated with large service areas.

PROBLEM AREAS FOR HSAs

Question: Which particular function do local health planning agencies -- the HSAs -- appear to have the most trouble conducting effectively -- review, development of plans, reporting requirements? What are you doing about this?

Answer: The problems encountered by the agencies differ to such an extent that the isolation of a particular function which is posing the maximum degree of difficulty is impossible. Some agencies have encountered management problems, some have governing body composition problems, and others have encountered plan development difficulties, and still others have problems with implementing the plans. Only in a few instances have the problems resulted in the non-renewal of an agency. As the program shifts to an increased focus on implementation, the Bureau of Health Planning will continue to provide, through the Regional Offices and Centers for Health Planning, technical assistance aimed at minimizing or resolving problems encountered by the agencies.

NEW CERTIFICATE OF NEED REQUIREMENTS

Question: The 1979 Health Planning Amendments made several significant changes in the Certificate of Need requirements pertaining to the local and State Planning Agencies. How many States will have to pass laws to accommodate these changes?

Answer: We expect every State to make changes in its program. We know of none which does not expect to enact legislative changes.

Question: How long will it take States to get into compliance with the new Certificate of Need provisions?

Answer: We believe that all of the States will be in compliance by January, 1982.

Question: How soon will the regulations covering the revised Certificate of Need provisions be coming out?

Answer: Public Law 96-79 requires publication within 180 days which works out to be April 1, 1980. We intend to meet that schedule. Additionally, the Secretary has published, on February 22, a notice which will provide some early guidance to States as to the position which she is likely to take on certain issues when the regulation's published.

Question: What assistance is the Bureau of Health Planning providing to the States to get their Certificate of Need programs into compliance?

Answer: In addition to the notice I mentioned earlier, both central and regional office staff have responded to requests for advice particularly with respect to proposed legislative provisions. Also the four planning centers published a number of technical assistance pieces interpreting certain aspects of the health planning amendments. Finally, we have developed an assistance strategy for the States which appear to us to have the more serious problems. That strategy employs the combined efforts of regional and central office staff as well as the centers in a concentrated attempt to help those States develop legislative and regulatory language acceptable both to the State and also to the Federal government.

COST SAVINGS THROUGH CERTIFICATE OF NEED

Question: In your opinion, are these cost savings a good long-term measure of impact? If not, what would be better?

Answer: The Certificate of Need programs, as administered by the States and found to be satisfactory for purposes of meeting review requirements of the health planning legislation, are found to have an impact upon planning for expansion in the health care delivery system. However, that impact, measured in dollars saved as a result of denials of proposed changes in services, can only be grossly estimated. Data with comparability across the country on savings of costs associated with denials of proposed capital investment projects, is not available. In some States and regions, the health planning agencies work very closely with provider proponents in modification of project plans, assuring the feasibility and need acceptability of the proposal. The rate of project denials is therefore much lower than in a neighboring region where such coordinative efforts in the project plan process are not carried out. Under examination by the Department are several methods of measuring cost savings that may better reflect results of CON programs and their variations as they are administered regionally, looking at capital expenditures against other units of measurement. For example, CON programs in many States require that the health care facility submit a long range master plan to accompany a capital expenditure proposal. This planning process by the facility administration and its trustees require detailed discussions and interaction with neighboring facilities in the community, thus extending the involvement of the community into the health systems planning process. These behavior impact results are not easily measured, but can be documented as part of areawide health planning.

Question: How effective have the local health systems agencies been in actually giving non-health care providers a greater role in deciding what health care facilities are needed in a community and where they should be located?

Answer: By legislative mandate, a majority (not to exceed 60%) of the membership of HSA governing bodies must be consumers of health care residing in the health service area. To give full access to the community in the health planning process, each HSA must give all interested persons an opportunity to comment on project review criteria and procedures before final adoption. Copies are widely distributed and notices published in local newspapers announcing proposed review criteria and the agency's review process. The HSA and State agency must make provisions for public hearings in the coarse of the review of capital expenditure proposals. Access to the public to all applications reviewed is to assured. This process is

monitored closely by the Department. There is abundant evidence that non-health care providers are participating in this process and are given every opportunity to do so.

Question: Is there sufficient representation of non-health care providers on the governing boards of health systems agencies?

Answer: The administering agency of the health planning program has under final development a consumer participation strategy to implement the recent legislative amendments which have the effect of strengthening consumer involvement. The law requires each HSA to assign at least one staff member to work with governing body members (particularly consumer members) to assist them in carrying out their responsibilities. The Department will have a long range plan to carry out at the national level contacts and ongoing activities with major consumer interest groups to resolve issues, maintain information flow on health planning, and scheduled events. This long range strategy includes specific assistance and guidance to the health planning agency network in meeting performance standards relating to public health.

PROPOSED USE OF FEDERAL FUNDS (PUFF)

Question: How much real authority are you giving the HSAs if you can override their decisions at any time you wish?

Answer: Health Systems Agencies (HSAs) have a considerable amount of authority for the review programs they perform. In fact, HEW cannot override decisions for State run programs like certificate of need, 1122, and appropriateness review. The only decisions which can be overridden are disapprovals of uses of Federal funds under the four covered Acts. The allowable overrides under the PUFF program do not happen at any time, but are allowed according to well defined procedures and time considerations. In order for an HEW program to overrule the findings of an HSA, the funding program must provide substantial justification for an override of a local decision. This written justification is submitted to the local planning agency. We are closely monitoring all disapprovals and overrides to assure that overrides are consistent with the criteria published in the regulations.

Question: Doesn't your approach have the potential for disrupting the planning process at the local level?

Answer: We do not anticipate that the proposed uses of Federal funds revidwa will disrupt the planning process at the local level. In fact, the review procedures and criteria give planning agencies and applicants for Federal funds a clear set of rules for the orderly review by local agencies for the Federal Health Program area. Since reasons for disapprovals, applicant appeals, and funding agency reasons to fund notwithstanding an HSA disapproval will all be documented (with reasons given), all parties will be aware of who made what decisions and why. Rather than be disruptive this documented and open process should be supportive of local planning.

Question: Under these regulations, how far can HSAs and HEW go in thwarting Congressional intent in making money available for vital health projects?

Answer: Under the PUFF regulations, the decisions rendered at the local level are based on the identified needs of the area as contained in the established Health Systems Plans (HSPs) and Annual Implementation Plans (AIPs) after consideration of the statutory review criteria in P.L. 93-641. These identified needs may not coincide with the program objectives of individual categorical pieces of legislation for vital health projects. Such differences may result in a Federal override of local disapprovals for specific projects. As the agencies become more experienced in weighing local needs with the goals of categorical programs and vice versa, we anticipate less conflict between goals. Federal agencies and HSAs are committed to carrying out the intent of Congress for both vital health projects and health planning.

Question: Would you comment on the effectiveness of HSAs in reviewing proposed uses of Federal health funds within their areas?

Answer: HSAs are precluded from performing this review until they have established procedures and criteria approved by the Federal government. Since November, 1979, many agencies have submitted requests to perform the PUFF function. As of February 21, 1980, a total of 87 HSAs have been authorized to conduct PUFF reviews. Since this activity has been performed for such a short period of time (three months), adequate data do not exist to measure the effectiveness of their reviews.

TECHNICAL ASSISTANCE

Question: How are the Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) provided with needed technical assistance when your previous testimony indicated that the National Health Planning Information Center (NHPIC) is already severely overburdened with requests for technical assistance by other health care planners and students?

Answer: While the reduction in support resources for the NHPIC requested in 1981 will limit our ability to continue the central data bank (which provides access to current information on health planning methods, technology, and issues required for the analysis of problems related to health planning and resources development), access to non-copyrighted documents already in the data base would still be available through the National Technical Information Service and copyrighted documents through the National Library of Medicine.

Question: Does not the reduction of Center positions create particular distribution problems for rural versus urban Health Systems Agencies in the provision of technical services?

Answer: We feel that the reduction of Centers from ten to four does not affect the provision of technical assistance more adversely in rural areas than in urban areas. The provision of technical assistance to date has been by having the Centers offer training, consultation reference services and materials upon request. Therefore, the diminishing funds and services will only adversely effect those that do not seek the services. The distribution of technical assistance efforts in the past has not been along rural/urban lines.

61-400 O - 80 - 57

Question: What is the future trend with decreased funding by the Health Resources Administration for the Centers that assist Health Systems Agencies and State Health Planning and Development Agencies in their planning?

Answer: The future trend for the Centers is to focus on the major problems encountered by the agencies. The provision of technical assistance by the Centers will be restricted to discrete areas such as training for governing body and SHCC members. This change in direction from the provision of more comprehensive technical assistance to that of prominent problems can be accommodated with the funds requested. This strategy will provide the State Health Planning and Development Agencies and Health System Agencies with the intensive assistance to meet their primary needs.

CAPITATION ASSISTANCE

Question: For FY 81, the Administration has proposed to eliminate capitation assistance for health professions schools. Why does it plan to do so?

Answer: Capitation support, which was designed to increase the numbers of health professionals, is no longer necessary as there is now adequate institutional capacity to produce and meet most health professionals needs.

Question: To what extent is capitation assistance still required for enrollment objectives or for the financial stability of health professions institutions?

Answer: Capitation grants are no longer needed to meet enrollment objectives because adequate numbers of health professionals are currently enrolled and are graduating from these schools. The financial stability of a very small number of schools may be adversely affected by the loss of capitation funds but their needs may be met through increased tuition, increased support from other sources or through Financial Distress Grants if they actually experience operating deficits.

Question: Specifically, what would be the effect on health professions schools if capitation assistance were phased out?

Answer: No specific study has been done but it is expected that the principle effect of phasing out capitation grant support would be to remove the incentive, based on these per capita grants, to health professions schools to increase the numbers of enrolled students.

Question: Is capitation assistance helping to achieve other health manpower objectives, such as alleviating geographic and specialty distributional problems?

Answer: The current capitation program does not impact directly on the problems of improving geographic and specialty distribution, increasing the efficiency in the delivery of services, and stabilizing the costs of the services provided. To qualify for capitation support medical schools must have specified percentages of filled first-year residency positions in direct or affiliated residency training programs in primary care. The required percentages are: 35% in 1978; 40% in 1979; and 50% in

1980. 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. Also, capitation funds support undergraduate medical training, and the most effective way to influence specialty choice is to influence graduate medical training.

Question If capitation assistance were phased out, how would the Bureau of Health Manpower (BHM) continue to meet these objectives?

Answer: In the 1981 budget request the Department continues to support those activities that most efficiently and effectively influence graduate training such as Primary Care and Family Medicine; and those that influence geographical location such as the National Health Service Corps, Area Health Education Centers and Loan Repayment Programs.

Question: For fiscal year 1980, Congress provided $87.7 million for medical school capitation. Yet a few months later, you come up here requesting a rescission of $81.2 million. Before deciding to rescind these funds, did you do a study of the effect on the medical schools that would be involved in the cutback? If so, what does your study show?

Answer: A formal study was not done. The current problem facing the nation in terms of health professionals is to a great extent no longer numbers but geographic and specialty distribution. The cut back in institutional funding through capitation grants is a reflection of the overall adequacy of numbers of health professionals.

FINANCIAL DISTRESS

Question: What became of the HEW plan to recommend ways to resolve the financial crisis at the Meharry Medical and Dental School?

Answer: A Department task force met in November of 1978 at Meharry to conduct a comprehensive examination of the College's financial condition and needs. The following recommendations by the Secretary's task force are being acted on or are in place:

1. Revitalization of the college's budget program in which each unit head will have a realistic budget based on sound projections is in process.
2. Problems in the budget and financial management system relative to officially recognizing or recording encumbrances in the current year have been corrected.
3. Full review and modification of all income and expense budgets are being done on a monthly basis.
4. A special in-house orientation program for the management staff to understand the institution's financial report is to be done on a continuous basis.
5. The new dental school building has been completed and is now occupied. The college is making an effort to budget adequate resources, by budget revisions, so that the building can be fully operational as soon as possible.
6. Total compensation of participants in the medical practice

plan is being reviewed to insure that gross imbalances are not being created.

7. The role of the financial committee of the board has been redefined and it now participates more fully in the budget performance and reviews the reports of the institution's outside auditors.

Meharry Medical College has designed a four-part plan to eliminate financial distress and increase income over the next five to eight year period. These parts are: special federal legislation, increases in tuition, private fund-raising campaign, and increased state support. A special legislative enactment program scheduled to occur in the fall of 1980, in the amount of $25,000,000 or more during a five year period, is the keystone to the overall plan to eliminate financial distress. This measure will allow the time necessary to activate the other three elements of the total plan in such a way that their implementation will provide real financial assistance to the institution after a required period of build-up and preparation.

The college will increase its tuition charges over the next eight year period, beginning in academic year 1979-1980. There will be annual increments of $1,000 except for the academic year of 1980-1981. The gradual increases in tuition charges will contribute meaningfully to increased revenues at the college.

The college embarked on a three-year, $25 million fund raising campaign on December 15, 1978. The initial benefits from this campaign will not be realized until 1982-1983 after principal build-up and interest accruals have reached appreciable levels. To date, some $6,000,000 has been pledged or raised in this effort.

Meharry's relationship with State government has increased during the past five years and is expectd to continue to do so in the next five years through appropriations and contracts with various agencies of the State of Tennessee. It is anticipated that the college will realize a net income from State sources by 1986. The State of Tennessee will in all likelihood, increase its capitation of Tennessee students enrolled at Meharry. Student support plans from the State of Illinois, California, New York, New Jersey, and Pennsylvania are being advanced along the same lines at this time.

We believe this total plan, with close coordination and watchfulness among its interrelated segments, represents a reasonable approach toward achieving Meharry's objective of eliminating financial distress by 1985-1986.

NEW MEXICO AREA HEALTH EDUCATION CENTERS

Question: Under the Area Health Education Centers (AHEC) Special Education Programs, New Mexico has had a special interest in the AHEC in Shiprock, New Mexico due to its special circumstances and extreme success in educating minority health students and achieving a high rate of return to rural communities. Due to its unique circumstances of being located on an Indian reservation and training primarily Indian people, this AHEC has had difficulty in meeting the requirements set forth in Sections 802 and 781 of Public Law 94-484. In previous years, the

Department has been most favorable toward the New Mexico AHEC and the Appropriations Committees have directed that funding be continued. Will the Department continue to fund the New Mexico AHEC in 1981 or must special provision be made for it?

Answer: In fiscal year 1980, the Department provided special consideration for the New Mexico AHEC program in three ways:

1. In response to the Congressional directive, funding was provided under authority of Section 788(d) because the program could not meet the requirements for funding under Sections 781 and 802.
2. The Department provided special supplemental funds to the New Mexico project to allow more gradual transition to State, Tribal, and other funding sources as compared to the other AHEC programs initiated in 1972.
3. A special review and recommendation for approval of related Federal grant assistance was provided.

The Department intends to continue to fund the New Mexico AHEC in fiscal year 1981. The long-term funding plan for the national AHEC program, submitted to Congress on February 25, 1978, calls for fiscal year 1981 to be a final year of decremental support for projects initiated in 1972, including the New Mexico program. In the Department's view, one significant indicator of progress as well as of the overall importance of the program to the Navajo Nation after eight years of Federal support, would be a Tribal appropriation to provide a stable core of on-going support for the program. This has been discussed with both university and Navajo officials and the Department will continue to work closely with the program to provide the special consideration requested.

Question: The University of New Mexico School of Medicine has initiated a unique Primary Care Curriculum for its entering students this year which puts those students selected for the program on a special curriculum track and puts them immediately into rural settings where they may train under local physicians. The University has the largest minority student population of any single school of medicine in the country. Yet this project is apparently ineligible to receive funds under the Special Educational Programs in Family Medicine or in Improvements and Development Projects. Would you outline exactly why this is and point out other programs under which this initiative might be eligible for a grant?

Answer: The University of New Mexico School of Medicine is eligible for support for its Primary Care Curriculum Program under several authorities of Title VII, of the Public Health Service Act. The most relevant authorities are: Section 780, Grants for the Establishment of Departments of Family Medicine; Section 786, Grants for Predoctoral Training in Family Medicine; and Section 788(d), Grants and Contracts for Numerous Health Manpower Developmental Activities.

Section 780 is a new grant program being initiated in fiscal year 1980. Applications were mailed on February 11 and are due back to the Bureau on April 7. New Mexico is an eligible applicant.

Section 786 predoctoral training in family medicine is an ongoing grant program started in fiscal year 1978 and has since been in a continuation mode. New Mexico is currently receiving some support for programmatic activity under this authority.

Section 788(d), the general purpose curriculum development grant and contract, authority is also appropriate for the type of activities described. However, because of prior commitments and specifically earmarked appropriations under Section 788(d) authority, activities of this nature have not been initiated.

PHYSICIAN EXTENDERS

Question: A 1979 Congressional Budget Office Study indicated the present use of physician extenders has, in most instances, not reduced costs of medical care, although there is some evidence that it has increased access and intensity of services to some previously underserved groups. Has the Department conducted any studies on the utilization of physician extenders and, if so, what do they tell us?

Answer: There have been several studies conducted on the utilization of physician assistants. Preliminary data from a 1978 longitudinal study indicates physician assistants locate in health manpower shortage areas more often than physicians. We also learned that the physician assistant is working in a variety of practice settings, including hospitals, private offices, Health Maintenance Organizations, and clinics. More recently, they have been utilized in penal institutions across the country.

Studies have also indicated that utilization of physician assistants will broaden as reimbursement practices are expanded to be more attractive to physician extender employers. Another factor which adversely affects utilization of physician assistants is the State enabling legislation. In some cases the legislation is so restrictive, it becomes unattractive to potential employers.

Studies being carried out by Graduate Medical Education National Advisory Council have indicated several sub-specialties in which the physician extender can be effectively and efficiently utilized. Here again, such utilization may be prohibited depending upon the enabling legislation and reimbursement practices.

Question: Does the Department plan to encourage the increased utilization of physician extenders? If so, How?

Answer: The Physician Extender Training Program provides funding preference to institution applicants providing substantial training in Health Manpower Shortage Areas, and/or in an Area Health Education Center (AHEC), and/or conducts training in conjunction with other programs training primary care physicians. It is felt that such training will enhance the utilization of physician assistants by physicians who have an opportunity to train with, or be involved in, physician assistant training activities.

Each medical or osteopathic school participating in an area health education program must be responsible for, or conduct a program for, the training of physician assistants or nurse practitioners. The school must give special consideration to the enrollment in these programs of individuals from, or who plan to practice in, the area served by the AHEC.

Primary care and family medicine programs provide funding preference to applicants who offer substantial training experiences in setting which exemplify interdependent utilization of physicians and physician assistants and/or nurse practitioners in the health care team.

Additionally, demonstration projects have been developed in rural and urban areas which provide reimbursement for physician assistant services under Medicare and Medicaid. The Health Care Financing Administration is also conducting a reimbursement study which provides varying percentages of reimbursement for physician assistant services in certified rural health services clinics.

The National Health Service Corps has recently been encouraging the utilization of physician assistants in clinics staffed by National Health Service Corps physicians. Many of these clinics are located in rural and inner city areas where there is or has been severe physician shortages.

Finally, HEW has sponsored a study which analyzed State enabling legislation and legislation regarding reimbursement practices in states to determine issues and restrictions which need to be addressed and/or modified to enhance physician assistance practice.

Question: What efforts are being made to strengthen physician extender training programs?

Answer: The physician assistant program strengthens physician extenders training by providing funds for:

- didatic and clinical instructors with expertise in medical education to assist in improving the quality of instruction;
- supplies and equipment to enhance the instructional methods being utilized in the programs;
- consultants with expertise in such areas as curriculum development and program evaluation to assist in the continued modification and assessment of the programmatic and instructional activities;
- facility enrichment to increase the quality of instruction and/or administration being provided by physician assistants involved in the program; and
- program faculty to attend professional meetings to enhance knowledge and skills related to the training of physician assistants.

In addition, studies which indirectly serve to strengthen physician assistant training programs are underway. These studies include the following areas:

- reimbursement, under Medicare and Medicaid, for physician assistant services;
- analyses of State-enabling legislation;
- evaluation of the physician assistant training programs in terms of deployment and other program characteristics;
- role delineation and practice setting;
- cost-effectiveness;
- productivity; and
- possible sub-specialty areas in which physician assistants can be utilized effectively.

DENTAL PROGRAMS

Question: Your budget proposes to eliminate funding for Extended Function Dental Auxiliaries (EFDA's). Isn't GAO about to publish a report praising these dental extenders?

Answer: The GAO apparently has completed but not yet published its study which is supportive of the use of dental extenders.

Question: What does the report say?

Answer: To our knowledge the final report has not yet been released. We understand the draft report encourages HEW:

-- to work with the States to persuade them to make the appropriate legislative changes necessary to permit EFDA's to complete restorations under the dentist's supervision;
-- and to determine whether a sufficient supply of appropriately trained EFDA's exists in States where they can be legally employed and if additional Federal support is needed to alleviate any shortage identified.

Question: Why do you propose to terminate funds for Dentistry Residencies and Training?

Answer: As with the Expanded Function Dental Auxiliary program, available funds in the budget request are directed to other higher priority programs such as National Health Service Corps (NHSC) Scholarships, Family Medicine, and Primary Care.

Question: Please explain why you propose to cut Dental Health activities from $8 million in fiscal year 1980 to $2 million in fiscal year 1981. What programs will be cut or terminated -- and what is your rationale for this?

Answer: The General Dentistry Residency Training and Dental Extenders programs will be terminated. Higher priority manpower programs such as NHSC Scholarships, Family Medicine, and Primary Care will be supported. Although $2 million is supported under the explicit Dental budget line in 1981, $17 million will be funded for Dental Health under other health professions areas such as the Financial Distress and Scholarship programs.

Question: Under funds supported but not budgeted under Dental Health, you propose to reduce spending from $33 million to $17 million. Please explain the reasons for these reductions.

Answer: Capitation, which accounts for more than $16 million, is the major reduction. This reduction is consistent with the policy of eliminating Federal financial incentives for unwarranted growth in the aggregate supply of health professionals. Health Education Student Loans and National Direct Student Loans will be replacement sources for the Health Professions Student Loan reduction. No funds are requested for the Regional Dental Education Project in favor of funding for higher priority programs such as National Health Service Scholarships, Family Medicine and Primary Care.

Question: The Administration's proposal provides funds for only one program related to dental education. Does this represent a belief that there are no national problems of distribution, specialty, curriculum, or cost in dental education or practice which would be responsive to federal initiative?

Answer: The Administration's budget does include support for activities which address dentistry issues such as the distribution of dentists, minority support to dental schools, and Exceptional Need Scholarships. These are included under other program headings.

Question: As you know, Chairman Magnuson has been very supportive of the Regional Dental Education Project. How much do you intend to spend on this in fiscal year 1981? How does this compare with 1979 and 1980?

Answer: Funds are not requested for this program in fiscal year 1981. In 1979, about $800,000 was spent for the Regional Dental Education program and in fiscal year 1980 we expect to have a funding level of approximately $900,000.

NURSING PROGRAMS

Question: Last year, the Committee increased training stipends for National Institutes of Health up to $15,000. Have you done the same thing for your nursing fellowships program? How much did or would this cost? Did you make provision for this in your 1981 budget request without cutting back on the number of awards?

Answer: As of July 1, 1980, the stipends for nursing predoctoral fellowship will be $5,040 an increase of $1,140, and the institutional allowance will remain $3,000. Postdoctoral stipends will range from $10,000 to $17,040 depending on the experience of the fellow. Very few postdoctoral awards are made. For 92 awards granted in fiscal year 1980, the increased cost for a full year would be $105,000. No funds are requested in 1981 for this program.

Question: Recent reports indicate there is a strong effort underway to train more nurses at the graduate level and that there is a long wait for admission to graduate programs. How many and what percentage of current registered nurses have graduate degrees -- and how many registered nurses are currently enrolled in graduate programs?

Answer: According to the 1977 National Sample Survey of Registered Nurses, an estimated 55,096, or 3.9% of the total registered nurse population in September 1977 have master's degrees. According to that same study, 2,304, or 2% of the registered nurse population had doctoral degrees. As of October 15, 1978, there were 949 registered nurses enrolled in all doctoral programs and 13,105 in nursing master's degree programs.

Question: What will be the projected need for nurses with graduate training by the mid-80's?

Answer: As reported in the Second Report to the Congress, March 15, 1979, (Revised) Nurse Training Act of 1975, the Panel of Expert Consultants convened by the Western Interstate Commission on Higher Education determined that as a lower limit, there would be a need for 189,000 full-time equivalent nurses with master's degrees and 15,000 with doctorates by 1982.

Question: What has been the trend in regard to enrollment in nursing masters and doctoral programs over the past ten years?

Answer: Since October 15, 1968, enrollments in master's degree programs have more than tripled. There were 4,018 enrollments in 1968 and 13,105 in 1978. Full-time enrollments, however, have not increased as much since the percent of students who were attending on a full-time basis consistently decreased from 76% to 50% in that time period. The total number of full-time enrollments as of October 15, 1978 was 6,561 and, in 1968, it was 3,034. The number of students enrolled in doctoral programs offering a major in nursing increased from 258 as of October 15, 1968 to 789 in 1978. Of these, the percent who were attending on a full-time basis varied, in no consistent pattern, during the period from a low of 37% to 59%. Generally, about 40 to 45% of the students were full-time.

Question: Note that the new program for nurse anesthetists is one of the very few nursing programs you plan to continue. What evidence do you have that shows there is so great a demand for nurse anesthetists that the federal government must engage in a new program to provide them?

Answer: The projected 1980 need for nurse anesthetists is 22,000 to 25,000 compared to the present supply of approximately 15,000. The need and supply are from a 1976 HEW study on Supply, Need and Distribution of Anesthesiologists and Nurse Anesthetists. Futher, there are approximately 2,100 anesthesiology residents in training. Foreign medical graduates (FMG's) constitute approximately 50% of the total residents in training, and between 30-35% of practiciing anesthesiologists.

The provision to phase out the FMG program under the Health Professions Educational Assistance Act of 1976 will have an impact on anesthesiology. The full impact is not known at this time, however, since there is and has been a high percentage of FMG's in anesthesiology residency programs, the impact could be severe.

ALLIED HEALTH

Question: Similarly, no funds are provided for Allied Health, representing well over half all health care personnel. Does the Administration not believe that there are national problems in this area?

Answer: As careers in allied health have become increasingly more attractive, community colleges and State universities have responded by creating large numbers of new programs and graduates. A core work force of about 442,000 in 1966 has grown to about 1,026,000 in 1978. Due in part to these large increases of allied health workers (an overall growth rate of 132 percent for 1966-1978) shortages have been alleviated for all allied health occupations and completely eliminated for some. As a result, the available information indicates that with some exceptions, national shortages are not a major problem. While distributional problems exist with respect to allied health personnel, many of these are local or regional in nature. Since allied health personnel tend to remain in the States or localities in which they are trained, the Department believes that funding for such educational programs should be from State and local resources, and that Federal dollars be directed toward higher priorities.

STUDENT ASSISTANCE PROGRAMS

Question: Your proposal (to dramatically increase loan repayments) seems to have a possibility for some double payment. If you are paying a salary to National Health Service Corps physicians and you have put them through school on scholarship, why do they also need a loan repayment?

Answer: A National Health Service Corp (NHSC) scholarship receipient is not eligible to receive loan repayment during the time he/she is fulfilling the service obligation, thus double payment cannot occur. Upon completion of the service obligation, the scholarship receipient becomes eligible for loan repayment if she/he wishes to remain in practice in a health manpower shortage area. A student may finance two years of education through borrowing and two years with NHSC scholarship support. Upon completion of the service obligation, loan repayment would apply to that portion of educational costs financed with educational loans.

Question: Based on the request of $11.7 million for loan repayment, HRA obviously expects to upgrade its efforts in this area. How many individuals are expected to receive repayment and what is the average amount likely to be?

Answer: It is expected that the funds requested will honor agreements to 1,875 applicants, with a range of costs of $6,500 to $7,200 per two year agreement.

Question: Is it true that the Health Resources Administration (HRA) is no longer accepting applications for repayment?

Answer: As of July 30, 1979, HRA is accepting applications for those volunteer members of the National Health Service Corps or Indian Health Service who were matched with an eligible practice site as of July 30, 1979.

Question: If so, will this process be reopened if Congress appropriates the requested funds?

Answer: It is planned to reopen the application process for new volunteers of the National Health Service Corps and Indian Health Service. This plan is supported in the fiscal year 1981 request for $11.7 million.

Question: The Health Professions Student Loan and Nursing Student Loan program are revolving funds in which repayments of loans by borrowers become available for new loans. How much money is expected to be available from these revolving funds for loans in fiscal year 1980 and for each year from fiscal year 1981 through fiscal year 1985?

Answer: We estimate that the following amounts will be repaid:

Fiscal Year	Health Professions	Nursing
1980	$16,000,000	$10,500,000
1981	$18,000,000	$11,500,000
1982	$20,000,000	$12,500,000
1983	$22,000,000	$13,500,000
1984	$24,000,000	$14,500,000
1985	$26,000,000	$15,500,000

Question: I note that you have not asked for any positions to administer the Health Education Assistance Loan (HEAL) program. How can you manage to operate this program without staff?

Answer: The HEAL program was transferred to the Health Resources Administration as a result of legislation creating the Department of Education. At present there are interdepartmental negotiations in process attempting to acquire the necessary number of positions from the Department of Education to administer this program.

Question: You have proposed to rescind the $16.5 million provided for student loans in fiscal year 1980. If your rescission goes through, what will happen to students who are participating in the loan program but have not finished college?

Answer: Loans will continue to be available from the revolving funds previously established in the schools. These students will be given a high priority in obtaining loans to complete their education.

Question: You are proposing better than a 100% increase in the Loan Repayment program, going from $1.5 million to $11.7 million. How does this proposal relate to your plan to rescind capitation funds?

Answer: This proposal has no relation to the capitation program. The big increase for the Loan Repayment program is to provide funds for the backlog of eligible students who have applied for this type support and who are presently working in shortage areas. We are honoring our moral commitment to these practitioners.

Question: You propose no new funding for the Nursing Student Loan program in fiscal year 1981. Yet at this time you are serving only about 7.5% of the enrollment that is eligible for these loans.

If the Nursing Student Loan program is phased down, or terminiated, what programs are available to provide student nurses with financial aid?

Answer: Students are eligible to apply for support through Basic Supplemental Educational Opportunity Grants, Work Study, and the Guaranteed Student Loan program all of which are administered by the Department of Education.

Question: You also propose to zero-fund the National Direct Student Loan (NDSL) program. If you're successful with this, how would it affect nursing students seeking financial aid?

Answer: Although the administration requests no new obligational authority for the NDSL program, there is currently over $400 million in NDSL revolving funds as well as $11,500,000 in the Nursing Student Loan program revolving fund in 1981.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS

Question: How does the Health Resources Administration evaluate National Health Service Corps (NHSC) Scholarships applicants to ascertain that they are likely to stay in underserved areas?

Answer: Since the inception of the Scholarship program in fiscal year 1974, there has been a continuing effort to improve the selection procedures for scholarship recipients in order to provide the best resources possible to the Corps for site placement.

Currently, the interim final regulations in effect as of September 27, 1978, provide that selection of recipients will be based on the following criteria: (1) work experience; (2) community background; (3) career goals; (4) faculty recommendations; and (5) academic performance. In conjunction with the Corps, a weighting and scoring value is placed on each of these criteria depending upon the discipline (or specialty) to be supported.

For the 1979-1980 academic year, heavy emphasis was placed on community background and work experience in an attempt to assure selection of those individuals who appeared to have the greatest likelihood of adapting to similar communities and backgrounds and remaining there once placed.

Question: If NHSC Scholarships were to be awarded only to individuals who have already received a scholarship, how many scholarship awards would need to be made in fiscal year 1981 and what would the cost be?

Answer: Our projections indicate that 4,810 scholarship recipients will be eligible for continuation awards in fiscal year 1981. The cost of these continuation awards would be about $67.1 million.

Question: How can the Scholarship program encourage more health professionals to remain in these areas?

Answer: Studies of the factors which influence medical practitioners to remain in health manpower shortage areas have found that three factors are most influential: the availability of continuing education, adequate finances, and the lack of professional isolation. The Scholarship program's legislation already provides for partial financial relief by means of one-time grants of $12,500 to $25,000 to aid previous scholarship recipients who have completed all of their service obligation with NHSC to establish a practice of their own in a health manpower shortage area. These grants, which help secure equipment, renovate facilities, and hire nurses and other personnel to assist in providing health services, depend upon the availability of appropriate funds, particularly as increasing numbers of scholarship recipients complete their service obligations. The availability of 21 federally-funded Area Health Education Centers serving 21 States helps provide for continuing a scholarship recipient's professional education and provides an additional incentive for continuing his practice in a health manpower shortage area.

Question: How many awards have been made to date under the NHSC Scholarship program? How many new awards will you make for fiscal year 1981?

Answer: A total of 22,670 new and continuing awards have been made to 11,446 students under the NHSC Scholarship program and its predecessor the Public Health Service Scholarship program. The Scholarship program expects to make 6,701 awards during fiscal year 1981, incuding 4,810 continuing and 1,891 new.

Question: What is the percentage of scholarship recipients who have decided not to serve their obligation?

Answer: As of January 9, 1980, 729 scholarship recipients who had completed their academic training had failed to begin or complete their service obligation. This represents 6.4 percent of the total number of recipients.

Of the 729, 716 had received scholarship awards under the Public Health Service Corps Scholarship program between the 1973-

1974 and 1977-1978 school years when a three-year repayment of funds at eight percent interest was permitted. An additional three recipients had received funds under the more stringent buy-out provisions of the National Health Service Corps Scholarship program, and another 10 had received funds under both Scholarship programs. The number of scholarship recipients who have determined not to serve represents about 25 to 30 percent of those who were to do so each year. The program is confident that under the triple payback penalty provisions of the NHSC Scholarship program there will be significant reduction in these figures once scholarship recipients begin to enter their service obligation.

Question: What percentage of Corp's scholarship recipients are minorities?

Answer: Applicants to the NHSC Scholarship program are not asked to give their racial/ethnic background. However, the Association of American Medical Colleges was able to match its demographic files of medical students with 97% of the scholarship recipients who received first-time awards during school years 1973-1974 through 1977-1978. Out of 4,566 scholarship recipients, 2,924 (64.04%) were identified as White, 892 (19.54%) as Black, 178 (3.89%) as Hispanic, 55 (1.2%) as American Indian, 68 (1.49%) as Oriental, 73 (1.6%) as Other, and 376 (8.24%) as Unknown.

Women received 22.5% of the new awards from 1973-1978.

Additional data covering later annual award cycles of the Scholarship program are being developed by the American Association of Medical Colleges and will be published when available.

Question: What is the retention rate for National Health Service Corps personnel?

Answer: The NHSC has completed an analysis of the length of Corps assignments which indicated that 33 percent of all assignees who had served with the Corps as of September 30, 1978, had remained in the Corps for more than two years.

Question: At what time period is the retention rate calculated? Is a long-term longitudinal study being undertaken? If so, when will data be available?

Answer: The retention rate is calculated for each fiscal year and is based on the number of NHSC personnel who complete their assignments during the fiscal year who are eligible to leave shortage areas. A separate rate is calculated for those assignees who extend with the Corps and those who leave the Corps to establish private practices in shortage areas. In 1979, these rates were 39 percent and 14 percent, respectively.

Question: Are NHSC personnel more likely to stay (past their obligated service) in urban or rural underserved areas?

Answer: We have only in the past two years begun assigning large numbers of NHSC personnel to urban areas. Data to provide an analysis of retention for urban areas as compared with rural areas will not be available until the fall, after a large number of urban assignees have completed their initial service commitments.

Question: What efforts are taken to prepare NHSC scholarship recipients to practice in underserved areas?

Answer: The NHSC has developed an integrated plan for a group of acclimation activities designed to disseminate information, to advise and assist career development for shortage area practice, and to attempt to instill a sensitivity and responsiveness to community primary care practices. All of these objectives are expected to promote provider performance, adjustment and retention in shortage area practice.

A summary of each of these acclimation activities designed to prepare NHSC scholarship recipients to practice in underserved area follows:

Summary of Acclimation Activities

NHSC National Scholarship Advocacy Network

The scholarship advocacy network is the basic information dissemination framework. Other acclimation activities fit into the advocacy framework. The purpose of this network is to identify one scholarship recipient and one faculty member (perferably Public Health Service (PHS) alumni), in each dental and medical school and to provide them with PHS program knowledge in order that they can operate as a conduit between PHS and students. These advocates attend a training conference at a PHS site, receive regular mailings and serve as the focal points for other students. Specific activities include:

- National conference for medical and dental scholarship recipients and a faculty member from each school.
- Regional workships for all scholarship recipients in urban areas with high concentration of scholarship recipients.
- Workships and special school-originated activities organized by advocates at schools throughout the country.
- Minority conferences to address special concerns of Black and Hispanic scholarship recipients.

Program content at workshops and the national conferences are designed to allow personal discussions between scholarship recipients and NHSC staff and field assignees as well as panel discussions, questions and answers and a visit to a NHSC site. Each program has workshops directed toward preparing students for NHSC community-based shortage area practices.

"Acclimation News" is sent periodically to members of the advocacy network. The NHSC newsletter, "Notes", is sent monthly to network members.

Preceptorship Program for NHSC Scholarship Recipients

The NHSC is presently in the third year of the Preceptorship program for scholarship recipients. Last year approximately 150 medical and dental students participated in the program. This year the goal is to place 400 medical and dental students. Placements are made in NHSC sites under the direct supervision of a NHSC physician or dentist.

EXCEPTIONAL FINANCIAL NEED SCHOLARSHIPS

Question: Scholarships for students with exceptional financial need (EFN Scholarships) are available to full-time students of health professions schools who are both needy and who are in their first-year of study. Regulations issued by the Department define EFN students as those who have zero financial resources. Federal funding for the program has been small, limiting the number of available scholarships.

Does the EFN program represent an adequate source of support for disadvantaged students?

Answer: By using the concept of zero financial resources, the health professions schools identified over 1,300 students as eligible recipients of the EFN Scholarship. The $7 million appropriated in fiscal year 1979 for the program was sufficient to provide scholarships for 644 students, almost 50% of those identified as eligible, for the first-year of study.

Question: Does the Bureau of Health Manpower propose to expand this program, or initiate any others, which might further encourage low-income students, particularly minorities, to enter health professions training?

Answer: At the present time, the Bureau does not intend to expand the program, or to initiate any other. The Health Resources Administration supports the disadvantaged assistance program which encourages low-income students, particularly minorities, to enter the health professions field.

Question: Do any plans exist to broaden the EFN definition beyond the requirement of zero financial resources, or to provide scholarship support beyond one year?

Answer: Proposed final regulations for the EFN program has broadened the scope of exceptional financial need from zero financial resources to resources not to exceed $5,000 or one-half the cost of attending school for one year, whichever is the lesser amount. At the present time, there is no legislation proposal to extend scholarship support beyond one year.

INTERDISCIPLINARY TRAINING

Question: Congress has steadily been increasing funding for Interdisciplinary Training. There is much pressure on this program to continue worthwhile projects and to expand into other areas, such as nutrition education and rural health. Why do you now propose to end all funding for this program?

Answer: Funds requested in the 1981 health manpower budget are directed toward the support of programs in high priority areas of primary care specialty and geographic

61-400 O - 80 - 58

maldistribution and public health programs. Projects relating to human nutrition, rural health, and other areas will be addressed in other health manpower programs such as public health special projects, National Health Service Corps Scholarships, Health Professions Loan Repayments, Area Health Education Centers, Physician Assistants and Nurse Practitioner programs.

Question: What will happen to projects that are still not completed?

Answer: Most projects were begun in fiscal year 1979 so will therefore have received two years of support prior to being terminated.

HUMANISTIC MEDICINE

Question: In the Committee's Report on the fiscal year 1980 budget, the Secretary was directed to renew his efforts to fund programs in humanistic medicine. How many projects are you funding?

Answer: We estimate that five to seven grants will be awarded with the $500,000 available in fiscal year 1980.

Question: What have been the results to date?

Answer: It is too soon to appraise the results from the humanistic medicine projects since the awards will not be made until late this year.

NUTRITION EDUCATION

Question: During a hearing last fall before a Senate Subcommittee, the Bureau of Health Manpower (BHM) was criticized for failing to monitor pilot programs in the field of nutrition education. What is the status of current BHM efforts regarding training of Health professionals in nutrition education? Does BHM intend to expand these efforts?

Answer: A new program of Curriculum Development Grants in Applied Nutrition was instituted by BHM in fiscal year 1979, with the award of 13 grants for $1,500,000. These grants provide for the development, expansion, or improvement of interdisciplinary education programs that provide students with the capability to apply nutritional knowledge in the promotion of health, the prevention of disease, and the amelioration of illness. Continuation awards will be made to these 13 grantees in fiscal year 1980 at $1.5 million. The budget does not include funds to continue these projects in 1981.

NEW LEGISLATION

Question: The Health Professions Educational Assistance Act of 1976 expires at the end of fiscal year 1980. Will new legislation reflect different objectives from the last major

health manpower program authorized in 1976?

Answer: The major objectives of the Administration in the health professions field are to

-- remove incentives for unwarranted growth in the aggregate supply to health professionals, especially physicians;
-- promote an increase in the supply of primary care health professionals, currently in short supply;
-- assure the availability of health professionals in medically underserved areas, largely by strengthening the role of the National Health Service Corps;
-- increase minority participation in the health professions;
-- target Federal resources to promote other national priorities, such as public health training, cost-containment and efficiency in delivery of health care services, and care for high-risk groups, such as the elderly, pregnant women, and children.

The Administration's legislative proposal will reflect these objectives.

Question: Describe any changes the Department plans to make in current programs, and the potential impact of these on the budget.

Answer: The Department's plans for changes in the health professions programs will be spelled out in detail in the legislative proposal that will be submitted to the Congress in the near future. The legislative proposal will be consistent with the President's Budget for fiscal year 1981.

Question: The Administration Health Manpower and Nurse Training legislative proposals were due May 15, 1979. When can Congress expect to receive them?

Answer: The Administration's health professions legislative proposal, covering nurse training as well as other health professions authorities, is being reviewed for consistency with the President's overall national program. It is the Department's intention that the proposal be sent to the Congress in early March.

HEALTH MANPOWER SHORTAGE AREAS

Question: For fiscal year 1980 Congress directed the Secretary to give special attention to programs which address health manpower shortages in medically underserved areas. What has been done to implement this directive?

Answer: One of the major objectives of the 1981 health manpower budget request is to assure the availability of health professionals in medically underserved areas. Programs that will be addressing this objective in 1981 are National Health Service Corps Scholarships, Health Professions Loan Repayment, Area Health Education Centers, Physician Assistance and Nurse Practitioner

grants and contracts.

Question: How much money will you earmark for this purpose and will it be sufficient?

Answer: Approximately $150,700,000 or 49% of the $309,327,000 requested in the 1981 President's Budget for health manpower programs will be directed toward funding activities that address health manpower shortages in medically underserved areas.

Question: What is your response to Committee directives to continue efforts in the areas of regional dental health, geriatric medicine, human nutrition and humanistic medicine?

Answer: On February 7, 1980, the Assistant Secretary for Management and Budget communicated a letter to the Chairman, Subcommittee on Labor and Health, Education and Welfare, Committee on Appropriations. This letter included a proposed spending plan for Section 788(d) for fiscal year 1980. All of the special activities of regional dental health, geriatric medicine, human nutrition, and humanistic medicine are included for funding in fiscal year 1980.

Question: The Administration has indicated many times it considers current and future supplies of nurses to be adequate to meet the nation's health care needs.

Recently, many parts of the country have reported nursing shortages as well as bounties being offered to recruit nurses. If the Administration retains the view that the Nation's nursing supply is adequate, how does it explain such efforts to recruit nurses?

Answer: Turnover of nursing and other personnel often leads to vacancies which, if there is not a readily available pool with the necessary skills, can result in serious shortages. Also, since the availability of registered nurses, in terms of numbers and skill levels, is obviously not uniform throughout the country, while on a national basis the aggregate supply might be adequate, distributional problems lead to shortage situations in certain areas. In addition, although there may be an adequate number of personnel in the aggregate to fill positions, there are and may always be vacancies in the least favorable settings, facilities, or shifts. Efforts to limit hospital use to those patients most seriously in need of care may also have an impact, in that this results in a higher level of intensity of care, which in turn requires greater input from registered nurses. Furthermore, the increased availability of registered nurses has led to a reversal of the practice of substituting lesser trained nursing personnel for registered nurses.

Question: How many areas are designated nurse shortage areas -- and how many nurses are needed in those areas?

Answer: At present time there are 541 areas designated as

nursing shortage areas with a need of 5,200 nurses.

QUALITY OF MEDICAL EDUCATION

Question: What does part-time faculty and tuition suggest with respect to the quality of medical education and the socioeconomic background of the student being educated?

Answer: No linear relationship appears to exist between percent of part-time faculty and quality of medical education. With the recent emphasis upon primary care in many medical schools, institutions have turned to part-time faculty to provide clinical role models to medical students. Preceptorships as well as ambulatory care clerkships are frequently handled by part-time, adjunct or community based faculty. Although high percentages of part-time faculty in a given institution may be cause for concern, no firm evidence exists which might demonstrate adverse impact.

It is common knowledge that significant increases in tuition have occurred in United States medical schools over the past several years. Tuition increases of this magnitude inflict the greatest hardships on those students least able to afford increased financial outlays. The inevitable result is economically disadvantaged students are either excluded from pursuing a medical education or they are to a greater extent dependent upon scholarships and loans. Even given the availability of scholarships and loans for medical education, it is likely that many economically disadvantaged students would elect not to pursue a pre-medical undergraduate curriculum and thus never enter the applicant pool.

STATUS OF PHYSICIANS' COMPETENCY

Question: Since 1971, HEW has issued at least three reports on credentialing of health manpower. These reports included recommendations designed to strengthen professional and state requirements for ensuring continued competence of practicing physicians. To what extent have HEW's recommendations been implemented, and what is HEW doing to encourage the states to adopt such proposals?

Answer: Following are some evidence of the implementation of HEW recommendations.

1. Recommendation: All states are urged to take action that will expand the functional scopes of their health practice acts and that will extend broader delegations authority...

   Today 44 states, versus 24 in 1972, largely through general delegatory legislation, have provided legal sanction for physicians' assistants.

2. Recommendation: The professional organizations and States are urged to incorporate a specific requirement for the assurance of a continued level of practitioner competence as one condition of the recredentialing process.

The American Board of Internal Medicine conducted the first recertification procedure for its diplomates in 1974, followed in 1976 by the American Board of Family Practice, and the American Board of Allergy and Immunology, the American Board of Obstetrics and Gynecology, and the American Board of Plastic Surgery in 1977. Others have since moved in this direction. (Note, however, that some of these organizations had started to move in this direction prior to the HEW 1971 publication.)

In 1978 The American Board of Medical Specialties conducted a Conference on Recertification in a continued effort to promote recertification which it first endorsed in 1973.

3. Recommendation: In the 1976 HEW draft report on "A Proposal for Credentialing Health Manpower" a recommendation was made for the "establishment of a broadly representative national (non-Federal) certification council." Medicine, nursing and dentistry were among the fields rejecting the recommendation and in the 1977 HEW publication the recommendation had been changed to establishment of "a National Voluntary System for Allied Health Certification." The latter now exists as the National Commission for Health Certifying Agencies. Interestingly, some newly formed groups of physicians who perceive that it takes 10 years to be recognized as a specialty by the American Board of Medical Specialties, have inquired about the new Commission.

Currently HRA has no specific program encouraging the medical disciplines and states to follow the HEW recommendations.

Question: To what extent is there currently a national problem with assuring the continued competency of practicing physicians? What assessment of the problem has HRA made?

Answer: The Council on Medical Education of the AMA has studied the situation and concluded that the numbers of practitioners providing "less than appropriate service/practice" is limited,that the problem is small; and that an effort is being made to deal with this small group. HRA has not assessed the situation.

Question: How effective are legal provisions recently enacted in some states which require practicing physicians to maintain competency through continuing medical education?

Answer: States have passed two types of laws: mandatory and permissive. The former indicates the licensing boards shall establish rules and regulations requiring continuing education for reregistration of licenses, while the later provides that the board may institute such rules.

As of July, 1979:

-- 21 State medical associations and the District of Columbia association required continuing medical education as a condition of membership.
-- 23 States and Puerto Rico had laws requiring continuing medical education of physicians.

-- In the following 12 States neither the medical association nor the law required continuing medical education of physicians: Connecticut Idaho, Indiana Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas, West Virginia and Wyoming.
-- 14 medical specialty societies and organizations require continuing medical education as a condition of membership. (Twenty-nine of these groups sponsor self-assessment programs.)
-- All medical specialty boards for physicians, with the exception of those listed below, have initiated, or have set dates to start, recertification.
American Board of Neurological Surgery
American Board of Orthopaedic Surgery
American Board of Psychiatry and Neurology

To the extent that legal provisions recently enacted in some states require physicians to maintain competency through continuing medical education as a condition of maintenance of lisencure to practice, this approach has been an effective mechanism to assure the acquisition of continuing medical education. A separate issue, though intimately related, is the measurable impact of continuing medical education on the quality of health care provided. This is currently under study by several professional groups. The type, amount, and quality of the continuing medical education offered and accepted, obviously affects the level of competency maintained.

Question: To what extent have the states attempted to strengthen and improve their efforts to identify, counsel, or discipline practicing physicians thought to be of questionable competence?

Answer: The Council on Medical Education perceives that both the profession and its leaders as well as the licensing authorities are increasingly aware of the need to identify and deal with the practitioners who provide "less than appropriate service/practice." In a July 1979 report, the Council has stressed the complexity of the issue of practitioner competency. It has defined competency and its component parts. In addition, the Council reports its perception that the profession, with the Professional Standard Review Organization thrust of the Federal Government, has induced changes in the state of mind regarding competency and its evaluation. The Council believes that evaluation should take place at the practice site and be done by peers, as opposed to national examination.

Question: What specific role does the Health Resources Administration play in ensuring continued competence of practicing physicians, and how is this role being carried out?

Answer: Licensure of health practitioners, such as physicians, is a matter between the State government, which carries the responsibility for safeguarding its citizens, and the given profession. It is not the prerogative of the Federal Government. Thus, HRA's role, is one of providing "catalytic action and support."

Following are some of the HRA activities in this arena:

1. The HRA Licensure Information System (a computerized information system on state licensing of health occupations), provides a large clientele with information on the state requirements of licensure and the data for analysis of progress.

2. HRA funded a model for continuing medical education for National Health Service Corps physicians.

3. In 1977 HRA published "Competence in the Medical Professions: A Strategy" which stemmed from a series of conferences dealing with topics including model practice act legislation.

4. HRA staff provide counsel to individual physicians and emerging specialty groups regarding State and Federal roles and responsibilities in this arena, as well as identifying contacts through which problems may be resolved.

5. The Division of Medicine anticipates development of an in-house document on the state of competence efforts in the medical field.

UNITED STATES STUDENTS STUDYING ABROAD

Question: To what extent are you involved with the Office of Education in providing guaranteed student loans for American students attending foreign medical schools?

Answer: The Health Resources Administration has no direct responsibility regarding the Guaranteed Student Loan Program. However, the Agency has worked closely with the Office of Education (OE) in defining the criteria for comparability of foreign medical schools which American students attend and, in general, advising OE in regards to procedures. The Health Resources Administration has been a source of information for U.S. foreign medical students, both those already enrolled in a foreign medical school and those contemplating a foreign medical education. Final decisions and operations, however, are the prerogative of OE.

Question: How many Americans presently are attending foreign medical schools?

Answer: Accurate data on the numbers of U.S. citizens enrolled in foreign medical schools is not available. The number flucuates from year to year and within a given year. Information offered by U.S. citizen foreign medical students indicates that the number of U.S. citizens attending any given foreign school is highest during the first semester of the academic year and drops radically during the following three to six months.

A survey conducted by United Nations Education Scientific and Cultural Organization for the Bureau of Health Manpower identified over 6,000 U.S. citizens studying abroad in 1972. Over the last few years, enrollment in foreign medical schools has become an increasingly elected alternative for U.S. students unable to gain admission to U.S. medical schools. The 1979 estimates of the number of U.S. citizens studying medicine in foreign schools range from 5,000 to as high as 12,000. Students are attending medical

schools in at least 34 different countries, with the largest proportions being located in Mexico, Italy and Spain. Smaller groups are at Belgian, French and Philippine medical schools. Medical schools in the United Kingdom and in Switzerland rarely accept U.S. citizens. A more recent development has been the establishment of entrepreneurial medical schools in the Caribbean intended to attract U.S. citizens. Two new medical schools have been established in the Dominican Republic and one each in Grenada, Dominica and Montserrat.

MINORITIES IN HEALTH PROFESSIONS SCHOOLS

Question: Over the past few years minority representation in health professions schools has shown little or no improvement. Can you tell us the cause of this situation?

Answer: We do not know the causes although the Association of American Medical Colleges does associate the progress of minority students with Federal support. This AAMC position was stated in its annual meeting in October, 1978.

Question: What are the principle barriers to increased minority enrollment?

Answer: There are at least three major barriers: inadequate financial aid, inadequate academic preparedness in the undergraduate as well as secondary school levels and continued presence of institutional racism, i.e., social/cutural discrimination.

Question How are the programs administered by the Health Resources Administration attempting to deal with these barriers?

Answer: Under the aegis of P.L. 94-484, the Health Education Assistance Act of 1976, the only manpower training program to directly address this question is the Health Careers Opportunity Program (HCOP). This program provides funds to help identify, prepare, admit and retain (counsel and tutor) minority students in entering and completing their health professional training.

PROGRAM SUPPORT

Question: I note in your budget you propose to cut 130 positions and related program support funds from the health manpower program. I am sure you are aware that Congress will be acting on new health manpower legislation this year. Please explain how your proposed cutbacks square with the impact of inflation on the program support function.

Answer: Although positions are being cut for programs that will not be conducted in fiscal year 1981, the budget does provide mandatory costs to keep up with increases caused by inflation for those remaining positions.

PHYSICIAN UTILIZATION AND DISTRIBUTION

Question: Is current professional development policy based on an incorrect notion that market forces do not affect physicians?

Answer: Current health professional development policy is based on many diverse factors and is not predicated solely on the assumption that market forces do not affect physicians. As a matter of fact, the degree to which physicians are affected by market forces has not yet been clearly determined. Some observers of the medical care delivery system contend that physicians control the market through their ability to set prices and to generate demands of care. They feel that a smaller aggregate number of physicians would contain costs and lessen the provision of marginally needed care. Other observers contend that market forces do influence the delivery of medical care through complex mechanisms, and contend that a larger number of physicians would tend to reduce prices and "monopoly rent" and thereby provide increased care value per dollar expended. The issue is a highly emotional, technical, and complex one, and while recent technical evidence seems to be increasingly supporting the view that market forces do play an important role in medical care delivery, the issue is far from satisfactorily resolved.

Question: Do specialists moving into rural areas practice primary or general care more than their specialties?

Answer: Information is not presently available as to whether any differences exist between the mixes of care provided by specialists in metropolitan and non-metropolitan areas. The importance of this information is recognized, however, and an analytic project has been begun, as part of the Graduate Medical Education National Advisory Committee effort, to determine whether such differences exist.

Question: Would you say that surplus numbers of specialists moving over into general care are compensating for the decline in numbers of general practitioners?

Answer: There is little hard evidence to indicate that the decline in general practitioners can be compensated for by board-certified specialists, especially in small rural areas or urban areas. The mere presence of a specialist in an area of need says little about the services he is actually providing. Even where specialists provide some primary care services--and it is estimated that primary care services may make up as much as 40 percent of some specialist's practices--this does not mean that the care provided meets the generally accepted five attributes of good primary care--accessibility, comprehensiveness, continuity, and accountability. Data are also not available on trends in the general care/specialty care content of different specialist's practices, and it cannot be determined if there has been an increase in the amount of general care being provided by specialists. It is nonetheless true, however, that the increasing numbers of family medicine specialists are now beginning to offset the long-term continued declines in the number of general practitioners.

Question: To what extent can specialty-trained physicians deliver appropriate cost-effective primary care?

Answer: In theory, all physicians are trained to deliver general care, and specialists have more or less equivalent preparation for delivering such general care as do general practitioners, even though they may lack the experience in many areas of general care which a general practitioner gains over the years. In addition, specialists by their very nature are trained to deliver specialty care, largely through hospital-based training and do not receive the ambulatory care training needed to provide the more general type of care. There is also general agreement that specialists do not adequately provide what are believed to be the five attributes of good primary care--accessibility, comprehensiveness, coordination, continuity, and accountability. However, there is little basis for setting precise boundaries on the extent to which it is appropriate or inappropriate for specialists to provide general care. The final report of the Graduate Medical Education National Advisory Committee is expected to provide some of this information in the form of judgements by expert physician panels as to the appropriate specialists for providing care by condition. In terms of cost-effectiveness of primary care delivery by specialists, specialists generally have higher rates of reimbursement for primary care procedures, so that costs per unit of service for general practitioners are less. Although it is not entirely appropriate to base definitive conclusions simply on the rates of reimbursement for the two groups, such rates are different enough to warrant the tentative conclusion that primary care delivered by specialty-trained physicians is probably less cost-effective.

Question: What are the policy implications of specialists serving as generalists in the financing and training of health manpower?

Answer: Excluding general internal medicine, family practice, and general pediatrics, few specialists are thought to be predominantly or exclusively providing general care outside of the area of their specialty. Instead, specialists provide varying amounts of general care, largely to established patients who originally consulted them as specialists. The amount of general care provided and the types of patients to whom it is provided may well relate to the availability of other physicians in the geographic area and to the workload the physician faces within his specialty.

In terms of financing of care and reimbursement, there has been substantial discussion as to whether a specialist providing care outside of his area of specialty should be reimbursed at a different rate than a general practitioner, and whether diffferences in reimbursement unrelated to special preparation are justifiable. In the absence of hard evidence that considerable numbers of specialists are predominantly providing general care or that the proportion of general care provided by such specialists is markedly and persistently increasing, the

existence of specialists providing some general care or fluctuations in the amount of general care provided would not appear to have significant implications for health manpower training policies. Although present data continue to show increasing specialization of physicians, an increasing provision of general care by specialists would suggest a greater need for general care than is being provided by family and other primary care physicians. Again, this does not address the quality and costs of general care when provided by specialists.

Question: What are the best indicators of satisfactory health professional distribution, i.e., health status measures, physician/population ratios, service area assessments?

Answer: No single measure provides a complete all-inclusive, definitive and unequivocal measure of health professional distribution, and a number of different measures are used to evaluate distribution from different perspectives. Mortality rates and health status measures are often used but present a problem in that they contain a large component of random disease incidence which masks the impact of health care provision, and do not address anything other than a few of the more quantifiable morbidity considerations. Mortality and health status measures also do not identify the population's perceived desires or expectations realted to health care, i.e., whether there is satisfactory delivery of health care services from the consumer's standpoint, nor do they address the issues of the socio-economic mix and life-styles of the population, their genetic background, their predisposition to disease, and their view of what level of wellness they are willing to pay for. The major purpose of health care resources is and will continue to be the treatment of morbidity, but mortality and quantifiable health status measures are influenced by so many factors other than provision of care that this measurement of distribution is weakened or totally lost in the other differences. Physician/population ratios provide another reasonable measure of differences in physician distribution. One problem with this type measure is that different types of health care necessitate different service areas, with patients probably traveling further for major surgery and certain specialty services than for routine primary care. In nearly all cases, little basis is provided for determining what is a satisfactory level of services for a given area.

Another approach is to measure differences in care provision among population groups of various kinds. One way is to examine utilization by the Medicare population, which faces lesser and more uniform cost barriers to seeking care, in order to analyze the differences relative to physician/population rates, waits for care, and other variables. Such an analysis, underway in HRA but not yet completed, cannot indicate what ratio is satisfactory, but can indicate the thresholds of physician availability and time-cost barriers to care consumption below which consumption of services is reduced. Similar analyses can

address the more complex general relationship of physician supply, producitivity, dollar price, and time costs. Preliminary findings from one such study suggest that systematic differences in quality of care exist between areas--such as physician preparation and credentials, availability of telephone consultation, use of aides, and amount of patient visit time with the physician--and that separate demands exist for both quantity and quality of care. This suggests that the distribution of physicians and the quality of care offered may occur in response to differing market demands between geographic areas. The complexity of such analysis and the limitations of available data, however, mean that additional study will be needed to clarify this approach.

A third approach is the use of professional medical consensus to identify what distribution of health professionals and services is appropriate. This approach is currently being taken by the Graduate Medical Education National Advisory Committee. A variation on this approach is use of patients' perceptions of the amount and type of care needed or unneeded, and the relationship of their perceptions to the availability of the health care resources in their geographic area.

In summary, there is no single ideal approach, and we must continue to examine all possible ways of identifying a satisfactory distribution, and avoid placing too much credence in any single measure to the exclusion of others.

HEALTH AND HUMAN SERVICES ROLE IN A CRISIS

Question: I understand that parts of HHS have rather substantial responsibilities for marshalling and coordinating the use of civilian medical resources in national emergency situations. Is the planning process routinely updated?

Answer: It has been the practice in the past to conduct periodic simulations of natural or national disasters to test the state of readiness of the various government agencies to respond to the real thing. About a year ago each health agency was asked by the Office of the Assistant Secretary for Health to develop a plan spelling out in detail what its role would be in the event of a natural or national disaster. HRA has since spent considerable time on developing its plan.

HEALTH MANPOWER DEVELOPMENT IN THE PACIFIC BASIN

Question: The Subcommittee has been quite impressed by your personal commitment over the past several years to insure the delivery of high quality health services and health manpower training to the residents of the Pacific Basin. We would appreciate, for the record, a report from you as to your progress to date and any specific recommendations you might have.

Answer: A report on health manpower development in the United States Trust Territory of the Pacific Islands, responding to a directive in Senate Report No. 95-1119, is currently being reviewed within the Department and will be submitted to the Appropriations Committee within the next couple of weeks.

HOSPITAL CONVERSION PROGRAM

Question: What is the present estimate of excess beds nationwide and the total cost of those beds?

Answer: Using the national guidelines and standards of 4.0 beds per thousand and 80% occupancy, the U.S. now has 130,000 excess beds. The Department of Health and Human Services estimates that 4 billion dollars annually can be saved by eliminating this excess.

Question: If we invest $10 million, or $30 million a year in some cases, to close facilities which the Federal Government probably helped to build--how much can we expect to save over the short and long run?

Answer: We do not really have very good estimates of the costs and savings of closing a bed. The discontinuance and conversion program will be designed as a demonstration, so that we can get some improved estimates in this area. At $10 million per year and using an estimate of $20,000 to close each bed, one may assume that 500 beds could be closed. Based on the HHS estimate of $4 billion saving for 130,000 beds, closing 500 beds can be assumed to save $15 million annually. This rate of savings may take a year or two to reach. To some extent, it depends on the rate at which excess use of the excess capacity is eliminated from the system. In the long run, we would expect to see additional savings when a critical mass of excess capacity has been reduced so as to make more effective such programs as Utilization Review and PSRO.

Question: Will this represent a true savings, or merely a transfer of costs from acute hospital services to long-term care?

Answer: That will depend on how savings are used. If excess capacity is simply closed, without conversion to another type of service, then it is likely this will provide true savings. If the capacity were converted to another type of service such as long-term care or outpatient care, then the extent of savings would likely be much less.

HILL-BURTON "FREE CARE" PROVISIONS

Question: Can you provide a state-by-state breakdown of "charity care"?

Answer: A precise state-by-state breakdown is not readily available. However, the table below indicates the total grant assistance to the states for which the "free care" obligation applies. Ten percent of the total would closely approximate each state's obligation, without adjusting for inflation.

Amount of Hill-Burton Grant Funds under Uncompensated Services Obligation (represents facilities whose obligations expire September 1979 and later)
(In millions of dollars)

Alabama	$ 90	Maryland	$ 41	South Carolina	$ 68
Alaska	9	Massachusetts	61	South Dakota	19
Arizona	28	Michigan	115	Tennessee	89
Arkansas	56	Minnesota	63	Texas	205
California	145	Mississippi	68	Utah	20
Colorado	33	Missouri	76	Vermont	12
Connecticut	23	Montana	15	Virginia	85
Delaware	13	Nebraska	28	Washington	40
District of Columbia	7	Nevada	11	West Virginia	49
Florida	101	New Hampshire	16	Wisconsin	65
Georgia	104	New Jersey	63	Wyoming	11
Hawaii	16	New Mexico	24	Guam	1
Idaho	18	New York	165	Puerto Rico	86
Illinois	87	North Carolina	120	Virgin Islands	2
Indiana	75	North Dakota	18		
Iowa	54	Ohio	132	Total	$3,125
Kansas	39	Oklahoma	52		
Kentucky	71	Oregon	28		
Louisiana	87	Pennsylvania	180		
Maine	24	Rhode Island	15		

Question: Why do you insist on adding an inflation factor to the dollar levels hospital must allocate to "charity care"?

Answer: The Department continues to believe that the inflation factor is appropriate policy. The effect of the policy is to keep the value of the services provided constant, so that the indigent are not deprived of services by inflation. Moreover, since the value of the services provided will stay approximately constant, the Department cannot agree that what is not an "onerous burden" now will become one in the future. Nevertheless, in view of the costs of this policy, the Department will reevaluate it in light of experience over the next three years.

Adjusting the 10% compliance levels by the inflation factor represents a reasonable Federal interpretation of what a "reasonable volume" is over time, and it also makes this compliance level consistent with the 3% of operating costs compliance level since the latter automatically incorporates inflation as costs increase.

While the Department recognizes that the Consumer Price Index for medical care does not perfectly reflect inflation in the cost of services from facilities, that index is the closest approximation available and therefore has been retained. It is used rather than the various measures of change in the cost of money since what is being measured is the required level of services not the underlying base of of Federal assistance. Although the Department recognizes that use of a national index penalizes those facilities whose costs have stayed below the national rate, it nevertheless believes that use of a national index is necessary in light of the compelling need to have

readily ascertainable compliance standards which the national CPI for medical care provides.

Question: What is the basis of the law suit brought by the American Hospital Association at the time the regulations were issued? What is your response to it and what is the status of the matter?

Answer: It would be inappropriate for the Agency to respond on a matter involving litigation. The response should come from the Office of the General Counsel. In preliminary hearings, the judge has ruled in favor of the Department.

CHARITY CARE AND MEDICAID

Question: How do "charity care" patients differ from those eligible for Medicaid?

Answer: The Hill-Burton "charity care" regulations use the Community Services Administration (CSA) Poverty Income Guidelines for patient eligibility determination rather than the states' eligibility under Medicaid. Medicaid criteria differ from state to state and are based largely on Aid to Families with Dependent Children guidelines. The CSA guidelines are less stringent than some states' Medicaid eligibility criteria.

Question: Do institutions receiving federal funds provide reasonable amounts of free service to persons unable to pay?

Answer: Although there has been substantial non-compliance with this requirement in the past, the issuance of regulations in 1979 and our expanded monitoring program are designed to improve the implementation of the requirement.

Question: Has health facility loan monitoring improved compliance with federal requirements?

Answer: Yes, loan monitoring has generally improved facility compliance with federal requirements. Compliance with the free care requirements is reviewed through our assurances monitoring program while our loan monitoring efforts emphasize review of various other financial and program requirements. We attribute the improvement to the following policies. First, key points of intervention in the loan administration process have been determined and approval responsibility has been centralized and, second, loan monitoring procedures have been established to provide continuous monitoring of the facilities loan portfolio on a regular basis.

Question: How has the new Health Resources Administration Bureau of Health Facilities Financing, Compliance, and Conversion fared in accomplishing its three stated goals? Is there now an HEW policy regarding health facility capital formation?

Answer: There is a need for the Department to refine its policy in this area. There has been a continuing shift in policy over the last ten years from encouraging more capital investment to promoting the most efficient development, distribution, and use of capital. In the next year the Department will further refine its position on a number of related issues in this area.

1979, the Administration announced a voluntary goal that a limit should be set on the level of capital expenditures approved. The proposed national goal was a level of $3 billion compared to current

approved levels of approximately $5.2 billion. This would require a substantial reduction in the level of capital expenditures across the country. In addition, the "National Guidelines for Health Planning" call for no more than 4.0 short-stay hospital beds per 1,000 population. This contrasts with the current level of 4.5 beds per 1,000 population . Along with the capital expenditure limit proposal, this implies a significant reduction in expenditures for new beds as well as encourages the closure or conversion of those beds considered unnecessary. Over the next year the Department will further refine its position on a number of related issues in this area.

REDUCING HOSPITAL OPERATING EXPENSES

Question: What estimates do you have to support the Health Resources Administration's claim that "Federal grant money is reimbursed through reduced hospital operating expenses?"

Answer: Grants under our conversion and discontinuance program are expected to result in reduced hospital operating expenses. This will be one of the items we will be studying as part of our demonstration program in this area. One approach to measuring savings from closing beds is based on the elimination of fixed costs, i.e., the cost of keeping an empty bed open. The variable costs associated with treating a patient in the bed would stay in the system since the patient and the variable costs would just be shifted to a bed that remained open. One estimate is that each bed closure will cost approximately $20,000 and save, on the average, $33,000 to $53,000 in operating costs each year for the useful life of the bed (conservatively five years beyond closure).

NATIONAL HEALTH SERVICE CORPS

Question: In a report to the Subcommittee, it was stated that, "HSA is not making final commitments for placement of volunteers due to the need to place currently obligated scholarship recipients." Is there a continuing need for obligated service?

Answer: During the past year, we did cut back on the placement of volunteers; however, this cutback was the result of limitations imposed by our personnel ceiling rather than in our ability to place scholarship recipients. We do not believe this problem will recur in future years. There is a continuing need for obligated service.

Question: One problem mentioned in the Report on the Organizational Location of the National Health Service Corps is that the Corps' rapidly accelerating growth might outrun the policy, program and administrative support capabilities of both HRA and HSA. How do you propose to address this problem? How is a projected growth in funding, as outlined in the report, related to this support need and that of projected manpower needs?

Answer: To date, the growth of the NHSC has not outrun our ability to manage it. The Department is currently reviewing questions on the future size of the Corps and relating them to the support need and projected primary care manpower needs. Another purpose of these deliberations is to see that the Corps and its placement activities are maintained within manageable limits.

61-400 O - 80 - 59

Question: Should the Government play a role in encouraging Board Certification among specialists? Do we have evidence to suggest that the quality of care received with board-certified or board-eligible physicians is better?

Answer: Postgraduate training after the award of the M.D. degree is becoming more prevalent in the United States. It is estimated that of the 16,000 graduating physicians annually, more than 90% pursue formal residency training beyond the first postgraduate year (formerly called the internship year). This trend is indicative of the recognition that medical education extends beyond medical school, when an individual physician's interests become more focused on an area of special expertise.

Board eligibility is a milestone in this educational process, when a physician has completed all the special requirements demanded by a Board, prior to actual certification. Board certification is the measurable benchmark of attainment of sufficient knowledge and skills necessary for professional recognition as a specialist.

Insofar as the Federal Government has a responsibility to assure the availability of quality health care for the Nation, residency training and Board certification should be encouraged.

Question: What incentives are necessary to encourage better specialty and geographic distribution of physicians?

Answer: The issue of specialty and geographic distribution of physician manpower is one of the most complex facing the Nation's health care delivery system. There are numerous dimensions to the many issues and these require multifaceted approaches and solutions. Initiatives needed include:

- Redirecting current reimbursement practices and solutions, both in the educational and the health care delivery system;

- Improving the analytical data base for decision-making, both for the educational processes and the health care delivery system;

- Improving health planning strategies and approaches;

- Making more primary care training opportunities available;

- Providing flexible student assistance programs (including those involving service commitments such as National Health Service Corps Scholarships);

- Continuing initiatives to produce and utilize nonphysician providers to provide services not requiring the specialized training of a physician; and

- Developing and improving regionalized systems of health professions education in order to assure requisite support services (e.g., AHEC).

PARA-PROFESSIONALS

Question: What is the current status and outlook for para-professionals (e.g., emergency medics) and physician extenders in the health field?

Answer: There are currently insufficient numbers of Emergency Medical Services (EMS) providers; however, precise numbers are unknown. Professional sources and Federal agencies generally estimate the need for 163,000 EMS providers above the current supply of approximately 308,600; this includes a need of approximately 9,300 physicians.

ORGANIZATION CHANGE

Question: Many problems affecting either HSA or HRA administratively need to be solved either separately or jointly in order for NHSC to continue to function in its current organizational position. The report suggests that joint resolution of policy and program problems is an effective, least-costly alternative to total organizational change. Would you comment on the political and administrative feasibility of this proposal? The report suggests that personnel involved in NHSC programs feel that the service elements of the NHSC in the Bureau of Community Health Service (BCHS) should be merged with the scholarship elements of NHSC now located in the Bureau of Health Manpower (BHM). The consensus was that this organizational merger should occur in HSA. Would you support this? Why? Would such a merger or change account for improving: Responsibility, heretofore lacking, for overall NHSC daily operations? Smoother program function and decision-making? Greater efficiency and Corps member faith in NHSC activities? Will the Corps, if re-organized under HSA, be better able to serve in a broker function matching service producers with communities in need? HEW has narrowed the report's proposed five alternatives down to three (see following). Would you please comment on the criteria involved and the time schedule it will take for the Surgeon General and Secretary Harris to choose a preferred option?

HEW's three chosen alternatives: These three alternatives involve organizational change for the Health Service Corps in various degrees--from partial transfer of only the scholarship program from HRA to HSA, to entire transfer of the Bureau of Health Manpower, HRA. (1) An organizational change limited to the transfer of the scholarship program from HRA to HSA; (2) An organizational change that would involve transferring the Division of Manpower Training Support, HRA, in addition to the scholarship program; and (3) A more comprehensive organizational change that would involve the transfer of the entire Bureau of Health Manpower, HRA.

Answer: It is the position of the Surgeon General that the National Health Service Corps could be more effectively managed if the scholarship program were combined with the service program in the Health Services Administration. The exact nature and timing of this proposed organizational change, and any accompanying changes, are still under consideration within the Department. Recommendations will be made by the Public Health Service to the Secretary who will in turn make the final decisions and inform the Congress.

MALDISTRIBUTION AS ADDRESSED BY THE NHSC

Question: What will be the focus of the Corps in coping with maldistribution of health professionals?

Answer: The Corps will continue to employ National Health Service Corps Scholarship recipients and volunteers who in turn will be assigned to work in designated health manpower shortage areas.

Thus, the Corps will continue to address the problem of maldistribution of health professionals.

STATE LICENSING OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS

Question: Are there problems with State licensing requirements for nurse practitioners and physician assistants who are in the National Health Service Corps?

Answer: There are some problems with state licensing requirements for nurse practitioners in that some states have difficulty dealing with the expanded role of nurse practitioners. Presently, about six states have not amended their statutes to allow for the expanded role of nurses. Most current revisions of Nurse Practice Acts are more broadly worded and lessen restrictions on nurses' activities. In this way they move to bring the legal definitions of nursing more in line with the current and projected scope of nursing practice. All nurse practitioners are licensed as RN's, but some States require an additional "certification" for nurse practitioners.

There are also some problems with State legal sanctions for physician assistants. In some cases legislation is quite restrictive such that physician assistants are prohibited from utilizing all their knowledge and skills which they have acquired. Statutory changes have been necessary because State law traditionally limited the legal right of physicians to delegate medical tasks "both as to whom they may delegate and as to the nature of the delegated task". Thirty States have the regulatory statute which authorizes an administrative agency, most often the State Board of Medical Examiners, to regulate physician assistants. Fourteen States have delegatory sanctions which are amendments to the Medical Practice Acts exempting physician assistants from their provisions and giving the physician sole responsibility for determining physician assistant qualifications and functions. All States require that the physician assistant act under the supervision of the physician. Only a few States are explicit in defining this requirement. Often it is unclear whether physicians must provide "over the shoulder" supervision, or be on the premise, or may provide remote monitoring via electronic means. The latter is advantageous since it facilitates physician assistants working in more remote underserved areas where fewer physicians practice.

SUBCOMMITTEE RECESS

Senator SCHWEIKER. We will recess until 1:30 tomorrow when Dr. Richmond will return for the health overview in the Office of the Assistant Secretary for Health.

Thank you.

[Whereupon, at 4 p.m., Thursday, February 7, the subcommittee was recessed to reconvene at 1:30 p.m., Friday, February 8.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1981

FRIDAY, FEBRUARY 8, 1980

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

The subcommittee met at 1:30 p.m. in room S-128, the Capitol, Hon. Daniel K. Inouye presiding.

Present: Senators Inouye and Burdick.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE ASSISTANT SECRETARY OF HEALTH

STATMENT OF JULIUS B. RICHMOND, M.D., ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL

ACCOMPANIED BY:

CHARLES MILLER, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS
RUTH S. HANFT, DEPUTY ASSISTANT SECRETARY FOR HEALTH RESEARCH, STATISTICS, AND TECHNOLOGY
HOWARD VEIT, DIRECTOR, OFFICE OF HEALTH MAINTENANCE ORGANIZATIONS
LULU M. NIX, DIRECTOR, OFFICE OF ADOLESCENT PREGNANCY PROGRAMS
PETER J. BERSANO, DIRECTOR, OFFICE OF RESOURCE MANAGEMENT, PUBLIC HEALTH SERVICE
DAVID E. JOHNSON, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
ALAIR TOWNSEND, DEPUTY ASSISTANT SECRETARY, BUDGET

BUDGET REQUEST

Senator INOUYE. This afternoon we will have the last in our series of hearings on the fiscal 1981 health programs budget.

Appearing before us this day is Dr. Julius Richmond, the Assistant Secretary for Health. During this afternoon's session, we will be discussing programs administered by Dr. Richmond's office, as well as an overview of other Public Health Service programs.

The Office of the Assistant Secretary for Health is sometimes thought of as the potpourri of health administrative offices. It is in charge of inplementing a variety of health programs, ranging from the adolescent

pregnancy program to the antismoking initiative. Among the activities of this Office are the health maintenance organization program, the health services research, health statistics, and health technology projects, Public Health Service management and much, much more.

For fiscal year 1981, the President has requested $214.8 million for the Office of the Assistant Secretary for Health—an increase of $21.4 million over the previous year's budget.

Dr. Richmond, at this time, I would like to extend to you the subcommittee's welcome. We have a few questions to address to you, but before we begin, would you first introduce your distinguished associates and then proceed with your opening remarks.

Dr. RICHMOND. Thank you very much, Mr. Chairman. On my left is Mr. Charles Miller, the Deputy Assistant Secretary for Health Operations; on his left, Mr. Howard Veit, Director, Health Maintenance Organization Program; on his left, Dr. Lulu Nix, who heads our adolescent pregnancy programs.

On my right, Mr. Peter Bersano, who runs our Budget Office; and on his right, Mrs. Ruth Hanft, who directs our centers for health statistics, research services, and our center for health care technology. And on her right is Miss Alair Townsend, Deputy Assistant Secretary for Budget.

Mr. Chairman, since I know time is very limited, I would condense my comments on the overview of the Public Health Service since we are embarking on a new decade, it is, I think, appropriate to comment on some of the progress we have seen in the health of the American people which reflects the impact of our programs.

Senator INOUYE. Without objection, your full statement will be made a part of the record.

Dr. RICHMOND. Thank you.

[The statement follows:]

Statement of Dr. Julius B. Richmond

I am pleased to be with you today to review some of the significant highlights in the health field which have occurred in the past decade, and the Public Health Service appropriations for fiscal year 1981.

Decade of the 1970s

The 1970s ended with a landmark in medical history. In 1979, smallpox was eradicated from the world. This global effort began in 1967 when there were millions of smallpox cases annually. Today, smallpox is no longer a threat to anyone, anywhere in the world.

In April 1977, HEW began to carry out an intensive campaign to immunize 90 percent of the nation's children against the major preventable childhood diseases--measles, mumps, rubella, polio, diphtheria, tetanus, and pertussis. The low level of childhood immunization at that time was a major threat to our public health. By the end of 1979, we had substantially achieved our goal. The incidence of childhood diseases is now at an all-time low in this country.

Deaths from heart disease, the country's leading killer, have dropped dramatically--about 22 percent over the past 10 years--and death from strokes are down 30 percent.

During the 12 years from 1965 to 1977, the infant mortality rate dropped by 5 percent per year for both white and black infants. During the preceding 10 years, 1955-1965, the annual rate of decline was less than 1 percent per year.

In 1965, 51 percent of all adult males were smokers. Today only 37 percent of men are smokers. Whereas some 42 percent of all adults smoked in 1965, this has now dropped to approximately 32 percent. Teenage smoking levels, which increased substantially from 1968 to 1974, also showed signs of a decrease by 1979.

The United States continues to lead the world in biomedical research and technical innovation and PHS is a major sponsor of this effort. In 1979, Dr. Herbert Brown became the 72nd PHS-sponsored scientist to win the Nobel Prize.

Many of the inequities between the poor and nonpoor in access to physicians and hospital services that existed prior to the Medicare and Medicaid programs have disappeared in this decade. For example, by 1977, the percent of low income persons contacting a physician at least once in the previous year had actually surpassed the percentage observed for either the middle or high income categories.

A growing concern of the 1970s had been the rapid rise in the cost of health care. PHS has played an ever increasing role in the area of health care cost containment through such major activities as:

- The encouragement of Health Maintenance Organizations (HMOs) as a cost-effective alternative to the traditional fee-for-service health care system. Since the inception of the Federal HMO program in 1972, the number of HMOs has increased from 50 programs in 20 states to over 220 HMOs in 37 states in 1980. In addition, HMO enrollment has nearly doubled since 1972.

- The development of a national health planning capability through the establishment of a nationwide network of Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs).

- The termination of the PHS assistance programs for constructing and modernizing hospitals because of the existing oversupply of hospital beds.

Decade of the 1980s

The 1980s offer many challenges as well as opportunities in the health field such as:

- The development and application of the techniques for producing recombinant DNA. Such research has already offered new hope in the treatment of diabetes through the development of a technique for potentially mass producing insulin in a test tube. In addition, the recent, widely publicized breakthrough in the production of interferon may provide an important new weapon against a wide range of diseases.

- The easing of the critical physician shortage we faced in the 1960s. In fact, at current capacity, indicators point to an adequate--or more than adequate--supply of physicians by 1990. The real problem for the 1980s will be the distribution of health care providers so that they can address the needs of the approximately 25-30 million persons who are now estimated as medically underserved.

- The prevention of disease. As stated in my Report on Health Promotion and Disease Prevention, it is through the prevention of disease, not through its treatment, that significant improvement in the Nation's health status will be made. Prevention saves lives, improves the quality of life, and is cost effective.

Fiscal Year 1981 PHS Budget

As I have just suggested, there are many worthwhile goals for the 1980s, and our 1981 PHS budget will help achieve many of our objectives for the decade ahead.

Our total 1981 request being heard before this Subcommittee is $7.5 billion for the Public Health Service. This represents an increase of 3.9 percent over the 1980 level of $7.2 billion. Within this total request for 1981, we have targeted the majority of our requested increases toward programs in the three areas of highest priority: (1) health care for the medically underserved; (2) prevention and protection; and (3) knowledge development.

I. Health Care for the Medically Underserved

The 1981 PHS budget request includes funding increases of 10.9 percent over the 1980 level for programs to reach the estimated 25-30 million persons who are currently deprived of adequate health care because of economic factors or because of their geographic location. Our 1981 request can best be explained in terms of a threefold approach:

- First, our 1981 budget requests increases of $51.3 million for the National Health Service Corps (NHSC) program and $8.0 million for the NHSC Scholarship program. The funding increase for the National Health Service Corps will support an additional 1,708 field assignees for a total of 4,528 assignees with the capacity to serve a total of 3.2 million persons.

- Second, PHS will continue its efforts to develop health services delivery capacity in rural and urban medically underserved areas primarily through the Primary Health Care Services and Migrant Health programs. For 1981, we are requesting increases of $54.4 million for the Primary Health Care Services program and $5.0 million for the Migrant Health program. As a result of these increases, these programs will have the capacity to serve a total of 6.9 million persons when fully operational.

- Third, we will increase the number of family medicine and primary care physicians who will establish practices or seek employment in underserved areas. We will stimulate the training of these physicians through the Area Health Education Centers (AHECs) program and by developing primary care residencies through the Family Medicine and Primary Care programs within the Health Resources Administration. We are requesting an additional $17.8 million for Family Medicine and Primary Care programs.

To further address the needs of the medically underserved, the 1981 budget request proposes funding increases to:

- Provide 7,400 additional maternity and family planning services and health care and assessment services to an additional 59,000 children through the Maternal and Child Health Grants to States program.

- Provide services to an additional 146,000 patients, including 65,300 adolescents, through the Family Planning program.

- Expand the Community-Based Mental Health and Alcohol Treatment programs of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). As a result of these increases, the number of beneficiaries for alcoholism treatment will increase by 21,000 to a total of 315,000 persons and patients treated in Community Mental Health Centers will increase by 300,000 to a total of 3.6 million patients.

II. Prevention and Protection

We are requesting an increase of 6.7 percent for prevention and protection programs including an increase of $25 million for construction of new facilities for employees doing vital research. Important as these increases are, it would miss the point to discuss our prevention strategy strictly in terms of "budget increases." What is needed far more than increased medical care and greater Federal health care expenditures is a renewed national commitment to efforts designed to prevent diseases and promote health.

Our 1981 budget proposes a balanced approach to prevention including:

- Continuation of our efforts to immunize 90 percent of the children against childhood diseases and to immunize high-risk populations against measles. Approximately 6.3 million children will receive childhood immunizations and approximately 3.1 million persons will receive measles immunizations as part of our plan to eliminate measles by 1982.

- Expansion of the Fluoridation program to support 43 additional fluoridated community water systems and 35 additional fluoridated rural school systems serving an estimated 1.8 million people.

- Implementation of a new Prevention Formula Grant program to strengthen the capacity to state and community preventive health services and to target resources to the five leading causes of morbidity or mortality in those states.

- Targeted support for my Office on Smoking and Health to expand efforts to reduce smoking among adolescents, pregnant women, and high-risk individuals.

- Intensified efforts in the Chronic Diseases area for nutritional surveillance and diabetes control.

III. Knowledge Development

The third major goal is to maintain a sufficient and stable funding strategy for biomedical and behavioral research and knowledge development. Research and knowledge development can improve ongoing programs in services and prevention and find new solutions to persistent disease problems. In this sense, research must be viewed as the foundation on which the objectives of all progrmas are based. Reflecting the importance of research and knowledge development, the 1981 budget request provides for increased research funding within the National Institutes of Health (NIH), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and the Office of the Assistant Secretary for Health (OASH).

- An additional $141.6 million will permit a total of 5,000 new and competing grants to be funded at NIH. This funding level will permit us to fund the same number of new and competing projects as in fiscal year 1980.

- An increase of $23.0 million at NIH for 100 additional bioassays of chemicals to test their ability to cause cancer or other toxic manifestations. This will bring the total number of bioassays to 320 in 1981.

- An increase of $25.0 million for research at ADAMHA with the majority of this increase targeted to expanding general mental health research in such areas as treatment of the chronically mentally ill, mental illness in the elderly, and problems of minority populations.

- An additional $4.4 million in Health Care Technology will permit an increase in the number of comprehensive assessments in such areas as ultrasound diagnostic procedures, fetal monitoring, coronary by-pass surgery, end-stage-renal-disease and will initiate a program of intramural research.

Thank you for this opportunity to discuss the fiscal year 1981 budget request for the Public Health Service. I will now be pleased to respond to your questions.

HEALTH STATUS

Dr. RICHMOND. We have had a remarkable decade. We have witnessed the eradication of smallpox, not only in this country but throughout the world; we have seen a remarkable reduction in the common childhood infectious diseases; and we are very pleased that the immunization initiative that was undertaken by this administration some 2½ years ago has borne some remarkable results.

The common contagious diseases of childhood are at the lowest point

in our history, and we are hopeful that measles will join the ranks of smallpox in the not-too-distant future—we hope by 1982—as having been eradicated as a disease in this country. The other childhood infectious diseases are indeed very low.

But perhaps even more striking, our National Center for Health Statistics has indicated that there has been a remarkable decline in this past decade in mortality from heart disease, a 22-percent drop over 10 years ago, and that deaths by stroke are down by some 33 percent. And we are very pleased to see this progress which has taken place.

Our infant mortality rate, comparably, is at the lowest point in our history. Our most recent data indicate that it's 13.1 per 1,000 live births.

Senator INOUYE. How do we rank in the industrialized world?

Dr. RICHMOND. We rank somewhere between 14 and 16. We do not have the most recent data on hand, but we have been at about that level. The Scandinavian countries and some of the western European countries have had a somewhat better record. Sweden, in particular, has been at the forefront and has a record of 8 per 1,000.

Senator INOUYE. You're pleased with the improvement, but are you satisfied with it?

Dr. RICHMOND. No; we are hoping to move aggressively to continue that downward decline. We know that some population groups in the United States—Japanese-Americans and Chinese-Americans—have significantly lower rates than any other group in the population.

Senator INOUYE. Where is the highest rate?

Dr. RICHMOND. The highest rates seem to be among the black population.

Senator INOUYE. Is there anything being done? Is your agency doing anything about that?

IMPROVED PREGNANCY OUTCOME

Dr. RICHMOND. We have a number of programs, Mr. Chairman. One of those which we have mounted in most recent years is an effort we call improved pregnancy outcome, in which we collaborate with the States to investigate why there are areas of higher mortality, and provide some funding for them to target their efforts more effectively.

We are also asking our State health offices to try to target their health care services at this problem.

We also currently are reviewing whether or not we can redevelop the efforts of local health departments, and particularly the role of public health nurses to focus on those population groups that have the greatest risk.

Senator INOUYE. Assume that the Congress supports you in your endeavor; where do you think the United States should be at the end of this decade?

Dr. RICHMOND. Well, at the end of this decade we're hoping that we would be at a level of 9 to 10 per 1,000 live births. With the heterogenity of our population, we perhaps may not be able to attain the rate that Sweden has attained, but we are hopeful that we can get very close.

Senator INOUYE. Proceed, sir.

AVAILABILITY OF HEALTH SERVICES

Dr. RICHMOND. We have seen, of course, in addition to the improvement of the health record of our Nation, some significant improvements in the availability of services to our population. We are pleased that since the passage of medicare/medicaid and the expansion of the community health center migrant health programs our poor population has better access to services.

This is reflected by the fact that our low-income population is now seeing providers about as frequently as our more affluent population. We, however, would like to have them be the recipients of better quality care than they often are. They often obtain emergency room care rather than having a clinical or private physician base for their medical care.

We have also been moving toward the development of some competition within the health care system, and we particularly have been pursuing the development of health maintenance organizations. We are pleased that there are now more than 220 health maintenance organizations, in contrast to some 50 that existed when the program got underway.

HEALTH PLANNING

Our national health planning activities have become more active. Our National Council on Health Resources and Health Planning is functioning at this time and is providing leadership for us throughout the country.

In the 1980's we anticipate that we would continue to develop our research base. We are very pleased to point out that as a consequence of the research advances we have seen some striking developments—those related to recombinant DNA, for example, which are now making it feasible to develop insulin from bacterial sources rather than having to rely entirely on animal sources.

We hope that the developments in relation to both hormones similarly from such sources would be a great advance in helping some people with specific illnesses, as may develop with the greater production of Interferon.

All of these are developments that would have been unthinkable a decade or so ago. It is the advances which have been taking place in our research endeavors which make these developments possible.

We hope to continue to extend our programs of services to our medically underserved populations, and to emphasize disease prevention and health promotion more fully, or more adequately. Last summer we issued the Surgeon General's report on health promotion and disease prevention, which we feel is making considerable impact in bringing the importance of prevention to the attention of our people.

For our 1981 budget, therefore, Mr. Chairman, our priorities are to provide improved and extended services to our medically underserved population and to expand our National Health Service Corps program. We hope to enhance our development of community health services and migrant health programs to deliver primary health services to particularly low-income groups in rural as well as urban areas, and to provide services for the elderly.

This will require an increase in the number of primary care physicians and we think our health manpower policies are addressing those issues. We also hope to expand our family planning services and to expand our community-based mental health and alcohol treatment programs of our Alcohol, Drug Abuse, and Mental Health Administration.

We certainly are hoping that we can enhance our efforts in prevention and health protection. We think in the longer perspective that the more effective we can become in prevention and health promotion, the more cost effective we will be in relationship to our service programs. We hope to continue our child immunization effort so that the promise of eliminating measles and German measles, in turn, can be kept. We want to expand our fluoridation programs because they are cost effective in helping children grow up with healthy teeth and reducing the expenditures for dental care. We hope to increase our collaboration with the States in prevention formula grants program.

FORMULA GRANTS

Our budget for this year for the formula grant program is very modest, but if this helps the State health offices and the local health offices to target their efforts at the five major causes of mortality this will be an effective program. We do hope to target the efforts of our Office on Smoking and Health to reduce the amount of smoking among adolescents, and pregnant women. As we talk about adolescents we would like to focus on female adolescents in particular as a greater percentage of older female adolescents and young adult women are smoking at the present time.

That's another effort.

We do want to intensify our rehabilitation efforts in chronic disease, not along control, but more effective rehabilitation; and our efforts in terms of improved nutrition is a part of this effort, as is diabetes control. We are pleased that just early this week we produced some material in collaboration with the Department of Agriculture called "Dietary Guidelines for the Nation," which seems to be stimulating a great deal of interest, and which we think will be very important for our people in terms of prevention.

In addition to improving our services to the underserved and our efforts in prevention, we, of course, must continue to expand our knowledge base. We are looked to throughout the world for our medical research, behavioral research, and services research efforts, and we want to maintain the quality and extensiveness of those programs.

RESEARCH EFFORTS

In the past year the National Institutes of Health, including our Alcohol, Drug Abuse, and Mental Health Administration and our Centers for Health Care Technology, Health Care Statistics, Health Services Research, have been involved in a planning process so that our research efforts will be stabilized at some appropriate level that will continue to foster the kind of quality that we have attained thus far. We have built into that effort a new program—our national toxicology program, in or-

61-400 O - 80 - 60

der to try to identify particular carcinogenic agents and also other toxic agents, so that we can bring those under control.

We are asking to increase our research effort at the Alcohol, Drug Abuse, and Mental Health Administration by some $25 million, and to add $4.4 million to our areas in health care technology, which is a developing effort. We are exploring that and we think it's a very promising one. We want to provide a more rational base for introduction of the very considerable developments which are taking place in that field of health care technology.

I think, Mr. Chairman, with those remarks and with those emphases in our programs, I would just like to submit the statement concerning the programs in the immediate Office of the Assistant Secretary for Health for the record.

My colleagues and I will be pleased to respond to any questions that you have to put to us.

[The statement follows:]

Statement of Dr. Julius B. Richmond

I am pleased to be here today to request funds for the various appropriations within my office.

Assistant Secretary for Health

The 1981 budget request for this appropriation emphasizes a number of health initiatives which represent high priority efforts for the Public Health Service. We are requesting $214.8 million of which $191.6 million is for specific health programs and $23.2 million for overall PHS management functions.

National Center for Health Services Research

The National Center for Health Services Research conducts and supports research, demonstrations, and evaluations on problems in the organization, delivery, and financing of health services. The Center's research program is designed to provide needed information to government, the health industry, and consumers of health services.

Major activities currently supported are research on cost containment and health planning, examination of the means to improve the economy and quality of drug prescribing, and the application of computers in the health sector to increase the efficiency and quality of health services.

The budget request of $34.6 million will provide for continuation and expansion of health services research and dissemination activities. New research in the area of disease prevention and health promotion will focus on the analyses of the organization, delivery, and impact of health promotion and prevention programs. Studies will also be funded to examine the factors and incentives that lead to cost-effective consolidation, mergers and sharing of institutional services. Also a new research training program will be initiated to fund institutional support and student stipends.

National Center for Health Statistics

The National Center for Health Statistics is the principal federal program for the collection, maintenance, and dissemination of general purpose health statistics and vital events for the nation such as births, deaths, marriages and divorces. Information is obtained through a program of continuing and periodic surveys and inventories, and through the Cooperative Health Statistics System. Statistics are produced on a wide range of topics including the health and nutritional status of the population, the extent and nature of illness and disability of the population and the costs of health care.

The information and statistics gathered are intended to serve the needs of the full range of our society including government and businesses, the health community, the academic and research community, public and private groups, and private citizens as well.

The 1981 budget of $41.6 million provides funds to obtain much-needed health information in two important areas. The first is a study of the health effects of environmental conditions and the health care cost savings that would result from reducing pollution and other adverse environmental factors. The second is an analysis

of the health and nutritional status of the Hispanic population in the U.S., which is thought to be worse than that of the general population. An increase of $4.3 million is requested for these two high priority activities. Other important surveys involving medical care utilization and expenditures, health and nutrition, and health interviews will be continued.

Beginning in 1981, the efforts of the Cooperative Health Statistics System will be redirected toward developing the capacity of the States to collect, analyze, utilize, and disseminate health statistics instead of emphasizing the collection of specific data elements. There is a decrease of $8.0 million in the Cooperative Health Statistics program resulting from a decision to collect health manpower and health facilities data on a periodic basis rather than on a continuing basis.

National Center for Health Care Technology

The National Center for Health Care Technology is the focal point in the Department for the coordination of technology assessment activities and joint resolution of technology-related issues. In addition to analyzing the safety, efficacy, and cost-effectiveness of particular health care technologies, our efforts will also focus on the ethical, social, and economic impacts of specific health technologies. The appropriate use of existing and new technologies and the introduction of new technologies into health care practice before their safety and efficacy are established are issues that warrant scientific assessment.

Funding will support the conduct of research and technology assessment activities in the areas identified and recommended as priorities by the National Council on Health Care Technology, the Departmental Technology Coordinating Committee, and others. Examples of health practices to be assessed are coronary bypass surgery, dental X-rays, and cardiac ultrasound. The budget increase of $4.6 million and added staff will permit the initiation of intramural research and further develop the extramural research capabilities. The National Center for Health Care Technology will continue to work with the Health Care Financing Administration to provide recommendations for developing guidelines on the reimbursement of selected medical services and procedures. The dissemination of research and study findings through publications and special conferences is also a principal effort of the Center and will be continued and expanded in 1981.

Health Maintenance Organizations

The Health Maintenance Organization program seeks to increase the availability of high quality health care at a reasonable cost. Evidence indicates that HMOs provide significant benefits to consumers, employers, and government. For example, the total cost of health care for HMO members is 10-40 percent less than for people with comparable health insurance. In addition to supporting the development and expansion of HMOs through grants, the Federal program continues to monitor the HMOs for compliance with legislative requirements. The 1981 budget request of $69.3 million includes an increase of $10.7 million over 1980 to fund 49 new feasibility grants and 20 additional expansion grants to allow operational HMOs that are federally qualified to expand both services and membership.

The loan and loan guarantee fund serves as a mechanism to provide working capital during the initial operating period of an HMO when operating deficits are expected and to assist HMOs in the establishment of ambulatory health care facilities. As loans are made, they are sold to the Federal Financing Bank and the proceeds are used to replenish the loan fund, providing a continuous source of funds.

Health Initiatives

The Adolescent Health Services program provides coordination, integration, and linkage to community efforts directed toward reducing the incidence of unwanted adolescent pregnancies and providing comprehensive services to the adolescent parents, their children and families. Technical assistance is provided to grantees in an effort to develop innovative approaches to meeting the health, educational, and social services needs of the pregnant adolescent, and adolescent parents. The budget will permit on-going program activities at the 1980 level.

Our efforts to develop, implement and coordinate a national smoking and health program as part of disease prevention activities will continue to receive our attention. Funding will support the expansion of our efforts in public awareness by the development and expansion of a comprehensive smoking information system. The grant program, which began in 1980, will provide support to state health departments for demonstrations and evaluations of community-based smoking prevention and education programs.

Another facet of the disease prevention and health promotion program is the National Health Promotion Media Campaign which uses radio, television, newspapers and magazines to increase public awareness of the health risks each of us face and the actions people can take to reduce these risks and maintain and improve their health. It is evident that more and more Americans are interested in pursuing a healthful lifestyle. To respond to the increasing number of inquiries, the National Health Information Clearinghouse will be expanded to include a broad range of health-related topics. Health promotion activities in a variety of settings such as schools, worksites, communities, health care facilities and homes are the keys to achieving our goal of promoting improved health. An increase of $3.6 million is requested to expand the clearinghouse, the media campaign, and other health promotion efforts.

The President's Council on Physical Fitness and Sports will fund activities to promote employee fitness programs, State and local exercise programs and fitness programs tailored to individuals at different life stages.

Public Health Service Management

The overall management responsibility for Public Health Service programs is supported in this activity. Strategies and plans for accomplishing national health goals are formulated, implemented and monitored to assure that staff and financial resources are properly utilized. On-going management activities in headquarters and the regions will be supported with the $23.2 million requested.

Scientific Activities Overseas

In 1981, this activity will continue to support health research, training, symposia and conferences, translations and related activities in the participating foreign countries. No new budget authority is requested for this activity in 1981. Funds carried over from prior years will permit obligations of $10 million in 1981, the same level as in 1980.

Retirement Pay and Medical Benefits for Commissioned Officers

The 1981 request of $92 million will provide mandatory 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 $15.0 million over 1980 includes $10.3 million for dependent's medical care, $4.5 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.

HEALTH STATISTICS

Senator INOUYE. Fine. Thank you very much, Dr. Richmond. Your brief statement, as indicated, will be made part of the record.

The President, in fiscal 1981, has submitted a request for $41,575,000 for all your health statistics programs. Last year, during a similar hearing, we were told that much of your health survey data is, "collected through a variety of national health and vital statistics surveys which are conducted either directly, through the Bureau of the Census, or through private contractors."

What percentage of the surveys, from which health statistics are gathered, are conducted directly?

Dr. RICHMOND. I think Ms. Hanft would like to respond to that.

Ms. HANFT. Our surveys are generally conducted through interviews done by the Bureau of the Census when they can accommodate us. For example, in fiscal 1980, about $5½ million of our funds go to Census to do the interviews for a number of the surveys.

They do the interviews for the Hanes survey, for the health interview survey, the hospital discharge survey, some natality studies, and marriages and divorces. We only contract out for interviews if the Census cannot accommodate us, and the only major or large survey in 1981 where that is true is the medical expenditures and use survey, which came at the time of the decennial census, and they couldn't accommodate that, plus the health interview survey. Normally, however, we go to them first.

Senator INOUYE. Do you do any survey directly? Does your Office?

Ms. HANFT. We do some telephone surveys, but we do not have a major field staff across the country.

Senator INOUYE. So you would say 95 percent is done by the Census?

Ms. HANFT. The interviews. We do the analysis, the data processing,

the correlation of the data. They do the actual household interviews for us.

Senator INOUYE. How are the questions developed? Do you develop the questions or does the Census do this or is it done together?

Ms. HANFT. It's all done in collaboration. Many of these are questions that are used—the core questions are used year-in and year-out, so that you do have even data to compare across time. We consult with Census if we're adding a supplement to any survey. We obviously consult with the agencies who are interested in data like, for example, on smoking and health, we consult with the people at CDC and with the Office on Smoking and Health.

HEALTH SERVICES RESEARCH

Senator INOUYE. I'd like now—incidentally, we have several questions which we will be submitting for your responses. Most of them are very technical, so I thought it might be well to give you time to think them over.

Now I would like to touch upon your health services research program.

You will be receiving about $4.5 million more in fiscal 1981, which brings the total to $34.6 million. What new activities would this $4.5 million increase be used for in fiscal 1981?

Ms. HANFT. The major new activity is the new solicitation—grant solicitation that's being prepared in the area of health promotion and disease prevention. It is designed to look at what's an effective health prevention program, and to then feed into the programmatic consideration of how to mount or modify programs. That is the largest of the efforts.

Another effort is in the area of multiorganizational arrangements, in particular, of hospitals. There are a number of natural experiments in mergers, consolidations, and in changes in hospital arrangements that we believe need to be looked at in terms of how you effectively mount cost containment programs: Does that change the quality of care, the health status of the community?

And finally, we are mounting again, after a lapse of a number of years, a modest start in health services research training of about $500,000 in fiscal 1981.

PHS RESEARCH FUNDING

Senator INOUYE. What is the total amount being spent for research?

Dr. RICHMOND. The NIH budget is $3.6 billion. That is requested.

Mr. BERSANO. Totally, the Public Health Service is requesting $3.7 billion for all types of research—biomedical research, behavioral research, and health services research.

Senator INOUYE. Do you include in that research training also?

Mr. BERSANO. No.

Senator INOUYE. How much do you spend for research training?

Mr. BERSANO. We are requesting $163 million for research training at NIH.

Senator INOUYE. $163 million. What was it last year?

Mr. BERSANO. $176 million.

Senator INOUYE. Research this year is $3.7 billion?

Mr. BERSANO. Yes.

Senator INOUYE. What was it last year?

Mr. BERSANO. It was $3.5 billion.

Senator INOUYE. Of this $3.7 billion, how much is contracted out?

Mr. BERSANO. I don't have the figure for the research that's contracted out.

Mr. MILLER. Mr. Chairman, certainly at least 85 percent of our research is done outside of our own installations by both grants and contracts. The larger proportion is by grants.

RESEARCH TRAINING

Senator INOUYE. I was just wondering why we don't spend a little more in training researchers for in-house activity. You have better control. We have been having all sorts of documentaries on TV programs with the suggestion that as a result of contracts the Government bureaucracy is completely out of control. We have absolutely no control of the pay or the standards of conduct, et cetera.

I see here where everything else went up and your research and training came down.

Dr. RICHMOND. Well, I think, Mr. Chairman, that I would again come back to some of my introductory comments. We have been in a period of reevaluation of our research enterprise, and trying to arrive at some judgment as to what our total expenditures ought to be. In terms of productivity in research we have concluded that we should be at a level of funding at least 5,000 new and competing grants each year for the NIH, and approximately 15,000 grants totally.

At the same time we have tried to make some judgments about the level at which we should be supporting research training. As you know, there has been some criticism in the past that we have been training more people than can be absorbed in the research enterprise. We have made a judgment that we ought to try, for the time, to stabilize this level and see if we are making a match between the output of our research training program and the needs of the community.

But I think you are aware of the fact that there has been considerable criticism of the fact that we have been training investigators who may not be productively employed.

CONSULTANTS

Senator INOUYE. On the one hand, the statistics look very favorable that we have cut down the level of employment in the U.S. Government bureaucracy, which is smaller. But then if you open the next page, you will see an increase in consultants, increase in grants, increase in researchers where the work is done outside by recently retired members of the staff, et cetera. I'm just curious, how much do you spend on consultants?

Dr. RICHMOND. We will provide you with that figure. But I should just go back to the research training situation for just a moment, if I may, Senator, and point out that most of the training is not done by the Government. Most of that training is conducted in universities

throughout the country. These are grants made to the universities to support research training. It's not training that we do directly.

[The information follows:]

The ceiling for consultant services spending is $59.2 million for fiscal year 1980 for the entire Public Health Service.

Senator INOUYE. How many universities receive those grants?

Dr. RICHMOND. Well, we will need to provide that. It's a sizable number.

[The information follows:]

RESEARCH TRAINING GRANTS

A total of 465 institutions received 6,572 grants totaling $408,722,000.

EMERGENCY MEDICAL SERVICES

Senator INOUYE. I would like to indicate here that I am fully supportive of the program, but in order to convince our colleagues to be supportive we must be able to shore up the case.

These articles that appear and the TV documentaries are of no help to us.

Now, I will bring up a November 11, 1979, Jack Anderson column and we'll see how we can handle this one. That column cited a National Center for Health Services research study on emergency medical devices and systems for local ambulance operators as being an $800,000 boondoggle. According to the article, this study was criticized by the official who read it as being of no value to ambulance companies.

The story went on to say that the really useful information, which criticized the design and function of the emergency rooms and ambulances, was censored out of the study.

Dr. RICHMOND. Well, I think, Mr. Chairman, my recollection of that study is that it was designed not to evaluate individual equipment or the manufacturers of specific products, but rather it was a study designed to establish a methodology by which products could be evaluated. And that particular study was not intended to undertake a product-by-product evaluation. It was designed to develop a state of the art so that those products could be evaluated.

Ms. Hanft may wish to add some comments to it, because I think that's one of her programs.

Ms. HANFT. It was to develop the methodology for looking at 31 or so categories of emergency medical equipment. The methodology was not expected to be employed by emergency medical systems across the country to test whether one or another piece of equipment was good or bad. In the process of doing that study and testing the methodology, obviously we had to try it on a few random pieces of equipment to see if the methodology worked.

But it was never designed, nor was the contract expected to evaluate specific equipment.

The report to the Center, as required by the contract, was on the methodology. Now, the contractor did publish, on his own, some information on individual pieces of equipment. The methodology, as far

as we know, is being used and actually the methodology moved into the food and drug operations on medical devices. The medical devices legislation was not in operation at the time this contract was let, and this has helped to feed into their method of assessing the devices.

The Anderson column is really not quite what the contract was all about.

Senator INOUYE. Are you satisfied that the taxpayer got his money's worth?

Ms. HANFT. Yes, very much so. It turned out to be a very useful study.

Senator INOUYE. Articles such as this are oftentimes cited in Senate debates when the time comes to add or subtract moneys. In order to shore up your case, would you provide for the record something about this national center?

Ms. HANFT. Yes.

Senator INOUYE. Just tell us what you have accomplished in the last 2 years or so, and be rather specific, if you would.

Ms. HANFT. Yes.

[The information follows:]

IMPACT OF NCHSR SUPPORTED RESEARCH

NCHSR has made a major effort to widely disseminate the research findings of the project which have been supported. The impact of NCHSR research, the role of research information dissemination workshops, and NCHSR publications are described below:

Impact and Accomplishments

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:

o The report on the "Policy Implications of Medical Information Systems," prepared by the Office of Technology Assessment and published November 1977, is based entirely on projects initiated and funded by NCHSR.

o 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.

o 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.

o 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.

o 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.

o An NCHSR supported review of current legislation, regulations, and third party reimbursement practices affecting nurse practitioners and physician assistants shows that these new health professionals are gaining increasing acceptance and recognition as part of the health work force.

o The proposed use of a uniform hospital reporting system in New York State is based on a system developed in California with support in part by NCHSR.

o An NCHSR assessment of the safety and cost-effectiveness of electronic fetal monitoring (EFM) indicated that the hazards posed

by EFM to mother and child cost American consumers $300 million annually.

o Results of a study conducted by the Duke University Medical Center and initiated under the sponsorship of NCHSR, show that heart attack victims who experience no complications during the first four days of illness might be considered for discharge on the seventh day--eight to ten days less than the average length of stay for the illness. The potential cost-savings could total about $360 million annually.

o Two studies on emergency care for cardiac arrest victims in King County, Seattle, Washington, funded by NCHSR, have led to the development of new methods that can help communities nationwide assess and plan their emergency medical services.

o 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.

o In December, 1978, NCHSR sponsored a Research Development Conference on Medical Technology to explore current issues and to help develop a research agenda for use by NCHSR and the new National Center for Health Care Technology (NCHCT).

o Several Research Information Dissemination Workshops have been held in various parts of the country. These NCHSR workshops provide the opportunity for making selected research findings meaningful to various users and have been cited by the Secretary for improving intergovernmental relations and facilitating the availability and application of research results to public policy problems at all levels of government.

o Current child abuse and neglect treatment programs can be successful in forty to fifty percent of all cases according to an evaluation of eleven Federally-funded demonstration projects, which was prepared for NCHSR by Berkeley Planning Associates. Treatment for child abuse and neglect was found to be more effective when professional services are combined with carefully supervised lay therapy and when treatment extends for more than six months.

o A recent review of research in both public and private health insurance programs, conducted by NCHSR, revealed that many Americans, especially the aged and poor, still face high financial risk from accidents and disease. One study estimates that as many as eighteen million Americans could have been without any form of health insurance in 1978.

o 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 of 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.

o As recommended by a 1974 NCHSR Research Development Conference, a baseline profile of the incidence, cost, and financing of catastrophically expensive illness in the United States was developed. The ratio of catastrophic illness expenses for the aged, disabled, and institutionalized to the remaining population was found to be 3 to 1.

o Two NCHSR studies on the use of preventive services have shown that low-come 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.

o Day care and homemaker services have increased total net Medicare costs for a sample, Medicare-eligible, population according to an NCHSR experimental study. These services become an added cost over and above existing Medicare covered services rather than a substitute for nursing home care.

o 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.

o Perhaps more important, but harder to document, is the general impact of the NCHSR program. A substantial part of the expert testimony provided in Committee hearings is given by researchers who, by virture of support from this organization, have been able to acquire their information and expertise. The influence of this small but active program is prevasive in the health area and its efforts are crucial to the formulation of sound and responsible legislative and program initiatives.

HEALTH PROMOTION EFFORTS

Senator INOUYE. Cite cases, so that we can tell the folks here that we did a good job.

We have had this problem of fly-by-night medical fads and overuse of certain legitimate technical advances in medicine for quite some time now.

How has your program had the most impact over the past year in improving the quality of life for the American care consumer by protecting them from the misapplication of modern medical technology?

Dr. RICHMOND. Well, I think, Mr. Chairman, we have been trying to target our efforts at providing health promotion and educational materials on major health problems.

Our focus, for example, on getting information out on smoking and its effects on health is related to the fact that we think there are approximately 320,000 deaths from heart disease and lung cancer and other kinds of cancer associated with cigarette smoking that could be prevented. We feel that our efforts in relationship to nutrition, for example, can be enhanced. This is the reason why we engaged in the col-

laborative effort with the Department of Agriculture, which has now resulted in a publication which we think will be very widely used.

Senator INOUYE. Is this information aimed at the medical practitioner or the consumer?

Dr. RICHMOND. Both; we have many communications which go out to the professions in the field of health. Our Food and Drug Administration is particularly active in this context, as is our Center for Disease Control. Our National Institutes of Health are also very active in getting information out to the health professionals.

But it has also become increasingly apparent that people generally can do much to promote their health and to prevent disease through improvement in lifestyle, so we are targeting specific efforts in that direction, and our Deputy Assistant Secretary for Disease Prevention and Health Promotion, Dr. McGinnis, is here today, and he provides coordination among all of our agencies for developing these efforts.

Senator INOUYE. This morning I received two telephone calls asking me for further information on programs very like that emanating from your agency, which suggested that an aspirin a day keeps heart attacks away.

Is that the work of your department?

Dr. RICHMOND. Well, there has been a combined study which was funded by the National Heart, Lung, and Blood Institute.

Senator INOUYE. Oh, that's where it came from.

Dr. RICHMOND. Yes; they have the responsibility for funding research. But that was a collaborative clinical study in which patients from a variety of medical centers around the country were involved. The study results really threw considerable doubt on the effectiveness of an aspirin a day really doing that.

Senator INOUYE. According to the calls—I believe it was on television—it gave the impression that this was the miracle cure.

Dr. RICHMOND. Well, it was hoped that it might be. Aspirin does have some rather remarkable effects on the clotting mechanism of the blood. We were very, very hopeful that it would prevent a second heart attack. But this collaborative clinical study which has been just presented really casts considerable doubt.

HEALTH MAINTENANCE ORGANIZATIONS

Senator INOUYE. May I now proceed to the health maintenance organizations.

In the departmental release dated October 5, 1979, HEW outlined a 10-year strategy to encourage the development of HMO's. The primary target areas for HMO development are metropolitan areas with populations of more than 250,000. But we have been advised that HMO's will be encouraged to expand their base of operations into rural areas as well.

We have also been told that a minimum population base of 200,000 is needed to support a staff model HMO. Is that correct?

Mr. VEIT. That's correct.

Senator INOUYE. If that's the case, how do you expect to expand into rural areas where you don't have 200,000?

Mr. VEIT. Mr. Chairman, what we have discovered is that if an HMO can develop successful operations in an urban area of, let's say, 200,000 to a quarter of a million people, that it is economically feasible for them to develop a satellite unit out in a nonmetropolitan or rural area and make that a financially viable unit with a much lower population base to serve.

Senator INOUYE. So the rural area center has to be a satellite of the metropolitan HMO?

Mr. VEIT. That's normally true, that if we develop a group practice or a staff model in a rural area, you find the most success where there is an urban-based program which it can relate to.

However, we do have some small number of group practice type HMO's in rural areas that are not related to an urban setting.

Senator INOUYE. Do you believe you have been successful in keeping down medical costs?

Mr. VEIT. We think so. Research that has been done recently that was reported in the New England Medical Journal by Dr. Harold Luft, who surveyed the literature on this subject, has shown that HMO's saved between 10 and 40 percent as compared to people who have their health coverage with conventional insurance.

FEDERAL HMO DEVELOPMENT

Senator INOUYE. The HMO law was passed in 1974, so it has been in operation for a little less than 6 years.

How many HMO's were there in 1974?

Mr. VEIT. In 1974, just before the passage of the act, there were around 50 organizations that were called prepaid health plans. Now, in that period between 1974, 1975, 1976, and so forth, there was quite an increase in the number of programs as a result of the administration's big push on HMO's at that point. There was somewhat of a slowdown in the 1976–77 era, and then came the HEW push on HMO's again in the late 1970's. We now have 226 programs, of which 111 are federally qualified.

Senator INOUYE. Are the others trying to be federally qualified?

Mr. VEIT. Yes; we are finding more and more of the programs that were not developed with Federal moneys are coming into Federal qualification, and we expect a fair number of those to come in the next couple of years.

Senator INOUYE. At this point I would like to yield to my distinguished colleague. He has a whole stack of HMO questions.

RURAL HMO'S

Senator BURDICK. Now, let's not discourage them. Not a stack.

A year ago I contacted the Office of the Health Maintenance Organization about the progress and development of these nonmetropolitan HMO's. I questioned you about implementing the law regarding a 20-percent set-aside for nonmetropolitan HMO's.

Have you got 20 percent in the rural set-aside?

Mr. VEIT. Senator, the statute, as you have indicated, does provide for

20-percent nonmetropolitan set-aside for the use of developing HMO's in those areas. We have generally not spent that amount of money. As a matter of fact, we have not spent over half of that for nonmetropolitan area HMO's since the program's inception.

I think there are a couple of reasons for that. As indicated earlier, HMO's are difficult to start in nonmetropolitan areas because of the fact that the population base is often not there; however, we have in recent years had some success, although not as much as we would like, in developing individual practice association type of HMO's.

Now, that's an HMO where the physicians do not come together in a group practice, but rather are continuing on as solo practitioner physicians under the umbrella of an HMO-like organization.

The startup cost of those HMO's, we find, are much less than the staff or group model, and therefore they need fewer people in order to make them financially self-sufficient, making them more applicable to a rural area.

We currently have nine HMO's that are qualified in nonmetropolitan areas and, as you know, one of these is in your State of North Dakota, and we have another grantee in North Dakota.

Senator BURDICK. You only have nine in the whole country?

Mr. VEIT. Nine, that's correct. We have eight programs now developing through the grant process, but there are currently only nine.

FEDERALLY QUALIFIED HMO'S

Senator BURDICK. How many HMO's do you have totally in the country?

Mr. VEIT. 226, totally—111 are federally qualified.

Senator BURDICK. We haven't got our 20 percent?

Mr. VEIT. Right.

Senator BURDICK. Well, are you aiming for it?

Mr. VEIT. Yes; we are. We have taken a number of steps to try to improve our track record in that area.

First of all, we have identified some people recently who are knowledgeable about the unique problems of starting an HMO in rural areas, and added them to our consultant list, and I think that by them going out and seeking out new projects and helping them get started that we may be able to increase our track record there.

We also are in the process of letting a contract that can help us develop, again, both technical assistance capabilities and the criteria that we need to appropriately evaluate these programs. You might be interested, Senator, to know there was a conference held about 4 months ago up in New York State, where we invited in about 50 people who are now operating HMO's and who are thinking about operating HMO's to talk about the problems of getting rural HMO's started. And we think that for one thing that many of the existing successful programs that are in metropolitan areas will, now that they have gotten to a point of success, will be expanding their services into rural areas—nonmetropolitan areas.

We are hopeful that the next 5 years will give us a better track record than we have had in the last 5.

Senator BURDICK. You know, the legislation does more than authorize you to develop them. The legislation directs you to promote them, too.

What promotion have you done?

Mr. VEIT. The meeting that I referred to is a promotional effort, we feel, with the HMO's that we think will expand in the rural areas.

We have in our office, in conjunction with the 10-year development strategy that the chairman referred to earlier, a group of about 25 experts whom we brought in to help us develop HMO's. A few of these people are knowledgeable about rural areas. A few of them are going out into rural areas to see what the possibilities of promoting HMO's have been.

I should emphasize, however, that what we have found is that when HMO's come to us from nonmetropolitan areas, that they face considerable problems in getting started. I might cite an example of one of those problems. In nonmetropolitan areas the employers tend to offer their employees relatively narrow health benefits as compared to urban areas. The HMO Act requires an HMO to offer rather broad services to their members. The broad health coverage required by an HMO often requires them to market a premium that is considerably higher than people in nonmetropolitan areas are used to paying, which makes it difficult for the HMO to enroll members.

We are considering some legislative changes for the 1982 legislation; for instance, allowing the nonmetropolitan HMO's to market a less comprehensive benefit package and some other things that we think will make it more feasible for HMO's to develop in the nonmetropolitan areas.

Senator BURDICK. You mean to say the insurance carriers that insure in the rural areas have contracts in cities that differ from those in the country?

Mr. VEIT. Yes; if I understand your question, I think it's fair to say that employees in these areas who offer Blue Cross and commercial insurance health coverage often offer much less comprehensive services, much less broad services than we find in many of the metropolitan areas, and that makes it difficult for HMO's to survive in those areas.

Senator BURDICK. In other words, if I live in a metropolitan area I get a better contract?

Mr. VEIT. In general, I think that's probably true, Senator, yes.

That's not true in all cases, but in general we are finding that to be a problem.

Senator BURDICK. Well, that's just another reason why we should get behind this and do some more promotion of HMO's.

Mr. VEIT. We agree.

Senator BURDICK. Well, we'll meet again next year and we'll see if that number nine has increased substantially.

Mr. VEIT. We hope it will be at least 25.

Senator BURDICK. OK. Thank you.

Senator INOUYE. Are you satisfied, sir?

Senator BURDICK. I'm not satisfied with the progress, but I am satisfied we're going to try to make some progress.

Dr. RICHMOND. I might just add, Senator, that since the HMO development really started in the rural areas, we are not happy with the fact that it's moved so slowly, but we are dependent on the communities to come forward and make these applications. And it's been more difficult to get rural communities to do this.

INFLUX OF REFUGEES

Senator INOUYE. Hawaii and a few other States might be in a rather unique position when it comes to the amount of aid to immigrants—refugees—for rather obvious reasons: A disproportionate number of refugees from Cambodia, Vietnam, and other countries are finding themselves congregating in Hawaii. As a result we have had health problems that heretofore were not anticipated.

I'd like to at this time for the record publicly thank you, Dr. Richmond, for your help, and I know that Hawaii is extremely grateful to you. You have been very helpful to us on the leprosy program. As most people are aware, there are only two centers for the disease, one in Louisiana and the other in Hawaii. And the one in Hawaii, as is to be expected, is now being filled by these new arrivals.

So the State of Hawaii, a few years ago, had the lowest incidence of tuberculosis; today we're No. 1. A few years ago, Hawaii had the lowest incidence of leprosy; we are now No. 1. I believe that your agency recognizes the unique problem we have, and we hope you can work it out.

We don't want to be too dependent on Big Brother, but ever so often we have to talk to him.

Dr. RICHMOND. Well, I think, Mr. Chairman, if I may, I would just like to commend the effort which you and the people of your State have been making on behalf of refugees and immigrants, and the resourcefulness of the health professionals in your community and their willingness to accept immigrants and refugees with their health problems.

Having had the opportunity to visit Thailand recently with Mrs. Carter and to observe what has happened to the refugees in the whole Indochina area, we know that those who are eligible to emigrate and can emigrate will have their health improved so much more rapidly once they get to our country than if they have to remain in the unfortunate circumstances that prevail there.

It really is a great humanitarian contribution to accept these people and provide for them the kind of medical care which your State has been doing so effectively, and I am pleased that your health officer feels that we have been helpful.

And we would want to continue to collaborate in that effort, in whatever way we can.

I also commend you for having the courage to maintain a leprosarium because not all communities are willing to undertake the care and management of those patients.

Senator INOUYE. Do you have any loose cash laying around?

Dr. RICHMOND. I would say two things: We like to be responsive but I would say your health officers in Hawaii are very, very resourceful, very imaginative in making proposals to us.

ADOLESCENT PREGNANCY

Senator INOUYE. Now I would like to touch upon a matter which is very real, especially to our young people—that is, adolescent pregnancy. I gather that your program has two priorities: To prevent initial and repeated pregnancy among adolescents and to provide care to pregnant adolescents.

How do you establish a priority among these two—preventive or after the fact?

Dr. RICHMOND. Dr. Nix, would you like to respond?

Dr. NIX. The statute itself states that priority must be given to adolescents who are 17 and under, so it sets forth that the major portion should be used for pregnant adolescents.

Senator INOUYE. After the fact?

Dr. NIX. Yes; in fact, there are 10 core services required under the statute. Seven of those are for pregnant adolescents, and three are to work in the area of prevention.

Senator INOUYE. In terms of dollars, what percentage has gone to adolescent pregnancies?

Dr. NIX. Well, it's really going to depend on the community itself and the kind of program that is submitted. For example, in one community there may already be a major prevention program existing, and our projects are not to duplicate what already exists, but are to utilize the programs that are already there.

Consequently, if three of the four services that relate to prevention of pregnancy are already existing in the community, then our dollars would not need to be used for those prevention services. The dollars from our office then could be used for health care and pregnant adolescents. They could be used to coordinate education, social services, and day care. So we can't say that a specific percentage must be used for pregnant adolescents and a specific percentage for nonpregnant adolescents.

PREGNANCY COUNSELING

Senator INOUYE. You have a full range of counseling services for the pregnant adolescent. Would you describe these services?

Dr. NIX. Yes; the counseling is full range. It's very comprehensive. It includes working with the adolescent the day she arrives in the program to find out what kinds of personal problems she may be having in the home, the relationship that she has with her family, or the nonrelationship among family members, and what her plans are for the care of the child if she's going to keep it.

There must be counseling on all options: Whether or not she wishes to carry the pregnancy to term, whether or not she wishes to place the child for adoption, or have an abortion.

There is counseling for the extended family. The fathers of the babies are very much involved in the counseling program, and it is a broad-based counseling program.

Senator INOUYE. I gather that your counseling on all options ranges from whether one should go to term or have an abortion?

Dr. NIX. Yes; true.

Senator INOUYE. What sort of counseling do you provide for that area?

Dr. NIX. Well, the statute specifically states that programs must tell the adolescent of the availability of counseling on all options.

Now, the programs receiving the funds are responsible for at least letting the adolescent know that counseling is available on all options. The program may do this itself, if it feels comfortable in doing it, or if it does not wish to do the counseling, they may set up a referral agreement with another agency that would do the counseling.

Now, the counseling must cover all of the options, and they are very clear, and we would hope that the counselor would be neutral, that a referral agreement would be set up with an agency that can do counseling on all of the options.

Senator INOUYE. Are you satisfied with the results of your program?

Dr. NIX. Well, we have only four projects at the present time. This is a very new program. We had $1 million appropriated in fiscal year 1979, and we made four grants. We are very pleased with the progress that's being made by those four projects, and we have been deluged with requests for grant application kits for fiscal year 1980.

I guess we sent out about 2,000 or 3,000 kits for the 1980 funds.

Senator INOUYE. So last year, it was $17.5 million—fiscal 1980?

Dr. NIX. For fiscal 1980, $17.5 million, yes.

Senator INOUYE. And 1981 is about the same?

Dr. NIX. About the same; yes.

Senator INOUYE. Will that do the job?

Dr. NIX. Well, this is a new program. It takes time certainly to get the communities across the country ready. We will hope to make at least 50 grants in fiscal year 1980, see what kinds of experiences we have, and then we will come back next year with a report.

INCREASE IN ADOLESCENT PREGNANCY

Senator INOUYE. I'm not certain of my statistics, but is it true that incidents of pregnancy among adolescents is rising?

Dr. NIX. It's rising, Senator, among the young adolescents. We're seeing a tremendous increase in the incidence of pregnancies among girls who are 13, 14, even 12 years of age. This is where the great changes are taking place.

Dr. RICHMOND. I think, Senator, if I might comment, the numbers per 100,000 has remained fairly constant, but as Dr. Nix has indicated, we are concerned about that younger group, and I should emphasize that a high priority is in trying to reach those very young adolescents.

And in addition to some of the programmatic directions that Dr. Nix has indicated, I would comment that another objective is the linkage of these programs with the schools. We think it is very important is to keep the parent or parents in school.

I would also comment, since you asked about the mortality rates earlier, that in this younger group of adolescents that we run very high risks of morbidity and mortality of the babies. So again, this is an effort—a beginning effort to explore how we can really develop these programs in communities in effective ways so that in addition to all of

the educational benefits, we also might improve our record in infant mortality.

Senator INOUYE. From what you tell me, there's a correlation with low-income and nonwhite populations.

Dr. RICHMOND. Yes; that is true.

Senator INOUYE. You have 3,000 requests for help?

Dr. NIX. We have had in the past year, I would imagine, about 5,000 or 6,000 requests for help—for information on the program, for application kits. We have run six seminars across the country to try to help people prepare successful applications and actually start to begin their programs. The response has been just overwhelming, and the need is there.

PROGRAM COORDINATION

Senator INOUYE. Can you cover that with $17 million?

Dr. NIX. It's going to be difficult. But one of the things about this program is the fact that all of the funds do not have to come from the Office of Adolescent Pregnancy Programs. We are encouraging communities to make use of other resources—other funds—so that even with the four projects that we funded last year, we have found that although we distributed from our office $740,000, there really was $1.5 million being put into the projects, so that putting all of this money together is going to be the greatest help, I think, that we have in the Department.

Dr. RICHMOND. Mr. Chairman, that's a very important aspect of this program. We think there's a good deal of innovation in this program in that we are not providing these funds to replicate all of the services that already exist.

In other words, we have learned in recent years from some studies which have been done that when communities make these programs more comprehensive and they bring the educational, the welfare, and the medical resources together in the service of these young people and their children, the yield is much more effective. We're putting funds in to provide a stimulus for that integrated effort—what some have called "glue" to bind those services together.

We are not using these funds to just produce a whole set of new services.

Senator INOUYE. Are you satisified that there's adequate coordination?

Dr. RICHMOND. That is precisely what these efforts are designed to do—try to get the kind of coordination that is needed at the local level.

I should also mention, Senator, that we have had some ongoing programs in many communities across the country. We have learned from those and transferred that knowledge to communities that haven't been so fortunate and so resourceful in developing such programs.

We do not expect this to do the job, because there are many other sources of services.

HEALTH PREVENTION COORDINATION

Senator INOUYE. Thank you very much.

I would like to touch upon health prevention facilities. Is there a focal point within the administration to coordinate all prevention activities of the Federal Government?

Dr. RICHMOND. The prevention efforts are really being coordinated, and we hope stimulated, by the Public Health Service for all of the Federal agencies and departments.

In my office, as I indicated earlier, we have established an Office for Prevention and Health Promotion. Dr. McGinnis, my Deputy Assistant Secretary, is the person who is responsible for that kind of coordinating effort.

But I hasten to say that we expect all of our Public Health Service agencies—all six of them—to be very active in prevention. We certainly intend to continue our collaborative efforts with other Departments like the Department of Agriculture to improve nutrition, with the Department of Transportation to minimize accidents, so that we can try to minimize morbidity and mortality from those causes, and with other Departments such as the Housing and Urban Development Department in the area of mental health to establish better resources and community services.

Senator INOUYE. Do the other agencies recognize the Public Health Service as a focal point for coordinating services?

Dr. RICHMOND. I think it's probably fair for us to say—it may not be modest for us to say it—but that's probably true.

Senator INOUYE. So you would be satisfied that successful steps have been taken to avoid duplication of effort?

Dr. RICHMOND. We think we are engaged in such efforts and certainly feel that Dr. McGinnis' efforts have been developing appropriate coordination processes in order to help us do that.

I think the recent effort in connection with the dietary guidelines which we developed with the Department of Agriculture is a rather outstanding example of the kind of collaborative activity that we have underway. There is a joint committee chaired jointly by an Assistant Secretary of the Department of Agriculture and myself together with our staffs whereby we bring together the various scientists within both Departments to develop this area.

Senator INOUYE. Well, I thank you very much. As I indicated to you earlier, Dr. Richmond, we have several questions we would like to submit to you and the staff for responses for the record.

I thank you very much for your patience this afternoon.

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:]

HEALTH STATISTICS

Question: What is the proportion of resources you devote to these health issue areas specified in your legislative mandate?

Answer: Virtually all of the Center's resources are devoted to the health issue areas specified in the legislative mandate. The legislation provides for the collection of health data on--

The extent and nature of illness and disability of the population in the United States...

The impact of illness and disability of the population on the economy of the United States...

Environmental, social, and other health hazards...

Determinants of health...

Health resources, including physicians, dentists, nurses, and other health professionals,...and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions...

Utilization of health care...

Health care costs and financing...

Family formation, growth, and dissolution

The family of surveys conducted by the Center addresses the major health issues identified in the legislation. The collection of data on specific diseases is an important, but incidental part of the health statistics programs which tend to address major national health issues. We are currently endeavoring to increase the focus on environmental health issues in many of the surveys, and in the analysis of data from the surveys in compliance with the legislative mandate. An epidemiologic analysis staff is currently being established in the Center.

Question: What is the turn-around time on health data collected through your program, for example, from the time information is collected on infant mortality, how long does it take before that data is available for public consumption.

Answer: The Center makes every effort to minimize the turn-around time of its data. Monthly provisional data from the vital statistics system are published in the Monthly Vital Statistics Report within two or three months of the month in which the events occur, with provisional statistics for the year being issued within eight to nine months after the end of the calendar year in which the event occurred. From the National Health Interview Survey, data are released within about nine months after the end of the calendar year of data collection. Other surveys which depend upon information from the records of medical providers take somewhat longer, up to about one year. We are optimistic that the first basic data reports from Cycle II of the Health and Nutrition Examination Survey (HANES II), for which data collection will end this month, will be available by the end of calendar year 1980; this will be about 2-3 years overall better than we were able to do for HANES

I, which ended in 1975. In addition to these publications, which typically require several months in the publication and printing process, it is important to remember that our data collection programs make unpublished data available on request even before their formal publication.

Question: How detailed a breakdown do we get on the information gathered?

Answer: The national vital statistics program produces data down to the county level for each State. In addition, health manpower and health facilities data are provided at this level of geographic detail.

The Center's sample surveys are designed to produce estimates at the National level. Some estimates can be made for the four geographic regions, and the National Health Interview Survey (HIS) and the Health and Nutrition Examination can be used to make limited estimates for smaller geographic areas such as large Standard Metropolitan Statistical Areas or groups of counties that are primary sampling units. In addition, statistical techniques to generate estimates for States and other small areas from data from the HIS have been used and reports containing estimates for some health characteristics have been published. The Center data collection programs that provide data below the State level are those based on complete coverage of individuals.

Members of the health professions have reported to us that the National Health Survey statistics are not adequately analyzed--in fact, the data are in fairly aggregate, basic form and not useful to researchers.

Question: How is the analysis framework decided upon from year to year?

Answer: The criticism to which you refer derives, in part, from a misunderstanding of the Federal statistical structure.

The system is organized around a relatively small number of multi-purpose collection agencies such as the Bureau of the Census, the Bureau of Labor Statistics, and the Energy Information Administration. The NCHS of which the national health surveys are an integral part, is the multi-purpose collection agency in the health sphere. The NCHS has the responsibility for collecting health statistics of general use be governmental units responsible for program planning and evaluation and for research on health and health care. A multitude of different functions are served by the data provided through the various NCHS data systems. In general, the NCHS carried out its mandate by conducting a wide array of surveys.

The Center's authority derives from Section 306 of the Public Health Service Act. In Paragraph (b) (1) of that Section, it is stated that the Secretary of DHHS, acting through the NCHS, shall collect statistics on

A) The extent and nature of illness and disability of the population of the United States (or of any grouping of people included in the population)...

The list of obligatory data collection tasks contains eight major areas of inquiry, with many subtopics under each. It is clear from the statute that the provision to many data users of a wide variety of statistical series is the primary responsibility. The NCHS has been performing that function very successfully through surveys. The issue becomes one of the dissemination of the statistics that are collected. Basic tabulations are made available through the large number of publications that the NCHS regularly issues. (I should like to submit the current NCHS publications catalogue for the record.) Highlights are published each year in the Secretary's report to the President and the Congress, Health, United States. In addition, the NCHS makes available at a nominal charge computer tapes which permit users to perform whatever tabulations they wish. As the NCHS computer capacity and staff time permits, special tabulations are also provided on request.

Within the constraints discussed above, we in DHHS are very eager to exand and deepen the analytic activities of the NCHS. In fact, major progress has been made in the past several years, In addition to the analytic work traditionally performed by the staffs of the various surveys, a Division of Analysis has been established. It is the responsibility of that Division to meet with the various users of national data to determine their analytic priorities. The problem is, of course, that the wants of the users are infinite while the capacity of the NCHS to produce analytic publications is finite. Nevertheless, hundreds of requests for statistical information are filled each year by the NCHS staff.

Question: What input can health professionals have in determining categories of data collection?

Answer: Health professionals have significant input into the topics selected for inclusion on our questionnaires and on the questions used to elicit the information from respondents through representation on advisory groups, individual consultation, and professional asssociations and organizations. Such consultation and input is vital to the usefulness of the data once it has been collected. Actual categories used for data collection are the result of advice from health professionals, of the planned analysis of the data, and of pretest experience in eliciting information from respondents. Included in the universe of health professionals that advised the Center on health topics are members of the National Committee on Vital and Health Statistics; members of APHA: and representatives of health professional associations.

COOPERATIVE HEALTH STATISTICS SYSTEM

This program was established for the purpose of producing comparable and uniform health information and to assure appropriate access to such data.

Question: How does this authority coordinate its activities with other health authorities within DHEW responsible for the collection of specific health statistics? Perhaps you could use the number of SIDS deaths in each state as compiled by the Bureau of Community Health as an example.

Answer: There are two principal formal committees within DHEW which share responsibility for decisions regarding health statistics activities. One is the Health Data Advisory Committee which serves as "a forum to advise the Secretary on important cross-cutting

61-400 O - 80 - 61

issues concerning the collection and analyses of health and health-related statistics throughout the Department." The second is the Public Health Service Health Statistics Coordinating Committee which assists "the Deputy Assistant Secretary for Health, Research, Statistics and Technology, in technical and operational coordination of health statistics activities of the Public Health Service." (Charters of these two committees have been submitted to the Committee.) In addition there are formal working groups such as that currently operating between ADAMHA/NCHS that facilitate the exchange of information and enhance the utility of existing statistical programs. The National Committee on Vital and Health Statistics, a public advisory committee to the Secretary, also addresses and advises on major issues brought before it and makes major contributions through its subcommittees. Its scope covers such topics as advising on the CHSS, proposing organizational changes to enhance health data coordination, and advising on minimum data sets and data needs under national health insurance. Also the States, through their working relationships with NCHS, may identify areas for the coordination and the sharing of data systems and other statistical resources. As minimum data sets, guidelines for State designated agencies, etc., are developed, the above mechanisms are used to assure coordination and the setting of priorities. The Sudden Infant Death Syndrome (SIDS) is a good example of how NCHS data is coordinated and used within the Department. The Bureau of Community Health Services (BCHS) of the Health Services Administration uses the data generated by the Center in its program and the NCHS Chief of Mortality Statistics sits on the BCHS Coordinating Committee for SIDS.

Question: Your biggest cut appears to come out of this program--why is it possible at this time to absorb such a reduction?

Answer: A decision has been made within the Department to transfer responsibility for the collection of health facilities data to the Health Care Financing Administration. Their systems will produce data beginning in 1983, and these data will flow to the Cooperative Health Statistics System. Since information on health facilities is not needed on an annual basis for national estimate purposes, this data will be collected biennially using survey methodology. A similar rationale exists for collecting health manpower data on a biennial basis using survey methodology, and work is underway in cooperation with the Bureau of Health Manpower of the Health Resources Administration to explore the collection of needed data through survey mechanisms.

In addition, the Cooperative Health Statistics program has been the subject of comprehensive evaluation by an outside group of health professionals. A final report from this group is expected soon. Therefore, in FY 1981 the program will be curtailed in the manpower and facilities components until the assessment of this program is completed. At the same time, greater emphasis is being given by the Department to the development of State Agency capability. Work will be continuing to support these agencies, which will coordinate health statistics programs at both State and local levels.

Question: What is the current status of the CHSS? Were you able to complete the System in all 50 States in FY 1980 as planned?

Answer: The Cooperative Health Statistics System (CHSS) has progressed to the extent that one or more of the CHSS components

are presently receiving contract support in 42 States, the District of Columbia and Puerto Rico. Thirty-four of these States and Puerto Rico have contracts which specifically provide for the coordination of health statistics activity. The current status of the CHSS is reflected in the table below which shows the number of States receiving contract support by CHSS component.

CHSS Component	Number of States Receiving Contract Support[1]	
	Current Status	Fiscal Year 1980
Vital Statistics	44	44
Health Manpower Statistics	36	36
Health Facilities Statistics	36	36
Hospital Care Statistics	8	0

[1] Includes the District of Columbia and Puerto Rico

The CHSS will not be established in all 50 States in FY 1980 as shown in the table above. Completion of the System would require establishing each health statistics component in each State.

With the shift of lead agency responsibility for health manpower, health facilities and hospital care statistics from the NCHS to other DHHS Agencies, the timetable for completing the System will be determined by the responsible agency.

NCHS PROGRAM SUPPORT

Question: Program Support will be receiving $3.2 million in fiscal year 1981. What activities are funded under the Program Support function?

Answer: The Program Support funds provide for the Office of the Center Director, the Office of Program Development, the Office of Program Support, and the financial and personnel staffs serving the Center. In addition to the direct support provided to these offices Program Support funds are used to meet some of the Center-wide operating costs not charged directly to programs.

Question: What portion of this authority is used for travel?

Answer: Travel costs for Program Support in 1981 are estimated to be $84,000 or less than 3 percent of the total costs.

Question: Will there be a change in staffing levels from FY 1980 to FY 1981?

Answer: No change in the Program Support staffing levels is proposed in 1981. A net decrease in 19 positions for the Center is proposed.

HEALTH SERVICES RESEARCH CENTERS

Question: What is the status of your Health Services Research Center Program? How many basic centers exist? How many special emphasis centers exist?

Answer: The NCHSR currently supports seven research centers--four basic centers and three special emphasis. The budget period of one of the seven centers will expire on June 30, 1980. That center is the Health Care Technology Center located at the University of Missouri. Four other centers will complete the five-year grant cycle with funding in FY 80.

Question: What activities does each of the above support?

Answer: The activities supported by the research centers are as follows:

o The National Health Care Management Center is located at the University of Pennsylvania in Philadelphia. If focuses on problems faced by managers of health care organizations (e.g. costs, utilization, planning, Health Maintenance Organization (HMO) enrollment), and it engages in training and retraining of administrators.

o The Health Services Policy Analysis Center is located at the University of California, San Francisco. It provides policy-relevant advice to members of Congress and other Federal decision-makers on the products of health services research in areas such as the organization of health services, the planning and regulation of services, financing, health manpower, and prescription drug policy. It has particular capabilities in HMO policy analysis with regard to competition, utilization, and HMO development. It is the only NCHSR center with a Washington, D.C. branch office.

o The Health Care Technology Center is located at the University of Missouri in Columbia. It has implemented research on computerized tomography, medical and drug information systems, microprocessors as used in the health field, and other health care technologies.

o The Health Services Research and Development Center at Johns Hopkins University has conducted research on health system performance, the organization of community services, and the evaluation of preventive services.

o The Center for Health Services Research at the University of Washington in Seattle has conducted research on health manpower, planning, the organization of rural care, and analyses of public expenditures for health care.

o The Health Services Research Center at the University of North Carolina at Chapel Hill undertakes research on health promotion and behavior modification, access to care in rural areas, dental services needs, and organized systems of care.

o The Health Services Research Center at the University of California, Los Angeles is doing research on health promotion, child health behavior, school health services, hospices and long-term care, and self-management of asthmatic children.

UNITED MINE WORKERS" STUDY

Question: Please bring me up to date on the United Mine Workers' study which assesses the effect that co-payments for health services are having on those services.

What studies do you presently have underway or planned?

Answer: The NCHSR analysis of the United Mine Workers' of America's (UMWA's) new health care program is based on a series of inter-related studies dealing with potential changes in health care utilization, quality, costs, and provider productivity. At the same time, NCHSR will assess the effectiveness of the new program in providng health care to miners and their families.

One study now underway examines changes in health services utilization resulting from the new cost-sharing provisions. It is based on bills for services submitted by a sample of beneficiaries during three different time periods: July 1, 1976 through June 30, 1977, when health care benefits for miners and their dependents were comprehensive and did not require cost-sharing; July 1, 1977 through December 30, 1977, the period in which the 40 percent cost-sharing was in effect; and March 27, 1978 through December 30, 1979 when the new contract provisions have been in operation.

This study will analyze changes in the use of services by UMWA members and their dependents during those three periods. Are there, for example, changes in the use of preventive services, such as well-baby care, immunizations, Pap smears, and physical examinations since the new cost-sharing agreement was started? Are low-income families affected more than higher income families? Have there been changes in the volume of physician visits, home care visits, hospital admissions, and lengths of stay? What factors are associated with identified changes?

The quality of care studies now planned will be carried out in selected provider settings. These will focus on tracer conditions or diagnoses where standards of care have been developed. Comparisons will be made between patients covered by the new UMWA cost-sharing provisions, and those who are not. Services provided for patients with diabetes, hypertension, arthritis, and other chronic conditions will be analyzed for a three-year period beginning in 1976. Emphasis will be placed on determining if changes have occurred in the types and amounts of services, such as laboratory tests, prescriptions, physician visits, and counselling. Changes in health status, reflected in increased incidence of strokes, staging of cancer diagnoses, and increased hospital admissions for acute diabetic conditions, also will be assessed.

Other studies will assess changes in provider staffing and costs of services before and after the new cost-sharing provisions, which in turn will be related to the volume of services provided. The studies will focus on the relationships between costs and productivity and changes in methods of provider payments.

Because coal companies now are responsible for providing group health insurance to all active employees and their dependents, a diverse group of insurance companies currently pay for miners' medical care. Studies are being undertaken on the insurance company organization, comparability of benefits, claims processing administration, and the costs of coverage to coal companies. These data

will be related to the characteristics of coal companies, including size and location. Emphasis will be placed on determining the relationships between the size of the coal company and the scope of health insurance coverage, as well as between the size of the company and the efficiency of claims processing. Insurance company characteristics will be compared to the actual use of services, such as physician visits and hospital admissions.

Question: How soon before you expect to have results that we can look at?

Answer: We expect with our present scheduling of data collection to have preliminary results that we can show as early as March or April of 1981. We plan to have a report, as required by the legislation, in May 1981 that will address the significant questions relating to the effect of co-payments on health services.

Question: How much funding is being made available for the study in FYs 80 and 81? Is it sufficient?

Answer: During FY 1980 funding for the UMWA study is expected to total $850,000. This includes a contract for 1) the data from the private insurance companies, 2) a survey of the miners and their families to obtain essential information on use of service, 3) data from medical records of the major medical providers, and 4) a study of present insurance arrangements for provision of health care.

During FY 1981, the funds necessary to complete the study will be made available.

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY (NCHCT)

Question: How has your program had the most impact over the past year in improving the quality of life for the American Health Care Consumer by protecting them from the misapplication of modern medical technology?

Answer: The PHS, through the NCHCT, provides advice to the HCFA, upon request, on Medicare coverage issues. These coverage issues are concerned with the safety and efficacy of particular medical tests and procedures, and the appropriateness of their coverage under Medicare. Such issues are usually identified and referred to HCFA by local Medicare intermediaries and carriers who have some reason to question coverage (reimbursement) for a particular technology. Issues referred to the NCHCT by HCFA range from questions about the safety and efficacy of simple devices such as home oxygen concentrators, to drugs such as BCG for treatment of cancer, to complex surgical procedures such as heart transplants. Based on PHS coverage recommendations, HCFA develops instructions to Medicare carriers and intermediaries about the covered services.

These decisions and subsequent instructions could have an impact on the quality of care and life for the consumer of health care. For example, whenever Medicare extends coverage to a test or procedure which has been demonstrated to be safe and effective, the quality of care is enhanced. If such a treatment replaces a more complex and costly procedure, money is saved. Conversely, if coverage is denied for a treatment which is unproven, the overall quality of care is improved for Medicare

beneficiaries (insofar as they are not receiving unsafe or ineffective service), and money is saved.

SAVINGS ACHIEVED

Question: What savings have been achieved thus far in the avoidance of the overuse of technological advances and the use of poorly-developed technological devices?

Answer: This year the NCHCT will begin to conduct its first assessments of health care technologies. Dental x-rays and coronary bypass surgery are among the technologies considered to be high priority, and will be assessed first, because of the concerns raised about their appropriate use. Economic analyses will be undertaken as part of the assessment of the impact of these technologies on the health care delivery system and society as a whole.

Studies designed to measure the impact of NCHCT assessments are being planned, but cannot be undertaken until several assessments are completed, results disseminated and recommendations are adopted in the medical setting.

Although this has not been measured, the advice which the NCHCT provides to HCFA on Medicare coverage could, in certain instances, result in potential savings. Cost savings could result, for example, if HCFA, based on NCHCT recommendations, denies coverage for a technology whose safety and efficacy are unproven, or in some way limits coverage for a particular technology based on valid medical or other consideration.

INFORMATION DISSEMINATION

Question: How is information assembled by your program disseminated to the practitioner?

Answer: The NCHCT is currently developing an organizational unit that will have primary responsibility for disseminating information derived from the Center's technology assessment activities to health care practitioners and other individuals and groups who have a need for this information.

A variety of mechanisms are used by the Center to disseminate information, e.g.: press releases; publications; direct mailings of Center-developed materials; the National Library of Medicine; sponsoring meetings with a variety of professional, governmental, and other groups; formal presentations at meetings of professional societies and associations; and, by engaging the assistance of the National Council on Health Care Technology, professional groups, etc. Also, through its coordinative function in the Department, the Center disseminates information to the HEW Technology Coordinating Committee and other units of the Department, and to other Federal agencies with interests in health care technology. Also, NCHCT has provided for the PHS, recommendations to HCFA regarding the appropriateness of Medicare coverage of certain health care technologies.

The Center will disseminate information to a wide variety of interested parties and groups, including, for example: the practicing and academic scientific and medical communities;

Federal agencies with health care interests; HMO's; PSRO's; State and local health planning agencies; third-party payors; industry; the Congress; and, the public.

The Center has not yet had an opportunity to fully activate its information dissemination program, since technology assessment and other information development activities are just now being initiated. Certain information, however, has been disseminated by the Center to appropriate individuals, groups, and agencies.

PRIORITIES

Question: How are your priorities developed?

Answer: Recommendations regarding candidate topics for technology assessment are made by a variety of individuals and groups including, for example, the National Council on Health Care Technology, the HEW Technology Coordinating Committee, Federal agencies outside HEW, the Office of the Assistant Secretary for Health, the Office of the Secretary, the Congress, medical and other professional health related groups in the private sector, industry, and the public.

The NCHCT, with the assistance of the National Council on Health Care Technology, is responsible for setting the priorities for health care technology assessment, and for final selection of the topics for assessment. The Council has developed a recommended set of criteria for selecting topics for technology assessment by the NCHCT. The Council decided that the priority assigned to a particular criterion might vary, depending upon the stage of development of the particular technology. Accordingly, three categories of development were recommended, viz., emerging, new, and established technologies, and for each category a different ordering of priorities was made. Examples of these selection criteria and priorities are summarized below.

Emerging technologies:
- Potential benefit
- Are there unusual health or safety questions, either known with certainty or unknown, asociated with the development of the technology?
- Are there potential ethical issues of a serious nature?
- Is there a potential for very wide utilization of an emerging technology?

New technologies:
- Benefits
- Potential ease of diffusion
- Safety
- Economic incentives
- Spin-off effects

Established technologies:
- Emerging safety concerns (risk-benefit)
- Substantial economic impact, including prevalence and cost per unit
- Cost-effectiveness
- Feasibility (e.g., whether the results of even a controlled clinical trial on a particular technology would

provide the kind of objective data that are needed to form an opinion about the clinical effectiveness of the technology, as in the case of diathermy)

A wide variety of interested parties and groups, including members of the practicing and academic scientific and medical communities,professional associations, industry, and others, are consulted in the priority-setting and selection processes.

TESTING NEW MEDICAL DEVICES

Question: Have you replaced PHS in testing new medical devices for reimbursement under Medicare?

Answer: The PHS has not conducted tests of new medical devices, procedures, etc., explicitly for purposes of making determinations regarding the appropriateness of coverage for a technology by Medicare. Agencies of the PHS, such as the NIH, FDA, CDC, and ADAMHA, do conduct basic scientific and biomedical research but this research is performed in relation to their own priorities and research agendas. Information resulting from this research, together with staff expertise within PHS agencies, is often the primary basis for Medicare coverage decision, however.

An important distinction must be made between the role of the FDA in evaluating and approving new devices for marketing purposes and the role of the NCHCT in evaluating particular technologies for purposes of making recommendations to the HCFA regarding the coverage of these technologies under Medicare. Although Medicare coverage decisions are always made consistent with FDA regulatory decisions about devices, etc., they often involve other considerations, particularly when complex medical procedures, such as heart transplantation, are in question.

As a matter of policy, the NCHCT will not itself undertake clinical trials and independent assessments of the safety and efficiency of health care technologies. Rather, the Center will rely on the expertise of those PHS agencies with principal responsibility for basic scientific and biomedical research. It is through the NIH scientific and medical consensus development mechanism, and the technology assessment activities of agencies such as the FDA, CDC, and ADAMHA, that the safety and efficiency of health care technologies will be evaluated. The NCHCT role is to set the priorities for such activities and to serve as a stimulus for joint and coordinated action among the agencies. Further, the Center performs or arranges for the conduct of economic, social, or ethical analysis that would complement the assessments of safety and efficacy, and undertakes assessments of the use of technology in different settings. These agencies do not undertake economic or ethical analyses of technology.

In addition NCHCT will fund research in technology assessment methodology to improve assessment activities.

LIAISON WITH THE HEALTH CARE PROFESSION

Question: To what extent does the National Center for Health Care Technology involve the health care professions in determinations made on medical technology?

Answer: The Center has established liaison and collaborative relationships with most of the professional health related groups in the private sector and, as a matter of policy, fosters broad and open participation by all groups interested in particular technology assessment activities of the Center. For example, a number of professional associations have participated in the public forums which have been held during the regularly scheduled meetings of the National Council on Health Care Technology. The major health care industrial alliances have been asked to participate as appropriate in providing data on the safety and efficacy of technologies. It is to be emphasized, however, that data and opinions are solicited from all individuals and groups who may have a stake in a particular technology and that conflict of interest is avoided.

A number of private professional associations with particular interests in health care technology assessment have willingly offered to assist the Center, in a variety of ways, in the discharge of its responsibilities. For example, the Council of Medical Specialty Societies and several medical societies and organizations have assisted the Center by providing information and data that have been used in the preparation of PHS recommendations to the HCFA on particular Medicare coverage issues.

The NCHCT convenes expert panels, which include representatives of the practicing health care professions, to advise on the safety and efficacy of specific technologies in order to provide the HCFA with the best possible recommendations regarding reimbursement policy.

A wide variety of interested individuals and groups, including representatives of the health care professions, are consulted in selecting topics and setting the priorities for health care technology assessment.

Professional health groups in the private sector have also identified and have made recommendations to the Center and the Council regarding candidate topics for technology assessment.

The NCHCT plans to publish in the Federal Register announcements regarding the technologies which it will be evaluating for purposes of making recommendations to the HCFA on Medicare reimbursement policy. The intent here is to engage all interested parties, including the concerned health care professions, in the PHS decision process regarding the appropriateness of Medicare coverage of specific health care technologies.

The NCHCT will convene national conferences, task forces, and special study groups, as appropriate, as part of its assessment of particular health care technologies. The health care professions will have integral involvement in these activities and thereby will have direct opportunity to contribute to determinations regarding the subject technology's safety and efficacy, and social, economic, and ethical impacts.

ADOLESCENT PREGNANCY

Question: When a young woman who suspects that she is pregnant comes to you for services and finds out that she is not pregnant, do you provide family planning services to her, or must she find them elsewhere, e.g., at a Title X family planning clinic, or Medicaid?

Answer: The regulations governing Title VI of P.L. 95-626 state that family planning services for non-pregnant adolescents should be limited to counseling and referral. However, if there are no suitable and/or appropriate family planning services in the community, such services may be provided directly. In addition, programs receiving Title VI funds are encouraged to work with Title X and other family planning agencies in their communities. If there is an existing Title X program, the non-pregnant adolescent would be referred there for services. One of the principal purposes of Title VI is to encourage the creation of linkage and networking to avoid duplication among community facilities and groups, thus providing a comprehensive approach to services.

SMOKING AND HEALTH

Question: Approximately two years ago, former Secretary Califano announced his antismoking initiative. To what extent has this program changed with the change in administration this past summer?

Answer: The antismoking program has not changed with the change in administration. This Department continues to support the antismoking program, and, when possible, to intensify this program in an effort to communicate the antismoking message to those groups in the population at high risk for smoking-related diseases. Shortly after taking office, Secretary Harris met with representatives of the Tobacco Institute at their request. At that time she told them that the evidence establishing the health hazards of cigarette smoking is overwhelming, and that she strongly supports the antismoking programs within the Department.

Question: Are we still doing all possible to encourage individuals not to start smoking or to give it up, or are we now concentrating on a more passive approach such as the development of a "safe cigarette" and publishing lists of "relatively safe" cigarettes?

Answer: We have intensified our efforts to encourage individuals, especially teenagers and women, to not start smoking or to quit smoking. Our past efforts have shown us that such public information activities do have a positive effect on reducing cigarette consumption. The judgment of the Public Health Service continues to be that although cigarettes with lower tar and nicotine are less hazardous, even the lowest yield cigarette presents risks, and that there will never be a safe cigarette. We are warning individuals who switch from high to low tar and nicotine cigarettes to be careful not to increase the number of cigarettes they smoke or to compensate by inhaling more deeply. Therefore, while we are committed to continuing work to find less hazardous ways of smoking, we believe that the single most effective way for smokers to reduce the hazards associated with cigarettes is to quit entirely.

Question: What is being done to inform special groups of their particular susceptibility to disease when their pre-existing condition is combined with smoking, e.g., women taking birth control pills, individuals who use saccharin, etc.?

Answer: We have recently issued a report devoted entirely to the health consequences of smoking for women. We will continue to disseminate the findings in the report to those groups of women who are particularly at high risk for smoking-related diseases, especially pregnant women and teenage females. One of the three principal goals of our current public information program is to inform pregnant women of the special health risks they incur for their unborn child. Other target groups to be the focus of antismoking information include women smokers who take oral contraceptives; minority group members, who run substantially higher risk of lung cancer and other smoking-related diseases; and individuals in certain hazardous occupations where the effect of smoking is synergistic with toxic elements in the workplace.

OFFICE OF POPULATION AFFAIRS

Approximately ten years ago, the position of Deputy Assistant Secretary for Population Affairs (DASPA) was statutorily created to administer and coordinate all Federal laws related to family planning services and population research which are carried out under the two aforementioned authorities, as well as those operated under the authority of the Maternal and Child Health program, Medicaid, and the Social Services programs.

Question: What steps are you taking to provide the Office of Population Affairs with adequate staff and resources to accomplish its coordination task?

Answer: The staffing and resources for the Office of Population Affairs will enable the Deputy Assistant Secretary for Population Affairs to carry out the provisions of the Family Planning Services and Population Research Act of 1970. This office provides a departmental focus for the administration of Federal laws and coordination of Department programs related to population research and family planning, including issues interrelated with the family planning aspects of Medicaid and Title V and Title XX Programs under the Social Security Act. We have made every effort to provide the Office of Population Affairs with adequate staff and resources for carrying out the provisions of the Family Planning Services and Population Research Act of 1970.

Public Health Service Management
Regional Management

Question: What percentage of your budget is used on travel: Within the region? From the regional to the central office.

Answer: In the Regional Management Activity, 54 percent of the travel is for trips within the region and 46 percent of the travel for the activity is for trips to headquarters.

Question: What degree of staff expansion is anticipated for fiscal 80? Fiscal 81?

Answer: The 1980 budget included a realignment of the operational functions in the regional offices and a reduction of one position in each of the 10 regions. In fiscal year 1981, no significant changes in the methods of operation or functions of the regional offices are anticipated; and thus, staffing and resources are consistent with the 1980 level.

It seems that many of the regional offices have simply become rubber stamps with virtually no decision making authority.

Question: What are your present and future plans for these offices?

Answer: The Regional Health Administrators will continue to advise the Assistant Secretary for Health on regional matters and to implement and to maintain regional Management systems that are reflective of Departmental and PHS policies and that are responsive to State and local needs. We are constanly reviewing the administration of our programs. Currently, it is felt that no changes are warranted for the foreseeable future.

PROGRAM DIRECTION AND SUPPORT SERVICES

Question: What percentage of their allotment is used on travel, in fiscal 1979? In fiscal 1980? In fiscal 1981?

Answer: The percentage of the budget for this activity used for travel was 2.8 percent in 1979; 2.6 percent in 1980; and 2.3 percent in 1981.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

Question: What is the status of the Federal pay bill?

Answer: We are assuming that the question refers to the Uniformed Services Health Professionals (H.R. 5235; S-523). The Senate passed its bill on December 20, 1979, subsequent to House passage on November 13. The Conferees have met and reached agreement on the report, which has been filed in the House and the Senate.

CLINICAL LABORATORY PERSONNEL REGULATIONS

Question: What are the Departments plans with regard to implementation of the October 12, 1979 proposed regulations relating to clinical laboratory personnel?

ANSWER: Over 8,000 comments have been received in response to the proposed standards for clinical laboratory personnel as published in the Federal Register on October 12, 1979. These replies will be analyzed over the course of the next few months. Included in this analysis will be the economic and manpower impacts of these standards on all catagories of clinical laboratories. The Departments decision as to which, if any, revisions of the personnel standards relating to clinical laboratory personnel are needed will be based in large measure on this analysis of the comments received.

CONSOLIDATION OF PREVENTION PROGRAM

Question: What reorganizations (such as consolidation of preventive services into CDC) are currently being contemplated or planned for health programs?

Answer: We are studing the disease prevention functions in OASH, CDC, HSA and HRA with a view toward consolidation. Our tentative proposal calls for transferring some of the activities in these agencies to the Center for Disease Control, together with a restructuring of CDC programs. No final decisions have been reached yet. When a final proposal is concluded, I shall be more than happy to inform the Congress.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CHARTER

PUBLIC HEALTH SERVICE

HEALTH STATISTICS COORDINATING COMMITTEE

PURPOSE

To assist the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics, in technical and operational coordination of health statistics activities of the Public Health Service (PHS).

In order to assure that the health statistics systems of PHS operate under policies that will result in coordinated activities, produce complementary statistics, and minimize the impact of Federal reporting demands on health institutions, individual providers of care and other respondents, the Committee will act as an internal forum for information exchange and coordination and will study and advise the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics, on guidelines, standards, procedures, and other issues concerning the collection, analysis, dissemination, and application of health and health-related statistics throughout the PHS. The Committee will coordinate with and complement the activity of the Departmental Health Data Advisory Committee.

FUNCTIONS

The Committee will perform the following functions:

1. Develop and recommend to the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics, procedures to assure operational coordination of all health statistics activities within the PHS.

2. Advise the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics, on baseline health statistics needed for current and long-term planning and policy formulation, as well as on data needed for program management and evaluation of the effect of Federal efforts in the field of health care. While the Committee's primary attention will be addressed to data needed within the Public Health Service and to the effective uses of health statistics, the Committee also will be responsive, in its recommendations, to the needs of other users.

3. Maintain continuing review of health data practices, procedures, statistical systems and data sets of the PHS, evaluate their effectiveness, and recommend desirable changes to the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics.

4. Identify and recommend to the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics, future needs for health statistics systems and analyses and for uniform data sets and standardized definitions of data elements, and identify appropriate organizations within the Public Health Service to carry out the

necessary activities. Recommendations which have an impact on other components of the Department will be channeled to and coordinated with the Health Data Advisory Committee for Departmental Policy considerations.

5. At the request of the PHS Reports Clearance Officer review major, complex health data proposals initiated within the PHS for practical utility, operational coordination, and technical adequacy, and recommend appropriate action.

6. Continually review requirements for data and data systems in PHS legislation, regulations, and guidelines to identify areas needing change or better management and areas where duplication of reporting requirements may exist.

7. Recommend special studies on selected issues regarding development, implementation and operation of health information systems and other related areas associated with the functions of the Committee.

STRUCTURE

The Committee will be chaired by the Director, National Center for Health Statistics, representing the Deputy Assistant Secretary for Health Policy, Research, and Statistics, who will also be a member of the Departmental Health Data Advisory Committee.

Within the Public Health Service, the Committee will have member representatives from:

Alcohol, Drug Abuse, and Mental Health Administration
Center for Disease Control
Food and Drug Administration
Health Resources Administration
Health Services Administration
National Center for Health Services Research
National Institutes of Health

Agency representatives will be formally designated by Agency Heads and will be familiar both with technical aspects of health data concerns and with Agency program planning, management and evaluation requirements for data. Representatives will serve for a period of three years.

Although not members of the Committee, officials of appropriate organizations within the Office of the Assistant Secretary for Health will be invited to participate in the meetings of the Committee.

Senior members or technicians of other organizations may be invited at the discretion of the Chairperson.

STAFFING

The Director, Office of Statistical Policy, Office of the Deputy Assistant Secretary for Health Policy, Research, and Statistics, will serve as Executive Director of the Committee and will direct the management and staffing of the Committee. While NCHS will serve as the primary technical staff support to the Committee, substantive staff support will also be provided by the other agencies represented on the Committee.

MEETINGS

Meetings of the Committee will be held monthly or at the call of the Chairperson.

REPORTS

The Chairperson will be responsible for keeping the Assistant Secretary for Health, through the Deputy Assistant Secretary for Health Policy, Research, and Statistics, informed on Committee activities and progress.

DURATION

The PHS Health Statistics Coordinating Committee will terminate three years from the date of its establishment unless extension beyond that date is requested and approved.

FORMAL DETERMINATION

I hereby determine that the formation of the PHS Health Statistics Coordinating Committee is in the public interest in connection with the performance of duties imposed on the Department by law, and that such duties can best be performed through the advice and counsel of such group.

MAY 10 1978
Date

/s/ James C. Lanhof
Assistant Secretary for Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CHARTER

HEALTH DATA ADVISORY COMMITTEE

PURPOSE

In order to assure that the health statistics systems of the Department of Health, Education, and Welfare (HEW) operate under policies that will result in coordinated activities, produce complementary statistics, and minimize the impact of Federal reporting demands on health institutions, individual providers of care and other respondents, the Committee will serve as a forum to advise the Secretary on important cross-cutting issues concerning the collection and analysis of health and health-related statistics throughout the Department.

FUNCTIONS

The Committee will perform the following functions:

1. Advise the Secretary on data policy issues for current cross-cutting and long-term planning and management. While the Committee's primary attention will be addressed to health data issues within the Department, it will also be responsive, in its recommendations, to the needs of other public and private users.

2. Develop and recommend to the Secretary policies and procedures to assure coordination of health statistics activities within the Department, with other Federal agencies and with other levels of government.

61-400 O - 80 - 62

3. Maintain continuing review of major cross-cutting policies, practices, statistical systems and data sets that affect Departmental health statistics activities, evaluate the effectiveness of these policies, practices, systems or data sets, and recommend desirable changes to the Secretary.

4. Identify and recommend to the Secretary current and future requirements for uniform health data sets, standard definitions of data elements and statistical systems.

5. Review major proposals initiated by operating components of the Department for establishment of, modifications in, or continuation of major health statistics systems and uniform data sets and recommend appropriate action to the Secretary.

6. Provide a viable structure and a locus within the Department for liaison between the Department and other organizations on any matter dealing with health data and to facilitate development of cooperative arrangements.

7. Recommend special studies on selected issues regarding development, implementation, and operation of data collection systems.

8. Oversee the development of the Health Statistics Plan on a periodic basis, incorporating the activities of the agencies represented on the Committee.

STRUCTURE

The Committee will be chaired by the Deputy Assistant Secretary for Health Research, Statistics, and Technology and the Associate Administrator for Policy, Planning and Research, HCFA, on an annual rotating basis.

The Committee will have a senior member representative from:

Office of Assistant Secretary for Management and Budget
Office of Assistant Secretary for Planning and Evaluation
Office of Assistant Secretary for Human Development
Office of Inspector General
Health Care Financing Administration
Public Health Service
Director, National Center for Health Statistics

Although not members of the Committee, senior officials of the Office of Federal Statistical Policy and Standards, Department of Commerce; Veterans Administration; and Department of Defense will be invited to participate in the meetings of the Committee.

Senior members of other organizations may be invited at the discretion of the Chairperson.

APPELLATE REVIEW

The Assistant Secretary for Management and Budget will serve as an arbiter when cross cutting issues cannot be resolved through the normal workings of the Committee. As appropriate, the Assistant Secretary for Management and Budget will chair any group set up for the purpose of resolving such issues.

STAFFING

The Director, Office of Statistical Policy, Office of Deputy Assistant Secretary for Health Research, Statistics, and Technology will serve as Executive Director of the Committee and will direct the management and staffing of the Committee. Where appropriate, necessary substantive staff support will be provided by agencies represented on the Committee.

MEETINGS

Meetings of the Committee will be held as needed at the call of the Chairperson.

REPORTS

An annual report shall be submitted to the Secretary through the Assistant Secretary for Health and the Administrator of HCFA. At a minimum, the report will include a list of the Committee's members, the Committee's functions, the dates of the Committee's meetings and a summary of the Committee's activities and recommendations made during the year.

The Departmental Health Statistics Plan will be developed on a periodic basis, incorporating the activities of the agencies represented on the Committee.

DURATION

The duration of the Health Data Advisory Committee is continuing, and a new charter shall be filed no later than three years from the signature date of this charter. Extension beyond that date must be requested and approved.

FORMAL DETERMINATION

I hereby determine that the formation of the Health Data Advisory Committee is in the public interest in connection with the performance of duties imposed on the Department by law, and that such duties can best be performed through the advice and counsel of such group. The Health Data Advisory Committee replaces the Health Data Policy Committee which was established by Charter, dated March 26, 1976.

Feb. 3, 1979
Date

Julie Thompson
Acting Secretary

SUBCOMMITTEE RECESS

Senator INOUYE. And the subcommittee will stand in recess until 1 p.m., Tuesday, February 19, at which time we will hear the Secretary of the Department of Education.

[Whereupon, at 2:45 p.m., Friday, February 8, the subcommittee was recessed to reconvene at 1 p.m., Tuesday, February 19.]

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

Page

Becker, Dr. Edwin D., Acting Director, John Fogarty International Center 295, 409
Statement of 417
Bersano, Peter J., Director, Office of Resource Management, Public Health Service 929
Bloom, James D., Executive Director, Center for Disease Control 213
Bohen, Frederick M., Assistant Secretary for Management and Budget 1
Bowery, Dr. Thomas, Director, Division of Research Resources 295, 425
Statement of 425
Butler, Dr. Robert N., Director, National Institute on Aging 295, 393
Statement of 394

Cummings, Dr. Martin M., Director, National Library of Medicine 295
Statement of 354

DeLuca, John R., Director, National Institute on Alcohol Abuse and Alcoholism 751
DeVita, Dr. Vincent, Jr., Acting Director, National Cancer Institute 295, 711
Statement of 712
Dobbs, William H., Acting Superintendent, Saint Elizabeths Hospital 751
Statement of 783

Erickson, Dr. James H., Director, Bureau of Medical Services 99

Fiori, Dr. Florence B., Director, Bureau of Health Facilities Financing, Compliance, and Conversion 849
Foege, Dr. William H., Director, Center for Disease Control 213
Statement of 215
Foley, Dr. Henry A., Administrator, Health Resources Administration 849
Statement of 851
Forbush, Wilford, Deputy Assistant Secretary, Budget Policy Coordination 99, 751, 849
Fredrickson, Dr. Donald S., Director, National Institutes of Health 295, 521, 623
Statement of 297

Goldberger, Dr., Deputy Director for Science, National Institutes of Health 295

Haley, Emily H., Director, Office of Financial Management 99
Hanft, Ruth S., Deputy Assistant Secretary for Health Operations 929
Harris, Patricia Roberts, Secretary, Department of Health and Human Services 1
Statement of 5
Hopkins, Dr. Donald R., Assistant Director for Operations, Center for Disease Control 213

Itteilag, Tony, Director, Division of Budget Policy and Management, Center for Disease Control 213, 295

Johnson, David E., Deputy Assistant Secretary for Legislation, Center for Disease Control 213, 751, 929

Kirschstein, Dr. Ruth, Director, National Institute of General Medical Sciences 295, 521, 537
Statement of 538

Page

Klerman, Gerald L., Administrator, Alcohol, Drug Abuse, and Mental Health Administration ... 751
Statement of ... 753
Krause, Dr. Richard M., Director, National Institute of Allergy and Infectious Diseases ... 295, 521, 561
Statement of ... 562
Kretchmer, Dr. Norman, Director, National Institute of Child Health and Human Development ... 295, 461
Statement of ... 462
Kupfer, Dr. Carl, Director, National Eye Institute ... 295, 371
Statement of ... 372

Levy, Dr. Robert I., Director, National Heart, Lung, and Blood Institute ... 295, 653
Statement of ... 654
Lythcott, Dr. George I., Administrator, Health Services Administration ... 99
Memorandum from ... 119

Martin, Dr. Edward D., Director, Bureau of Community Health Services ... 99
McFee, Thomas S., Assistant Secretary for Personnel Administration, National Institutes of Health, letter from ... 412
Miller, Charles, Deputy Assistant Secretary for Health Operations ... 751, 929

Nicholas, Mr. Edward, Acting Associate Director for Administration, National Institutes of Health ... 295, 521
Statement of ... 523
Nix, Lulu M., Director, Office of Adolescent Pregnancy Programs ... 929

Pardes, Herbert, Director, National Institute of Mental Health ... 751
Pollin, William, Director, National Institute on Drug Abuse ... 751

Rall, Dr. David P., Director, National Institute of Environmental Health Sciences ... 295, 435
Statement of ... 436
Richmond, Dr. Julius B., Assistant Secretary for Health and Surgeon General. 849, 929
Statements of ... 931, 939
Robbins, Dr. Anthony, Director, National Institute for Occupational Safety and Health ... 213
Rorrie, Dr. Colin C., Jr., Director, Bureau of Health Planning ... 849

Sammons, Dr. James H., Executive Vice President, American Medical Association, letter from ... 117
Memorandum from ... 118
Scott, Dr. David B., Director, National Institute of Dental Research ... 295, 635
Statement of ... 636
Stark, Nathan J., Under Secretary of Health, Education, and Welfare ... 1

Tower, Dr. Donald B., Director, National Institute of Neurological and Communicative Disorders and Stroke ... 295, 521, 589
Statement of ... 590
Townsend, Alair, Deputy Assistant Secretary, Budget ... 1, 929

Veit, Howard, Director, Office of Health Maintenance Organizations ... 929

Walsh, Dr. James A., Associate Administrator for Operations and Management ... 849
Welsh, William B., Assistant Secretary for Legislation ... 1
Whedon, Dr. G. Donald, Director, National Institute of Arthritis, Metabolism, and Digestive Diseases ... 491
Statement of ... 492
Whiteside, Dr. Daniel F., Director, Bureau of Health Manpower ... 849

SUBJECT INDEX

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

	Page
Activities, supplemental	24
AFDC and medicaid, reduction in	61
Aging programs	45
Audit backlog growth	64
Black lung funding	30
Budget:	
Cuts	48
Graphic display of	22
Request	24
Capitation grants	28
Consultants	58
Cost containment, hospital	34
Cost controls, health	52
Education and promotion, health	31
Employment	48
HEW	47
Social Security	48
GAO:	
Recommendations, past	54
Report—November 1979	52
Grantee funds, misspending	64
Grants appeal board	65
Health Care Financing Administration	33
Health Services Administration rescission	27
Head Start program	45
Initiatives, management	63
Inspector General:	
And POC's, meetings between	65
Appointment of	58
Vacancy	66
Medicaid:	
Program	34
Supplemental	35
Mental health	33
Nurse training	27
Office of Human Development Services	44
Audits	46
Paperwork:	
Burden	59
Hours of	58
OMB regulations on	60
Reduction, report of	55
Payments, Federal Government	39
Prevention grants	31
Prevention, promotion, and protection	30
Programs considered by Labor-HEW Subcommittee	25
Public Health Service:	
Hospitals	57
Theme, by	26

	Page
Refugee:	
Assistance	39
Education	42
Education programs, administration of	42
Housing	43
Legislation	44
Regulations, processing of	56
Rescission	51
Research:	
Biomedical	32
Stability in	33
Training	32
Savings proposals, implementation of	53
Social Security Administration	38
Administration of	39
Trust funds, payments to	41
Uncashed checks	41
Standards review organizations, professional	36
Certification of	37
State:	
Computerization	61
Matching funds, delay in	35
Supplementals	50
Travel, reduction of	55
Unauthorized program	22
Violence, domestic	49
Work incentives	46

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Accomplishments	757
Activities, Federal	782
Alcoholism:	
Consumption	779
Initiatives	758
Programs	778
Applications, program	758
Backlog, CMHC	765
Community support program	766
Distress grants	768
Drug abuse request	759
Education program, HEW drug and alcohol	781
Funds, use of new CMHC	764
Information, public	781
Mental health:	
Deinstitutionalization	767
Needs assessment	767
Request	760
Training programs	774, 777
Mental Health Systems Act	776
Methadone information, availability of	771
Patients to the community, return of	766
Personnel shortages, report on	773
Prescriptions, physician	771
Priorities, research	763
Priority scores	760
Psychiatry shortages	775
Supplemental, alcoholism	759
Supplemental request	756
Training programs	772
Tranquilizer abuse	769

	Page
Treatment program:	
Freestanding versus comprehensive	762
Linkages	761
Underserved areas	765
Valium abuse	770
Youth programs	780

CENTER FOR DISEASE CONTROL

Absenteeism decrease	242
Budgeting, zero-based	261
Department of Labor, interaction with	224
Diabetes	246
Duration, program	234
Education program, health	243
Education:	
Advisory structure for school health	260
Health	258
Employee survey	231
Flu:	
Predictability of	240
Program for 1980	241
Fluoridation	255
Community opposition	257
Program, goals for	256
Gonnorrhea	222
Incidence	251
Grants, formula	231
Heart attacks and strokes	231
Hispanic study	246
Immunization	222
Flu	239
Migrant children	243
Preschool children	237
Justification for new program	232
Kidney transplant	254
Lactase	255
Legionnaires' disease	222
Developments	248
Matching requirements	235
Measles eradication	241
Medicaid	246
Nutrition	244
Coordination with other Federal programs	245
Funding, increased	244
Occupational:	
Health	224
Skin disease	252
Opportunities, future	227
Oversight, management	225
Personnel requirements	233
Polio	223
Pregnancies, unwanted adolescent	259
Preventive medicine:	
Objectives for	228
Standards for	228
Prevention:	
Cost benefits of	253
Strategies	229
Refugees, Southeast Asia	223
Smallpox eradication	221
Smoke, sidestream	259

	Page
Smoking	229
Activities overlap	258
Marihuana	230
State budgets	233
Surpluses	233
Sex education personnel, qualifications for	260
Technology, control	226
Temperature reduction	242
Trichlorethylene	247
Tuberculosis:	
Resistant	252
Vaccine	251
Unimmunized children	237
Venereal diseases	235
Education	236
Workers, migrant	254
HEALTH RESOURCES ADMINISTRATION	
Capital formation	860
Capitation, medical school	866
Corps scholarships, recipients of	868
Staying in underserved areas	869
Education, health professions	856
Facilities, health	856
Financial distress, supplemental requested	859
Hill-Burton provisions on free care	864
Hospital bankruptcy, free care and	865
Hospital conversion:	
Demonstration approach in	863
Plan	862
HSA boards, membership on	862
Implementation plan, annual	861
National Health Service Corps scholarship, increase in	867
Nurse:	
Anesthetist program	877
Salaries	878
Practitioners	878
Compared with physician-extender	879
Production versus substitution	873
Program, decreases	873
Recruitment bonuses	875
Research	876
Salaries	875
Shortage, hospital	870
Problem, aspects of the	872
Training, advanced	876
Nurses, adequacy of supply of	869
Planning agencies, efforts of	860
Planning, health	855
Rand Corp. study	858
Rescission requested	859
Change in	867
Specialties, medical	857
State action, need for	861
HEALTH SERVICES ADMINISTRATION	
Activities, integration of	123
Aliens, illegal, costs of treating	136
Black lung clinics	134

	Page
Communications technology	106
Dust levels, reduction of	134
Education, followup and patient	108
Family planning	101, 133
Genetic disease programs	132
Grantees, management of	120
Health centers, community	101, 103, 104
Health professionals, nonphysician	128
Home health	109
Cost savings	110
Hospitals:	
And clinics	102
Assistance to small	119
Hypertension	107
Maternal and child health	102
Medical services, emergency	104
Migrant:	
Aliens, health services for	135
Health	101
Reports on	139
Temporary legal	136
National Health Service Corps	101, 113, 133
Physician supply	121
Pregnancy:	
Outcome, improved	112
Programs, teenage	110
Private sector, coordination with	116
Projections, report on future	122
Research and demonstration:	
Primary care	105
Projects	107
Retention rate	115
Specialists, retention of	114
Sudden infant death syndrome	128
Accomplishments of programs	129
Statistical information on	131
Supplemental request, fiscal year 1980	102
Support and self-support, Federal	123
Transportation to facilities	113

National Institutes of Health

Activities, unique specialized	357
Appropriation request, 1981	632
Association of American Medical Colleges	360
Backlog and resource-sharing plan	359
Biographical sketches, computerized	356
Budget increase	306
Buildings and facilities	525
Renovation of obsolete	530
Clinical center modernization, requested reprograming for	525
Funds, earmarking of	318
Grants:	
Applications	310
Funded, percentage of	309
Hiring delay, solving the	629
Inflation rates	359
Intramural program funds, alternative utilization of transferred	526
Investigators, clinical	314

	Page
Library:	
Costs, increasing	358
Network, regional medical	357
National Library of Medicine	353
Office of the Director	631
Recruitment, senior executive	632
Research:	
Applications	303
Biomedical, inflation rate for	311
Career program	312
Grants, funding for	307
Investigator-initiated	312
Intramural	303
Project:	
Awards, increase in competing	309
Grants	302, 320
Training	312
Science base	301
Stabilizing the	308
Senior executive service	623
Support, other	303
Decline	306
Time lag, hiring	625
Training:	
Funds, reduction in	316
NIGMS	317
Program, stabilization of	313
Transfer and training	303

DIVISION OF RESEARCH RESOURCES

Animals in research, use of	427
Funding for research equipment	428
Grant program, BRS	427
Inflation on DRR programs, effect of	428
Instrumentation, shared	429
Overview of mission	426
Primate research plan	428

JOHN FOGARTY INTERNATIONAL CENTER

Budget increase, allocation	410
Clinical trials	410
Gorgas Memorial Institute	420
Program:	
Impact of budget	420
Plans	416
Radiation, research on low-level	414
Recommendations, response to task force	416
Research training	409
Role of Fogarty Center, task force to examine	415
Scientific personnel, recruitment	411
Senior executive service	412
Change in recruitment	413

NATIONAL CANCER INSTITUTE

Achievements	726
Categories, budget	718
Contraceptives and associated risk, oral	727
Epidemiology	718
Fat in cancer, role of	724

	Page
Interferon	721
Cost	723
Promotion	722
Mortality and morbidity	717
National toxicology program	718
NIAID, coordination	724
Prevention	719
Promoters	719
Research results	720
Stroke and the pill	726
Treatment	719
NATIONAL EYE INSTITUTE	
Activities, unique specialized	357
Budget increase	377
Cataracts	379
Construction	378
Positions, new	378
Research:	
Balance between intramural and extramural	377
Progress	375
Treatment techniques, better	377
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE	
Balance, program	664
Budget strategy	665
Grants, funding for competing research project	663
Grant awards, research	663
High blood pressure education program, national	662
Hypertension:	
Alternative treatments of	664
Detection and followup program conclusions	662
Program	658
Training awards	663
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	
Immunity system	571
Infections	566
Information, dissemination of	567
Microbiology and immunology, advances from	566
Research, basic/applied	567
Training, research	568
Vaccine development, new	567
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES	
Brittle bone disease	498
Cell transplantation, pancreatic	501
Diabetes coordinating committee	501
Drugs	498
Enthusiasm	505
Insulin:	
Hormonal trigger for	500
Infusion devices	501
Recombinant DNA research on	502
Juvenile:	
Arthritis	497
Diabetes, onset	499
Kidney disease	499
Quackery	497

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Page

Abuse and neglect, child 467
Infant mortality 467
Mental retardation 468
Pregnancy and infant mortality, diabetic 469
Sudden infant death syndrome 468
  Funding for 469
  Research progress in 469

NATIONAL INSTITUTE OF DENTAL RESEARCH

Caries prevention 639
Craniofacial malformations 641
Diabetes 640, 641
Herpes 640
Implants 641
Oral diseases 639
Pain control 641
Periodontal disease 640, 641
Sweeteners, substitute 642

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Asbestos 444
Budget, increases in the 1981 441
Chemical exposures 439
  From waste dumps, multiple 440
National toxicology program 443
NIH Institutes, coordination with other 444
NIOSH and NCI, coordination with 442
Testing, species differences in 443
Trichloroethylene 441

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Budget request 543
Disorders, hereditary 544
Genetics 542
  Counseling 543
  Screening 546
Information, public 546
MARC program 543
Research:
  Basic 541, 546
  Cellular and molecular 542
Sciences, pharmacological 543
Training 543
  Medical scientists 543
  Research 549
Trauma and burn 542, 547
  Research report 548

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Clinical research, unique needs for 598
Electrode, new 597
Neuroendocrinology 598
Priority setting 600
Regeneration:
  Central nervous system 596
  Spinal cord injury and 599
Stroke, drop in causes of 595
Training, research 599

NATIONAL INSTITUTE ON AGING

Page

Animal resources 400
Position ceilings 399
Research:
- Aging, development of 397
- Basic science 398
- Collaborative effort 398
- Intramural 399
- Training 400

Social science and demographic data 398

OFFICE OF THE ASSISTANT SECRETARY OF HEALTH

Consultants 944
Coordination, program 957
Emergency medical services 945
Grants, formula 937
Health:
- Maintenance organizations 950
  - Development, Federal 951
  - Federally qualified 952
  - Rural 951
    - Promotion 953
- Planning 936
- Prevention coordination 957
- Promotion efforts 949
- Services:
  - Availability 936
  - Research 943
- Statistics 942
- Status 934

Public Health Service research funding 943
Pregnancy:
- Adolescent 955
  - Increase in 956
- Counseling 955
- Outcome, improved 935

Refugees, influx of 954
Research:
- Efforts 937
- Training 944