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Fiscal Year 1982

97*th* CONGRESS, FIRST SESSION

PART 2—(Pages 1-928)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH SERVICE ADMINISTRATION
CENTERS FOR DISEASE CONTROL
NATIONAL INSTITUTES OF HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1982

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

FIRST SESSION

PART 2 (Pages 1–928)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH SERVICES ADMINISTRATION
CENTERS FOR DISEASE CONTROL
NATIONAL INSTITUTES OF HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1982

TUESDAY, FEBRUARY 17, 1981

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

The subcommittee met at 10 a.m., in room 1114, Everett McKinley Dirksen Senate Office Building, Hon. Warren Rudman presiding.

Present: Senators Rudman, Andrews, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH SERVICES ADMINISTRATION

STATEMENT OF JOHN H. KELSO, ACTING ADMINISTRATOR

ACCOMPANIED BY:

DR. EDWARD MARTIN, DIRECTOR, BUREAU OF COMMUNITY HEALTH SERVICES
DR. LEONARD BACHMAN, DIRECTOR, BUREAU OF MEDICAL SERVICES
DR. DANIEL F. WHITESIDE, DIRECTOR, BUREAU OF HEALTH PERSONNEL DEVELOPMENT AND SERVICE
W. HARELL LITTLE, DEPUTY ASSOCIATE ADMINISTRATOR FOR MANAGEMENT
EMILY L. HALEY, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT
ANTHONY L. ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

SUBCOMMITTEE PROCEDURE

Senator RUDMAN. Good morning. Today the subcommittee is going to resume its fiscal 1982 hearings. We will hear this morning from the Department of Health and Human Services. The first hearing today will be on the Health Services Administration. These programs, administered by HSA, are designed to improve health services for high-risk groups, assist areas that have shortages in trained medical personnel, and provide direct care to special groups.

Here to tell us this morning about those programs is the Acting Administrator, John H. Kelso. Mr. Kelso, if you would like to introduce your colleagues at the table. We welcome you here this morning.

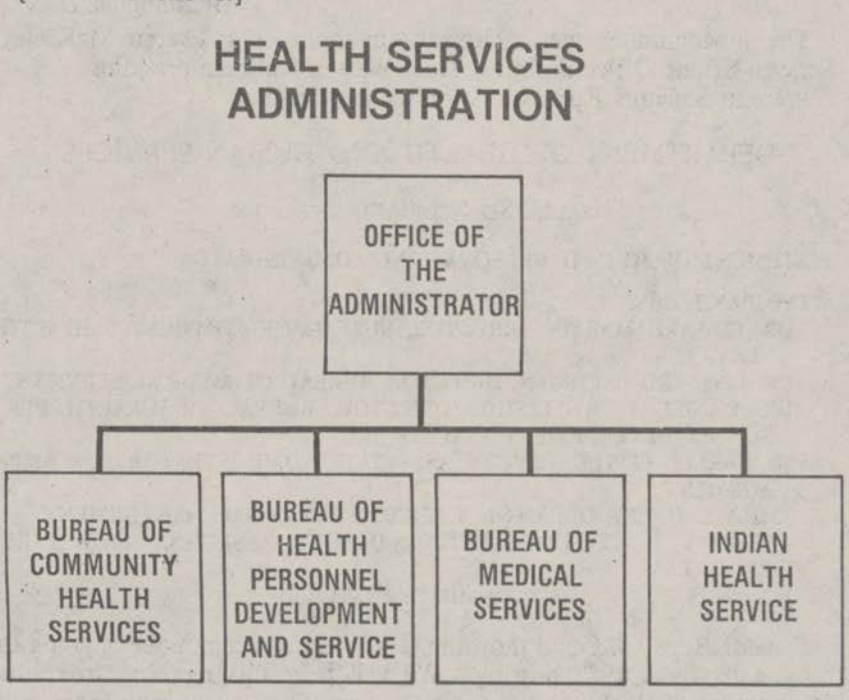
INTRODUCTION OF ASSOCIATES

Mr. KELSO. On my far right is Mr. Tony Itteilag from the Department's Budget Office. Next to him is Dr. Daniel Whiteside, who is Director of the Bureau of Health Personnel Development and Service. Next to me is Dr. Edward Martin, who is Director of the Bureau of Community Health Services. To my left is Mr. Harell Little, who is the Deputy Associate Administrator for Management, Health Services Administration. On my far left, Dr. Leonard Bachman, who is the Director of the Bureau of Medical Services.

Mr. Chairman, if I might, I have some charts which I can go through rather quickly, and then we can get to any questions you might have.

The charts are related to my opening statement, which, with your permission, I will file for the record.

[The chart follows:]



PREPARED STATEMENT

Senator RUDMAN. The prepared statement and charts will be received and inserted in the record at this point.

[The statement and charts follow:]

Statement of John H. Kelso

I would like to express my appreciation to you and the other members of the Committee for giving me this opportunity to present to you a programmatic overview of the Health Services Administration.

The Health Services Administration (HSA) is comprised of the Office of the Administrator and four Bureaus: the Bureau of Community Health Services (BCHS), which operates its programs through project and formula grants to States and to private non-profit groups and institutions; the Bureau of Health Personnel Development and Service (BHPDS), which is the newest of our bureaus, most of its programs having been recently transferred from the Health Resources Administration, and which supports service oriented health professions and nursing education programs; the Bureau of Medical Services (BMS) and the Indian Health Service (IHS). These latter two bureaus operate direct delivery systems of medical and preventive health care through hospitals, clinics, and contract care providers. Although the Indian Health Service is one of the four bureaus operating within HSA, its appropriations request is considered by the Interior and Related Agencies Appropriations Subcommittee.

The Health Services Administration is a very large organization. Under the fiscal year 1981 Continuing Resolution, this Agency will employ 20,125 people, over half of whom are in the the Indian Health Service. Because this Agency is a services delivery organization, most of these people are employed in the field -- where the actual delivery of health care services is taking place. Approximately 94 percent of the people working in HSA are located in either the field or regional offices, with only 6 percent in headquarters positions.

Primary Health Care Centers

The Primary Health Care Centers program is made up of three activities: Community Health Centers, Primary Care Research and Demonstration, and Black Lung Clinics.

The Community Health Centers activity provides project grants to public and nonprofit private organizations which support the development and operation of ambulatory health care centers. These centers provide basic, family-oriented, out-of-hospital care and make referrals for specialized or institutional care. Their target populations are rural and urban groups which are medically underserved. Funding priority is given to projects that serve areas having high infant mortality rates; large numbers of people over age 65; large numbers of individuals living in poverty; and shortages of health care personnel. We are currently supporting 872 community health centers. Of this number, 573 are located in rural areas providing services to approximately 2.5 million people, and 299 are urban projects which serve about 2.5 million people. The 5 million people served by the Community Health Centers are located in about 983 counties throughout the nation.

Primary Care Research and Demonstration projects provide grant support to develop or demonstrate new and innovative methods for the provision of primary health care. In fiscal year 1980, 56 projects were supported, all of which were located in rural areas.

The Black Lung Clinics activity provides project grants to support clinics located in areas where there are significant numbers of active and disabled coal miners. These clinics build upon existing community health centers or other resources in order that they may serve the specialized needs of black lung victims. Fifty-six (56) Black Lung Clinics are currently being supported, of which 44 are rural and 12 are urban. The rural clinics are providing services to approximately 26,000 individuals, and about 4,000 people are being served by urban projects. The program emphasizes outreach, education, and follow-up to assure that victims of black lung disease receive care that is timely and appropriate.

Migrant Health Care Centers

The Migrant Health program supports the establishment of health delivery systems to provide health care services for migrant and seasonal farmworkers and their families. Project grants are made to public and nonprofit private entities to establish and support centers which serve the health needs of migrants and seasonal farmworkers. Priority is given to projects in areas heavily impacted by migrants and seasonal farmworkers and where local health resources are inadequate to handle the additional seasonal demand for services that the migrants require.

There are currently 129 projects being supported by this program. These projects provide services to 581,000 people, of which 219,000 are migrants and 362,000 are seasonal farmworkers. The services provided by these projects include primary health services such as physician services, diagnostic, laboratory and radiological services, preventive health services, emergency medical services and transportation services, as well as outreach and limited hospitalization.

Maternal and Child Health

The Maternal and Child Health (MCH) program is comprised of four major sub-activities: Grants to States, MCH Training, MCH Research, and Supplemental Security Income Disabled Children's program.

The Grants to States activity provides formula grants to States for maternal and child health services and for services to crippled children. Services include maternal and infant care, children and youth services, intensive newborn care and specialized diagnostic and treatment services to prevent or correct crippling conditions. Special grants for projects of regional or national significance are made to develop innovative activities such as improving pregnancy outcome. Assuring prenatal care and reaching high risk patients are essential to achieving reduced levels of infant mortality. Priority is given to reaching rural and economically depressed areas. In fiscal year 1981, 28 Improved Pregnancy Outcome projects, 13 Improved Child Health Care projects, and 3 Accident Prevention projects are being supported.

The Maternal and Child Health Training activity provides project grants to institutions of higher learning to train personnel in the delivery of health care and related services for mothers and children, particularly mentally retarded children and children with multiple handicaps. During the past year, 21 University Affiliated Centers and 11 Pediatric Pulmonary Centers provided training for 5,025 health professionals, and 28 Allied Health Disciplines supported training for 2,297 health professionals.

The Maternal and Child Health Research activity supports applied research relating to both clinical problems and health services delivery issues. The Research program supports the identification of methods for improving the delivery of health services in such areas as adolescent health, child trauma and congenital malformation. Research is of an applied nature in contrast to the basic laboratory research conducted by the National Institutes of Health. In fiscal year 1980, 50 research projects were supported by this program.

The Supplemental Security Income Disabled Children's program (SSI) provides formula grants to States for the delivery of medical, social, developmental, and rehabilitative services to SSI disabled children who are under seven years of age or who have never attended public school. The SSI program also provides for counseling, the development of individual service plans, and referrals and monitoring of the service plans for SSI disabled children under sixteen years of age. We are currently providing services to 70,000 children under the auspices of this program.

High Blood Pressure Control

The High Blood Pressure Control program supports the establishment, through State health authorities, of programs for the screening, detection, diagnosis, prevention and referral for treatment of hypertension. Project grants are awarded to State health authorities to assure that systems exist to make blood pressure screening available and accessible to high risk populations and to provide referral linkages and follow-up with patients' physicians. All 57 health authorities are supported by this program, providing screening for 5.4 million persons.

Genetic Services

The Genetic Services program provides education, testing, counseling and referral services with respect to genetic diseases such as Down's syndrome, cystic fibrosis, hemophilia, sickle cell disease, and other genetic diseases for those who voluntarily request to receive such services. In addition, the program provides treatment to individuals suffering from hemophilia. In fiscal year 1980, this program was conducted through 34 areawide genetic networks serving 2.5 million people, 11 sickle cell clinics serving 150 thousand people, and 23 Hemophilia Treatment Centers which provided treatment to 6,000 patients.

Sudden Infant Death Syndrome Program

The Sudden Infant Death Syndrome program provides project grants to public and nonprofit private entities to create a nationwide awareness of the nature and scope of the SIDS problem, to ensure the provision of specialized, informational and educational training required by persons in health professions and by police, fire and other emergency personnel, and to ensure counseling for families affected by SIDS. Information and counseling services are currently provided to 5,500 families through 42 SIDS projects.

Family Planning

The Family Planning program operates through grants and contracts to public and nonprofit private entities, some of which

operate on a Statewide basis, to provide comprehensive voluntary family planning services to low-income and high-risk clients, including adolescents; to develop educational and informational materials; and to conduct demonstration studies concerning improvement of family planning services delivery. This program supports all methods of voluntary family planning, including sterilization, prescription, non-prescription and natural family planning. The program also supports infertility projects that provide more accessible and affordable services to couples in need and serve as a resource to deliver basic infertility services. During FY 1980, 3.8 million patients received services in clinics partially funded by this program.

Emergency Medical Services

The nation has been divided into 303 EMS regions which cover the total population. The purpose of the program is to assist communities in the planning, organization, establishment and improvement of emergency medical systems. Communities may seek to achieve a Basic Life Support System or an Advanced Life Support System. Both types focus on communications, transportation, education, training and the establishment of service agreements between hospitals to optimize efficiency and effectiveness and to reduce duplication and competition. The advanced systems also include telemetric patient monitoring on site or in transit and rely on paramedics trained to a higher level. Fifty seven (57) regions, with a population of 39.9 million, have completed advanced systems, and 7 regions with a population of 53.9 million have completed basic systems.

Next, I would like to discuss with you the programs administered by the Bureau of Health Personnel Development and Service.

National Health Service Corps

The National Health Service Corps (NHSC) provides medical and dental services to people in urban and rural communities which are designated as health manpower shortage areas. Usually the areas have less than one primary care physician for every 3,500 persons. There are currently 1,855 areas in the nation which are designated as primary care shortage areas, and 881 dental shortage areas. During fiscal year 1980, the National Health Service Corps had 2,058 health professionals, including physicians, dentists, nurse practitioners, physician assistants and other health care personnel serving in areas that have shortages of health manpower. Services were provided to 1.2 million people. Of the 2,058 NHSC assignees, 1,016 were scholarship recipients and 1,042 were volunteers.

National Health Service Corps Scholarships

The National Health Service Corps Scholarship program provides scholarship support to health professions students during academic training in exchange for a service pay back in health manpower shortage areas. Scholarship recipients provide one year of service commitment for each year of scholarship support received. However, a minimum of two years of service is required and can be met by serving either as a salaried member of the National Health Service Corps or by private practice in a health manpower shortage area.

The scholarship benefits provide for the payment to the school of tuition and required fees plus monthly stipends to the students for living expenses (adjusted annually to Federal salary changes). An additional amount is provided to cover other educational expenses such as: fees, books, equipment, and laboratory expenses. In fiscal year 1980, 6,118 students received NHSC Scholarships, of which 1,731 were new awardees and 4,387 were students already in the program who continued to receive support.

Health Professions Student Assistance

The Health Professions Student Assistance activity is comprised of three programs - Health Professions Loans, Loan Repayments and Cancellations and Exceptional Financial Need Scholarships.

The Health Professions loan program authorizes long-term, seven percent interest loans up to $2,500 per year, plus tuition, to health professions students (MOD/VOPP). These loan funds are given to schools which in turn make awards to students with limited financial resources. Since 1965, this program has made approximately 374,000 loans to students. Through the Loan Repayment program, we are able to attract health professionals to health manpower shortage areas in exchange for repayment of up to 85 percent of their educational loans. The Exceptional Need Scholarship program provides financial support to persons with limited resources during their first year of education in a health professional school.

Nursing Student Assistance

The Nursing Student Assistance activity is comprised of three programs - Nursing Loans, Nursing Scholarships, and Loan Repayments and Cancellations.

The Nursing Student Assistance loan program authorizes long term, low interest loans of up to $2,500 per academic year. The program assists nursing students (who are either full or half-time) having need for financial assistance in undertaking a course of study leading to a diploma, associate degree, bachelor's degree, or graduate degree in nursing. Loans are repayable over a 10-year period following completion of training. The Nursing Scholarship program provides scholarships of up to $2,000 per academic year to students who have exceptional financial need. The Nursing Loan Repayment program provides for up to 85 percent repayment of loans in exchange for service in shortage areas.

I would like now to discuss with you the programs administered by the Bureau of Medical Services.

PHS Hospitals and Clinics

The PHS Hospital and Clinic system, which consists of eight general and surgical hospitals, 27 urban freestanding outpatient clinics and a network of contract health care providers, provides health services to American Seafarers, active duty members of the Coast Guard, and commissioned officers of the Public Health Service and National Oceanic and Atmospheric Administration who are statutorily entitled to health care services. On a reimbursable basis, health care is also provided to beneficiaries of other Federal agencies, foreign seamen, and community groups. In 1980, this program provided for 543,800 inpatient days and for 982,500

outpatient visits. This activity also supports the National Hansen's Disease Center at Carville, Louisiana for the care and treatment of persons with Hansen's disease.

Federal Employee Occupational Health

The purpose of the Federal Employee Occupational Health program is to meet the occupational health care and safety needs of Federal employees. This program, on a reimbursable basis, operates 167 health units providing occupational health services to approximately 270,000 Federal employees. When requested by Federal agencies, this program also conducts surveys of existing health services and provides advice and consultation on the conduct by Federal employee occupational health programs.

Payments to Hawaii

The payments to Hawaii provide partial support (approximately 74%) for the cost of care and treatment for the Hansen's disease patients in Hawaii.

Buildings and Facilities

The Buildings and Facilities program provides for the correction of life safety code deficiencies, renovations and modernization, and maintenance of the PHS hospitals in order to assure that the facilities provide a safe and functional environment for the delivery of patient care.

Regulations

Finally, Mr. Chairman, I would like to briefly discuss with you the types of activities associated with the development, promulgation and enforcement of Federal regulations in this Agency. I would like to point out that we are not a regulatory Agency. Rather, our regulations are designed to assure program integrity and consistency with Congressional intent in the legislative authorizations for the service delivery programs. The enforcement of these regulations is part of the ongoing program management carried out by project and grants management officers on a day-to-day basis. The character of this enforcement is to assure that grantees are expending Federal funds in conformance with the purpose for which they were appropriated.

Mr. Chairman and members of the Committee, this concludes my programmatic overview presentation. I hope that I have been able to successfully provide you with a description of the major programs within the Health Services Administration and how the Agency is organized to carry out those programs.

At this time, Mr. Chairman, my staff and I will be pleased to answer any questions which you and the Committee may have.

BIOGRAPHICAL SKETCH

Name:	JOHN H. KELSO
Position:	Acting Administrator Health Services Administration U.S. Public Health Service Department of Health and Human Services
Birthplace and Date:	Iowa City, Iowa, June 16, 1925
Education:	B. A. -- 1949 and M.A. -- 1950, State University of Iowa
Experience:	
Jan. 1980 - to present	Acting Administrator Health Services Administration, PHS, DHHS
June 1976-1980	Deputy Administrator Health Services Administration, PHS, DHEW
1973-1976	Director, Office of Regional Operations, Office of the Assistant Secretary for Health, DHEW
1971-1973	Associate Administrator for Management, Health Services and Mental Health Administration, DHEW
1968-1971	Assistant Administrator for Management, Health Services and Mental Health Administration, DHEW
1966-1968	Executive Officer, Public Health Service, DHEW
1962-1966	Assistant Executive Officer, BSS/Environmental Health, PHS, DHEW
1960-1962	Chief, Management Advisory Branch, ESS/EH, PHS, DHEW
1957-1960	Management Analyst, PHS, DHEW
1955-1957	Management Analyst, Department of Agriculture
1951-1955	Occupational Research Analyst, Department of the Navy
Awards:	DHEW Superior Service Award - 1969 DHEW Distinguished Service Award - 1972

HEALTH CARE DELIVERY

Mr. KELSO. As you indicated, the Health Services Administration is responsible for the delivery of health care to the underserved or unserved. It is one of six agencies within the Public Health Service. As you can see, it is divided into four bureaus. The Indian Health Service, which is the box on the far right of the chart, is a bureau within the Health Services Administration, but its appropriations requests are heard by the Appropriations Committees responsible for the Department of the Interior and therefore will not be discussed today.

We carry out our mission through project grants and through the direct delivery of health care by Federal employees. This chart is just to show you that we are a large agency, in excess of 20,000 people. Most of these people, 91 percent of them, are in the field, in the Indian Health Service and the National Health Service Corps, and in the Bureau of Medical Services.

Only 6 percent of our people are here in Washington, thus we are a largely decentralized field organization.

[The chart follows:]

DISTRIBUTION OF HSA PERSONNEL

	Regional Offices	Field Activities	Hdqtrs.	TOTAL
Bureau of Community Health Services...	416	---	245	661
Bureau of Health Personnel Development and Services.....	210	2,060	268	2,538
Bureau of Medical Services	---	5,819	145	5,964
Office of the Administrator.....	---	---	198	198
Subtotal, Health Services	626	7,879	856	9,361
	(7%)	(84%)	(9%)	(100%)
Indian Health Service.....	5	10,410	349	10,764
TOTAL, HSA	631	18,289	1,205	20,125
	(3%)	(91%)	(6%)	(100%)

BUREAU OF COMMUNITY HEALTH SERVICES

PRINCIPAL OBJECTIVES

Provision of primary and preventive health care services to underserved and unserved populations.

Provision of health services to special segments of the general population.

Development of new and improved systems for the provision of health services.

BUREAU OF COMMUNITY HEALTH SERVICES

Mr. KELSO. The first Bureau I'd like to discuss is the Bureau of Community Health Services which is responsible for the provision of primary and preventive health care to the underserved and unserved. We do that through community health centers and through the provision of health services to special segments of the general population particularly in the area of maternal and child health. There we're talking about genetics, hemophilia, SIDS, and the large maternal and child health and crippled children's grants to States, and the development of new and improved systems for the provision of health services. In that Bureau also is the emergency medical services program.

[The chart follows:]

MAJOR PROGRAMS
(dollars in thousands)

	F.Y. 1980	F.Y. 1981
Primary Health Care Centers	$334,500	$336,500
Migrant Health Care Centers	39,700	43,400
Maternal and Child Health	396,179	417,400
High Blood Pressure Control	20,000	20,000
Genetic and Sudden Infant Death Syndrome Services	17,369	19,247
Family Planning	162,000	166,047
Emergency Medical Services	32,125	30,000
Positions	659	661

PRIMARY HEALTH CARE CENTERS

Mr. KELSO. There you can see the funds that we have for fiscal year 1980 and in fiscal year 1981. Fiscal year 1981 represents the continuing resolution. Under the first line item on primary health care centers, we have three programs: Community health centers, which includes hospital-affiliated primary health care centers; the primary care research and demonstration projects; and the black lung clinics.

As far as the community health centers program is concerned, this is one of the big programs within the Bureau. They provide project grants to public and nonprofit organizations to develop ambulatory health care centers in areas that are medically underserved. In both urban and rural areas, we have approximately 872 of these centers—573 are rural and 299 are urban, serving about 5 million people in this country.

The primary care research and demonstration projects are project grants that develop and demonstrate new and innovative ways for delivering health care. We have 56 projects, and they are all in rural areas.

The third category is the black lung clinics. These are project grants to support clinics in areas where there is a significant number of active or disabled coal miners. We have 56 such clinics—44 rural, 12 urban. The rural clinics serve about 26,000 people; the urban serve about 4,000.

MIGRANT HEALTH CENTERS

The next line is the migrant health centers. As you can see, there is a small amount of money devoted to these centers. We administer project grants to public and nonprofit entities to support migrant health centers. We have about 122 of these projects, and they serve about 581,000 people. This program also provides a limited amount of hospitalization for patients.

MATERNAL AND CHILD HEALTH

The next big program within the Bureau is maternal and child health. Maternal and child health is really broken into four separate pieces: Grants to the States, maternal and child health training, maternal and child health research, and supplemental security income for disabled children.

The grants to States for maternal and child health and crippled children are formula grants, and priority is given to reaching rural and economically depressed areas. The preponderance of funds goes into these grants. In addition, we are supporting, through special project grants, 28 improved pregnancy outcome projects and 13 improved child health care projects, intended particularly to provide leadership in reducing infant mortality.

The maternal and child health training activity supports project grants to colleges and universities for training of professional personnel. During the last year, we trained about 7,000 health professionals.

Maternal and child health research is an applied research activity as contrasted with some of the basic research at NIH. It relates to both clinical and health services delivery problems. We had about 50 such projects in 1980.

The supplemental security income activity is a program we administer under the social security authority. It's actually to provide medical and social health care to children of those people who are eligible for SSI benefits in the Social Security Administration.

HIGH BLOOD PRESSURE CONTROL

The next is high blood pressure control. These again are project grants through State health authorities for screening, detection, diagnosis, prevention, and referral for treatment of hypertension.

All 57 health authorities are supported by the program. And we did provide screening for about 5.4 million people in fiscal year 1980.

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GENETICS AND SUDDEN INFANT DEATH SYNDROME

The next one is genetics and sudden infant death syndrome services. These are basically two programs: First, for genetic diseases, the program provides education, testing, counseling, and referral services for persons suffering from or concerned about various genetic diseases. It also considers those suffering from hemophilia. In 1980, there were 34 areawide genetic networks serving 2.6 million people; 11 sickle cell clinics serving 150,000 people; and 23 hemophilia centers for 6,000 patients.

Second, the SIDS program, or sudden infant death syndrome, awards project grants to public and nonprofit agencies, largely for the use of counseling SIDS parents and providing information and education to people who have suffered a SIDS death. We are currently providing counseling for 5,500 families throughout 42 SIDS projects.

FAMILY PLANNING

The next one is family planning. Here again, through project grants, we have provided a comprehensive program of family planning including education and the rendering of services. We served about 3.8 million patients in fiscal year 1980.

EMERGENCY MEDICAL SERVICES

The last one is emergency medical services program. This again is a grant program. We have divided the United States into 303 regions and we provide a 5-year grant program, all the way from planning, through basic life support, to advanced life support. In 1982, we hope to have about 90 percent of the country covered in some form or another with EMS grants.

[The chart follows:]

BUREAU OF HEALTH PERSONNEL DEVELOPMENT AND SERVICE

PRINCIPAL OBJECTIVES

Improve the delivery of health care services in health manpower shortage areas.

Provide assistance to build capacity to serve the Nation's medically underserved and unserved populations.

BUREAU OF HEALTH PERSONNEL DEVELOPMENT AND SERVICE

Mr. KELSO. The next one is the Bureau of Health Personnel Development and Service. Most of this Bureau's functions were recently transferred to this agency from the Health Resources Administration. This Bureau has two objectives: To improve the delivery of health care services in health manpower shortage areas, which is the role of the National Health Service Corps; and to provide educational assistance to students who will serve the Nation's medically underserved and unserved populations, which is primarily done through a scholarship program that, as I said, we got from HRA in the last few months.

NATIONAL HEALTH SERVICE CORPS

The National Health Service Corps is a mechanism whereby we assign medical and dental health professionals to health manpower shortage areas to provide primary health care. There are about 1,855 primary health shortage areas. In 1980, we had about 2,058 health professionals assigned, serving about 1.2 million people, equally split between volunteers and scholarships.

[The chart follows:]

MAJOR PROGRAMS
(dollars in thousands)

	F.Y. 1980	F.Y. 1981
National Health Service Corps	$74,075	$79,429
National Health Service Corps Scholarships	79,500	79,500
Health Professions Student Assistance	28,000	28,000
Nursing Student Assistance	23,250	23,250
POSITIONS:		
Field (NHSC)	2,060	2,060
Program Support	436	478

NATIONAL HEALTH SERVICE SCHOLARSHIPS

Mr. KELSO. The next one is the National Health Service scholarship program, which is a program from which we get the National Health Service Corps manpower. This program provides scholarships for students in health professions schools who will be willing to pay back on a one-to-one basis through service in our underserved areas. They have to agree to stay at least a minimum of 2 years. We had 6,118 scholarship recipients in fiscal year 1980.

HEALTH PROFESSIONS STUDENT ASSISTANCE

The health professions student assistance program encompasses three programs: health professions loans, loan repayments and cancellations, and exceptional financial need scholarships.

The health professions loan is a long-term loan, 7-percent interest, up to $2,500 a year plus tuition. Since 1965, we have had approximately 374,000 loans. The loan repayment program is for service in a health manpower shortage area. If a person agrees to serve in a health manpower shortage area, we will agree to pay up to 85 percent of his/her educational loans.

Exceptional financial need scholarships provide financial support to those with very limited resources.

NURSING STUDENT ASSISTANCE

The nursing student assistance also is divided into three programs: nursing loans, nursing scholarships, and loan repayments and cancellations.

Nursing loans are low-interest loans, up to $2,500 per year, repayable over a 10-year period. Nursing scholarships are up to $2,000 per year to those who have exceptional financial need. Nursing loan repayment, again, very similar to the other, repays up to 85 percent of the loan in return for service in an underserved area.

Again, you can see the field strength of 2,060, which represents the National Health Service Corps.

[The chart follows:]

BUREAU OF MEDICAL SERVICES

PRINCIPAL OBJECTIVE

Provide direct delivery of health care services to Federal beneficiaries.

MAJOR PROGRAMS
(dollars in thousands)

	F.Y. 1980	F.Y. 1981
Hospital and Clinic System	$171,572	$162,485
Federal Employee Occupational Health	938	964
Payment to Hawaii for Hansen's Disease	1,800	1,800
Buildings and Facilities	3,000	4,769
Positions:		
Field	5,820	5,819
Headquarters	142	145

BUREAU OF MEDICAL SERVICES

Mr. KELSO. The last program is the Bureau of Medical Services. Their objective is to provide direct delivery of health care services to Federal beneficiaries. The first line, hospitals and clinics system, represents eight general purpose hospitals; the Carville Hospital in Louisiana, which provides for care and treatment of persons with Hansen's disease; and 27 outpatient clinics.

The primary beneficiaries that we serve are American seafarers, active-duty Coast Guard personnel, Public Health Service commissioned officers, and commissioned officers of the National Oceanic and Atmos-

pheric Administration. The Federal employee occupational health program is a reimbursable program whereby we operate 167 health units in various buildings throughout the Federal Government. We serve about 270,000 Federal employees. The payments to Hawaii is a direct payment from the Federal Government to the State of Hawaii for the care and treatment of persons with Hansen's disease. We have very little to do with the administration of this program. We just pass the money on to the State.

The buildings and facilities account is the activity in which we have money to maintain the physical structures of the hospitals and clinics and insure that they are up to accreditation standards.

Mr. Chairman, that's a quick overview of the agency and some of our programs. It was my understanding you also wanted me to say something about regulations.

REGULATIONS

Basically, we are not a regulatory agency. Regulations that we develop are really to assure program integrity and consistency with congressional intent in the legislative authorizations. These regulations are enforced largely with project officers and grants management officers out of the regional offices who work with our projects on a day-to-day basis.

In 1981, our total cost for regulations was $90,000. We also had 4 person-years involved in regulation functions. In 1982 we estimate it will go up to $106,000 and the workload will increase to 5 person-years.

Mr. Chairman, that concludes my opening statement. My colleagues and I will be glad to respond.

Senator RUDMAN. Thank you, Mr. Kelso.

I would like you to go back to the second chart. Better still, go to the one entitled "Major programs," with the first item being primary health care centers.

Mr. Kelso, your statement is an excellent statement in terms of advising us of the general allocation of funds within the programs, and a reasonably good, broad-brush treatment on what each of these programs does. I think it might be helpful for purposes of this hearing, given some of the budgetary constraints that we are going to be faced with during the next 3 months, for you and the people that you have here with you this morning to go through each of these areas once more, but with a slightly different goal in mind.

I would like you to tell this committee essentially what each one of these agency groups does in a very direct and personal way, so that I and other members of the committee this morning, and later those who read the record, might better understand what the high blood pressure control unit does, where it does it, and how it does it, rather than taking what is an excellent but nevertheless a programmatic approach in your testimony this morning. If you could do that, I think it would be very helpful before we get to some of the questions we have for the record.

Mr. KELSO. Mr. Chairman, if it's all right with you, I think the best person to do this is the person who deals with it day by day, that is, Dr. Martin.

Senator RUDMAN. That is obviously your choice.

BUREAU OF COMMUNITY HEALTH SERVICES

Dr. MARTIN. I think the key elements of the seven major program activities within the Bureau of Community Health Services is that they are direct patient care programs. Let me be specific, starting with the top program. The primary health care centers program is a grant-funded program which provides funding support for some 850-plus centers which, in communities across the country, varying from very large urban centers, for example, in the south Bronx to rural centers in small towns like Harlingen, Tex., provide essentially the same services that primary care physicians provide to the bulk of Americans. They provide these particularly through organized settings in areas where there are not available services.

In rural America, basically, what those centers do is to provide Federal support for satellites or primary care centers in rural communities where there are no alternative services, either available, or where they are not adequate. Reduced to its basic element, the 850-plus centers provide family-oriented physician services, some dental services, and other related health services, to about 5 million people, in a way comparable to that of the private sector, but provided in communities where private sector resources are not available or are insufficient.

MEDICALLY UNDERSERVED AREAS DESIGNATION

Senator RUDMAN. Let me interrupt you there for one moment.

I'm sure that the other members of the committee know the answer to this question. I don't. What was the criteria for establishing that the need existed in each of these areas around the country before you decided to create a center in a particular community? How was that criteria evolved?

Dr. MARTIN. The statutory criteria requirement is the designation as a medically underserved area. We define areas using an index, a quantifiable index, which provides a gross indicator for underservice. For every community, every census tract, there is computed a number based on infant mortality, the proportion of population under poverty, proportion over the age of 65, and the ratio of physicians to population. Scores below a certain number result in a community being tentatively designated as medically underserved.

The process of determination of need and approval of services is one of local health planning assessment. Through Public Law 641, the Health Planning Act, the health systems agencies are responsible for gathering current data and making an assessment or determination of need for that community. That meant some communities we thought were medically underserved turned out to have adequate immediate or contiguous services. Others that we were not aware were underserved were so designated.

After that designation process, each community submits an application and goes through a competitive discretionary award process. And that process involves the determination of need and the application's review and approval.

There has been considerable criticism of the very gross nature of the designation measure. It was designed to be gross, a gross measure, and continues to be one.

I think the critical part of the designation indeed has to do with the local community participation in determination of that need. That's really where we get the current information.

Senator RUDMAN. Thank you. Continue, if you will, sir.

MIGRANT HEALTH CENTERS

Dr. MARTIN. The migrant health centers essentially provide the same kinds of services, but rather than to a geographic area, to a population at high risk, migrant and seasonal farmworkers.

The predominant number of these migrant workers are in the Far West or Midwest streams, but there are continuing to be some Eastern stream migrant services responsibilities.

As you know, the migrant stream consists of about three-quarters of a million of migrating workers and their families who move up through the farm belts each year. In addition to this number of migrants who are moving up through this stream, there are about 2 million seasonal workers other than students who work in the agricultural industry.

The law essentially requires us to establish in high impact areas where there are large numbers of these migrants and seasonals, centers, or programs to reach out to them. We do not establish, in this program, migrant centers or projects everywhere there are migrants and seasonal workers, but only where there is a high impact of those workers on a particular community.

Again, need determination and the mechanism for implementation of the program is comparable to community health centers, except in this case, we are using a determination of high impact migrant area based on the number of migrants and seasonals.

So, the first programs are very much focused on providing services in those kinds of need areas.

MATERNAL AND CHILD HEALTH

The maternal and child health program is a descendant of the original Children's Bureau program, which has been a Federal program since the early 1900's—I think it was 1912—carrying out a Federal effort regarding protection of children. The present health program has a series of dimensions. The heart of the program is a Federal-State partnership in the provision of maternal and child health and crippled children's services through State health departments and State agencies for crippled children and rehabilitative services for crippled children whereby the Federal Government provides matching funds to the States on a formula basis, based on the State's rurality or the poverty levels. Those moneys are used by the State against a State plan originated by the State to prioritize on a set of major activities that are, in priority, related to child health, crippled children, and maternal health—to assure that there is a statewide system of services available to women and children.

In the context of the people being served, this really translates into the well baby clinics, maternity clinics, maternity-infant care programs, especially the public health nurses at the local and county level who provide much of the hands-on care to children, particularly high-risk children.

I think it's fairly stated that this program is well known as a program where Federal assistance is providing for local service to people. This program touches, in some way or other, 10 to 14 million mothers and children in the country every year, overwhelmingly through local agencies, county, and local health departments.

HIGH BLOOD PRESSURE CONTROL

The high blood pressure control program is a relatively new program. It's carried out in conjunction with the national high blood pressure control program led by NHLBI at NIH. Our responsibility in this program is to provide the resources and technical assistance to State and local governments for the implementation of statewide and locally developed high blood pressure control activities including special screening programs, detection, followup, and tracking of those individuals having high blood pressure.

This program has been substantially expanded over the last 3 or 4 years, based on the congressional direction related to the fact that this particular disease, hypertension, is beginning to come under control and has a high benefit-cost ratio, which has been demonstrated at a number of hearings. And the work being done in this area has a very immediate measurable impact on individuals.

The real impact, of course, as you might anticipate, has to do with the detection of individuals, predominantly adults, including those in high-risk categories, and moving those people into the health care system to assure that their hypertension is kept under control. The change in morbidity-mortality related to this program as a part of the bigger NIH program has been very substantial over the last 2 or 3 years, and there has been a marked statistical decrease in morbidity-mortality associated with hypertension and related diseases.

GENETICS AND SUDDEN INFANT DEATH SYNDROME

Genetics and sudden infant death syndrome programs are again relatively new programs in the last 4 or 5 years. In both cases, they are programs which are set up through the State health departments and local agencies. Systems of screening, detection, community information and education programs are set up so that providers across States and localities will have the information and the technical capability to provide screening in a very large number of genetic diseases.

There are over 3,000 genetic diseases in the country, and we're finding out a great deal more about genetic disease and its involvement with the population all the time. Our responsibility in this regard is predominantly to support existing systems of communication and to assure that there is high quality laboratory backup for practitioners, local medical facilities, and local health departments.

FAMILY PLANNING

Family planning programs, I think, can best be visualized as some 5,125 local clinics providing family planning, counseling, and services, predominantly contraceptive services, to in excess of 3.6 million women every year. It's not the same 3.6 million women every year, because there's about a 50-percent turnover. So there's a new group of people at risk coming into that system every year.

Family planning services available through this program are provided through local and State health departments—38 of 50 States administer this program through State health departments, and they essentially operate the program through subgrantees in cooperation with local agencies and local health departments.

Again, this can be translated into the fairly specialized but nonetheless essential family planning, contraceptive services to these high-risk women.

EMERGENCY MEDICAL SERVICES

The emergency medical services program is a program which provides grants in aid to regional government-like organizations or States to establish basic life support or advanced life support systems—developing regionalized emergency medical services in areas like spinal cord, trauma, burns, and the like. It's a program that's been very effective in inspiring a great deal of local and State interest. I think it has been a success in the last 5 to 7 years in fairly remarkably turning around our capability to provide emergency services at the contact level, by paramedics and very importantly also by medical control elements within secondary and tertiary hospitals, which are crucial to the survival in this type of setting.

In a way, you can also see this program as being the program which trains the staff, who deal with people at the point of the emergency and immediately upon their arrival in the hospital, which are two crucial times for survival in these kinds of emergencies.

I hope, Senator, that was responsive to your question.

Senator RUDMAN. That's exactly what I had in mind. I think it gives us, as I say, a better feel for each of these programs in terms of their high impact.

Question from Senator Andrews?

Senator ANDREWS. Yes, Mr. Chairman. I appreciate the opportunity to follow up on the overview you gave the committee.

RURAL AMERICA

Certainly, in the primary health care centers there is a great need for this operation in migrant and health care centers. In rural America, however, we don't seem to fit, ever. You said that we need migrant health care centers to take the medical services to people where they are, where they happen to be, the next migrant group coming along. In North Dakota, we've got a problem we answer in agriculture through what we call the extension service. We have centers of information, universities, land grant colleges, and then we have the extension services that takes out to the people in the field.

CARES PROJECT

We have a project that is trying to do the same thing in the field of medicine, and it's called the CARES project, which is coordinated ambulatory rehabilitation and evaluation services.

They always get these big labels on a project like this. It comes under your PCRD program. I don't think it belongs there. I don't think it ought to be there. As a matter of fact, a year ago the administration cut out the $7 million for the PCRD's, which are grants, and we in the House Appropriations Committee put it back in again, largely because Chairman Natcher was aware of my concern. He had been briefed on the value of this project.

Now the $7 million again goes out. My staff has been talking to your people, and you say this doesn't fit an ongoing program. It's really the research and development program. It isn't. Essentially, what it does is it does exactly what you have pointed out needs doing, in a migrant health care center, or primary health care center. It takes the knowledge of our rehabilitation hospital and moves it out, in this case, in North Dakota, 400 miles away from the rehab hospital, in a clinic that's held for 4 days every couple of months for the people there and/or their doctors come in and are treated.

If we don't do it this way, the people have to travel the 400 miles to get the treatment, or they don't get the treatment. Why does your shop insist that this kind of a program can only function as a research and demonstration project? Why in rural America don't the same guidelines hold that you described so effectively as the need for the migrant health care centers and primary health care centers to extend, in effect, the knowledge that we have in our rehab center out in the countryside where it's needed?

Dr. MARTIN. Well, a point of clarification, Senator. I agree with everything you said about what that program does.

As you're well aware, I'm acutely oriented to that program, specifically.

Senator ANDREWS. I know you're acutely oriented.

Dr. MARTIN. Last year, it was a point of much discussion.

Senator ANDREWS. In fact, it turned out to be, by your own people's description, general; among some others, let us say, significant. But I don't think it belongs in the category you've got it in.

PRIMARY CARE RESEARCH AND DEMONSTRATION

Dr. MARTIN. I think to the question of the identification of that program as a research and demonstration program, and that particular project as such a project, it does fall within the statutory design of the primary care research and demonstration authority. Frankly, we would like to be able to fund them under a broader 330 program which was discussed with both the House and Senate authorizing committees for a number of years—to have more flexibility under 330 and 329.

It was discussed in the previous administration, and in a statement by Senator Schweiker a number of times—Secretary Schweiker or Senator Schweiker—around flexibility, to be able to do indeed, things in different places like North Dakota, south Texas—where we shouldn't be

boxed into specific statutory authorities which limit our ability to do that.

So we agree, it would be better to call this a service program. Unfortunately, in order to fund it, the one statutory authority we had to support that activity was the 340 program. The choice, then, was either not to fund a good idea or to fund it through an authority which was the most flexible authority we had. I think that's fairly much an authorizing issue in regard to classification, but it certainly isn't the bureau staff's intent to classify it.

Their intent, as you are fully aware, is to fund it. And that's the best authority we have.

Senator ANDREWS. The problem still gets down to the point, how do you remedy the situation, because we're talking not only health care of individuals, but let's put our dollar-and-cents budget appropriations hat on. It's going to cost the Federal Government far more if we don't have this outreach program than if we do, because if you move these patients 400 miles, you put them into the rehab center as in-patients in a hospitalization category—it's going to cost us a whale of a lot more money than the structure of this program as an outreach program.

And I don't think that you want to say, "Look, we're adamantly against finding an answer to this kind of a problem."

RURAL HEALTH

Dr. MARTIN. I think the concern you raise is certainly one the Department has. Specifically the Secretary and the staff have considerable concern about: One, rural America; two, the flexibility of programs designed and efficient ways of providing those services.

The concerns you raised are concerns that are being fairly critically looked at right now in the context of some of the alternatives that may be proposed in the next month or so.

Senator ANDREWS. This feeds right into what you describe as the need for migrant health care centers almost word for word: The reaching of underserved people. And here, we're seeing a budget increase of $4 million for that program, and $243 million as an adjunct to that program that's important to people. The rural poor, the rural agencies are every bit as needful of a program like this as our migrant sector.

And I would appreciate very much if you would take another look and see where we can put this program, so that we don't have to continue to try to save a whole PCRD category in order to continue to keep the program going that probably should be under a different category.

Senator RUDMAN. Thank you, Senator Andrews. We are going to move on and get back to you.

Mr. Kelso, we will incorporate your entire statement in the record as requested.

I want to go through a number of questions that have been of concern to the committee and staff, and give you the option of delegating the responsibility for answering to anyone on your panel who you wish to.

COMMUNITY HEALTH CENTERS FINANCIAL MANAGEMENT CONCERNS

I'm sure you know there has been some concern over the quality of financial management of some of these centers. And particular concern has been expressed about the ability of people to do some rather simple tasks, such as reconciling their funds, balancing their checkbooks, and planning to meet expenses and payroll.

I wonder if you think the criticism is justified. And if it is, what are you doing about it?

Mr. KELSO. Mr. Chairman, I am sure that in any community health center we can find some difficulties. We have been made aware of these. I might say over the past 5 years Dr. Martin and the Bureau have, I think, made an extraordinary effort in this arena, basically the management of community health centers.

They have strengthened the reporting requirements, they have increased the monitoring of the community health centers, and I think that they have come a long way.

That isn't to say that there still aren't problems in that area.

PROJECT TRAINING

Senator RUDMAN. Do you require any training in financial management of people in these administrative positions? And what is the criteria for having them assume these responsibilities?

Dr. MARTIN. I think the key part of our response that is important, is the one that you just touched on. I think rather than imposing increased reporting requirements, what we did was to focus reporting requirements in such a way that, coupled with technical assistance and expectations of training, we began to see a fairly dramatic increase in financial capability within centers.

The proportion of people working—particularly in the medium and large centers, who are fully trained in accounting and bookkeeping—has increased very substantially.

We have developed a series of fiscal guides and training activities at the community level. In addition to that we have made it very clear to centers that they need to hire staff within the center who are very thoroughly grounded in these skills.

In rural America this has not been as great a problem as it has been to some of the more urbanized or inner city areas. But we have had a substantial improvement in that regard.

PROJECT AUDITS

Lastly, we have required an annual CPA audit, and we track on that audit and work with the centers.

The criticisms made in 1973 and 1976 GAO audits, in response to your first question, were criticisms to serious problems, and there were serious problems in a lot of centers. I think the performance over the last 4 or 5 years at the community level in those programs has been substantial.

I think one way to look at it—we have had in excess of 55 investigations that we have called for or somebody else has called for—and we only had 1 case of malfeasance or fraud out of 850 centers. As a batting

average—and that was an investigation we asked for—as a batting average with the use of Federal funds, I think we are a lot more comfortable than we would have been 5 years ago.

Senator RUDMAN. I don't think we are probably as concerned—although we are always concerned about fraud—as we are about incompetence. And incompetence always costs a great deal more in government than fraud. Although some people won't admit that.

The increase in reporting requirements is fine, so long as there is increased competence among the people who are in fact doing the work. Or else you will have reports that show growing incompetence. So, it is the committee's concern that it might be nice to increase the financial training necessary for those people that keep these records.

THIRD-PARTY COLLECTIONS

I want to talk about third-party collections for a minute. I would like to know about your efforts to increase payment by those third-party individuals and groups that tend to, in fact, discharge those obligations.

Mr. KELSO. Here again, Mr. Chairman, with the limited budgets, with what we have added, and with the increased cost of doing business, the capturing of third-party reimbursements has had a high priority within the Bureau.

In 1974 we had a third-party reimbursement rate of 17 percent. By 1980, it has gone up to 40 percent. So we think we are doing much better in the third-party reimbursement area.

I think we can probably continue to improve and we will certainly try to do that.

Senator RUDMAN. Have you any idea at all as to what percentage of the operating costs of these centers are being defrayed by the collections of third-party costs?

Mr. KELSO. Approximately 40 to 45 percent.

Senator RUDMAN. Has that changed markedly in the last 2 years? Or has that remained static?

Mr. KELSO. Yes; it has changed. Dr. Martin tells me it has tripled.

Senator ANDREWS. I appreciate your bringing up that point. I would like to go back and play my same tune again.

RURAL AMERICA

The cost input, the payment for services rendered is not the key thing in rural underserved areas. These people at these outreach clinics are paying. The Federal part of it is merely to transport the uniquely skilled doctors out into this area so they can share their knowledge with the doctors in that area.

And in an area of North Dakota that I represent, we have whole counties without a physician, if you can imagine a county without a doctor. We have some counties that only have two or three doctors.

Let me put it in the words of a local doctor in Dickinson, N. Dak., who said they were skeptical of this type of approach at the beginning, but after seeing what it does, they go on to say, they can't begin to describe their current enthusiasm as well as their appreciation for its existence.

And it gives four reasons for why it works:

It has provided me with an opportunity to increase the quality of care to the patients that I have referred, as well as improving their quality of living. Two, it solves some long-neglected problems with some of these patients. Three, it has improved the cooperation and coordination of the various agencies in both education and health within the area. Fourth, it has also increased professional awareness of the availability and benefits of rehabilitation services, which is an ever-changing field.

Our problem in rural America, is I have a county seat town—and I do in North Dakota with a population of 70 people in that county seat town—and one of those 70 comes down with a unique problem needing a specialist in rehabilitation, that person is as medically underserved as a migrant, or as a person who lives in the ghetto area.

But, by volume, a person in the ghetto area can get to those medical service centers. In our area of rural America, we have to have an outreach capability. And I would certainly hope—and, Mr. Chairman, if I might include for the record this article—that not only can we keep our program ongoing, but that your shop takes a close look at instituting this type of program in other areas. Because I think you will get probably much more medical service to the particular patient per dollar, than virtually any other program you can run.

Medicine today is knowledge. Both of my grandparents were doctors. In fact, my grandmother was one of the first women doctors in this country. She graduated back in the 1870's. Practiced in New York City; went out to the Dakota territory.

Medicine has changed fantastically in the century since she was practicing medicine and my grandfather was practicing medicine.

In rural America we have doctors that are in a sense isolated and keeping up with the newest things in practice by magazines and periodicals and the rest. And when we can bring specialists into the area to upgrade their knowledge it helps measurably.

And I would hope that we could put it in as an ongoing overall part of the medical group assistance.

And I would appreciate, as I said before, if you could see just exactly how it can benefit among these ongoing programs. I think the research demonstration has been proven, it has been going on for years. It is a 5-year program. But, it is much more important than a 5-year program because of the sharing of information that is a key part of it.

Dr. MARTIN. We agree, Senator. I think the key point to make over and over in all these programs across the entire agency is, there is an enormous amount of heterogeneity in the programs, resources, and approaches in the south Bronx as well as North Dakota where there is an Indian reservation, and Alaska as well as a reservation in Arizona.

One of the great strengths I think both of these programs we are talking about have, and the way we try to administer them across the agency, is to recognize that heterogeneity and strength and the differences in local communities. I think if we didn't recognize that there would be a terrific tendency just to put things out there which would not work.

I think your point is well made in regard to that basic question with regard to all of those programs.

Senator ANDREWS. That's right. If it works in our area, it is not necessarily going to work in other areas. And I hope it doesn't get cut out be-

cause it doesn't categorize itself into a convenient category. That it will not only be kept on but expanded, so that it can serve other areas that are similarly rural and underserved.

The statistics we get about the oversupply of doctors, people will laugh at you in North Dakota if you say there is an oversupply of doctors today in America, or there will be in the next couple or 3 years. There isn't, it is a matter of getting service out to the people where they are.

I appreciate your comments and your support and look forward to working with you as we broaden our interest in this.

Senator RUDMAN. We will put this in the record as you requested.

[The information follows:]

[From Commentary, Medical Center Rehabilitation Hospital, University of North Dakota]

ON THE ROAD

REHAB'S OUTREACH PROGRAMS SHARE SERVICE, EXPERTISE

Early one recent Wednesday morning, orthotist Dale Brekke of the Medical Center Rehabilitation Hospital checked the contents of a battered case, tossed it into the back seat of his car and headed into the sunrise for a 2-hour drive to Bemidji, Minn.

The previous week, he had received a letter from the physical therapy department at Bemidji Community Hospital asking if he could make one of his periodic visits. A child's leg brace, the letter explained, required a small but crucial adjustment. A resident at a nearby nursing home needed some work done on his wheelchair, and a Bemidji woman wanted to be fitted for a pair of custom-made orthopedic shoes to reduce the pressure on a foot deformity.

More patients would be lined up, the letter continued, once word spread through the area that Brekke was coming to Bemidji again. Because of financial, physical, or time constraints, few of these people could visit Brekke at the Rehab.

"A lot of people around here simply would not receive these necessary services if Dale didn't come," asserts Shannon Tangen, physical therapy director at Bemidji Community. Pointing to a patient Brekke was working with, Tangen added, "She just couldn't make it clear to Grand Forks; she can't tolerate sitting in a car that long."

Brekke is one of many Rehab professionals who pay regular calls on other facilities scattered throughout the Rehab service area. Like Tangen, colleagues at all these facilities believe that without the Rehab outreach effort, their patients would lack important aspects of comprehensive health care.

"Sometimes it's not appropriate—and sometimes it's a sheer impossibility—for people to come to Grand Forks," explains Donald Barcome, M.D., Rehab Hospital medical director. "But if they need a service that's not available in their area—one that we can provide—we can try to come to them."

Barcome said that when he came to the Rehab 15 years ago as medical director, he dreamed of someday providing comprehensive rehabilitation services for all North Dakotans and northwestern Minnesotans who needed them.

"There was nothing wrong with that dream," he now declares, "but we had to change our methods if we wanted to make it a reality. Because of the distances, or the costs, or any number of reasons, we found that some people who needed our help weren't able to get it. We realized that we had to reach out beyond the hospital walls if we wanted to serve these people."

This is not to suggest that all rehabilitation needs in the region could be met through even the most extensive outreach system. Barcome stresses that only a specialized regional center such as the Rehab can provide high-quality, comprehensive rehabilitative care with any efficiency. And last fiscal year, more than 1,000 persons availed themselves of that care as inpatients here; the number is sure to grow this year.

But when a Watford City truck driver, a rancher's wife in Zahl, and an oilfield worker in Tioga all need minor adjustments made on their artificial limbs, why should they all make 700-mile round trips to the Rehab? Wouldn't it make more sense to set up a prosthetics clinic at a central, nearby location like Williston?

Such a clinic has been established: Rich Kabat, a Rehab prosthetist, now makes regular trips to Williston's Mercy Hospital, seeing up to 15 patients in the course of his 2-day clinic.

Sometimes the problem is strictly financial. Molly Wiesen, physical therapist at the hard-pressed State school in Grafton, has been trying for years without success to get an occupational therapist on the staff to help some 800 mentally retarded residents there. Nonetheless, those residents receive occupational therapy thanks to a contractual arrangement with the Rehab's child evaluation and treatment program under which Doug Sala, a CETP occupational therapist, pays monthly visits to the school.

Other examples abound. Until this past August, when staffing demands at the Rehab itself simply became too great, the hospital sent a physical therapist to a Larimore nursing home to treat residents there for 4 hours a day, 5 days a week. The communication disorders department recently completed work on an agreement to provide speech pathology and audiology services at Good Samaritan Nursing Center in East Grand Forks, and the CETP sends both a physcial therapist and an occupational therapist to the North Dakota School for the Blind in Grand Forks for regular evaluation and treatment sessions with students there.

But perhaps the most ambitious outreach effort ever undertaken by the Rehab is its coordinated ambulatory rehabilitation and evaluation services project.

Now in its second year, this one-of-a-kind project brings an entire multidisciplinary team of rehabilitation professionals to St. Joseph's Hospital in Dickinson for 4-day clinics every 2 months. A Federal grant covers travel costs for the team and pays for on-site office staff and space, but just as at the Rehab itself, evaluation and treatment are provided on a fee-for-service basis.

Four CARES clinics were held during the project's first year, with more than 60 patients referred by 16 primary-care physicians for evaluation or treatment.

Dennis Wolf, M.D., chief of staff at St. Joseph's, admits that he and his colleagues in the area were "very skeptical" of the project in its initial stages. But after seeing what the project could do for many of his patients, Wolf said, "I can't begin to describe my current enthusiasm of the project as well as my appreciation for its existence."

He also cited what he believes are the four major advantages of the CARES project: "It has, one, provided me with an opportunity to increase the quality of care to the patients that I have referred as well as improving their quality of living. Two, it has solved some long-neglected problems with some of these patients. Three, it has improved the cooperation and coordination of the various agencies, in both education and health, within the area. Four, it has also increased professional awareness of the availability and benefits of rehabilitation services, which is an ever-changing field."

Wolf's fourth point refers to the numerous inservice education sessions led by Rehab staff members for their colleagues in the Dickinson area. Similar educational activities have been conducted by Rehab professionals over the years throughout the region, and these seminars and workshops are another important aspect of outreach.

By sharing such knowledge, as well as showing by example the benefits of providing rehabilitation services, Barcome believes CARES can accomplish a goal even more important than providing physicians in southwestern North Dakota with additional patient-care support previously available only through referral to the Rehab in Grand Forks.

"Through CARES and our other outreach efforts," he explained, "we can try to help each rural area, at least regionally, develop capabilities of being more independent in providing necessary and appropriate outpatient rehabilitation services within their own community."

The CARES project, Barcome said, is designed to foster an awareness of the need to provide ambulatory, or outpatient, rehabilitation services within the local community. As that awareness develops, he added, and appropriate services begin to be offered locally, it may become possible to shorten the length of time patients from that area need to be hospitalized at the Rehab.

Barcome estimates that only about one out of every four patients in need of rehabilitation services actually requires hospitalization at the Rehab for its comprehensive care. The remaining 75 percent, he says, can perhaps be better served within their community—but only if the necessary services and expertise are available to them there.

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"It's not brick and mortar that make rehabilitation, it's people who make rehabilitation," he said. "So, while we do have a beautiful, comprehensive center to work out of, our current step is to move out into the State to make rehabilitation philosphy and concepts available to people in all walks of life throughout our service area."

MEDICALLY UNDERSERVED AREAS

Senator RUDMAN. I want to go on for a moment with the whole question of how you target your efforts, and where your statistics come from.

In your statements and the information the committee has, when we talk about medically underserved areas, they say about 51 million people reside in those areas. And you serve about 20 million as the target population.

I am particularly curious on how you get that figure and what assurance do you have that it is reliable.

Mr. KELSO. We use the census as available. And, as you know, the most recent census is the 1970 census.

We plan to take another hard look at this once the 1980 census is available, which we understand will be in sometime toward the end of the calendar year.

Dr. MARTIN. I think the crucial point really has three parts. First of all, the number 51 million is cast around quite a bit—51 million is a number which simply reflects, if you take all the geographic entities like the counties that have medically underserved designations and add up the total numbers of people in those counties, then that would be 51 million.

Now that was not meant when the designation process was implemented. While Congress directed us to develop that index, it was supposed to be a use indicator. When you come up with that number, 51 million, in no way was that supposed to say there were 51 million people underserved in this country. In fact, I think one would have to stretch a great deal of credibility in a lot of those counties to say everybody in those counties are medically underserved. There are people in those counties who are medically underserved; there's a fairly good indicator of that—and there are substantial numbers—not 50, 100, or 70.

There are also people in areas not medically underserved, as Senator Andrews pointed out, who by dint of their geographic location, still don't have access to service.

When we look critically at the data around that 51 million in those geographic areas, we come up with an assessment of somewhere between 18 and 21 million people in those geographic areas who do not have functional access to primary care physicians and the like. That's about 1 out of every 11 Americans.

If one figures a little over half of that is in the inner city, when you look at Bedford Stuyvesant and the Bronx and Harlem and East LA, it is very easy to see how you can come up with numbers of 50,000 or 100,000 at a time.

A large part of that population lives in Appalachia, in communities where there is substantial difference in ratio of physicians to population than in the rest of the country. That 20 million is an estimate.

The third part of the estimate that becomes crucial and important, is that estimate for planning purposes I think is a good and the best professional judgment the Department has made to date. That does not translate into how many things have to be done in a given community. That particular judgment has to be made based on that local community, the resources in that community, the continuous resources in that community, and the mechanisms that work best in the community.

And I think that has been one of the difficulties in running the program. Some people have thought that simply because you are designated as a medically underserved area, you must have a community health center—that is not true.

What that means is that it is an indicator of underservice; let's look more carefully at it and determine whether it is appropriate to do this, that or the other thing. In fact, now there are many areas designated as medically underserved which we don't feel are appropriate to put a facility in, and some which have become undesignated that we are preparing to take them out of.

BLACK LUNG CLINICS

Senator RUDMAN. I just want to go on to another area of your statement concerning services you provide, and that has to do with black lung clinics.

Particularly, what I would like you to do this morning is to give us the justification as to why they have to be held as separate entities, as opposed to going through the system of primary care centers.

Mr. KELSO. As you know, the black lung program is primarily for miners or retired miners who suffer from pneumoconiosis.

These people are located in certain parts of the country, and we have felt that a separate program would be beneficial. That doesn't mean to say that we don't tie the black lung clinics into other existing clinics of care. We do work with the States, with the community health centers, and other entities.

So, there is this cooperative relationship between them.

Senator RUDMAN. I don't think that really answers the question. I hear your statement, but I don't think it is responsive, Mr. Kelso.

What I am simply saying to you is: What data is your agency working on that could give this committee a feeling as to whether or not some consolidation may be in order?

We are facing—it should come as no surprise to anyone here this morning—some difficult decisions. I don't think there is a member of this committee that hasn't got a deep concern about health care, and a showing that those people in need and underserved, get that care.

CONSOLIDATION

One of the ways to do that is to look at these programs and see if any consolidation is possible, and see if any money can be saved without, in fact, decreasing the services that we certainly, honestly, want to give to people.

So, I will repeat my question: I would like to know whether or not we can take these black lung clinics which obviously have a substantial

cost, according to the figures I have here this morning, and in any way consolidate them with other timely health care centers that we have in those regions.

And whether or not, if you don't have the answer here this morning, whether you think you ought to get the answer and get it back to the committee?

Dr. MARTIN. Senator, I think the data we used in 1973 when Congress determined that we would have this program, had to do with a study that was done in the coal fields that showed that this particular disease was somehow not getting cared for in the appropriate ways, whether it be West Virginia or Montana, by practitioners and clinics.

In other words, the kinds of specialized services, counseling, and skills related to this particular disease simply were not being made available to these patients. And we are talking about a quarter of a million patients with pneumoconiosis.

The purpose of the program, which at one time was funded at $7.5 million, was to direct these patients, specifically as you indicated, to primary care resources. It has been decreased by almost half from its highest point since it was reinstated in 1979.

We agree completely that, indeed, these patients can be referred and cared for in consolidated clinics, where they exist, or coordinated with individual physicians. In fact, all of our black lung clinic sites are located in existing community health centers, hospitals, or local health departments.

What is a unique part of the program that needs to be determined about continuing, or even as a part of a consolidation as a whole, because we are only talking about 5 or 10 States, is the part that makes sure that local providers and clinics provide those services, and to use this program to pay for the services. There is indeed duplication and that needs to be validated.

Senator RUDMAN. I think that is good to know. It seems to me and I am sure it will to other members of the committee as we go through all these programs, that any information this agency can give to this committee that would show where we might consolidate, to keep the level of health care up and still eliminate some of this duplication will be helpful.

It is obvious to me that the easy thing to do for us dealing on this subcommittee—and I serve on five in appropriations—but just as one subcommittee dealing with about $105 billion, the easy thing to do is to take an arithmetic approach. That is very easy, it won't take too much time, and we could probably do it with a computer.

I'm not sure though, that that is the kind of approach that we owe the people of this country who are in need of certain key social services, services we would like to keep where they are needed.

The way to do it is to look at these programs individually, and we are going to need your help to do that. And I would like to ask you here this morning to come back to us in this particular area and any other area where you think consolidation might, in fact, be a way to maintain the level of services. I understand all of the political problems associated with that, but I am not particularly concerned about those this morning. I am concerned about seeing what we can do to consolidate some of these programs.

I want to go on, to move along here, because hopefully we are going to have a hearing that will not last more than 2 hours.

MIGRANT HEALTH

Originally when these programs were put into place for the migrant farmworker population, we were talking about very high infant mortality, lower life expectancy and certainly a very high incidence of disease.

Now, in 1981, what changes do we see? Is it still true in each of these three areas? Has it improved? Is it closer to the base statistic of the general population?

Dr. MARTIN. I think, Senator, it would be fair to say that there has been continuing improvement among the migrant population as a population due to a whole set of services being provided. Improvement, particularly in the environment, sanitation, and sewage, which is where you see the biggest increases in improvement of infant mortality and the like.

I think the difference between this population, and other populations, particularly those migrants who are black or hispanic, is still considerable—so, that when one looks at the relative danger of an infant death, or the relative danger of tuberculosis, we are talking about rates two and three times higher than the general population.

To the degree that this is the result of preventive services not being available, this program can do and does do something about it, it has—like the Indian Health Service and other programs—shown a precipitous decrease in these kinds of illnesses.

Some of the bigger problems that I am sure the Senate hears a lot about in regard to environment, housing, sanitation, things like that, are problems which, of course, we can't deal with but they go hand in hand with the health problems of the migrants. And, in fact, they are part of a serious problem associated with infant mortality, high rates of tuberculosis.

Our best accomplishments, I think, are in the area of prenatal care and infant mortality.

Chronic diseases like alcoholism, drug diseases, mental health problems are still a very serious, major problem particularly among migrant workers. But, there has been substantial improvement.

CONSOLIDATION

Senator RUDMAN. I think the only question I would ask—I don't necessarily want you to answer it this morning, but it is along the lines of the previous question, and that is: As the impact of what we have

been doing with these programs starts to have some measurable effect, I wonder whether or not we have to start looking at whether or not we can eliminate duplication. If we have community health centers in the same areas where we are setting up these special services, is consolidation possible?

Dr. MARTIN. In that case, Senator, where there is a high migrant impact area that is eligible for a community health center, in almost all cases we have consolidated it at the local project level—the community health center and migrant health center services. And that has been a major effort over the last 6 years, which began in 1974.

So that has been accomplished for precisely the reason you stated today.

HYPERTENSION SCREENING

Senator RUDMAN. I want to direct my next question to hypertension screening.

Is there any State program anywhere in this country or are these all Federal programs?

Do any of the States supplement these programs?

Dr. MARTIN. The Federal program is to supplement and augment and develop State programs. In fact, the models that many States use that we fund with Federal money are models that were developed by States and localities. So basically, our job has been to take effective local and State programs and expand them into other States and assist States, for example, that are affected to develop new mechanisms and techniques in screening.

I think the key thing here is, this is not a Federal program in that sense. It is really a program which is Federal assistance to develop, expand, and insure and cooperate with local—not only State and local governments, but many private organizations—American Heart Association, American Lung Association—many different groups of people at the local level.

Our ability there has been to develop that system into getting millions of people into care who otherwise would not have gotten care.

Senator RUDMAN. We are going to take a short recess at this time.

[A brief recess was taken.]

Senator RUDMAN. We will call the hearing back into session.

I want to go on now to a number of items that we will cover in the next hour, which we think are important to have your comments on in the record this morning.

SUDDEN INFANT DEATH SYNDROME

The first of those would be your sudden infant death syndrome project and the services you provide. I particularly want to get into the GAO report that was recently issued, which I am sure someone interested here, like Mr. Kelso, would like to address.

Let me summarize my understanding of that report.

Not surprisingly, the GAO said the performance varied. I think that probably could be said for many programs. But I thought it very serious that they said many projects failed to collect sufficient data. Certainly a data base in this project is probably more important than data bases in many other kinds of medical projects.

You had problems with medical examiners promptly reporting SIDS deaths; you had varying community performance because of insufficient guidance—at least that was the GAO comment—finally they thought there was excessive funding of these projects.

They recommended a consolidation with the maternal and child health services program.

I just want your comments and recommendations on the conclusions, and what you might propose to us here this morning in terms of doing something with this program that would maintain its effectiveness, improve its effectiveness, and possibly save some money by consolidation.

Dr. MARTIN. Yes, sir.

I think in regard to the findings—they were findings, in fact, that the Department had anticipated, had, in fact, shared with the auditors themselves.

In regard to the difficulties in data collection, I think it is critical to point out that part of the reason for the development of the SIDS program was that 5 or 6 years ago, not only was data collection poor, but the community awareness of SIDS itself was intolerably low. It was very, very serious.

The SIDS program has had a great deal to do with changing that level of awareness, changing medical examiner attitudes that an infant death, which was unexplained, wouldn't be the fault of the parent; so that the police wouldn't initiate prosecution against the parent; so that parents wouldn't feel that if they had done something, the child would not have died.

That data deficit still exists. But the difference between 5 or 6 years ago and today is very substantial among both parents and the professional.

In regard to overfunding some of the projects, we concurred partly—when we do a retrospective assessment of funding, when we fund a project, we fund them for what they say they are going to do. In retrospect, when you go back and measure what they have done and what we funded them to do, that shortfall wasn't overfunding, it was underperformance.

I think, in fact, a number of those got defunded subsequently.

CONSOLIDATION

The Department's initial position on the recommendation of consolidation is that we support it. We did feel the program had had a major impact in creating professional and parent-level sensitivity; however, there would need to be a consolidation of departments.

The initial response to GAO was to maintain sensitivity to needs, while focusing on continuing service within State and local maternal and child health activities.

The Department certainly concurs with the recommendation that it be an integral part—and not disappear—of the title V child and maternal care program, less for budgetary reasons than for organizational coherence at the State and local level, which to some degree will save some money. However, particularly with medical examiners, we need to continue training to make people sensitive to this.

We are talking about one of the largest causes of death among children, and for some age categories, probably 1 to 5, the largest. The next highest is vehicular accidents.

Senator RUDMAN. Again, in further data you might supply to the committee—you know, I appreciate your comment about the budgetary savings not being substantial at this point, but historically, whenever missions are consolidated where they make sense, the savings over a long term become substantial because of the natural growth of bureaucracy with any agencies that tend to be pretty much by themselves.

I think you probably have detected by now some thread running through our questions this morning, and that might give you some feeling as to what you might expect.

Dr. MARTIN. Yes, sir; we have picked that up.

FAMILY PLANNING

Senator RUDMAN. I want to go on now to another item that was contained in your testimony here this morning, and that is your family planning services.

There tends to be, at least in our view, a possible proliferation of these services—not within your agency, but within the Federal Government itself. There are some family planning services available certainly with your programs, but also grants to various States of the social service programs, medicaid.

What's your position on whether or not that entire Federal involvement ought to be consolidated?

Dr. MARTIN. The observation that there are a number of programs financed, and service programs which include family planning is fairly accurate. The title XX program is the social service program. Title XIX is the medicaid program which supports family planning, basically as a payment program.

The only services programs which provide for developing clinics and providing capacity are titles V and X. As you may be aware, the Department is looking critically at the degree and nature of possible consolidations of those kinds of programs. And I would think that there would be a series of proposals later that relate specifically to the question of how this and other kinds of programs can be consolidated.

There is no present policy on that, sir.

NATIONAL HEALTH SERVICE CORPS

Senator RUDMAN. I would like to move on now to the National Health Service Corps.

You are proposing a significant increase and received $79.4 million under continuing resolution. The Carter budget sought to increase it to about $91 million in the current fiscal year, and to go to $123.8 million in fiscal 1982.

Then there is your request for a $100 million advance in the 1982—$180 million advance in the 1982 bill for use in 1983.

I assume you are familiar with each other's figures. I would particularly like to hear your justification for those increases, Mr. Kelso, from either yourself or that person whom you think qualifies.

Mr. KELSO. Mr. Chairman, first of all, as you know, the whole question of the strength of the National Health Service Corps is under very critical scrutiny within the Department. So the budget before you reflects what the thinking was during the prior administration.

I think the whole question of the Corps and its strength will be looked at very closely.

Dr. WHITESIDE. The 1981 estimate of 2,660 assignees included placing all our scholarship people that become available, allowing people in the National Health Service Corps to extend their assignments, as well as including about 100 new volunteers in the National Health Service Corps.

For 1982, the field strength of 3,569 allows for full placement of NHSC scholarship recipients, as they become available for service, and for the recruitment of 350 volunteer physicians into the Corps, as well as allowing people who have concluded their assignments, to continue to serve the National Health Service Corps.

Senator RUDMAN. Senator Specter, do you have any questions at this time?

REAGAN BUDGET

Senator SPECTER. Thank you, Mr. Chairman.

I have noted that at least according to the press reports this morning, Secretary Schweiker had recommended even more extensive budget cuts than had been adopted by President Reagan's administration.

And my question is, to what extent have you gentlemen been consulted early on in this administration about possible cuts in the budgets which you are submitting here this morning?

Mr. ITTEILAG. Senator, if I could, the budget revision process thus far has been one of the Department reacting to proposals that have been put forth by the Office of Management and Budget.

In addition to that, we have been proposing alternatives to them, a process that is still going on.

The process has varied somewhat from past practice where budgets have been recommended at a very low level within the Department, reviewed by the Secretary, and subsequently proposed to the President through the Office of Management and Budget.

Senator SPECTER. Have you—had Secretary Schweiker been consulted in advance of the budget cuts proposed by Mr. Stockman?

Mr. ITTEILAG. Yes.

Senator SPECTER. Has Secretary Schweiker had an opportunity to consult with the gentlemen who are here, for example, to determine Secretary Schweiker's position on those proposed budget cuts?

Mr. ITTEILAG. I think consultation has varied by program. In some cases, it has been extensive. In other cases, it has not been as extensive. I think it's fair to say, in total, that the consultation has not been as extensive as it would have been under different circumstances.

Senator SPECTER. I can understand that. What I'm trying to determine quite directly is, what inputs have there been, if any, from people from former President Carter's administration in making suggestions as to budget cuts? As Chairman Rudman has alluded a few moments ago, it is plain that there is a massive sentiment for budget cuts from the Reagan administration, from the Congress and, I think, from the public, given the problems that we are all aware of.

As a first step it would seem to me that those people who have been administering these programs would be, should be either asked, "Where can you make changes, say, in the magnitude of 3, 5, or 8 percent," or even more, depending on what goals are set by the President and then determined by the Secretary.

HEALTH SERVICES ADMINISTRATION

Mr. Kelso, you are the Acting Administrator?

Mr. KELSO. Yes.

Senator SPECTER. How long have you been in that position?

Mr. KELSO. Since January 20.

Senator SPECTER. Had you been in the Department prior to January 20?

Mr. KELSO. Yes, sir.

Senator SPECTER. And the Administrator resigned as of Inauguration Day?

Mr. KELSO. He was reassigned within the Public Health Service.

Senator SPECTER. What position has he been reassigned to?

Mr. KELSO. He's currently Special Assistant to the Surgeon General.

REAGAN BUDGET

Senator SPECTER. Have you been consulted by anyone with respect to the proposed budget cuts since January 20?

Mr. KELSO. We have been involved to varying degrees, and I think, as Mr. Itteilag says, there's been a very short timeframe on all of this. We in the Department have had an opportunity to react to some of the proposals.

Senator SPECTER. Has anybody talked to you about proposed budget cuts, to restate my question?

Mr. KELSO. Yes; through my budget staff.

Senator SPECTER. People from Mr. Stockman's department have consulted with you?

Mr. KELSO. No; I have a budget staff which Mr. Little heads, and usually the interface has been down through the budget side of the organization.

Senator SPECTER. Mr. Little, have you been consulted by Mr. Stockman or his subordinates?

Mr. LITTLE. No, sir; I have not.

Mr. ITTEILAG. Senator, if I could, the normal practice, not only in these kinds of budget revisions but under normal situations in budget proposals, is that the proposals and recommendations of the Office of Management and Budget go through the normal organizational lines within the Department. That is, they come first to the attention of the budget office within the Office of the Secretary, of which I am the Acting Director. Then they are presented to the budget office of the Assistant Secretary for Health, and then subsequently, farther down into the organization of the Public Health Service.

I know this probably sounds very bureaucratic, but we are talking about a very large and complicated organization. Under normal circumstances, the Office of Management and Budget would not talk

directly to either Mr. Kelso or Mr. Little. So in that sense, the process hasn't been——

Senator SPECTER. Forgive me if I haven't followed whom the Office of Management Budget ought to to talk to, but who should they talk to?

Mr. ITTEILAG. Well, my sense, given the complexity of the process and the very short period of time that we had to deal with, I think the Office of Management Budget has acted appropriately. In other words, they work through the Secretary and his immediate representatives, among whom is me. We have, in turn, worked through the normal organization of the Department. We have tried to avoid crossing up normal lines of communication.

Senator SPECTER. Mr. Itteilag, I'm not suggesting that anyone has not worked appropriately. What I am suggesting is that the people who are here today are presenting a budget for consideration of the appropriations subcommittee. And speaking for myself, I would like to have inputs from you gentlemen as to where you would cut the budget, if we ultimately determine the budget must be cut, say, in the 3-, 5-, or an 8-percent amount, as starting points, because it would be my thought that you men would have some substantial idea about where cuts ought to be made, if they are to come.

So that would be one request. And moving from that, my question would be, who would the proper person be for Mr. Stockman or his subordinates to talk to in the Department of Health and Human Services?

Mr. ITTEILAG. Observing normal lines of communications, it would be the Secretary, the Under Secretary Designate, and the Assistant Secretary for Management and Budget.

PUBLIC HEALTH SERVICE HOSPITALS AND CLINICS

Senator RUDMAN. I want to go through several more questions that the committee and various members have wanted to ask this morning, Senator Specter, and then we can come back, if you want to continue that line of questioning.

I want to turn to the Public Health Service hospitals and the statistical data we have, which indicates that although their original mission, of course, was to care for merchant seamen, roughly 40 percent of the patients at the hospitals now come into that category.

I guess we have three questions for you this morning. No. 1, if that is so, why continue the hospitals in their present status?

Second, what is the status of other private hospitals in the eight cities that are involved and, finally, is there any possibility in those cities of consolidating this function with other Federal health care facilities that are located in those cities and, in effect, to have availability?

Mr. KELSO. First, Mr. Chairman, I would like to say that the Department is rethinking its whole approach to this budget, and we have been participating in that review. I'm sure that some of the things we are thinking about are some of the things that you address in your question.

Second, this budget does propose the closure of the inpatient activity in Boston. So, we have been aware of the workload in the hospitals.

The reason we are proposing the closing of the inpatient care in Boston is because of a reduction in the inpatient workload at that facility. Hopefully, we can either contract the patient workload out or shift it to other places.

Dr. BACHMAN. Perhaps I could provide some additional data on this question with regard to the American seafarers using 40 percent of the capacity of the hospitals.

In my opinion, the system is the most economical way to provide the entitlement to the merchant seamen, but the system has to be flexible enough to do the kinds of things that are being proposed in Boston. In other words, there are areas where having a facility is economically viable, and there are areas where having a facility is not economically viable. Economic planning of that type is necessary throughout the system, and a good bit of that kind of review is being done through the local health planning agency.

With regard to using existing Federal resources, there have been a number of activities going on in that area, and I think this is good.

For example, there is a Federal health services resources sharing committee, which is made up of the leaders of the Army, Navy, Air Force, Veterans' Administration, and me representing the Public Health Service. We have made efforts to consolidate and share services wherever we can, and there is legislation that has been suggested to attempt to remove barriers to sharing.

Senator RUDMAN. We might be able to remove some of those barriers.

Dr. BACHMAN. Yes; that would be good. In our particular situation, there is a large percentage of our workload which is actually Department of Defense beneficiaries, and the Department of Defense reimburses us for that workload. In fact, it would be much more expensive for the Department of Defense to acquire those services in the private market.

So, there is a good deal of sharing going on between us and the Department of Defense.

There are some legal constraints to our sharing with the Veterans' Administration. Although we can provide care for their patients, legally they cannot provide care for our patients.

So, there is a good bit to be done in that area.

Senator RUDMAN. I hope it's done. I hope the recommendations are made, when you come back with what I am sure will be several more meetings with this committee in one form or another.

You know, you have much evidence pointing to this as being an area of possible consolidation without loss of services. I note the congressional budget report—I'm sure you're familiar with its enclosures, and I don't have to restate them here, but they are here.

Dr. BACHMAN. Yes, I understand.

THREE PROGRAM SUPPORT FUNCTIONS

Senator RUDMAN. I have one final question. Then I'm going to have Senator Specter ask whatever other questions he may have. I guess this is really in terms of the other questions we have discussed this morning, a summary of all of those questions.

I am looking at your program support functions. You have three of them. Maybe you need three of them. They cost $59 million. They have 1,235 people. Has anyone considered whether or not there are any substantial economies? I'm not talking about mythical economies, but real economies, in eliminating these three separate program support functions, recognizing all of the political problems that there are in addressing that kind of a question, whether or not your whole program could not be better administered by a centralization of what we now have as three separate program support functions, which we've heard about in separate presentations this morning.

Mr. LITTLE. Senator, I think there are two or three areas that we should mention that are centralized among the three bureaus we have discussed today. First is the accounting and finance activity. This activity is centralized in the Health Services Administration. Not only is it centralized in the Health Services Administration for the three bureaus we discussed, but it also is centralized in HSA for two or three other Public Health Service agencies, such as the Health Resources Administration and, I believe, elements of all of the Alcohol, Drug Abuse, and Mental Health Administration.

Second, another area of centralization is in the personnel office. All of the headquarters personnel staffing operations of the three bureaus that we discussed today is centralized in one central office, the Office of the Administrator, HSA.

And the third area is contract management. We have the central contract office which processes and makes all of the contract awards which originate in the central offices of these three bureaus.

Therefore, to the degree where management activities exist which lend themselves to centralization, I think we have done that. I think the other elements of the three bureaus are distinctly different, such that they need a cadre of people who actually manage their individual activities. For example, Dr. Bachman and his staff manage 8 hospitals and 27 outpatient clinics. The other two bureaus do not manage hospitals and clinics; they are involved in two other distinct activities, one of primarily outpatient care through private, nonprofit organizations, and in the communities, and the other dealing with the development of health manpower personnel and service.

So I think the three areas are different and do, in fact, require a cadre of specialists.

PROGRAM MANAGEMENT

Mr. KELSO. I think we have to draw a distinction between those people who provide centralized administrative services, such as personnel, budget, and accounting, and those people who are, in effect, line managers at agencies, such as the people you see here today.

There is a difference between those people who are program directors here in Washington, and those who provide central services. They are both involved in what is called "program management." As you can see, only 6 percent of the whole agency is located here in Washington. However, not all of those people are included in the program management activity in the Office of the Administrator.

Senator RUDMAN. I have asked a number of questions this morning and asked you for some specific responses with our staff. I would ap-

preciate receiving those, and I also have a number of additional questions which we will give to you, and you can provide them at the time, if you give us back a corrected hearing transcript.

BUREAU OF MEDICAL SERVICES

Senator Specter, do you have any other questions?

Senator SPECTER. Yes, I have some.

Before I proceed, Dr. Bachman, it's nice to see you in Washington.

Dr. BACHMAN. It's good to see you again, Senator.

Senator SPECTER. May I ask you what your duties involve as Director of the Bureau of Medical Services?

Dr. BACHMAN. The Bureau of Medical Services' major responsibility is to operate the 8 general U.S. Public Health Hospitals, the 27 clinics, and the National Center for Hansen's Disease in Carville, La. In addition to that, the Bureau of Medical Services operates the Federal employee health program nationwide.

Senator SPECTER. I note you appear here in a Navy uniform.

Dr. BACHMAN. While the uniform is similar to a Navy uniform, it is actually the uniform of the U.S. Public Health Service. The U.S. Public Health Service is one of the uniformed health services, and most of the providers of health services in our system, for example, physicians, pharmacists, and nurses, are commissioned officers in the U.S. Public Health Service. Our hospitals are uniformed services hospitals, and serve Department of Defense beneficiaries, as well as our own beneficiaries.

Senator SPECTER. What rank do you wear here today?

Dr. BACHMAN. The rank is Assistant Surgeon General, which is equivalent to rear admiral.

Senator SPECTER. Have you been in the Public Health Service prior to the time you received this commission?

Dr. BACHMAN. No; but I have been a retired reservist of the U.S. Navy for about 30 years.

REAGAN BUDGET

Senator SPECTER. Mr. Itteilag, you are the Acting Deputy Assistant Secretary for the Budget?

Mr. ITTEILAG. Yes, sir.

Senator SPECTER. Have you joined the Department since Senator Schweiker became the Secretary?

Mr. ITTEILAG. No, sir. I've been an employee of the Department for more than 5 years.

Senator SPECTER. We face a somewhat different situation here with this appropriations subcommittee than is customary when a budget is being considered which has been presented by the presidential administration which is in office. My question is what inputs, if any, the men here today or the Department as a whole have had on the budget cuts which are now being proposed by Mr. Stockman?

Could you tell me what procedures have been followed in a general way by Mr. Stockman in consulting, if at all, with your Department?

Mr. ITTEILAG. Yes, sir; I think there have been a number of different activities going on at the same time, some of which I have already explained. The initial activity directed by Mr. Stockman was to have recommendations from this staff, from others he brought in——

Senator SPECTER. You're talking about Mr. Stockman's staff?

Mr. ITTEILAG. Yes, sir; I'm talking about Mr. Stockman's staff.

Senator SPECTER. How do you know what his procedures are?

Mr. ITTEILAG. Because his staff has explained them to me. As a result of those activities, a number of recommendations, that have been well documented in the press, were made.

Senator SPECTER. Do you have any information, aside from what has been well documented in the press?

Mr. ITTEILAG. Yes, sir; I have some additional information. At the same time that these activities were going on, the results of which will be announced tomorrow, former Senator Schweiker assumed the office of Secretary of the Department and asked the budget staff to make independent proposals.

Senator SPECTER. This is budget staff within Secretary Schweiker's Department?

Mr. ITTEILAG. Yes, sir; we basically have followed two tracks, if I could, and I hope I'm not going into too much detail.

Senator SPECTER. You haven't yet.

Mr. ITTEILAG. We decided to ask each of the primary agencies within the Department, the Public Health Service being one, to make various budget reduction proposals using 2 percent as a starting point.

In addition to that, we asked Secretary Schweiker's immediate budget staff, those people who work in my office to independently come up with proposals of their own. These activities, both on the part of OMB and within the Department, are now coming together.

Secretary Schweiker has been actively involved with Mr. Stockman and with Cabinet members in discussing each of the major proposals put forth by OMB. Those proposals have been considered both by Secretary Schweiker and his immediate advisers and have been referred to my staff for reaction.

Secretary Schweiker has gone back to Mr. Stockman, and indeed, to the President, on all the initial OMB proposals. In some cases he has proposed alternatives; in some cases he has asked for clarification, while in others he has indicated that slight changes in the proposals would make them more logical.

Many of the major proposals have been decided upon and will be announced by the President tomorrow night.

In addition to that, there is a second category of proposals of lesser dollar value, but in a sense involving more items because they cover the remainder of the budget, both of our department and I suspect of the rest of the executive branch. The rest of those proposals are now under consideration.

At this time the Under Secretary Designate of HHS is chairing meetings to consider various alternatives. Those proposals include additional items from the Office of Management and Budget, additional items proposed by my staff, and items proposed by the operating components within the Department.

The detailed, final decisions on those proposals, according to information from the Office of Management and Budget, will be made in another week or so. The result of those decisions, and the ones that the President has already made, will be presented to the Congress in detail

on March 10; the date when you can expect a very detailed budget revision.

That Senator, is the process that has occurred to date.

Senator SPECTER. When you say that Mr. Stockman and his colleagues made the first round of determinations, was that prior to consultation with anybody from the Department of Health and Human Services?

Mr. ITTEILAG. I think it is fair to say, Senator, that some of that activity indeed started just as the new administration took office, and at a time when new policy officials had not been appointed. So the initial effort did take place as you suggest; keeping in mind, however, that the professional staff of the Office of Management and Budget is almost entirely a career staff. They have reviewed our budgets in detail for several years, most recently in the timeframe of October through December 1980. So we are not talking about people who are at all unfamiliar with the Department's program.

Senator SPECTER. Are you talking, now, about people on Mr. Stockman's staff who are not as familiar with your Department's programs?

Mr. ITTEILAG. Yes, sir; I think, sir, the complexity of the Federal budget formulation process has reached a degree which startles even those of us who have been working within it for several years. Essentially, the process of formulating and reconsidering budgets has been continuing on a year-round basis for the past 4 or 5 years.

Senator SPECTER. Well, my question goes to a rather simple point, as to what Mr. Stockman and his colleagues had considered; and that was whether they had made some preliminary assessments without consulting with your Department. And if so, what was the basis of those preliminary assessments?

And your answer was, "Yes, they have made preliminary assessments"; and they have had some guidance from their prior experience with the Department of Health and Human Services. Is that essentially correct?

Mr. ITTEILAG. Yes, sir; and I think it is fair to say that the issues that are currently being addressed are not issues that are unfamiliar to those who have been considering budgetary matters for the past several years.

Senator SPECTER. Mr. Itteilag, do you know if these men who have been here today have been consulted by anyone either within your unit or Mr. Stockman's unit, to get their inputs as to possible budget cuts?

Mr. ITTEILAG. They have been consulted by members of my staff. They were asked, as I indicated before to make proposals of their own with no guidance, other than to meet a certain percent target.

Senator SPECTER. And the dollar target you had was a 2 percent cut?

Mr. ITTEILAG. That was the target Secretary Schweiker asked us to use. It was not a target that we received from outside the Department, however, we thought it was a reasonable basis from which to start.

I think, Senator, it's also well to point out that in the absence of new policy officials being appointed within the Department at that stage, that merely to propose any budget revisions is very difficult, since most of us are career officials both in the budget and program areas. Our job is to carry out policies of the administration consistent with that which would occur under normal circumstances.

It is difficult when, for example, there isn't an Assistant Secretary for Health who is a policy official, to ask to make budget revision proposals. That is one of the things that has caused the situation to be more complicated than it might otherwise be.

Senator SPECTER. When you talk about 2 percent, that was 2 percent proposed cut for fiscal 1982?

Mr. ITTEILAG. We looked at both fiscal years 1981 and 1982. The target for fiscal year 1982 was 2 percent.

Senator SPECTER. Was there a request made for a cut, for proposed cuts for fiscal year 1981?

Mr. ITTEILAG. Yes, sir; we have looked at fiscal year 1981 in terms of a possible 1-percent reduction.

Senator SPECTER. Are the press reports accurate that Secretary Schweiker wanted to make cuts beyond those which the President decided upon?

Mr. ITTEILAG. In discussing his preferences with us, he indicated that he did not want to simply react to what OMB had already proposed, but wanted to make proposals of his own. So while it is difficult at this stage to talk in terms of total magnitude of reductions, it is appropriate to say that we are making, proposals of our own, in addition to reacting to those proposals which have come from the Office of Management and Budget.

Senator SPECTER. Is that a qualified, "Yes"?

Mr. ITTEILAG. Yes, sir.

Senator SPECTER. Thank you.

Thank you, Mr. Chairman.

Senator RUDMAN. Additional questions will be submitted to you, to be answered for the record.

[The following questions were not asked at the hearing but were submitted for response for the record:]

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Questions Submitted by the Subcommittee

COMMUNITY HEALTH CENTERS FINANCIAL MANAGEMENT CONCERNS

Question: There has, as you know, been concern about the quality of financial management at Community Health Centers (CHCs). It's been reported that some staff don't know how to reconcile checkbooks, prepare monthly statements, balance books or plan for meeting payroll and other expenses. How much money has been lost because of financial mismanagement?

Answer: The Bureau of Community Health Services (BCHS) is quite concerned that some primary care centers still have administrative and financial management problems including: provider productivity, staffing patterns, billings and collections, and administrator skill levels.

When BCHS began its initiative to improve project management in 1974, there were no existing measures of management "efficiency." We were aware then that current project performance was inadequate: provider productivity of 3,100 encounters per year, administrative costs of 25 percent, third-party reimbursements of only 17 percent, and $44 cost/encounter.

There is no means of calculating the total costs of the projects' inability to implement total management controls.

Question: Has there been any improvement?

Answer: Since 1974, BCHS has mounted an aggressive effort to improve management of Community Health Centers through: allocating resources based on performance; setting management standards for funding criteria; improving project accounting systems; developing common reporting format; conducting intensive program reviews of a sample of projects annually; and providing technical assistance and training.

While we are still not satisfied with management efficiency, by 1980, projects demonstrated significant improvements: provider productivity increased to 4,100 encounters per year, administrative costs dropped to 21 percent, third-party reimbursements and patient payments were up to 40 percent, and cost per comprehensive encounter decreased to $30.

It should be noted that the $30 per comprehensive encounter is comparable to costs in organized outpatient departments and lower than those for emergency rooms, the two alternative sources of care for patients seen in Community Health Centers. A recently completed study, by JRB Associates, of Medicaid patients in three States showed that the total annual medical costs per patient for primary care center users was from $48 to $260 less than the costs for alternative sources of care.

However, we are not content with these improvements. Within the past year, we have redoubled our efforts, including: developing a system to track projects' audits and corrective action plans; developing standards for project accounting and billing systems, and auditing; training in financial management for regional office staff, including grants management staff and project officers; developing a policy on denial of services to any who are able but unwilling to pay; identifying non-compliant projects which are "at risk" for reduced or termination of funding; for example, 1) those

more than 10 percent from compliance with two or more management indicators, and 2) those who have lost Medically Underserved Area (MUA) designation.

Question: Given this situation, why do you propose to pour an extra $50 million into the CHC program?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

THIRD-PARTY COLLECTIONS

Question: The authorizing legislation for the Community Health Centers program requires centers to charge those who can afford to pay for care and to collect from third-party payers for covered patients.

The House Appropriations Committee Investigative Staff claims that third-party collections in your program are a low priority. What is your response to this?

Answer: Beginning in 1975, the Bureau of Community Health Services has focused on third-party and patient fee collections, demonstrated by the increase of third-party collections from 17 percent to almost 40 percent currently. Especially in the developmental years of projects, however, our prime concern has been the elimination of barriers to the receipt and delivery of services. Assuring the appropriate use of services, particularly preventive care, has been of higher priority than financial management activities.

However, within the past year, we have redoubled our fiscal administration improvement efforts, and these efforts are being continued this year.

EXTENT OF FUNDING FOR CHCs

Question: If an area is no longer considered underserved, what is your policy toward continued funding for CHC projects it contains? You retain the option for providing centers with continuation grants indefinitely. Why should this be so? Why not limit total funding to, say, about seven years to nudge the centers toward self-sufficiency? What are your thoughts on reducing the level of grants after a center has received Federal funds for a reasonable period?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

IS THIS APPROACH JUSTIFIED?

Question: The Community health Centers program is designed to bring health services to so-called Medically Underserved Areas (MUAs). What is HHS doing to evaluate the validity of the criteria used to designate Medically Underserved Areas?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Since the index of medical underservice needs to be periodically updated, when was it most recently made current?

Answer: In October, 1976, the Department published in the Federal Register the original list of MUAs. Since 1976, the Department has revised the MUA list on the average of every six months. The most recent updating of the MUA list was on June 1, 1980. The next revision, as of December 31, 1980, is scheduled for release in the near future.

Question: What source data was used?

Answer: The process for revising the MUA list has relied on a number of recommendations and updating of various national data estimates.

The Department will be publishing a MUA list this year. The data sources for updating the MUA list are: ratio of primary care physicians/population (American Medical Association and American Osteopathic Association submitted data on M.D.'s and D.O.'s for 1978); infant mortality rate (National Center for Health Statistics for 1973-77); percentage of population aged 65 or older (using 1978 revised county estimates by the Census Bureau with the Administration on Aging); percentage of the population with incomes below the poverty level.

Question: What impact did the most recent updating have on the number of MUAs?

Answer: The most recent updating of the MUA list was on June 1, 1980. As of this date, there were 7,519 MUAs. The number of MUAs increased by 1.4 percent since November, 1977, from 7,416.

UNDERSERVED RURAL AREAS

Question: A recent report published in The New England Journal of Medicine* indicated that more physicians are beginning to locate in smaller towns. For example, the study shows that in 1970, only 9 percent of small towns with populations between 5 and 10 thousand had a specialist in internal medicine. By 1977, the percentage had jumped to 25 percent. Similar gains were recorded in other specialties. Moreover, with all the new doctors coming out of our medical schools, it is expected that even more doctors will be setting up practice in smaller towns in the years ahead.

Since market forces seem to be taking care of the geographic distribution problem, why can't we begin to phase out the Community Health Center program?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

*William B. Schwartz, et al., "The Changing Geographic Distribution of Board-Certified Physicians," The New England Journal of Medicine, 303:1032, 1980.

BLACK LUNG CLINICS

Question: You presently have about 56 Black Lung clinics. How many of these are located in Community Health Centers and other Federally supported clinics?

Answer: Nineteen Black Lung clinics are located in Community Health Centers. There are no Black Lung clinics located in other Federally funded clinics.

Question: What percentage of the operating expenses of these clinics are reimbursed by third-party payers?

Answer: An estimated 40 percent of Black Lung clinics' operating costs in 1981 were reimbursed by third-party payers.

Question: How much, if any, is reimbursed by the Labor Department?

Answer: The Department of Labor (DOL) is the largest single reimbursement source; virtually all of the 40 percent comes from the DOL.

HEALTH OF MIGRANTS AND SEASONAL FARMWORKERS

Question: We still hear that the migrant farmworker population suffers from high infant mortality, lower life expectancy and high disease incidence. What evidence can you give that your program is improving the health status of migrants and seasonal farmworkers?

Answer: The health status of migrants and seasonal farmworkers that we serve are substantially affected by the services extended through the Migrant Health program. For example, the levels of immunizations, hypertension screening and treatment, and pap smear testing are comparable to the levels achieved for the general population. Specific efforts at emphasizing prenatal, maternity and preventive care through services to children and women in childbearing ages are reflected in the higher proportion of these age groups served in migrant projects (compared with the pattern of medical services for the general population).

The indicators of improved health status apply only to those migrant and seasonal farmworkers that the program serves and cannot be generalized to the target group as a whole. The program only reaches approximately 20 percent of the migrant and seasonal farmworker population. In addition, this occupational group experiences a turnover annually of approximately 20 to 30 percent. As a result, improvements attributed to the program would be substantially diluted when merged with the target occupational group.

It should be noted that health status is not affected only by clinic services available to migrant and seasonal farmworkers through the Migrant Health program. Of equal or greater importance are factors related to environment, life style, and income. The levels of nutrition, the incidences of debilitating diseases and mortality among the migrants brought about by these factors undermine improvements affected by health care. Examples of these factors are: 1) the marginal income levels of migrants; 2) poor

diets; 3) exposure to unsanitary living conditions such as poor water, sewage disposal and housing; 4) lower levels of education; and 5) occupational hazards.

Question: What happens to a center when the migrants move on? Close? Stay open? Why?

Answer: When migrants leave the service area of a center, the clinic may either close or continue to operate depending on the continuing local demand for care, e.g., seasonal farmworkers who will remain in the service area will continue to receive care.

When a center is also located in a Medically Underserved Area, receiving section 330 Community Health Center funding, as well as Migrant Health funding, the center would operate year round, serving the resident population of the underserved area and receiving migrant support only for the migrant program beneficiaries served.

Approximately two-thirds of the Migrant Health projects are integrated or conjointly funded with section 330 funds. Through integration, the programs eliminate overlapping or duplicative services and all facilities thus extend care more efficiently and effectively. From the migrant health perspective, it also reduces or eliminates the necessity of establishing health care capacity for use during only part of the year.

TARGETING HOME HEALTH AGENCIES

Question: It appears the previous Administration proposed to kill the Home Health Agency program. How many areas -- and how many Americans -- still do not have access to home health services? What will be done for underserved areas if Federal support is terminated? Since continued Federal funding is by no means certain, what are you doing to stimulate the private sector to do more in this field? Why is it that few private entrepreneurs are setting up home health services in rural areas?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HIGH BLOOD PRESSURE SCREENING

Question: It's good to note that hypertension screening and referral has resulted in a decline in the number of fatal strokes. What has been your experience with the changeover from formula to project grants? More people covered -- or fewer?

Answer: With respect to persons served, in 1979, State health agencies had a total of 235 projects providing hypertension services. Of the projects reported, 3.8 million persons were screened for hypertension. An estimated 5.4 million persons were served by the end of fiscal year 1980.

Question: What percentage of persons you screen and refer for treatment do you contact to see if they have actually gotten treatment?

Answer: The Association of State and Territorial Health Officers publication on hypertension programs reported in fiscal year 1979 that 87 percent of persons newly-diagnosed as hypertensive received treatment for this condition.

Question: How does your program relate to the hypertension work carried out through the National Heart, Lung and Blood Institute? Do you exchange information?

Answer: The National Heart, Lung and Blood Institute (NHLBI) staff has been of immeasurable assistance in the development of guidelines for State hypertension grant programs under the former formula grant program as well as in the new program of competitive project grants to State Health Agencies. NHLBI staff reviewed draft implementation plans for the 317(A)(1) program and the two agencies are working together on the development of standards, definitions and goals that are compatible between programs.

NHLBI contributes names to a resources list of hypertension experts used in forming the grant review panels for the project grant proposals. NHLBI staff also participate in the reviews. Assistance from the NHLBI is anticipated in the development of new evaluation procedures and technical assistance for the State programs. Staff of the State Hypertension program and Regional Offices responsible for implementing the program will participate in several of the National High Blood Pressure Education Program regional conferences and in meetings of the National High Blood Pressure Coordinating Committee. A State Hypertension Program Managers' Conference is planned in conjunction with the National Conference on High Blood Pressure Control in May, 1981, in New York City.

MATERNAL AND CHILD HEALTH (MCH) GRANTS

Question: The current infant mortality rate for the United States is about 14 per 1,000 live births. Is this rate lower than last year -- and what is your current goal?

Answer: The final infant mortality rate for 1978 is 13.8 per 1,000 live births. The provisional rate for 1979 is 13.0 per 1,000 live births, according to the latest data available. The goal for the United States is an infant mortality rate reduced by 35 percent or to fewer than 9 per 1,000 live births by 1990.

Question: To what extent is the Secretary's discretion limited in dividing funds between MCH services and Crippled Children's services?

Answer: The Secretary has discretion to determine the portion of the appropriation request for Maternal and Child Health and Crippled Children's programs. The Appropriation Committees and the Congress have the final authority. In the past, the Congress has accepted the Administration's proposed split for these programs.

Question: What's been the effect of this?

Answer: The effect of this has been a balanced program between the prevention-focused MCH program and medical-care-and-treatment-focused CC program. This has contributed significantly to the

decrease in infant mortality and also to the habilitation of handicapped children.

Question: The law requires dollar-for-dollar State matching for formula MCH grants to the States, but requires no match for "Fund B" or special project grants. Why shouldn't "Fund B" also have a State match?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: To what extent do you try to get the private sector involved in the MCH program other than through contracting for services?

Answer: The private sector is involved in the MCH/CC program through 1) the adoption of standards of the professional organizations, 2) the use of specialist and subspecialist panels in the provision of clinical services, 3) consultation to State programs by professional organizations in developing support for continuing educational programs, and 4) guidance material. The private sector serves in advisory capacities to State programs which often provide for continuing education for private physicians.

Question: How do schools participate? Could they take over some of this work?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Why does the Carter budget propose a 25 percent decrease (from 28 to 21) in Improved Pregnancy Outcome projects? These help to reduce infant mortality, don't they?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

PROGRESS OF GENETIC SERVICES PROGRAM

Question: The Genetic Services program is supposed to be national in scope as it provides education, testing and counseling on genetic diseases. To what extent have you achieved the goal of establishing a nationwide program?

Answer: There are areawide genetic disease programs in 33 States and the District of Columbia. There are also sickle cell screening and education clinics in 4 additional States and Puerto Rico. Some of the areawide genetic programs provide limited services to neighboring States. For example, the Washington State project provides some services to Idaho and Alaska, and Colorado provides limited services to New Mexico, Arizona, and Wyoming. All States are screening for phenylketonuria (PKU).

Question: How many people are eligible for the program nationally -- and how many are served at present?

Answer: Anyone at risk of inheriting or transmitting a genetic disease is eligible for service. There currently are no special restrictions. It is estimated that 12 million people, approximately 6 percent of the population, are affected by a handicapping genetic condition. Preliminary data indicates that approximately 2.7 million people are receiving genetic services yearly through our program. It should be noted that programs providing these services receive funding from multiple sources, including Federal, State, local and national voluntary and private resources.

Question: Explain how your Areawide Networks work. Do they function through existing projects, such as Community Health Centers?

Answer: Areawide service networks are comprehensive Statewide or multi-State projects which are required to develop linkages with other related health care programs including Community Health Centers (CHCs) and in particular with Maternal and Child Health (MCH) and Crippled Children's (CC) programs. These programs may act as intake units referring patients to the genetics programs, as is frequently the case with CHCs. These programs may also receive patients referred from the genetics programs for confirmatory diagnosis and treatment. MCH and CC programs may play either role. Networks may function through State health departments or major tertiary health care centers in the State, usually university hospitals, and normally include outreach clinics and satellite centers as part of their overall structure.

Question: Which diseases are covered and which are not?

Answer: The legislation requires that all persons who are at risk of having or transmitting a genetic disorder be eligible for services. There are approximately 3,000 such diseases and none are specifically excluded. Areawide networks deal with problems as they arise, but focus their attention on the major concerns in their service areas.

Question: Is lactose deficiency not covered?

Answer: Lactose deficiency is a familial disorder and affected individuals would be eligible for services.

SICKLE CELL AND HEMOPHILIA

Question: The Sickle Cell program awards grants to provide screening, diagnosis, counseling and referral services. Why does the Carter budget propose to reduce funding for the Sickle Cell program by $2.6 million?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Will Sickle Cell and Hemophilia eventually be brought under the Areawide Genetics Services Networks? Will this reduce the cost of the program? For Hemophilia, you're serving 6,000 people at present. Will the patient load go up or down? Are you working on a plan to have the States take over the cost of treatment and care?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question: The Sudden Infant Death Counseling and Information program provides assistance to families which suffer the sudden, unexpected and unexplained death of an apparently healthy infant. This month the General Accounting Office issued a report on the program stating that while the program is helpful, it still needs improvement.

Specifically, GAO stated that of the 11 projects it checked, it found that:

-- Performance varied.
-- Many projects failed to collect sufficient data.
-- Some medical examiners failed to promptly inform the projects of SIDS deaths.
-- Participation by community groups "varied" because of insufficient guidance from HHS.
-- There was "excessive" funding of several projects.

Among other matters, GAO recommended that the SIDS program be consolidated with the larger Maternal and Child Health program. GAO recommended providing "adequate" staff for the program. What is the current staffing situation?

Answer: Staff positions for the SIDS Program Office are as follows: 1) Director, SIDS Program Office; 2) Consultant for SIDS Grants, SIDS Program Office; 3) Staff Assistant, SIDS Program Office, 4) Secretary, SIDS Program Office. Two additional full-time equivalent positions are provided from various functional units within BCHS (e.g., Grants Management Specialists, Information and Publication Specialists, and Contract Management Specialists).

Question: To what extent would the SIDS program be submerged or lost by consolidation with Maternal and Child Health?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

RELATIONSHIP OF FAMILY PLANNING PROGRAM TO OTHER PROGRAMS

Question: Family planning services are available not only through the Health Services Administration's program, but also under Medicaid and Grants to States for Social Services. How much does the Department provide <u>overall</u> for family planning services?

Answer: In 1980, the Department provided a total of $258,885,000 for the support of family planning services. Of this amount, $155,885,000 was under Title X, Public Health Service Act; $25,000,000 was under Title V, Social Security Act (SSA); and $78,000,000 was under Titles XIX and XX of the SSA.

Question: How do these programs interrelate, if at all?

Answer: The objective of the Title X service program is to make comprehensive voluntary family planning services available and accessible to low-income and other high risk women with limited access to other sources of services. Under this authority, a broad population is served through a national dispersed system using 5,125 delivery sites. Services include medical examinations, counseling, pregnancy tests, information and education activities and birth control methods. Title X funding supports less than half of the total cost of services in program clinics. The remainder is provided by client fees, insurance, local sources, and reimbursements from Title XIX and, in some States, Title XX.

The prime responsibility of the Title X activity is to develop organized family planning delivery settings in which comprehensive services of high quality are available and accessible. Titles XIX and XX relate to Title X primarily as financing for the services provided in these organized settings.

Title V authorizes Maternal and Child Health formula grants to assist States in extending and improving their services for promoting the health of mothers and children, especially in rural areas and areas suffering from severe economic distress. As part of its effort to assure quality health services, Title V provides family planning services using not less than 6 percent of the funds available to the States. The persons served through Title V are largely post-partum patients.

In most areas there is close cooperation between the Title V agency and the Title X agency to assure the effective use of limited resources to serve those seeking pregnancy, those who are pregnant, and those seeking to avoid pregnancy. Both programs are administered by the Bureau of Community Health Services, Health Services Administration, which allows for planning and assessment to occur. In 37 States the State health department is the administering agency for both programs.

Title XIX reimburses those providers of services willing to accept Medicaid rates for covered eligibles. The State Title XIX agencies have no authority to initiate services where they are needed nor to require private sector providers to serve Medicaid clients.

Title XX funds are limited in amount and are used by States for a wide variety of social and health activities. Some States apply no Title XX funds to family planning, and many others elect to reimburse only for specific types of services.

All Title X and Title V family planning projects make every effort to collect funds for services provided to Title XIX and XX eligibles. Costs for covered eligibles are billed to the State agency.

Question: To what extent do the States match Federal funding for Family Planning?

Answer: Under Title X, there is no requirement for State matching. However, Title X cannot provide the total cost of providing services. Additional monies are provided by State and local resources, patient fees, and reimbursements under Titles XIX and XX.

Under Title V, the total Maternal and Child Health formula grants to States has statute-matching requirements. Specific family planning projects supported with those funds do not have an individual matching requirement.

Under Titles XIX and XX, States are reimbursed for 90 percent of the cost of providing family planning services to covered eligibles.

Question: Why couldn't the States take over more of the funding of this assistance?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NATIONAL HEALTH SERVICE CORPS GROWTH

Question: I note you are proposing significant increases for the National Health Service Corps. You received $79.4 million under the Continuing Resolution, the Carter budget seeks to increase this to $91.2 million in the current fiscal year and go to $123.8 million in FY 1982. In addition, the budget requests a $180 million advance in the 1982 bill for use in fiscal year 1983. What is your authority for requesting funds for fiscal years 1982 and 1983 for the NHSC? What field strength do you propose for the NHSC under the Carter budget proposals? If you don't get the funding levels you seek, how many medical students with service obligations will escape the service requirement? And...how many volunteers would you lose?

If you do get sufficient funds for placing all scholarship recipients available for service, what strategies have you developed to assure the placement of as many as possible -- or relieving some of their service obligations? Why does your advance request of $180 million for 1983 more than double the NHSC level of $79 million under the Second Continuing Resolution?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

NHSC ASSIGNEE REQUIREMENTS

Question: We understand that current projections are for the National Health Service Corps to grow from 2,060 at present to around 11,000 by 1990. If true, how does that estimate compare with the number of NHSC assignees needed by 1990? Even if new awards were stopped today, what level of field strength would the NHSC reach by 1990? To what extent are physicians locating voluntarily in smaller communities and thereby reducing the shortage of primary care doctors in those places? Isn't it possible that those awarded scholarships at this time won't help the doctor shortage in small towns because the problem will have been substantially resolved by the time they are available for service?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

IMPACT OF THE CORPS SCHOLARSHIP PROGRAM

Question: Under the National Health Service Corps scholarship program, health professions students agree to serve in a Health Manpower Shortage Area in return for scholarship support. What impact has the NHSC scholarship program had on the problem of geographic maldistribution of health personnel in the nation?

Answer: The NHSC is designed to address the maldistribution issue. For the past several years, emphasis has been placed on matching scholarship assignees to the areas of greatest need in the NHSC. This has resulted in 771 of 1,038 matches, or 73 percent, in 1979; and 578 of 754 matches; or 77 percent, in 1980 to Health Manpower Shortage Areas in severest need of medical services providers.

Question: How many scholarship recipients remain in shortage areas after they have fulfilled their service obligations? For how long?

Answer: Scholarship recipients began to enter the NHSC in 1976. 1979 was the first year in which any significant number of scholarship assignees were eligible to terminate their service. Of 103 eligible, 16 extended with the NHSC and 11 converted to private practice in Health Manpower Shortage Areas.

Question: What success -- and what problems -- are you having with the Private Practice Option?

Answer: We initiated the Private Practice Option (PPO) on a large scale in August, 1980. Since that time, we have had written and telephone conversations with a number of organizations with potential PPO placements as well as with all scholarship recipients eligible to select the PPO. Successes have included a wide dissemination of PPO data and the identification of a number of PPO vacancies. To date, more that 200 scholarship recipients have expressed positive interest in the PPO; 38 have been matched to PPO sites. Problems have been related primarily to information dissemination in a timely fashion.

Question: What are you doing to encourage the Private Practice Option?

Answer: Communication continues to be the main means of encouraging the PPO. In addition, we are supporting the following activities to encourage the PPO: one visit per scholarship recipient to a PPO site; provision of contractual technical assistance to aid in PPO site development; and work with national organizations, such as the American Hospital Association, the American Group Practice Association, the Hospital Corporation of America, the American Medical Association, and the Adventist Hospital Association of America, to identify PPO vacancies.

REAGAN BUDGET CUTS

Question: The newspapers have carried reports indicating the Reagan Administration is planning to cut back the National Health Service Corps and to eliminate the Public Health Service Hospitals. Please explain the rationale behind these cuts as well as their

impact on beneficiaries of both programs. The two programs do provide some services needed by beneficiaries of both. How do you propose to continue to provide essential services if the cuts do take place? According to newpaper reports, a number of the programs in HSA may be put in block grants minus about 20 percent of their current funding level. What would happen to the HSA programs under this circumstance? To what extent would the problems these programs are designed to serve no longer be dealt with?

Answer: The budget amounts for these programs are currently under discussion within the Reagan Administration. After the revised budgets are forwarded to the Congress, we will provide appropriate answers to these questions.

PHS HOSPITALS -- FINDING AN ALTERNATIVE

Question: Would you comment on the proposition that there ought to be a less expensive way for the Federal Government to provide health care to merchant seamen than by maintaining Public Health Service Hospitals with their large staffs? What studies have you done on the difference in cost between maintaining the eight PHS hospitals and providing care by contract? What do such studies show? Don't you plan to eliminate inpatient services at the Boston PHS hospital and turn this over to contract care? Why do you propose this? Will you actually shut down the old hospital itself? Why should these hospitals provide services to Defense and Commerce Department personnel? Are there reimbursements for these services? How much?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HEALTH PROFESSIONS STUDENT LOANS -- PROPOSAL FOR TERMINATION

Question: What is your rationale for proposing to terminate the Health Professions Student Loans program in 1981? How does the cost of a student loan compare with the cost of a Health Education Assistance (HEAL) loan? What would be the cost to a student of a HEAL loan over 4 years of medical school? What is the difference in cost of these loans to the Federal Government? How successful has the HEAL program been in attracting applicants?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NURSING LOANS -- PROPOSAL TO TERMINATE

Question: The Carter budget proposes to terminate Nursing Student Loans in the face of a number of private studies showing a continuing shortage of nurses. How do you justify this proposal in light of such evidence as well as the bounties some hospitals are offering to get registered nurses onto their staff?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: You propose that student nurses resort instead to Federal grants and loans to finance their education. Aren't these programs already heavily subscribed and costing the government huge amounts of money?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: What is the Department doing about the basic problems underlying the nurse shortage -- low salaries and poor working conditions -- for example?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NURSING SCHOLARSHIPS TO BE "ZEROED"

Question: Why do you propose to terminate the Nursing Scholarship program with a $9 million rescission in fiscal year 1981? You suggest instead that nurses turn to the National Health Service Scholarship program which the Carter budget proposes to reduce by $10 million in 1982, leading to fewer nursing scholarships in 1982 than previous years. How do you explain this? To what extent are nursing students in special need of scholarship and loan support? What help do nursing students get from the States? Why don't the States do more to solve their own nurse shortage problem?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

PROGRAM SUPPORT - STUDENT PROGRAMS

Question: Please explain why you want to spend $762,000 for an assessment of more than 400 health professions schools receiving student assistance funds.

Answer: The 400 assessments and $762,000 will help strengthen the debt management practices at health professions schools which are responsible for managing student assistance funds.

Question: What problems led to this request?

Answer: A Presidential Management Improvement Council on Debt Collection Projects in the Office of Management and Budget and the Department's Office of the Inspector General conducted a study to review debt management collection activities in all student assistance programs. This study indicated that there was a general need for improved collection practices at schools to recover outstanding student loans. As of June 30, 1980, the total student loans owed by health professions schools to the Federal Government was $344,608,155.

Question: Who would do the study?

Answer: The assessments will be conducted by qualified consultants under contract with the Bureau of Health Personnel Development and Service.

Question: How long will it take?

Answer: It will take approximately one full year from initial contact date to conduct the 400 assessments.

Question: How does your "Program Management" function at a projected cost of $6.6 million differ from "Program Support"?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

HELP FOR SUPPLEMENTAL SECURITY INCOME DISABLED CHILDREN

Question: Why do we have a Supplemental Security Income (SSI) program for disabled children funded under the Health Services Administration?

Answer: Many of the children eligible for SSI benefits are known and registered in the Crippled Children's (CC) program administered by the Health Services Administration. This integration is an outgrowth of State based CC programs providing services to handicapped children on a regular and timely basis.

The SSI-Disabled Children's Program (DCP) was designed to provide for the delivery of medical, social, developmental and rehabilitative services to a special group of low income handicapped children. The aim is to improve the individual child's ability to benefit from education and training, and to improve his or her opportunities for self-sufficiency or self-support as an adult.

This program is responsible for locating these children and for assuring that needed care is provided on an individualized basis. Most of these children are multi-handicapped and require highly specialized and expensive care. The private medical sector does not routinely provide care for these children. A number of them were known to existing programs prior to Public Law 94-566, but few received services that met the total health needs of the child.

Question: How is this program coordinated with the Crippled Children's program under Maternal and Child Health?

Answer: In all but 5 of the 50 States and the District of Columbia, the SSI Disabled Children's program is directly administered by the State Crippled Children's program. A legislative requirement that the SSI-DCP collaborate its activities with other programs providing services for handicapped children has led to formal written agreements between the two programs to provide medical, social, developmental, and rehabilitative services on an individualized basis for handicapped children who are receiving Supplemental Security Income benefits.

The SSI-DCP is a last dollar program and must make maximum utilization of the services provided for by the CC program before SSI-DCP funds can be utilized. SSI-DCP funds cannot be used to pay

for services for eligible handicapped children who are between the ages of 6 and 15. Many of these children are eligible to receive services from the State CC programs and are referred for such services under the cooperative agreements between the two programs. Both programs share in the development of the individual service plans for these children and in monitoring the care that is provided for under the service plans.

Through this coordination, the total needs of these children are met and gaps in services are eliminated.

STATUS OF EMERGENCY MEDICAL SERVICES (EMS) PROGRAMS

Question: The law requires that EMS recipients provide a plan which demonstrates they will become self-sufficient when Federal funding ends. Have the plans been provided and are the projects continuing? Are they self-sufficient?

Answer: The plans have been submitted and the projects are self-sufficient. A total of 57 EMS regional systems have completed the funding cycle of the programs. We recently surveyed each of the 57 systems and found 54 were continuing to function as regional EMS systems. The other three continue to function, but have been subdivided into separate county systems.

Question: What evidence can you supply that the EMS program is helping to reduce the incidence of death from traumatic injury?

Answer: In 1980, the EMS program requested 1979 data from grantees to obtain an answer to this question. It was decided to use, as an indicator group, those persons injured in motor vehicle accidents (MVA). The assumption is that the results from MVA injuries is indicative of EMS results for other types of traumatic injury.

Data was collected from 98 EMS regions at all phases of development (planning, establishment, and improvement). The data for calendar year 1979 showed the following:

1) The median number of fatalities per 100 MVA injuries decreased for each year of development in the EMS program: in planning phase (8 regions) was 3.1 deaths per 100 injuries; in establishment phase (65 regions) was 2.0 deaths per 100 injuries; and in improvement phase (25 regions) was 1.6 deaths per 100 injuries.

2) This represents a mean reduction of 16.5 percent from the year prior to the Federal EMS program or a 5 to 10 percent improvement for each year of EMS program involvement.

We also looked at prehospital deaths from "serious" injury and total deaths from serious injury. These results showed:

1) A 29 percent decrease in prehospital MVA deaths for 47 regions reporting, with an incremental improvement for each phase of the program.

2) A 9.5 percent decrease in all "serious" MVA injury deaths for the 66 regions reporting, with an incremental improvement for each phase of the program.

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Question: Why should the Federal Government continue to support this program now that it is off the ground? Why can't the States take it over if it is so important to them?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Have any of the EMS systems been Federally funded for more than basic life support -- as distinguished from advanced life support?

Answer: By 1980, 56 systems had begun development of an advanced life support system, 16 were completing development of an advanced life support system, and 41 had completed their eligibility under Title XII of the Public Health Service Act.

HURA REPROGRAMMING

Question: It's my understanding that you have withdrawn the request to reprogram $6.5 million from the old HURA program to the National Health Service Corps. If you were able to retain these funds, what would you do with them? What have we learned from the various HURA projects? (Note: HURA is "Health in Underserved Rural Areas" program; now called the "Primary Care Research and Demonstration program.")

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

HOSPITAL-AFFILIATED CENTERS

Question: The Health Services Centers Amendments of 1978 authorized grants to set up primary care centers in or adjacent to certain community hospitals. The authorization was for a three-year period beginning in 1979. However, the Department did not request funding until fiscal 1980 and then only asked for funds to begin planning and development activities. What is the status of this primary care program?

Answer: During the first year (fiscal year 1980), the Hospital Affiliated Primary Care Centers (HAPCC) program awarded $1 million in planning and development grants to eleven hospitals throughout the nation. These hospitals are beginning to reorganize their outpatient facilities and to develop health care centers to provide comprehensive, continuous care to populations in medically underserved areas.

Question: Why did you wait until the 1980 budget to request funds?

Answer: Funds were requested by the Administration under a supplemental for the HAPCC program, as part of the Inner-City Health Initiative, in fiscal year 1979; however, the Congress directed that this request be addressed in the regular fiscal year 1980 appropriations measure.

Question: Can the people who would be served by this program be taken care of just as well under other existing programs? If the answer is yes, please explain.

Answer: The persons who would be served by HAPCC projects may have access to acute, episodic care in the high cost emergency room (ER) or outpatient departments (OPD) setting at area hospitals. The HAPCC permits access to care in a comprehensive setting which provides preventive and followup services as well.

If HAPCCs were not available, patients would have to be served in emergency rooms at higher costs: Data from hospital associations and third-party payers compares costs of care in emergency rooms with those of primary care centers:

City	Average Cost per Medical Encounter for CHCs* in City	Comparable ER or OPD Cost Per Medical Encounter in Same City
Washington, D.C.	$21	$55-$82
Providence, Rhode Island	33	43
Harlinger, Texas	25	64
New York, New York	44	52-54

*While HAPCCs are too new to have comparable data, experience with the Robert Wood Johnson Foundation community hospital program has provided costs comparable to those of Community Health Centers.

Question: How much could be saved by not starting this program?

Answer: The planning and development phase of the HAPCC program has started in 1980 at a funding level of $1 million. The 1981 Continuing Resolution continues the planning and developmental phase at the same funding level as 1980.

Question: How much is available for rescission?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

GROWTH OF COMMUNITY HEALTH CENTERS PROGRAM

Question: The Community Health Centers program has nearly doubled since 1976 and may double again by 1985. What specific efforts have you made to evaluate whether these centers are meeting their objectives?

Answer: The major objectives of the Community Health Centers program are: to provide good quality, efficient medical care; to develop project-level financial management to permit maximum feasible independence of grant support; and to target resources to build medical delivery capacity in needy areas.

We have made specific efforts both to monitor project performance through the Bureau of Community Health Services (BCHS)

management information system and to engage in periodic assessments of specific performance measures.

The Bureau has developed management and clinical standards to assure both efficiency and quality of care. Implementation of these standards has led to significant program improvements as shown below:

	1974	1980
Number of people served	1.6 million	4.2 million
Provider productivity (encounters/year)	3,100	4,100
Administrative costs	25 percent	21 percent
Third-party reimbursements	17 percent	40 percent
Cost/comprehensive encounter	$44	$30

The most recent evaluation of CHCs' efficiency and effectiveness compared the total costs to Medicaid for all care (including hospital) for CHC users with costs for non-users in three States. CHCs achieved significant savings for Medicaid, ranging from $48 to $260 per patient annually. The Department is currently engaged in another major evaluation of rural health delivery models, including CHCs.

BCHS' efforts to target resources at the needy include use of the four following criteria to determine priorities: designated Medically Underserved Area; High Infant Mortality Area; High Migrant Impact Area; designated Health Manpower Shortage Area.

1980 RURAL COUNTIES AND CHCs

Need Criteria Met	Number of Counties	Counties reached by Centers	Number of Centers
4	11	9 (82%)	7
3	254	154 (61%)	111
2	1,023	375 (37%)	212
1	826	130 (16%)	35
	2,114	668	365

1980 URBAN COUNTIES AND CHCS

Need Criteria Met	Number of Counties	Counties reached by Centers	Number of Centers
4	15	15 (100%)	41
3	137	98 (72%)	172
2	210	92 (44%)	82
1	213	109 (51%)	33
	575	314	328

Question: How does the Department of Health and Human Services verify the accuracy and validity of data in grant applications?

Answer: Data defining needs in the proposed service area of the applicant are reviewed by the regional office staff taking into account their experience with and knowledge of this area. It would include verification of data with local, regional, and national sources of information.

Question: How and what level of confidence is placed on Health Systems Agencies in regard to true identification of health need suggested in grant applications?

Answer: Particular reliance was placed on the review/approval/comment function of the cognizant Health Systems Agencies as the responsible organization most knowledgeable about local needs and resources.

HOME HEALTH AT CROSSROADS

Question: If the Home Health service program has accomplished its original purpose of capacity building, why should we continue its existence?

Answer: The Home Health services program has demonstrated successfully that moderate amounts of grant monies can be successful in developing and expanding home health services.

State and local governments through the use of public funds and funds available from private sources such as charitable organizations and private foundations could continue to finance the development of new home health agencies and the expansion of existing agencies. In recently passed legislation, home health care benefits are encouraged by removing the requirement for three-day prior hospitalization under Medicare, Part A.

Question: If the program is extended in 1981, what modifications would you recommend to target assistance for the highest priority need?

Answer: If the Home Health services program were extended in 1981, the preference criteria for the award of service grants should remain unchanged. The legislative criteria for providing preference to elderly, poor, and elderly poor has been successful in getting project monies to the areas of highest need.

Question: Why should there be additional emphasis on expansion of hospice services?

Answer: If the Home Health program were extended, its efforts should continue to be devoted to reaching those still having inadequate access to basic home health services rather than being directed to new priorities such as hospice services.

Question: To what extent, if at all, do we need to continue training home health aides and administrative personnel?

Answer: Training of this type of personnel is not a Federal priority. State and local levels of government might want to

support training for a number of reasons: home health aides within all but a few States receive no organized or standard training; there is a constant and significantly larger turnover of home health aides annually; patients are in jeopardy and quality of care is poorer when aides are not properly trained; most home health agencies, because of their small size, cannot afford to establish their own training program; the home health services providers are primarily small agencies which lack the trained administrative staff to cope with the intricacies of today's demands placed upon them by third-party payors; and the need for fiscal and management information systems and requirements of governmental regulatory agencies require well-trained personnel.

MIGRANT HEALTH CARE

Question: To what extent are the health care needs of the migrants and seasonal farmworkers similar to the health care needs of the poor in home base locations? What are the differences, if any?

Answer: The health care needs of migrants and seasonal farmworkers are similar to those of the rural poor in home base locations. Occupational factors that are particular to agricultural workers result in higher incidences of specific illness, for example, pesticide poisoning and work related accidents and injuries. The physical strain and the often unsanitary working conditions of farm field work are likely to result in higher incidences of illness related to muscles and joints, upper respiratory infections, dermatitis, gastro enteritis and parasite infection. However, there are some differences, for example, migrants lack availability to care except on a periodic basis.

Question: Migrant Health program beneficiaries have need for transportation, outreach and continuity of care to meet the special needs of the migrants. How are these special needs addressed in allocation of funds from central office to regional offices and Public Health Service regional offices to health centers? Be specific.

Answer: The allocation of resources to regional offices for support of Migrant Health projects does not earmark resources for transportation or outreach. The allocation does recognize the special needs of migrants for such services, e.g., bilingual staff and evening clinics, by doubling the weight of migrants served in the formula used to distribute available service dollars. In addition, a 6 percent differential in administrative costs is allowed proportionate to the number of migrants served.

The allocation would favor services to migrants by doubling the weight of migrants served to others served in distributing resources. In addition, the level of acceptable administrative expenses would be increased to assist in covering the special needs of migrants. Earmarking has not been used, principally to allow projects the flexibility in addressing these needs taking into account unique local circumstances.

Specific guidance addressing program expectations in transportation, outreach, bilingual staff and evening clinics have been issued and are implemented through the regional offices by

Migrant Health projects within the level of their grant review and approvals.

Continuity of care is addressed through a grant with the National Migrant Referral Project and an allocation to the regions to assist projects in operating and maintaining a health record for migrant school-age children. This effort allows projects to receive and exchange immunization and health screening information, as well as problem lists to reduce duplication of services and foster continuity of care.

Question: How has the migrant referral system been measured for its success?

Answer: The objective of the National Referral System is to foster access and continuity of care for migrants as they move from State to State seeking employment. These objectives are addressed by: 1) maintaining and distributing a directory listing organizations extending care to migrants and 2) maintaining a system that develops a summary medical record on migrants that can be accessed by clinics for purposes of delivering care.

Currently, the directory of clinics contains a listing of over 1,000 public and private projects and clinic sites that have extended care to migrants. These directories are distributed to 1,100 organizations and are used to 1) alert migrants where they can assume continuity of care in their next location of employment and 2) allow one clinic to alert another clinic of a health problem that needs continuing care.

The system of maintaining summary medical records for migrants is on the basis of wallet-sized hardcopy forms containing summary screening, medication, and problem lists for migrant children and adults. Approximately 100,000 personal health record forms are distributed and used by established Migrant Health projects. In addition, summary medical information is maintained for migrant school-age children through a computer-based system operated by the Department of Education. The National Medical Record Program (NMRP) provides the mechanism through which Migrant Health centers can access or add information on school-age children to the system. The records of approximately 250,000 active migrant children are maintained in the system and between 10 and 20 thousand transactions are processed on an annual basis.

Question: What are the problems in the current system?

Answer: The problems in the current system relate to the periodic loss by migrants of hardcopy personal health records and the fact that the computer-based system only covers children of school age. Efforts are being made to develp a computer interfacing with the existing data base to allow pre-school and adult migrants to be served. Once the computer system is able to serve all migrants, any lost hardcopy records on the system could be reproduced on request. This capability is scheduled to be developed and implemented by the summer of 1981.

Question: What are the costs associated with this system?

Answer: The current budget for NMRP is approximately $440,000 per year. Of this amount, approximately $100,000 covers one-time developmental costs. Ongoing costs for the project are expected to remain at $300,000 to $350,000.

Question: Over the past several years, the Department of Health and Human Services (HHS) has funded health centers with a combination of funding under section 329 (Migrant Health) and 330 (Community Health Centers) of the Public Health Service Act. How does HHS assure itself that the migrant population is receiving health care services from health centers in proportion to that part of the funds attributable to section 329?

Answer: Migrant Health allocations to the regions and regional allocations to projects are made based on the number of migrants and seasonal farmworkers served. These numbers are routinely collected on the Bureau Common Reporting Requirement (BCRR). A random check on these counts are made annually to assure that the numbers are accurately reflected on the required reports. Further, the proportionate levels of section 329 and 330 grant funding by projects have been monitored to assure equitable funding by the regions. Those administrative procedures have resulted in keeping funding in the programs for services to migrant and seasonal farmworkers equitable in conjointly funded or integrated projects.

Question: How many Migrant Health projects during fiscal year 1981 received only section 329 migrant funding and how many received a combination of both sections 329 and 330 funding?

Answer: It is estimated that, during 1981, 30 Migrant Health projects will receive only section 329 funding and 99 will receive a combination of both sections 329 and 330 funding.

Question: Is the total still 112 -- or is it greater? Please explain.

Answer: The current number of projects of 129 represents our latest estimate. Project data is received throughout the year and the estimate will routinely fluctuate. Factors that impact on these fluctuations are: 1) expansion of existing project capacity in high impact areas to serve migrant needs; 2) termination of projects for non-performance or a change in the number of migrants in the area; 3) the conversion of satellite clinics into independent grantees; and 4) the merger of grantees to achieve greater cost savings.

Question: How do you determine whether a Migrant Health center should be funded under section 329 or section 330?

Answer: If a project is to serve a Migrant High Impact Area (4,000 or more migrant and seasonal farmworkers and dependents), it is eligible to receive support from section 329 which authorizes the Migrant Health program.

If a project is to serve a Medically Underserved Area (an area with a low index of medical underservice based on the infant mortality rate; the percent of population 65 years and older; the percent of the population with incomes below the poverty level; and the ratio of physicians to total population), it is eligible to receive support from section 330 which authorizes the Community Health Centers program.

If the project is to serve both a Migrant High Impact Area and a Medically Underserved Area, the project is eligible to receive support from both sections 329 and 330.

Question: During fiscal year 1981 hearings you said that an area must be High Migrant Impact Area before a grant would be approved. What is the justification for combined funding of projects which treat only a small percentage of migrants and seasonals?

Answer: The level of Migrant Health funding in combined or integrated centers is limited to the number of migrants and seasonal farmworkers served. If few migrants are served, lower levels of funding result.

Question: Couldn't section 330 funding be used since everyone is eligible for care at section 330 funded centers, including migrants?

Answer: Section 330 funding can be used to serve migrants. Currently, in 40 projects that serve migrants, only section 330 funding is used. The reason for integrating Migrant Health funds in section 330 projects in Migrant High Impact Areas, aside from a desire to foster efficiency and non-duplication, is to provide the incentive and to expand the capacity of such projects to serve the migrants. This incentive and capacity relate to the increased needs of migrants for such services as clinic outreach, transportation, special night sessions, and bilingual staffing, as well as the increased seasonal demand for health services that the migrant requires.

MATERNAL AND CHILD HEALTH (MCH)

Question: What type of activity do the States fund with Title V MCH grants?

Answer: The States receive funds for Maternal and Child Health and Crippled Children's health services activities. In the area of Maternal and Child Health, the States fund activities aimed at reducing infant and maternal morbidity and mortality. Services include physician, nursing and dental services for children; and physician and nursing maternity services for women, as well as nurse midwifery services. Prenatal care is provided as early as possible during pregnancy, with special emphasis being placed on prenatal care for high-risk patients, such as adolescents. The States also provide preventive health services to children, such as immunizations, screening, counseling, accident prevention, dental health and nutrition.

The activities which States support with Crippled Children's funds include services for locating, diagnosing, treating and hospitalizing children who are crippled or who suffer from conditions which lead to crippling. Medical and rehabilitative services for crippled children are also provided.

Question: How much money goes into each activity?

Answer: In fiscal year 1980, the Title V appropriation for the MCH program was $345.5 million. Of this amount, $243.4 million was

for MCH services and $102.1 million was for Crippled Children's (CC) services.

Of the $243.4 million for MCH services, $214.0 million was used for formula grants to States and $29.4 million was used for projects of regional or national significance.

Of the $102.1 million for CC services, $86.1 million was used for formula grants to States and $16.0 million was used for projects of regional or national significance.

Question: How do the projects of regional or national significance under Title V differ from those initiated by the States?

Answer: Projects of regional or national significance address health care problems which have been identified in certain population groups or in geographic regions of the nation or particular handicapping conditions such as mental retardation, cleft palate, and cardiac conditions. They also support Improved Child Health and Improved Pregnancy Outcome programs which provide special health care services to mothers and children and develop integrated care plans for areas served.

Question: Are they coordinated with State-initiated projects?

Answer: Projects of regional or national significance are initiated by States and become a part of the State health plans for mothers and children.

Question: What types of research and training activities will be funded?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What research activities have received priority funding in the past?

Answer: Priority research efforts have included delivering health services to mothers and children with emphasis on reaching the high risk groups; costs and quality of care received; regionalization of services; outcome of health care; and handicapped children's studies including demography, etiological factors influencing the degree of impairment, early detection strategies, and effectiveness of interventions.

Question: What research activities will receive priority funding?

Answer: Efforts identified for priority funding in 1981 include studies of health care of the adolescent age group especially of utilization, preventive intervention in the newborn period with emphasis on maternal-infant interaction, intervention techniques with high-risk infants, and effectiveness of home visitation programs.

Question: What new research funding is being planned?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

SUDDEN INFANT DEATH SYNDROME

Question: What is the status of the Sudden Infant Death Syndrome (SIDS) program?

Answer: Current counseling and information services include the following: 1) 35 States have Statewide projects supported with Federal funds; 2) 2 States have SIDS services in the major population areas supported with Federal funds; 3) 11 States, territories, and possessions currently are not receiving Federal support although most have initiated some services; and all have requested grant application kits for the 1981 award cycle; 4) 2 States have Statewide services and plan to continue independent of Federal support; 5) 3 States provide services in selected areas of their States and plan to continue independent of Federal support; and 6) 4 territories and possessions are not ready to initiate SIDS services at this time.

Other significant activities include: 1) A study, under contract, of State laws, death investigation systems and practices, and their impact (study findings will be available in 1981); 2) the Clearinghouse for SIDS Information and Educational Materials, under contract, has developed mailing keys to distribute correspondence, news and new publications to interested persons, organizations and agencies; 3) an annotated bibliography, including SIDS research and grief counseling items, is being prepared; 4) two issues of the "SIDS Information Exchange" have been published and distributed and others are scheduled for the remainder of this year; 5) requests for materials, references and referrals have been filled promptly; 6) one article on SIDS which appeared in Woman's Day, February, 1981, precipitated more than 700 letters and telephone calls requesting information about SIDS and related topics.

Question: What have we learned from this program?

Answer: The following represent a few of the major findings learned from the SIDS program.

1) Contrary to our beliefs of 5 years ago, we now know that, as a group, infants who die of SIDS are different from normal infants anatomically, histologically, chemically, and physiologically. Nevertheless, there is no single difference that can be employed, before or after death, as a predictive or diagnostic criteria.

2) SIDS is a worldwide public health problem. It is the leading cause of death between the ages of one week and twelve months of age. In this country, about 7,000 infants, who die annually, predominantly between the ages of one and six months, die suddenly, quietly and unexpectedly.

3) A number of developmental, environmental and physiological influences may precipitate a sequence of events that

culminate in a SIDS death. About 30 percent of infants who died of SIDS had experienced episodes of prolonged apnea and about 4 percent had infant botullism.

4) The complexity and problems of the multitude of death investigation systems in this country continue to be identified. While most systems have the authority to require post mortem studies of infants who die suddenly and unexpectedly, they were not routinely done for a number of reasons including cost and attitudes. When they were done, it often was for forensic purposes and not for clinical findings nor to assist the family in understanding why their infant dies. Prior to this program's inception, there was no accepted protocol for conducting infant post mortem studies. This program supported the development of death investigation and autopsy procedures in cases of infant deaths. The radical shift from not informing families about the autopsy findings to informing them promptly in a compassionate manner has been an extremely helpful factor in aiding families through their earliest period of grief.

5) The impact of SIDS upon all family members and the extended family network is immediate and recurring throughout the lives of the survivors. The grief process, coping mechanisms, and types of helpful support are now better understood and appreciated by the complex of individuals, organizations, and agencies that come into contact with the bereaved (e.g., police, emergency room personnel, death investigation personnel, physicians, nurses, clergy, funeral directors, voluntary organizations). The awareness level of the general public about SIDS and related issues has improved considerably but needs to be updated continually. As a result of more accessible, informed, compassionate and coordinated services, the secondary traumas previously experienced by families are now being prevented and the grief process is being ameliorated more quickly and satisfactorily.

6) Another important effect is that the SIDS program findings are being generalized to other health areas. The infant post mortem protocol served as a successful model for those in the death investigative systems and they have now formalized protocols for the study of numerous other types of death.

There now is recognition that fetal, infant and childhood deaths (stillborns, accidents and acute illnesses) are family crises that require public health preventive measures. As contributing factors are identified, the findings are being communicated to health professionals providing prenatal, postnatal, neonatal, and infant care. Such examples include smoking; substance abuse, infections during pregnancy, stressors such as immunizations or illnesses; depressed rates of growth and development; prolonged apnea; and infant botullism.

7) The programs administered by State Maternal and Child Health programs, where counseling has largely been done by public health nurses, have been very successful. The reason is due to their medical and health training and experience, their knowledge of community resources, and their access to other health related programs.

6) Programs can be administered by organized health care agencies without creating new systems or organizations.

Question: To what extent do you coordinate your efforts with the SIDS research being conducted at the Child Health Institute of NIH?

Answer: Since the inception of the SIDS program in the Bureau of Community Health Services (BCHS), there have been significant efforts to work collaboratively with a number of Federal programs concerned with SIDS or SIDS-related issues. This insures the coordination of efforts, maximizes the use of Federal resources and additional expertise, and serves as a natural conduit for incorporation of new knowledge into health care delivery systems.

In December 1973, the Assistant Secretary for Health recognized the importance of coordinating SIDS efforts and established the Interagency Panel on SIDS. The National Institute of Child Health and Human Development (NICHD) was appointed as the chairing and reporting agency. Representatives from the NICHD and other Institutes at the National Institutes of Health; the National Institute of Mental Health (NIMH); the Alcohol, Drug Abuse, and Mental Health Administration; the National Center for Health Statistics (NCHS), Office of the Assistant Secretary for Health; and the BCHS have continued to meet periodically. They continue to plan and share in the conduct of several SIDS-related activities.

A close working relationship exists between NICHD and the SIDS Program Office, as well as between researchers and the service projects. An example is the NICHD "Cooperative Epidemiological Study of SIDS Risk Factors" which is a national study to identify risk factors associated with SIDS and to develop a risk prediction scheme to identify those who are at risk for SIDS early in life. Several SIDS projects are participating in the design, conduct, and analysis phases of this study. The Director of the SIDS Program Office has attended meetings of the steering committee and the project directors for this research study. Further, NICHD staff report their research program activities and findings at the annual meetings of the SIDS projects. The staffs of NICHD and the SIDS Program Office are in frequent communication regarding SIDS program activities and related topics.

Question: To what degree do you coordinate your work with the family organizations concerned with SIDS?

Answer: Since the inception of this program every effort has been made to work cooperatively with the two major voluntary organizations concerned with SIDS, the National SIDS Foundations (NSIDSF) and the Council of Guilds for Infant Survival (CGIS) and the numerous other more-recently organized groups.

The following are some examples of the SIDS Program Office's endeavors: Representatives of the voluntary organizations always are invited to participate on ad hoc advisory panels and on grant application review panels. They also have participated in planning and organizing the national meetings of the SIDS projects. In fact, numerous members have received financial support from the SIDS program in order to facilitate the participation of the voluntary membership at these national meetings. The NSIDSF has been the

recipient of Federal contracts from NICHD, NIMH, and BCHS. The BCHS contracts were to provide technical assistance and consultation in areas of the country that had received no Fededal support for SIDS projects. The two major voluntary organizations are identified in Federal SIDS publications as valuable resources for families bereaved by SIDS. Prior to publication of each issue of the "SIDS Information Exchange," items are sought from each organization.

In addition to the above endeavors, each project grantee must include representatives of the active voluntary organizations in their area on the project advisory council. They are encouraged to recognize these organizations as supportive peer contacts and to refer families to them when appropriate.

The SIDS program recognizes that the cooperative relationships among the project staff, peer contacts, and professional resources are most vital since they have direct impact upon the families recently bereaved by SIDS.

OFFICE OF FAMILY PLANNING

Question: The Family Planning program is intended to provide comprehensive family planning services to all persons desiring such services. Emphasis is to be on making services available to the poor, but provision is to be made to collect fees for services rendered to the non-poor. What percentage of program beneficiaries served during the past three fiscal years had incomes below the poverty level income?

Answer: The following table shows the distribution of low-income clients served by Title X grantees:

Year	At or below 150% of Poverty	At or below 200% of Poverty
1978	73.3%	84.3%
1979	72.6%	84.7%
1980	73.5%	85.2%

Question: Of the program beneficiaries whose income exceeded the poverty level, what percent paid the full fee for services rendered? What percent paid part of the established fees? What percent did not pay?

Answer: The reporting system for Family Planning projects does not collect information that identifies a client by sources of payment; therefore, it is not possible to identify the percent of clients that fully paid, partially paid or did not pay for services.

Reported direct payments from all clients in 1979 were 7.1 percent of total operating costs.

Question: How much did the program collect from individuals and how much was collected from the Medicaid program?

Answer: The data available for 1979 on the distribution of funds from Title X and third-party payments are as follows: Title X (49 percent); Title XX, 17 percent (ranged from zero to 85 percent, with 23 States and territories reporting no family planning funds to

Title X grants); Medicaid, 6.4 percent; patient fees, 7.1 percent; and insurance payments, State and local funds and other, 20.5 percent.

NATIONAL HEALTH SERVICE CORPS

Question: The Carter budget requests a substantial increase for the National Health Service Corps, boosting the supply of doctors, even as it proposes to reduce National Health Service Corps Scholarships by $10 million; to terminate Health Professions Student Loans, and to terminate health professions capitation. Would you please explain this seeming contradiction in HHS' approach to dealing with the physician supply? If you plan to reduce or terminate assistance for medical education, why not reduce or eliminate growth in the National Health Service Corps program? If the States feel they need NHSC doctors, why not put the burden on them to recommend -- and fund -- candidates for the program? What are your existing and planned assignee retention and extension rates?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HEALTH PROFESSIONS LOAN REPAYMENT

Question: Why does the Carter budget propose to increase the Health Professions Loan Repayment and Cancellation program by $4 million in fiscal year 1981?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NURSING LOAN REPAYMENT AND CANCELLATION

Question: The Carter budget proposes to increase funding for the Nurse Loan Repayment and Cancellation program while other student nursing programs are being reduced or terminated. I note this program provides assistance in return for service in a shortage area. If we wanted to help nursing students get their education and deal with the shortage of nurses, why not put more money into this program? Why hasn't the program attracted more people (111 served since 1973)? Do you make its existence known?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NURSING STUDENT ASSISTANCE

Question: To what extent are nursing students in special need of scholarship and loan support?

Answer: Over 51 percent of all nursing students receiving nursing student loans and nursing student scholarships are from families with annual income levels at or below $7,500. The nursing student loan recipients represent approximately 7.5 percent of the eligible enrollment in nursing schools while nursing scholarship

recipients represent 3.5 percent of eligible enrollment in nursing schools. It is estimated that from 10 to 11 percent of the eligible students enrolled in nursing education programs benefit from the present Nursing Student Loan and Nursing Scholarship programs. Nursing students may benefit from both programs simultaneously.

Question: What levels of loans can nurses be reasonably expected to assume for their education expenses, given the average earnings of registered nurses?

Answer: The Department's coordinated two-year study, which is scheduled to be completed in 1983, with the National Academy of Sciences' Institute of Medicine will review several issues associated with the nursing profession including the level of loans the nurses can be expected to assume for their education expenses given the average earnings of registered nurses.

Question: To what degree are loan funds available to nursing students from non-Federal sources?

Answer: The Department's coordinated two-year study with the National Academy of Sciences' Institute of Medicine also will review the availability of other sources of support for nursing education under State and other public and private sources.

Support for nursing students by individual States does not appear to be very extensive. Moreover, precise data on this subject is quite limited. The Education Commission of the States (ECS), in their publication, "Higher Education in the States," published the following information as of January 1, 1979:

Alabama	$16,000 in scholarships for RN students.
California	$2.6 million distributed between family medicine residencies, physician assistants and nurse practitioners.
Louisiana	$200,000 for stipends to nursing faculty to pursue advanced degrees in nursing or related fields.
Massachusetts	$500,000 for scholarships for medical, dental and nursing scholarships.
Minnesota	$155,000 for programs of grants to students enrolled in nursing education programs.
Mississippi	$100,000 for nursing students working on bachelor or master's degrees.
North Carolina	$578,650 to students in hospital diploma nursing programs.
North Dakota	$65,000 for loan forgiveness programs for RN students.
Rhode Island	$52,500 for nursing scholarships.

Virginia	$234,000 for service scholarship program distributed between nursing and dental hygiene students.
TOTAL	$4,723,350

It should be understood that the above estimate is not totally for nursing. Some of the figures are for students in nursing as well as other fields. While the ECS figures focus primarily on State support of private education, some of these figures include public education as well. One can assume, however, that there is probably a small amount of additional State support for nursing students not included in the above figures.

(Source: Personal communication with Constance Holleran, Director Washington Office, American Nurses Association, February 19, 1981.)

NHSC SCHOLARSHIPS

Question: For purposes of selecting students with firm career commitments to serve in health manpower shortage areas, explain why the Department wouldn't be in a better position to select such students after they enter their second or third years of study? To what extent would program expenditures be contained by this procedure?

The Senate health manpower bill, S. 2375, proposed a State scholarship program intended to encourage the States to meet their own needs for health professionals in shortage areas within their boundaries. To what extent should the National Health Service Corps scholarship program be a State effort and responsibility? Aren't the States a more appropriate focus for determining special health manpower needs? What evidence do you have that States could be expected to assume a service-scholarship program effort? Is Federal funding required to encourage States to establish and operate service-scholarship programs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

PHS HOSPITALS -- EXCEPTION TO 1973 LAW

Question: The Carter budget proposes bill language to permit the PHS Hospitals and Clinics to operate at a level of $172.1 million. What is the purpose of this language? Will it result in a reduction of services from the required 1973 level? Why can't you operate at the FY 1981 Continuing Resolution rate of $167.4 million and save $4.7 million?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

GAP BETWEEN BUDGET AUTHORITY AND OBLIGATIONS

Question: In fiscal 1982 you request $172.1 million in budget authority for PHS Hospitals, but you plan to spend $234.8 million, a difference of $62.7 million. What accounts for the large difference between request and obligations? What then is your carry-in amount from fiscal 1981?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

OCCUPANCY RATES OF HOSPITALS

Question: The National Health Planning Guidelines established an average daily patient load of 80 percent of operating bed capacity as a measure of hospital efficiency. In fiscal year 1981 appropriation hearings, the Department also said that the fiscal year 1979 occupancy rate for the PHS hospitals was 66.3 percent. However, the 1978 report of the Ad Hoc Committee on PHS hospitals showed that the hospitals significantly reduced their operating bed capacity from fiscal years 1972 through 1977 by more than 300 beds, which would seem to distort the occupancy rate statistics. For each of the 8 PHS hospitals, provide the operating bed capacity, as of January 1, 1973 and the capacity as of January 1, 1981.

Answer: Operating beds for January 1, 1973, and January 1, 1981, are as follows:

Hospital	Operating Beds FY 1973	Operating Beds FY 1980
Baltimore	222	208
Boston	110	110
Galveston	150	---
Nassau Bay	---	125
New Orleans	390	300
Norfolk	210	115
San Francisco	321	260
Seattle	257	220
Staten Island	500	500
Total	2,170	1,839

Question: What are the current occupancy rates based on the 1973 bed capacity?

Answer: A calculation of occupancy in 1980 based on the 1973 operating bed capacity can be made but represents a gross distortion of actual utilization based on flaws in the use of occupancy as an indicator of workload. Occupancy is a function of (Average Daily Patient Load ÷ Operating Beds) x 100. Occupancy thus determined can be reduced by changing the denominators, but it can also be increased by increasing the length of stay or raising the average daily patient load. In either instance, occupancy would increase, but utilization might be unnecessarily increased together with total costs per admission.

The table provided below also does not reflect the fact that the average length of stay in PHS general medical surgical hospitals declined by 23.6 percent from the 1975 level of 16.1 days to the 1980 level of 12.3 days. It also does not show that admissions increased by 12.9 percent over the same period from 31,190 to 35,208, the intensity of services increased as the result of a more difficult case mix as shown in a measurement using average weighted dispositions (diagnostic related groupings), and an increase of 22.6 percent occurred in outpatient workload. The apparent reduction of occupancy actually masks a real increase in workload which has been facilitated in part by reducing unneeded beds.

Hospital	1980 Occupancy Based on 1975 Operating Bed Levels
Baltimore	55%
Boston	48%
Nassau Bay	N/A
New Orleans	55.3%
Norfolk	42.6%
San Francisco	60.4%
Seattle	45.2%
Staten Island	65.8%

Question: What are the reasons for reducing operating bed capacity?

Answer: Bed capacity has been reduced for a variety of reasons since 1975, including the following:

1) Reduced length of stay (-23.6%);
2) Increased emphasis on ambulatory care (+22.6%);
3) Conversion of inpatient capacity to ambulatory care and other alternate uses;
4) Closure of obsolete and unsafe Galveston Hospital (160 beds) and purchase of smaller facility (125 beds);
5) Elimination of some obsolete capacity by converting open wards to semi-private rooms.

Question: What further reductions in operating bed capacity are planned?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

PAYMENTS TO HAWAII

Question: With the average daily patient load and patient days going down, why does the Carter budget request a $169,000 increase in the proposed payment to Hawaii for care and treatment of leprosy victims?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

HEALTH SERVICES ADMINISTRATION PROGRAM SUPPORT

Question: What accounts for the $962,000 increase you request for such areas as service and supply, Federal Telecommunications Systems, postage, etc.? Why couldn't you get along without this increase?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide appropriate answers to these questions.

BUILDINGS AND FACILITIES

Question: When do you expect to complete the second phase of the patient dormitory upgrading at the National Hansen's Disease Center in Carville, Louisiana?

Answer: It is expected that the second phase can be completed in approximately twelve months from the date work starts.

Question: How much more will it cost to do this?

Answer: The estimated cost of completing the second phase is $2.4 million.

Question: What is the status of the work to replace the 60-year-old dining facility at Carville?

Answer: No design work has yet been completed on the project to replace the dining facility.

EXCEPTIONAL FINANCIAL NEED SCHOLARSHIP

Question: To what extent does the Exceptional Financial Need (EFN) Scholarship program make a career in the health professions a more real possibility for students in greatest financial need?

Answer: The EFN Scholarship program may be the only one of its kind. It provides a chance for students in greatest financial need to attempt a health professions career by removing the financial burden normally associated with the first year of a health professions education.

Question: How many students continue with their education after their first year of EFN assistance?

Answer: An agency evaluation study, scheduled to be completed in 1982, is underway to cover the first two years (fiscal years 1978 and 1979) of the Exceptional Financial Need Scholarship program.

The purpose of this study is to determine not only the demographic characteristics of the scholarship recipients but data related to continuation of their course of study following one year of support under the Exceptional Financial Need Scholarship program.

Question: What kind of assistance do these students most generally receive after their first year of assistance?

Answer: After first-year support under the Exceptional Financial Need Scholarship, the recipients have priority to obtain a National Health Service Corps Scholarship if they choose to apply. In addition, the Exceptional Financial Need recipients are eligible to apply to the Department of Education programs, such as National Direct Student Loan, Pell grant, and Guaranteed Student Loan.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

COMMUNITY HEALTH CENTERS FINANCIAL MANAGEMENT CONCERNS

Question: Given this situation, why do you propose to pour an extra $50 million into the CHC program?

Answer: The 1982 budget request of the Carter Administration proposed an increase of approximately $50 million for the CHC program.

The 1982 revised budget request of the Reagan Administration proposes the consolidation of the categorical Community Health Centers program into a Health Care Block Grant to the States at 75 percent of the current funding level.

EXTENT OF FUNDING FOR CHCs

Question: If an area is no longer considered underserved, what is your policy toward continued funding for CHC projects it contains?

Answer: The Bureau of Community Health Services (BCHS) is concerned that Community Health Centers serve only the truly needy and that Federal resources are provided only to those areas which still lack private sector medical care.

Accordingly, in 1981, BCHS has undertaken three efforts to identify areas which are no longer underserved. Projects in those areas will be terminated:

1) Areas which were designated Medically Underserved Areas (MUAs) solely because they were Health Manpower Shortage Areas. (Nineteen projects currently face defunding for this reason.)

2) Areas which are deleted from the MUA list as the result of updated data.

3) Projects which serve areas where the majority of the population is not medically underserved.

In 1982, it is anticipated that the flexibility inherent in the Reagan Administration's block grant proposal will permit States to shift funds to the most needy populations as determined by State officials.

Question: You retain the option for providing centers with continuation grants indefinitely. Why should this be so? Why not limit total funding to, say, about seven years to nudge the centers toward self-sufficiency?

Answer: States should be allowed to retain that option under the Reagan Administration's 1982 budget proposal.

If States target the program to the most needy areas, they will be funding projects in communities which have multiple problems, including poverty, which make them unattractive to private physicians. These same factors make project self-sufficiency unattainable in those areas. In addition, the centers are committed to serving the truly needy, many of whom are not covered by third-party payors. For example, Medicaid does not cover 47 percent of people under the poverty line; moreover, States are reducing Medicaid eligibility, benefits, and reimbursement levels.

Total self-sufficiency could be reached only through two methods: 1) neglecting the truly needy for whom the center serves as provider of last resort, and 2) competing with private sector physicians for non-poverty patients. Neither method would be satisfactory.

While total self-sufficiency is not attainable in the foreseeable future, the following steps would assure maximum financial independence:

1) continued emphasis on efficient service provision;

2) increased standards for financial management, including billings and collections systems;

3) annual review of continued need for the project through service area needs assessment.

Question: What are your thoughts on reducing the level of grants after a center has received Federal funds for a reasonable period?

Answer: This decision is best made on a case-by-case basis. The block grant proposal of the Reagan Administration will permit States to make decisions about reducing grant support on whatever basis is deemed appropriate by State officials.

UNDERSERVED RURAL AREAS

Question: A recent report published in The New England Journal of Medicine* indicated that more physicians are beginning to locate in smaller towns. For example, the study shows that in 1970, only 9 percent of small towns with populations between 5 and 10 thousand had a specialist in internal medicine. By 1977, the percentage had jumped to 23 percent. Similar gains were recorded in other specialties. Moreover, with all the new doctors coming out of our medical schools, it is expected that even more doctors will be setting up practice in smaller towns in the years ahead.

Since market forces seem to be taking care of the geographic distribution problem, why can't we begin to phase out the Community Health Center program?

*William B. Schwartz, et al., "The Changing Geographic Distribution of Board-Certified Physicians," The New England Journal of Medicine, 303:1032, 1980.

not present or because other providers do not accept poor or Medicaid patients.

The Rand study shows, as we would expect, that the market seems to work for medium-sized rural towns, but not for the poorest or most rural areas. As an editorial in Annals of Internal Medicine

Answer: The Department of Health and Human Services has been monitoring the trends of physician locations. We are concerned that primary care centers are located only where they are needed as providers of last resort, either because other health resources are (June, 1980) noted, "Rural and underserved are different concepts that should serve as proxies for each other only rarely. Fifty-five percent of Americans live in communities of less than 25,000 population, but it is the six percent in medically underserved rural America ... that feel the physician shortage most critically."

These poorest and most rural areas are not generally benefitting from the increasing physician supply. According to American Medical Association data:

1) Between 1971-1977, the physician/population ratio improved 14.1 percent for the total population. However, for those living in the most rural categories of counties, the increase was 4.5 percent.

2) Despite increases in the supply of specialists, more than 40 percent of all rural counties still do not have a medical, surgical or other specialist practicing in their county.

3) In high poverty areas, the physician/population ratio increased from 66 physicians per 100,000 to 74 physicians per 100,000 population, compared to 200 per 100,000 for the nation as a whole.

4) In 1977, counties with more than 20 percent of the population below the poverty level averaged 15 surgical specialists per 100,000 population, while less poor counties averaged 35.

The Rand study adds to our understanding of some of the economic forces at work in locating rural physicians. (Note: The study does not address inner-city areas.) However, an accompanying editorial in the New England Journal of Medicine cautions that personal and professional factors affecting physician location choices are very complex, and adds "a purely economic interpretation of these trends is premature. We need a much better understanding of all factors determining the choice of specialty and location and the characteristics of practice."

A recent review of over 100 studies of the factors affecting physicians' location decisions points to these complexities. Physicians often avoid poor and rural areas because of professional isolation, 24-hour duty, and lack of opportunities for continuing education, as well as for economic reasons. Presence of an organized practice such as a community health center improves the probability of a poor or remote area's attracting and keeping physicians.

These findings are consistent with those of a recent Public Health Service study, "Hierarchical Patterns in the Location of Physician Specialists Among Counties," which shows that higher-order

specialists rely on a broad base of less specialized physician types for support, and thus should not be expected in an area unless an adequate physician base is developed.

However elegant the design of these national studies, their application and relevance to local situations must be tempered by a knowledge of special factors at work in the community. Freedom from Federal criteria and standards, based on national norms, will permit States to shift resources according to local conditions.

TARGETING HOME HEALTH AGENCIES

Question: It appears the previous Administration proposed to kill the Home Health Agency program. How many areas -- and how many Americans -- still do not have access to home health services?

Answer: There are 500 counties without the services of a Medicare-certified home health agency. The 500 counties are in nonmetropolitan areas and are rural counties with an aggregate population of approximately 3 million persons. However, there are many more persons who reside in areas served by a Medicare-certified home health agency who do not receive home health services because the agencies are small and lack the service capacity to serve all those persons who need service.

For example, of the 2,977 Medicare-certified home health agencies, 2,449 (82 percent) have four or less full-time equivalent nurses on staff to provide services. Therefore, while the majority of areas of the country are served by a Medicare-certified home health agency, many aged, ill, and handicapped persons go without needed services.

The current Administration has included the Home Health program in its block grant proposal. States would be able to use block grant funds to finance the development of home health agencies or to expand existing agencies. Also, third-party reimbursements are available for home health services, and Medicare/Medicaid expenditures are projected to more than double in five years, going from $668 million in 1978 to a projected level of $1.4 billion in 1982. And in recently passed legislation home health care benefits were encouraged by removing the requirement for three-day prior hospitalization under Medicare, Part A.

Question: What will be done for underserved areas if Federal support is terminated?

Answer: Our hope is that State and local, public and private resources would be applied in relationship to the priority of need identified for these services. The new Administration has included home health in its block grant proposal so Federal funds would continue to be available for home health at State discretion through the block grant funds as well as through available third-party payments.

Question: Since continued Federal funding is by no means certain, what are you doing to stimulate the private sector to do more in this field?

Answer: The Federally funded Home Health program completed its demonstration objectives by showing that small amounts of funding to dedicated local groups can be effective in the development of new

home health agencies and in the expansion and upgrading of existing home health agencies. State and local governments through the use of public funds and funds available from private sources such as charitable organizations and private foundations could continue to finance the development of new agencies and the expansion of existing ones. The Reagan Administration has included the Home Health program in its block grant proposal so Federal funding could continue to be available at the discretion of the States for home health program uses, and third-party payments continue to be available through the Federal Medicare and Medicaid programs.

Question: Why is it that few private entrepreneurs are setting up home health services in rural areas?

Answer: Few private entrepreneurs set up home health agencies in rural areas because there often is insufficient population base to yield a profit which is worth the investment of time and money. Metropolitan areas with greater concentrations of persons allow for bigger agency caseloads and greater volume profits.

MATERNAL AND CHILD HEALTH (MCH) GRANTS

Question: The law requires dollar-for-dollar State matching for formula MCH grants to the States, but requires no match for "Fund B" or special project grants. Why shouldn't "Fund B" also have a State match?

Answer: To require a match would not be consistent with the principle of maximizing State flexibility.

Question: How do schools participate? Could they take over some of this work?

Answer: Schools participate and serve as the locus for some public health programs such as screening, immunizations and health information. School health resources, however, are usually limited when patient conditions require secondary and tertiary services. Also, school programs provide intermittent care rather than continuity of care, which is an extremely important factor in child health services.

Additionally, medical practice acts often forbid school involvement and the limited tax base makes extensive involvement impossible. In essence, schools could not "take over" child health but schools should participate in the assurance that health care needs of children are met.

Question: Why does the Carter budget propose a 25 percent decrease (from 28 to 21) in Improved Pregnancy Outcome projects? These help to reduce infant mortality, don't they?

Answer: The decrease in the number of Improved Pregnancy Outcome projects reflects the end of the five-year funding cycle for these projects. The intent of the IPO program was a time-limited availability of special funds. These seven States funded will have achieved the essential objectives and further funding would not have an additional significant impact.

SICKLE CELL AND HEMOPHILIA

Question: The Sickle Cell program awards grants to provide screening, diagnosis, counseling and referral services. Why does the Carter budget propose to reduce funding for the Sickle Cell program by $2.8 million?

Answer: There is no proposal under either the Carter or the Reagan Administration's budget to reduce funding of the Sickle Cell program by $2.8 million. What is happening is that the currently supported sickle cell screening and education clinics, previously supported under a separate appropriation, are gradually being merged with areawide genetic projects in those States which have such programs. The clinics will continue to operate and be funded under the areawide genetic projects and funds are merged accordingly.

Question: Will Sickle Cell and Hemophilia eventually be brought under the Areawide Genetics Services Networks? Will this reduce the cost of the program? For Hemophilia, you're serving 6,000 people at present. Will the patient load go up or down? Are you working on a plan to have the States take over the cost of treatment and care?

Answer: The 1982 revised budget request of the Reagan Administration proposes that the Sickle Cell and Hemophilia categorical programs be consolidated into a preventive health block grant to States. The States will have maximum flexibility in administering their own programs.

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question: To what extent would the SIDS program be submerged or lost by consolidation with Maternal and Child Health?

Answer: Consolidating the SIDS program with the MCH program would not result in the loss of the SIDS program efforts. The need for the SIDS program efforts is recognized and the identification of resources as well as the ways to coordinate them for comprehensive and compassionate services has been identified.

The identity of the program can be maintained by the States' taking action to provide a focus within the State Health Department for the major activities of the program: 1) the creation of a coordinated and comprehensive system of services for family survivors of SIDS victims, including the certification and prompt notification of the family about the cause of death and the provision of counseling support; 2) the collection and analysis of data; 3) the development and dissemination of accurate and current information and educational materials for various professional and paraprofessional personnel as well as for the general public.

The network of family relationships and the understanding of child development already established by the MCH program would make that program an effective mechanism for achieving the purposes of the SIDS program: reducing the trauma and providing help for families experiencing this life crisis; keeping all who may encounter survivors of a SIDS death accurately informed about this syndrome and its effects; and ultimately, instituting measures to prevent these sudden and unexpected infant deaths.

RELATIONSHIP OF FAMILY PLANNING PROGRAM TO OTHER PROGRAMS

Question: Why couldn't the States take over more of the funding of this assistance?

Answer: The 1982 revised budget of the Reagan Administration proposes that the categorical Family Planning program be consolidated into a Preventive Health block Grant to States.

In the past, the States, using funds available under Titles XIX and XX and other State and local funds, provided approximately 43 percent of the total support for family planning services. In a review of funding for family planning services in three States (Georgia, Tennessee, and New York) for the period 1973-1978, the Title X contribution changed from 81.8 percent of total support in 1973 to 45.7 percent in 1978.

Improvements in project efficiency and improvements in direct client billing practices may provide more State, local and direct payments for services. These improvements would further reduce reliance on grant support.

NATIONAL HEALTH SERVICE CORPS GROWTH

Question: I note you are proposing significant increases for the National Health Service Corps. You received $79.4 million under the Continuing Resolution, the Carter budget seeks to increase this to $91.2 million in the current fiscal year and go to $123.8 million in FY 1982. In addition, the budget requests a $180 million advance in the 1982 bill for use in fiscal year 1983. What is your authority for requesting funds for fiscal years 1982 and 1983 for the NHSC?

Answer: The 1982 revised budget request of the Reagan Administration does not propose advanced budget authority for the NHSC for 1983. The current Administration will submit proposed extension legislative authority to support the 1982 budget request.

Question: What field strength do you propose for the NHSC under the Carter budget proposals?

Answer: In the Carter budget request, the field strength proposed was 2,660 assignees in 1981 and 3,569 in 1982. The revised budget requests of the Reagan Administration propose 2,060 assignees in 1981 and 2,500 in 1982.

Question: If you don't get the funding levels you seek, how many medical students with service obligations will escape the service requirement? And...how many volunteers would you lose?

Answer: The current 1981 and 1982 budget requests for the NHSC require the program to examine options designed to avoid releasing scholarship recipients from service requirements. Among such options are not permitting people now in the NHSC to extend their service beyond their current period of employment, as well as increased emphasis on the Private Practice Option by expanding areas of participation. Reductions below the current budget requests for 1981 and 1982 also would require the program to seek alternative service for scholarship obligees with other government departments and agencies.

The implementation of the option to prevent volunteers from extending in the NHSC in order to identify places for obligated scholarship recipients would reduce the volunteer Corps participation over the next two years. The specific number, if any, is impossible to project because it is unclear as to how many scholarship recipients will apply for the Private Practice Option, thereby leaving slots open for volunteers.

Question: If you do not get sufficient funds for placing all scholarship recipients available for service, what strategies have you developed to assure the placement of as many as possible -- or relieving some of their service obligations?

Answer: The program is considering several options to place all scholarship recipients available for service. Among these are not permitting those presently on duty to extend their period of service as well as expansion of the Private Practice Option, and alternative service with other government departments and agencies.

Question: Why does your advance request of $180 million for 1983 more than double the NHSC level of $79 million under the Second Continuing Resolution?

Answer: The 1982 revised budget request of the Reagan Administration does not propose advanced budget authority for the NHSC for 1983.

NHSC ASSIGNEE REQUIREMENTS

Question: We understand that current projections are for the National Health Service Corps to grow from 2,060 at present to around 11,000 by 1990. If true, how does that estimate compare with the number of NHSC assignees needed by 1990?

Answer: The Carter Administration's "Report on the Plan for the Future of the National Health Service Corps" was submitted to the Congress in October, 1980. The Plan included a projected NHSC field strength of 9,049 primary care providers in 1990.

At the present time, projections of health services needs are under review. The role of the NHSC in meeting those needs will be determined after these reassessments are completed.

Question: Even if new awards were stopped today, what level of field strength would the NHSC reach by 1990?

Answer: The revised budget request of the Reagan Administration for the NHSC scholarship program proposes that no new awards be made in fiscal years 1981 and 1982. Assuming the last new scholarship awards were made in 1980, the Private Practice Option becomes fully operational, the NHSC places no new volunteers and does not allow assignees to extend beyond their obligated service, by 1990, the NHSC scholarship field strength would be at an approximate level of 600 to 700 assignees.

Question: To what extent are physicians locating voluntarily in smaller communities and thereby reducing the shortage of primary care doctors in those places?

Answer: The Rand Study suggests that between 1960 and 1977, as the number of board-certified specialists tripled, there was a

diffusion of these specialists (internal medicine, surgery, pediatrics, OB-GYN, radiology and urology) to towns with populations of 5,000 and above. At the same time, there has been a 16 percent gain in the total physician/population ratio in non-metropolitan areas of the United States.

In a paper titled "Location Pattern of Recent Physician Settlers in Rural America" (Mathison and Combs), of 951 primary care physicians that settled in the most rural communities (10,000 or less) between 1973 and 1976, most located in towns where there was already a medical community. They did not tend to choose to be the only physician in town. Two-thirds of the 951 physicians settling in towns of 10,000 or less chose places where four or more physicians were in practice.

In summary, it could be expected that as the physician supply increases, specialists will tend to locate in smaller communities of 5,000 and above. However, there is no evidence to indicate that primary care physicians will voluntarily locate in a community of 5,000 or below having no existing medical practices.

Question: Isn't it possible that those awarded scholarships at this time won't help the doctor shortage in small towns because the problem will have been substantially resolved by the time they are available for service?

Answer: The Reagan budget proposes that no new scholarships be awarded in fiscal years 1981 and 1982. One of the major factors underpinning this decision involves recent studies that indicate the U.S. physician supply is increasing and that distribution of physicians to small towns is improving. The supply of health professionals to serve in the most critically underserved areas through the National Health Service Corps is adequate for the immediate future.

REAGAN BUDGET CUTS

Question: The newspapers have carried reports indicating the Reagan Administration is planning to cut back the National Health Service Corps and to eliminate the Public Health Service Hospitals. Please explain the rationale behind these cuts as well as their impact on beneficiaries of both programs. The two programs do provide some services needed by beneficiaries of both. How do you propose to continue to provide essential services if the cuts do take place?

Answer: The NHSC field strength is proposed at a level of 2,500 assignees in the 1982 Reagan budget. In addition, it is expected that a significant number of NHSC scholarship recipients will opt to practice in shortage areas in private settings and this will extend service capacity as well.

The rationale for eliminating the PHS Hospitals and Clinics system is based on:

1) The merchant seamen entitlement to free medical care at public expense is inequitable and unwarranted. This population includes tugboat operators, offshore drilling crewmen, as well as oceangoing seamen. There is little justification why the Federal government should provide free care for these selected occupations;

2) Once entitlement to medical care for the merchant seamen is discontinued, there is no reason for continued Department of Health and Human Services' support for the PHS Hospitals and Clinics system.

With regard to providing essential services to the individuals currently receiving care in the system, the following are proposed by the Reagan Administration's budget requests:

1) In 1982, eligible Federal beneficiaries and other individuals (section 327A agreements) will be provided health care by contract care, or, should communities assume control of the hospitals, through the new locally controlled and operated facilities on a billable basis.

2) Beginning in 1983, the responsibility for providing health care to non-PHS Federal employees (active duty members of the Coast Guard, commissioned officers of the National Oceanic and Atmospheric Administration, etc.) will be turned over to their employing agencies.

Question: According to newspaper reports, a number of the programs in HSA may be put in block grants minus about 20 percent of their current funding level. What would happen to the HSA programs under this circumstance?

Answer: The Reagan budget for 1982 proposes to fund the block grants at approximately 75 percent of the current services level for the programs which would be consolidated into block grants. Savings realized through the elimination of duplication in activities and administration and reductions achieved through the deletion of unnecessary administrative requirements would make possible significant cost savings.

Question: To what extent would the problems these programs are designed to serve no longer be dealt with?

Answer: The 1982 revised budget of the Reagan Administration proposes to provide States with sufficient resources and appropriate control of those resources so that the critical health services to the most needy will continue.

PHS HOSPITALS -- FINDING AN ALTERNATIVE

Question: Would you comment on the proposition that there ought to be a less expensive way for the Federal Government to provide health care to merchant seamen than by maintaining Public Health Service Hospitals with their large staffs?

Answer: Although the Department has explored other ways to provide care to merchant seafarers and has been unable to identify less expensive alternatives than the present system, the merchant seamen's entitlement to free medical care at public expense is inequitable and unwarranted. There is little justification for the Federal government to provide free care for these individuals.

Therefore, the 1982 revised budget request of the Reagan Administration proposes language disentitling the merchant seamen, effective October 1, 1981.

Question: What studies have you done on the difference in cost between maintaining the eight PHS hospitals and providing care by contract? What do such studies show?

Answer: Costs in PHS facilities as compared with the private sector have been studied both formally and informally since 1973. A study performed by GEOMET, Inc., in 1974 revealed that the cost per case admitted to a sample of PHS hospitals ranged from 33 to 49 percent below the cost of comparable cases admitted to a matched sample of private, voluntary hospitals, in spite of an average shorter stay in the latter facilities (GEOMET Report No. HF-497, September 16, 1975: "Public Health Service Hospitals: An Approach to Service and Cost Comparisons.")

In the Senate budget hearings for 1980, then Secretary Califano proposed to conduct a comprehensive and systemmatic cost-benefit study on the direct provision of inpatient services. The information contained 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. A contract for the study was awarded in the fall of 1979 to Abt Associates of Cambridge, Massachusetts. It is anticipated that the study findings will be completed and reported to the Secretary in the next few months.

The question of cost comparison has proven to be quite complex throughout the industry, varying with the size and character of the institution, the case mix, the level of technology, and training programs offered. The earlier studies suggested that PHS had somewhat lower costs than their counterparts. These differences were ascribed to the lack of a financial incentive to the PHS to provide services not medically justified, to somewhat lower rate of capital investment in PHS facilities, and to noncomparable methodologies of evaluation, such as not including capital costs in PHS hospital costs. Further information may be available following completion of the Abt study.

Question: Don't you plan to eliminate inpatient services at the Boston PHS hospital and turn this over to contract care?

Answer: The Carter Administration's budget request for 1982 did propose the elimination of acute inpatient services at the Boston Hospital.

The 1982 revised budget request of the Reagan Administration proposes the elimination of Department of Health and Human Services' support for the PHS Hospital and Clinic system in its entirety in fiscal year 1982.

Question: Why do you propose this?

Answer: The basis for eliminating acute inpatient services at the Boston hospital is:

1) It has the lowest number of inpatient days and smallest percentage of primary beneficiaries of any hospital in the PHS system.

2) Although fully conforming to JCAH requirements, the facility would require significant renovations to be aligned with the

new mission of the system as well as to achieve current standards applicable to health care institutions.

3) The Boston area currently has a surplus of more than 800 acute medical/surgical beds.

4) The lack of critical mass of inpatients could have a serious detrimental impact on the quality and safety of the patient care program at the Boston hospital.

The reason the Reagan Administration proposes closure of the entire PHS Hospital and Clinic system follows:

1) The merchant seamen entitlement to free medical care at public expense is inequitable and unwarranted. This population includes tugboat operators, offshore drilling crewmen, as well as oceangoing seamen. There is little justification why the Federal government should provide free care for these selected occupations.

2) Once entitlement to medical care for the merchant seamen is discontinued there is no economical reason for keeping the PHS Hospitals and Clinics system.

Question: Will you actually shut down the old hospital itself?

Answer: Under the Carter budget, the plan called for the Boston hospital to be operated as an outpatient clinic beginning in 1982 rather than to be completely closed. Phasedown and conversion activities would require the consolidation of ambulatory care activities in the main hospital building and the closure of unneeded areas to reduce upkeep costs. Support building housing the warehouse, boiler plant, and maintenance shops would also be retained, but consideration would be given to disposing of the remaining buildings on the station.

The Reagan Administration's proposal will allow States or communities to assume fiscal and operating responsibility for the hospitals or clinics within the PHS Hospitals and Clinics system.

Question: Why should these hospitals provide services to Defense and Commerce Department personnel?

Answer: Members of the National Oceanic and Atmospheric Administration (NOAA) who are part of the Department of Commerce have a statutory entitlement to health care from the PHS based on 42 USC 253 which was enacted in 1919. NOAA personnel are classified as primary beneficiaries of the system who, together with merchant seafarers, commissioned officers of the Public Health Service (PHS) and United States Coast Guard, and members of the National Ocean Survey, have first claim on services within the system.

The PHS hospitals and clinics have provided services to Department of Defense (DoD) beneficiaries since enactment of the Defense Medical Care Act of 1956 (10 USC 1074 and 1077), which designated PHS facilities as uniformed service facilities. Active duty and retired members of the DoD and their eligible dependents are classified as secondary beneficiaries of the system. These persons receive care on a space-available basis and the PHS is reimbursed at the OMB rate by the sponsoring Armed Service for care provided. By law, retired members and dependents are required to

obtain inpatient care and obstetrical ambulatory care from a uniformed service facility if such a facility is located within forty miles of their place of residence unless granted a certificate of nonavailability by the hospital. Active duty members, who constitute less than 10 percent of the DoD workload in PHS facilities are required to obtain all care from uniformed service facilities if available.

Under the Reagan Administration's 1982 revised budget, the health care provided to non-PHS Federal employees (active duty members of the Coast Guard, commissioned officers of the National Oceanic and Atmospheric Administration, etc.) will become the responsibility of their employing agency beginning in 1983.

Question: Are there reimbursements for these services? How much?

Answer: The PHS is not reimbursed for services provided to primary beneficiaries, which include members of NOAA. The PHS is reimbursed by the Department of Defense; during 1980, DoD reimbursements were $45.6 million.

HEALTH PROFESSIONS STUDENT LOANS -- PROPOSAL FOR TERMINATION

Question: What is your rationale for proposing to terminate the Health Professions Student Loans program in 1981?

Answer: The Reagan budget proposal, as well as the Carter budget, proposes the termination of the Health Professions Student Loans program in 1981. This termination is proposed consistent with efforts to remove incentives for unwarranted growth in the aggregate supply of health professionals and target limited resources to programs directed toward addressing high priority health professions training, supply, and distribution problems.

Question: How does the cost of a student loan compare with the cost of a Health Education Assistance (HEAL) loan?

Answer: The HEAL loan is comparatively at a higher cost for the student and at a lower cost for the government because the private lenders who make the loans charge interest at current market rates and the loan interest rate on the health Professions Student Loans is held at 7 percent. The latter are in effect loans subsidized by the Federal Government.

Question: What would be the cost to a student of a HEAL loan over 4 years of medical school?

Answer: Assuming an interest rate of 15 percent, the estimated amount a HEAL borrower would owe at the end of four years is $50,000 principal and $27,261 interest, for a total of $67,261.

Question: What is the difference in cost of these loans to the Federal Government?

Answer: The HEAL borrower pays all interest at the current market rate (Treasury bill from the time the loan is made until it is repaid in full plus 3-1/2 percent). The Government pays no part of the cost of borrowing at any time.

The Health Professions Student Loan borrower pays no interest while in school or in deferment or during the one-year grace period. The borrower pays 7 percent interest after the repayment period begins. The Government, in effect, pays all interest on the loan at its own cost of borrowing before the repayment period begins, and the difference between 7 percent and its cost of borrowing during the repayment period.

If the Government's cost of borrowing is measured by the auction price of 13-week Treasury Bill, it is currently paying more than 15 percent to borrow the money for the Health Professions Student Loan program. Therefore, the Government's current cost for the loans under the Health Professions Student Loan program is 15 percent for those loans not yet in repayment and 8 percent (15 percent minus 7 percent) for the loans under the Health Professions Student Loan program that are in repayment.

Question: How successful has the HEAL program been in attracting applicants?

Answer: The HEAL program has made 3,572 loans in fiscal year 1980. Over 32 lender applicants have signed agreements to participate in the HEAL program.

NURSING LOANS -- PROPOSAL TO TERMINATE

Question: The Carter budget proposes to terminate Nursing Student Loans in the face of a number of private studies showing a continuing shortage of nurses. How do you justify this proposal in light of such evidence as well as the bounties some hospitals are offering to get registered nurses onto their staff?

Answer: The Reagan budget, as well as the Carter budget, proposes termination of the Nursing Student Loans. Direct nurse student assistance is being discontinued because of the apparent adequacy of training capacity of nursing educational institutions. Concern is shifting to problems related to the distribution and retention of trained nurses.

The Department is currently involved in a study, authorized by Congress and scheduled for completion in 1983, which has an one of its major areas of focus the problem of retention of nurses. The supply appears adequate and Federal subsidies are not required to increase that supply.

Question: You propose that student nurses resort instead to Federal grants and loans to finance their education. Aren't these programs already heavily subscribed and costing the government huge amounts of money?

Answer: Both the Carter and the Reagan Administration's budget proposals have requested the termination of direct nurse student assistance because the more serious problems of nursing profession retention and distribution must be dealt with and educational capacity is adequate.

Question: What is the Department doing about the basic problems underlying the nurse shortage -- low salaries and poor working conditions -- for example?

Answer: The Department is currently supporting a study with the Institute of Medicine which will examine several issues associated with the nursing profession. A major area of study will involve the problem of nurse retention and how low salaries and poor working conditions, where they exist, can be improved. The study was authorized by the Congress and is now in the initial stages of development. It is scheduled for completion in 1983.

NURSING SCHOLARSHIPS TO BE "ZEROED"

Question: Why do you propose to terminate the Nursing Scholarship program with a $9 million rescission in fiscal year 1981?

Answer: The nurse scholarship program is direct student assistance which does not address the more serious post-educational problems of retention and distribution of nurses within the profession.

Question: You suggest instead that nurses turn to the National Health Service Scholarship program which the Carter budget proposes to reduce by $10 million in 1982, leading to fewer nursing scholarships in 1982 than previous years. How do you explain this?

Answer: The 1982 revised budget of the Reagan Administration proposes no new scholarships in fiscal years 1981 and 1982. There is sufficient educational capacity to train nurses.

Question: To what extent are nursing students in special need of scholarship and loan support?

Answer: Over 51 percent of all nursing students receiving nursing student loans and nursing student scholarships are from families with annual income levels at or below $7,500. The nursing student loan recipients represent approximately 7.5 percent of the eligible enrollment in nursing schools while nursing scholarship recipients represent 3.5 percent of eligible enrollment in nursing schools. It is estimated that from 10 to 11 percent of the eligible students enrolled in nursing education programs benefit from the present Nursing Student Loan and Nursing Scholarship programs. Nursing students may benefit from both programs simultaneously.

Question: What help do nursing students get from the States?

Answer: The Department's coordinated two-year study with the National Academy of Sciences' Institute of Medicine will review several issues associated with the nursing professions including the availability of other sources of support for nursing education under State and other public and private sources.

Support for nursing students by individual States does not appear to be very extensive. Moreover, precise data on this subject is quite limited. The Education Commission of the States (ECS), in their publication "Higher Education in the States," published the following information as of January 1, 1979:

Alabama	$10,000 in scholarships for RN students.
California	$2.6 million distributed between family medicine residencies, physician assistants and nurse practitioners.

Louisiana	$200,000 for stipends to nursing faculty to pursue advanced degrees in nursing or related fields.
Massachusetts	$500,000 for scholarships for medical, dental and nursing scholarships.
Minnesota	$155,000 for programs of grants to students enrolled in nursing education programs.
Mississippi	$100,000 for nursing students working on bachelors or master's degrees.
North Carolina	$578,650 to students in hospital diploma nursing programs.
North Dakota	$65,000 for loan forgiveness programs for RN students.
Rhode Island	$52,500 for nursing scholarships.
Virginia	$234,000 for service scholarship program distributed between nursing and dental hygiene students.
TOTAL	$4,725,350

It should be understood that the above estimate is not totally for nursing. Some of the figures are for students in nursing as well as other fields. While the ECS figures focus primarily on State support of private education, some of these figures include public education as well. One can assume, however, that there is probably a small amount of additional State support for nursing students not included in the above figures.

Question: Why don't the States do more to solve their own nurse shortage problem?

Answer: The Department's coordinated two-year study with the National Academy of Sciences' Institute of Medicine will review several issues associated with the nursing professions, including the availability of other sources of support for nursing education under State and other public and private sources. It also will focus on the critical questions surrounding the retention of nurses in the work force.

PROGRAM SUPPORT - STUDENT PROGRAMS

Question: How does your "Program Management" function at a projected cost of $6.6 million differ from "Program Support"?

Answer: The Program Management activity encompasses the Office of the Administrator, Health Services Administration (HSA), and various staff functions for the Office of the Administrator and support functions for the four Bureaus of HSA. These HSA consolidated support functions include personnel management and contracts management.

The Bureaus' program support activities provide program direction and administration and other management support for the

various programs administered by the Bureaus. Because of the programmatic differences of the programs administered by the Bureaus, each of the Bureau's has a separate program support activity.

The $6.6 million was the Carter budget request for Program Management in 1982; the 1982 revised budget request of the Reagan Administration proposes a Program Management level of $4,692,000, which is the amount required to support program management activities associated with the programs to be administered in 1982.

STATUS OF EMERGENCY MEDICAL SERVICES (EMS) PROGRAMS

Question: Why should the Federal Government continue to support this program now that it is off the ground? Why can't the States take it over if it is so important to them?

Answer: States will have that flexibility under the consolidated Health Care Block Grant to States proposal of the Reagan Administration.

HURA REPROGRAMMING

Question: It's my understanding that you have withdrawn the request to reprogram $6.5 million from the old HURA program to the National Health Service Corps. If you were able to retain these funds, what would you do with them?

Answer: The reprogramming request was withdrawn. However, the Reagan Administration's revised 1981 budget request for the Primary Care Research and Demonstration program (formerly titled HURA) requests a rescission of $6,524,000.

The remaining $476,000 of the $7 million 1981 Continuing Resolution level for PCR&D will be used to support 4 projects. The funds were obligated prior to the decision to rescind funding for this program.

Question: What have we learned from the various HURA projects?

Answer: Through the HURA experience and from early Primary Care Research and Demonstration projects, we have learned that:

1) Solutions to the barriers of bringing basic health care to underserved areas lie in the broad issues of coordinating and distributing existing resources. Central to these issues is collaboration among private sector, State and Federal resources. These partnerships can provide the continuity essential to bringing primary care to underserved populations.

2) Physicians can be attracted to rural areas and existing practices can be strengthened if the resources from medical schools, medical centers and community hospitals are made available to rural isolated practices.
3) Central management organizations which provide development and clinical support can provide independent, financially viable rural practices.
4) Mobile vans are not suitable as a regular source of care. They are effective for screening services, for market assessment, or for temporary use until a permanent clinic is built or renovated.

5) Both improved health status and cost-effective care can be achieved through available preventive and primary health care. But financial disincentives both to physicians and to patients under existing reimbursement policies impede major progress in this area.

6) Automated health information systems can increase efficiency and quality of care in rural medical clinics. If properly tailored to the size and type of medical setting, they are cost effective.

HOSPITAL-AFFILIATED CENTERS

Question: How much is available for rescission?

Answer: The 1981 Continuing Resolution provides $1 million, the same level as 1980, for the Hospital-Affiliated Primary Care Centers. Neither the Carter nor the Reagan Administration propose rescission of this amount.

MATERNAL AND CHILD HEALTH (MCH)

Question: What types of research and training activities will be funded?

Answer: The 1982 revised budget request of the Reagan Administration proposes termination of the Maternal and Child Health Research and Training programs.

Question: What new research funding is being planned?

Answer: Because no funding is requested for 1982, no research efforts are planned for the MCH research program.

NATIONAL HEALTH SERVICE CORPS

Question: The Carter budget requests a substantial increase for the National Health Service Corps, boosting the supply of doctors, even as it proposes to reduce National Health Service Corps Scholarships by $10 million; to terminate Health Professions Student Loans, and to terminate health professions capitation. Would you please explain this seeming contradiction in HHS' approach to dealing with the physician supply?

Answer: As a result of government assistance to medical education during the past 20 years, the number of medical schools, students and physicians has increased many fold. Recent studies and reports such as that of the Graduate Medical Education National Advisory Committee indicate that the supply of U.S. physicians may be adequate to meet overall American needs.

Despite the increase in net physician numbers, the problem of physician maldistribution still remains. For that reason the Carter, as well as the Reagan Administration's, budget requests an increase in 1982 to carry out the NHSC function of redistributing health manpower.

Question: If you plan to reduce or terminate assistance for medical education, why not reduce or eliminate growth in the National Health Service Corps program?

Answer: Medical education deals with the issues of physician supply and training. The NHSC deals with the problem of redistribution of physician manpower. The maldistribution of physician manpower persists despite the increase in absolute numbers of physicians.

Question: If the States feel they need NHSC doctors, why not put the burden on them to recommend -- and -- fund candidates for the program?

Answer: Thirty-one States presently have some form of limited State educational service conditional support programs for medical students. These programs alone cannot alleviate maldistribution problems although they help in retaining physicians, at least for limited times within the State. However, most State-based programs, at this time, do not attempt to place recipients in the highest areas of need.

Because there is an uneven geographical distribution of medical schools and postgraduate training programs throughout the country, many States find it difficult to attract enough physicians to their underserved areas through their own State-based programs.

The National Health Service Corps plans to continue and to expand cooperation with all State-based programs.

Question: What are your existing and planned assignee retention and extension rates?

Answer: The following table provides NHSC retention rates from 1976 through 1980:

	1976	1977	1978	1979	1980
Conversion to Private Practice	2%	2%	3%	9%	12%
Extension with NHSC	27%	27%	27%	35%	42%

It is not possible to project the 1981 retention rate because we are discouraging extension with the NHSC in an effort to achieve ceiling limits established under the continuing resolution and the current budget request.

HEALTH PROFESSIONS LOAN REPAYMENT

Question: Why does the Carter budget propose to increase the Health Professions Loan Repayment and Cancellation program by $4 million in fiscal year 1981?

Answer: The Carter budget proposed to fund 726 applications (which were received prior to the phase out of this program on July 30, 1979) in a single fiscal year, i.e., 1981. The 1981 and 1982 revised budget requests of the Reagan Administration propose to permit the program to buy out a backlog of 726 applications now on hand during a two-year, 1981 and 1982, budget period.

NURSING LOAN REPAYMENT AND CANCELLATION

Question: The Carter budget proposes to increase funding for the Nurse Loan Repayment and Cancellation program while other

student nursing programs are being reduced or terminated. I note this program provides assistance in return for service in a shortage area. If we wanted to help nursing students get their education and deal with the shortage of nurses, why not put more money into this program?

Answer: The Reagan, as well as the Carter, budget proposes to increase the program from $750,000 in 1981 to $1 million in 1982. It is expected that $1 million would continue to fund 750 loan cancellation reimbursements to the nursing schools which is mandated by law.

Question: Why hasn't the program attracted more people (111 served since 1975)? Do you make its existence known?

Answer: The Loan Repayment program has not been utilized as much as the Loan Cancellation program for nurses. Nurses have been able to have their Nursing Student Loans cancelled by working full-time as registered nurses in any public or non-profit private agency, institution, or organization. As a matter of fact, more nurses are working in settings that tend to qualify them for cancellation of their loans. The Loan Repayment program provides for a minimum of two years of service in a shortage area.

The program is covered in our program guidelines, as well as in our exit interview brochure provided to all our participating nurse programs.

NHSC SCHOLARSHIPS

Question: For purposes of selecting students with firm career commitments to serve in health manpower shortage areas, explain why the Department wouldn't be in a better position to select such students after they enter their second or third years of study?

Answer: The revised budget request of the Reagan Administration proposes that no new scholarship awards be made in fiscal years 1981 and 1982. The Department is currently assessing future health manpower needs and various alternatives to meet these needs.

Question: To what extent would program expenditures be contained by this procedure?

Answer: If the scholarship program were to make awards only to students in their second or third year of medical school, at approximately an equal number of awards per class, the total program costs for producing health providers for service would initially be reduced.

However, in the long term, because years of service in the NHSC are equated to years of support under the scholarship program, some of these cost advantages would be lessened.

PHS HOSPITALS -- EXCEPTION TO 1976 LAW

Question: The Carter budget proposes bill language to permit the PHS Hospitals and Clinics to operate at a level of $172.1 million. What is the purpose of this language?

Answer: The Carter Administration's proposed language would have allowed the Public Health Service hospital and clinic system to

operate at a level lower than that currently required by section 818 of P.L. 95-155 which stipulates that services will be maintained at the level provided on January 1, 1978. Specifically, the change was requested to permit the elimination of acute inpatient services at Boston.

The 1981 and 1982 revised budget requests of the Reagan Administration assumes Congressional passage of appropriations language changing the manner in which services are provided at PHS hospitals effective approximately July 1, 1981, in order to allow the system to phase down operations in preparation for the elimination of Department of Health and Human Services' support; and language disentitling merchant seamen, effective October 1, 1981.

Question: Will it result in a reduction of services from the required 1978 level?

Answer: The Carter Administration's budget request proposed the elimination of acute inpatient services at the Boston PHS hospital and the provision of necessary services through contract care. While the level of service would not change, the manner in which they would have been provided would change and that required bill language.

The language proposed by the Reagan Administration will allow the elimination of Department of Health and Human Services' support for the PHS Hospitals and Clinics System and the discontinuation of free medical care to merchant seamen.

Question: Why can't you operate at the FY 1981 Continuing Resolution rate of $167.4 million and save $4.7 million?

Answer: The Carter Administration's request of $172.1 million in 1982 included certain uncontrollable mandatory increases such as continued funding of the October 1980 pay raise, rental increases, and increased costs for items such as fuel, electricity and drugs.

GAP BETWEEN BUDGET AUTHORITY AND OBLIGATIONS

Question: In fiscal year 1982 you request $172.1 million in budget authority for PHS Hospitals, but you plan to spend $234.8 million, a difference of $62.7 million. What accounts for the large difference between request and obligations?

Answer: The $234.8 million represents total obligations under the Carter Administration's budget request. Under this request, the total budget authority requested for the hospitals and clinics system was $172.1 million. Together with an estimated $62.7 million in reimbursements earned by this activity for services rendered to other than our statutory beneficiaries, the total obligations would have been $234.8 million.

Question: What then is your carry-in amount from fiscal 1981?

Answer: There were to be no funds carried over into fiscal year 1982. All funds appropriated for operations in 1981 would have been used during that year. Unobligated funds would have been returned to the Treasury as statutory limitations prohibit carrying over operational funds from one year to the next.

Question: What further reductions in operating bed capacity are planned?

Answer: The 1982 revised budget request of the Reagan Administration proposes the elimination of Department of Health and Human Services' funding for the entire PHS Hospitals and Clinics system. Communities or other governmental entities may decide to take over some or all of the facilities.

PAYMENTS TO HAWAII

Question: With the average daily patient load and patient days going down, why does the Carter budget request a $169,000 increase in the proposed payment to Hawaii for care and treatment of leprosy victims?

Answer: The increase represents an allowance for inflation only. The request of $1,969,000 represents approximately 74 percent of the anticipated total cost for this program to the State of Hawaii. This would maintain the 1981 Federal level of support of the total amount required.

HEALTH SERVICES ADMINISTRATION PROGRAM SUPPORT

Question: What accounts for the $962,000 increase you request for such areas as service and supply, Federal Telecommunications Systems, postage, etc.?

Answer: The $962,000 represented the mandatory increases for the Bureau of Community Health Services (BCHS) program support activity requested in the Carter Administration's budget request for 1982.

However, no funds are requested in the 1982 revised budget of the Reagan Administration for BCHS program support because of the proposed consolidation of the BCHS categorical programs into block grants to the States.

Question: Why couldn't you get along without this increase?

Answer: This increase proposed by the Carter Administration reflected a real operational cost resulting from inflation.

NHSC SCHOLARSHIPS

Question: The Senate health manpower bill, S. 2375, proposed a State scholarship program intended to encourage the States to meet their own needs for health professionals in shortage areas within their boundaries. To what extent should the National Health Service Corps scholarship program be a State effort and responsibility?

Answer: State-operated programs are not without positive features. They can tailor their awardee selection methods and criteria to best match the personal and educational characteristics of applicants to specific needs within their areas. They may also be more accommodating to the career goals and family, educational, and employment requirements of scholarship recipients. However, many States have insufficient funds for support of service agreements to satisfy their shortage area needs. In addition, States without medical schools might have difficulty in obtaining physicians to serve in underserved areas within their shortage

communities. Programs that are operated exclusively by the States would lose the national focus for maintaining a balance of placements of health care providers into shortage areas based on priority needs. The Federal government would continue to provide health manpower for Federal prisons and Indian reservations.

Question: Aren't the States a more appropriate focus for determining special health manpower needs?

Answer: States have considerable effect on determining shortage areas and practitioner types via their State health planning and development agencies, State health coordinating councils, and health systems agencies. These organizations provide data which contribute to Federal determinations of shortage areas. These State-level recommendations are made in liaison with State Governors' offices, State and county medical societies, and other interested groups that reflect local health care needs.

Question: What evidence do you have that States could be expected to assume a service-scholarship program effort?

Answer: Thirty-one States now operate some form of support for service or support for enrollment-type programs. Federal funding could expand these efforts and provide incentives for starting up other such programs. Because of lack of resources or lack of commitment, some States could not be expected to participate. Many of these States have high priority needs for health care providers. In such States, the National Health Service Corps would need to maintain its activities.

Question: Is Federal funding required to encourage States to establish and operate service-scholarship programs?

Answer: Where resources and commitments are strong, Federal funding is probably not required. In States with commitments to meeting health care needs, but with limited resources, Federal funding would enrich these efforts. In States with little commitment, Federal funds would probably not be requested.

IS THIS APPROACH JUSTIFIED?

Question: The Community Health Centers program is designed to bring health services to so-called Medically Underserved Areas (MUAs). What is HHS doing to evaluate the validity of the criteria used to designate Medically Underserved Areas?

Answer: The Department regards the Index of Medical Underservice as a valid gross screen to identify potentially Medically Underserved Areas. This perception has been confirmed by two studies (Kleinman at the National Center for Health Statistics and Aday at the University of Chicago).

After identification of an area as Medically Underserved, the Department has relied upon local and State planning processes to assure compatibility with needs and assessments contained in health systems plans.

Because this process has not worked as well as we had hoped, the Department is currently developing a methodology for assessing community-level need for primary care, to be performed as part of the grant application and review process. It will supplement the existing MUA process by providing a more detailed look at health needs and health resources, including contiguous area resources.

SUBCOMMITTEE RECESS

Senator RUDMAN. The subcommittee is going to stand in recess until 2, when we are going to hear testimony from the Center for Disease Control.

[Whereupon, at 11:50 a.m., Tuesday, February 17, the subcommittee was recessed, to reconvene at 2 p.m., this same day.]

(AFTERNOON SESSION, 2 P.M., FEBRUARY 17, 1981)

CENTERS FOR DISEASE CONTROL

STATEMENT OF DR. WILLIAM H. FOEGE, DIRECTOR

ACCOMPANIED BY:
DR. GEORGE E. HARDY, JR., ASSISTANT DIRECTOR/WASHINGTON
JAMES D. BLOOM, EXECUTIVE OFFICER
DR. ANTHONY ROBBINS, DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SCHMITT [presiding]. The subcommittee will come to order. This afternoon we will continue hearings on the budget requests for the Department of Health and Human Services. Specifically, we will consider the requests and potential amendments to the requests for the Centers for Disease Control.

As chairman of the subcommittee, I want to make it clear that over this year and in succeeding years, the subcommittee will be evaluating much of what is going on in the Center, as well as other aspects of health and human services in the context of how to reduce medical costs.

I would think it's safe to say that most people in this country expect medical costs to continue to increase, rather than decrease. I don't take that personally as an a priori condition. Clearly, basic research in preventive medicine has the opportunity to, in some areas, significantly reduce medical costs by preventing disease and injury. There is the continuing problem we will always have of bad habits in the served population; however, it doesn't mean that we can't reduce the effects of those bad habits, either because we reduce the frequency of them or because we learn to counter their effects through other initiatives.

It should be the hope of this subcommittee and the hope of the agency that we do in the long run make all medical care affordable, both by the patient and by the taxpayer. You'll note in the thrust of questions that I ask as chairman, and hopefully in the questions of other members of the subcommittee, I will ask how can we not only minimize cost in the agency's activities, but how can we strike the proper balance between activities that respond to immediate problems within the served community and problems that we know occur somewhere in the future.

Today we will consider not only appropriations and programs for fiscal 1982, but will review fiscal 1981 supplementals, rescissions, and deferrals that may be proposed as well.

Although the Reagan administration proposals are not yet before us, these hearings will provide the background necessary to evaluate those programs, and enable us to begin to establish priorities. It's conceivable at some time later this winter or spring it will be necessary to have some review of proposals from the new administration, but at this time we hope that the background the subcommittee is receiving will be sufficient.

This year we have asked the principal witnesses to highlight in their prepared statements the regulatory aspects of programs under their jurisdiction, estimating both Federal administrative costs and private-sector economic impact from complying with said regulations.

The principal witnesses have also been asked to present a brief oral summary of the programs within their jurisdictions and summarize their opening statements. The full statements will be included in the record, should they be long relative to the summary.

[The statement follows:]

Statement of Dr. William H. Foege

Mr. Chairman and Members of the Committee: I want to highlight some activities of the past year.

Newer Directions

Of particular note are those programs designed to help individuals make personal choices that can improve their health and well being or prevent specific consequences. We have assisted states in the establishment of health promotion and risk reduction programs, including specific efforts to help people avoid the problems associated with smoking and alcohol use. We have continued our diabetes community demonstration program in 20 states. The projects have been varied, but particularly noteworthy is the work that has been done tying ambulatory diabetes education and services to third party reimbursement. Another of our newer programs is directed toward the application of fluoridation to drinking water. The resultant improvement in dental health will not only save public and private dollars, it will be a significant step toward individual well-being--especially for the older generations of the future.

Nationwide Federal/State Programs

The sexually transmitted diseases continue, as a group, to be one of the major infectious disease problems facing the nation. We have been able to prevent the spread of a pencillin resistant strain of gonorrhea and there has been a slight downturn in the reported incidence of gonorrhea in the face of societal pressures that would lead one to expect continuing increases among our sexually active populations.

One of our most outstanding program accomplishments was the Childhood Immunization Initiative. Through concerted and coordinated efforts by Federal, state and local workers, record low levels of diptheria, tetanus, measles, mumps, and rubella were reported in 1980. Indeed, only a single case of childhood diptheria was reported in the entire U.S. in 1980. Diptheria was the third leading cause of premature years lost in the U.S. in 1900. Measles, which was a certainty of childhood 20 years ago, infected less than 164 children in December 1980. We have acheived 90 percent immunization levels among the nation's school children. During the past decade, there have been significant decreases in the major vaccine-preventable childhood diseases.

Environmental Health

Taking advantage of CDC's relationship with States, its experience in reacting to epidemics and disease outbreaks, and its capabilities for performing field investigations (epidemiologic and laboratory), the Centers was given lead responsibility for responding to environmental emergencies. We have developed one of the nation's foremost laboratories for identifying unknown toxic agents.

While we were involved in a number of environmental problems, the most dramatic was the volcanic eruption of Mt. St. Helens. CDC had the lead for the Department in assessing possible health problems, especially possible respiratory problems associated with the volcanic ash. CDC had public health physicians, scientists, and advisors operating on-site with backup from our laboratories in Atlanta, Cincinnati, and Morgantown.

Occupational Safety and Health

In the area of occupational health, we have doubled in two years the number of health hazard evaluations performed. Upon request from employers or employees we investigate workplace hazards and recommend specific controls. For example, a Health Hazard Evaluation at a Pennsylvania plant found workers exposed to high levels of the established carcinogenic trichloroethylene. A followup visit showed that use of the controls recommended by NIOSH reduced exposure levels below the recommended average levels.

We have also learned more about the potential hazards in the workplace that could effect the reproductive capabilities of the men and women that make up our Nation's work force. In response to inadequacies conerning personal protective equipment, we have redirected and improved our certification program.

Epidemic Services

CDC has become well known over the years for our provision of epidemic aid, and the investigation of puzzling disease problems. During the year, we responded to more than 130 epidemic investigations from headquarters and our offices in the field have been involved in more than 1,200 investigations. Of the many outbreaks investigated in 1980, perhaps the most widely known was our investigation of Toxic Shock Syndrome. In early 1980, CDC became aware, through its disease surveillance network, of an apparent increase in this syndrome. It was only after intensive investigation that it was found that the disease occurred primarily during a woman's menstrual cycle and that women who used tampons were at increased risk. When this finding was made, CDC immediately notified the Food and Drug Administration, which has regulatory authority. These two agencies working cooperatively with tampon manufacturers took the steps necessary to alert and protect our citizens.

In addition to the more glamorous disease detective work, we were also engaged in activities related to public health practice. During the year there were two scientific/technical advances worthy of special note. CDC undertook field trials of a killed virus vaccine against Hepatitis B -- the results of these trials are expected to show the vaccine to be highly effective and safe. We are now working on Hepatitis A which has been shown to be a problem in day-care centers. We are hoping that we are finally seeing a payoff for the years of research that have been devoted to this extremely serious infectious disease.

Prevention Technology

We have continued to share our practical knowledge and experience in disease prevention and control with public health workers across the country through our training efforts, our laboratory improvement program, and our hospital infections initiatives. Perhaps the most exciting aspect is our work on hybridomas. Using cloning techniques, CDC participated in the development of methods for producing highly purified antigens. The use of these systems, called hybridomas, is expected to revolutionize clinical laboratory diagnosis and may prove to be an important factor in the future development of vaccines. This technology is one of the most significant advances in laboratory science in decades. We will

share the results of our efforts with clinical laboratories across the country.

Lethal Viruses

CDC is the only civilian agency operating laboratories that are equipped to handle Class 4 agents (disease agents that are characterized as being highly infectious, deadly, and lacking in means of prevention or treatment). For example, we assisted in the handling of an outbreak of Marburg Fever in Nairobi. To strengthen our protection against possible importations of these agents, we have developed a system of quarantine, surveillance, and treatment of persons suspected of having been infected by a Class 4 agent.

Federal Regulations

CDC is primarily a service organization, therefore, most regulations developed by the Centers are required to clarify and implement assistance programs. Few are regulatory in nature.

The regulatory activities include:

1. Quarantine activities and medical examinations of aliens mandated by the Public Health Service Act.

2. Regulations relating to the interstate shipment of etiologic agents to provide safeguards to transportation personnel, the public, and the environment from exposure to infectious materials in interstate commerce.

3. Regulations pertaining to respirator and air sampling equipment require that NIOSH certify such equipment before marketing.

4. Under an Interagency Agreement between PHS and HCFA concerning clinical laboratories, development and promulgation of standards and provision of quality control for the uniformity and effectiveness of the enforcement of those standards.

5. Under the Federal Mine Safety and Health Act in 1977, assurance that all miners have an opportunity to have medical exams.

As a rule, CDC's other regulations do not impact upon the general public. They have the most direct application for agency grantees and contractors. Enforcement of grant guidelines and regulations is part of the ongoing program management carried out by project and grants management officers on a day-to-day basis. The character of this enforcement is to assure that grantees are expending Federal funds in conformance with the purpose for which they were appropriated. The amount of resources devoted to regulation activities in 1981 is: $1.4 million and 39 workyears for development, $.1 million and 4.5 workyears for promulgation, and $2 million and 60 workyears for enforcement. For 1981, the burden on the private sector is $.95 million.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control
Biographical Sketch

NAME : William H. Foege, M.D.

POSITION : Director, Centers for Disease Control

BIRTHPLACE AND DATE : Decorah, Iowa, March 12, 1936

EDUCATION : Pacific Lutheran University, 1957, B.A.
University of Washington Medical School, 1961, M.D.
Harvard University, 1965, M.P.H.

EXPERIENCE

1977-Present	Director, Centers for Disease Control, Atlanta, Georgia
1976-1977	Assistant Director for Operations, Center for Disease Control
1975-1976	Assistant to the Director, Center for Disease Control
1973-1975	Medical Officer, World Health Organization, New Delhi, India
1970-1973	Director, Smallpox Eradication Program, Center for Disease Control
1969-1970	Chief, International Branch, Smallpox Eradication Program, National Communicable Disease Center
1968-1969	Chief of Operations Area B, Nigeria, Dahomey, Togo, and Ghana, Smallpox Eradication/Measles Control Program, National Communicable Disease Center
1966-1967	Epidemiologist, Smallpox Eradication/Measles Control Program Eastern Nigeria
1965-1966	Medical Officer, Immanuel Medical Center, Yahe, Eastern Nigeria
1962-1964	Epidemic Intelligence Service, Communicable Disease Center
1961-1962	Intern, USPHS Hospital, Staten Island, New York
1967-1976	World Health Organization Consultant

TEACHING APPOINTMENTS : Visiting Lecturer on Tropical Public Health in the School of Public Health, Harvard Medical School, Boston, Massachusetts
Clinical Professor, School of Medicine, Emory University, Atlanta, Georgia

ASSOCIATION MEMBERSHIPS : American Public Health Association
Royal Society of Tropical Medicine
American Academy for the Advancement of Science
American College of Preventive Medicine

CAUSES OF YEARS OF POTENTIAL LIFE LOST U.S.A.

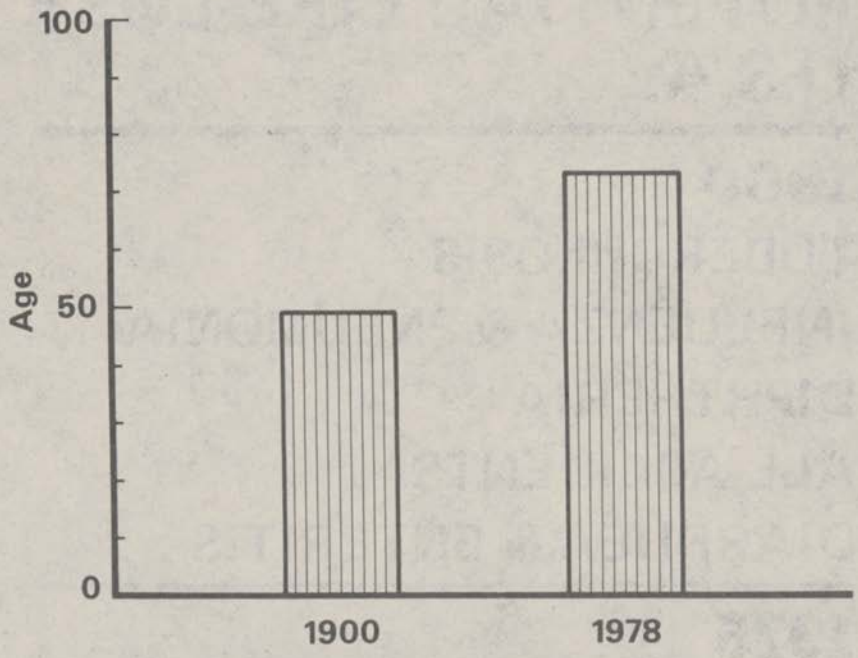
1900

TUBERCULOSIS
INFLUENZA & PNEUMONIA
DIPHTHERIA
ALL ACCIDENTS
DIARRHEA & ENTERITIS

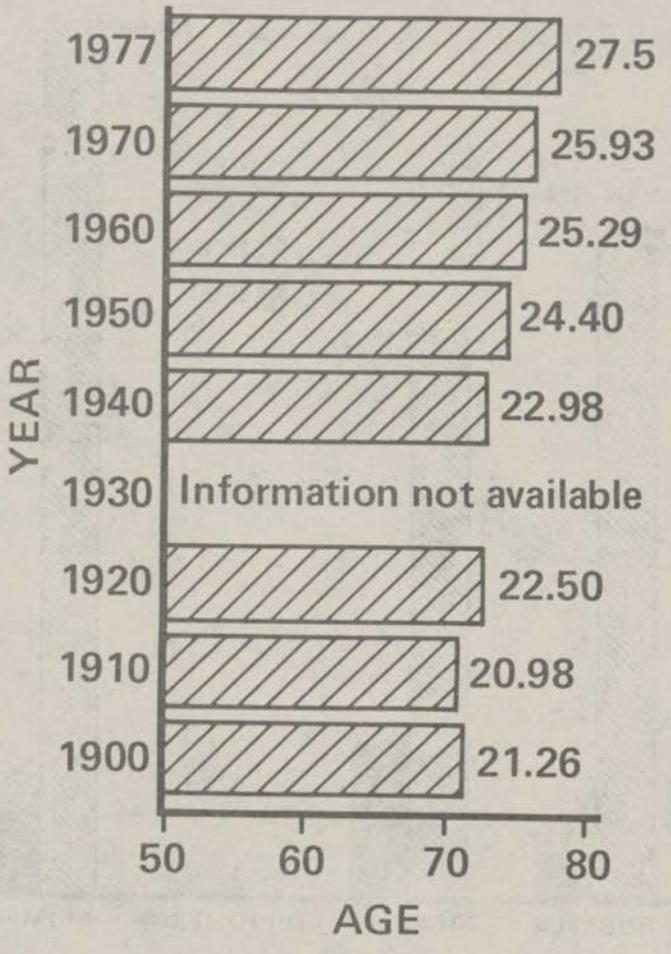
1975

ALL ACCIDENTS
CANCER
DISEASES OF HEART
HOMICIDE
SUICIDE

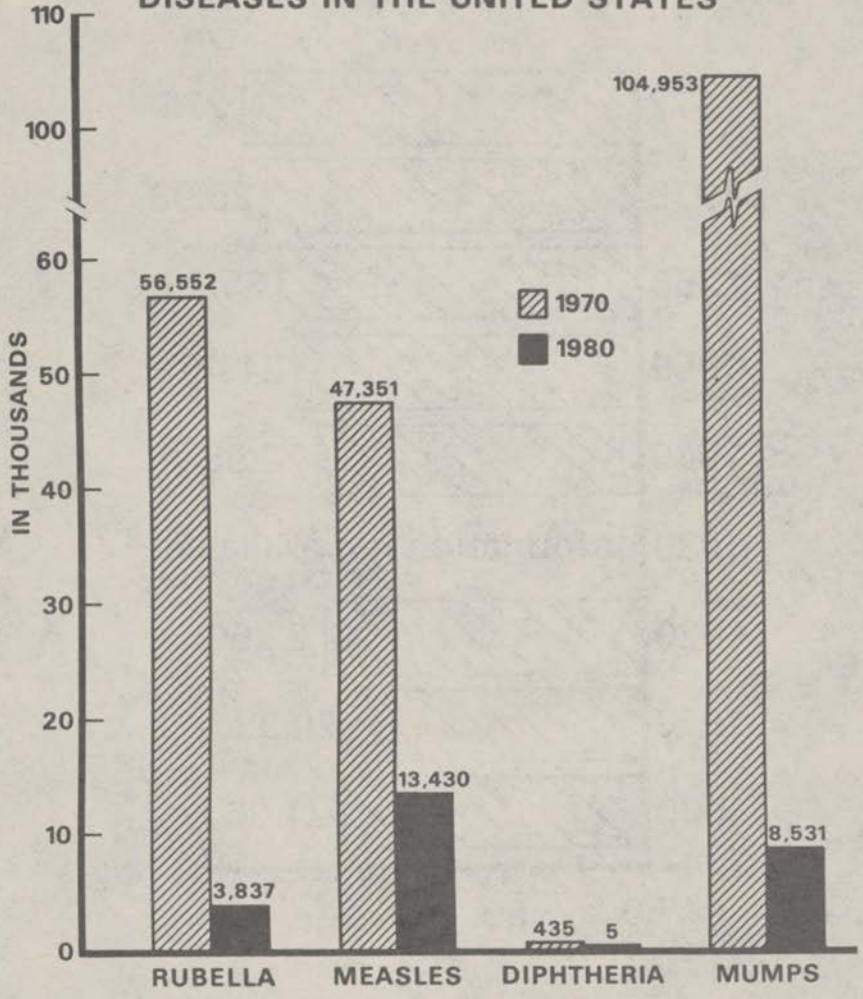
LIFE EXPECTANCY AT BIRTH



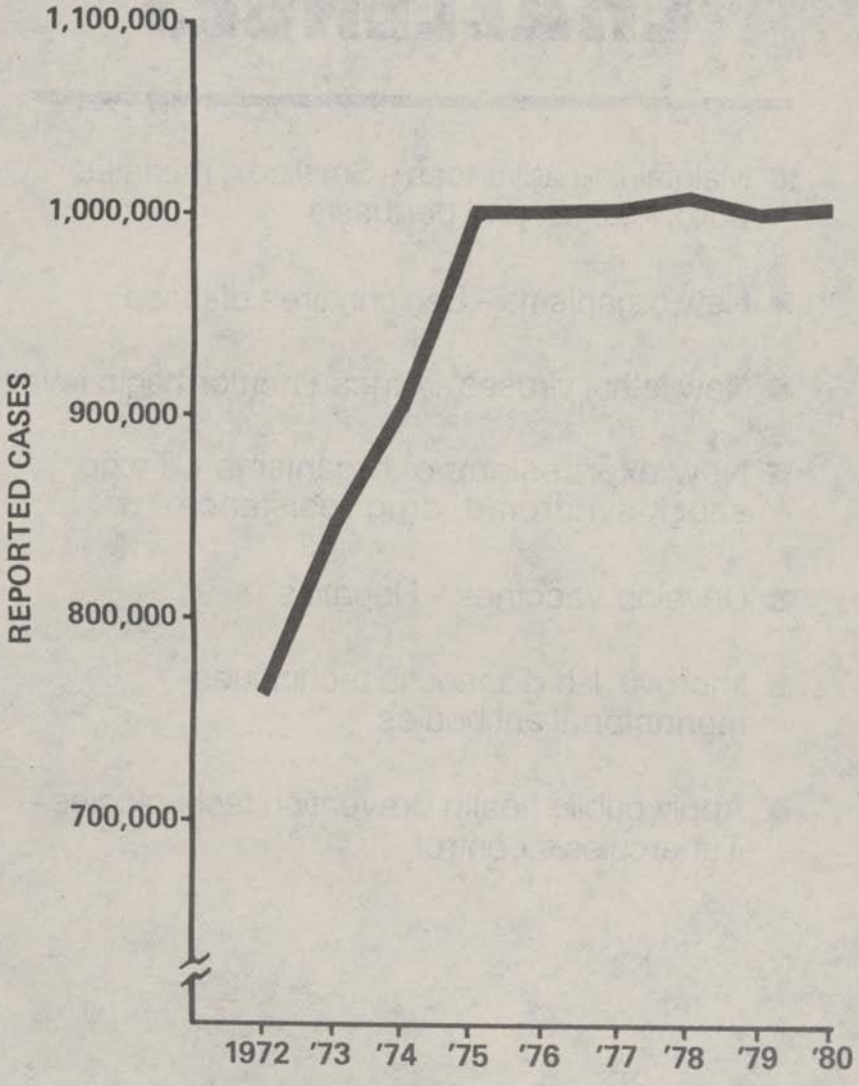
LIFE EXPECTANCY AT AGE 50



REPORTED MORBIDITY FOR SELECTED DISEASES IN THE UNITED STATES



REPORTED GONORRHEA U.S. 1972 – 1979



PROBLEMS AND CHALLENGES

- Maintaining advances - Smallpox, measles, polio, tetanus, and pertussis
- New organisms - Legionnaires disease
- New lethal viruses - African hemorrhagic fever
- New expressions of organisms - Toxic shock syndrome, drug resistance
- Develop vaccines - Hepatitis
- Improve lab diagnostic techniques- monoclonal antibodies
- Apply public health prevention technologies - Tuberculosis control

PROGRAM FUNCTIONS

- Epidemiology
- Surveillance
- Training
- Laboratory services
- Applied public health technology

OPERATIONAL FUNCTIONS

- Providing scientific/technical leadership
- Conducting applied research
- Providing technical assistance
- Providing financial assistance
- Developing voluntary standards and guidelines

CDC EMPLOYMENT

APPROXIMATELY:

- 4000 Persons
- 170 Occupations

1/2
Atlanta

1/2
Washington area

- **Field stations**
  Fort Collins, Phoenix, Anchorage, Cincinnati, Morgantown, San Juan
- **Quarantine Offices**
  Selected ports-of-entry
- **State and local health agencies**

CDC FACILITIES

Total	764,000 sq. ft.
Laboratory and special purpose	567,000 sq. ft.
Capitalization	$45,700,000

■ CDC operates the only civilian laboratory capable of handling Class 4 agents - deadly viruses and unknown disease agents

BUDGET AUTHORITY

	1980	1981
	(Amount x 1000)	
Basic Preventive Health	$91,500	$59,717
Disease Prevention	84,540	84,872
Control of Chronic Diseases	48,166	48,850
Occupational Safety and Health	80,382	81,181
Epidemic Services	28,052	29,153
Technology Development & Application	26,033	26,823
Buildings and Facilities	11,436	4,951
Program Management	3,851	3,894
Total, CDC	**373,960**	**339,441**

BUDGET AUTHORITY

Page 2. Additional Budget Activity Breakout

	1980 Rev. Approp. Comp. Amount	1981 Cont. Resol. Rev. Comp. Amount
Basic Preventive Health	$91,500,000	$59,717,000
(a) Health incentive grants	68,000,000	36,000,000
(b) Risk reduction & health education	23,500,000	23,717,000
Disease Prevention	84,540,000	84,872,000
(a) Venereal diseases	47,479,000	47,637,000
(b) Immunization	30,288,000	30,422,000
(c) Fluoridation	6,773,000	6,813,000
Control of Chronic Conditions	48,166,000	48,850,000
(a) Chronic diseases	18,184,000	19,284,000
(b) Environmental hazards:		
Urban rat control	14,517,000	13,538,000
Lead-based paint poison prev.	11,784,000	10,805,000
Other environmental hazards	3,681,000	5,223,000
Occupational Safety and Health	80,382,000	81,181,000
(a) Research	62,195,000	62,383,000
(b) Training	13,882,000	14,252,000
(c) Scientific & tech. services	4,305,000	4,546,000

OVERVIEW

Senator SCHMITT. I should add that the Secretary's overview will be deferred for a few weeks so that he can develop his own justifications for the various programs and provide any commentary that he wishes to provide on the preceding testimony.

Recognizing that there is a new administration and that there is much going on, we will be very tolerant of modifications in positions taken on the part of the Secretary.

The Director for the Center for Disease Control, Dr. Foege, is with us today. We welcome you, Doctor, and ask at this point that you introduce your colleagues to the subcommittee.

INTRODUCTION OF ASSOCIATES

Dr. FOEGE. Thank you, Mr. Chairman. On my extreme left is Dr. George Hardy, Assistant Director for CDC. Next to him is Mr. Jim Bloom, who is the Executive Officer of CDC. On my right, Dr. Tony Robbins, who is the Director for the National Institute for Occupational Safety and Health. On his right, Mr. Tony Itteilag, Acting Deputy Assistant Secretary for Budget for the Department of Health and Human Services.

Senator SCHMITT. Thank you. If you would proceed with your overview, we would appreciate it.

Dr. FOEGE. Thank you, Mr. Chairman.

CDC is charged specifically with reducing the unnecessary morbidity and premature mortality and unnecessary disability in this country. It's obviously been necessary to change our priorities over the years because of changes in the disease problems.

The Surgeon General recently, in the publication on prevention, said that we're on the brink of a second public health revolution. If we compare 1900 to 1975, it clarifies the changes in the first and second public health revolution.

In 1900, four of five principal causes of years lost before age 65 were infectious diseases. On the contrary, in 1975, there's not a single infectious disease on that list. We have accidents heading the list, cancer second, diseases of the heart third, and homicide and suicide. It's clear in retrospect that in 1900 the five leading causes were susceptible to prevention, but it appears to us that the same holds true even now, in 1975–80; that the five leading causes of years lost are amenable to prevention. The techniques will be different, however.

Senator SCHMITT. Doctor, if I could interrupt, would you supply for the record that 1975 list and update it if possible. Also indicate any changes relative to the different age groups.

Dr. FOEGE. Yes; and I should say that this is not a list of leading causes of death, but a list of years lost before age 65.

Senator SCHMITT. I understand.

Dr. FOEGE. Yes; we can provide that for you.

[CLERK'S NOTE.—The information submitted was voluminous and is being retained in the subcommittee's files.]

Senator SCHMITT. That does still relate to different age groups?

Dr. FOEGE. That's right.

BAD HABITS

Senator SCHMITT. Now, you'll find that I may be overly repetitive with my concern about the effect of bad habits. Bad habits obviously may be integrated into the cancer and heart disease equations. There are many other problems that bad habits, as we grow up and grow older, would cause years of potential life lost.

Have you ever tried to integrate those kinds of habits into this equation?

Dr. FOEGE. Indeed, if you look at three of these—accidents, homicide, and suicide—it's clear now that someplace between a third and a half of those premature deaths are related to alcohol. It's clear with cancer that a great deal of this is due to cigarette smoking. And it's clear that

with diseases of the heart, we're talking about cigarette smoking, improper diet, and insufficient exercise.

That's why we think all five of these are really susceptible to prevention techniques.

Senator SCHMITT. But as you say, a very different kind of prevention.

Dr. FOEGE. That's right.

Senator SCHMITT. What about susceptibility to those diseases in early tests? Is basic research now identifying a person's susceptibility to these diseases, so at least that can be used as a warning against a particular bad habit?

Dr. FOEGE. There's a great deal of research being done on, can one screen out people who are susceptible to alcohol, for instance? There of course are risk factors that are now clearly identifiable for cancer and heart disease, so that kind of research has been going on, and in some instances, particularly with heart disease, we know that not only heredity but we know that hypertension, cigarette smoking, and improper diet are all related as risk factors.

Senator SCHMITT. We'll get into this in more detail later. Please go ahead.

Dr. FOEGE. If one compares 1900 life expectancy to 1978, there's a 50-percent increase in life expectancy realized in this country just in this century. However, the problem with that is we tend to think therefore that people our age might have 25 extra years to live, which is not true. The difference here is because our children now survive infancy.

If you look at what our life expectancy is at our age, the next chart, you can see that when I reach 50, I will have only 6 years more life expectancy than my grandfather did at the same age of 50—which means that all that medical science can offer me at my age only 6 additional years, compared to my grandfather.

On the other hand, there are now studies, particularly from California, that show a 50-year-old who follows certain life habits of refraining from cigarettes, alcohol, having good diet, and so forth, can show a 10-year difference from his counterpart who does not do that, which means what we do for ourselves and to ourselves may now be more powerful than all of 20th century science. I think that's an important point to keep in mind as we look at what can be done in the future.

Senator SCHMITT. Is that an argument against basic research?

Dr. FOEGE. No; it's an argument for applying what we already know.

I believe basic research has to continue, but at the same time, we have to apply what we have already discovered in the past in basic research.

I think it also raises the question of continuously defining the Federal, State, local role, the private role, and the individual's role, as we look at prevention. We obviously have to be very careful as we're talking about these new areas to not lose what we've already attained in infectious diseases.

Next chart, please.

IMMUNIZABLE DISEASES

The successes in the past 10 years just in the immunizable diseases have been very impressive. With rubella we see a decrease of 93 percent just in the past 10 years. With measles, a decrease of 72 percent in

the last 10 years: diphtheria, a decrease of 98 percent. In fact, in 1980, the five cases of diphtheria that were recorded—only one occurred in a child under the age of 15. You will recall that, on the first chart, from 1900, diphtheria was the third leading cause of years lost in this country. In 1980, only a single case in a child in this country.

It's also true that we've had only one childhood tetanus case in 1980. Mumps has seen a decrease now of over 95 percent. So there have been great gains in the last 10 years.

Senator SCHMITT. Do you have similar kinds of charts for a broader range of diseases?

Dr. FOEGE. We do; indeed, we put out once a year a summary of infectious diseases, what's happened over time, and we compare it over decades.

Senator SCHMITT. Could you make your latest such summary available to the committee?

Dr. FOEGE. We will.

[CLERK'S NOTE.—The information submitted was voluminous and is being retained in the subcommittee's files.]

MENINGITIS PROBLEM

Senator SCHMITT. I'm sure there's considerable public interest right now in the current meningitis problem in Houston. Does that summary include some recognition of this problem?

Dr. FOEGE. It includes meningitis in general. What we can do is provide an extra summary of the meningitis problem in Texas.

Senator SCHMITT. I presume that your center is actively involved in trying to figure out what in the world is happening down in Houston.

Dr. FOEGE. We are; yes.

Senator SCHMITT. It's my understanding it's a very unusual situation, in that, one classroom had five cases.

Dr. FOEGE. That's right.

Senator SCHMITT. Do you have anything new to report to the committee on this?

Dr. FOEGE. No, we don't; we have started immunization programs with meningitis vaccine to protect the class members. By and large, in recent years, meningitis in this country has been a problem in the military. The military, however, has been doing a good job of immunizing. So there have not been many meningitis outbreaks in recent years. This is an unusual one.

Senator SCHMITT. Is there anything in the military experience that compares with the classroom experience?

Dr. FOEGE. Yes; I think that recruits, where a single case has been introduced, we've seen widespread transmission of meningitis organisms, so that we do have some military experiences that bear on this.

Senator SCHMITT. Please go ahead—excuse me. The vaccine for meningitis, is that a difficult procedure?

Dr. FOEGE. No, it is not.

Senator SCHMITT. Merely a shot?

Dr. FOEGE. It has not been widely used in this country because there has not been a large meningitis problem. But it has been widely used in other countries, in countries such as Brazil. Tens of millions of doses

have been given of meningitis vaccine. In West Africa, it's frequently given.

So it's a widely used vaccine, but not necessarily in the United States.

Senator SCHMITT. Is there any danger in the vaccine itself?

Dr. FOEGE. There are very few side effects except for local reactions, as one would get with influenza.

Senator SCHMITT. What are the types of vaccines?

Dr. FOEGE. There are types A, B, and C meningitis vaccines. In this country, by and large, we use A and C.

Senator SCHMITT. What does that mean?

Dr. FOEGE. It's a killed vaccine that's made up of certain of the ingredients of meningitis, not even the whole organism, but certain fragments of the organism.

Senator SCHMITT. Thank you.

GONORRHEA

Dr. FOEGE. With the marked improvement in the immunizable diseases, we've also seen an arrest of the rapid rise of gonorrhea. In the past 5 years, gonorrhea incidence in this country has leveled off. Our next challenge is to get a lowering of that rate.

Senator SCHMITT. What happened in 1975?

Dr. FOEGE. In 1972, the Federal Government launched its first gonorrhea control program. It took 2 or 3 years for full development of this program, which was a program of looking for cases, rather than waiting for the passive reporting of cases.

There is a marked increase that has gone back to the 1950's. By 1975, the strategy of treating cases, finding the contacts, and treating contacts—even, sometimes, if one could not prove they had the disease—did slow the spread of gonorrhea. The problem we have now is with the penicillin-resistant strains of gonorrhea, a very difficult problem.

We've had about 2,000 cases in the last 4 years. We have put a lot of our attention from regular gonorrhea control to control of penicillin-resistant gonorrhea.

Senator SCHMITT. That's a very, very unusual curve.

Dr. FOEGE. It is.

Senator SCHMITT. Are you sure there aren't other factors involved there? I just find that curve hard to believe.

Dr. FOEGE. If one looks between the 1950's and 1972, there was an increase of gonorrhea going on. In 1972, there's no question that there was an increase in the number of cases being recognized and reported, because there were now screening procedures that were going on for gonorrhea cases. Prior to that time, the laboratory diagnosis had not been that easy. So there is an artifact here, in the program.

Senator SCHMITT. But does the sharp break in 1975 mean that you have saturated the reporting; there are no more cases to be reported that were going unreported; is that what that means?

Dr. FOEGE. No: of the 1 million cases being reported a year, our best estimates are that for every case being reported there's another case unreported, so that we have at least 2 million cases of gonorrhea a year.

Senator SCHMITT. Did you run out of funds in order to continue the reporting mechanism in 1975, to expand it, or what?

Dr. FOEGE. No; in fact, the program has expanded since 1975, and I think what we're seeing here is a true control. But we are not able to change the reporting rate from one to one, which is what we're hoping to do in the future. But I think this is the result of the control program.

Senator SCHMITT. That's a very weird curve. Please go ahead.

NEW DISEASE ORGANISMS

Dr. FOEGE. The next chart, please.

In addition to the problem of how to maintain what has happened with childhood immunization, with gonorrhea and so forth, we have the problem of new organisms, such as the legionnaire's disease organism. We now know that this consists of at least five or six different serotypes, and the investigation of legionnaire's organism has shown at least five other species of the genus.

We are dealing with new lethal viruses, and new viruses in general. The 1970's found more new viruses discovered than any other previous decade. The ones we are chiefly concerned about are the lethal ones, such as African hemorrhagic fever.

Senator SCHMITT. Is that because of improved laboratory techniques, or an increased influx of disease carriers into the country?

Dr. FOEGE. We think it is almost totally due to better techniques: Our ability to isolate organisms is vastly improved. We have new expressions of old organisms, such as with toxic shock syndrome, where we now have about 1,000 cases reported since the first ones were reported about a year ago.

DRUG-RESISTANT TUBERCULOSIS

We have the problem of drug resistance to face. This is particularly troublesome with such things as tuberculosis, where we have now had outbreaks of tuberculosis that is resistant to all three of the mainline drugs for tuberculosis.

Senator SCHMITT. Where are they generally?

Dr. FOEGE. The outbreaks we have had, the biggest one has been in Alabama, but we have had problems with resistant organisms in Southern California, Arizona, Louisiana, Alabama, across the southern part of the country.

Senator SCHMITT. That situation is based on the long practice of treatment in this country, I guess, rather than the influx of new tuberculosis strains from Vietnam or Southeast Asia in general.

Dr. FOEGE. The resistance problem is basically a domestic problem, but we have had cases imported from Mexico and from Southeast Asia.

Senator SCHMITT. Are they resistant to treatment?

Dr. FOEGE. Some of them are. They are resistant to the mainline drugs, and it's been necessary to go to more expensive and more toxic drugs to treat these. They are still treatable, but it's of concern to us that we're having this problem, whereas with the gonorrhea, the penicillin-resistant gonorrhea, we now have to treat that with a drug that's 4 times as expensive. And, we know that the resistant strain of gonorrhea, which has a plasmid with certain genetic characteristics, is set up to be resistant to other drugs. It won't be just penicillin. Eventually it will be resistant to other drugs as well.

Senator SCHMITT. How does polio look right now? Sorry to jump back.

Dr. FOEGE. Polio has looked very good in the last year. You will recall 2 years ago we had an outbreak in the Amish community of Pennsylvania. We've had no true outbreak since then. We've had isolated cases, some of these related to the vaccine itself; others related to importation. But the polio situation has been very good in this country.

Senator SCHMITT. Has the vaccination rate increased due to publicity in the last couple of years? Have you found a more responsive community for polio vaccination?

Dr. FOEGE. Yes; in 1977, the polio immunization rates in this country were between 60 and 65 percent. Currently, 93 percent of all schoolchildren have received polio immunization. Last year I believe there were only six or seven cases, and we are now at a point with the polio virus where we can actually fingerprint the virus so that we can tell whether a case is related to the vaccine or comes from another country.

Senator SCHMITT. Thank you.

Please proceed.

HEPATITIS VACCINE

Dr. FOEGE. Another challenge in the future is to make use of the technology that's developing. One of the most exciting things in the last year has been the development of a hepatitis B vaccine.

Hepatitis B was at one point known as serum hepatitis, that it had to be spread by needles and syringes. We now know that it can be spread person to person. In fact, it is frequently spread by homosexuals. There are about 800,000 chronic carriers of hepatitis B in this country, with 200,000 cases each year.

We now have a vaccine and are in the final stages of the field trials. It appears to be about 95 or 96 percent effective, and we would expect within the next year that this vaccine can be used for control purposes.

I should also say we're only a few years away now from a hepatitis A vaccine, the garden variety of hepatitis. I can see that sometime in the future this will be a standard childhood immunization.

In the laboratory, one of the exciting developments in the last several years has been something called hybridomas. Precise antibodies now can be developed against each strain of organism. We are expanding in the use of this, and we will provide reagents to the States.

MONOCLONAL HYBRIDOMAS

Senator SCHMITT. You don't mean a diagnostic technique; you mean a treatment technique?

Dr. FOEGE. At the present time, it's a diagnostic technique.

Senator SCHMITT. In order to see what the body is protecting itself from?

Dr. FOEGE. That's right.

Senator SCHMITT. But it has potential, does it not, as a treatment?

Dr. FOEGE. We think it does have potential for treatment; that's right.

Senator SCHMITT. Have you begun to work on any specific disease where you are having trouble with drug treatments such as tuberculosis?

Dr. FOEGE. We're not at the point where we're actually using it in treatment. We are at the point where this is being used in vaccine development. For instance, in the malaria vaccine field, it is believed that the development of hybridomas will shorten the time for the malaria vaccine by about 3 years.

Senator SCHMITT. Isn't the greatest potential for benefit in this area of research in the development of drug-resistant strains?

Dr. FOEGE. There is a potential for developing a specific gammaglobulin for specific diseases. I know of no disease where this has actually happened with monoclonal antibodies, but the potential is certainly there. People are thinking about that and working on it. I've not seen anyone get to the point of actually using it.

Senator SCHMITT. What are the loopholes in this particular line of research? Is it money? Is it people? Is it insight? Or what?

Dr. FOEGE. It's a labor-intensive research project at the moment, and it's very difficult to get the right cell out of a spleen with a myeloma cell and develop, if you will, the right kind of factory. It takes many trials and errors before this is done.

CELL-SORTING TECHNIQUES

Senator SCHMITT. We have cell-sorting techniques right now that are remarkable in their capability. Los Alamos Laborabories in New Mexico has a very sophisticated state of the art cell-sorting technique. Is that still not adequate?

Dr. FOEGE. My understanding is the real difficulty is once one gets the cell out of the spleen, you have to go through the process to see what it will produce before you know whether you have the right cell or not. So at the moment, cell sorting will not provide that information.

Senator SCHMITT. OK; do you know if your researchers have specifically looked at the latest developments at Los Alamos?

Dr. FOEGE. I do not know, but I could certainly check.

Senator SCHMITT. Could you check and report back?

Dr. FOEGE. I will.

Senator SCHMITT. The fact that they are sorting cells does not necessarily mean they are now applying that technique to the sorting of chromosomes.

Dr. FOEGE. That's right.

And we use the cell-sorting techniques in other areas.

Senator SCHMITT. They are able to specifically sort individual chromosomes right now with that technique, and they're doing it.

Dr. FOEGE. I'll be happy to check on that and report back.

Senator SCHMITT. OK.

PREVENTION PRIORITIES

Dr. FOEGE. Finally, in the delivery of techniques—I already mentioned tuberculosis—we have looked at what our priorities should be, given the wide range of things we could do. I mentioned some of these to you last year. We have had a group of experts consider prevention priorities for the entire Nation. They came up with a report on what they expect that the most important prevention projects should be in the country at this time.

We had groups looking at objectives for the Nation for 1990: What should the health status of the country be in 1990 for different areas of health? What should the infant mortality rate be? And so forth. This has now been finalized, that we have in 15 broad objectives for the country.

The Surgeon General, using these objectives, has developed a prevention strategy that described the kind of programs that should be conducted in order to reach those objectives.

Working with the county health officers, State health officers, and the American Public Health Association, we now have model standards for community programs.

Senator SCHMITT. We will make those part of our committee files. I presume there are executive summaries in each one of them. If there are, those will be made part of our permanent record. If there are not, maybe you could supply those, a short summary of the document.

[CLERK'S NOTE.—The Department did not submit summaries in time for inclusion in the printed hearing record; the detailed material is being put in the subcommittee's files.]

Senator SCHMITT. If there are no executive summaries in those documents, let me suggest strongly that future publications include such summaries. If you want to communicate with the Congress, that's the best way to do it.

Dr. FOEGE. Out of this, we've selected our own priorities which are to keep constantly in touch with current preventable health problems in the country, to maintain our gains in infectious diseases while we're working in three other areas, environmental health, occupational health, and chronic diseases.

We've also selected as a priority the development of capacity building at State and local levels with scientific backup from CDC.

A final priority is to capitalize on the new technological changes that are occurring.

PROGRAM FUNCTIONS

The basic functions that we conduct, whether we're involved in infectious diseases or environmental health or occupational health are:

Epidemiology—finding the cause, the distribution, and the effects and the control procedures for health problems.

Surveillance—Systems that are constantly bringing in information and analyzing it. We have a very extensive surveillance system that involves receiving reports every Tuesday from every State. By Friday we have made that information available to 100,000 people in health departments, universities, and practicing physicians. We provide surveillance reports, annual summaries, and so forth.

Training—We now train about 20,000 people a year—in short courses primarily—that is, 2-day, 1-week courses—but also in longer courses, sometimes for a year.

Laboratory services—We provide reference diagnostic services to States. We do about 2½ million diagnostic procedures a year.

In addition, we're involved in developing reagents for the States, proficiency testing, consultation for State and university laboratories.

Finally, applied public health technology, which is delivered through State and local health departments.

OPERATIONAL FUNCTIONS

From an operational point of view, we provide scientific technical leadership. We conduct applied research. And by "applied research" we're talking about things that are one step away from application.

For example, with the difficulty we have had isolating the penicillin-resistant gonorrhea strain, our research has been targeted on how to develop needed laboratory techniques and to differentiate between penicillin resistant and nonpenicillin-resistant strains.

We provide technical assistance, for example, epidemic aid. We provide financial assistance and grants. And we help develop voluntary standards and guidelines.

We started as a one-disease organization for malaria during the Second World War, when there were problems with troops being trained in the South. That's how we happened to be located in Atlanta.

In 1946, this was expanded from malaria to communicable diseases in general.

In the 1950's, we started an epidemic intelligence service, and began, for the first time, nationwide surveillance for diseases.

In the 1960's, we became involved in international activities, particularly the smallpox eradication program.

And in the 1970's, we have been involved in prevention in general.

In the 1970's, with the other charges we've been given, we've also been given special responsibilities to protect the civilian population against biological and chemical agents as part of this.

We do review the plans of the Department of Defense when they move or test chemical agents, but we're also involved in a wider look at the civilian defense against biological and chemical agents.

Senator SCHMITT. When did that start?

Dr. FOEGE. We've been doing the biological and chemical work for about 5 or 6 years. In the last 2 or 3 years we've looked very intensely at the civilian defense aspects of this.

Senator SCHMITT. Are you working with FEMA in this regard?

Dr. FOEGE. We are; we're working with the Department of Defense, the State Department, the Justice Department, and the Department of Energy.

Senator SCHMITT. Please go ahead.

Dr. FOEGE. Next chart, please.

CDC EMPLOYMENT

Of the 4,000 people employed at CDC, about half of them are at our headquarters in Atlanta; about half of them in other places, including the Washington area; the field stations, quarantine stations, and in State and local health departments.

Next chart, please.

CDC FACILITIES

We have a total of 764,000 square feet.

Senator SCHMITT. Excuse me. I notice in your request for control of chronic conditions, that you want a geologist. Is this your first geologist that you've asked for under environmental hazards?

Dr. FOEGE. We have had people in this area, in the occupational safety and health field. Increasingly, this has become a problem though with asbestos and other substances, where it's not directly related to occupation. Mount St. Helens was an example of this, where we really needed the ability to analyze ash and to be able to tell how much free silica there was in it.

Senator SCHMITT. Do you think you're going to get the kind of geological expertise you need at the GS-7 level?

Dr. FOEGE. I'm not sure.

Senator SCHMITT. Even my first job was at the GS-11 level.

Dr. FOEGE. It's part of our cost-saving plan. [Laughter.]

Senator SCHMITT. Take it out on the poor geologists.

Do you have other professional geologists? I'm surprised, in your analysis of disease vector and propagation and so forth—if I have the right terminology—that you haven't utilized earth scientists in the past?

Dr. FOEGE. Yes; when we've needed this, we've used consultants, or we've used people from the occupational safety and health component of CDC.

RELATIONSHIP WITH U.S. GEOLOGICAL SURVEY

Senator SCHMITT. Do you have any ongoing relationship with the U.S. Geological Survey?

Dr. FOEGE. Let me ask Dr. Robbins to comment.

Dr. ROBBINS. We certainly do. Both the people from Atlanta and the people from Cincinnati and Morgantown worked with USGS during the Mount St. Helens eruption.

Senator SCHMITT. That's one of the more obvious things. I'm talking about the environmental characteristics of disease propagation.

Dr. ROBBINS. I believe that our laboratory proficiency testing programs exchanges samples of silica, asbestos, and other minerals with a variety of labs, including some labs that are primarily geological. Our mining research group in Morgantown relies heavily on USGS information when it studies health hazards in the mines. I'm not aware that we are working on any joint projects with USGS.

Senator SCHMITT. One of the aspects of disease propagation is the characteristics of the local environment, particularly if you're talking about biological and chemical agents that might be introduced in that environment for less than altruistic purposes.

It seems to me that that kind of expertise would be important. I'm not suggesting that you hire another person, but I certainly would suggest that you consult with the U.S. Geological Survey and see if there shouldn't be some easily workable relationship developed.

Dr. FOEGE. Let me check and be sure. but I think there are two areas that we have dealt with. One has been water safety, and the other has been examination of chemical dumps and the contamination of the water supplies. But I will check and submit that for the record.

Senator SCHMITT. Please do.

[The information follows:]

U.S. GEOLOGICAL SURVEY

The Center has had discussions with members of the U.S. Geological Survey on many occasions, especially in the area of water and water pollution. Also, Centers for Disease Control (CDC) has on its staff one individual who is trained in geology and oceanography. This individual has a graduate degree in public health and worked for approximately 8 years with the Environmental Protection Agency prior to being employed by CDC. The skills of this individual are utilized in the review and analysis of environmental impact statements, water resources projects, solid and hazardous waste disposal siting, and in other situations whereby an analysis of geologic and topographic featues is critical to the protection of ground and/or surface water supplies which may be utilized by humans or animals.

CDC FACILITIES

Senator SCHMITT. Please proceed.

Dr. FOEGE. We have 764,000 square feet in our facilities, about two-thirds of this have to do with laboratory and special purpose space. The Public Health Service has title to most of this space. We have the only civilian laboratory for handling class 4 agents. In general, class 4 agents are the agents that are easily transmittable, have a high-fatality rate, with no known prevention or treatment.

Lhasa fever, the Bolivian hemorrhagic fever, those sorts of agents.

Senator SCHMITT. Is that space fully utilized at this time?

Dr. FOEGE. It is more than utilized. We have capacity to handle a number of agents at one time. So far, this has been OK, in emergencies, but we are looking for ways to increase our capacity for handling more agents at one time.

CDC PROGRAMS

Finally, I would like to show, by budget authority, some of the programs that we are engaged in.

The first one, basic preventive health involves the health incentive grants to the States. These are grants that the States use to support a variety of health services including, laboratory services and tuberculosis control.

In addition, this line item includes risk-reduction grants. We have risk-reduction grants now with all States. Some 160 intervention projects were started in the last year, ranging from smoking projects to highway safety projects, to surveillance projects, to try to reduce the self-imposed risks that people have.

The second item, disease prevention, includes targeted programs, where we provide assistance in VD, immunization, and fluoridation. This includes the grant programs to States, but it also includes our surveillance systems, our applied research, and our laboratory support for those programs.

MEDICAID OR MEDICARE REIMBURSEMENTS

Senator SCHMITT. Excuse me. It's my understanding that preventive medicine is not reimbursable under either medicaid or medicare. Is that correct?

Dr. FOEGE. That's correct.

Senator SCHMITT. Have you ever been asked—or have you ever tried to define, preventive medicine techniques, that are specific enough that they could be considered as reimbursable?

Dr. FOEGE. When one defines preventive techniques, by and large, we have techniques applied through a community, for instance, surveillance or vector control; and those applied to individuals, such as the immunization programs. We have felt that those that applied to individuals should be, in fact, eligible for payment by other third parties, such as medicaid or medicare.

Senator SCHMITT. Are you talking about some specific act of immunization, a vaccine or something like that?

Dr. FOEGE. The Health Care Financing Administration has looked this year at specifically introducing influenza, the pneumococcal vaccine, and Pap smears, to their programs. We think this would be a step forward.

Senator SCHMITT. What about the cost of other types of preventive medicine activities?

Dr. FOEGE. We think that many educational programs should be reimbursable. For instance, in diabetes, we now have some projects where Blue Cross/Blue Shield will reimburse patient education, because we've been able to show that a patient educated has fewer hospital days, a lower risk of coma, a lower risk of amputation; therefore, it's cost beneficial.

We do have some projects now where third-party payers are paying for health education materials. I think whenever we can show that something is cost beneficial or potentially cost beneficial, that this would be a candidate for that.

Senator SCHMITT. I guess, in essence, you're telling me that, yes, you are working with other aspects of the Health and Human Services Department to continally try to define those areas of preventive medicine that are specific enough to be reimbursable.

Dr. FOEGE. That's right; we are.

Senator SCHMITT. Do you feel that progress is sufficient in that area?

Dr. FOEGE. The people in prevention always had the feeling that it is difficult to come up with the kind of cost-benefit figures needed. There are certain areas where there's no problem, such as in polio. There's a real problem, however, when we're talking about lifestyle areas. One can make the case that if you are successful in lifestyle areas that total medical costs during an individual's lifetime will increase, because they will have more years to incur costs. It becomes very difficult to provide the kind of arguments that are needed. But I think that there has been a renaissance in thinking on prevention.

Senator SCHMITT. In that kind of analysis, do they also put in the increased income earned by that individual, and taxes paid?

Dr. FOEGE. Of course, one has to look at the indirect benefits in order to make the case.

Senator SCHMITT. They did, in saying the person is going to live longer, and therefore they need more medical care. Did they also include the fact that living longer they are more productive members of the society?

Dr. FOEGE. We include that. [Laughter.]

But I must say that the climate for prevention has never been better than it is now. I am as optimistic as I've been in 20 years. People are paying attention to the impact of their own actions on their health. You can see this in the mortality rates going down. I think it's a direct result of what's been happening in prevention.

CHRONIC DISEASES

The next item, control of chronic diseases, includes the rat control program, the lead screening program. The lead screening program has projects directed toward areas where one expects high lead levels in children, and to screen them. These would be children who live in houses with lead paint, in ghetto areas.

We've been screening about 500,000 children a year, and finding in the neighborhood of 25,000 who required a pediatric followup because of increased lead levels. At the same time, we've been finding about 25,000 children with anemia—500,000 screened yield about 50,000 children who need pediatric followup.

This includes the diabetes program, which is a program in 20 States attempting to look at the population with diabetes, the resources available, and bring them together in a more efficient way. We believe that it's possible to reduce the increased perinatal mortality, it's possible to decrease the 28,000 amputations that result from diabetes, it's possible to decrease hospital days.

The typical diabetic spends 5.5 days in a hospital per year, as compared to 1.5 for a nondiabetic. And we have pilot projects now in 20 States. We are convinced that we can show some reductions in these costs from diabetes. This includes a nutrition program in 35 States, where we have nutritional surveillance.

And it includes environmental emergency programs. The environmental program has been looking at not only Mount St. Helens, but also such things as asbestos in Arizona, and the Titan missile accident—those kind of environmental chemical problems.

Occupational safety and health runs the entire range from detection of occupational health problems to analysis of how great is the problem, to control technology, how to prevent the problem to disseminating information on the problem.

We have in occupational safety and health doubled the number of health hazard evaluations that we do where an employer, or employee, if they believe there's a hazard in the workplace, can request an evaluation, epidemic aid, if you will. We're receiving 400 to 500 requests per year at the present time.

Senator SCHMITT. What did you call that?

Dr. FOEGE. A health hazard evaluation, which is the counterpart to epidemic aid in the infectious diseases area.

Senator SCHMITT. Excuse me. Do you work with NIOSH?

Dr. FOEGE. NIOSH is part of CDC.

Senator SCHMITT. Do you work with your counterpart in OSHA?

Do you have a counterpart also in the Mine Safety and Health Administration?

Dr. FOEGE. We do, yes. We work both with OSHA and the Mine Health and Safety. In fact, they're involved in developing with us priorities on what sort of research should be done in NIOSH.

Epidemic services includes all of the infectious diseases that were not included in specific programs. This is where the toxic shock investigations, legionnaire's, rabies surveillance, and other laboratory services, would be included.

Technology development and application covers activities to more rapidly use the information that becomes available. This includes our laboratory improvement program. It includes our hospital infection program, where we are attempting to reduce the 2 million hospital infections that occur each year. We figure that this is now costing about $1½ billion a year, because each of the 2 million excess hospital infections costs about $700.

We have been doing extensive work in determining why do people get hospital infections, what steps could be taken to correct them. And we have in the last month supplied every hospital in the United States with the first two of seven volumes that they will be receiving on specific hospital infection problems. I think there's been good coordination between the private and the Government sector on this. This also includes the work that we are doing on hybridomas.

BUILDINGS AND FACILITIES

I mentioned that we own most of our own buildings. This line item is to protect a sophisticated complex.

Senator SCHMITT. That's rehabilitation and maintenance mainly, or what?

Dr. FOEGE. That's right; in 1980, it included $6 million for an addition to the center in Cincinnati for NIOSH, but the rest is basically repair and maintenance.

Senator SCHMITT. Is it sufficient to meet the deterioration of your facilities?

Dr. FOEGE. We have to draw priorities on what we do in this area. By and large, in high-priority areas, such as the virus area, we do maintain these buildings. We've also been able to do energy conservation with this, and have in Atlanta a computerized program that has been able to show savings of 15 to 20 percent in energy in the first year of operation.

Program management includes our general management and direction of CDC.

This concludes the overview, Mr. Chairman. We have additional items that we would submit for the record, if this meets your approval.

Senator SCHMITT. Thank you. I think you probably covered most of what you had in the text before us; is that correct?

Dr. FOEGE. That's right.

DIABETES

Senator SCHMITT. Let me just add one question. Then I will yield to Senator Specter.

Are you involved at all in the ongoing research that looks increasingly promising, to provide human insulin in normal release patterns, as an attempt to counteract the potential side effects of diabetes treatment?

Dr. FOEGE. We have not been involved specifically in that. We work with NIH. They're working on the latest treatment modalities in diabetes. Our efforts are to make sure that the diabetic community has access to the resources, that we get the best use of resources, and to monitor what's happening. Therefore, we have not been directly involved in treatment research.

Senator SCHMITT. Senator Specter.

BUDGET CUTS

Senator SPECTER. Thank you, Mr. Chairman.

Doctor, what is your sense as to whether your budget ought to be subjected to the kinds of cuts which are being discussed all around today?

Dr. FOEGE. We think our budget, like every budget, should be looked at for where can savings be found. We are attempting to do some of that in our reduction this year, in grants. But we think our budget should not be different from others, but should be subjected to scrutiny.

Senator SPECTER. Have you been consulted by anybody from Mr. Stockman's staff with respect to suggested cuts that you would have on your own from the budget?

Dr. FOEGE. We've been asked by the Department to provide suggestions. I might ask Mr. Itteilag from the Department to comment on that.

Mr. ITTEILAG. Senator, this is roughly the same situation as we discussed this morning. Dr. Foege has indicated very briefly that his participation has been roughly of the same type as that of the Health Services Administration.

Senator SPECTER. I heard from Mr. Itteilag at some length this morning, Doctor, with respect to the procedures which have been followed by the Department. I would be interested to know about your personal participation, or the participation of any of those who are with you today, with respect to any contacts you have had with anybody on the subject of budget cuts.

What have you had, directly, on that subject?

Dr. FOEGE. We were asked by the Department to look at and prioritize our programs. To identify where we would be willing to take cuts, if cuts of different levels were requested? We, of course, do this on an ongoing basis, as part of our zero-base budgeting process, which already ranks activities in priority order. But we did go back, when requested by the Department, to consider where we would take cuts.

Senator SPECTER. Were you asked to make an evaluation as to where you would recommend the cuts if they were to be, say, a 2-percent cut for fiscal year 1982?

Dr. FOEGE. We were; yes.

Senator SPECTER. Did you make those submissions?

Dr. FOEGE. We did.

Senator SPECTER. For the year 1981, were you asked to make suggested cuts?

Dr. FOEGE. Yes; I believe we were asked to look at 1 percent for 1981. But we were asked to look at 1982, also.

Senator SPECTER. I know that in the press a comment by Secretary Schweiker that he was not proposing cuts in preventive health services—is that report accurate?

Dr. FOEGE. Let me ask Mr. Itteilag.

Mr. ITTEILAG. Senator, I'm not familiar with that specific reference you made. My sense is that this area is being looked at, as well as all other areas. While we might place somewhat of a different priority here, it is unlikely that the Centers for Disease Control or other centers that finance preventive-type activities, will remain unchanged.

CONTROL OF CANCER

Senator SPECTER. Doctor, does your Department on Disease Control play a material role in cancer research or the efforts to control cancer?

Dr. FOEGE. Yes, in two ways: One, we're very interested in the problem of cancer from the occupational safety and health point of view, and are trying to relate occupational exposures to cancers of different kinds. We've also been involved in the nonoccupational area, looking at clusters of cancer, for instance, clusters of leukemia, to see if there are common characteristics that can be found, that might provide some information on cause.

We've also been involved in such things as the Smoky bomb blast study, to determine whether people who were at the Smoky blast in 1957 have increased rates of leukemia. We have just this past year reported that in the people we have been able to follow from the Smoky bomb blast, we did find 9 cases of leukemia, as compared to an expected rate of 3.5. So we found an increase. We don't know whether this is because low levels of radiation cause more leukemia than we thought, or whether the Smoky particulates had more radiation than we thought.

Senator SPECTER. What are you referring to, with respect to the Smoky issue?

SMOKY ISSUE

Dr. FOEGE. The Smoky issue was some 3,200 participants at an atomic blast in 1957 who've been followed up now, 23 years later, to see what is the leukemia rate in those participants. The real question has been whether low levels of radiation lead to more leukemia than scientists previously thought.

Senator SPECTER. What are the conclusions of your studies to date?

Dr. FOEGE. The conclusions are that we're definitely finding more leukemia cases than one would expect, over twice as many. But it is difficult to determine, what was the actual radiation exposure of the participants. For instance, it's not clear how many of them also attended other bomb blasts. It's not clear what kind of other radiation they've had for medical reasons.

So, it's difficult to answer the question precisely on whether low-level radiation causes more cancer than expected.

Senator SPECTER. Are you able to make the determination as to what effect radiation exposure may have had by questioning those individuals?

Does your program lend itself to that kind of detail?

Dr. FOEGE. By and large, the only measurements that we can get would be from the badges they wore. We've been able to get those measurements. The military has retained the badges. What we cannot do is determine how much radiation they might have had when they didn't have badges on, or if they attended other exercises.

Senator SPECTER. Why can't you ask that?

Dr. FOEGE. Many of them are no longer living, so we're using military records to look at exposure.

Senator SPECTER. How do you determine the incidence or cancer if they're no longer living?

Dr. FOEGE. If a person has died, we follow up and get a medical record on them for cause of death. If the cause of death has been leukemia, or if it's even been suggested, we then attempt to get slides and have an independent hematologist read those slides. I should say that we've also just completed a study through NIOSH of the Portsmouth Yard to see if we could answer the same question.

At Portsmouth, we have not been able to show an increase in ill-health effects due to radiation. This may be because there is no increase in health effects, or it may be that we'd have to keep following people longer than we've been able to follow them.

BUDGET FOR CANCER ACTIVITIES

Senator SPECTER. How much of your budget is allocated to the cancer issue?

Dr. FOEGE. I'll ask Dr. Robbins in NIOSH how much goes for cancer.

Dr. ROBBINS. Senator, within NIOSH, we will spend $3.6 million this fiscal year for cancer.

Senator SPECTER. Is that the total amount spent on cancer by the entire Center for Disease Control?

Dr. FOEGE. I would add to that, specific cancer studies we've done outside of the occupational study, have been at the level of about $340,000 per year.

Senator SPECTER. How does this compare with the other funds which are spent on cancer research, if you know?

Dr. FOEGE. This is a very, very small fraction of, for instance, the National Cancer Institute budget.

Senator SPECTER. Based on your work with the Center for Disease Control, Doctor, do you have an opinion as to what the possibilities would be to eradicate cancer, or make very material inroads on the cure and prevention of cancer, if substantial additional Federal funds were made available for that purpose?

Dr. FOEGE. I have a difficult time knowing how much cancer can be prevented. I am sure, based on what we already know, that a great deal of cancer in this country could be prevented, particularly the cancer that is related to cigarette smoking.

I think cigarette smoking is one of the one or two largest public health problems we have before us. Just for lung cancer alone, not counting other cancers, we are in the neighborhood of 100,000 deaths per year.

Senator SPECTER. Does your Center for Disease Control deal with heart disease?

Dr. FOEGE. We deal with heart disease in the risk-reduction program—we have grants for all States now—to develop programs to help people reduce their risks such as from hypertension and from improper diet. We are not involved in basic heart disease research.

Senator SPECTER. Do you have an opinion as to what might be done with the prevention or cure of heart disease, if there were substantial additional Federal funds available for that subject?

Dr. FOEGE. There has been a 25-percent reduction in fatal heart attacks in the last decade. We believe this has been, by and large, due to the application of what we know about prevention. We know that much more could be done in this area.

Considering whan can be done about hypertension, diet, exercise, and smoking, it's my belief that the potential for prevention of heart disease is very good.

Senator SPECTER. Thank you very much. Thank you, Mr. Chairman.

HEALTH INCENTIVES GRANTS

Senator SCHMITT. The health incentive formula grants program, more popularly known as section 314(d) of the Public Health Service Act, has sustained large cutbacks in recent years. What would be the effect of eliminating this program, as proposed by the Carter administration?

Dr. FOEGE. There has been a reduction over the last several years, and the States, of course, have had to prioritize what has been funded by the health incentive grants, to see what they retain. I would expect that some of the services may be eliminated, but I would think that many or most of the services would be financed through some other mechanism.

Senator SCHMITT. Do you have any information on how the States have reacted to this reduction in funding?

Dr. FOEGE. The major way this money was being used had to do with such things as tuberculosis control, laboratory services, rural health, this type of thing.

We have found, for instance, in laboratory services, that the States have had to prioritize which services they will perform. In some cases, they're now asking for more services from other labs.

By and large, I think the States are finding ways to compensate for the loss of revenue.

Senator SCHMITT. What evidence do you have that there has been a positive impact in the past, by this program on health problems?

Dr. FOEGE. I can cite such areas as vector control. For example, at the present time, we're expecting that dengue fever may be a problem this summer.

States have over the years, developed vector control capabilities out of these funds. Some State laboratories have been vastly improved because of access to these funds.

The majority of tuberculosis work being done by Federal financing has been done through the section 314(d) or health incentive grants in recent years.

There's evidence that these funds were being used, and being used well. It's only in the last several years that we've had a tracking system, though, to know exactly how the funds have been used.

Senator SCHMITT. How have they been used in general for facility improvement?

Dr. FOEGE. About 48 percent of the funds have been used for personal services of one kind or another. About 23 percent have been used for laboratory improvement. About 12 percent have gone directly to local health departments. And the remainder have been a variety of programs, but that's the bulk.

Senator SCHMITT. If there was a major reduction as proposed by the Carter administration, with something like $9 million remaining, how would that money be used?

Dr. FOEGE. From our point of view, the money would be distributed according to how we'd distibuted it in recent years. From the States' perspective, I would guess that they would continue to use about half of that for personal services. We don't have a good reading, however, on the 1981 response from the States on what they will do with the services that they had intended to fund.

COST OF DENTAL DISEASES

Senator SCHMITT. Do you have an estimate on the annual cost of dental disease to the American people?

Dr. FOEGE. I don't have that at my fingertips. It's something that we can provide. We are involved, of course, in the fluoridation program.

Senator SCHMITT. That's where I'm headed. I just wanted to set the stage for what scale problem are we dealing with? Is it a few million, a few billion, tens of billions?

Dr. FOEGE. It's in the billions, but I do not have the figure in front of me.

Senator SCHMITT. If you could supply that for the record it would be helpful.

[The information follows:]

DENTAL DISEASE

In calendar year 1979, an estimated total of $13.6 billion was spent on dental services in the United States. About half of that amount was spent for the treatment of dental caries and their sequelae.

FLUORIDATION STUDIES

Senator SCHMITT. I agree. It's my understanding it's several billions of dollars per year from dental disease alone. Now, if we eliminated any kind of problems that existed at birth, and just talked about those things that potentially are preventable, would the numbers still be in the billions of dollars?

Dr. FOEGE. It would still be in the billions, but we would expect substantial reductions if, for instance, universal fluoridation would be available.

Senator SCHMITT. Now, the controversy has been, of course, that fluoridation somehow or other is not safe.

Could you summarize the status of objective analysis of this, including studies of populations with high natural fluoridation?

Dr. FOEGE. There have been a large number of studies, not only with natural fluoridation, but with artificial fluoridation, both in this country, and abroad.

The studies have repeatedly shown that fluoridation, at the level recommended, one part per million, is safe, and does not cause problems.

There are potential problems with large doses, of course, of fluorine, but at the one-part-per-million levels that are recommended, it has been found repeatedly, by NIH and by other groups, to be safe.

Senator SCHMITT. Do we know whether or not monoclonal antibodies exist to counteract any adverse effects of fluoride into the body systems?

Dr. FOEGE. I do not know if they do. I have not seen information on that.

Senator SCHMITT. It's my understanding that some of that research has shown that such antibodies are produced to fight some of the heavy elements—silenium, germanium, I think. But you don't know of any research on lighter elements, like fluorine?

Dr. FOEGE. I do not; not on monoclonal antibodies. The research I've seen on monoclonal antibodies has had to do with organisms which cause dental decay. I've not seen any on fluoride itself.

Senator SCHMITT. I am correct, am I not, that there has been research on the heavy elements, the natural resistance in the body?

Dr. FOEGE. I'm just not familiar with that.

Senator SCHMITT. It seems to me that that might be part of your work with DOD on chemical agents. Would you check and see if that is, and supply it to us for the record?

Dr. FOEGE. I will.

[The information follows:]

RESEARCH ON HUMAN NATURAL RESISTANCE TO HEAVY ELEMENTS

The Centers for Disease Control is not aware of any research or investigation to evaluate the development in humans of antibodies to heavy metals. There are some reports of animal studies in this area. The focus of the CDC effort has been in the identification of heavy metals or changes in human metabolism resulting from exposure to toxic materials.

FLUORIDATION OF WATER SUPPLIES

Senator SCHMITT. And if not, why it has not been included.

Dr. FOEGE. I will.

Senator SCHMITT. Again, I think there's been some research done on that at Los Alamos, in their life sciences division. Is there any evidence at all, that fluoride is a carcinogen?

Dr. FOEGE. There is no evidence, and this has been repeatedly looked at, again by NIH. They have found no evidence it's a carcinogen.

Senator SCHMITT. What proportion of the population of the country is subjected to artificial fluoridation of the water supply?

Dr. FOEGE. We estimate that about 110 million people, approximately half the population, is now receiving fluoridation. Most of this is fluoridation that's added.

Senator SCHMITT. Have any fluoridation programs been repealed in the last few years? If so, how many?

Dr. FOEGE. In the recent election, there were some places that did repeal. There were other places that added.

The net gain, as I recall, was about 1.5 million population in the last election.

Senator SCHMITT. Can you characterize the intensity of the campaign against fluoridation by various political groups?

Dr. FOEGE. I believe that the people who are opposed to fluoridation honestly believe that this is a danger. And they have been extremely active in trying to convince communities and Congress that this is something that should not be done.

Senator SCHMITT. Is that activity on the upswing? Or about steady for the last few years?

Dr. FOEGE. It certainly has not diminished. In some ways, it may be on the upswing. We have concentrated simply on providing technical assistance to communities that have decided they want to fluoridate; so that we have not been drawn heavily into that battle.

Senator SCHMITT. How widespread is your research information on the beneficial effects of fluoridation, and the absence of any harmful effects?

Dr. FOEGE. I believe that the various non-CDC groups that have looked at this, and there have been many, have provided a great deal of evidence. We've been looking at the beneficial side of this. What can one expect? Some of the best studies now show that per dollar invested in fluoridation, $50 can be saved ultimately in dental health care. This makes it one of the best benefit-cost ratios in public health. It ranks with the immunizable diseases.

FEDERAL ROLE IN FLUORIDATION

Senator SCHMITT. Why should the Federal Government be involved now that the research is largely done. Why can't it be done by the States?

Dr. FOEGE. I think the Federal Government's role is a transient one here. The Federal Government, in the fluoridation grant program, is attempting to provide communities with the technical scientific information that they need, the one-time funds required to install equipment, and to help them develop surveillance systems for fluoride in the water. Once this is complete, the Federal support stops and other communities are assisted.

We expect that the fluoridation grant program should cease by 1990. The recipients are, of course, rotating all the time. But we would expect that the goal will have been achieved by 1990. Communities that want fluoridation now have asked us for the support they need to install it, and then the Federal Government can move out.

Senator SCHMITT. But why should the Federal Government supply a grant at this stage; if the benefits are obvious, why should it not be left to the State legislatures?

Dr. FOEGE. I think the local departments, though, have had a great deal of difficulty getting expertise they need, in simple things such as surveillance of fluoride systems. This has provided an impetus to local health departments to install something that they might not otherwise.

Senator SCHMITT. There are certainly good arguments for basic Federal research that would not be done otherwise. And even for the dissemination of the results of that research. But when you get to words like "might not do otherwise," then you start to tread on very thin ground, as far as the appropriateness of the Federal Government's funding activities.

Dr. FOEGE. I would say that there's an analogy here with the childhood vaccines, in that measles vaccine was clearly shown scientifically to be beneficial. Indeed, it's hard to find a preventive technique that pediatricians are more in favor of.

Yet, there was a large group of children, about half the population, somehow not receiving measles vaccine. It required a Federal push, because by and large, those were disadvantaged children.

In the fluoridation field, there are also communities that despite all the scientific evidence, cannot get themselves to do this without some additional help from the Federal Government.

Senator SCHMITT. Well, I would only say that there's a basic difference between the problem of measles and the problem of fluoridation. One is communicable and the other is not.

Where you're dealing with communicable diseases, you have, I think, again a very strong rationale for Federal activity. The fact is, the basic rationale for the continuing existence of your center comes largely, I think, under that umbrella.

One State cannot protect another State from the spread of a disease, particulary in our modern, highly mobile society. Fluoridation, though, that's a different situation.

Dr. FOEGE. The argument that is sometimes made there is—what is communicable about this, of course, is the cost. The entire community, of course, ends up picking up the excess cost.

Senator SCHMITT. Why do you feel you need increased funding in your 1982 request, in the Carter budget anyway, almost 50 percent higher than the request for fiscal year 1981?

Dr. FOEGE. As we are getting experience in the fluoridation program, we are finding that more and more communities are in fact, ready to start, if they receive a little assistance. It's taken us a while to reach our capacity in delivering this program, but I think we're at a point where we can deliver that much more. We've been reluctant to move too quickly in this field, until we had some experience.

Senator SCHMITT. Do you believe that concentrating on providing information to the various State governments would be ineffective, and that you must work directly with the communities?

Dr. FOEGE. It's hard to tell how much information alone would do. It's certainly been effective to help provide the technical and financial assistance.

Senator SCHMITT. What I am getting at is, why shouldn't the community go to their State government for these funds, rather than to the Federal Government?

Dr. FOEGE. I think the answer here is to see what has happened, even with that information available: that people have not availed themselves.

Senator SCHMITT. There's no incentive. As long as your budget keeps going up, there's no incentive to go to the State government for funding for this program.

Dr. FOEGE. Our budget is strictly for startup costs. There is no maintenance in our budget at all, so this is simply a startup system. Then it's turned over. A community has to make the basic decision that they are going to maintain the system. Then they're eligible for a startup grant, to help get equipment and to get it started. That's why I say in 1990 there should be no fluoridation budget left. By that time, all the startup is completed.

Senator SCHMITT. We don't need to pursue this. But you still haven't convinced me that the startup costs could not be borne by State governments, particularly with their budgets in surplus more often than not, and our budget in deficit.

HERPES SIMPLEX TYPE II

How serious is the problem of the herpes simplex type II today? You can begin by telling us very briefly what the medical consequences of that disease are.

Dr. FOEGE. Herpes type II is either an increasing-type problem or, as with some other things, we're now better able to diagnose it. It is a problem, I believe, that ranks with gonorrhea as a difficult venereal disease. We do not have the same tools with herpes as we do with syphilis and gonorrhea, and as we are now getting with hepatitis B.

We have been working in the past years on ways to treat herpes. We do have some chemotherapy trials underway. We should within the next year have the results of those trials. It is a problem, though. It leads, of course, to a certain number of children being infected each year.

We expect that there are about 500 deaths to newborns each year because of herpes which they've acquired from their mother.

Senator SCHMITT. What is the nature of the disease? Is it a viral disease?

Dr. FOEGE. It's a viral disease.

Senator SCHMITT. That attacks what?

Dr. FOEGE. It's a viral disease that in the mother is similar to the cold sores that we're familiar with, with herpes I, except in the genitalia. It causes intense itching, real pain. People with recurrent herpes infection complain about how it becomes the dominant part of their life, when they're having an attack. They simply cannot get away from it. It disappears for a period of time, and then reappears. It is easily spread, sexually from one person to the next, during those periods. When the mother has herpes in the birth canal at the time of the birth, the child might be infected.

It is estimated that about 1,000 children a year are infected at birth, about 500 of them die. With the child, the danger is that the infection can turn out to be an infection of the central nervous system, which can lead to death.

Senator SCHMITT. Why would it infect the central nervous system in the child and not in the parent?

Dr. FOEGE. I'm not sure. It is usually localized, in the parent but it is possible also to have herpes encephalitis in the adult. It's just not a common complication.

FUNDING REDUCTION EFFECT ON VD CONTROL

Senator SCHMITT. To what degree would the proposed reduction in VD control of $1.3 million in fiscal year 1982 versus fiscal year 1981 affect the planned activities in this area?

Dr. FOEGE. It will obviously delay what we do in herpes. We've had to select some priorities in venereal disease, and have felt that we must give priority to the problem of congenital syphilis. We must give priority to the problem of penicillin-resistant gonorrhea. And we must give priority to the problem of pelvic inflammatory disease relating to gonorrhea.

All these are very severe, particular in regard to pelvic inflammatory disease, which is a very prominent problem resulting in some 75,000 sterilizations a year in women, and perhaps a quarter of a million hospital episodes.

Senator SCHMITT. How do you set your priorities?

Dr. FOEGE. We look at mortality, particularly premature mortality, and morbidity, and quality of life. At the present time, the gonorrhea program has received a great deal of attention, not only because of the large numbers—1 million reported cases a year—but also because of the concern we have about penicillin-resistant strains. I mentioned we've had 2,000 cases. We've been able to contain almost every outbreak of penicillin-resistant gonorrhea. We continue to have importations. Only once in the last year has it really gotten away from us. That was in an outbreak in Los Angeles. This is now coming under control. We think it's important to put that level of attention to penicillin-resistant gonorrhea.

Senator SCHMITT. What would be the consequences of not continuing this attempt at controlling penicillin-resistant gonorrhea?

Dr. FOEGE. I think in a very short period of time, that is, a number of years, 2 or 3 years, it would become the dominant strain in the United States. It is already the dominant strain in some areas, such as in Manila, among certain subpopulations. If it becomes the dominant strain in the United States, it would increase the cost of gonorrhea treatment at least fourfold, and it would have the potential to become resistant to other antibiotics, also.

There are cost factors, and there are many quality of life factors, because to treat the resistant strain with penicillin, simply means that the person continues to have the disease. This can lead to more pelvic inflammatory disease. There are both human and economic costs.

GONORRHEA TREATMENT COST

Senator SCHMITT. What is the dollar cost of gonorrhea treatment in the country today? Your estimate.

Dr. FOEGE. I may have to get that for the record. I can tell you what we are spending on gonorrhea.

Senator SCHMITT. You said a fourfold increase in the cost of treatment. Multiply 4 times something.

Dr. FOEGE. That's right. There are 2 million cases a year in the United States. I'll have to get a per capita cost figure on that. The drug that has to be used—penicillin can't be used—is streptomycin, and that's 4 times the cost.

Senator SCHMITT. I see; it's the cost of that particular drug.

Dr. FOEGE. That's right.

Senator SCHMITT. Does gonorrhea treatment require hospitalization, ordinarily?

Dr. FOEGE. It does not, unless we're dealing with pelvic inflammatory disease, and then it often does require hospitalization.

Senator SCHMITT. We covered some of the results of your VD education and training activities. Would a proposed cut of the magnitude of $1.3 million result in major changes in your education and training activities?

Dr. FOEGE. Not in the education portion of this; no.

Senator SCHMITT. Do you consider that as your highest priority area in your whole attack on venereal disease?

Dr. FOEGE. I think education is one of the top two or three priorities. I believe the whole system of following the contacts has been a very effective way to break the chains of transmission.

Senator SCHMITT. Does your proposed reduction of about $2 million, in risk retention and health education, in any way relate to venereal disease?

Dr. FOEGE. This is by and large a reduction of what we would be doing in sex education projects, in health education.

Senator SCHMITT. So it does relate to the venereal disease problem?

Dr. FOEGE. Sex education projects, of course, have venereal disease as one objective. Another objective, the key objective, has been to reduce teenage pregnancies.

Senator SCHMITT. Teenage pregnancy is certainly a problem. I'm not sure I'd classify it as a disease, though.

Senator Specter, did you have another question or so?

Senator SPECTER. Thank you, Mr. Chairman. I would be interested in pursuing the question which Chairman Schmitt just asked with respect to sex education.

Teenage pregnancy, be it whatever, it's certainly not a disease. I may have missed some of the substantive material, since I have not been able to be present.

Senator SCHMITT. Senator, let me just say, we were concentrating on their activities relative to gonorrhea and venereal disease in general and subsequent to that, we started to touch on the education issue.

SEX EDUCATION

Senator SPECTER. I would be interested to hear testimony on the budgeting for sex education, because that has received a substantial amount of public attention with Secretary Schweiker's publicized comments 10 days ago. He favored a reduction of Federal expenditures in that line.

Dr. FOEGE. I'll be happy to tell you what we have been doing in this area. In 1977, we began looking at the question of how to reduce teenage pregnancies, and also looking at venereal disease in teenagers. We had a contract with Math Tech in 1977, specifically to catalog some of the sex education programs in this country, ask the question: How are they evaluated? And is there a way to evaluate sex education programs? There are so many of them now that are put on by schools, PTA's, church groups, and so forth.

In 1979, Math Tech did provide a report. It showed in general that there are many sex education programs in this country. Very few have ever looked at the question of evaluation. They have not looked at results in terms of reducing teenage pregnancies, reducing venereal disease, or other indicators to let us know that they have worked.

Math Tech did come up with some samples of evaluation techniques for looking at sex education programs. As part of this evaluation technique, Math Tech had suggested that students be asked questions on knowledge, behavior, attitudes toward sex, and sexual practices. It's this part of the program that has received a lot of attention. The Federal Government has not administered that questionnaire. A contractor has suggested that that would be one way to measure sex education programs.

We have not been involved in sex education programs per se. We're involved in how to evaluate them. For example, parents say that they would like to have parents provide sex education, yet surveys show that they don't. By and large, parents are not involved with sex education. However, we are not involved in programs to help parents become sex educators with their children.

Senator SPECTER. Are you saying there is no Federal funding, or has in the past been that no Federal funding for sex education programs?

Dr. FOEGE. No; I'm only speaking for CDC. Our funds have been for other purposes. We have not been putting on sex education programs.

Senator SPECTER. Are there sex education programs, to your knowledge, in some other facet, or phase, of the Health and Human Services Department budget?

Dr. FOEGE. I am not familiar with that area, but I will ask Mr. Itteilag if he is.

Mr. ITTEILAG. I think, Senator, I probably will have to answer for the record in some detail. But my sense is that inherent in some of the other programs of the Department, there could be some facets of sex education that take place. But I think I would like to look and examine some in detail at the Department, and insert something for the record, if I could.

Senator SCHMITT. We would like that for the record.

[The information follows:]

SEX EDUCATION PROGRAMS

The Department of Health and Human Services is not directly involved in the delivery of sex education programs. However, certain program activities which relate to sex education have been incorporated into the family planning program budget for fiscal year 1981. These activities have been directed to providing literature to schools, church groups, youth-serving community organizations, and others, for the purpose of educating young people in the methods of preventing unwanted pregnancies and controlling venereal diseases.

Fiscal year 1982 funds for the activities referred to above are proposed for inclusion in the block grants to States, to be used at the discretion of the States.

FAMILY PLANNING

Senator SCHMITT. The information this subcommittee has is that there is considerable activity in the family planning activities under the Health Services Administration.

Mr. ITTEILAG. I would agree, Senator. That's one of the places I will look at.

Senator SCHMITT. Whatever your judgment is on the propriety of that kind of education, or certain aspects of that kind of education, I think that's a legitimate question, to wonder whether we ought to be con-ducting that kind of effort or related efforts within the Center for Dis-ease Control.

I hope you will review that carefully. Excuse me for interrupting, Senator.

Senator SPECTER. Doctor, were you saying that aside from the issue of sex education of teenagers that there was some effort within your Department to provide information for parents to give sex education to their own teenagers?

PARENT EDUCATION FOR SEXUAL INSTRUCTION

Dr. FOEGE. That's right. We are developing programs for parents to use in the sex education of their own teenagers. In particular, we have been looking at the difficult question of providing information for handicapped teenagers.

Senator SPECTER. Sex education for handicapped teenagers?

Dr. FOEGE. That's right. This is an area of particular difficulty, and we have been trying to come up with ways that parents can deal with this.

Senator SPECTER. Thank you, Mr. Chairman.

Senator SCHMITT. Thank you. I would just follow up on that.

Doctor, there's a difference between providing information and providing education. Information to a school system or parents can be in the form of different kinds of materials, pamphlets, and so forth. Education, though, might include teacher training, the development of curriculums of various kinds, and so forth.

Would you put your activities in either one or both of those activities—information versus education?

Dr. FOEGE. I think that by and large our activities have been to try to find approaches that lead people to have information that changes behavior, so that just the provision of information would not answer that. We've also been looking for model programs that could be used around the country. So it's education in that sense.

Senator SCHMITT. What have been your results? Have you been able to influence behavior? Assuming a positive influence would be a reduction in teenage pregnancies.

Dr. FOEGE. Well, our evaluation from Math Tech in 1979 indicated that very few sex eduation programs of any kind had an evaluation phase, therefore, it was not possible to look at them and say, "What has this led to?"

There are some specific instances, though, around the country, where one can show reductions in teenage pregnancies. These are small projects.

Senator SCHMITT. Funded by your center? Local initiative, or what?

Dr. FOEGE. They have not been been funded by CDC. They have been evaluated by CDC, and I think all three of them have been local initiatives.

Senator SCHMITT. Could you provide for the record information on those three initiatives, and what you think is the reason for their success.

Dr. FOEGE. Yes.

Senator SCHMITT. In relationship to others for which there is no measure of success.

Dr. FOEGE. Yes; for those where there's been no measure for success, it's because they've had no measuring tools, not necessarily that there is no success.

[The information follows:]

THREE TEENAGE PREGNANCY INITIATIVES

The three local programs which show some documented success in reducing the occurrence of unwanted pregnancies in teenagers are located in St. Paul, Minn.; Philadelphia, Pa.; and Washington, D.C. In St. Paul, a hospital maternal and infant care center established a clinic on the grounds of a local high school. The program provided sex education instruction in the school while the clinic provided general health exams, pelvic exams, and contraceptive followups. Contraception was made readily accessible to students off campus. Over a 3-year period the fertility rate in the high school declined by 56 percent. The Philadelphia program, similar in that it combined sex education instruction in school with referral and access to contraception, is less well documented but appears to have significantly decreased pregnancy rates. The Washington, D.C. program, which combined sex education instruction of students with counseling and emotional support, also appears to have had a significant reduction in pregnancies in the school in which it has been conducted.

The reasons for the success of these programs, at least in St. Paul and Philadelphia, seem to relate to the combination of effective instruction and access to contraception. It has been shown in many programs that sex education in schools raised the level of knowledge about the consequences of sexual behavior, and about the importance of contraception. Where this instruction is integrated with access to contraceptive services, significant declines in teenage pregnancy can be expected to occur. Data on the effectiveness of educational approaches alone are less conclusive, in large part because objective evaluation has rarely been built into such programs.

HEALTH EDUCATION

Senator SCHMITT. Do you know of any attempts to measure success or failure, where failure has been indicated?

Dr. FOEGE. There are many others where there's been no attempt to look at both rates before or after, to look at knowledge and attitude before or after. These three stand out because one can have objective measurements.

Senator SCHMITT. The subcommittee is going to try to sort out the totality of health education programs within the Department. There is a great deal of activity in various areas, in addition to your own.

In areas other than sex education, do you have any measure of accomplishment in your education program, which amounts to how much for fiscal year 1981? 23.8 million? The budget request by the Carter administration was $21.7 million.

Dr. FOEGE. Much of the training in education is for professionals in the sense that they are at CDC for courses in laboratory sciences, epidemiology, and so forth. In the health education area specifically, much of this money is involved in the risk reduction grants. These grants have only been given in the last year to the States.

We have 160 projects that have been undertaken in the last year. These all have evaluation phases in them. This has been one of the requirements for the grant programs, that they have an evaluation phase.

I can't answer your question at the present time. But I feel confident that we will be able to answer it as we go along, because that's been a requirement of the grant.

Senator SCHMITT. Those projects are directed specifically at public schools.

Dr. FOEGE. Ten million dollars of the grants are specifically for tobacco and alcohol, and they are aimed at teenagers. The remainder of the grants have not been targeted specifically at teenagers, but at all age groups.

We also have some grants included therein, however, to school and health curriculums. One has been a project that goes from kindergarten to seventh grade; the other one, I believe, from kindergarten to fifth grade, now being used in 34 States and about 450 school districts. So it's made up of different components.

Those who are aimed at the schools, the $10 million in tobacco and alcohol, have been retained.

Senator SCHMITT. Would you agree with me that the Center for Disease Control probably is a repository of most of the information in the Federal Government on the causes and effects of communicable diseases and other medically disadvantageous activities?

Dr. FOEGE. There's a great deal of knowledge there. However, the communicable diseases—we work closely with NIAID, the National Institutes of Health, and the Bureau of Biologics in FDA. In fact, we have interagency groups working on most of the infectious diseases that the three of us are involved in.

Senator SCHMITT. But as far as our working practical knowledge of the disease, of how a specific disease interacts with the population as a whole, don't you think you represent the repository of most of that knowledge and expertise?

Dr. FOEGE. I think so, yes.

EXPERT CONSULTANT ROLE

Senator SCHMITT. There are a number of other things going on in the Federal Government that affect either the spread of or cause of the susceptibility to disease. For example, the child nutrition programs of the Department of Agriculture, the preschool education programs of the Department of Education, the general activities of the Department of Education in the elementary and secondary school systems.

To what degree are you utilized as sort of expert consultants within the Federal Government by these other Departments?

Dr. FOEGE. I think the answer to that can be seen by how much we do in reimbursables. About $30 million of reimbursable agreements are conducted each year. That constitutes about 150 separate agreements.

About 100 of those for within the Department, 50 from outside the Department. You are correct that we are looked to by these people.

For instance, the nutrition program, while other people are involved in providing nutritional supplements, we are involved in the surveillance of the nutrition for the WIC program, for other programs in 35 States, and in other States this is growing. Eventually we will have a nationwide nutrition surveillance system. That can be added, then, to the periodic surveys, the Hanes surveys, the health and nutrition surveys.

We have worked closely with the Department of Education. The two curriculums that I have mentioned have been approved by the Department of Education. They are the only two health curriculums to have been approved specifically by them. We have a close working relationship there.

Senator SCHMITT. What about the EPA?

Dr. FOEGE. This is developing. It's not historically as strong as some of the other relationships; but we now have within the Department a coordinating committee for environmental and related problems. The coordinating committee has an executive group. That executive group is now the interface with EPA. We found over the last several years we simply need that relationship, so we have a system there for relating to EPA that we did not have a year ago. We have a single voice by which the Department can talk to them.

Senator SCHMITT. Can you supply us with a list of those agencies that are conducting activities that relate directly or indirectly to disease control, and indicate on that list which ones you do have a working relationship, and a very short summary of the nature of that relationship?

Dr. FOEGE. I'd be happy to.

[The information follows:]

RELATIONSHIPS WITH OTHER FEDERAL AGENCIES

Agency	Subject Area
Alcohol, Drug Abuse and Mental Health Administration	Genetic and metabolic factors associated with alcohol use. Cooperation on grants for community and school-based alcohol and smoking programs. Proficiency testing for drug abuse research. Toxic Emergency Response.
Food and Drug Administration	Vaccine development and testing (also with NIH). Provision of biological products. Health effects of radiation exposure (e.g., Three Mile Island). Nutrition. Infectious and chronic disease surveillance and control (e.g., toxic shock syndrome, infant formula deficiencies). Toxic emergency response. Genetic diseases (Feta-alpha protein). Analysis of blood lead levels. National Toxicology Program.
Health Resources Administration	Cooperation on work with Schools of Public Health. Participation in development of National Health Planning Guidelines.
Health Services Administration	Assistance to the Indian Health Service with respect to Immunizations, Venereal Disease Control, Diabetes Control. Carribean Refugee Assistance. Family Planning Program Evaluation. Genetic disease laboratory and epidemiology. Childhood Immunization Initiative.
National Institutes of Health	Toxic emergency response. National Toxicology Program. Cancer epidemiology. Production of rotavirus serum. Relationship of oral contraceptive use to ovarian and breast cancer. Health consequences of PBB exposure in Michigan. Maintenance of laboratories for the National Eye Institute.

Agency	Subject Area
National Institutes of Health	Clinical chemistry standards for lipid Research clinics and Multiple Risk Factor Intervention Trials. Study of Myocardial Infarction and Aspirin. Vaccine development (also with FDA). Diabetes Control. Lassa fever research. Provision of diagnostic reagents for dental research. Laboratory support for sickle cell research. Leprosy research. Radiation research. Hospital infection control.
National Center for Health Statistics	Morbidity and Mortality Surveillance. Nutrition Surveilance. Natality surveys.
National Center for Health Care Technology	Technology Assessment. Feta-alpha protein study.
Office of Disease Prevention and Health Promotion	Health Promotion Programs. Prevention Policy Development. Nutrition Programs.
Office of Smoking and Health	Community and school-based smoking and alcohol programs.
Office of Human Development Services	Hepatitis and day care centers. Accident Prevention.
Social Security Administration	Indochinese Refugee Assistance.
Other Federal Agencies	
ACTION	Training for Peace Corps volunteers in community water sanitation, venereal disease control, malaria control.
Department of Agriculture	Nutrition surveillance and research. Health education. Provision of biological products.
Consumer Product Safety Commission	Assessment of the National Electronic Injury Surveillance System. Accident prevention.

Other Federal Agencies	Subject Area
Department of Defense	Test of cultures for U. S. Navy. Provision of biological products. Agent Orange Studies. Transportation and open air testing of biological and chemical weapons. Portsmouth
Department of Education	Health education programs.
Environmental Protection Agency	Toxic Emergency Response. PBB exposure in Michigan. Investigations in Memphis on toxic chemical dumps. Provision of biological products. Coordination of environmental health programs.
Federal Emergency Management Agency	Disaster response. Mosquito borne vector control. Toxic Emergency Response. Epidemiological study of morbidity and mortality associated with FEMA mobile homes. Love Canal Mount Saint Helens
General Services Administration	Analysis of water samples for DDT. Provision of biological products.
Department of the Interior	Provision of environmental health services assistance for the National Park Services. Health Promotion Programs.
Department of Energy	Production of new forms of energy.
Department of Housing and Urban Development	Lead-based Paint Poisoning Program. Urban Rat Control Program.
Department of Justice	Emergency response to biological and chemical hostilities (with Departments of State and Defense).
Department of Labor	Occupational Safety and Health. Mine Safety and Health. Blood Lead Analysis.
Department of State/Agency for International Development	International Family Planning Evaluation. Lassa fever in Sierre Leone. Expanded Immunization Initiative in Zaire. Childhood Preventive Diseases Program in Africa. Nutrition Status Surveys.

Other Federal Agencies	Subject Area
Department of State/Agency for International Development	African Regional Office--Health Delivery Systems. Schistosomiasis in Dominican Republic. Primary Health Care in Lesser Developed Countries. Somalia Refugee Program. Potable Water Studies. Assessment of health needs associated with typhoid outbreaks in Mauritis. Training programs.
Veterans Administration	Laboratory specimen testing. Provision of biological products. Agent Orange Studies.

NATIONAL CURRICULUM ON SCHOOL HEALTH

Senator SCHMITT. The Bureau of Health Education is part of your Center for Disease Control?

Dr. FOEGE. Yes, it is.

Senator SCHMITT. I understand, a national curriculum for school health has been developed by the Bureau.

Dr. FOEGE. That's right.

Senator SCHMITT. Is that available for our files?

Dr. FOEGE. Yes, it is.

Senator SCHMITT. What is the status of that?

Dr. FOEGE. This is one of the two I was mentioning. It was originally called the Berkeley Curriculum because it started there in the early 1970's. This is one of the two that has now been approved by the Department of Education and is being used in over 30 States.

Senator SCHMITT. OK; I misunderstood that. And we can get a copy of that, then, for our file?

Dr. FOEGE. Yes.

Senator SCHMITT. Senator Specter, if you have any further questions, don't hesitate to interrupt.

PHS SEX EDUCATION ACTIVITIES

Senator SPECTER. I have one question which follows from the brief description that you gave about the program providing for the basic education of parents on sexual instruction. The information provided by our staff here, that there is a sex education program within the family planning unit in the Health Services Administration.

My question is, wouldn't those two programs be sufficiently similar to be administered by the same unit within the Department?

Dr. FOEGE. I think, Senator, the Health Services Administration and family planning in general, has been involved in delivering the product. We've been involved in developing techniques and evaluation, for instance, of family planning in general.

Senator SPECTER. Developing a product that goes to developing techniques?

Dr. FOEGE. That's right.

Senator SPECTER. What's the difference?

Dr. FOEGE. For example, in family planning in general, the Health Services Administration delivers a great deal of family planning information. They have clinics; they do sterilizations; they provide the pill, and so forth. We are involved in evaluating what are the morbidity and mortality complications of sterilization, of the pill; what are the safest techniques to use. But we are not involved in actually delivering it.

I think there is a similar analogy for sex education. We are involved in looking at the techniques and evaluating the techniques, but not necessarily delivering them.

Senator SPECTER. With respect to the program that you described, albeit briefly, about information for parents, isn't that a program for the dissemination of information? An educational program as opposed to evaluating something to see if it's the safest?

Dr. FOEGE. In that particular program we would be looking at what are the barriers to parents delivering sex education to their children. What are the problems that the programs have had in the past in doing this? What would be an optimal approach to it?

Then the Health Services Administration might in fact use this, or might not. But they would be delivering something while we're developing the techniques.

Senator SPECTER. How do you coordinate between evaluating techniques and delivering techniques? What you're saying is those two items, No. 1, evaluating the technique; and No. 2, delivering the techniques, are handled by separate agencies and separate divisions. Why?

Dr. FOEGE. I think one reason has been to keep evaluation objective and conducted by people other than those who are actually responsible for delivering the program. Sterilization is a good example. We determine the health complications of sterilization and how can they be overcome. While we don't have clinics for sterilizing people, we do have interests in the morbidity and mortality that is occurring and that could be prevented. We evaluate the techniques and then evaluate the programs. What's the impact on the family planning program? What are, for instance, birth rates in the community?

Senator SPECTER. Is that a standard approach, to your knowledge, to have separation between those who deliver programs and those who make evaluations of them?

Dr. FOEGE. I think it works two ways. At CDC, looking at our own programs, we have tried to build in evaluation techniques and do our own programs. We also have had outside evaluators to look at our programs because they don't have a vested interest in how the evaluation comes out. Thus, we have internal management-oriented evaluation and we also have outside evaluation.

Senator SPECTER. On that one item, which is the dissemination of information for parents to pass on to their children, why wouldn't it make more sense to have that kind of a program, which is essentially an educational program, be administered by the family planning unit?

Dr. FOEGE. It's more than just providing information for parents. It's testing out approaches that parents can use. It's not simply deciding what sort of information they have to give to their children, but what

seems to work in real life situations; what program works in what area; what could be replicated.

And having provided this kind of a model, then we are not involved in actually delivering it.

Senator SPECTER. Could you be specific and give us a more precise frame of reference as to what you're talking about on information to parents, on sex education?

Dr. FOEGE. If I could use a different example, one of the success programs in sex education did not necessarily take a sex education approach, but took an approach of self-image. That is, the teenagers were given a great deal of information on how to dress attractively, how to fill out forms for job applications, how to do things that were not generally thought of as being part of sex education. It has been shown that self-image has a lot to do with whether people decide to use contraception or not.

That is not necessarily something ordinarily thought of as being part of sex education. I suspect that as we are dealing with the handicapped, and we are only now getting into this, that self-image is going to be an important part of what a parent can convey to a handicapped teenager.

Senator SPECTER. And your point is that self-image might have an impact on whether a teenager would use contraceptives?

Dr. FOEGE. It certainly does in the nonhandicapped area. I am referring to a self-image, that leads a teenager to realize that one does not have to have a child because they are 16. But that at 16 they can do other things. In at least one program that has turned out to be an important factor.

Senator SPECTER. Thank you very much.

Thank you, Mr. Chairman.

DIABETES

Senator SCHMITT. Thank you, Senator.

In the diabetes control program, could you estimate what proportion of the $20 to $21 million that was spent there in fiscal year 1981, or is being spent, goes to diabetes control? I didn't phrase that question very well. That's the total in the chronic diseases program.

Dr. FOEGE. That's right. About $5.25 million goes to diabetes.

Senator SCHMITT. Last year you testified about the development of an approach for the prevention of the progression and consequences of diabetes—what progress had been made in your program to control diabetes progression and the consequences of such progression?

Dr. FOEGE. As I mentioned last year, we now have 20 States in different phases of this program. Some have been in it for 2 or 3 years; others are only starting. It's become clear to me that for a number of years we will be dealing with anecdotal information, that one place has a success and they report on it to others. In some programs, third-party payers have agreed to pay for health education for the diabetic patients. We've also been able to see, in some programs, in Michigan, for instance, where there has been a reduction in hospital days for a targeted population; that diabetics have been able to change their habits and reduce these hospital days.

Each program is using a slightly different approach. There's not a unified approach for the 20 States, so they begin showing different

things. What is clearly shown is that surveillance systems have demonstrated the problem with a clarity that we've never had before.

There are approximately 28,000 amputations per year. It's possible to say how many hospital days are being spent over and above what one would expect. I am confident that this program is showing a prevention of progression of the disease, but it may be some time before we can present a full cost-benefit case.

Senator SCHMITT. Do we understand why the progression of diabetes results in the necessity for amputation?

Dr. FOEGE. It's not clear what all the problems are, but I think that there is a lot of research that has been going on at the cellular level, about what is happening. I think what we're finding——

Senator SCHMITT. Is it reflected as a circulatory problem?

Dr. FOEGE. That is what is causing many of the amputations; that's right. But with proper levels of treatment, people can stay on their insulin. They can periodically be evaluated and not go long periods of time where they are going off insulin. We can reduce many of these complications, and in particular reduce the total days of hospitalization and so forth.

DIABETES TREATMENT

Senator SCHMITT. Is there any generally agreed to evidence that part of the problem is that our treatment of diabetes is to maintain a steady level of insulin in the body systems, rather than a timed release as the body normally does under its own devices?

Dr. FOEGE. This appears to be one problem; yes.

Senator SCHMITT. So the research going on elsewhere into developing time-release mechanisms for insulin injection into the body, into the bloodstream, is, you would say, a very important area of research that can lead to a more effective program on the part of the CDC?

Dr. FOEGE. We think so. But again I would emphasize, even without these research breakthroughs, what we already know needs application. One of our projects, for instance, looked at people admitted to the hospital for coma; found that very few of them had contacted a physician in the previous 48 hours, even with signs and symptoms that should have let them know they were in trouble. They simply did not have the information to say: When this happens, call your physician. So they ended up in the hospital.

Applying what we already know again is a theme we keep bringing up.

Senator SCHMITT. Is there any evidence that you're aware of that if we can more readily duplicate the natural body mechanisms in the treatment of diabetes, then we will prevent the progressive deterioration that comes with diabetes?

Dr. FOEGE. That's a possibility.

Senator SCHMITT. Why is it only a possibility? Doesn't it follow that if you duplicate the natural body mechanism, there will be no progressive deterioration?

Dr. FOEGE. Dr. Robbins?

Dr. ROBBINS. It's been a while. I am certainly no expert on that.

Senator SCHMITT. You're talking to a geologist. You ought to feel very comfortable.

Dr. ROBBINS. In general, diabetes is a dysfunction in the sugar metabolism, but also has a vascular component. If you could control the insulin release, it's always been assumed you could avoid the crises that come with not enough insulin, and therefore too high blood sugar, or the crisis associated with too much insulin, and too low blood sugar. Clearly, if you could adjust the administration of insulin to respond to the needs of sugar metabolism, you would deal very much more effectively with those problems.

The other question has not been fully resolved, whether simply administering insulin at a proper level would eliminate the vascular effects, that affect the eyes, the brain, the kidneys, and the peripheral circulation. It's clear that you could get some small improvement in the vascular effect, but it's not clear that they could be eliminated.

Senator SCHMITT. Is there any evidence that there's a chemical other than insulin involved here, that is also not being produced by the body?

Dr. ROBBINS. Now you're getting beyond me. I will stop.

Senator SCHMITT. I haven't heard anything to that effect.

I think it's important for the subcommittee to realize that one area of research, not under your specific auspices, is providing a mechanism by which this particular program, I think, could become far more effective than it already is. It is apparently quite an effective program.

Dr. FOEGE. We work very closely with the NIH people, and the 20 States that are involved in this work closely with clinical centers that have NIH grants, in order to see that clinical information is quickly passed on.

DIABETES COST TO SOCIETY

Senator SCHMITT. Well, it's my understanding that within this year, and maybe sooner, we should have the potential to begin to produce these programed insulin injection systems. I just hope it hurries up. Do you have any idea what the cost of diabetes is to this society as a whole, on an annual basis?

Dr. FOEGE. I believe that there are something in the neighborhood of 22 million excess hospital days that can be attributed to diabetes in this country.

Senator SCHMITT. What does an excess hospital day cost us these days?

Dr. ROBBINS. I'd say it costs between $100 and $200.

Senator SCHMITT. Is that all?

Dr. ROBBINS. Maybe it's more now.

Dr. HARDY. $350.

Dr. ROBBINS. $350 or $400.

Senator SCHMITT. It sounds like an awfully inexpensive hospital.

Anyway, we're again, like with dental disease, we're talking about billions of dollars. Potentially, maybe even $20 billion.

Dr. FOEGE. That's right: 22 million excess hospital days, 28,000 amputations—it's estimated that some 300,000 deaths a year are directly attributable to diabetes, or where diabetes has at least contributed.

Senator SCHMITT. So, it's a problem. If you have any other figures for the record, we'd appreciate it, on this, and obviously, there are other areas where we're trying to develop a feeling for what is the total cost to the society of a particular disease or problem with which you are working. It's going to help the committee, I think, prioritize its actions.

It also helps us evaluate how important it is to pursue certain lines of research. But it would seem in this case more than likely, at least $10 billion a year are lost by the society, just to pay for the excess hospital days, if your figure of 22 million is correct.

Dr. FOEGE. I do have one other figure that has been estimated, that diabetes costs $7 billion annually. The health effects of diabetes.

Senator SCHMITT. My back-of-the-envelope calculations would say that that might be a little bit low if it's 22 million hospital days, especially, if you don't count the cost of lost productivity of those individuals who die from the disease.

BAD HABITS

Now, as I indicated earlier, it seems that many health problems that you are concerned with can be attributed to poor habits—I would say, "bad habits." A partial list would be smoking, bad diet, excessive drinking, soft drug use, hard drug use, driving at excessive speeds, carelessness in general, sexual carelessness specifically, tooth care neglect, lack of exercise, and lack of prevention against childhood diseases. Certainly we have made progress in the last item on the list.

Do you know of any way to quantify the cost to the Government and the cost to the economy as a whole, and the cost in lives, resulting from these bad habits, on an annual basis? I'm not expecting you to do that off the top of your head.

But could you take that list, and give us at least some generalized feeling of what your estimate is of the cost.

Dr. FOEGE. Yes.

Senator SCHMITT. You may want to add one or two other items to the list. That list was prepared very quickly.

Dr. FOEGE. We can certainly do that for the record.

[The information follows:]

BAD HABITS

Examples of the cost of bad habits are:

Economic cost of smoking, United States—1979

	Billions
Medical care	$5 to $8
Lost productivity	12 to 18
Total	17 to 26

Economic cost of alcohol abuse and alcoholism, United States—1975

	Billions
Medical care	$12.7
Social costs	1.9
Motor vehicle accidents	5.1
Fires	.4
Lost productivity	19.6
Total	39.7

SMOKING AND LUNG CANCER

Dr. FOEGE. I might just point out that in cigarette smoking alone, there is an enormous toll. There are 100,000 lung cancer deaths per year to the other cancers—pancreas, bladder—that we know increase with cigarette smoking. There is premature mortality from coronary

heart disease. The Surgeon General's report on smoking shows that there are in excess of 320,000 premature deaths each year, just because of smoking. This means we're approaching the point of 1,000 excess deaths a day in this country, as the result of cigarette smoking.

Senator SCHMITT. If that were polio or smallpox, we would be keeping our kids out of theaters, away from school, and everything else.

Dr. FOEGE. That's right. And, as I mentioned, in three of the five leading causes of death, one-third to one-half of those deaths, are related to alcohol abuse. The only section of the population in this country with increasing mortality rate is the 16 to 24 age group. Upon examination it's clear that accidents, homicides, and suicides are the cause. Further analysis shows that alcohol is playing a major role in those increases.

Senator SCHMITT. More than drug abuse?

Dr. FOEGE. Drug abuse is obviously contributing.

Senator SCHMITT. Drugs other than alcohol?

Dr. FOEGE. That's right. Both of them are involved. But alcohol is a very significant problem.

Senator SCHMITT. So we're losing that battle right now?

Dr. FOEGE. The per capita alcohol intake rates in this country are back up to about where they were at the beginning of this century, which of course was one of the things that led to prohibition.

Senator SCHMITT. You're not proposing that we try that again?

Dr. FOEGE. It was a medical success, but a social failure. [Laughter.]

It is clear, though, that when one looks at Scandinavian countries, it is possible to do something about the toll of alcohol. In this country, 50 percent of our traffic fatalities are related to alcohol. In Sweden, I believe it's down now to about 10 percent. They've done this because of programs that say, "You can't drink when you're driving."

Senator SCHMITT. I'll tell you, if it's anything like Norway, where I spent some time, those are good programs. They really are. I don't know whether we have a society that will accept the consequences, but as you say, we certainly know that programs can work, at least within a homogeneous and small society.

Do you think that maybe we would be better off focusing the Centers' total activities on bad habits, rather than on the activities you presently have underway? Aren't most of the things you're doing now relatively insignificant under the umbrella of this particular list?

CIGARETTE SMOKING

Dr. FOEGE. We have a problem, of course, of maintenance. I frequently use the example of living in a jungle clearing. If we stop these other activities, it's predictable what will happen: there is a resurgence of the problem. We can't stop those things, despite our best efforts. Things such as toxic shock keep appearing each year.

So I think we have to maintain the core that we've had in the past, but there's no question in my mind that in the 1980's and 1990's the real changes in morbidity and mortality we'll see in this country will be changes that have come from programs that are directed at the self-destructive behavior.

I believe also that by the year 2000 the Third World will find that their No. 1 health problem is cigarette smoking.

Senator SCHMITT. Do you know of any way in which criteria could be developed that would restrict access to Federal medical assistance if the reason for the need of that assistance was caused by cigarette smoking?

Dr. FOEGE. I'm not sure I understand.

Senator SCHMITT. Do you know of any criteria that would be not only technically supportable but politically acceptable, that would prevent access to Federal medical assistance if the need for that access was the result of smoking?

Dr. FOEGE. No. I don't.

Senator SCHMITT. Has anybody ever sat down and brainstormed on that one, within your organization?

Dr. FOEGE. Yes, we've looked, in other ways. Do you want to say something about that, Dr. Robbins?

Senator SCHMITT. Please.

Dr. ROBBINS. I was only going to say that we do have some experience trying to determine how you would find the cause of occupational disease. It's probably a little bit more complicated in general than the cigarette issue. We're left at this point with only a few diseases that very clearly on an individual basis can be associated with a particular environmental—in the same sense that cigarettes are environmental—cause: for example, asbestos-caused disease, mesothelioma.

Senator SCHMITT. No, no, no; asbestos-caused diseases are not necessarily voluntary diseases. Diseases resulting from smoking are voluntary diseases.

Dr. ROBBINS. I am saying exactly what you're saying.

Senator SCHMITT. The individual who smokes made a conscious decision to accept the risk of illnesses resulting from smoking?

Dr. ROBBINS. I completely agree with you. I am simply suggesting that NIOSH has attempted to lay out criteria for the establishment of the cause of occupationally related diseases. The task of separating most of the lung cancers, which are probably associated in some way with cigarettes, though maybe not entirely, from the others, is a very difficult problem. There's no way to do it for any individual patient at the present time.

SMOKING AND ILLNESS

Dr. FOEGE. I think that's the major problem. Cigarette smoking does not cause a disease that's not known to nonsmokers. Therefore, you have a hard time relating any particular problem in the individual to cigarettes.

Senator SCHMITT. I'm just saying that if that disease appears, and you are a smoker, then no assistance is accessible, to you.

Dr. FOEGE. That's right. You include in your question "politically acceptable," which is why I said, "No." But there is one approach that has been suggested. If cigarettes were taxed to the point that they paid for the excess cost to society, this would be a way to make sure that smokers pay for the unnecessary illnesses they have.

Senator SCHMITT. In that context, apparently, some insurance companies have higher medical insurance rates for people who smoke than those who don't smoke. So basically, they're taxing cigarettes in that respect.

Is that the way you interpret it?

Dr. FOEGE. That's right.

Senator SCHMITT. Would you agree, though, that from a technical point of view, one might, be able to develop criteria that would distinguish those individuals who have a particular disease, like lung cancer, into two groups: one that smoked, and one that didn't smoke?

Dr. FOEGE. The difficulty there will be that there will be some who gave up smoking 5 years ago, 10 years ago, 2 years ago—which category will they be put in?

Senator SCHMITT. But statistically, don't we know that the danger pretty much goes back to the normal population after about 10 years; is that correct?

Dr. FOEGE. That's right.

Senator SCHMITT. Technically, you could work out a set of criteria of that kind. Whether you could sell them politically is another issue.

Dr. FOEGE. They would probably not be in the yes/no categories, but statistical risk categories.

Senator SCHMITT. Sure; by relating a specific disease to whether they were smoking or nonsmoking, increasing in 10 years, is one example of such a criterion. Certainly, technically it would make sense. It would be justifiable statistically and technically.

Dr. FOEGE. That's right.

ENVIRONMENTALLY CAUSED DISEASES

Senator SCHMITT. One of the issues related to smoking is that several other environmentally caused diseases, particularly lung diseases, are advanced by smoking. Do you agree with that?

Dr. FOEGE. That's right.

Senator SCHMITT. For example, the lung cancers that were produced, or that are unfortunately common, in uranium miners, from my home State of New Mexico, up to 1970, anyway, are predominantly in miners who smoked. It's a slightly higher risk among nonsmokers, but the risk jumps several factors if you are a smoker as well as a miner.

Are you familiar with that research?

Dr. FOEGE. Yes; in fact, NIOSH has been working on a uranium miner study.

Senator SCHMITT. Does the same thing apply to coal mining, the history of coal miners and so forth?

Dr. ROBBINS. In many of these situations, as you describe, an effect of enhancing the disease process with cigarettes, the disease is not absent in nonsmokers, but stopping smoking or nonsmoking does provide a certain amount of protection. In the uranium miner case, the evidence suggests that there is about a twofold increase in both the smokers and nonsmokers versus male nonminers. The cancer is presumably caused by radon daughter exposure in both smokers and nonsmokers. The total effect is much worse in smokers because of the very close association between lung cancer and smoking.

ANTISMOKING CAMPAIGN

Senator SCHMITT. What is the status of the antismoking campaign that Secretary Califano initiated? Is that still a campaign, or did we forget about it?

Dr. FOEGE. There is a smoking and health program that is in the Office of the Assistant Secretary for Health.

Senator SCHMITT. You have no role in that effort, other than, I presume, providing information?

Dr. FOEGE. We work closely with them, but we are not involved directly.

LEAD-BASED PAINT POISONING PREVENTION

Senator SCHMITT. The Carter administration budget for the lead-based poisoning prevention program in fiscal year 1982 indicated that you would like to make an attempt to assist local programs in identifying other resources to address the problem. What does that mean? What kind of assistance would you provide to identify those resources?

Dr. FOEGE. I think this is particularly true in health education. There are many other resources, PTA's, employers, community organizations, that are willing to get involved in health education if they have some guidance and leadership. The health risk appraisals that we have been using as part of our risk reduction system have been used by an array of people, and I think as with the diabetes program and other programs, that people find other resources.

Let me just mention one example. In the childhood immunization program, in some areas we have been able to get Blue Cross-Blue Shield to support the childhood immunization program because of the cost benefits there. So it is seeking other resources of other groups, parents groups, departments of education have been particularly important in the immunization program.

RAT CONTROL

Senator SCHMITT. Is that true of the rat control program, too?

Dr. FOEGE. The rat control program, this is also true. But for every dollar of Federal money there has been more than a dollar of local money provided for the rat control program. And using CETA funds, it's been possible to use local workers working in their own communities.

Senator SCHMITT. You have presumably, by your coordination with EPA, prevented any duplication of effort in the past on these various environmental control programs.

Dr. FOEGE. We have attempted to. I wouldn't say categorically that we have not duplicated effort. But I think that in the last year or two we not only have some national coordination with EPA, but we now have it at many regional levels.

Senator SCHMITT. Would it be appropriate for what you are doing in these kinds of programs, to be on a reimbursable basis from EPA? I saw one head shake.

Dr. FOEGE. I think it's someone else's turn. [Laughter.]

Senator SCHMITT. Let me phrase the question another way. Could you operate the program, these environmental control programs, or educa-

tion programs, depending upon how you want to phrase them, on a reimbursable basis? I mean, if the funding was all localized in one agency, EPA, there would be no inherent difficulty, would there, in operating on a reimbursable basis?

Dr. FOEGE. I think we've demonstrated with the other 30 million dollars' worth of reimbursables that we do, that we can operate that way.

Senator SCHMITT. Would you summarize your work relative to public health emergencies associated with Love Canal, in New York and Mount St. Helens, in Oregon and Washington.

MOUNT ST. HELENS

Dr. FOEGE. Let me mention Mount St. Helens, then ask Dr. Hardy to talk about the Love Canal. In Mount St. Helens we worked closely with EPA in getting ash samples, and not only analyzing them in the lab, but we did a roundrobin at other labs with ash samples. We also instituted surveillance systems for human disease, particular respiratory disease. And NIOSH has included a study of loggers in the Mount St. Helens area to help determine what sort of control devices they have to use.

Do you want me to say anything more about Mount St. Helens?

Senator SCHMITT. Are you distinguishing smokers from nonsmokers in that study?

Dr. ROBBINS. The studies we were doing were prospective studies. Workers are going back in to clean up, and loggers are going to be working on trees covered with the dust. And yes, we do distinguish smokers. We don't have any results except some early measurements that indicate that they may be exposed to fairly high levels of dust, which are about 5 percent crystalline silica, so there is potentially some very small hazard there, particularly if they don't have adequate respiratory protection—masks or respirators.

Dr. FOEGE. It's rare for us to do any studies, however, when we do not distinguish smokers from nonsmokers, just because it is such a pervading problem. Dr. Hardy can tell where we are on Love Canal.

LOVE CANAL

Dr. HARDY. The experience of Love Canal is not dissimilar. There's been a collaborative effort, at least in the design of the proposed studies with EPA, the New York State Health Department, the medical school at Buffalo, a series of scientific review panels, both within the Government and external to Government; and the development of the protocols and sharing in those for additional comments with several citizens' organizations representing the Love Canal community.

We are at a point now where the protocols have been essentially agreed upon although there are still some concerns in the area. The problem now is a question of money being made available to implement the protocols.

Senator SCHMITT. Can you summarize the nature of those protocols?

Dr. HARDY. Yes; the original proposal was a two-pronged approach. One would be the offering of a physical exam, a comprehensive physi-

cal exam to every resident of the Love Canal area, to tell that individual the status of his or her health at that moment. It would not be a cause and effect report on health status. It would be a report on the individual's health status at that time.

The second component was a series of long-term health effects studies in a variety of areas. One would be case control study on chromosome damage, another on nerve conduction. These were two areas that were particularly of concern to the citizenry of the community because of some earlier studies that were equivocal, in their findings.

There was a proposal for a study on stress, the mental health effects on citizens living in this kind of environment, and a proposal for the development of a voluntary registry to follow these people over time to see if indeed, something develops several years hence in this population.

Senator SCHMITT. Is a chromosomal analysis part of the physical examination?

Dr. HARDY. Not on each individual; unfortunately, the state of the art is not what residents of that area would like. In public meetings one of the citizens said, "I want a chromosome test on my daughter so I can know whether she should get pregnant and I am going to have deformed grandchildren."

It would be very nice if we were able to do that, but the fact is that these tests are just simply not individually predictive and we could not provide that type of information that the individual may want. Chromosome tests would not be a routine part of the physical exam. They are a very expensive procedure, and at best can be used for group analysis in long-term predictive effects.

Senator SCHMITT. What if it was not an expensive procedure? What if there was a systematic low-cost procedure? Would you gain anything from an individual test?

Dr. HARDY. At this point in time, even if it were a simple low-cost procedure, we still could not predict for an individual what the outcome of a pregnancy in the third generation would be.

Senator SCHMITT. So you would not encourage obtaining that information?

Dr. HARDY. There is a proposal for chromosome studies in a case control fashion, but again, the best we can hope to show is that there are differences in breakage rates between citizens who live at Love Canal and control groups who live elsewhere. Of course, if differences are not seen, the question is: Is it because of sample size or is there really not a difference? And, of course, the ultimate question is what does all this mean?

Senator SCHMITT. The chromosomal sorting at Los Alamos, if you're not aware of it, would be worth looking at, because it looks like they are adopting their cell sorting technology. They can sort and count broken versus whole chromosomes. I think this effort came about as a result of someone else's work on the Love Canal.

Dr. HARDY. We will certainly look into that.

Senator SCHMITT. Back to Mount St. Helens, don't we have populations that have been exposed to significant amounts of volcanic dust or dust from volcanic materials of a similar nature?

Dr. FOEGE. I'm not sure if we have examples of the same kind of volcanic ash.

Senator SCHMITT. Do you know what perlite is?

Dr. FOEGE. I don't know.

Senator SCHMITT. Perlite is a volcanic material used in construction. It has a unique property. When you heat it up, it expands like popcorn, but it still retains its value as an aggregate, so you make very lightweight but still reasonably strong cement construction units. Perlite mines, I would guess, would have a significant amount of glassy, crystalline dust associated with them. You don't know if any tests in populations in those areas have been made?

Dr. FOEGE. I was going to say, as our examples, we did have in Japan and Central America and other places, but we found that our best information came from looking at occupational health and silica exposure.

Dr. ROBBINS. That's right. The mineral we were dealing with, the greatest quantity was something called crystoballite. As I said, the crystalline silica was about at the 5-percent level. You could extrapolate from other silica exposures, if you assume that all of the other material is harmless.

Senator SCHMITT. Do we have any reason to think that silica glass is any less harmless than crystalline silica? Is there any research?

Dr. ROBBINS. In a general sort of way—now I'm going to get above my head in terms of the geology—but in a general sort of way, the crystalline forms of silica are the ones that have been associated with disease, and the so-called amorphous silica does not seem to have the same disease producing characteristics.

Senator SCHMITT. There is data to that effect?

Dr. ROBBINS. Yes.

Senator SCHMITT. Silicosis, refresh my memory. What is the specific nature of the disease? Is it the lung's rejection of the silica?

Dr. ROBBINS. It's an inflammatory-type reaction that develops into fibrosis and restriction of the lungs.

Senator SCHMITT. If you haven't worked in this area, this is going to sound very parochial. Geochemists who are expert in silica glasses, the main scale structure of those glasses and how you would predict from that structure, could also explore whether silica glasses would have the same effect in the lung systems as crystalline glass. It might be worth exploring that, because on the domain scale, silica glasses are not very much different from crystalline silica. One thing they tend to do is hydrolyze much more rapidly. Potentially, that would be the protection that you would have.

Dr. ROBBINS. We do also have some studies going on in fibrous glasses that do not see the same kinds of problems that we see with asbestos used in installation. I would think that at some time in the future there will be a unifying theory of fibers and crystals, and how they produce reactivity in the lung.

Asbestos is now more broadly defined than it was. We know much more about the dimensions of the fibers, and our people in our laboratory in Morgantown are working on these issues.

You mentioned perlite. We have done a recent study on looking at some workers involved with vermiculite, which also has the property of expanding. This was brought to our attention because three workers were reported to have bloody pleural effusions. Now, the question has been raised, is that due to asbestos contaminate, or do we have a problem with the vermiculite.

Senator SCHMITT. I would be very surprised if your vermiculite has similar reactions to asbestos. Vermiculite is a clay mineral.

Dr. ROBBINS. That is why we immediately thought that a contaminant is more likely.

Senator SCHMITT. I am also not aware that asbestos and vermiculite generally occur together.

Dr. ROBBINS. We are not either.

Senator SCHMITT. Is that the situation in this case?

Dr. ROBBINS. We're not aware yet. I will send you a report.

Dr. FOEGE. I just wanted to mention that with the analysis of Mount St. Helens ash, we've been working with geologists at the University of Washington, Washington State University, and the University of Cincinnati.

Senator SCHMITT. You better say Oregon or the chairman will be upset.

Dr. FOEGE. And the University of Oregon. [Laughter.]

I'll go beyond that and say the University of Oregon is not only working on that, it is coordinating what is being done in the Mount St. Helens followup.

Senator SCHMITT. Gentlemen, I could go on all day and you don't want me to, so I will have additional questions for the record. I would appreciate that the answers be returned, if possible, when you return the corrected hearing transcript which will be available to you shortly.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

BAD HABITS

Question: It seems that many of the health problems that CDC focuses on can be attributed to poor habits, such as:

-- smoking
-- bad diet
-- excessive drinking
-- soft drug use
-- hard drug use
-- driving at high speeds
-- sexual carelessness
-- tooth care neglect
-- lack of exercise
-- lack of prevention against childhood diseases

Can you provide us with a breakdown of costs to the government, costs to the economy and costs in lives resulting from these "bad habits"?

Answer: There is no doubt that there remain significant preventable health problems, with consequent direct and indirect costs to society, such as health care use and lost productivity. A major portion of these preventable problems result from choices an individual makes that directly affect his or her own health. The economic costs associated with these problems are not always established with precision, but a great deal of useful information has begun to emerge. The information that follows has been abstracted from various sources cited in footnotes.

Smoking

Costs to Government: Smoking and Health 1/ - estimated 1980 resources, Department of Health and Human Services - $18,095,992. OSH - $2.5 million. CDC - $10 million - smoking and alcohol grants for youths - not separated categorically.

Costs to Economy: According to one recent analysis, the total direct and indirect economic costs of smoking-induced diseases was $27.5 billion in 1976. This figure includes direct health-care costs totalling $8.2 billion, indirect costs due to loss of earnings because of morbidity and mortality totalling $19.1 billion, and property costs from fires totalling $17 billion. 2/

Currently employed smokers report more days lost from work as a result of illness and injury than do employed persons who have never smoked. If excess workdays are calculated for employed persons under 65, there would be an estimated 81,368,000 "excess" work-loss days among smokers and former smokers, accounting for over 21 percent of all workdays lost. 3/

Costs of Lives: Approximately 300,000 excess deaths per year are attributable to cigarette smoking, Demographers identify 80,000 deaths each year from lung cancer, 22,000 deaths from other cancers, up to 225,000 deaths from cardiovascular disease, and more than 19,000 deaths from chronic pulmonary disease to be related to smoking.

Estimated Percent of Disease Attributable to Smoking 4/

Disease	Percent	
	Male	Female
Diseases of the heart	30	30
Bronchitis/emphysema	85	85
Arteriosclerosis	33	33
Cancer of the oral cavity	70	70
Cancer of the esophagus	40	20
Cancer of the pancreas	35	35
Cancer of the larynx	50	50
Cancer of the trachea and bronchus	90	85
Cancer of the kidney	25	15
Cancer of the bladder	50	30

1/ Prevention '80.
2/ Luce, Bryan R. and Stuart O. Schweitzer: Smoking and alcohol abuse: a comparison of their economic consequences. New England Journal of Medicine 298(10): 569-571, March 9, 1978.
3/ Smoking and Health: a Report of the Surgeon General, 1979.
4/ Smoking and Health: a Program to Reduce the Risk of Disease in Smokers. National Cancer Institute, December 1977.

Bad Diet

Costs to Government: Improved Nutrition 1/ --estimated 1980 resources, Department of Health and Human Services --$480,070,191.

Costs to Economy: Not known.

Costs in Lives: Not known.

Groups at high risk of malnutrition are the poor, preschool children, women of childbearing ages, and the elderly. 2/

Despite a general presumption that obesity is unhealthy and despite a large body of research into the physiology of adiposity, scientists have made little progress in unraveling its determinants, and its health consequences remain controversial.

Mortality: There is ample evidence that obesity, or at least overweight, is associated with increasing mortality. A series of mortality/weight investigations of insured lives has shown consistent results since the turn of the century. One study found that the mortality rate increases with higher degrees of overweight and that this increase is more than proportionate to the departure from average weight. For example, men 20 percent above average weight showed about 25 percent more mortality; those 40 percent and 60 percent above average weight showed an increase in mortality of 67 percent and 150 percent, respectively. The rise in mortality among overweight women was distinctly lower. The mortality rate among overweight persons is increased significantly by the presence of other medical conditions. Optimum weights, that is, the weights associated with the lowest mortality rate, were generally 15-25 pounds below present average weights.

It is interesting, however, that in the Framingham Study relative weight was not found to be correlated linearly with mortality. 3/

1/ Prevention '80.
2/ White House Conference on Food, Nutrition, and Health: Final Report of Panel I-1, Washington, D. C., 1969. p.24.
3/ Obesity in America. USDHEW, PHS, NIH, No. 80-359, Reprinted May 1980.

Excessive Drinking

Costs to Government: Misuse of Alcohol and Drugs 1/ --estimated 1980 resources, Department of Health and Human Services --$145,288,367.

Costs to Economy: According to one recent analysis, the total estimated cost of alcohol abuse is $44.2 billion.

	Alcohol Abuse
Lost production	20,587.3
Direct health-care costs	11,929.3
Fire losses	375.2
Motor-vehicle-accident losses	6,586.8
Cost of violent crime	2,061.2
Cost of certain social responses .	2,654.0
	44,193.8

Costs in Lives: Estimated no. of alcohol abusers = 9 million. Deaths due to cirrhosis of liver (alcoholic) = 13,289 in 1976.

1/ Prevention '80.
2/ Luce, Bryan R. and Stuart O. Schweitzer: Smoking and alcohol abuse: a comparison of their economic consequences. New England Journal of Medicine 298(10):569-571, March 9, 1978.

Drug Use

Costs to Government: Misuse of Alcohol and Drugs 1/ --estimated 1980 resources, Department of Health and Human Services --$145,288,367.

Costs to Economy: Drug abuse costs include a number of direct costs such as medical treatment, law-enforcement, prevention and indirect costs such as mortality and reduced productivity. A recent study of economic costs related to drug abuse cites $15 billion as the total costs incurred by society for drug abuse. 2/

Costs to Lives: Although there is no question that drug misuse is a major problem, reliable information on actual prevalence or drug-related deaths is hard to obtain. It has been estimated that there are approximately 2,500,000 persons (roughly 2 percent of the population age 18 and over) having serious drug problems. 3/

1/ Prevention '80.
2/ To be published data from Economic Costs to Society of Alcohol, Drug Abuse, and Mental Health, Alcohol, Drug Abuse, and Mental Health Administration, 1981.
3/ Promoting Health, Preventing Disease, Objectives For the Nation.

Driving at High Speeds

Motor Vehicle Accidents

Data on motor vehicle accidents resulting from driving at high speeds are suggested by comparison of pre- and post-55 m.p.h. figures. 1/, 2/

	Pre 55 m.p.h.		Post 55 m.p.h.				
	1972	1973	1974	1975	1976	1977	1979
No. of Deaths ...	54,589	54,052	45,196	45,853	46,700	47,671	51,900
No. of Disability Injuries .					1.8 million		2 million
Costs					24.7 billion		35.8 billion

Note: Ages 15 to 24, males, leading cause of death. In 1979 the number of 15 to 24 year-old-males in U.S. population is projected to have peaked:

1977	20,864,000
1978	21,000,000
1979	21,059,000
1980	20,988,000
1981	20,789,000
1982	20,463,000

During the 10 years 1963-1973, average speed on main rural roads increased more than 9% with a corresponding increase in crash speeds. In 1974, the average speed dropped 8% below that of 1973. During this period, highway fatalities dropped 17%. In 1975, 1976, & 1977, the average speed increased slightly, but it was still below the 1973 average speed. 1/

1/ 55 MPH Fact Book, U.S. Dept. of Transportation, Sept. 1978.
2/ Accident Facts. National Safety Council. 1977 Final Condensed Edition; Accident Facts: 1980 Edition, National Safety Council.

Sexual Carelessness

Costs to Government: Family Planning 1/ --estimated 1980 resources, Department of Health and Human Services -$459,750,567.

Costs to Economy: All pregnancies should be wanted. Any child whose birth is planned is far more likely to get off to a healthy start in life and to receive continuing parental love and support needed for healthy development. Quantifying the costs of unwanted

birth is very difficult. The magnitude of the problem is illustrated by these examples. 2/

- By 1976, 68 percent of married U.S. couples were using contraception.
- Each year an estimated 300,000 married women have children they say they do not want.
- The association of unwanted births with lower socioeconomic conditions and poverty also persists.
- Of more than four million pregnancies, more than a million are terminated by abortion. Women with three children have twice the abortion rate of women with one child.

1/ Prevention '80.
2/ Healthy People, DHEW, PHS, 1979.

Tooth Care Neglect

Costs to Government: 1980 resources, Department of Health and Human Services, FY 1980--$11,785,932. 1/ CDC Fluoridation Grant Program - $6.2 million (37 States and 12 city or county governments).

Costs to the Economy: Dental diseases probably constitute, in the aggregate, the most prevalent health problem in the nation, and affect all age groups from the very young to the elderly. According to the American Academy of Pediatrics, nearly all children 3 years and older have dental disease 2/ and dental caries affects 98 percent of the U.S. population. 3/ Tooth decay is chiefly responsible for tooth loss before age 35, and fluoridation is the most effective measure to reduce the incidence of tooth decay or caries--fluoridation prevents up to 65% of all caries or 2 out of every 3. After age 35, the greatest cause of tooth loss is peridontal disease which is so widespread it might be considered epidemic. By age 65, over 90% of the population is affected. 4/

In 1979, up to $8 billion was spent in the U.S. on dental care in direct treatment costs and repair services alone. 4/ Currently, the average cost of fluoridation/person/year is a mere 25 cents and every dollar spent on fluoridation results in a savings of $50 in dental treatment costs.

Costs in Lives: Not known. Other areas of concern for potential consideration:

(1) social and psychological problems resulting from oral care neglect, i.e., restricted job potential of person with disfiguration of mouth due to severe caries.
(2) nutritional problems and pain due to caries and tooth loss.
(3) severe caries resulting in septicemia.
(4) deaths due to use of anesthesia during repair of severe dental caries.

1/ Prevention '80.
2/ American Academy of Pediatrics. A guide to Screening for the EPSTD Program Under Medicaid, 1974.
3/ Promoting Health/Preventing Disease; Objectives for the Nation, 1980.
4/ Healthy People, DHEW, PHS, 1979.

Exercise

Costs to Government: Physical Fitness and Exercise 1/ -estimated 1980 resources, Department of Health and Human Services --$145,288,367.

Costs to the Economy: Unknown.

Costs in Lives: Unknown.

1/ Prevention '80.

HEALTH EDUCATION

Question: We understand the Bureau of Health Education has developed a National curriculum for school health. Since curriculum development is a function of State and local agencies, how do you plan to use this plan you have developed?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

DIABETES CONTROL PROGRAM/CHRONIC DISEASES

Question: How much do you plan to spend for this program in FY 1982?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: How many projects will be supported in the new fiscal year?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: To what extent could this effort be carried out through other Federal or State health programs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: To what extent are public information activities duplicated within the public information offices at NIH, more specifically, the Arthritis Institute (NIAMDD)?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

LEAD-BASED PAINT POISONING PREVENTION

Question: The Carter Administration budget for the Lead-Based Poising Prevention Program in fiscal 1982 indicates that an attempt will be made to assist local programs in identifying other resources to address the problem. Since lead-based paint poisoning is common in older dwelling units, usually found in the inner city, to what extent has HUD been involved in identifying dwellings with lead paint.

Answer: The Housing and Urban Development Department activities to identify lead paint in the older dwellings of the country has been limited.

Question: How successful has the lead-based paint poisoning prevention program been in protecting children from permanent neurologic damage caused by the ingestion of lead?

Answer: Prevention of permanent neurologic damage from lead can only occur through early detection of the estimated 150,000 children with the disease and providing the required intervention services. Since the program was initiated deaths from the disease have become rare, the number of children found with symptoms has decreased dramatically and the frequency of extremely high lead levels in children has decreased. Most of the 26,500 children identified in fiscal year 1980 were asymptomatic, and as a result of project services 25 percent of the children under followup each quarter achieved a reduced risk of continued lead damage. However, levels of lead previously considered safe have now been implicated in subtle neurologic deficits and learning disabilities only apparent later in life. Only routine screening of all children aged 1-5 will detect the presence of the disease.

LOVE CANAL/MT. ST. HELENS

Senator Hatfield: How are you currently addressing the public health emergencies associated with Love Canal in New York and the Mt. St. Helens eruption in Oregon and Washington?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: The Carter Administration requested funds to begin clinical health studies for the residents in the area of Love Canal. Yet no funds were requested to implement the Mt. St. Helens volcanic ash study that CDC helped to plan. Why were no funds requested?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

LEGIONNAIRES' DISEASE

Question: What progress has been made in the treatment and cure of Legionnaires' disease?

Answer: Clinical observations suggest that the antibiotic erythromycin is effective against L. pneumophia infection in humans. During the 1976 Philadelphia outbreak, patients either untreated with antibiotics or treated with antibiotics that have subsequently been shown to have no activity against the organism, had mortality rates in excess of 40 percent. Persons treated with erythromycin had a mortality rate of 11 percent. In an outbreak in Vermont in late 1977, the mortality rate for patients treated with erythromycin early in their clinical course was 5 percent.

Question: How does the disease spread?

Answer: Airborne transmission of L. pneumophila has been the only documented natural mode of spread. Secondary cases of Legionnaires' disease have never been identified and to date there has been no documented instance of person-to-person spread.

Question: How many cases are there each year?

Answer: Approximately 1,000 cases of Legionnaires' disease are reported to the Centers for Disease Control annually. The precise incidence of the disease in the United States is unknown. However, in a comprehensive study of community-acquired disease in a large metropolitan area known not to be hyperendemic for disease and conducted over many years, found that 1 percent of patients with pneumonia of uncertain etiology had Legionnaires' disease. This would represent an incidence of 12 cases per 100,000 population per year, or 25,000-30,000 annually in the United States. Since this study did not include those cases acquired in the hospital setting (5 percent of sporadic Legionnaires' disease) and did not include testing for the newer serogroups of L. pneumophila, a current estimate is that there are approximately 40,000-50,000 cases per year in the United States.

Question: On the average, how many deaths result?

Answer: Overall, the mortality rate associated with both sporadic and outbreak associated cases is approximately 16 percent (this is 6,000-8,000 deaths annually in the U.S.). This figure contrasts sharply with the data presented by Fay et al. (JAMA 1980;243:2311-13) of over 70,000 deaths each year in the U.S. In the February 20, 1981 issue of JAMA we discuss some of the potential problems associated with Dr. Fay's analysis.

Question: How much has CDC spent irvestigating Legionnaires' disease?

Answer: To date (since the original Philadelphia) the Centers for Disease Control has spent approximately $5,000,000 on all phases of investigation of Legionnaires' disease.

LABORATORY ERROR RATES

Question: In last year's testimony CDC stated that an important method for reducing health care costs associated with laboratory services is reducing clinical laboratory error rates. What does CDC plan to do alone or with other public or private agencies to reduce the occurrence and cost of clinical laboratory errors?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

TECHNOLOGY DEVELOPMENT

Question: On what priority areas will the Technology Development and Application Program focus in fiscal 1982?

Answer: Research efforts are concentrated on improving and standardizing current methodologies and materials and developing new methodologies and materials for the detection, control, and prevention of a wide variety of diseases. These efforts are designed to produce improvements in both clinical laboratory diagnosis of disease and patient management. Disease prevention strategy is developed through increased understanding of disease etiology, early diagnosis and containment, and management of risk factors. High priority areas for focus of efforts in 1982 are:

Hospital Infections: To reduce hospital infections by 20% by 1984, guidelines for infection control are being developed and will be disseminated. Demonstration projects will be conducted to establish and evaluate model hospital infection prevention and control programs and to provide a basis for training to improve patient care practices.

Legionnaires' Disease: New methods of detection and new diagnostic products will be developed, evaluated, and produced as new species and subgroups are identified. Newly developed antibiotics will be evaluated for effectiveness in medical management of the disease.

Toxic-Shock Syndrome: It is expected that by fiscal year 1982 the incidence of Toxic-Shock Syndrome will have been substantially reduced through current prevention and control efforts. However, work will continue to better define the etiology of the disease and to develop rapid diagnostic techniques and more effective medical management of the disease.

Monoclonal/Hybridoma Antibodies: A centralized program to develop and produce high titer specific monoclonal antibodies from hybridomas was made available to all organizational units of the CDC in fiscal year 1980. The program coordinates the production of materials for improved laboratory diagnostic capability in infectious and noninfectious diseases, and to expedite research in further understanding the etiology of diseases and early diagnostic possibilities. The products made will be evaluated and distributed as standard materials and diagnostic reference reagents.

Ultrasensitive Chromatographic Applications: Techniques will be developed to determine the chemical composition of microorganisms or products of metabolism as a basis for rapid identification of pathogens in body fluids. Concentrated efforts will be made to apply these techniques in the diagnosis of a variety of microbiological diseases including acute and chronic meningitis and encephalitis.

Laboratory Improvement: Highest priority for this program will be on those aspects of laboratory improvement in which there is little, if any, State and local or private sector activity. Technology transfer will occur at two levels: (1) Training in newer or more cost-effective tests and methodologies developed by CDC and others for advanced laboratories through headquarters courses and technical manuals. (2) Development of training based upon needs of the nation's smaller or rural laboratories which are not served by any public or private organizations, through CDC-assisted State field courses or other types of training activities. Priority also will be given to special problems of national importance such as: 1) laboratory identification of malaria and other exotic parasites associated with the refugees, not previously seen in the United States; 2) Rabies and other viral disease problems for which the State and Federal governments assume responsibility in the absence of private sector involvement.

There will be increased priorities in efforts to assist State Health Laboratories to develop and expand their own laboratory improvement programs to improve local and private laboratories in their State. For example, CDC is presenting training courses to State, local and private trainers and to present technical laboratory courses. A major problem for these trainers, however, is the lack of availability of appropriate training materials. Training materials produced by the private sector are generally product oriented. In the past few years, a number of program items have been initiated by CDC to remedy this situation. These programs will receive increasing effort in order to place appropriate training materials in the hands of local trainers. Some of these include: 1) State telephone teaching network lecture support, 2) "Laboratory Update" an audiovisual series of more than 100 lectures on laboratory subjects which are distributed to all State laboratories who in turn use the "Laboratory Updates" in their training and make free loan of them to people in their States, 3) methodology oriented video tapes, 4) technical manuals, and 5) complete course packages to be used by local trainers. All of these matrials are made available to those responsible for developing local training. This activity is in addition to the regular training efforts CDC conducts such as headquarters and field laboratory and management courses which will continue.

Question: To what extent is private sector activity involved in Technology Improvement?

Answer: Private sector is quite active in the area of the development and production of laboratory equipment, reagents, and kits and to a lesser extent in basic methodology. In the past few years, the private sector has shown an interest in this area, and a small, but growing amount of activity is taking place as evidenced

by the starting up of companies or associations developing some laboratory instructional materials, seminar type courses, information exchange systems, management-consultation services for clinical laboratories, and proficiency testing services.

Many universities through their continuing education departments are beginning to enter the laboratory training field, generally by sponsoring seminars, but not yet workshops.

There are more than 50 scientific professional organizations and societies involved at various levels of participation of technology improvement. Only a few, however, offer organized short-term laboratory training which is usually restricted to their membership. Along this same line, only a few organizations such as College of American Pathologists, American Association of Bioanalysts, and American Association of Blood Banks provide proficiency testing services.

CDC's efforts will be devoted to those problem areas where activities of the private sector arenot addressed as mentioned in the answer to the previous question.

Question: How is CDC encouraging such private sector involvement?

Answer: Commercial producers and users of laboratory materials are informed of the methods and products developed by CDC scientist through publications, consultations and training activities. Commercial producers of reagents are encouraged to voluntarily participate with CDC in the evaluation of developmental commercial products through informal and formal agreements. Individual CDC scientists provide consultation on the production and clinical field evaluation of new or improved products.

Advisory committees (CDC specialty scientists, physicians, production scientists, product evaluators, and statisticians) provide guidance, on request from industry, in the design, production, packaging, and field evaluation of new products. A structured Premarket Evaluation Program provides industry the opportunity to voluntarily and routinely submit samples of selected marketable products for performance evaluation prior to commercial sale. Reports of these routine performance evaluations are reported directly to clinical laboratories. Complaints from users of commercial products are investigated by in-house testing of the products and results are reported to both the user and the commercial producer. Suggestions for correction of deficiencies are provided.

CDC also encourages the development of locally-funded telephone lecture networks for laboratory improvement. This is becoming more important since travel costs have increased, but more important, offers continuing education to personnel in small laboratories who formerly could not participate in such activity.

Many of the training courses and instructional materials developed for CDC-assisted State laboratory training programs are made available in shortened versions to professional societies at their national and regional meetings.

TOXIC-SHOCK SYNDROME

Question: We've been hearing quite a lot lately about Toxic Shock Syndrome (TSS). How many deaths have been reported in the past year that were directly attributable to TSS?

Answer: Of the 941 cases of TSS reported to CDC, 73 have resulted in deaths. Of these, 45 occurred in 1980.

Question: Have you established the relationship between tampon use and susceptibility to TSS?

Answer: All cases of TSS are caused by the absorption of a toxin produced by the bacterium Staphylococcus aureus. A strong statistical association between the use of tampons and the development of TSS in menstruating women has been demonstrated. Cases of TSS in men and non-menstruating women are not associated with the use of tampons. In menstrually associated TSS, the bacterial infection resides in the vagina, and tampons play a major contributing role in this infection.

Question: What hypotheses are you investigating?

Answer: Work currently in progress includes:

1. Investigation of risk factors which predispose to the acquisition of S. aureaus and the development of TSS.
2. Determination of the source of the strain of S. aureus associated with TSS.
3. Microbiological characterization of this strain of S. aureus.
4. Development of a rapid diagnostic test for TSS.

Question: What are you currently recommending to women about their use of tampons?

Answer: Current recommendations about the use of tampons are made with the understanding that the risk of developing TSS is extremely low, even among tampon-users, and that individuals will have to decide for themselves whether the risks of continued tampon use outweigh the benefits.

Women can almost entirely eliminate risk of developing TSS by not wearing tampons. Women who choose to continue using tampons may reduce their already small risk by wearing them intermittently during each menstrual period (i.e., switch to pads at night and when flow is reduced). Intermittent use has been found to decrease the risk of developing TSS.

VACCINES

Question: The Carter Budget requests funding to establish stockpile vaccines to protect against a possible shortage. Why has it become necessary to stockpile vaccines?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been

established, it will be provided to the Subcommittee.

Question: How many manufacturers currently make polio vaccine?

Answer: There is now only one American manufacturer of live polio vaccine. The only source of inactivated polio vaccine in the United States is from Connaught Laboratories, Ltd., a Canadian firm.

Question: What can be done to encourage other companies to manufacture vaccines?

Answer: Advances in genetics and molecular biologics have made possible the development of improved forms of vaccines as well as new vaccines. However, these advances have greatly increased the cost of manufacturing vaccines and require much greater technical expertise. The static nature of the market discourages new manufacturers from entering the market, and all companies, present manufacturers as well as potential manufacturers, are greatly concerned over the issue of liability for illness or injury following the administration of vaccine.

It is conceivable that present U.S. manufacturers, on economic grounds, might elect to discontinue production of one or more commonly used vaccines. As long as the liability issue is not resolved, manufacturers may not be willing to invest large sums of capital in production facilities for vaccines which have limited market potential. Consequently, it seems unlikely that there will be new entries into the marketplace.

TUBERCULOSIS

Question: What is the budget request for programs for TB control?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: How serious a problem is tuberculosis today?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NIOSH PRIVATE SECTOR COSTS

Question: To what extent are you aware of the costs to the private sector of exposure level standards that you recommend to OSHA and MSHA?

Answer: Specifications for medical examinations, warning signs, sampling and analyses procedures, sanitation facilities, and recordkeeping, all or some of which may be apart of NIOSH recommendations, are all developed with cost considerations in

mind. NIOSH also considers technological feasibility in making its recommendations. However, cost has not been a limiting factor in making recommendations to protect adequately the health and safety of workers. Cost is weighed by OSHA if and when standards are developed.

The costs which are incurred by the private sector are highly variable, and depend on the types of requirements, the extent and methods of control required, and the existing state of controls. Costs also may be offset by such things as product recovery, more efficient processes, and reduced medical costs.

SYNTHETIC FUELS

Question: What studies has NIOSH undertaken in the field of synfuels production?

Answer: For the last 4 years NIOSH has had underway hygiene studies to characterize occupational hazards of coal gasification and liquefaction technologies at several pilot plants. Coodinated studies are also underway assessing workplace control technologies.

Industrial hygiene characterizations have been performed at the Wilsonville, Alabama pilot plant of the Solvent Refined Coal SRC II coal liquefaction process, and at the now closed Cresap, West Virginia coal liquefaction facility. Such studies are planned for the Ashland Oil H-Coal pilot plant and the Exxon Donor solvent pilot plant liquefaction facilities.

Industrial hygiene preliminary studies have been performed for coal gasification processes at the Catepillar Tractor fixed bed gasifier facility, the Combustion Engineering entrained gasifier pilot, and at the now closed Department of Energy Synthane pilot plant. Full industrial hygiene characterizations are planned for the Caterpillar and Combustion Engineering facilities, at the Tennessee Valley Authority Texaco Gasifier, at the DOE-Morgantown Energy Technology Center pressurized fixed bed gasification system, and at the fluidized bed gasification facility. An interagency effort with DOE and EPA is reviewing plans for a study of a commericial gasification facility in Yugoslavia. NIOSH representatives have conducted a walk through at the Sasol indirect liquefaction facility in South Africa.

A partial retrospective epidemiology study of wokers at a now closed direct liquefaction process development unit in Institute, West Virginia has been performed.

A retrospective epidemiology study of oil shale workers has been performed.

This fiscal year new projects are to start concerning industrial hygiene characterizations of oil shale industries and of indirect liquefaction processes; and initial work on a prospective epidemiological synfuels workers registry is to begin. These new efforts await FY81 pass-through funding from the Environmental Protection Agency, the major source of support for NIOSH energy industry studies.

Question: What new hazards or increases in hazards are likely to occur once commercial production begins?

Answer: Making gaseous or liquid synfuels from coal results in converting much of the sulfur and nitrogen compounds in coal into known toxic gases such as hydrogen sulfide and ammonia with smaller amounts of cyanide, carbonyl sufide, and other toxic producing gases. Technologies exist to separate these toxic gaseous by-products from the process stream for environmental protection for required fuel quality. Fugitive emissions into the workplace are possible, particularly around valves and pumps at coal feeding and by-product removal operations.

The high loadings of minerals in coal and the trace metal content of coal are also released in conversion processes and in some cases can present possible respirable particle hazard due to fugitive emissions or by-product handling. Some of these mineral dusts have been shown to have high surface concentrations of trace metals and/or polycyclic making these particles potentially more toxic than indicated by gross elemental analysis.

Carbon monoxide gas is a principal product of most gasification processes and a major by-product process gas of liquefaction processes.

Heavy aromatic tars are constituents of the major product of direct liquefaction processes; and tars or chars are major by-products of gasification processes. Some of these polycyclic aromatic hydrocarbons and nitrogen-bearing aromatics are potent mutagens; and in some cases have shown to be powerful inducers of cancers in animal tests. These hazardous materials are present to a greater or lesser extent in the various synfuel technologies. For example, solvent refined coal direct liquefaction processes produces potentially carcinogenic tars as substantial fractions of the primary product and some by-products; while entrained coal gasification processes produce char but little or no carcinogenic tars. The potential for hazardous exposures in commercial plants will be a function of the type of conversion process used, the process design, the reliability of components liable to failure, and workplace controls used in the plant.

Additionally, hazards to workers involved in routine plant operation and hazards to maintenance workers may be substantially different. Current frequent replacement needs for critical synfuel plant components make protection of maintenance workers a major concern.

Question: Is the Institute working with engineers who are building the conversion plants, to ensure that the plants will be built with adequate protection controls?

Answer: The goal of the NIOSH program for occupational safety and health protection in emerging energy industries is to identify specific process hazards in a sufficiently timely and detailed manner to permit energy system selection, design, and workplace controls to be used by technology developers and technology sponsors to protect workers. This is possible because of the

staged pilot plant - demonstration plant - commercial plant deployment sequence being fostered by the Department of Energy and Synfuels Corporation activities. This year NIOSH has approved and is initiating a "Demonstration Plant Design Review" project. This project will use information developed in pilot plant studies to review the plans for major demonstration plants. First, immediately apparent additional measures needed for workers protection in the demonstration plant will be recommended to the plant sponsor. Second, a detailed plan for industrial hygiene studies and medical surveillance for the operational demonstration plant will be developed and reviewed with the plant sponsor. Third, the program of studies will be performed in the plant and the results used to detail recommendations for worker protection in commercial plants.

Question: Have you identified the single worst hazard that can be expected from occupational exposure to coal conversion?

Answer: Because synfuel plants will produce complex mixtures of materials, there will be many chemicals that workers must be protected against. A catastrophic event such as a major fire or an explosion which could occur in any process plant, would probably be the worst hazard to the workers.

IMMIGRATION OF REFUGEES WITH HEALTH PROBLEMS

Question: The Immigration and Nationality Act provides that people with certain medical problems be excluded from admission to the United States. Do you know to what extent these excludable conditions are being waived?

Answer: Section 207(a)(3) of the Refugee Act of 1980 permits the Attorney General to waive medical exclusions from admissions in certain circumstances for humanitarian purposes, to assure family unity, or when it is otherwise in the public interest. Any such waiver by the Attorney General must be in writing and can be granted only on an individual basis following an investigation.

Since March 17, 1980, the effective date of the Refugee Act of 1980, through the end of fiscal year 1980, refugees have entered the United Staes with the following excludable medical conditions waived by the Immigration and Naturalization Service overseas prior to their departure:

Section 212(a)(1) Mental Retardation	78
Section 212(a)(3) Previous attack of insanity, recovery demonstrated	2
Section 212(a)(6) Active or suspected active tuberculosis	2,776*

* Followup testing on active or suspected active tuberculosis cases in this country has confirmed the diagnosis of active tuberculosis on 18.7 percent of these individuals. These tests also indicate 33.3 percent non-tuberculosis findings, and 31 percent determinations pending complete diagnosis.

Question: Does their admission pose any significant threat to public health?

Answer: The subsequent admission of the refugee to the United States with Class A tuberculosis (the only communicable condition being "waived") does not pose a significant public health threat to the United States population. No refugees with Class A tuberculosis are permitted entry until they are found to be noninfectious. They are then followed by health departments to ensure that treatment is completed.

Question: Are CDC's resources sufficient to address the health problems of incoming refugees?

Answer: Through interagency agreements with the HHS Office of Refugee Resettlement, CDC is budgeted for three refugee activities: (1) Overseas medical screening, disease monitoring, and inspection and notification at ports of entry; (2) a health assessment grant program; and (3) Cuban/Haitian medical screening programs.

	FY 81 (estimated)
Screening, monitoring, inspection, and notification	$3,020,000
Health Assessment Grants	4,839,000
Cuban/Haitian Screening	50,000

The current levels of CDC resources are adequate for medical screening overseas, disease monitoring, and inspection and notification at the ports of entry at the current level of refugee immigration from Southeast Asia. Funding is also adequate for Cuban/Haitian refugee activities if no further influx occurs in FY 1981.

Health problems beyond those related to entry into the United States are addressed by State and local governments, voluntary agencies, and through other forms of Federal assistance, including Medicaid and a special grant program to provide health assessments for resettled refugees and to address problems of potential public health significance. At the request of the Office of Refugee Resettlement in HHS, CDC is administering this latter grant program. In FY 1980, 46 grants were awarded, ranging from $4,237 to $1,463,762. The grant is used to coordinate health assessment and followup activities, supply expertise such as laboratorians for parasite testing, and provide special resources such as bilingual outreach workers and on-site interpreters. It appears that the $4.839 million grant programs is beginning to help supply the coordination State and local programs have been needing to do an effective job.

Question: What coordination is there between CDC's refugee health activities and the Immigration and Naturalization Service?

Answer: The CDC advisors overseas in Southeast Asia are assigned to work with the Embassies and Consulates to ensure that the health screening examinations provided to Indochinese refugees are performed to the standards of the USPHS and Immigration and

Naturalization Service. The CDC Quarantine Inspectors work closely with the INS at the U.S. ports of entry. CDC Headquarters staff maintain regular communication with their counterparts at INS to resolve problems of mutual concern.

Question: Do you believe there is adequate coordination between these activities in CDC and those falling within the jurisdiction of the Medical Assistance Program in the Office of Refugee Assistance in HHS?

Answer: The CDC refugee activities maintain close cooperation with the Office of Refugee Resettlement in HHS through exchange of data and resources. The CDC staff and ORR Office of Policy and Analysis recently met and discussed medical assistance policy as it relates to the health assessment grant program. The ORR invited CDC to provide analysis and recommendation on medical assistance policy and assured that CDC input would receive significant consideration in shaping future medical assistance policy.

URBAN RAT CONTROL

Question: The Carter Administration budget proposes to terminate grant support for communities under the Urban Rat Control Program, funded at $13 million in fiscal 1981. To what extent would technical assistance continue to be provided to communities?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: To what extent have other Federal agencies, such as the Environmental Protection Agency, been involved in the Urban Rat Control Program?

Answer: Urban Rat Control Projects have made maximum use possible of other Federal resources available in the community. Effective rat control is through education of community residents to eliminate rat harborage by cleaning up the environment and eliminating the rat's food supply by good sanitary practices. The killing of rats through poisoning is secondary. The role played by the Environmental Protection Agency in rat control, through licensing of rodenticides, has had minimal impact on the rat infestation problem in the inner cities. Other Federal agencies have made their greatest contribution by financial support from CETA and the Community Development Programs. In 1978 for example, $8.8 million from CETA and $2 million in CDA funds were utilized by local urban rat control projects.

Question: What type of followup activities have been used in the Urban Rat Control Program to assure that a rat free environment be maintained?

Answer: Federal funds are used as seed money to establish local programs to reduce rat infestations and environmental deterioration to a level which local resources can maintain. Federal funds are directed to the most blighted neighborhoods, where it costs an estimated $650 per block per year to achieve rat

free status. Once achieved, it costs approximately $37 per block per year to maintain. State and local governments then sustain the rat free status, and grant funds are redirected to other neighborhoods with severe problems.

Each grantee must commit resources and submit an acceptable plan to the Urban Rat Control Program describing how the project accomplishments in establishing a rat free environment will be maintained. These plans focus on integrating coordinated rat control services into the ongoing local housing, health, and sanitation programs. Local programs carry out semi-annual statistically valid surveys of the rat free areas to verify status of the blocks.

Question: Why couldn't this program be taken over by local governments?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

NEW FACILITY

Question: How much of a priority is the budget request for $24 million to construct a new laboratory facility in Atlanta? Have you explored the possibility of renovating existing facilities in lieu of any new construction?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

BIRTH DEFECTS

Question: CDC has established a birth defects registry, and is performing the Agent Orange study to watch for birth defects in offspring of Vietnam-era veterans. What is the status of the Agent Orange birth defects study?

Answer: CDC has developed detailed protocol which outlines the procedures to be followed in trying to determine if Vietnam veterans are at increased risk of siring babies with birth defects. This protocol has been given peer review by CDC scientists, by a group of university-based scientists, by the Scientific Committee of the Interagency Workgroup on Phenoxy Herbicides and by four veterans groups; it is now in the final stages of OMB review. CDC will be releasing a Request for Proposals in February to obtain interviewing services required to complete the study.

Question: How is the Atlanta registry of birth defects being used in the study?

Answer: This study is being done in the case-control format. Cases will be babies born with major birth defects and controls will be normal babies. The objective of the study is to determine if a larger proportion of case's fathers are Vietnam veterans.

Such a study requires a registry of babies born with birth defects. CDC began a registry of such babies in Atlanta in 1968 and these babies will serve as the study cases. CDC's Atlanta registry is a unique resource, without which this study would not be possible.

Question: Do you have any noteworthy findings up to this point?

Answer: There are no findings at present. The protocol for this very large study calls for completion of all data collection before analysis and reporting of findings. Project completion is scheduled for the fall of 1983.

Question: What other studies are being conducted to explore the relationship between birth defects and food, drugs and exposure to chemicals?

Answer: CDC's Atlanta birth defects registry data has been used for numerous studies, most of which have been published in the scientific literature. Examples of such studies include those done to explore the relationship between the occurrence of defects and: community exposures to factors such as airport noise; maternal exposures to drugs (e.g., Bendectin, Valium) and other environmental agents such as fever and water fluoridation; the role of vitamins in the occurrence of certain defects; and the role of paternal and maternal occupational exposures.

INTERGOVERNMENTAL COOPERATION

Question: The fiscal 1982 budget justification of the Center administration reports a shift in function for CDC to increased involvement in monitoring community environmental health problems. CDC's role in relation to other Government agencies, however, needs further clarification. To what extent is CDC coordinating its activities with other Federal agencies and with State and local officials?

Answer: A significant portion of CDC's efforts over the past year have been devoted to improving inter-agency and inter-departmental coordination in the area of community environmental problems. Aside from sitting on the many Federal inter-agency committees, CDC has developed stronger ties to regional offices, the National Response Team, and to State health departments.

Question: When was CDC assigned the responsibility to coordinate responses to public health emergencies involving environmental exposures? Who had responsibility prior to this change?

Answer: CDC was given coordinating responsibility in May 1979. Prior to that time, requests were handled on a case by case basis, depending upon the nature of the emergency.

Question: What are the respective roles of CDC and EPA in monitoring toxic substances due to water contamination and inadequate water disposal?

Answer: The basic difference between CDC and EPA is that CDC

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moves to protect the public health and safety in those instances where toxic substances have been shown to present a threat to people. Generally, this means that the substance has a clear pathway to humans through contamination of air, soil, or water. EPA has broader responsibility to monitor the entire environment for the presence of toxic substances and move to protect air, soil, or water from unnecessary pollutions even if there is no immediate threat to the public health.

REFUGEE HEALTH

Question: CDC has been conducting surveillance on refugees' medical problems for several years, including tuberculosis, venereal disease, malaria, and mental problems. How much will be spent in fiscal year 1981 for refugee health programs, assuming that the current number of refugees will not increase significantly?

Answer: The CDC through Interagency agreements with the HHS Office of Refugee Resettlement, is budgeted for these refugee activities: (1) Overseas medical screening, disease monitoring, and inspection and notification at ports of entry; (2) a health assessment grant program; and (3) Cuban/Haitian medical screening programs:

	FY 81	FY 82
Screening, monitoring, inspection and notification	$3,020,000	$2,000,000
Health Assessment Grants	4,839,000	5,132,000
Cuban/Haitians	50,000	-

Question: What are the health problems most often reported for Indochinese refugees? Cubans? Haitians?

Answer: The CDC refugee activity has assembled the following data from health screening examinations of refugees:

FY 1980 - Tuberculosis

Refugee Group	Abnormal Chest X-Ray % of Total Screened in Refugee Camps	Followup Diagnoses in U.S. % Active TB	% Inactive TB	% Activity Undetermined	% No/Non TB Abnormality
Indochinese	5.0	14.6	37.2	25.2	23.0
Cubans	1.8	8.4	35.7	12.7	43.2
Haitians	2.5	8.6	26.1	-	65.3

FY 1980 - Syphilis

Refugee Group	Reactive Syphilis Serology (% of Total Screened)
Indochinese	3.0
Cubans	4.3
Haitians	19.2*

* These high reactor rates for syphilis are doubtlessly inflated by the incidence of yaws on the Island. Serologic tests cannot distinguish patients who are infected with syphilis or yaws. The reactor rate in this population probably overestimates the incidence of syphilis.

Question: To what extent is the necessity for health screening and treatment program in the United States minimized by effective screening and treatment programs in overseas processing areas?

Answer: The overseas medical screening examinations are designed to identify certain diseases (infectious tuberculosis, infectious leprosy, untreated venereal diseases) and conditions (insanity, mental retardation, sexual deviation, chronic alcoholism and drug addiction). These examinations are the same as the visa medical examination provided to aliens seeking immigration status to the United States. One addition to the refugee medical examination in Southeast Asia is an immunization program for all individuals. The overseas medical screening is not designed to identify and treat personal health problems (e.g., injuries, parasitic diseases, heart disease). Health programs in the United States rely on the continued effective medical screening overseas to identify and treat certain infectious disease problems (TB, VD), initiate immunizations, and identify mental conditions (mental retardation) so they may concentrate on refugees' personal health problems.

CONSULTANTS

Question: The fiscal 1982 Carter Administration budget requests a 10 percent increase in consultant services. Please justify the need for this increase, particularly in the areas of epidemic services and in technology.

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

ENVIRONMENTAL HAZARDS

Question: Does CDC's response team conduct physical examinations on the people living in areas affected by environmental hazards?

Answer: Only in certain limited events is it necessary to conduct physical examinations of people living in areas affected by environmental hazards. Often, however, it is necessary to review

and confirm the health status of citizens with their private physicians or to collect samples of blood and/or urine for laboratory analysis. CDC has the ability to carry out these kinds of activities.

Question: Do you have adequate personnel to conduct thorough examinations?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Do you plan to establish a registry of public health incidents where health problems have been reported?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

VENEREAL DISEASE

Question: While the Centers for Disease Control has been successful in stemming such sexually transmitted diseases as syphilis and gonorrhea, we are now experiencing a rise in others, such as hepatitis B and herpes. What strides have you made in identifying those persons with genital herpes or hepatitis B?

Answer: Patients with genital herpes account for 2-7% of visits to sentinel STD clinics now reporting to CDC. The majority of genital herpes sufferers seen in these clinics are white heterosexual men and women. Though the initial occurrence is most common among 20-29 years old, no age group is spared. Genital herpes occurs in persons of all economic levels; more than half of the patients with genital herpes are seen by private physicians.

The distribution of reported hepatitis B is highly focal. Eighty percent of reported cases in the U.S. occur in persons 15-39 years of age. The following groups have been shown to carry a disproportionate share of the hepatitis B disease burden: patients and staff of hemodialysis centers, close contacts to known cases and carriers, homosexual men, persons institutionalized for mental retardation, Southeast Asian refugees, American Indians, and selected health care professionals. CDC is conducting studies in sentinel counties in order to more clearly define how the use of hepatitis B vaccine might maximize benefit to individuals and interrupt transmission in the community.

Question: What is the estimated population affected by these two diseases?

Answer: The incidence of genital herpes in the U.S. is from 200,000-500,000 cases annually; several million persons suffer recurrent outbreaks of sores while up to 20-30 percent of the population have evidence of silent or latent infection by middle age.

An estimated 200,000 cases of hepatitis B occur annually with

approximately 50,000 of these demonstrating jaundice. Over 10,000 infected persons require hospitalization for hepatitis B, with 250 of these dying from fulminant hepatitis. Approximately 12,000 infected persons become chronic "carriers" of hepatitis B virus. Twenty to twenty-five percent of carriers develop chronic active hepatitis, requiring repeated hospitalization and often leading to chronic disability and death.

Question: Have you specific information on the infant population affected by herpes as a result of the mother having an active or undetected case at the time of birth?

Answer: It is estimated that 150-600 infants per year are affected by neonatal herpes. The risk appears greatest among infants born to teenage women.

Question: Have any investigations been initiated yet with regard to interferon as a possible treatment for herpes? If so, what has been done?

Answer: There have been no studies of treatment of genital herpes with interferon since this drug is currently extremely scarce and expensive. With new advances in the production of interferon, studies of genital herpes may be expected, since use of this substance has shown promise in other herpes infections.

VENEREAL DISEASE - HEPATITIS B

Senator Proxmire: Last year you mentioned that CDC was working cooperatively with the manufacturer and with health departments to evaluate a prototype Hepatitis B vaccine in order to immunize against yet another sexually transmitted disease. As you mentioned in your opening statement, in 1980 a vaccine trial was begun. What is the status of this?

Answer: The killed-virus hepatitis B vaccine trial is progressing extremely well in all five study sites. The study sample size of 1,400 participants has been reached and entry of new study patients ceased on December 31, 1980.

Senator Proxmire: When are results likely to be available?

Answer: The study code will be broken in late March 1981 and the preliminary results, which are expected to show that the vaccine is highly effective and safe, will be available in early April 1981.

Senator Proxmire: How much has been spent by CDC to date on this and what is the amount the health departments and manufacturer provide?

Answer: The CDC, in addition to support staff and providing all hepatitis serologic testing, is spending approximately $500,000 a year to support this vaccine trial. Although no cost figures are available, each study center provides a principal and co-principal investigator and sufficient clinical facilities to house and conduct this study. In addition to their estimate of between 20 and 30 million dollars in developmental costs, the manufacturer

bears the cost of supplying all study vaccine and placebo and liability protection.

Senator Proxmire: Are there any plans for Health Departments to fully take over responsibility for this program in the near future?

Answer: Once this trial has been completed and if the vaccine proves to be as effective and safe as preliminary data suggest, the vaccine will be licensed and made available. Recommendations concerning who should receive the vaccine and how it should be delivered to identified high-risk groups are still under consideration. Health departments will play a key role in all decisions concerning future programs for the delivery of this vaccine, particularly since initially the vaccine will be in limited supply.

MT. ST. HELENS

Senator Proxmire: In last year's supplemental request, the Committee directed CDC and NIH to assist the University of Oregon's Center in developing its plan with reference to resources, personnel and costs necessary in carrying out CDC's study of short- and long-term effects of Mt. St. Helen's eruption(s) on humans and animals in the Pacific northwest region. It is my understanding that a planning committee was formed by the University of Oregon and has met at least four times. For the record, please provide us with a list of members and their affiliation.

Answer:

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Question: Has the Committee developed any short- or long-range plan to study the effects of ash fallout yet? If not, when do they anticipate accomplishing this?

Answer: The Committee has developed a long-range plan for several studies of the effects of the volcanic ash on human and animal health.

Question: What is CDC's role currently?

Answer: The Centers for Disease Control entered into a cooperative agreement with the University of Oregon Health Sciences Center. Under the terms of this agreement, CDC participated in the development of long- and short-range planning, reviews study protocols, and provides epidemiologic, medical and other (i.e., laboratory and statistical) assistance.

Question: Is CDC continuing assisting the Washington State Department of Social and Health Services in its evaluations of health effects related to these eruptions?

Answer: The Centers for Disease Control also entered into a cooperative agreement with the Washington State Department of Health and Social Services. Under this effort, the State and CDC are jointly reviewing the short-range impact of the ash on human health by examining the kinds of ash-related illness treated in hospitals in the fallout zones.

Question: How much CDC funds have been spent on Mt. St. Helen's efforts thus far?

Answer: Approximately $700,000.

Question: Couldn't State and local funds be used to implement any short- or long-range plan that CDC and the Committee have developed since no funds have yet been requested in the Carter budget for this?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

CONTROL OF CHRONIC DISEASES

Senator Proxmire: Last year the Committee directed that a portion of funds for control of chronic diseases be used to

continue an epidemiology program for arthritis, and further directed CDC to consult with the National Institute of Arthritis, Metabolism, and Digestive Diseases in carrying out this program. How much to date has CDC spent on this?

Answer: Approximately $150,000 on arthritis related activities.

Senator Proxmire: Is this accomplishing a better understanding of the causes of this terrible and often crippling disease?

Answer: The intent of the activity is to learn some of the causes or individual risk factors associated with a limited number of varieties of this complex disease.

Senator Proxmire: Is this duplicative of efforts by other agencies, such as NIAMDD? If not, how is it different?

Answer: The CDC focus is to concentrate on a very few varieties of arthritis and attempt to find ways to prevent its occurrence or to reduce its severity. This effort is done in concert with NIAMDD and State health department epidemiologists.

FLUORIDATION

Question: Would you provide for the record a State by State breakdown of the percent of public water supplies that are fluoridated?

Answer: There is no accurate information available on the percentage of each State's public water supplies that are fluoridated. A tabulation, by State, of the percent of the total population and percent of population on public water supplies being served fluoridated water is available. The table follows:

	Percentage of Total Population Served by Fluoridated Water	Percentage of Persons on Public Water Supplies Served by Fluoridated Water
United States	49.4	59.3
Alabama	31.5	45.0
Alaska	47.2	53.0
Arizona	31.2	26.0
Arkansas	38.3	62.0
California	22.0	25.0
Colorado	83.8	85.0
Connecticut	79.4	98.0
Delaware	39.5	43.0
District of Columbia	100.0	100.0
Florida	35.8	43.0
Georgia	41.4	53.0
Hawaii	6.4	9.0
Idaho	33.5	41.0
Illinois	86.2	90.0
Indiana	61.2	85.0

	Percentage of Total Population Served by Fluoridated Water	Percentage of Persons on Public Water Supplies Served by Fluoridated Water
Iowa	61.9	84.0
Kansas	51.5	59.0
Kentucky	51.0	69.0
Louisiana	23.2	25.0
Maine	40.6	55.0
Maryland	68.1	79.0
Massachusetts	49.1	46.0
Michigan	76.1	98.0
Minnesota	71.5	89.0
Mississippi	24.7	33.0
Missouri	42.0	52.0
Montana	26.7	38.0
Nebraska	45.8	64.0
Nevada	3.0	3.0
New Hampshire	13.3	16.0
New Jersey	21.4	26.0
New Mexico	63.8	75.0
New York	66.1	71.0
North Carolina	45.4	63.0
North Dakota	50.8	69.0
Ohio	41.4	45.0
Oklahoma	63.3	75.0
Oregon	10.7	12.0
Pennsylvania	46.2	61.0
Rhode Island	66.7	74.0
South Carolina	52.8	76.0
South Dakota	61.5	93.0
Tennessee	66.9	89.0
Texas	58.7	80.0
Utah	2.4	4.0
Vermont	37.0	50.0
Virginia	51.2	71.0
Washington	39.8	44.0
West Virginia	50.7	66.0
Wisconsin	62.2	79.0
Wyoming	21.3	31.0
Puerto Rico	81.4	UA
Virgin Islands	0.0	UA

VENEREAL DISEASE

Question: How much is being spent on the various diseases that fall within the category of venereal disease?

Answer: During fiscal year 1980, the Federal Government spent through project grants and CDC direct operations some $47,479,000 to support the investigation of special VD problems, the development of new, practical approaches to venereal disease control, the rapid transfer of advances in venereal disease technology to operating programs, and to support venereal disease prevention and control. Also, an estimated $10,000,000 was spent through NIH grants to support basic venereal disease research. It is estimated that States spend an additional $69,000,000 annually to provide

direct medical services in support of venereal disease control efforts.

Question: What have we learned from the VD National Hotline?

Answer: We have learned that there is a definite need for a confidential, highly visible, readily available and acceptable source for advice, information and referral which can be tailored to people seeking venereal disease services. This is supported by the fact that approximately 120,000 people seek venereal disease information and referral through the national hotline annually; 70,000 of whom are referred to medical care facilities. The majority of these calls request information on gonorrhea and herpes and are from teenagers and young adults; 76 percent of all callers are 29 years of age or younger and 27 percent are less than 19 years old.

Question: Has the VD Hotline been a successful component to the overall program:

Answer: A major goal of the venereal disease control effort is to bring exposed and infected people to treatment as rapidly as possible. This prevents further spread of the disease and if treatment occurs early in the infection, it can prevent the development of serious complications. The VD Hotline contributes significantly to this process. This is particularly true for young people who often are reluctant to turn to parents, teachers, or even their friends when it comes to a problem like venereal disease. The confidential nature of the VD Hotline makes it an especially helpful tool.

ENVIRONMENTAL HEALTH

Question: Do you expect the focus of CDC to change in the next 10 years from infectious disease control to environmental disease control?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: As CDC broadens the scope of its responsibility in environmental health problems, the use of toxicological testing facilities and equipment will expand. Are current resources sufficient to respond to requests for toxicological assistance in emergencies?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

EPIDEMIC SERVICES

Question: How many epidemics were reported in 1980?

Answer: Actually, 710 epidemics were reported in 1980; however, we have accurate information from only 2/3 of the States so that we would estimate that approximately 1,050 epidemics would have been reported had all State reported epidemics to CDC. Many more epidemics occur than are reported, but are not reported for a variety of reasons such as local sensitivities, existence of the epidemic unknown to health authorities, the epidemic is investigated and solved locally, etc.

Question: What were they?

Answer: The breakdown of the epidemics is as follows:

Bacterial	33%
Viral	17%
Parasitic	8%
Hepatitis	8%
Toxic Exposures	9%
Other	25%
	100%

Question: What services did CDC provide for them?

Answer: CDC provided all of the requested and required services including epidemiologists, veterinarians, laboratorians and laboratory support, statisticians, sanitary engineers, nurses, public health advisors, and demographers.

Question: How many people were affected in each epidemic?

Answer: Our data concerned the number of people affected is not exact, but we would estimate from 1 to 800 people were affected. This is less than the entire number who would be involved in the epidemic.

Question: How are you able to measure the efficiency of personnel assigned to epidemic services?

Answer: By close supervision of field investigations either directly from Atlanta and/or through discussions with field personnel who supervise the activities of EIS officers. Field investigators discuss their ongoing activities with Atlanta-based personnel regularly throughout the investigation which allows constant supervision of the investigative activities. Upon completing the investigation, reports are prepared and reviewed by the supervisor before being prepared in final form for distribution. Also, the investigation may be reviewed at a meeting or seminar attended by peers and supervisors. Efficiency can also be monitored by knowing if the epidemic was solved, that is, was the source/reservoir identified; was the method of transmission categorized; were host factors related to the occurrence of the epidemic identified? With identification of these factors, was the epidemic brought under control and preventive measures instituted. Ongoing surveillance for the disease will answer these questions.

Question: In 1979, several townships in the Philadelphia area found that their water supplies were contaminated with a degreasing

solvent called trichloroethylene (TCE). What assistance did CDC give to the local health authorities in testing for potential health hazards?

Answer: CDC provided medical epidemiologists to assist in a survey of exposed people for TCE levels in urine and to assess liver cancer incidence in the area.

Question: What are the results of your study?

Answer: Seven of one hundred and seventeen residents whose urine was tested had detectable TCD metabolite levels, indicating recent TCE exposure. The level of cancer incidence was not found to be increased over expected levels.

IMMUNIZATION/MEASLES

Question: Last year, your budget justification reported an all-out effort to eliminate measles from the United States by October 1982. What progress has been made toward eliminating measles by that date? How many cases of measles were reported in the United States during calendar year 1980, as compared with 1979?

Answer: Provisional data indicate that reported measles cases occurred at a record low level in 1980. The 13,430 reported cases in 1980 represent a 76.6 percent decrease from 1977, a 50 percent decrease from 1978, and a 1.2 percent decrease from 1979. However, reported measles was 40 percent lower during the last half of 1980 (1840) compared to the last half of 1979 (3023). These record-low numbers persisted through the first 6 weeks of 1981. A cumulative total of 210 cases for the first 6 weeks of 1980, a decrease of 68.4 percent. During 1980, more than 75 percent of the nation's 3,144 counties were free of reported measles for the entire year.

Of special interest is the low number of reported measles cases during the last 6 months of 1980. The seasonal low occurred during the summer months, as in past years, but persisted throughout the early fall and winter months of 1980. In fact, fewer than 50 cases were reported in 16 of the last 20 weeks. A total of 18 weeks in 1980 had fewer than 50 cases, whereas only 5 such low weeks were ever recorded in all the years before 1980.

Question: Last year you also indicated you were testing your system for getting accurate reports on measles cases, as recommended by GAO. What progress has been made to test the accuracy of your statistics on measles cases?

Answer: Every case of suspected measles which is reported is being epidemiologically investigated. These investigations seek to determine the source of infection, associated cases, and spread of infection. If reported efficiency is low, we would expect to frequently find unreported cases. This is not the case -- unreported cases are not frequently encountered during investigations. We presently estimate that at least 80 percent of cases of measles which occur are reported.

CHRONIC CONDITIONS

Question: The Carter budget requests $4 million to initiate an Emergency Response Fund. How would these funds be used?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: What essential activities were not addressed expeditiously because funds were not available in the past year?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: How was the $4 million figure arrived at?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

PREVENTABLE DISEASES

Question: Periodically, the Department provides this Subcommittee with a list of preventable diseases and prominent risk factors. Have you revised this list in the last two years? If not, please do so for the record. What reductions in mortality rates have occurred in certain diseases, and how has CDC contributed to the reductions?

Answer: The list previously supplied to the Subcommittee by the Office of the Assistant Secretary for Health remains a valid display of the leading causes of death and their most important risk factors (see attached).

The adjusted death rates for all causes of death have declined an average of 2.1 percent annually during the period 1968-1977, but only 1.1 percent between 1977-1978. Death rates for major causes such as heart disease and stroke, diabetes, cirrhosis and suicide decreased in 1978, but cancer (especially lung cancer), accidents, and homicides all increased.

Cardiovascular disease has been decreasing for a decade. The age-adjusted death rates delined by one-fourth between 1968 and 1978. Some suggested explantations include:

- o decreasing smoking
- o improved management of hypertension
- o decreased dietary intake of saturated fats

- o more widespread physical activity
- o improved medical emergency services
- o more widespread use and increased efficiency of coronary care units

Unfortunately, no definitive evidence exists to determine how much of the decline might be attributable to each of these possible explanations.

LEAD-BASED PAINT POISONING PREVENTION

Question: How successful has this program been in reducing the incidence of lead poisoning?

Answer: Through the provision of routine screening services high risk children are detected early, generally before symptoms develop. Through medical services and environmental epidemiology to identify and remove the lead source the risk of neurologic damage from lead ingestion is reduced. In each quarter 25 percent of the average 24,000 children reported under care for lead toxicity get better. Very few children are being found with extremely high levels of lead and death from the disease is now a rarity as a result of this comprehensive approach which is generally not available in non-project communities.

Question: To what extent have Federal funds been responsible for the early detection and treatment of lead poisoning?

Answer: Grant funds have been used to establish comprehensive programs in 105 areas since 1972. This focus of expertise and service capability has resulted in other local child health service providers incorporating lead screening services into their standard medical practice. This has occurred as a result of the lead poisoning prevention grants coordinating and insuring that necessary services are available to complete the epidemiologic and environmental intervention required to reduce the risk of lead poisoning for the children.

Question: What percent of the children being screened under the Lead-Based Paint Program are referred by the Early and Periodic Screening, Diagnosis and Treatment Program, the Child Health Assessment Program of the Health Services Administration, and the Women, Infants, and Children Program of the USDA?

Answer: In fiscal year 1980, 65 percent of the children screened in the program areas were tested by the other federally supported child health programs, private physicians, hospitals and State and local health programs within the program area. The lead poisoning prevention projects initiate and coordinate these activities and insure the required followup and environmental intervention.

Question: How are the other children chosen to be screened?

Answer: Outreach activities of the projects concentrate their screening in high risk areas associated with older housing and

other known sources of lead to identify those children at risk. High risk children are also identified by screening children who are in the immediate neighborhood of children with lead toxicity. This procedure, called cluster testing, has resulted in four-fold increase in identifying children with lead toxicity over fixed site, clinic testing and is a part of the epidemiologic process conducted by the projects.

Question: Does the screening examination test for learning disabilities and signs of abnormal behavior?

Answer: No. The programs insure, however, that high risk children with lead toxicity are referred and receive the required specialized evaluative services.

Question: Are children of lead workers being examined in the program?

Answer: They are being examined when identified. These children constitute a high risk group if proper industrial hygenic practices are not followed by the lead workers.

TOXIC-SHOCK SYNDROME

Question: Researchers from three midwestern health departments have found a possible link between absorbency and incidence of TSS. How are these figures different from CDC's?

Answer: The CDC study which examined the relationship between TSS and tampon absorbency did not find an increased risk among users of "super-absorbent" tampons. A recent study by 3 midwestern State health departments did find that the risk of developing TSS might be correleated with the absorbency of the tampon used. A major difference in these studies was the method used to detemine the absorbency of tampons, which does not necessarily correlate with the labeled absorbency. The difference in results between the two studies indicates that additional research in this area is necessary.

Question: Will CDC use measurements and data from the midwestern health researchers for further study?

Answer: CDC will evaluate the data from the Tri-state Study if and when it is made available.

NIOSH - DIOXIN REGISTRY

Question: What is the status of the dioxin registry?

Answer: Data collection is completed or underway and close to completion for 5 sites, involving 11 companies. For the remaining 5 sites, data needs to be collected from 4 companies. Coding of the data collected and follow-up through the Social Security Administration have begun.

Question: What information will be contained in the registry?

Answer: The NIOSH dioxin registry is an exposure registry of all workers in the U. S. who have worked at the synthesis of 2, 4, 5-trichlorophenoxyacetic acid (2, 4, 5-T) which is contaminated with the dioxin isomer 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin (TCDD). It also will contain information on workers exposed to dioxin isomer contaminants through the synthesis of 2, 4, 5-trichlorophenol (TCP), pentachlorophenol (PCP) and hexachlorophene. The primary purpose of the registry is to assemble the data necessary for an epidemiologic study of the mortality experience of the workers. Data are being collected from 10 synthesis sites in the U. S., many of which have been operated by two or more companies in the past.

For each exposed worker, copies of all medical and personnel records are being collected from each industry. Additionally, specific information about the history and type of synthesis process to which the workers were exposed is being assembled to define exposure.

Question: Who will have access to it?

Answer: The dioxin registry is being assembled and maintained by NIOSH for the purpose of epidemiologic study. Access for persons other than NIOSH personnel with the need to know is available within the constraints of the Freedom of Information Act and Privacy Act.

NIOSH - APPALACHIAN LABORATORY OF OCCUPATIONAL SAFETY AND HEALTH

Question: Due to the projected increase in use of coal as an energy source, coal mining safety and health problems are receiving increased attention. What progress have you made in coal mining safety in the past 10 years?

Answer: NIOSH has accomplished the following in the past decade:

1. In order to provide routine medical examinations of underground coal miners in the United States, and to detect the incidence and prevalance of Coal Workers Pneumoconiosis (CWP), NIOSH has established qualified examination facilities, radiographic interpretations and workers' notification as mandated by Congress in 1969.

2. NIOSH has established a miners autopsy program to detect the existence of CWP undetectable by radiographic examination. This is important to establish survivor claims.

3. NIOSH has initiated a separate national study to measure pulmonary functions to see if there are changes due to CWP and/or other respiratory ailments in the exposed worker population. Data is now being collected to determine the effectiveness and adequacy of the dust standards.

4. NIOSH established a testing and certification program. Two of the primary program areas have been the performance evaluation of respirators, and coal mine dust personal

sampling units - devices designed to protect coal miners health and safety by limiting and monitoring the miners exposure to hazardous levels of coal dust. Both of these programs are congressional mandated and executed cooperately with the Mining Safety and Health Administration. In 1972, NIOSH assumed the responsibility of this program and has subsequently established testing procedures and criteria associated with the evaluation of both respirators and coal mine dust personal sampling units.

NIOSH TRAINING

Question: NIOSH Education Research Centers (ERCs) located at U.S. Universities are supported by Occupational Safety and Health training grants. How many ERC's are currently being funded and at what levels?

Answer: There are currently 12 ERC's funded in NIOSH for total dollar value of $10,355,000. Nine of these are in the fifth year of funding; two are in the third year; and one is going into its second year. They vary in dollar levels from a low of $101,000 to a high of $1,110,000.

Question: What is the current trend in number of applications for training in occupational health studies?

Answer: The number of applications for both long-term and short term training increased from approximately 1,000 to 10,000 during the last four years. This has leveled off to approximately an increase of 1,000 to 2,000 per year in FY 1980 and it is anticipated that this level of increase can be expected each year.

MANAGEMENT INFORMATION SYSTEMS

Question: How reliable are the management information systems for assuring that refugees are screened, tracked and treated as intended?

Answer: First, there is a multiphase system to ensure that refugees receive medical screening and are medically cleared prior to arrival at their resettlement site in the United States. At the medical screening site, whether in Southeast Asia (Indochinese) or in the United States (Cuban/Haitian), a medical screening record is generated for each refugee which must be reviewed for medical clearance by CDC and/or INS inspectors prior to departure of the refugee. For the Indochinese, all refugees are also visually examined upon arrival in the United States port of entry and their medical records are reviewed. Any refugee without a properly completed medical screening document is put on "medical hold" at the port of arrival for completion of medical screening.

Second, for all refugees with Class A medical conditions identified during screening, special notification procedures are undertaken at ports of arrival or upon outprocessing at the screening sites in the United States. Refugees are referred to the appropriate local health department; and notifications are made in writing (and telephone for tuberculosis) to the local and State

health departments and to CDC to monitor followup by local health departments.

Third, notifications are made to the appropriate State and local health departments of the arrival of all Indochinese refugees to their jurisdictions. This permits States to provide additional health services to refugees over and above those required for admission to the United States.

When CDC does not receive confirmation within a specified time period that the refugee has received needed followup by the local health department or other health care provider, CDC initiates procedures with appropriate State health department officials to ensure that every reasonable followup effort is made.

OTHER ENVIRONMENTAL HAZARDS

Question: The Carter budget asks for $4 million to establish an Environmental Health Emergency Response Fund. Do you expect to request in your budget, funds to establish an Emergency Response Fund?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: If so, how much would you request for this purpose?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: How would CDC mitigate confusion and delay which reportedly has plagued the Public Health Service's response to emerging environmental problems?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How would the funds be administered?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

CONSULTANTS

Question: To what extent do you expect to use consultant services in the coming year?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HEALTH EDUCATION

Question: The Fiscal '82 budget narrative makes mention of a national patient education workshop project as one of the accomplishments of the Bureau of Health Education. The American Hospital Association is said to be involved in this project. What has this project accomplished?

Answer: The AHA patient education project has accomplished:

- o Two nationwide surveys of the extent, nature, staffing and funding of patient education programs in U.S. hospitals, results disseminated by publications and articles in AHA journals;
- o Development and use of 8 model handbooks for patient education in such categories as diabetes, hypertension, chronic lung disease, arthritis, plus handbooks on medication teaching to encourage patients to comply with prescribed regimens and handbooks on use of audiovisual and other aids in patient education;
- o Conduct of more than 50 workshops for patient educators, administrators and clinicians (nutritionists, nurses, etc.) involved in patient education, nationwide, under AHA auspices;
- o Development of a publication (now in press) reporting on approaches to financing patient education costs, based on a national conference involving third-party payers, hospital administrators, educators and others;
- o An increase between the 1975 and 1978 surveys of 65%--from 1218 to 2009--in the number of hospitals with a department formally responsible for patient education;
- o Convening of producers and users of patient education materials, visual aids, pamphlets, etc., working toward development of annotated listings of quality materials on various subjects for various patient audiences;
- o Development and dissemination of a nationwide listing of experienced patient educators available for consultation and technical assistance in every State.
- o Most of the work prior to 1979 was devoted to education of patient inside the hospital. Work now underway concentrates on out-patient education and will produce a similar set of products.

Question: How much has the Federal Government spent on this particular program since 1974, when the Bureau of Health Education was established?

Answer:	For Fiscal Years 1975 - 78	$532,302
	For Fiscal Years 1979 - 81	675,860
	Total	$1,208,162

Question: How much has the American Hospital Association Contributed?

Answer: Direct Contributions

1975 - 78 Contract Period
$10,000 on the survey
$30,000 project staff salaries

1979 - 80
Salaries $12,000

Supporting Services Contribution by AHA

Creation of a Center for Health Promotion at AHA headquarters
Professional and technical services from other divisions
Computer facilities and services
Duplication and mailing services
Supply of equipment to operate program
Access to extensive network of hospitals and affiliated associations and other organizations in Health Care
Credibility and status to project
Dissemination of products through AHA publications

Question: Why should the federal government continue to fund this project?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

IMMUNIZATION GOALS AND ACCOMPLISHMENTS

Question: What are your specific goals for the coming year in the immunization program?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What problems do you expect to encounter in achieving these goals?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What percentage of school children have been immunized against the major childhood diseases?

Answer: In 1977, immunization levels against the vaccine-preventable diseases ranged from 45-75 percent, although safe and effective vaccines were available. As many as 20 million children under age 15 were not completely immunized against one or more of the diseases.

During the past 3 years, a determined effort has been made to assess the immunization status of children entering school throughout the United States. Each year immunization records of approximately 2.5 million school enterers were reviewed in 60 of the 63 projects. The national weighted results of immunization levels determined by this assessment for school year 1979/1980 were 94 percent for measles; 93 percent for polio, DTP, and rubella; and 86 percent for mumps. In 1978/1979 school year more than 28 million immunization records of students from kindergarten through the 12th grade were reviewed. The national weighted results of immunization levels are: 91 percent for measles; 83 percent for rubella, 58 percent for mumps; 89 percent for polio, and 90 percent for DTP.

In addition to achieving these high immunization levels, substantial progress has been made in the reduction of vaccine-preventable childhood diseases. Preliminary data indicate record low numbers of cases were reported in 1980 for rubella (3,837), diphtheria (5), mumps (8,531), and tetatus (74). Reported cases of pertussis (1,651) and paralytic polio (7) were also very low. Only three cases of tetanus and one case of diphtheria were reported in children under age 15.

CHRONIC DISEASES

Question: One accomplishment listed in the budget narrative is the CDC-conducted comprehensive surveillance of birth defects at the national level. What conclusions can be drawn or national trends noted regarding birth defects based upon the information obtained?

Answer: Birth defects are the major cause of infant and childhood deaths and disabilities. The incidence of most birth defects remained stable from 1970 through 1980. The incidence of several birth defects (patent ductus arteriosus, ventricular septal defect, and renal agenesis) has steadily increased since 1970. The reasons for the increases are unknown. The incidence of two common and serious birth defects (anencephalus and spina bifida) is unusually high in the Appalachian Mountains. The system also identifies more local geographic areas with significant increase in the incidence of one or more birth defects.

Question: What is the annual cost of maintaining this surveillance?

Answer: The contract and in-house maintenance costs are $200,000 a year.

FLUORIDATION

Question: Fluoridation as a public health measure was introduced in the U.S. in 1945. While controversy continues, a consensus of scientific experts believe that fluoridation is a safe and effective method of dental caries prevention. Do you have any estimates as to how much is saved in dental costs per child for every dollar we put into fluoridation?

Answer: Community fluoridation produces economies in

children's dental care in terms of both costs and treatment time. The costs of children's dental care in fluoridated areas can be less than one-half the costs in fluoride-deficient areas. For every dollar expended on community water fluoridation it is estimated that $50.00 is saved in dental treatment cost. Children receiving the benefits of fluoridation require fewer treatment services and the treatment that is required is less complex and, therefore, less costly and less time consuming to provide. These facts are vividly illustrated in the following table:

EXAMPLES OF LOWER DENTAL CARE COSTS PER CHILD IN TAX-SUPPORTED PROGRAMS (HEAD START, ETC.) IN FLUORIDATED AREAS

FLUORIDATED	NONFLUORIDATED
ARIZONA	
$41.61 (Tucson, part)	$62.97 (Tucson)
CALIFORNIA	
$26.35 (San Francisco)	$70.01 (Berkeley)
$27.77 (Vallejo)	$66.76 (San Mateo)
MISSOURI	
$26.60 (St. Louis)	$41.55 (Kansas City) $63.37 (Springfield)
OHIO	
$27.62 (Portsmouth City)	$75.29 (Mad River Township)
$24.32 (Portsmouth Minford School)	$86.88 (Scioto County Northwest School)
$22.09 (Lake County)	$78.84 (Perry County) (New Lexington)
$21.45 (Northwestern Ohio, 5) communities)	$60.50 (Hocking County) (Logan)

A goal of near-universal community water fluoridation by 1990 will provide maximum protection against tooth decay for about 76 percent of future generations of Americans. It is roughly estimated that for each generation of children born in fluoridation communities after near-universal fluoridation is attained, a total savings of $3.5 billion in the cost of treatment for dental caries can accrue.

Question: Are there noticeable regional differences in percent of fluoridated public water supplies?

Answer: Although good data are not available on the percentage of public water supplies which are fluoridated, we know

that significant differences exist between regions of the country. This fact is illustrated by the differences observed among the 10 Regions recognized by the Department of Health and Human Services with respect to the percentage of the population which is served with fluoridated water:

DHHS Region	Percent of Population Served with Fluoridated Water
I	41.5
II	56.1
III	52.7
IV	43.5
V	66.7
VI	51.4
VII	49.4
VIII	51.6
IX	21.8
X	29.9

Question: What efforts have been made to investigate claims that fluoride is a carcinogen?

Answer: Every effort has been made to investigate claims that fluoride is a carcinogen by a number of competent, respected scientists, researchers, and epidemiologists, both in this country and abroad. Papers supporting a fluoride-cancer link have been reviewed and refuted by well defined, controlled studies since the 1950's. Because the implications of a cancer-fluoride link were so great, they demanded very careful examination. All of the resulting independent analyses and assessments have refuted any correlation between fluoridation of water and cancer incidence or mortality (a tabulation including these studies was provided in a previous question).

Within the last year, a "Report of the Committee of Inquiry into the Fluoridation of Victorian Water Supplies" was published in Australia. After an exhaustive review of the literature and interviews, the committee made the following conclusion: "Assertions that fluoridation of water supplies at recommended levels has toxic, carcinogenic, mutagenic, teratogenic, or allergenic effects on humans are not supported by sound, scientific evidence. Whilst a null proposition can never be proved, there is massive evidence to show that fluoridation at recommended levels has no harmful effect on the health of the community." The committee further engaged two consultants to independently review a work which claims a fluoride-cancer link. Both consultants reached the same general conclusion: The evidence (study) presented fails to show any association and that a positive association between fluoridation and increased cancer incidence has not been established.

The National Cancer Institute of the National Institutes of Health initiated in early 1980 a Carcinogenesis Bioassay of Sodium Fluoride (C 55221). It is anticipated that the results of this extensive study will be available in 1983.

In 1977 a team of scientists from the National Institute of

Dental Research of the National Institutes of Health, Litton Bionics, Inc., and the University of Minnesota undertook four separate studies to test fluoride as a mammalian mutagen. None of these studies produced any evidence of chromosomal damage to mouse bone marrow or testis cells. In addition, fluoride was not found to be mutagenic in a widely used bacterial mutagenesis assay.

Preliminary results of a mutagenesis test employing Salmonella typhimurium was released by the National Toxicology Program in December 1980. Fluoride was one of 165 chemicals tested and evaluated. The results were negative. Sodium fluoride is not shown to be mutagenic by the Ames test--the single best test of carcinogenicity or mutagenicity that is currently available.

Question: Why should the Federal Government continue to sponsor such a program instead of it being left to the States and communities?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HEALTH INCENTIVE GRANTS

Question: The Health Incentive formula grants program, more popularly known as Section 314(d) of the Public Health Service Act, has sustained large cutbacks in recent years. What would be the effect of eliminating this program, as proposed by the Carter Administration?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What would you do with the remaining $9 million in fiscal year 1981, assuming Congress agrees with the $27 million rescission proposal of the Carter Administration?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HERPES

Question: What are the medical consequences of the disease?

Answer: Genital herpes may be transmitted from mother to infant during birth. Of the infants infected, half die, and over half of the survivors are severely mentally retarded or suffer other serious sequelae. Women with genital herpes have a 5 to 7 fold increased risk for developing cervical cancer, though a causal relationship has not been definitely established.

Question: Without a cure or treatment, how much worse can we expect the problem to get?

Answer: More serious. The number of patients with active

disease in the United States increases each year. Although immunity to HSV2 infection probably protects some individuals, the immune mechanisms have not been identified.

Question: What help are you getting from the Allergy Institute in the effort against herpes?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) provided $1.6 million in support of basic and applied herpes virus research in fiscal year 1979 and more than this in 1980. During the past year, NIAID-supported investigators have indicated the importance of asymptomatic shedding of the virus in transmission, demonstrated the effectiveness of adenine arabinoside in treating newborns with disseminated herpes infection (reducing mortality from this disease by 40 percent), and identified important immunologic differences in persons who suffer multiple recurrences. Other NIAID-supported research is seeking the identification and purification of viral proteins necessary for developing a subunit vaccine.

VENEREAL DISEASE

Question: The problem of venereal disease and other sexually transmitted diseases is largely one of ignorance and apathy. There seems to be neglect in education about such diseases at all education levels, including the training of health professionals. What kinds of venereal disease education and training activities do you fund?

Answer: The kinds of venereal disease education activities that are funded are those which focus on and contribute to the prevention of disease. States are encouraged to direct their venereal disease education funds towards those persons most related to the disease problem. This includes venereal disease patients themselves, health care providers, persons at high-risk for exposure and infection, and adolescents and young adults, generally. Consequently, educational activities are an integral part of and complement and support all other venereal disease control efforts.

The training of employees engaged in venereal disease counseling and related patient management and followup activities is one of the most important services provided to the State and local health departments. All public, private, and military personnel requiring training are scheduled for available courses offered at one of five geographically dispersed training sites throughout the country. Other courses included problem solving workshops, supervisory seminars, and advanced management courses. These sessions are provided on an as-requested basis in any State needing training. Each course deals with knowledge and skills in patient interaction, patient and employee motivation, information analysis, and critical decisionmaking.

The CDC has also initiated a program to assist State and local health departments upgrade clinical and epidemiologic services for sexually transmitted diseases. One facet of this effort has been the creation of 9 geographically dispersed STD Prevention/Training

Clinics in cooperation with State and local health departments and selected medical schools. These clinics focus upon the training and upgrading of nurses; physician assistants; physicians in private, group, hospital or medical school based practice; health professions, students and housestaffs.

Question: How effective are these activities in reaching audiences that need to be reached to bring these diseases under control?

Answer: Since educational efforts are a part of and complement and support all venereal disease control efforts, the overall success of venereal disease control programs reflects in part the effectiveness of educational efforts. Grant supported educational efforts focused primarily on those persons at greatest risk of infection continue to show improved patient compliance indices, specifically in the areas of sex-partner referral, return for followup testing and early response to symptomatic infection. A general increase in public clinic utilization by infected persons is attributed to improved public information efforts, as well as to improvements in the quality of care provided by these clinics. Our latest figures show that more than half of reported VD cases are now being seen in the public sector, rather than roughly 40% several years ago.

During fiscal year 1980, CDC conducted 96 training courses for 1,047 Federal, State, and local venereal disease workers. Of these courses, 38 were for newly employed VD workers, 39 were for experienced employees and the remaining 19 courses were for supervisory and managerial personnel.

The medical population in need of training represents widely diverse groups. There are approximately 3,500 public health venereal disease clinics in the United States with a projected clinician population of 10,000, including normal personnel turnover. In less than 2 years, over 1,700 clinicians have successfully completed training courses. It is projected that approximately 1,400 clinicians, medical students and housestaffs' members will be trained yearly.

Question: Please cite specific increases or decreases in venereal disease cases reported.

Answer: Since the initiation of Federal assistance and efforts to control venereal disease in the 1930's, the reported cases of syphilis have declined from an all-time high of 575,593 reported cases in 1943 to 69,265 in 1980; a reduction of more than one-half million cases. Since the 1940's infant deaths due to syphilis have declined 99 percent and first admissions to mental hospitals with syphilis psychoses, all other deaths from syphilis, and reported cases of congenital syphilis have declined by 98 percent. The reported incidence of primary and secondary syphilis rose from 11 per 100,000 population in 1979 to 12.3 per 100,000 children under 1 year of age in 1979 to 3.6 cases per 100,000 such children in 1980. The trend in reported cases of gonorrhea generally decreased from 1947 through 1957 but began to increase steadily thereafter. Since fiscal year 1972, when Federal

assistance to State and local gonorrhea control programs became available, the annual increase in reported cases began to slow from 10.7 percent in fiscal year 1973 to 3.1 percent in 1976 to essentially stable levels since 1977. The age adjusted gonorrhea morbidity rates per 100,000 population for each race, sex category show an even greater decline between 1975 and 1979 than the unadjusted gonorrhea rates and crude morbidity.

Question: How does the United States compare to other nations in the incidence of venereal disease? Cite specific data comparing the United States to the 10 countries with the greatest incidence of venereal disease.

Answer: The reported incidence rates for venereal diseases are relatively accurate in countries such as the United Kingdom and Singapore where most cases of venereal disease are seen in clinics for sexually transmitted diseases (STD), or Denmark, where most tests are processed in a single laboratory. In the United States, reporting is less complete, but incidence rates show trends and are useful for comparing incidence between different segments of the population. Supplementary information has been needed to obtain more accurate estimates of true incidence rates for the reported STD, gonorrhea and syphilis, and the nonreported STD, e.g., genital herpes, chlamydial infections, trichomoniasis, hepatitis B, etc. In most developing countries the reporting of venereal diseases is even more incomplete. In general, only periodic studies of the prevalence of disease in selected populations are available in these countries.

Selected data on gonorrhea and syphilis incidence rates are available from country reports and reports prepared by the World Health Organization:

	Incidence Rates/100,000 population	
	Gonorrhea	Syphilis
United States	460	30
United Kingdom	115	6
Sweden	304	4
Denmark	188	11
Singapore	570	40
Papua New Guinea	290	120
New Caledonia	210	250
Congo	1,214	10
Mauritania	313	160
Domican Republic	356	342
Costa Rica	303	172

Other comparative information relevant to the public health impact of STD includes proportion of all gonorrhea which is penicillin resistant (PPNG). This varies from .1% in the United States to 2-5% in the Netherlands, Germany, and Zambia to 30-50% in Singapore, Thailand, Malaysia, Philippines. Congenital syphilis is a substantial problem in several countries; thus in Ethiopia 10% of neonatal deaths are attributed to congenital syphilis. Pelvic inflammatory disease is an important problem in many countries

contributing to excessibe hospitalizations and resulting in infertility; however, comparable data to United States surveillance systems are not available.

Question: Is the World Health Organization involved in eradication of this health problem? If so, is the Centers for Disease Control involved in that effort?

Answer: The World Health Organization arranges for short-term consultations to national programs to assist in the evaluation and planning of national control programs. The CDC has provided short-term consultants to WHO for 11 country programs in 1980. WHO also provides technical summaries of current information and sets standards for country control programs. CDC supported these efforts by providing technical consultants to prepare background papers and write reports on 3 occasions in this past year. WHO trains venereal disease control personnel by establishing national and regional training programs and by providing traveling fellowships to personnel. CDC provided consultants to 3 separate training courses, provided training for 17 WHO fellows in the STD training centers, and provided individual consultations at the CDC for other WHO fellows. A course for national VD control program managers is under development through the collaboration of WHO and CDC. The WHO and CDC were among the cosponsors of the pelvic inflammatory disease symposium held at CDC. This program provided the forum for sharing of current information on this major complication of STD.

Support has been provided by CDC to the World Health Organization's efforts to establish laboratory standards, perform proficiency testing and provide reference backup to national laboratories.

Efforts to improve research capabilities and to study unusual disease problems have been undertaken by CDC in collaboration with selected researchers in other countries including: Thailand, Malaysia, Zambia, Kenya, Central African Republic, Argentina and Chile. These efforts are consistent with World Health Organization's efforts to transfer technology to less developed countries.

Visiting Scientists have also spent periods of 10 months to 2 years with the VDCD sharing information and assisting in CDC's program development.

HEALTH EDUCATION

Question: A multiplicity of Federal health education programs can be found throughout HHS. In addition, there is the Office of Comprehensive School Health in the Department of Education. In an effort to consolidate, we understand that the Smoking and Health Office under the Assistant Secretary for Health transferred most of their money to the Bureau of Health Education. How much is budgeted in CDC for health education programs?

Answer: The 1981 comparable budget for risk reduction-health education activities at CDC is $23,818,000, including the $10

million grant program to deter smoking and alcohol misuse by children and adolescents, appropriated the Office of Smoking and Health, OASH, but administered by CDC.

Question: How are these funds administered?

Answer: $6.2 million are awarded to 54 State and Territorial health departments to establish and strengthen State level risk reduction programs and support a limited number of innovative educational programs at the local level funded through the States. The $10 million in smoking and alcohol grants support 130 local projects in these categorial areas directed to young people through schools and community-based organizations.

$7.6 million in Direct Operations funds are used to s. port contracts designed to develop and test improved educational methods in such fields as school health, patient education, Health Risk Appraisal, and evaluation methods for determining the impact and effectiveness of health education approaches in various settings; to provide technical assistance and dissemination of the results of these contracts to other Federal education programs, to schools, health care agencies, and others working in the field; and to provide consultation activities to State and local grantees.

Question: This Subcommittee has received criticisms from various State health education programs that funds are not getting to the schools from the local health departments. Since the Department of Education has access to local school systems through State education departments, wouldn't it be more effective to have ED administer this program?

Answer: School systems are only one of many channels and media used in carrying out health education programs for youth and adults. Furthermore, CDC does not support the actual delivery of health education in schools, which is done through local funding, but rather makes available for local adoption excellent tested curriculum models requiring both educational and health expertise in their development, and supports the availability of teacher training to implement these products for communities wishing to do so. More than 50 percent of the $10 million in smoking and alcohol grants for youth is being used by school systems, in close partnership with local health departments and voluntary agencies. These are supplemented by other CDC-supported youth programs conducted by 4-H clubs, ethnic groups, and other community youth-serving organizations outside the formal school system.

An important principle in health education related to life-style is that messages should be communicated through as many channels as possible to any audience, youth or adults. The need for reliability of the health content and consistency of messages being transmitted is an important reason for administering health education through a health agency devoted to disease prevention and the promotion of health.

Question: For the record, can you provide this Committee with a breakdown of programs within HHS aimed at Health Education along with funds appropriated?

Answer: Numerous categorical disease programs, including those of NHLBI, NCI, Alcohol and Drug Abuse, Immunization, Venereal Disease Control and others, carry out public information or education activities related to their specific missions. Similarly many of the health service delivery programs, such as the Indian Health Service, community health centers, migrant health programs, etc., have an educational function as part of patient care. However the educational activities are generally conducted as part of other duties, and do not carry a separate identifiable budget item. Estimates in the past have been found to vary widely as to types of activities included and are generally non-comparable. Three units within the Public Health Service are generically dedicated to health education and promotion activities. These are:

CDC Bureau of Health Education:	1981 Budget	$23.8 million/1
Office of Health Promotion, OASH:	1981 Budget	$6.0 million
Office of Smoking and Health, OASH:	1981 Budget	$3.0 million/1

/1 Comparable appropriation amounts adjusted for the includes $10 million in grants to deter smoking and misuse of alcohol in children and adolescents, which has been appropriated to the Office of the Assistant Secretary for Health but which is administered by the Bureau of Health Education CDC through its Health Education Risk Reduction grant program.

ALOSH

Senator Byrd: Could you please bring the Committee up-to-date on the kinds of health and safety activities the National Institute for Occupational Safety and Health (NIOSH) is conducting at the Appalachian Laboratory for Occupational Safety and Health (ALOSH) at Morgantown, West Virginia?

Answer: In the Respiratory Disease Studies Program at Morgantown we are currently conducting research in the following areas: (1) Mutagenesis Research - It is known that many mutagenic chemicals could cause not only genetic damage but also malformation, cancer, and reproductive effects. We currently have two projects underway in this area. One is "Mutagenic Monitoring for High Risk Workers", which is a project designed to determine whether any chemicals released in the air at coal liquefaction and gasification plants are mutagenic. The other project is designed to test suspected various workplace chemicals for mutagenic activities.

(2) Surveillance - We are continuing the National Coal Workers' Surveillance Program which provides the opportunity for every underground coal miner to receive, a chest x-ray examination and interpretation of results. To date, approximately 310,000 chest x-rays of underground coal miners have been processed. This program provides for early detection of coal workers pneumoconiosis in underground miners. Another on-going program is the National Coal Workers' Autopsy Study. This program was established in 1971 to aid survivors of coal miners in establishing valid claims for black lung benefits under the Federal Coal Mine Health and Safety Act of 1969. The Mining Health Hazard Evaluation and Technical Assistance Program is still on-going. In FY 1980 62 requests for

Health Hazard Evaluations or Technical Assistance were handled.

(3) Energy Research - The realization that the Nation's secure reliance on abundant supplies of inexpensive foreign crude oil was at an end has spurred development and demonstration of a multitude of energy technologies that would utilize domestic energy resources. Deployment of any of these technologies on a scale sufficient to make a significant contribution to the Nation's energy needs would entail quite large numbers of workers at the sites of conversion utilization plants. It is known that a number of these technologies contain some of the most hazardous chemical substances known. Among these are acutely poisonous gases, carcinogenic and mutagenic compounds, and a variety of other noxious or hazardous chemical and physical agents.

(4) Respiratory Disease Research - Originally conceived and limited to the study of coalworkers' pneumoconiosis, the Occupational Respiratory Disease (ORD) program has grown to include any pulmonary disorder associated with one's occupation. For instance, this year NIOSH is conducting a morbidity and industrial hygiene study of cement workers. Workers in the cement industry will be examined for evidence of both obstructive and restrictive (fibrotic) lung disease. Also, as a result of researchers finding asbestos fibers in crushed rock being quarried in Maryland, NIOSH is doing a national mortality study of workers in the crushed stone industry. Emphasis will be placed on causes of death related to cancer and pulmonary diseases.

In the Safety Research Program at Morgantown, the emphasis is on testing and certification of personal protective equipment - in an particular respirators. NIOSH is currently developing a significant, viable respirator research program. This vital effort is essential to the development of performance criteria for respirators. The Safety Program also is conducting an epidemiological investigation of falls from ladders, which is one of the most frequent types of accidents. It is estimated that there are approximately 30,000 people injured each year in the United States by falling from ladders. Another epidemiological study being conducted this year is investigations of lathe injuries. This project will consist of interviews of 350 caught-in lathe or struck by lathe injury victims along with 350 interviews of uninjured employees successfully performing the same kind of work. A final report will be produced on the causal factors involved in these types of injuries.

Also, the Institute's safety resarch program is conducting a project to develop a method of testing concrete so that an accurate and rapid prediction of concrete strengths can be achieved at the construction site. By predetermining what concrete strength is needed to support the structure and/or scaffolding (benchmark strength), the safe removal of concrete forms can be achieved by comparing the in-situ concrete strength to the benchmark strength. This practice could prevent scaffolding failures such as Willow Island in 1978, where 51 construction workers were killed.

MINE SAFETY AND HEALTH ACT AMENDMENTS OF 1977

Senator Byrd: Please explain what steps have been taken by

NIOSH to implement the additional program responsibilities which were mandated by the Mine Safety and Health Act Amendments of 1977. To what extent is the Morgantown facility involved in these new responsibilities?

Answer: With passage of the Federal Mine Safety and Health Act of 1977, NIOSH initiated a specific program to respond to its new provisions requiring mining surveillance, Health Hazard Evaluations, and research on health effects in metal and non-metal mines. An initial Mining Surveillance Report reviewing toxic substances found or used in mines was made and forwarded to the Department of Labor in May 1979. Three other surveillance profects were subsequently initiated. A Health Effects Target Surveillance project is presently reviewing state data files for information on miners' health. A Mining Environmental Target Surveillance project is conducting short term investigations of specific mine environmental hazards such as Sillimonite, Welding, Zeolites and Explosives in order to identify potential future research effort needs. Morgantown has also begun planning an extensive National Occupational Hazards Survey of mining, which will gather environmental exposure data from a probability sample of mines across the mandate of the Act to continually monitor and report on potentially toxic conditions found in mines.

Section 501 (a)(11) Begun in fiscal year 1978, the Act mandated that NIOSH conduct Health Hazard Evaluations in mines. From that program it has expanded so that it how consists of approximately 17 person-years covering six full-time industrial hygienists and the part-time support of several physicians, epidemiologists, laboratory researchers, statisticians and field investigation team members. Morgantown also contracts mining health hazard evaluation work to various universities with occupational health programs. Examples of this are a study of trona miners to be conducted by the University of Utah, and of borax miners by the University of Southern California. The number of requests to this program has increased from three in the first year (1978) to a current 65, some of which have required large epidemiological studies to complete. Examples of this include studies in the liginate coal mining industry, rock drillers in coal surface mining operations and vanadium mill workers. In addition to the specific task of performing Mining Health Hazard Evaluations the Division responds to similar requests from other industries which indicate the presence of respiratory problems. This has included extensive personnel and financial commitments dedicated to a study of lumbermen exposed to the ash fall-out of Mt. St. Helens, asbestos-related respiratory disease in railraod shop workers and respiratory problems reported in USDA insect-rearing facilities.

In addition to the coal related research previously authorized under the Coal Mine Health and Safety Act of 1969, Morgantown has initiated numerous laboratory and field effort projects to specifically address the 1977 Act's metal and non-metal mining research provisions. A case control study has been initiated to determine the risk factors involved in the excessive cancer rate among metal miners. Mortality studies of oil shale and metal miners have been completed, with specific attention paid to lung

cancer rates in the workers in these industries, and the extent to which factors such as ore type, smoking, and diesel engine exhaust may contribute to the observed changes to the expected mortality rates. Separate morbidity studies of over 5000 metal and non-metal miner cohorts have been completed to examine the impact of exposure to silica dust and diesel exhaust. Major morbidity and mortality studies of workers within the cement industry have been recently initiated. Studies are underway to collect and analyze morbidity data for selected operations involving exposure to fibrous minerals, such as attapulgite clay and talc, in order to determine morbidity and mortality in these industries.

The metals mining and processing industries in the United States will become increasingly important during the next 20 years due to the current world shortage of certain critical metals. In response to the Act a number of laboratory projects have been initiated in Morgantown to study the effects of metals to which there is worker exposure have toxic effects upon the lung. Mercury, cadmium, copper, and lead seem to inhibit the antibacterial activity of alveolar macrophages, which may lead to an increased susceptability to infection among metal workers. Exposure to iron and combined exposures to iron and zinc or iron and cadmium may cause cell membrane damage in the lungs. Other metals, such as aluminum, cobalt, chromium, nickel, and zinc, also demonstrate toxic effects upon lung cells; any of these conditions may lead to pulmonary disease. The overall goals of this program in metal mining are to determine the risk factors, the composition of the atmosphere, and the health effects of these exposures in the workplace.

ALOSH CONSTRUCTION

Senator Byrd: The Department of Health, Education and Welfare recommended in 1978 that an extension to the ALOSH facility be constructed to house NIOSH's expanded activities. I secured funds for the architectural and engineering design work on the proposed facility in fiscal year 1978. I understand that the A & E work has been completed. What is the status of the construction work?

Answer: The design is not completed at this time. It is scheduled to be completed May 25, 1981.

Senator Byrd: I noted in your fiscal year 1982 budget requests that there are no funds for construction of this facility. Could you explain why?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Senator Byrd: What is the latest cost estimate for construction of the proposed facility?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

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Senator Byrd: What percentage, if any, of this amount is due to inflation as a result of construction delays?

Answer: None of this amount is inflation cost because the construction wasn't scheduled to start until October 31, 1981.

Senator Byrd: In the event that future delays are encountered, what would be the inflationary impact on construction costs?

Answer: Inflationary impact on construction to be about 12-20% per year.

Senator Byrd: I understand that the current facility is experiencing overcrowded conditions. Could you describe these conditions? What are their effects on the day-to-day operations of the facility?

Answer: The present building is at slightly above maximum capacity. Some corridor areas have been modified into laboratories. The heating, ventilating, and air conditioning (HVAC) systems need modernization and upgrading in order to provide necessary support to programs.

FLUORIDATION

Fluoridation as a public health measure was introduced in the United States in 1945. While controversy continues, it is the consensus of scientific opinion that fluoridation is a safe and effective method of dental caries prevention.

Question: What can you tell us about the safety of fluoridation?

Answer: Many epidemiological studies conducted in the United States and abroad attest to the safety of fluoridation. In the area of fluoride toxicity, the Council of the Society of Toxicology, Inc., in 1968 stated, "... an extraordinary and exceptional reliability is conferred on the safety of water fluoridation because nature in a sense has already made the demonstration in hundreds of communities where the drinking water naturally contains fluoride. Under controlled conditions as recommended by qualified public health authorities, the Society of Toxicology finds water fluoridation to be a safe measure."

At the request of the United States Public Health Service, the American Academy of Allergy was asked to do an evaluation of the question of allergy to fluoride as used in the fluoridation of community water supplies. As a result of this review the Academy adopted the following statement: "There is no evidence of allergy or intolerance to fluorides as used in the fluoridation of community water supplies."

The Food and Nutrition Board, National Research Council, National Academy of Sciences, in 1974 also made recommendations regarding the safety and essentiality of fluoride. A section of their "Recommended Dietary Allowances" includes the statement, "Standardization of water supplies by addition of fluoride to bring the concentration to 1 mg/liter has proved to be a safe, economical, and efficient way to reduce the incidence of tooth decay--a very important nutritional public health measure in areas where natural water supplies contain less than this amount."

Numerous other studies have been conducted over the past 30 years which have consistently reinforced the conclusion that fluoridation is a safe and effective public health measure.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

HEALTH EDUCATION

Question: We understand the Bureau of Health Education has developed a National curriculum for school health. Since curriculum development is a function of State and local agencies, how do you plan to use this plan you have developed?

Answer: The school health curricula developed by CDC through contracts with the American Lung Association and other organizations are completed for Grades K through 7. Two sets of curricula (K-3 and 4-7) have been adopted by the National Diffusion Network of the Department of Education, the only two health curricula so designated. One or both of the models are in place in some 600 school systems in 40 States, adopted by the local systems and supported by local funds. FY 1981 contracts are designed to update portions of these and support limited dissemination through teacher training, and to complete development of high school modules. No further Federal funding is anticipated for FY 1982, but the model will continue to be made available through normal curriculum adoption channels in the educational systemswithout CDC support.

DIABETES CONTROL PROGRAM/CHRONIC DISEASES

Question: How much do you plan to spend for this program in FY 1982?

Answer: The budget request for FY 1982 is $5.250 million. This will support the continuation of cooperative agreements in the existing State Diabetes Demonstration Control Projects, as well as national leadership, coordination, and technical assistance to States.

Question: How many projects will be supported in the new fiscal year?

Answer: Current projections are to continue the support of the 20 existing project States with the following assumptions:

- States continue to provide their resources necessary to continue present intervention activities.

- State-Federal partnership retains sufficient technical and financial capacity to assure the demonstration value of each project. Highest priority will be given to those States which retain these capacities.

Question: To what extent could this effort be carried out through other Federal or State health programs?

Answer: CDC's Diabetes Control Program is conducted in partnership with State health agencies, and provides a mechanism for coordination of effort among States and with diabetes researchers, care providers, third party payors and voluntary organizations. While State health agencies are in a unique position to analyze problems on a community-wide basis and develop programs based on community needs and resources, such programs must also be based on sound technical knowledge, evidence of what works, and the capacity of the States to apply epidemiology, surveillance,

and other disease control techniques to a complex public health problem like diabetes.

This effort is still in a developmental stage, and the States need continued technical assistance, training, and assistance in analysis of demonstration results to determine the most effective control strategies and to achieve self-sufficiency. To date, 37 States comprising over 85 percent of the U.S. population have requested technical and financial assistance from CDC for this purpose. This assistance is provided for a maximum of 5 years to build State capacity for management and operation of an effective diabetes control program, with non-Federal resources maintaining that effort beyond that initial period.

Question: To what extent are public information activities duplicated within the public information offices at NIH, more specifically, the Arthritis Institute (NIAMDD)?

Answer: There is no duplication. CDC's information dissemination activities are aimed at targeting with increasing preciseness, patient and professional education toward specific needs. In this regard, States receiving CDC assistance are promoting education based on a particular need at the community level.

CDC also provides a vehicle for disseminating information from NIH's Diabetes Information Clearinghouse through 20 project States, reaching over 500 members of State advisory boards and State staffs.

In brief, CDC and the project States provide a ready-made framework for facilitating the dissemination and translation of new medical advances, including NIH-supported research findings, into community practice along with results from a mix of CDC-supported demonstration projects.

LOVE CANAL/MT. ST. HELENS

Senator Hatfield: How are you currently addressing the public health emergencies associated with Love Canal in New York and the Mt. St. Helens eruption in Oregon and Washington?

Answer: CDC entered into a cooperative agreement with the State University of New York at Buffalo School of Medicine to provide health examinations and special studies to residents of the Love Canal neighborhood. Protocols for these activities were prepared and reviewed by scientists inside and outside government. Representatives of the community groups in the neighborhood were consulted and asked to endorse the studies.

In order to carry out the most essential components of the project, the Department has forwarded its request to reprogram $950,000 of the funds appropriated to the National Institutes of Health. This amount, together with $125,000 currently available to CDC, will provide funding for targetted health studies of the Love Canal residents. These studies include chromosome breakage, nerve conduction and prevalence of learning disabilities among elementary school children. A prevously submitted supplemental request of $3,860,000 has been withdrawn.

Immediately after the eruption on May 18, CDC sent a team of scientists to Washington to assist in the evaluation of public health risk and potential hazard to emergency workers and cleanup crews from the ash. Recommendations from this group were implemented immediately. CDC issued biweekly information on their evaluation through a series of reporters which were given the widest distribution. Over the summer, CDC participated in studies to determine how further deaths and illness could be prevented in the event of more eruptions. At present we are working to develop a plan for long-range studies of the health effects of the ash on animals and humans. A group of scientists from the Pacific-Northwest has been assembled by the University of Oregon Health Sciences Center for this purpose. CDC supports this group through a cooperative agreement.

Question: The Carter Administration requested funds to begin clinical health studies for the residents in the area of Love Canal. Yet no funds were requested to implement the Mt. St. Helens volcanic ash study that CDC helped to plan. Why were no funds requested?

Answer: The department has prepared a request for reprogramming of $500,000 within the NIH appropriation to initiate the health effect of volcanic ash from Mt. St. Helens. This reprogramming will establish a monitoring and sampling network of high risk groups and will conduct morbidity studies.

LABORATORY ERROR RATES

Question: In last year's testimony CDC stated that an important method for reducing health care costs associated with laboratory services is reducing clinical laboratory error rates. What does CDC plan to do alone or with other public or private agencies to reduce the occurrence and cost of clinical laboratory errors?

Answer: CDC is undertaking studies designed to (1) develop a model output-oriented performance evaluation system for use by States that will determine the extent and cause of laboratory errors with patient specimens, and (2) develop a model laboratory assistance system for use by States so laboratories with a problem can obtain help in quickly solving their problem. This system will build on the CDC's existing effective program of technical training and consultation to States and private organizations for transferring the methodology for proven diagnostic procedures and correcting recognized deficiencies in laboratory personnel. These two systems, once developed, field tested and shown to be sensitive and cost effective, will be offered as a substitute for the current laboratory evaluation systems that depend heavily upon personnel qualifications and strict standards for internal quality control processes.

VACCINES

Question: The Carter Budget requests funding to establish stockpile vaccines to protect against a possible shortage. Why has it become necessary to stockpile vaccines?

Answer: Vaccines pose special problems in production and testing. The complex modern vaccines such as those used to prevent polio, measles, and rubella are prepared only by a handful of particularly experienced manufacturers based in a few technically advanced nations. In the United States, there is presently only one manufacturer for polio vaccine and only one for measles, mumps, and rubella vaccines. This proposed stockpile was requested in the Carter Budget as a safeguard against the possibility of the supply of vaccine being interrupted; however, because of the need to reduce the level of spending in Federal programs, this increase has been eliminated from our budget request.

TUBERCULOSIS

Question: What is the budget request for programs for TB control?

Answer: The budget request for FY 1982 is $3.252 million.

Question: How serious a problem is tuberculosis today?

Answer: In 1980, a provisional total of 27,983 cases of tuberculosis were reported to the Centers for Disease Control.

Tuberculosis is a communicable bacterial disease, usually affecting the lungs, resulting in transmission of bacteria through the air to other persons. Most people have natural body defense mechanisms which combat the infection, but the bacteria may remain alive in the body in a dormant state for years. There are an estimated 10 million infected individuals in the United States. Unless preventive treatment is given for the dormant infection, about 10 percent of these infected individuals will eventually develop tuberculosis and become spreaders of the disease.

Tuberculosis control is a joint private-public effort. Clinical care (diagnosis and treatment of individual patients) is available from a variety of private and government-supported health care providers. Health departments have the community responsibility of: Assuring that persons with infectious tuberculosis are treated so that they do not spread the disease; identifying exposed persons and referring them for examination; assuring that high-risk infected individuals receive preventive treatment so that they do not develop tuberculosis; and monitoring and reporting to the public the extent of the tuberculosis problem and the success or failure of containment efforts.

Although tuberculosis has been slowly declining for years, there are indications that the direction of the trend in the number of tuberculosis cases may be changing. From 1953 through 1978, the average annual decrease was about 5 percent; however, in 1979 the decrease was only 3 percent. Provisional data for 1980 showed a 0.6 percent increase, and cases reported through the sixth week of 1981 are 2 percent above 1980.

Tuberculosis in children, an indicator of recent transmission in the community has also shown a trend reversal. In 1979, there were 989 cases of tuberculosis in children 0-4 years of age, an increase of 18.3 percent over 1978.

Modern treatment has dramatically reduced tuberculosis mortality and has eliminated the need for long-term institutional care. The closing of sanitoria and other past progress in tuberculosis control have led to a public perception that it is no longer a problem and have made it more difficult to convince many patients to complete long-term daily treatment without interruption.

Control has been complicated by the ability of the bacteria to develop resistance to antituberculosis drugs when treatment is not properly taken. Community outbreaks of drug-resistant tuberculosis have occurred and presently about 7 percent of newly diagnosed cases have disease caused by drug-resistant bacteria, indicating transmission of these difficult to treat organisms. Changes in patterns of immigration and influx of refugees have impacted on tuberculosis control because many new arrivals come from areas where dormant tuberculosis infection and drug resistance are prevalent.

These factors have contributed to the persistence of tuberculosis as a serious community health problem, despite the availability of diagnostic and curative services for individual patients.

URBAN RAT CONTROL

Question: The Carter Administration budget proposes to terminate grant support for communities under the Urban Rat Control Program, funded at $13 million in fiscal 1981. To what extent would technical assistance continue to be provided to communities?

Answer: None. Since the inception of the program in 1969, managerial and technical assistance has been provided to 10 States including the District of Columbia and 102 individual communities. This has resulted in the transfer of technology necessary to continue components of a comprehensive urban rat control program. Continued technical assistance to the States and local communities is no longer needed since technical expertise exists in the States and local areas where a significant problem remains.

Should State and local governments place sufficient priority on urban rat control activities, funds are available in the block health grants to continue the activities.

Question: Why couldn't this program be taken over by local governments?

Answer: This program is designed to be taken over by local governments. In the past, local communities have not had adequate resources to initiate comprehensive rat control measures to address the severe problems created over the years. Federal funds are used as seed money to establish local programs to reduce rat infestations and environmental deterioration to a level which local resources can maintain. Federal funds are directed to the most blighted neighborhoods where it costs an estimated $650 per block per year to achieve rat free status. Once achieved, it costs

approximately $37 per block per year to maintain. State and local governments then sustain the rat free status, and grant funds are redirected to other neighborhoods with severe problems.

Similar approaches on a demonstration basis are underway in Public Housing Authorities in Atlanta and Miami. Comprehensive urban rat control programs have been established in these Public Housing Authorities to demonstrate the program and financial benefits of comprehensive rat control, including improved refuse storage, and the elimination of rat harborage conditions, rather than the usual rat baiting approach.

NEW FACILITY

Question: How much of a priority is the budget request for $24 million to construct a new laboratory facility in Atlanta? Have you explored the possibility of renovating existing facilities in lieu of any new construction?

Answer: In the 1982 amended budget, given the health priorities, the $24 million to construct a new laboratory was deleted.

The possibility of renovating was examined, but was decided against for the following reasons.

1. The existing buildings used for virology investigation are, at best, only marginally adequate in size for meeting our needs for working with relatively low risk organisms. The result is crowding with the inherent potential for unsafe conditions. The total net area in the existing virology building 7 and maximum security laboratory, buildings 8 and 9, is only 32,000 square feet for our work with high risk organisms. The proposed new building would have 70,000 net square feet assigned to level 3 and level 4 virology laboratories (the levels refer to degree of risk with level 4 being high hazard).

2. The existing maximum security laboratories are located at ground level where physical security is difficult to maintain. These will be relocated to the top floor of the proposed new facility.

3. Animal facilities separate from our central animal facilities are needed in order to carry out animal studies at the P-3 level risk with minimal hazard to employees and the community.

4. The zone sterilization method of using only one sterilizer per floor is used in the existing building. Sterilizers for individual modular areas are now required. To install these in the existing space would greatly reduce the available laboratory area so that the remaining space would be even more inadequate than it is currently.

5. The ventilation system in the existing building is adequate for general level 1 and 2 virology work. However, at

level 3, the result of the possibility for cross contamination among laboratories which exists becomes a matter of serious concern.

In summary, to convert the existing virology building for level 3 work would require major renovation and, upon completion, the building would still reflect compromise in design and would be totally inadequate in the resulting net space for the work which must be done in level 3 and 4 virology.

CONSULTANTS

Question: The fiscal 1982 Carter Administration budget requests a 10 percent increase in consultant services. Please justify the need for this increase, particularly in the areas of epidemic services and in technology.

Answer: The 1982 Reagan Budget reflects a decrease from the previous year of 13.8 percent for all consultant services. Epidemic Services and Technology Development and Application remain at the 1981 level.

ENVIRONMENTAL HAZARDS

Question: Do you have adequate personnel to conduct thorough examinations?

Answer: Our current staff of physicians and other medical personnel is not large enough to provide the examinations without severely disrupting other critical CDC functions in the areas of epidemiology and laboratory services. We are, however, looking within the PHS and to private medical institutions and at State health agencies for support in this area.

Question: Do you plan to establish a registry of public health incidents where health problems have been reported?

Answer: The question of registries is complex, both from a scientific standpoint as well as logistically and financially. PHS has set up a committee with representatives from NIH, FDA, CDC, the Office of the Assistant Secretary for Health, and from IRS to examine the issues and make recommendations to the Assistant Secretary. Their report is due May 1, 1981. In the interim, registries are already in place for a number of incidents such as the Love Canal episode, the PBB spill in Michigan, DDT and PCB in Triana, Alabama, and the Three Mile Island and Smokey radiation incidents.

MT. ST. HELENS

Question: Couldn't State and local funds be used to implement any short- or long-range plan that CDC and the Committee have develope since no funds have yet been requested in the Carter budget for this?

Answer: State and local resources for these kinds of complex epidemiologic and health studies are not immediately available.

ENVIRONMENTAL HEALTH

Question: Do you expect the focus of CDC to change in the next 10 years from infectious disease control to environmental disease control?

Answer: No. Instead of a change in the focus of CDC away from infectious disease control to environmental health, I expect to see the maturation of environmental health from its present state to a major mission of CDC. The result will be a CDC that provides national leadership for a comprehensive effort to prevent death and disease from both infectious and environmental threats.

There is little indication that the infectious diseases will disappear as a public health problem in the years ahead; whereas many of the "old line" infectious diseases (diphtheria, tetanus, typhoid fever, measles, mumps, and rubella) are under substantial control, maintenance of that control will require continued application of the best available disease control expertise and technology. Moreover, control of newly recognized infectious disease problems (as exemplified by Legionnaires' disease and the Toxic Shock Syndrome) will require sustained scientific and technologic leadership. On the other hand, CDC's expertise in epidemiology will be increasingly called upon to address environmental health problems as the public becomes more aware of the hazards.

The relationship between toxic hazards (especially toxic wastes) and health has not been clearly defined. It must be. CDC will be increasingly called upon to provide this definition. Moreover, CDC should provide the nation with an accurate view of the nature of overall environmental risks to which Americans are exposed. In this regard, accidents and violence are profound environmental hazards for Ameicans for the first 5 decades of life. The public does not yet clearly perceive these risks as problems of public health.

Question: As CDC broadens the scope of its responsibility in environmental health problems, the use of toxicological testing facilities and equipment will expand. Are current resources sufficient to respond to requests for toxicological assistance in emergencies?

Answer: As CDC services and responses to States and local agencies expand, the requests will continually grow. There will never be sufficient resources to respond to all requests. The most difficult task is disengagement from an investigation and turning over the health problem to local units. This requires a buildup of State and local resources for dealing with more problems locally.

CHRONIC CONDITIONS

Question: The Carter budget requests $4 million to initiate an Emergency Response Fund. How would these funds be used?

Answer: The monies would be allocated at the Secretary's discretion to fund the immediate activities necessary to protect the public health and safety in the event of relatively short term emergencies short of major disasters. These kinds of emergencies

cannot be specifically planned for in the usual budget cycle.

Question: What essential activities were not addressed expeditiously because funds were not available in the past year?

Answer: The medical screening of Southeast Asian refugees and the health studies of residents of the Love Canal neighborhood.

Question: How was the $4 million figure arrived at?

Answer: It was based on the review of our experiences in such activities as Legionnaires' Disease investigations, the response to the Mount St. Helen's eruption, and the Three Mile Island emergency. We feel that had an emergency fund been available, the response coule have been even better and would have clearly been less disruptive to out on-going programs.

OTHER ENVIRONMENTAL HAZARDS

Question: The Carter budget asks for $4 million to establish an Environmental Health Emergency Response Fund. Do you expect to request in your budget, funds to establish an Emergency Response Fund?

Answer: The Reagan Administration budget will ask for funds to provide for immediate support for a number of emergencies including, but not limited to, environmental emergencies.

Question: If so, how much would you request for this purpose?

Answer: The revised FY 1982 budget requests $20 million. During emergencies in the past, PHS could draw upon resources such as the PHS hospitals and health professions employed in its categorical programs. The revised budget however, proposes the elimination of direct Federal support for these resources. The current request would provide the financial resources essential to assure immediate and effective services, including direct patient care, dependent upon the nature and extent of the emergency, and the resource requirements of the local community and the State.

Question: How would CDC mitigate confusion and delay which reportedly has plagued the Public Health Service's response to emerging environmental problems?

Answer: The Department has made significant progress in recent months in improving internal coordination for environmental emergency planning and response through a small formal policy group under the Chairmanship of the Director of CDC, through a Memorandum of Understanding between CDC and FDA for radiologic emergency response and by improving relationships with State and local officials.

Question: How would the funds be administered?

Answer: The fund would be administered by the Assistant Secretary for Health. Any expenditure would require the approval of the Secretary. There would be a system of checks established to prevent use of the fund to "bail out" programs which were poorly planned, budgeted for or managed. There will also be a strict time limit for use of monies from the fund.

CONSULTANTS

Question: To what extent do you expect to use consultant services in the coming year?

Answer: The request for consultant services in 1982 is 13.8 percent or $362,000 less than 1981. The primary use of these services will be for evaluation projects to determine what is effective and not effective in disease prevention and/or control.

HEALTH EDUCATION

Question: Why should the federal government continue to fund this project?

Answer: Funds already obligated for FY 1981 will support completion of the current phase of the American Hospital Association patient education project. No further Federal funding is anticipated for FY 1982.

IMMUNIZATION GOALS AND ACCOMPLISHMENTS

Question: What are your specific goals for the coming year in the immunization program?

Answer: Our major goals for vaccine-preventable diseases in 1982 are to eliminate indigenous measles by the end of the year, and to see a continued downward trend in rubella, mumps diphtheria, and tetanus--all of which reached all-time lows in 1980. Our major operational goals are to implement immunization systems in all States directed toward newborns which will prevent the development of large numbers of susceptible children and adults in the future; to ensure that the supply of childhood vaccines is obtained in a cost-effective manner; and to continue to add to our store of knowledge about the safety, efficacy, and appropriate use of existing and new vaccines. The accomplishment of these important objectives depends on the continued emphasis on immunization by the States after categorical grant support is replaced by block grants.

Question: What problems do you expect to encounter in achieving these goals?

Answer: We believe that the nation has the necessary tools to achieve precedent-setting reductions, and in some cases elimination, of childhood vaccine-preventable diseases. The key to success is continued commitment to the implementation of aggressive programs in all States so that disease problems in one State do not compromise the control of disease in neighboring States.

The major focus of activity in 1982 will be the refinement of newborn followup systems in all States to ensure that children begin and complete immunizations on time; the elimination of persisting pockets of susceptible children in junior and senior high schools; and a coordinated, interstate effort to eliminate the spread of measles in the United States by the end of the year. Also critical to success is the maintenance of a cost-effective supply of vaccines and the responsiveness of the Federal government to the individual needs of State programs. Emphasis at the Federal level will be placed on ensuring that all federally-assisted child health programs do their part in supporting State immunization

programs; elimination of disease spread from military recruits to the general public; coordination of the interstate exchange of information on measles cases and contacts; and continued surveillance and investigation of possible vaccine reactions.

FLUORIDATION

Question: Why should the Federal Government continue to sponsor such a program instead of it being left to the States and communities?

Answer: The fluoridation of community water supplies is the most effective public health measure available for preventing dental caries. It is the only means whereby all children in an area can be reached from birth and at low cost. The cost of children's dental care in fluoridated areas can be less than one-half the costs in fluoride-deficient areas. For every dollar spent on community water fluoridation, an estimated $50 is saved in dental treatment costs.

Although there is compelling evidence of the substantial benefits to be derived from water fluoridation, many communities have not undertaken the fluoridation of their water supplies because of a lack of resources for the purchase and installation of fluoridation equipment. A Federal focus for fluoridation was established in 1979 with the initiation of the fluoridation grant program. Through the resulting cooperative effort among Federal, State, and local levels, more than 300 community water systems serving 5.2 million people have been fluoridated.

HEALTH INCENTIVE GRANTS

Question: The Health Incentive formula grants program, more popularly known as Section 314(d) of the Public Health Service Act, has sustained large cutbacks in recent years. What would be the effect of eliminating this program, as proposed by the Carter Administration?

Answer: The States and local areas use these flexible block funds to assist in addressing a core of 60 public health problems such as: reduction of radiation exposure; control of disease outbreaks associated with unsafe water supplies; tuberculosis control - and preventive health services that can reduce disease rates. Within these categories, nationwide, the funds support 4,400 local public health professionals. Some States have elected to use 314(d) funds to support large proportions of specific programs such as tuberculosis control and public health laboratories. These grants also provide a flexible mechanism to respond to unusual events, such as outbreaks and emergency environmental hazards.

It is not known what actions each individual State will take to compensate for the loss of the $27 million.

In addition, the funds support 63 federal professional positions assigned to and at the request of the States. Most of

the positions are assigned to Tuberculosis Control activities. With the rescission all assignments will be terminated.

Question: What would you do with the remaining $9 million in fiscal year 1981, assuming Congress agrees with the $27 million rescission proposal of the Carter Administration?

Answer: The $9 million distribution, as required by the statute, is based on a pro rata share of the amount received for fiscal year 1979. The 57 eligible recipients are States, Territories and the District of Columbia.

ALOSH CONSTRUCTION

Senator Byrd: I noted in your fiscal year 1982 budget requests that there are no funds for construction of this facility. Could you explain why?

Answer: A request for $25,000,000 in funds for the construction of this facility was included in the original FY 1981 budget. In response to the economic concerns of the Nation, the Administration has placed a moratorium on all new Federal construction.

Senator Byrd: What is the latest cost estimate for construction of the proposed facility?

Answer: At this time the approximate cost estimate is $28,000,000 for construction of the building.

SUBCOMMITTEE RECESS

Senator SCHMITT. Let me thank you for your tolerance and for the information you provided the subcommittee. It is going to be very helpful in our examination of the budgetary issues before us.

The subcommittee will stand in recess until 9:30 a.m. tomorrow, when we will meet again in this room to hear testimony on appropriations requests for the National Institutes of Health.

[Whereupon, at 4:30 p.m., Tuesday, February 17, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, February 18.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1982

WEDNESDAY, FEBRUARY 18, 1981

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

The subcommittee met at 10:10 a.m., in room 1114, Everett McKinley Dirksen Senate Office Building, Hon. Harrison Schmitt (chairman) presiding.

Present: Senators Schmitt, Andrews, Hollings, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. DONALD S. FREDRICKSON, DIRECTOR

ACCOMPANIED BY:
DR. THOMAS E. MALONE, DEPUTY DIRECTOR
CALVIN B. BALDWIN, JR., ASSOCIATE DIRECTOR FOR ADMINISTRATION
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT
ANTHONY L. ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

SUBCOMMITTEE PROCEDURE

Senator SCHMITT. The subcommittee will come to order, and the chairman apologizes for a mixup in schedules.

Today the subcommittee begins 2 days of hearings on one of the most important programs in our labor, health, human services, and education appropriations bill, the National Institutes of Health.

NIH is the Federal Government's principal program for conducting and supporting biomedical research. NIH seeks to advance the capabilities of medical science to diagnose, treat, and prevent disease.

To achieve this goal, NIH supports biomedical research in institutions throughout the United States, conducts research in its own laboratories, and supports the training of promising researchers.

I believe it is not too much to say that NIH is known and respected throughout the United States and throughout the world.

Before going further, let me reiterate that we have set the stage for

our subcommittee's annual hearings with a very comprehensive set of overview hearings by the full Appropriations Committee at the end of last month. The purpose of that overview was to find out more about the state of the economy and to develop insights into how we might go about reducing the rate of growth of Federal expenditures.

At the present time, we are examining in detail the specific programs in the labor, health, human services, and education bill, along with appropriations requests, not only for fiscal year 1982 but for fiscal year 1981 potential supplementals, rescissions, and deferrals.

Although the Reagan administration's budget proposals are not yet before us, our subcommittee's hearings today will provide the background necessary to evaluate these proposals when they get here as they relate to the National Institutes of Health.

I would say from my own personal view that one of the additional purposes of these hearings is to examine, in as great depth as time allows, the balance in the Institutes' programs between very necessary research on how to treat disease once it occurs and activities designed to provide the basic information necessary to anticipate and therefore prevent disease.

You'll see many of my questions aimed at determining where you believe that balance should be, where it is today, and where it is going to be in the future.

The leadoff witness for the National Institutes of Health is Dr. Donald S. Fredrickson, Director of NIH.

Dr. Fredrickson, it's good to see you again.

It's exciting for me to have a chance to participate now, as chairman of this subcommittee, to assist you and others in designing the best possible program for this very, very critical activity.

Would you please introduce your associates who are with you today, and then proceed with your overview and description of the major programs for which you're responsible.

Dr. Fredrickson.

INTRODUCTION OF ASSOCIATES

Dr. FREDRICKSON. Thank you, Mr. Chairman.

On my right, your left, is Tony Itteilag from the Department.

On my left is Norman Mansfield, who is Director of the Division of Financial Management at NIH.

Next to him is the Associate Director for Administration, Calvin Baldwin.

Next to him is Dr. Tom Malone, who is the Deputy Director of the National Institutes of Health.

Senator SCHMITT. Please proceed.

Dr. FREDRICKSON. Mr. Chairman, let me speak for all the Institute Directors and witnesses who will appear before you in the next 2 days, to say that we welcome the opportunity to discuss the programs of the NIH before you and your subcommittee.

I have an opening statement, which I will submit for the record, if I may.

Senator SCHMITT. It will be included in the record in its entirety.

[The statement follows:]

Statement of Dr. Donald S. Fredrickson

Mr. Chairman, I welcome the opportunity to appear before this Subcommittee to review with you the programs of the National Institutes of Health. I should like to begin with a brief overview of the organization, purposes, and activities of NIH before proceeding to a consideration of a few of the important issues facing this agency. For your convenience, I have provided a few charts and other information to which I shall refer in my presentation.

Introduction: Mission and Overview

The purposes of the National Institutes of Health are the conduct and support of biomedical and behavioral research, more broadly referred to today as the health sciences. The purpose of this research, in turn, is to prevent disease and premature death and assure each person born the maximum opportunity for freedom from pain and disability. Such research has had profound effects on mortality and life expectancy in the past 75 years.

In the last 25 years, the American contributions to the health sciences have been among the greatest in the world. It is generally conceded that knowledge of living things is increasing at an extraordinary rate. Biomedical technology has advanced very rapidly to a state which promises further important transformations in health practices, agriculture,* and industry. It is widely acknowledged, Mr. Chairman, that we are today experiencing a "revolution in biology."

This advent of a new age--comparable to the Space Age in which you had so noteworthy a role, Mr. Chairman--is the product of vigorous public support for scientific research in this country beginning right after World War II.

Since 1950 approximately $75 billion, both public and private, has been spent on health science in the United States. The amount spent in 1980, about $7.8 billion (chart 1), represents just over 0.3 percent of the Gross National Product and 3 percent of the annual cost of health estimated at around $240 billion in 1980.

About 60 percent of the total support for the health sciences now comes from the Federal Government, with the next largest contribution coming from the pharmaceutical industry. An estimated 80 to 90 percent of the support for undifferentiated, fundamental or basic research is underwritten by the Federal Government. One could not expect industry with its need to show profits in the short term to have ventured the large amounts of risk capital to support the basic science efforts over several decades which have led to gene recombination, the production of pure antibodies by fusion of a malignant cell with a lymphocyte (hybridomas), the tireless search and capture of the agents causing hepatitis, the remarkable discovery of slow viruses that cause brain degeneration, the elucidation of brain structure and function which explains the actions of lithium or other tranquilizers, to name but a tiny handful of modern discoveries. Even most of the current drugs used to cure cancer or to prolong the lives of cancer patients must be developed to a stage

* Recombinant DNA techniques may, for example, permit increased food production through the development of new disease-resistant plant strains.

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nearing profitability before their final development can be picked up by industry.

Of the $7.8 billion estimated to be spent for biomedical research in 1980, half is represented by the budget of DHHS, with programs of 8 agencies contributing to the total. The budgets and activities of these agencies and how they interrelate in health research are described in a report, Health Research Activities of the Department of Health and Human Services, issued in December 1980 (copies of which have been provided to you). With its FY 1980 budget of $3.4 billion, NIH supported approximately 85 percent of the Department's total research.

NIH was founded in 1930, but went through its most rapid phase of growth from 1955 to 1965. It has been the largest single supporter of biomedical research in the world for many years.

In 1948 NIH comprised four Institutes. Now it consists of 11, in addition to the National Library of Medicine and several research and support divisions. The organization of NIH is shown in chart 2, and the organization of a "typical" Institute in chart 3. FY 1980 obligations by Institute are presented in chart 4. About 80 percent of the resources of the Institutes are used to fund extramural research and training principally by grants to university scientists. NIH has been for some time the largest single source of R&D funds to American universities, especially the academic medical centers. The NIH intramural programs are concentrated primarily on a single reservation in Bethesda, where the Warren G. Magnuson Clinical Center, a 540-bed hospital, is integrated with more than a thousand laboratories. Intramural research is also conducted at other locations--a 500-acre animal center at Poolesville, Md., a fundamental science laboratory at Frederick, Md., the Aging Institute's gerontology clinic in Baltimore, the National Institute of Environmental Health Sciences facility at Research Triangle Park, N.C., and the Rocky Mountain Laboratory for the study of infectious diseases at Hamilton, Montana.

The Science Base

A useful way to view the allocation of NIH resources in the aggregate is presented in chart 5. The left-hand cluster of bars represents dollar amounts allocated in FY 1980 for developing new knowledge at more fundamental levels--identified as "Science Base" activities. Note that the bar on the extreme left, labeled "Research Project Grants," shows the total for the most traditional or "classic" mode of research support. Investigators submit research proposals, which are then examined intensively by experts under peer review procedures and are approved or disapproved. If approved, the application is given a priority score. The Institute's Advisory Council considers the proposals in light of biomedical and social needs. Taking into account these needs, the Council recommends funding as appropriate (chart 6).

Research grants are awarded for an average period of 3.5 years. Thus, in any year, the majority of grants are continuing commitments, which have first command on available resources. About one-third of previously supported grants compete each year for selection along with new grant proposals. In sum, the number of competing applications which can be funded in a given year represents the share of the excellent ideas which the Government can afford to support.

The categories identified in chart 5 to the right of Research Project Grants represent all types of activities essential in a continuum designed to move discoveries from fundamental research to practical applications.

Included in the activities contributing to the Science Base are categorical center grants, which integrate research with applications and provide multidisciplinary reach. Here are essential communal resources such as the National Library of Medicine's information systems, which provide service to the entire world. Here also are the programs which supply the large instruments and data handling capability to many research institutions, the beds to permit clinical research, and other institutional resources. The largest single biomedical research center is the NIH's own intramural program. This year should see completion of the Ambulatory Care Research Facility, which adds a new dimension to multidisciplinary, ambulatory research.

The remaining 25 percent of NIH resources (those not in the Science Base) are critical for maintaining the continuity of research and its vitality. The largest component here is Applications Research, which includes development contracts to carry inventions into practice, and clinical trials to prove their safety and efficacy. A small, but key amount of NIH resources goes to technology transfer. Included here are demonstration and control activities to determine the practicality, safety, and efficacy of health practices. About four-fifths of the NLM budget is in this area. Finally, a small but important 4 to 5 percent of our resources go to training and to the extended career development of especially promising scientists.

From its inception, NIH has supported the preparation of an important fraction of the Nation's biomedical researchers. Such research training support is now reduced from the time when the biomedical research system was growing. It is now in a pattern of replenishment to keep young minds and energies flowing into an enterprise in which up to 10 percent of principal investigators are replaced each year.

The balance among each of the elements in the NIH allocation of resources is extremely important in maintaining the maximum efficiency and effectiveness of the system.

An important matter requiring attention is the relationship of NIH research programs to industry, particularly in the areas of application and technology transfer. NIH will explore in some depth the question of royalty income from Federally held patents as part of a larger assessment of Government-private sector relationships at a forthcoming meeting of the public Advisory Committee to the Director.

Regulatory Activities

Finally, Mr. Chairman, I should like to address the Federal regulatory activities for which the NIH is responsible. I want to emphasize that the NIH has not had major regulatory responsibilities since the Bureau of Biologics was transferred to the Food and Drug Administration in 1972. This left the NIH with only a few specific and discrete regulatory activities.

Certain of these pertain to the award of research grants. Such regulations are issued by PHS or DHHS offices, although the NIH actively participates in their preparation. Compliance with this class of regulation is required as a prerequisite for receiving NIH research support. Of all the regulations that have bearing on the NIH program and activities, these involve the greatest amount of time and attention from the private sector; however, the responsible and equitable distribution of NIH research grant awards could not be conducted without them.

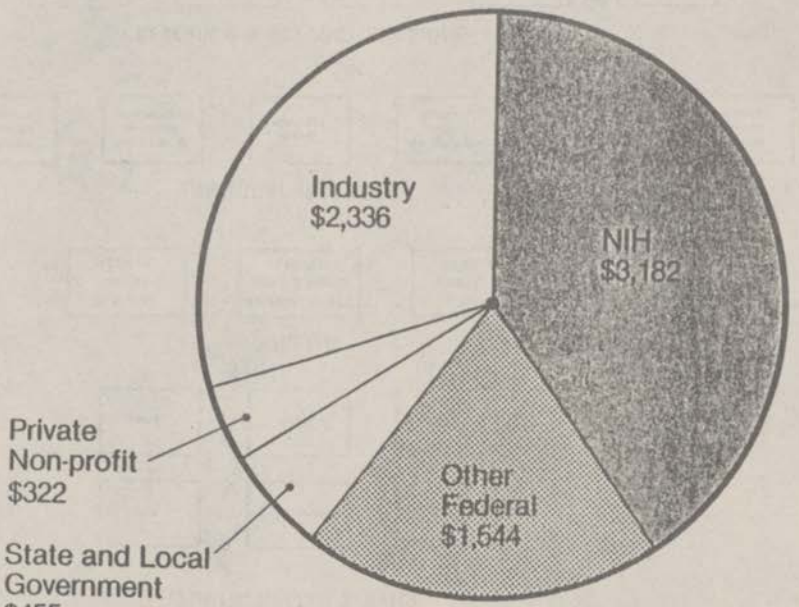
The NIH tries to keep such requirements to a minimum and has recently simplified the standard research grant application form. A corresponding simplification of the progress reporting requirements for grantees is underway. Thus, the primary NIH involvement is the revision and simplification of forms and regulations. Costs associated with such activities are minimal.

A significant class of regulations are those which protect the rights and welfare of human and animal research subjects. Such regulations, first issued in 1974, are based on recommendations of the National Commission for the Protection of Human Subjects. The NIH's Office of Protection from Research Risks (OPRR) is responsible for developing and monitoring these; only minor revisions, however, are anticipated in the near future. OPRR is also responsible for educating the public on the implications of the regulations and for giving assistance and guidance to the scientific community as they take action to comply with the regulations.

Mr. Chairman, as you and the Committee members hear the testimony of the Directors of the Institutes, all of us will attempt to provide you the maximum of information you need in the extremely difficult decisions you must make concerning the allocation of Federal financial resources.

Chart 1

NATIONAL COST OF HEALTH R&D, 1980
(IN MILLIONS OF DOLLARS)



$7,839

Chart 2

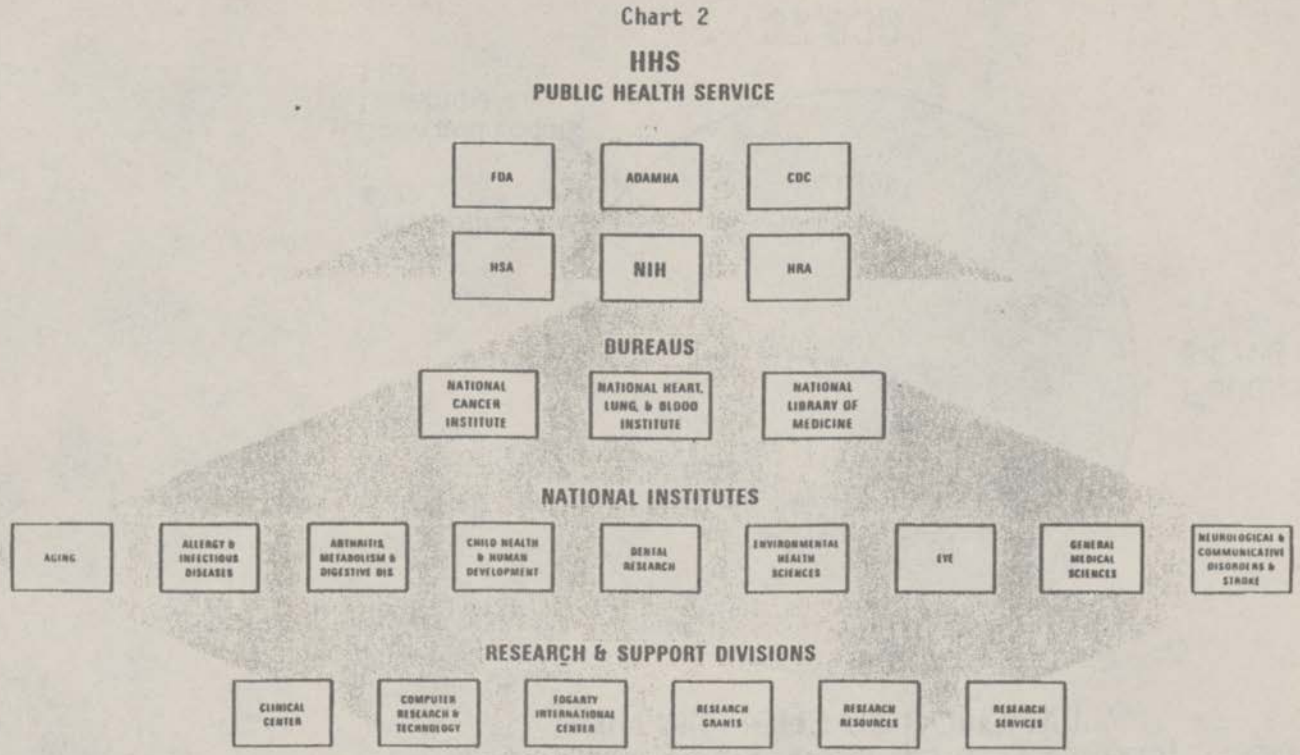

HHS
PUBLIC HEALTH SERVICE
FDA
ADAMHA
CDC
HSA
NIH
HRA
BUREAUS
NATIONAL CANCER INSTITUTE
NATIONAL HEART, LUNG, & BLOOD INSTITUTE
NATIONAL LIBRARY OF MEDICINE
NATIONAL INSTITUTES
AGING
ALLERGY & INFECTIOUS DISEASES
ARTHRITIS, METABOLISM & DIGESTIVE DIS
CHILD HEALTH & HUMAN DEVELOPMENT
DENTAL RESEARCH
ENVIRONMENTAL HEALTH SCIENCES
EYE
GENERAL MEDICAL SCIENCES
NEUROLOGICAL & COMMUNICATIVE DISORDERS & STROKE
RESEARCH & SUPPORT DIVISIONS
CLINICAL CENTER
COMPUTER RESEARCH & TECHNOLOGY
FOGARTY INTERNATIONAL CENTER
RESEARCH GRANTS
RESEARCH RESOURCES
RESEARCH SERVICES

Chart 3

TYPICAL INSTITUTE OF NIH

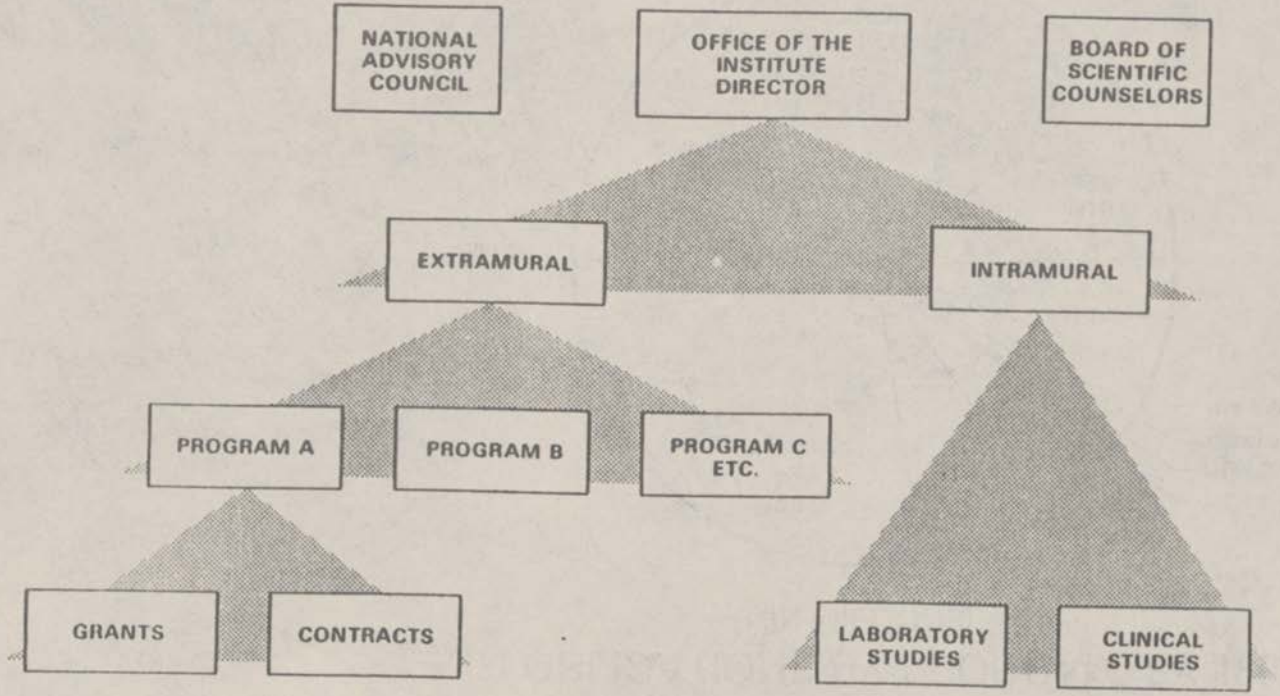
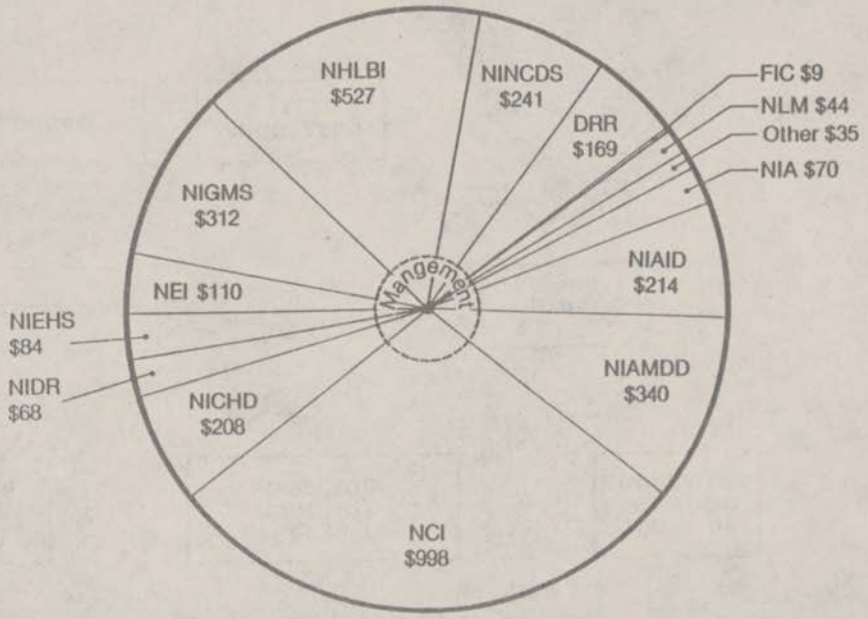


Chart 4

NIH OBLIGATIONS BY PROGRAM, FY 1980

(IN MILLIONS)



$3,429 Million

Chart 5

DISTRIBUTION OF NIH OBLIGATIONS, FY 1980

(IN MILLIONS)

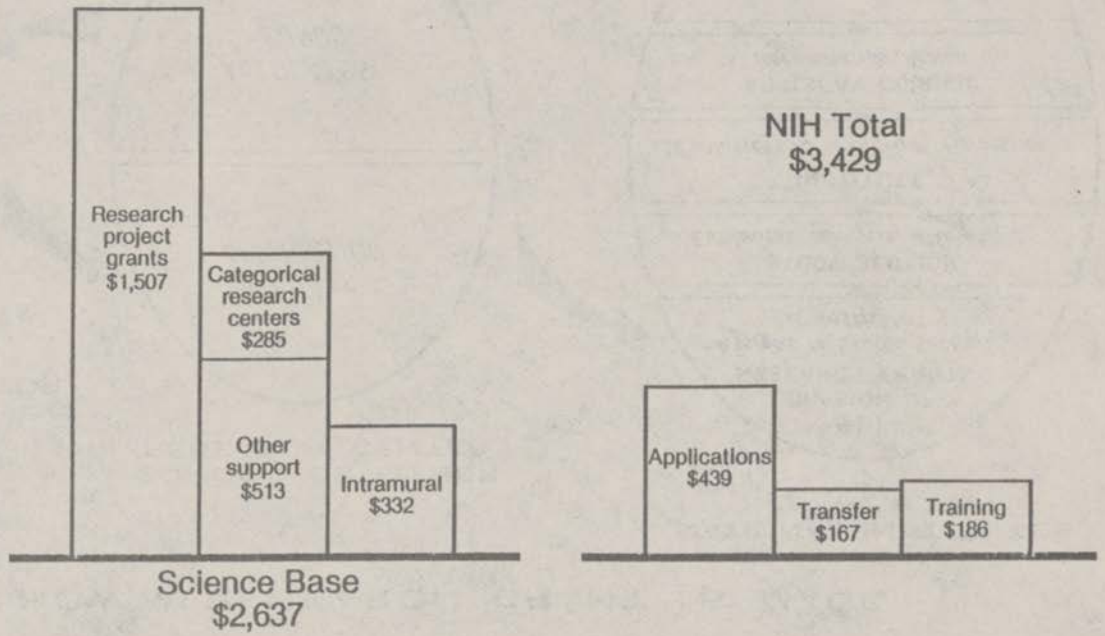
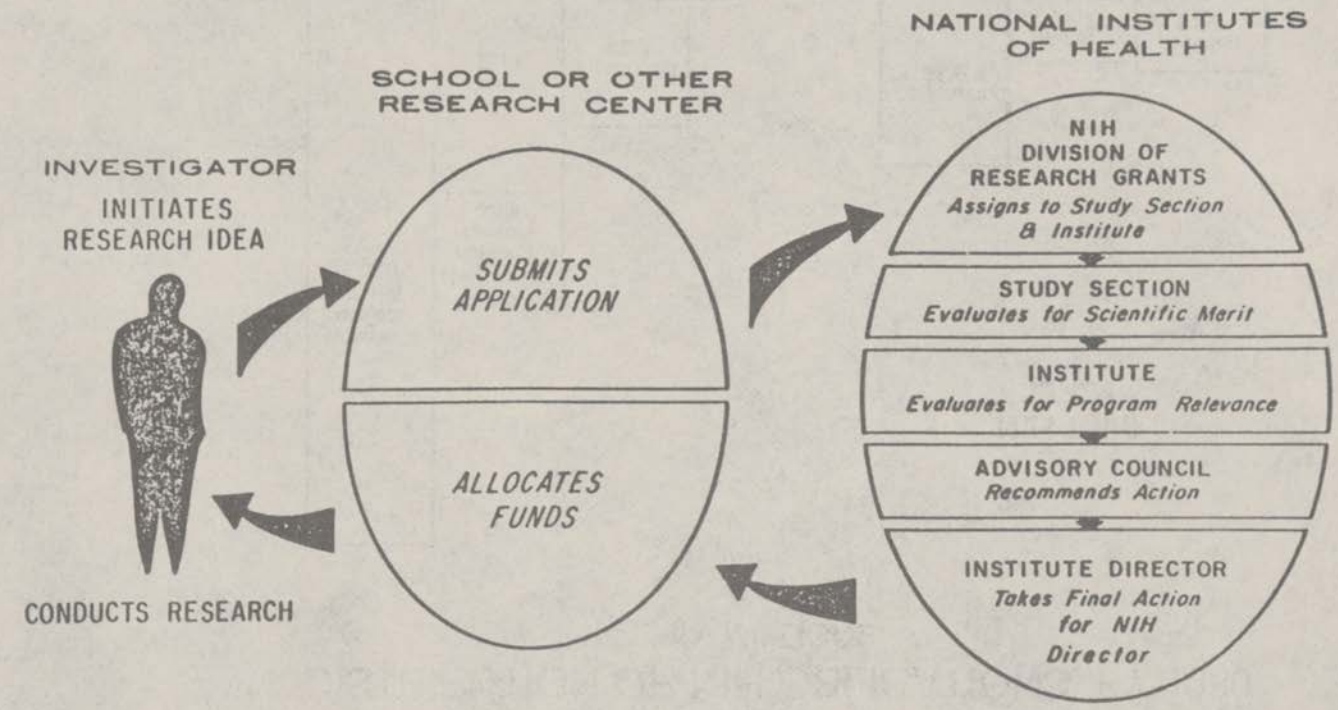


Chart 6

HOW A RESEARCH GRANT IS MADE



DR. DONALD S. FREDRICKSON

Director, National Institutes of Health

August 8, 1924. Canon City, Colorado.
Married, two children.

Education: University of Colorado, 1942-1943. B.S., University of Michigan, 1946. M.D., University of Michigan, 1949. Certified: American Board of Internal Medicine, 1957.

Professional History: 1949-1950, House Officer, Peter Bent Brigham Hospital. 1950-1951, James Jackson Cabot Research Fellow in Medicine, Harvard Medical School. 1952-1953, Research Fellow in Medicine, Massachusetts General Hospital. 1953-1955, Clinical Associate, National Heart Institute, NIH. 1955-1961, Member, Laboratory of Cellular Physiology and Metabolism, NHI. 1961-1966, Clinical Director, NHI. 1962-1966, Head, Section on Molecular Diseases, NHI. 1966-1968, Director, NHI. 1966-1974, Chief, Molecular Disease Branch, NHLI. 1969-1974, Director of Intramural Research, NHLI. 1974-1975, President, Institute of Medicine, National Academy of Sciences. July 1, 1975, to present, Director, National Institutes of Health. 1959 to present, Special Lecturer in Internal Medicine, George Washington University School of Medicine. 1963 to present, Lecturer in Preventive Medicine, Georgetown University School of Medicine.

Professional Organizations: Alpha Omega Alpha; American Academy of Arts and Sciences; American Association for the Advancement of Science; American College of Cardiology (Fellow); American College of Physicians (Fellow); American Federation for Clinical Research; American Heart Association, Council for the Study of Arteriosclerosis; American Physiology Society; American Society for Clinical Investigation; American Society for Human Genetics; Association of American Physicians; British Cardiac Society (Corresponding Member); College of Medicine of Valencia (Honorary); Deutsche Gesellschaft fur Innere Medizin (Corresponding Member); Harvey Society (Honorary); Institute of Medicine, National Academy of Sciences; Institute of Society, Ethics and the Life Sciences (Associate Member); International Society of Cardiology; Medical Society of Sweden (Honorary); National Academy of Sciences; Peripatetic Club; Phi Beta Kappa; Phi Kappa Phi.

Honors, Awards: Gold Medal Award, The American College of Cardiology, 1967. The James F. Mitchell International Award for Heart and Vascular Research, 1968. DHEW Superior Service Award, 1970, and Distinguished Service Award, 1971. The McCollum Award, The American Society for Clinical Nutrition, 1971. Harvey Lecture, 1973. Election to the National Academy of Sciences, 1973. Jimenez-Diaz Award (Madrid), 1974. Intrascience Award, 1974. La Modannina Prize for Science (Milan), 1975. The American College of Physicians Award, 1976. The American Heart Association Award of Merit, 1976. Honorary Doctor of Medicine, Karolinska Institutet, 1977. Purkinje Award (Prague), 1977. Honorary Doctor of Science, University of Michigan, 1977. Irving Cutter Medal, Phi Rho Sigma, 1978. Honorary Doctor of Science, Mount Sinai School of Medicine, 1978. The Gairdner Foundation Annual Award, 1978. Honorary Doctor of Science, University of North Carolina, 1979. Geronimo Forteza Lecture (Valencia), 1979. Fondazione Lorenzini Medal (Milan), 1980.

PURPOSES OF THE NIH

Dr. FREDRICKSON. I believe that perhaps I can be of greater service to you and other members of the subcommittee if I provide a setting, both in organizational and program terms, of the National Institutes of Health, which will allow you to examine speedily the individual Institutes and programs as they come before you.

With your permission, Mr. Chairman, I will use a set of charts in my presentation.

May I note that you have been provided, along with my opening statement, a copy of each of the charts that I will use.

Mr. Chairman, you have already stated, quite succinctly, the purpose of the National Institutes of Health. It is to conduct biomedical and behaviorial research in health science, as its popularly known today, and to seek ways to prevent and to cure disease, particularly aiming at attempting to provide each individual in our society and our whole civilization a fair shot at the number of years allotted to him by the biological time clock and without undue pain and disability.

NATIONAL HEALTH RESEARCH AND DEVELOPMENT

It may be useful, just for the moment, to put the NIH programs in the context of the total effort in the United States relative to health research and development.

As shown in chart 1, NIH and other agencies of the Federal Government are supporting about 60 percent of the total, 30 percent being supported by the industrial sector, primarily the pharmaceutical industry.

I think it is important to note, Mr. Chairman, that this division, however, is not the same for basic and for applied research. We estimate that the NIH and other agencies in the Federal Government are supporting between 80 and 90 percent of the basic research that is necessary to seek out fundamental information from which developments and applications may arise.

Senator SCHMITT. Are you happy with that pie as it stands right now, not the absolute numbers, but the distribution?

Dr. FREDRICKSON. I think it is a reasonable distribution, Mr. Chairman, in the sense that there must be a partnership with industry, especially in the areas of development and application. I think that the main thing is that the distribution not be disturbed by an imbalance based on the supposition that the industrial sector, for example, could possibly amortize a great deal of the fundamental research, for which I think public funds are clearly required.

Senator SCHMITT. Private, nonprofit—are you satisfied with that portion?

Dr. FREDRICKSON. It would always be desirable to see if we could get an increase in the private nonprofit contribution to the support of biomedical research, because I think a plural approach is extremely important.

FEDERAL FUNDING OF BASIC RESEARCH

Senator SCHMITT. Dr. Milton Friedman criticized the Federal funding of basic research in that it restricted the freedom of that research, by necessity I guess one might say, because it is directed funding and it comes under certain line items within the budget. Therefore, there's no absolute freedom of research.

Do you feel that such freedom could be enhanced if the Congress found ways to stimulate an increase in support by the private nonprofit sector for basic research?

Dr. FREDRICKSON. I think that such freedom might be enhanced to a certain extent, but I must respectfully disagree with Dr. Friedman. I think he is wrong. And I think that if the Government were to take away its support, as he suggests, then that area of research would die.

Senator SCHMITT. But would we enhance freedom of basic research if we could increase the support from the private nonprofit sector, while maintaining the same level of support from the Government?

Dr. FREDRICKSON. I think it would not really enhance the freedom. I think the relationship between those who perform research in the private sector and the Government is extremely efficient and effective. I do not believe that there is any inhibition on the freedom of the private sector or any of those in science because of the nature of this public support.

Senator SCHMITT. You know of no private or public criticism of the health research programs with respect to restrictions on freedom of basic research within the community itself?

Dr. FREDRICKSON. No, I do not. I know of no serious criticism within the community itself.

Senator SCHMITT. Thank you.

Please proceed.

Dr. FREDRICKSON. Mr. Chairman, for the next few minutes, I would like to dwell just briefly——

Senator SCHMITT. Excuse me, Doctor, I'm sorry. Do you think it's appropriate that other Federal agencies should be supporting health research to the extent shown on the chart? Why shouldn't NIH be the coordinating and funding agency for all Federal research and health?

Dr. FREDRICKSON. For several reasons, Mr. Chairman. I think it is important that other Federal agencies have a research capability. Primarily, this is because they have missions that require the search for new knowledge and its development within the context of their responsibilities. It is not possible for one agency to effectively, I think, serve the needs of all agencies, particularly in the areas of developmental and applications research. It is necessary for these agencies to have some capacity for searching out answers to the questions that they are faced with all the time.

Senator SCHMITT. So that line between gray and dark gray is one of mission orientation versus more general research?

Dr. FREDRICKSON. I think that is so, and I think it is becoming more so all the time. I think the proportion of basic and fundamental research being supported by NIH probably is slowly increasing as these agencies concern themselves with mission.

I must say this also includes the National Science Foundation, which supports basic research, as do the Veterans' Administration, the Energy Department, and Defense. Most of their research is mission oriented and necessarily so.

Senator SCHMITT. Thank you.

Please proceed.

ORGANIZATION OF NIH

Dr. FREDRICKSON. The figures you see in chart 1 for 1980 do not include training and construction costs.

Mr. Chairman, the NIH is about 50 years old. As shown in chart 2, it is one of the six major agencies in the Public Health Service and consists of 11 Institutes, the National Library of Medicine, and several Divisions, the relationship of each being my subject for the next few moments.

Senator SCHMITT. Was that chart prepared by an optometrist? [Laughter.]

Medical researchers are just as bad in their preparation of charts for meetings as geologists. Please go ahead.

Dr. FREDRICKSON. That's one reason why we supplied you with copies, Mr. Chairman.

The National Institutes of Health consists of 11 Institutes. The National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Library of Medicine are called bureaus. The chart then shows the remaining Institutes and a number of research and support divisions.

The NIH began in 1930 as the National Institute of Health. In 1937 the first categorical Institute was created by statute: that being the National Cancer Institute.

It was not until 1948 that the next three Institutes were created, that being at the time when the Federal investment in support of science became real through action of the Congress.

From that time until the present, several new Institutes have been created, and a division of the territory of biomedical research has resulted, in the form of these particular Institutes and Divisions.

Let me briefly tell you about each of these organizations. You will have your chance to examine them closely, as you wish.

The National Cancer Institute has the stated purpose of seeking to prevent and to treat the problems of malignancy.

The National Heart Institute began in 1948 as "Heart," concerned with cardiovascular diseases; since that time it has grown to include a very vigorous program in the lung diseases, and has many activities related to blood products and blood-forming organs.

The National Library of Medicine is our oldest organizational unit, having begun as the Armed Forces Library more than 100 years ago. It is now, as you know, an extraordinarily important part of the health sciences communications link. It is, in fact, the curator of the world's biomedical research information. It contains facilities for computerized information services that serve the whole world: it is in turn served by the world, making use of foreign scientists to prepare scientific abstracts, a vitally important aspect of worldwide information exchange.

The next Institutes, in order——

NATIONAL LIBRARY OF MEDICINE

Senator SCHMITT. Does the Library make value judgments in what it includes in its information systems? Or is that left to the individual who taps the system?

Dr. FREDRICKSON. It makes value judgments of a certain kind. It tries to collect all the information it can without attempting to make from the beginning a decision as to whether it is worth collecting or not. We feel that is not proper.

When the Library scales down its programs for the most effective use, as in MEDLARS, it will select certain journals that are most widely used and will provide that information. In that sense it does make certain decisions on basis of information about the use of the data files that it has.

The Library also has special information services—TOXLINE and others—that deal with special problems.

Senator SCHMITT. Does it try to determine what is good research on the cardiovascular system, or bad?

Dr. FREDRICKSON. It does not. It provides the scientist with everything that is known when it possibly can and allows the scientists to make that decision.

Senator SCHMITT. Thank you.

ORGANIZATION OF NIH

Dr. FREDRICKSON. The next Institutes, not in order of their creation, include the following:

The Institute on Aging is the newest. It will be 6 years old this year. It is a very interesting Institute in that it was created to deal with the problems related to an increasing portion of the health care problems and costs in this Nation. With this Institute, NIH has a particular interface between the social sciences and the biological, in an attempt to enrich the activities of both as they relate to aging, to the diseases of aging, and the care of those who are in later life.

The National Institute of Allergy and Infectious Diseases is an old Institute. Its name defines considerably what it does. In one sense, biomedical research has perhaps been outstandingly most successful in the area of infectious disease, because it is this sector that has responded the most, both to the search for treatments and particularly for preventives.

The National Institute of Arthritis, Metabolism, and Digestive Diseases is now, by a December-last enactment of Congress, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. This actually defines the four divisions among which the Institute's resources are spread. It is a major Institute for diseases of endocrinology and metabolism, as its name used to imply. It has a very diverse mandate and is one of the major supporters of research grants across fields that are not even mentioned in its mandate, such as dermatology and hematology, and other special programs.

Child Health and Human Development——

Senator SCHMITT. Excuse me; is that last Institute that you discussed unmanageable in any way because of its diversity?

Dr. FREDRICKSON. No; I think it is not. I think that it is going to experiment with some new organization, but I think that it is not made unwieldy by this last legislative move. I think the selection of priorities among so many competing fields is a very difficult job for all the Institutes, but perhaps it is more manifold here, where there are so many programs with special scientific areas and constituencies highly interested and involved.

RESEARCH PRIORITY SETTING

Senator SCHMITT. Is there any set means by which the Institutes select their priorities? Is it on the basis of economic impact of a particular problem on the society or in the numbers of individuals involved?

Dr. FREDRICKSON. Yes; more and more of such priority setting has become the case in the last few years, Mr. Chairman. It consists of an evaluation of the opportunities in science against the needs related to a particular mandate. Decisions are first made at the program level within the Institute.

All Institutes consult with their councils regularly on the decisions they make. But more than that, they engage in very intensive studies of particular problems involving much of the scientific community and other interested individuals in setting priorities.

Program development is something that the NIH engaged in during the last decade. Before that it was primarily concerned with good disbursement, effective peer review, and so forth. But now all the Institutes have, in effect, become organized, so that these individual problems are managed and overseen through a hierarchy of authority. It progresses on up to this point, where we appear before you.

Senator SCHMITT. I don't think you answered my question. Maybe it wasn't clear.

Are there certain set criteria that you weigh in order to determine whether you work on a particular metabolism problem or a dermatological problem or what?

Dr. FREDRICKSON. There are no set criteria that state that we shall apply so many dollars to a problem, dependent only upon the number of people who are affected by it. The mandates from these Institutes have actually come from the Congress, Mr. Chairman.

Senator SCHMITT. I understand. There's some flexibility in how you apply your resources.

Dr. FREDRICKSON. There is; and I think there is in every real sense an attempt to apply these resources primarily in those areas where there is a scientific opportunity to move ahead. These are weighted by need, but there is no mathematical formula that exists and that can be applied generally. I do not think there is any question but that the larger number that can be served by discovery influences very much the degree of effort that is put forth.

I think the same is true, Mr. Chairman, in regard to seeking for prevention of a disease as opposed to the treatment of a few who may already have the disease.

Senator SCHMITT. Thank you, please proceed.

ORGANIZATION OF NIH

Dr. FREDRICKSON. The next Institute on chart 2 is the National Institute of Child Health and Human Development, which has two centers with which it is primarily constituted; that is the Center for Population Research and the Center for Research for Mothers and Children.

Child Health, like Aging, is a noncategorical Institute. It seeks to bear upon human health from a particular age point, or a particular relationship, and is not categorically concerned primarily with a given organ system and its diseases.

The National Institute of Dental Research is one of the oldest Institutes. It is one of the few supporters of dental research in the United States. There are perhaps fewer private sector sources for support of that kind of research than there are in areas covered by the other Institutes.

The National Institute of Environmental Health Sciences is a relatively young Institute. Its concern is to learn more about the effects of environmental forces upon man and to seek some prevention from the degradation of biological resources. It is located in Research Triangle Park in North Carolina—the only Institute that is completely removed from the NIH campus in Bethesda.

The National Eye Institute is very much concerned with the eye and the optical system. It is also a major supporter of neurobiology, because of the enormous utility of that particular system in studying more general problems of the nervous system's structure and function.

The National Institute of General Medical Sciences is also noncategorical, and has as a primary purpose the undershoring of basic science that may not be adequately covered by the other Institutes with their categorical thrust. It has also been the major locus for NIH training programs, although again the Institutes have training programs related to their own categorical areas.

The National Institute of Neurological and Communicative Disorders and Stroke does attend to those areas designated by its name.

In addition to the Institutes that I have briefly mentioned, there are two organizational components that you will hear from who have separate appropriations. The larger of these is the Division of Research Resources, which provides for communal resources that underwrite and underpin the activities of the various Institutes. These resources include instrumentation, the biotechnology program, the provision of clinical research beds in various institutions, and certain programs that undershore the activities of institutions that are provided categorical support by the Institutes.

The second is the Fogarty International Center, the focus for our relationships with science abroad, which tries to facilitate keeping science as one universe, so that we may most effectively understand what is going on abroad, communicate with foreign scientists, and use the information that is developed by all scientists everywhere.

The Clinical Center, now recently honored with the name of the Warren G. Magnuson Clinical Center, is the 544-bed hospital on the campus at NIH. It is being modernized, and an ambulatory care

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research facility, to be completed in 1982, will allow a new dimension to multidisciplinary ambulatory research in Bethesda.

The other Divisions on chart 2 are essential ones on the campus: Computer Research and Technology; Research Services, which supplies primarily the intramural scientists; and finally Research Grants, whose activities we will discuss in just a moment.

PREVENTION COORDINATION

Senator SCHMITT. Is it at all significant that there isn't an institute that deals with coordinating prevention and cure?

Dr. FREDRICKSON. I think it is significant, Mr. Chairman, because we believe that every single one of these Institutes must have prevention as a primary objective. We cannot effectively harness the expertise of all these people in a single organization with that objective.

I think that the way to do that is through another dynamic, where you are concerned about all these programs and the balance of their effort toward prevention.

It almost would be like having, in my view, an institute of treatment—that nonspecific. Prevention must be a part of the thrust of every one of these programs, and the whole movement of the NIH research effort.

Senator SCHMITT. Is there political pressure on the Institutes, to deal with treatment of current medical problems? Treatment versus the more uncertain and cloudy future of prevention and cure?

Dr. FREDRICKSON. There is always that pressure, Mr. Chairman.

Senator SCHMITT. How do you deal with it?

Dr. FREDRICKSON. By making hard choices. Decisions must be made, within the Cancer Institute, for example—hard decisions as to how much effort to put in the areas of treatment, diagnosis, and prevention.

Senator SCHMITT. Wouldn't you say that the political forces that created each of these Institutes and bureaus were a reaction to the existence of a disease, and the necessity for treatment of that disease?

Dr. FREDRICKSON. I think that is true, although clearly prevention was also in the minds of the Congress when these Institutes were created. It was, after all, the era when vaccines had already demonstrated extraordinary possibilities for prevention.

It is in our enabling statute to prevent and otherwise treat disease, and I think more and more, as the cost of health rises, that concern for cost containment is also caught up in the dynamics of research. For example, choices are made not to continue to refine the development of renal dialysis on the one hand, an extremely important way of keeping people alive, as opposed to the allocation of resources to find out what causes kidney disease. These are conscious choices discussed and made every day at NIH.

Senator SCHMITT. Would you say, that in that specific area, that the balance is shifting toward the study of basic causes?

Dr. FREDRICKSON. I think it is shifting everywhere in that direction, Mr. Chairman, it is true you cannot neglect the immediate problems of treatments.

Senator SCHMITT. Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman. I have a question. This might be an appropriate time to inquire. How much of your budget is directed toward cancer research?

Dr. FREDRICKSON. The budget of the National Cancer Institute itself is approximately $1 billion. I think it is very important, Senator Specter, to emphasize that a very large fraction of that goes to underwrite research in immunology, cell biology, and genetics—research that enriches the activities of all the Institutes. The same is true for the activities throughout the whole spectrum. But $1 billion is the budget of the Cancer Institute specifically.

Senator SPECTER. Is it possible to make any projection on the long-range possibility of finding ways to either prevent or cure cancer?

Dr. FREDRICKSON. Yes; I think it is possible to say where we are at this moment. I will not try to preempt all the thoughts of the Director of that Institute. I will tell you my own belief.

I believe that within the decade we will understand, at the very basic molecular cellular level, the cause of at least one kind of cancer. By that I mean that the study of cell biology—of how cells are transformed from a benign, controlled process to a malignant state, where they are almost immortal and cannot be further controlled by themselves or the rest of the body—is moving so fast and so remarkably that I think we are going to understand the cause of cancer of at least one kind at the cellular level.

Senator SPECTER. You said one kind. How many kinds are there?

Dr. FREDRICKSON. There may be hundreds. We just do not know. I think to talk about cancer as a single disease is misleading, though, in terms of displaying the problems confronted by a scientific approach to it. Yet one kind of cancer may then lead you to unzip numerous other causes of cell transformation of a malignant kind. That's the first step.

That first step must be translated, then, into some form of prevention. But I think it can. I think there is plenty of reason to believe that science is marching toward that goal.

Senator SPECTER. Do you have a general parameter for a timetable as to the next step?

Dr. FREDRICKSON. No; I do not, Senator Specter. I think it would be incorrect for me to make any predictions. I have dared to make one within a timeframe because I believe it will happen, but I do not know about the next step. I don't see any way that we could predict precisely when things will happen.

Senator SPECTER. If costs were not a factor, and you had unlimited resources, how much would you like to direct to the National Cancer Institute?

Dr. FREDRICKSON. I think that we would not take resources from any of the other Institutes to further enhance that activity. I am not sure that cost is the major determinant. I think it is the conjunction of scientific discoveries that will allow that leap from one fact to another, piece by piece, to put this discovery together.

Senator SPECTER. So you don't think by doubling the $1 billion allocated for the National Cancer Institute that you could make a significant stride in finding the cause of cancer?

Dr. FREDRICKSON. I have no doubt that it would increase the rate somewhat, but I don't think it would double the rate, and I would not recommend that investment at the present time.

Senator SPECTER. Are there prominent people in the field who totally disagree with that conclusion?

Dr. FREDRICKSON. Yes, there are; a number of good scientists and people do not necessarily believe in doubling the budget, but they note the rate at which the Cancer Institute budget has not been increasing, and they are concerned about that, it would be honest to say.

HEART DISEASE RESEARCH

Senator SPECTER. One more question before returning the microphone to the chairman. Could you respond in the same manner on heart disease as you did on the cancer issue?

Dr. FREDRICKSON. I can indeed. I can be even more optimistic about heart disease, because the data are in, and the Director of the National Heart, Lung, and Blood Institute can give you statistics to show this remarkable decrease in mortality from coronary artery disease and a lessening frequency of strokes that has clearly occurred over the last 10 years. I think we have to ascribe to that a great deal of the research that preceded.

Senator SPECTER. Would you be more optimistic as to the problems of heart disease than you testified as to the problems of cancer?

Dr. FREDRICKSON. I think cancer is in a different stage of understanding, Senator Specter. All these problems are in very different states of maturity. Heart is a pretty mature business, and the impact of research here has been most evident among major health problems—since the revolution in treating infectious diseases with vaccines.

Senator SPECTER. Thank you.

Senator SCHMITT. Thank you. please proceed.

NIH PROGRAM OBLIGATIONS

Dr. FREDRICKSON. Mr. Chairman, you have a copy of chart 4. We probably need not take much more time to look at it.

This is a division by dollars of the NIH budget, among the several programs.

Unless you have questions, I'll proceed on from this. It is provided for your use in examining the distribution of the various Institute budgets.

Senator SCHMITT. Please go ahead.

ORGANIZATION OF TYPICAL INSTITUTE

Dr. FREDRICKSON. Let me just tell you briefly about the organization of a typical Institute, as shown in chart 3, because it bears on an important process which I want to discuss.

All the Institutes are different. For example, we have discussed one that has four major divisions now, and so forth. But they have certain fundamental things in common.

Each has an intramural research program, except General Medical Sciences, that is conducted largely on the campus at Bethesda, or in

several other NIH facilities around the country. The bulk of the resources, about 80 percent, goes into the extramural programs, where we support scientific activities related to our missions, mainly in the universities, but in other nonprofit areas as well, and sometimes in industry. There are two principal mechanisms for supporting such research: grants and contracts. In addition, there are training activities, which are supported by the various Institutes.

I would like to turn just for a moment to the process of awarding a grant.

ADVISORY COUNCILS

Senator SCHMITT. Before you do, the National Advisory Council and the Board of Scientific Counsellors, do they interact at all levels?

Dr. FREDRICKSON. Yes; each Institute has by statute a National Advisory Council, whose functions I will describe later. But—they are the advisors, the board of trustees, so to speak, and they have certain statutory responsibilities.

The Boards review the intramural research program. They constitute the peer review that maintains quality control on the intramural side.

The interactions between these vary among the Institutes. The Advisory Councils are aware of the reports to the Boards, but they act independently and do not, for example, meet together.

Senator SCHMITT. Thank you.

PROCESS OF GRANT AWARDS

Dr. FREDRICKSON. The Division of Research Grants, which I passed over with only a sentence, is one of the busiest organizations at NIH. This Division handles all grant applications for the Public Health Service; and about 25,000 such applications are received every year. About 18,000 of those will be NIH programs, and will be reviewed and handled in the following way.

Applications for support represent investigator-initiated science. They are ideas of scientists outside, who have a hypothesis, and who describe at length what they hope to learn and the methods they will pursue.

The judgment that follows is one of attempting to rate the idea, or the quality of science that is proposed to be supported, and to compare it with all the other programs, all the other ideas, the other grant applications that are submitted for possible funding by the NIH. It is an annual process, and three such examinations are conducted each year.

Senator SCHMITT. What's the total number of applications that are evaluated?

Dr. FREDRICKSON. We are evaluating at NIH about 18,000 applications every year.

Senator SCHMITT. How do you do that?

Dr. FREDRICKSON. I'll describe it to you, sir.

The peer review process that has evolved at NIH, almost from the beginning, is the quality control on public support of science. It is the most valuable single mechanism that we maintain, and we strive to keep it both vital and effective.

It works like this. There are two levels of review. Each grant is assigned to a study section, and to an Institute. The assignments to Institutes has been worked out long beforehand, because each Institute is responsible for a sector of the biomedical research continuum that we have talked about. There may be coassignment. A grant may be of interest to more than one Institute.

An application for grant will be assigned to a study section, of which we now have about 54. These offer primary review of the scientific quality of each application.

Senator SCHMITT. These are in-house reviewers?

Dr. FREDRICKSON. The reviewers are almost all from the outside community.

Senator SCHMITT. The reviewers in the study section are they from the outside community also?

Dr. FREDRICKSON. The study section is almost entirely outside, although we may use one or two intramural scientists for this purpose.

The study sections are all expert committees, so that each member of that committee is an expert in a particular area.

Senator SCHMITT. There is no preliminary filtering by the NIH of the raw applications sent to the study center?

Dr. FREDRICKSON. That is correct, sir.

Each application is submitted to a study section, comprised of experts who carry out a very burdensome task, three times a year, coming to Bethesda with bales of material, which they will have examined, usually over a 3- or 4-day period prior to their arrival.

Senator SCHMITT. When I sat on a peer review panel, we had certain requirements to prevent any obvious conflict of interest in that review. I presume you also have some?

Dr. FREDRICKSON. Yes, we do, sir. We can submit them for the record, or describe them very briefly.

Senator SCHMITT. Just provide them for the record.

[The information follows:]

PEER REVIEW—CONFLICT-OF-INTEREST POLICY

The NIH review group members adhere to strict conflict-of-interest procedures designed to prevent favoritism, or the appearance of favoritism, in the peer review system. When an application is received by NIH from a member of a review group, or from any close relative or professional associate, it must be reviewed by a different group from that on which the applicant investigator is serving. Also, members of review groups must leave the meeting room when any application from their own institution is being discussed or reviewed, even though they may have no prior knowledge of or direct association with the request. The term "own institution" indicates, in the case of multicampus State institutions of higher education, any part of the entire system in which the member is an employee, consultant, officer, director, or trustee. If the member has any possible financial interest in an application, he or she must be absent from its review. The same is true for any situation where there might be a personal conflict of interest, such as an application from a mentor or from a former student. Following all review group meetings, all members must sign a formal certification that they absented themselves from, and were not involved in, the review of any application when such participation would have constituted a real or apparent conflict of interest.

Before appointment to any review group and annually during the term of service thereafter, each member must disclose all employment and financial interests in a confidential statement to the National Institutes of Health. During the term of services, members are considered "special Government employees" for determining in a legal

sense whether conflict-of-interest situations exist. The Department standards of conduct apply to them while they are "special Government employees." New members of review groups are given specific orientation material regarding conflicts of interest and are briefed on the matter. All members are reminded at each meeting of the procedures to be followed in situations where conflicts of interest may arise. Finally, formal training is provided to the NIH staff in the prevention of conflict-of-interest situations in the peer review process.

The members of the scientific review groups are appointed for 4-year terms, and the terms are staggered; thus each year there is a constant turnover of membership. The NIH publishes semiannually and distributes widely the membership rosters of all its advisory committees. In addition, all principal investigators automatically receive at the completion of the review process the critiques of their grant applications, accompanied by a completed list of the membership of the pertinent scientific review group. Applicant principal investigators thus know—and can enter protest about—those who review their applications.

In addition to these procedural measures, an extraordinarily effective control on conflicts of interest is the face-to-face panel meetings required of all NIH review groups. In these meetings, evaluations of proposed research are conducted under the scrutiny of 15 to 20 peers and several NIH staff members, all of whom are sensitive to avoiding even the possible appearance of conflict of interest. Considerable peer pressure is generated in such a setting to be scrupulous in shunning decisions based on considerations other than scientific merit.

DISQUALIFIED REVIEWERS

Senator SCHMITT. Are the reviewers disqualified, if the reviewer's home Institute is involved?

Dr. FREDRICKSON. Such reviewers may not participate. They may not even attend that section of the meeting where an application is discussed. Indeed, we are very careful about that, and attempt to prevent any kind of logrolling.

The study sections then will review from 80 to 120 applications over a 2½- to 3-day period. Each application is discussed by at least two reviewers, with committee interchange.

NIH believes that this is a very important process, with human interaction to examine the opinions of the reviewers, rather than attempting to take mail ballots, and to coalesce these in an administrative fashion. Thus the review, and the interaction in a committee, is a very important part of the review process.

For the next step, the study sections take one of two major actions: They may disapprove the grant, or they may approve it for funding. For those that are approved, the study section assigns a priority number from 100 to 500. The maximum is 100—the top quality in their judgment.

These applications, then, are collected from the study section, where they are evaluated for scientific merit, and they are sent to the Institute to which they were originally assigned.

The Institute now receives an independent value of the quality of the grant application.

Senator SCHMITT. Is that quality based on the relative quality of applications under review, or on a subjective judgment of its quality, relative to what the reviewers generally would think is good science?

Dr. FREDRICKSON. To a certain extent both of those judgments apply, but the primary judgment is to be scientific; that is, to use the orthodox rules of scientific evidence in pursuit of a problem. The quality of the idea is very important, but one clearly must be able to pursue it.

And that judgment rests on several things. Is the budget realistic? Does the investigator have the instruments that he needs? Study sections concern themselves constantly with minor items in the budget. They are always trimming. A very conservative kind of review goes on.

The study sections also want to know about the background of the individual and his experience, and something about the institution involved. In other words, what is the chance of success?

Senator SCHMITT. Senator?

OTHER SOURCES OF RESEARCH SUPPORT

Senator SPECTER. Thank you, Mr. Chairman.

Doctor, what options does an applicant for such a grant have to go to others besides your Institute?

Dr. FREDRICKSON. Other than the NIH?

Senator SPECTER. Yes.

Dr. FREDRICKSON. There are several other places where he may seek support: The National Science Foundation is one, if he is working in an area of biology for which they have support.

The National Science Foundation and NIH interact, so we know what the other is reviewing. But we do not prevent an application from being considered by both agencies. That is, we do nothing to withdraw an application even if we know that another agency is looking at it.

An applicant may then also apply to the private societies, such as the American Cancer Society or the American Heart Association, which really have very small research budgets, and do not offer a great statistical probability of success.

Senator SPECTER. How big are their budgets?

Dr. FREDRICKSON. I should say the Heart Association has a budget of about $20 million a year, and Cancer about $35 million, so you can see in relative terms the chances are very small.

There are very few private foundations now supporting biomedical research of the kind we are discussing here.

Probably the largest is the Hughes Medical Research Institute, which I think is supporting approximately $25 to $50 million a year. But there are very few chances outside the Federal sources for support of basic research of the kind that we are describing.

I should hasten to add that there are other Government agencies that also award grants: The Veterans' Administration, the Defense Department to a certain extent, Agriculture, and the Department of Energy. These are significant sources of support, but the applicants must again get closer and closer to mission when they want to apply to those specific agencies.

Senator SPECTER. When you outlined the opening of your comments, the total allocation of resources in excess of $7 billion, that was the total for all available funding in the United States?

Dr. FREDRICKSON. Yes, it is; and 30 percent of that is industrial funding, which is largely self-used within the industrial houses themselves. They do not provide very much support for external activities, although that happens to be a subject of an upcoming examination this year.

We are trying to find out industry's real interest. What is its capability of supporting both basic and applied research? We are having an

important meeting in March to that purpose, because we think that is a very important question—the relationship between public and private sector support.

Senator SPECTER. Do you know what the figure would be on a worldwide basis?

Dr. FREDRICKSON. We constantly try to keep abreast with the worldwide support of science, Senator Specter, but it is extremely difficult for the following reason: The organization of the support of science and of the universities is different in every other country. There is much more State support of the universities around the world than there is in the United States; for example, in West Germany and France. For the West Germans, we can tell what the Deutsche Forschung Gemeinschaft, the research society, budget is, and we follow it every year. We also know what the Max Planck Institute's support is. But the provinces or states in West Germany support the university; and these societies do not.

Our support of the universities is critical; that is, the NIH contribution.

Senator SPECTER. Do you know what the Soviet Union spends?

Dr. FREDRICKSON. No; we do not. Some figures are available, but we cannot tell precisely, because much of the Soviet research is in state-supported institutes, and we cannot get complete budget data on those.

Senator SPECTER. Would you be in a position to give a ball park estimate as to what is spent by the rest of the world compared to our $7 billion plus?

Dr. FREDRICKSON. I would say that NIH must be underwriting about one-third of the world's basic science in this field, but most of that is going on in the United States, of course, because we are that important a contributor to health research.

Senator SPECTER. Thank you.

Senator SCHMITT. Please proceed.

PROCESS OF GRANT AWARDS

Dr. FREDRICKSON. We last left our grant applications reviewed as approved or disapproved, and, if approved, with a priority rating. The approved applications go to the Institutes, where they become the subject of an advisory council meeting, where the members will review the actions of the study section. The Council must recommend approval; that is their statutory responsibility.

So the Council reviews the applications—en bloc. It cannot review in the detail that the study sections have, but it makes the judgments. And if the Council also approves, then the Institute, generally speaking, funds according to priority score.

Funding decisions are based in part on the availability of resources in any particular budget cycle period.

In instances within each of the Institutes, decisions will be made based on program relevance, so that the priority score may not be the sole determinant of whether a particular grant is funded. In the main, however, the priority score is the principal factor upon which this decision is made.

DISTRIBUTION OF NIH OBLIGATIONS

I will now turn to chart 5, Mr. Chairman, and answer perhaps one more of your questions about the support of grant applications, representing investigator-initiated research relative to all the NIH. This is an aggregate distribution of NIH activities, displayed in several ways which we feel are useful, in attempting to depict the nature of our total activities across the spectrum.

We support most of the research by grants in the various categories that you see here. The category to the left is primarily basic science, or fundamental science, which is conducted in three principal ways.

RESEARCH PROJECT GRANTS

The first bar represents research project grants, which is the main item on the budget display tables. The second bar represents other kinds of grant research, including categorical centers, comprehensive cancer centers, arthritis, diabetes, et cetera, which you may wish to explore with the Institutes as you proceed. Some of the communal resources that I described in the Division of Research Resources and the Library are also included.

The third bar represents the intramural program which is roughly 10 percent of the budget.

APPLICATIONS, TRANSFER, AND TRAINING

The bars on the right represent the applied and developmental stages as opposed to these fundamental science activities. The fine distinction, as you know, Mr. Chairman, cannot be made for every research activity, but these applications represent primarily two things: Contracts for the development of products that are moving in the direction of practical use in man for prevention, treatment, or diagnosis with vaccines being a good example; and clinical trials, with between $100 and $120 million a year being invested to determine the value of an intervention, whether it be for prevention or for treatment.

About 5 percent of the NIH funds are allocated toward demonstration: Control activities—the determination of the value of intervention in medical practice—including the consensus exercises that we can describe to you later, which look at current practices. Four-fifths of the Library budget is included here.

And finally, about 5 percent of our investment is in the training of the new scientists who must replace the old.

RESEARCH PROJECT GRANTS

Mr. Chairman, let me point out that in the research project grant line are primarily the RO–1 and PO–1 grants, which are the jargon of the NIH. But when you read about research grants, and the stabilization of the ability of NIH to fund grants, it primarily concerns this line.

There are now about 16,500 grants that are active at NIH in this line. About one-third of those come in for the review and approval process that we just described, so that one-third of the scientists who are doing their work with this kind of support are coming in annually for renewal

and are competing with new scientists who are entering the pool for the first time.

This is a very competitive process. It offers little compromise: peer review at the beginning, and peer review at the end. This is the quality control of the NIH operation.

Peer review, however, applies to every other activity in which we engage, including contracts.

PEER RESTRICTION

Senator SCHMITT. How do you keep promising young scientists from being restricted by their peers?

Dr. FREDRICKSON. The principal method that we use to track this is to look at the number of people who apply for the first time to the NIH system and the number who succeed.

The success rate of the young scientists who become principal investigators—that is, to win a grant—is very good. It is better now than for some of the older scientists, and we try to track that from year to year.

We know that an investigator can, if he is really good and has a good idea, still get support. He can do it very well in competition with the existing scientists, but we have to watch it constantly. Your question is very germane to the whole operation.

Senator SCHMITT. What about institutions? Don't the larger, more established institutions prosper, while smaller, newer, or less-established institutions languish in the backwaters?

Dr. FREDRICKSON. There is no question that there tends to be a concentration of research activities within certain institutions. We, of course, review them all without reference to institution, and the geographical spread of support is very great.

But, it is the nature of some institutions to concentrate, to attract, to hold, the best scientists for a variety of reasons. So there is an asymmetry, of course, in distribution. This must be, if one uses this kind of quality judgment. But we have special programs, particularly in minority and developing institutions, where we try to maintain against that gradient the capability to grow and to enter the mainstream of scientific activity.

There is always this dynamic in research, Mr. Chairman, but I think that we have been able to keep effectively as heterogeneous and as egalitarian an opportunity as quality judgment will allow.

FACILITIES MAINTENANCE

Senator SCHMITT. Where in your distribution of obligations, is the support for maintenance and improvement of facilities?

Dr. FREDRICKSON. Largely in the areas of science base support.

Senator SCHMITT. Are you keeping abreast of the need for maintenance through modernization of facilities?

Dr. FREDRICKSON. I think we probably are not, Mr. Chairman. We have not had much construction activity for a number of years, except for a little residual activity in the National Cancer Institute. So to the extent that Federal support is required for underwriting a facility change, we have not been able to provide that.

Senator SCHMITT. To what degree should we consider a temporary period of bias toward funds for modernization, rather than actual research? Have we reached a point of diminishing returns in actual research, as a result of the deterioration of our facilities?

Dr. FREDRICKSON. That is a very important and difficult question to answer. I do not know the answer to it, Senator Schmitt. I think that we must attempt to find out.

Senator SCHMITT. If you do not know the answer, how are we supposed to know the answer?

Dr. FREDRICKSON. I do not know that any of us know the answer, but I think it is our responsibility to try to tell you.

Senator SCHMITT. Have you ever asked your advisory council that question?

Dr. FREDRICKSON. Yes, we have.

Senator SCHMITT. Can they project at what point it is no longer profitable to support research grants, because our facilities have fallen behind what is necessary to support modern research?

Dr. FREDRICKSON. I think there are several determinants to answering that question. One is that we are now able to fund only about 30 percent of approved applications. Therefore, I think we should attempt to keep that much scientific activity alive, because those ideas are extremely good, and the priority is high.

If the research must be conducted in somewhat moldy circumstances, that is better than letting the human capital go. But we are attempting to get inventories from the universities as to their most urgent needs. We have set out this year to see if we can, to get a clear picture of the physical plant status and how much Federal contribution might be applied.

We do have some funds for modernization. These are provided through the biomedical research support grant program, which is approximately $40 million. The purchasing power of that line has been declining over the last years, but it does permit a certain amount of extremely urgent and necessary renovation in order for our research grant activities to continue.

Senator SCHMITT. Let me give you an example. When the space program was at its height in real funding, the explosion of new facilities that were provided in a variety of the geochemical activities revolutionized geochemistry in general; isotope geochemistry, as well as elemental geochemistry.

The entire science and the entire country benefited from those new facilities, and still does. Although those facilities in the intervening 10 to 15 years have seen advances move beyond what we had seen at that time, the result of that was, we began to count atoms, where we used to count concentrations.

Dr. FREDRICKSON. You are correct.

Senator SCHMITT. The benefits of that explosion of new facilities was incalculable in science, and in the economy. Is there anything comparable in the medical science and in health sciences areas?

Dr. FREDRICKSON. In terms of creating new facilities that will open up?

Senator SCHMITT. Yes; for example, the state of the art of cell sorting, which we discussed a little bit yesterday and which has been advancing within certain very confined laboratory situations by unbelievable leaps and bounds, is not generally available within the profession.

Dr. FREDRICKSON. That is true, sir; we understand that. We support a great deal of that activity now.

To the extent that new facilities or new buildings are required to permit something to go on in science, we find this not to be a terribly important requirement.

Renovation of facilities, however, and particularly the provision of new, large pieces of equipment, are very important, and it is in the Division of Research Resources that we have a particular opportunity to use funds for this purpose.

This is indeed one of the NIH's major concerns, and it is frequently discussed among the Institutes. Are we doing enough for this kind of collective set of resources in order to enable categorical missions to go on? And I think that we are in an age where we cannot let the purchasing power of that Division of Research Resources to decline relative to the other activities.

Senator SCHMITT. But you cannot tell us whether we're at the point where, if we're going to be limited in total funds, we should change the distribution of the bar that you showed us in that chart.

Dr. FREDRICKSON. I think we are at a point where we cannot let the purchasing power of research resources, the terms that you and I are using here, decline relative to other categorical activities. I think we are definitely at that point.

INFLATION RATE FOR BIOMEDICAL RESEARCH

Senator SCHMITT. We will now ask you a few questions, Doctor. You've summarized the programs very well.

As I said, your prepared testimony will be included in its entirety in the hearing record.

The fiscal year 1982 budget continues to emphasize the stabilization of new investigator-initiated research grants at 5,000. How much funding will you need in fiscal year 1982 to maintain this goal of 5,000 new and competing research grants? Is that the figure we just were looking at?

Dr. FREDRICKSON. That is the figure we were looking at. The bar at the extreme left of chart 5 is where those grants are located. The cost of the average grant is going up annually, Mr. Chairman. We estimate that in 1982 the cost of each grant, on the average—and they vary tremendously—will be on the order of $116,000. It is our estimate that we would need something on the order of $582 million to maintain the ability to fund 5,000 competing research project grants.

Senator SCHMITT. What inflation figure are you using?

Dr. FREDRICKSON. We are using a biomedical deflater of approximately 9.5 percent.

Senator SCHMITT. What is the basis of that number?

Dr. FREDRICKSON. That is a number that was provided to us from the OMB, that it uses generally for its calculations.

Senator SCHMITT. Do you believe it?

Dr. FREDRICKSON. Well, I don't believe it for certain categories of research.

Senator SCHMITT. I speak just generally, and I recognize where you got the figure. But our hearings of a few weeks ago indicated that all of the projections of the CPI would be at least 12-or-more percent for this fiscal year and for the next fiscal year if we have business as usual. If we do make some progress in economic recovery, that rate might drop to below 10 percent. But still, the average will be far in excess of 9.5.

Dr. FREDRICKSON. For consumer products, we find a rate of inflation which exceeds the total rate of our activities, because about 70 percent is personnel, and the salaries simply aren't going up at comparable rates.

Senator SCHMITT. They are not?

Dr. FREDRICKSON. They are not, no, not in our institutions. They're certainly not in Federal science.

Senator SCHMITT. So most of the cost of those 5,000 grants is in salaries?

Dr. FREDRICKSON. About 70 percent, Mr. Chairman, yes. That is roughly the figure for the average grant. It varies, of course. Nevertheless, I agree with you that inflation will be very conservatively estimated perhaps by the deflaters that we use.

STABILIZING THE SCIENCE BASE

Senator SCHMITT. And it is your feeling that the 5,000 is sort of a basic number that, if you go significantly below that number, you will begin to impact the reservoir of information that you feel is necessary to sustain medical progress in this country?

Dr. FREDRICKSON. Mr. Chairman, that is a very important question. Let me answer it carefully, in two ways. We think that is a good level of activity to maintain, relative to what we have been maintaining in the capacity of the system.

But I think one must evaluate the stabilization through 5,000 grants in terms of the total balance of the system, because, for example, if we were to use all the research resources that we just discussed in order to fund the 5,000 grants, then I think we would be making a serious mistake.

So the total balance of the system, which is quite complex, has to be taken into account.

Therefore, I think we have to consider that as a first priority when we examine the total resources that we have available to us. But the number 5,000 has no magical quality, if indeed we can maintain an appropriate balance on the other activities.

Senator SCHMITT. Is there any subdivision within the 5,000 aimed at research for prevention and cure versus research for improved treatment?

Dr. FREDRICKSON. Clearly, if one sorted the applications, which change every year, they could be allocated into three piles: those obviously moving toward prevention, some probably toward treatment,

but there would be a great large middle pile where we wouldn't be sure, because much of this is investigator-initiated research—ideas that are designed to increase our basis of knowledge from which either prevention or treatment may arise.

I think, for example, if one had looked at recombinant DNA technology in 1972, nobody would have had the faintest idea that such a concept could go toward the eventual production of vaccines in states of purity and efficiency that no one had ever dreamed of before.

Here then is a mechanism for prevention of the highest order, but we could never have sorted out that idea and defended it at the time. That is true of so much basic science.

QUALITY OF SCIENTIFIC INVESTIGATORS

Senator SCHMITT. You used the words "purity" and "efficiency." Wouldn't you also include in that list "human specificity"?

Dr. FREDRICKSON. Yes, I would.

Senator SCHMITT. I chaired a hearing of the Science, Technology, and Space Subcommittee of Commerce in Albuquerque, the other day, in which there was great concern expressed by high-technology industries, that the individuals they were looking at for purposes of hiring into both technical as well as scientific jobs had some basic weaknesses in their fundamental education.

Are you looking at the cream of the crop in terms of the investigators who will carry out these 5,000 new and competing research grants? Do you see any signs of deterioration of their basic education?

Dr. FREDRICKSON. Again, you have posed a very important question, particularly as it relates to M.D.'s, because it is very, very difficult now to keep up with science. But I think if we look across the spectrum and take samples, as we do, the quality of the scientists we are supporting is better than it ever was.

First of all, we are more competitive. The young associates that we get at NIH, where we can measure their performance and examine them against the context of 30 years, suggests that they are better than perhaps we were. The quality of science that we are supporting seems to me to be suffering no deterioration at all.

Senator SCHMITT. Do you have any comparisons with foreign researchers or new researchers on the quality of science being proposed and carried out?

Dr. FREDRICKSON. I think we are certainly second to none in the quality of science being carried out and proposed. I am quite sure of that.

Naturally, there are, at the apex of science, in all the developed countries, people who are every bit as good as our good people. And, in fact, we support a few of them—not very many.

Senator SCHMITT. I have no problem with that. That has been a tradition of federally sponsored research, and I don't know if there is anything inherently wrong with it. It obviously could get out of hand.

Dr. FREDRICKSON. We are watching our foreign portfolio, because when we have austerity at home we cannot be lavish abroad.

SHORTAGE OF CLINICAL INVESTIGATORS

Senator SCHMITT. The prediction for general engineering Ph. D.'s is that there will be an annual shortfall of something like 10,000, which means in a decade, 100,000.

What is the situation with respect to medical science?

Dr. FREDRICKSON. I believe that we face the most serious problem in the medical sciences in the number of clinicians or clinically capable people who are also scientists—that is, the medical scientist who is also an M.D. and who is capable of carrying out a clinical investigation.

Because these individuals are falling in the percentage of those that we train, we have switched over the decade from a system that was preponderantly peopled by M.D. scientists, maybe two-thirds, to a current configuration of about one-third who are M.D.'s.

That is not all harmful, because it means that the depth and sophistication of many of the biological sciences have required people who simply should not be distracted by the medical problems of learning how to treat patients and deal with them.

The entry of good Ph. D.'s into this field has consequently strengthened. But we will reach, of course, a time, if this trend continues, where we will not have enough clinical investigators. Thus, we will find our spectrum moving beautifully toward application, but we will reach the point where we cannot determine it and answer the tremendous number of questions that are outstanding.

For example, interferon products from the new technology, the new biology, in which there is a tremendous American investment, are going to require clinical trials of a very high quality in order to determine whether they should be marketed.

We cannot do that without clinical investigators. Therefore, we are concerned and are trying to devise ways to make sure that the fraction of investigators we train, who are medically oriented, is large.

At the same time, we are not ever going to be able to go back to the old 2 to 1. Probably we shouldn't. Science is too complicated. Therefore, we have a concern about making sure that the Ph. D. scientist is oriented to the clinical spectrum so that he, too, can use the maximum of his imagination to enrich the quality of science. We do have these special problems within our particular field of biomedical science.

RESEARCH TRAINING

Senator SCHMITT. Do you believe the balance of support of graduate education in the total program is adequate today?

Dr. FREDRICKSON. We are now at about 5 percent for training. I think that is, in my own view, a personal view, about the minimum. We are probably in balance, and we would not like to see that shrink very much.

Senator SCHMITT. Do you expect 10 years from now, with the current balance and level of real support, that there will be a shortfall, assuming that the internal balance is maintained?

Dr. FREDRICKSON. Providing that we can maintain that balance, we believe we are training about the right number of such people through NIH training programs. We are not the sole trainer of such people. We

are somewhat buttressed in this belief by the National Academy of Sciences, which since 1974 has conducted an annual study recommending the number of people that we should be training to be nearly the number, or slightly higher than the number, we are currently carrying.

The prediction is soft, Mr. Chairman. I must be very honest with you. I know we have to keep training a certain number of people, because the turnover in science is very high. The turnover rate is approximately 10 percent per year for principal investigators.

There are many reasons why this turnover is so great, but we must constantly bring highly technologically trained and gifted young people into the system. There is no question in my mind about that.

Senator SCHMITT. Do you have any idea what proportion of the students who are currently in graduate school in fields of importance to the maintenance of the Institute's programs are foreign nationals?

Dr. FREDRICKSON. I do not, sir. I should think it would be a fairly small number.

Senator SCHMITT. In most other sciences it is now half.

Dr. FREDRICKSON. I think that is not true of the biomedical sciences in this country. Again, we have to be careful, because in certain medical specialties there is a great enrichment by foreign medical graduates—but we will seek some of that data for you.

Senator SCHMITT. Would you look into that for the record, please?

Dr. FREDRICKSON. Yes, we will.

[The information follows:]

FOREIGN NATIONALS IN RELEVANT GRADUATE STUDIES

A December 1980 issue of the Journal of the American Medical Association reports that of the 64,195 students enrolled in medical school during 1979-80: 833, or 1.3 percent, were foreign nationals: 78 of these were Canadians.

A 1980 National Science Foundation report, "Academic Science 1972-77," indicated that as of 1977, approximately 6 percent of the graduate students in the field of life sciences were foreign nationals.

No NIH research training support is provided to foreign nationals.

PROGRAM BALANCE

Senator SCHMITT. In most other sciences and in engineering, we currently are training the rest of the world and not training ourselves—at least not nearly to the degree that would seem to be appropriate.

If the Institutes were faced with a major budget cutback, what are your priorities within the programs? Is it a priority to maintain balance or to maintain a particular level within the areas shown?

Dr. FREDRICKSON. In looking at the situation in aggregate, we would try to keep that in balance to the best of our ability.

Senator SCHMITT. So the topology of that diagram you would like to maintain?

Dr. FREDRICKSON. Yes; in general, I would like to see the contours maintained. I think that is the kind of balance that has been achieved over the last 20 to 30 years. So that, in the aggregate, we would attempt to maintain an appropriate balance.

FUNDING LEVEL

Senator SCHMITT. But I take it your basic feeling is that in absolute funding you're just about at your minimum advisable level right now, sort of a maintenance level, rather than a level that will guarantee major breakthroughs in prevention, care, and treatment?

Dr. FREDRICKSON. Mr. Chairman, we are at a maintenance level in the sense that our purchasing power has not grown since 1979. It has come back down a little bit, in dollar terms. We are still a very strong system, however. And I am sure that within that level of resources we can, and must, provide an excellent program.

INDIRECT COSTS

Senator SCHMITT. What has been the trend in indirect costs over the past 10 years?

Dr. FREDRICKSON. The indirect costs have been slowly rising over the past 10 years. They are now at a level of 28.6 percent of the total cost of research grants, compared to about 19 percent in 1968. It has been a very slow creep in the last few years, but it is likely to continue to push upward.

Senator SCHMITT. Is this principally labor costs?

Dr. FREDRICKSON. It is probably not labor costs. It is much more likely to be the cost of energy for heating the plants from which the institutions derive a certain share of their costs. It is actually a variety of costs. We are getting the auditors to try to give us a better breakdown of the elements that make up indirect costs, because we are convinced that we are going to have to engage this year in some very careful analysis about costsnaring with our institutions.

Senator SCHMITT. Did the Institutes enter into the program on energy conservation that most Federal agencies participated in beginning in 1974?

Dr. FREDRICKSON. Yes, we did.

Senator SCHMITT. To what degree have you been able to cut energy costs?

Dr. FREDRICKSON. Let me turn to Mr. Mansfield.

Mr. MANSFIELD. We do not have the set of figures at hand. We will supply them for the record, but they will represent all central costs for NIH itself, not at the grantee level.

Senator SCHMITT. I understand.

[The information follows:]

ENERGY-USE REDUCTION

Overall at the NIH there has been a 12- to 15-percent reduction in the use of energy compared to the early 1970's. This saving has been accomplished principally through modifications of operating procedures, e.g., reduced lighting levels in halls and offices; adjustment of thermostats to minimize energy consumption for heating and cooling; no air conditioning or heating in office buildings after regular working hours; and refined control systems on heating and chilling plants. This saving has been made without major capital investment since no funds have been made available specifically for an energy saving program. Nevertheless, in spite of our efforts, NIH utility costs, including water, have increased from $3.5 million in fiscal year 1971 to $15.6 million in fiscal year 1980.

CAL TECH DATA

Senator SCHMITT. I'm only familiar with Cal Tech data, because I happened to be out there off and on during that period of time. They were in 1974 and 1975 able to cut their plant costs or the plant's use of energy by 20 to 25 percent. Costs are obviously rising.

Is that a comparable figure for most universities in the country, do you think?

Dr. FREDRICKSON. I do not know what the figures are for the universities.

Senator SCHMITT. Do you think that the intramural institute activity would have realized a comparable savings?

Dr. FREDRICKSON. I doubt if it would, sir.

Mr. MANSFIELD. It probably has not, because there has not been that much in the way of new facilities at the NIH campus.

Dr. FREDRICKSON. The energy loss from those buildings is what it was 4 years ago.

Senator SCHMITT. I know what was going on at Cal Tech at the time, and it was mostly in the operational procedures of the institution, not in modification of the facilities, just the operational procedure.

Mr. MANSFIELD. Reductions have been reported across the Federal Government in terms of fuel efficiencies in automobiles, and turning down thermostats to save on heat in winter and turning up thermostats to save on air conditioning in the summer. I just do not know what the precise figures are.

Senator SCHMITT. If you could provide us with some information, particularly since you believe that is the principal factor in the rising indirect costs.

Dr. FREDRICKSON. I am sure it is a factor, Mr. Chairman.

Senator SCHMITT. We'll expect some more information for the record on that.

NONFEDERAL RESEARCH TRAINING

Has there been a growth in non-Federal support of biomedical training?

Dr. FREDRICKSON. I think that, to a certain extent, there has perhaps been a growth at the State level, Mr. Chairman. We have some figures that suggest that, as NIH programs have declined from approximately 15,000 full-time equivalents to 10,000 over the last 10 years, the total number of people in training has not fallen to that extent. We believe that the State and local contributions to training may have increased somewhat.

We are not really sure where all the other support for training is derived. It is impossible for us to get that data.

CONSENSUS DEVELOPMENT

Senator SCHMITT. What is a consensus development conference?

Dr. FREDRICKSON. These are exercises held at the NIH for the last 3 or 4 years in which we have attempted to examine questions that are outstanding and seem to beg better information, or a determination of the state of the art. These conferences are particularly applicable to questions that affect a great many people, perhaps millions of people, and the practice of medicine surrounding a certain problem.

For example, one of the most recent conferences was the question about the need for as many caesarian operations as we have now in this country, which represents a very high-cost rate for obstetrics. Another conference considered the advisability of extracting wisdom teeth. And yet another was on the safety and usefulness of mammography by radiation in the detection of breast cancer.

At these conferences we attempt to bring the experts together, to balance their views, to make as complete a presentation as possible. We also have other participants: patients and consumers, and often other Federal authorities who must make decisions about certain procedures, and members of the medical profession, and colleges. We have a high stake in the answers to these questions.

A set of questions is outlined in the beginning, and the participants attempt to answer these over a 2- to 3-day period of extremely hard work.

Finally, the output of these conferences, the conclusions, are stated very carefully and explicitly and are widely distributed.

Now, in this country, each conference is published in the Journal of the American Medical Association, the New England Journal of Medicine, and a variety of other publications. The conferences are now actually being taken up abroad. I suppose that imitation is the most sincere form of flattery, because they are trying to do similar things in Europe.

Senator SCHMITT. How many do you conduct a year?

Dr. FREDRICKSON. We conduct approximately 12 per year.

Senator SCHMITT. Do you have any measure of the impact of the conference?

Dr. FREDRICKSON. We are attempting to do that now. We have an evaluation study in progress to assemble certain populations, particularly physicians. Judging by the mail we get from physicians, which is considerable, at least 90 percent of them find the conferences to be extremely useful, and they are very grateful for them. I think the consensus exercises are performing a needed service in accelerating conclusions about where we stand in the technical state of the art.

We also do this in connection with the current seminar on health care technology.

DUPLICATION OF RESEARCH

Senator SCHMITT. Do you coordinate interagency activities to prevent duplication—unnecessary duplication of work? I want to underline "unnecessary," because very often duplicative research projects can turn out to be far more useful than one by itself.

Dr. FREDRICKSON. Mr. Chairman, we do that in an accelerated way. And I think we have already provided this committee with an example of how the Department, which has eight to nine agencies conducting biomedical research, attempts to coordinate its own activities. This is an examination of all the activities in biomedical research in the Department—a description of where it takes place and what processes are used in planning. It also combines certain interagency programs or initiatives that relate to problems in common among more than one agency.

So I think coordination within the Department has increased tremendously in the past year.

There are also, throughout Government, some new experiments in coordination, for which we have had a great deal of input.

One is the Interagency Radiation Research Committee, which is an all-Federal committee, of which I am the chairman, where we are reviewing and are in the process of assisting the National Academy of Sciences in reviewing all research related to the biological effects of ionizing radiation undertaken throughout the Federal Government. As part of this effort, we are also reviewing all large-scale epidemiological proposals to see that there is no overlap, and to bring the best possible scientific recommendations to bear.

Coordination clearly is increasing in the Federal Government. I think ecumenical efforts, that we never could have imagined if we'd worked a decade ago, are functioning and are proving to be effective.

Senator SCHMITT. Do you think there is unnecessary duplication?

Dr. FREDRICKSON. No, I do not.

Senator SCHMITT. You're not aware of any significant areas?

Dr. FREDRICKSON. I think, Senator Schmitt, that the overriding concern of the scientists is that they have priority and that they not be simply engaged in redundant activities, because it doesn't advance their careers or their personal satisfaction when they do. That is the best monitor of all excessive duplication, I think, in the kind of science that we are supporting.

Senator SCHMITT. Research in the Veterans' Administration, for example, includes areas such as aging, alcoholism, schizophrenia, tissue regeneration, diabetes, spinal cord injuries; studies in visual, hearing, and speech disorders.

Is your experience with the VA program that they are supportive and synergistic, rather than duplicative?

Dr. FREDRICKSON. I am convinced that they are supportive, and for a particularly important reason, Mr. Chairman. We support a lot of that research and it comes in through peers.

Senator SCHMITT. On a reimbursable basis?

Dr. FREDRICKSON. Indeed; they must apply for grants and go through the same review process that I have described.

Senator SCHMITT. What is your impression of the Veterans' Administration research organization?

Dr. FREDRICKSON. I think in general that it is quite good. It is located mainly in university hospitals, where we have a tremendous investment. The quality controls that exist at the local level by peers is very good. I think that arrangement is excellent.

I know the research that we fund for the Veterans' Administration has been excellent, competing with everybody else, so I think their research is good.

Senator SCHMITT. It's not broadly known that the Veterans' Administration has basic research activity.

Dr. FREDRICKSON. It is not as broadly known as the Veterans' Administration would like to have it, I'm sure.

Senator SCHMITT. Yes.

Also, a number of Nobel Prize winners, I believe, are working within the VA's organization.

Dr. FREDRICKSON. They have a Nobel Prize winner from the Bronx VA Hospital, whom we have had the privilege, also, of supporting, Mr. Chairman.

Mr. Chairman, for the record, there is also another one in Tulane.

NONEVALUATION CONSULTANT SERVICES

Senator SCHMITT. The Carter administration's budget for consultants for fiscal year 1982 for your Institutes increased by $1.6 million over fiscal year 1981 for nonevaulation activities.

What accounts for the proposed increases, particularly 150 percent for the Fogerty Center and 98 percent for the Environmental Health Institute?

You could answer that for the record.

Dr. FREDRICKSON. If we could, Mr. Chairman.

[The information follows:]

NONEVALUATION CONSULTANT SERVICES

The National Institutes of Health is held accountable for launching major new research initiatives of the highest national priority in such areas as cancer prevention, low-level radiation, biological response modifiers, e.g., interferon, and chemical testing. Reliance on a variety of consultant services mechanisms is absolutely essential to the effective development and monitoring of these crucial new programs and for the promulgation of scientific and health information.

The proposed increase for NIEHS nonevaluation activities would provide for the initiation of a contract to supply the national toxicology program management with a comprehensive assessment of existing capabilities and future program requirements. The final system may serve as a model for independent laboratories as well as for the Government in carrying out testing responsibility under the Toxic Substance Control Act. The increase would also allow continued funding for the National Advisory Health Sciences Council, the NIEHS Board of Scientific Counselors, and the NTP Board of Scientific Counselors.

The proposed increases in nonevaluation funds at FIC will support new projects such as the establishment of the international issues study program to address international biomedical research issues of importance to the United States. About one-half of the FIC request is projected for the continued management support of the 10 to 12 international conferences that it expects to initiate and sponsor in 1982 on behalf of the individual Institutes.

SUBMITTED QUESTIONS

Senator SCHMITT. Doctor, thank you very much, I appreciate your testimony. We'll have a number of questions for the record and, as with other witnesses, we hope that the answers can be provided, along with your corrected testimony, which will be available to you shortly.

Dr. FREDRICKSON. Thank you, Mr. Chairman.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

PRIVATE FOUNDATION FUNDING

Question: We understand you support a substantial portion of the research effort carried out by the Nation's medical schools. How does this compare with the funding the schools receive from private foundations?

Answer: The following table lists the support provided to medical schools by the NIH, private foundations, and voluntary health agencies for the years 1974 through 1980:

(millions of dollars)

Fiscal Year	NIH	Private Foundations	Voluntary Health Agencies
1974	$ 716	$24	$24
1975	764	26	24
1976	813	23	26
1977	907	22	29
1978	1,047	20	32
1979	1,240	19	37
1980	1,429	18	40

Private foundations include those nonprofit organizations possessing financial resources in the form of endowments, which use earnings from assets to support a wide variety of charitable purposes; well-known examples include the Ford Foundation, the Charles F. Kettering Foundation, and the Rockefeller Foundation.

Voluntary health agencies are distinguished by their heavy reliance on annual campaign contributions, which are typically made up of small gifts from millions of contributors; examples of such agencies are the American Cancer Society, the American Heart Association, and the American Kidney Fund.

Question: Why can't private foundations do more to support biomedical research so as to take some of the burden off the Federal Government?

Answer: There are over 25,000 private foundations in the United States. They range in size from small family foundations with little or no staff and limited assets to the well-known giants of the foundation world (such as Rockefeller and Ford) managed and operated by substantial numbers of professional staff. Approximately 2,500 of the largest foundations account for about 70 percent of the foundation support for charitable causes.

A number of different areas have traditionally been the focus of the foundations' support -- including education, health services and research, welfare, humanities, community development, and international activities. While smaller foundations may concentrate in particular areas, the larger ones more often operate programs embracing support for several distinct areas of activities.

The possibility of substantially expanded biomedical research support by U.S. foundations is limited in important ways.

The structure and make-up of the total national foundation pool impose inherent limitations. Most smaller organizations have limited resources to maintain the specialized professional staff necessary to make informed granting decisions and monitor supported activities in complex biomedical research areas. Rather, they tend to concentrate in less specialized and demanding areas and thus represent little potential for any substantially increased funding for biomedical research.

The larger foundations, which already make important contributions to the support of biomedical research, have finite resources. In addition, their funding philosophies and strategies tend to emphasize support for several program areas that are selected to best meet perceived needs. Such a strategy (combined with limited resources) inevitably leads to a focus on supplementing, not supplanting, the support by other larger funding instrumentalities (such as the Federal Government) that concentrate and specialize in particular areas.

The voluntary health agencies do not limit themselves to research support. On the contrary, each of them, regardless of size, distributes its support over a number of interrelated health services and research areas, including public health education, professional education, community services, medical services, and research.

INDIRECT COSTS

Question: What has been the trend in indirect costs over the past 10 years, and especially over the past five years?

Answer: Indirect costs have been gradually increasing both in terms of actual dollars and as a percentage of total costs. In FY 1971, NIH awarded $126 million for indirect costs (22.6 percent of total costs) for all research grants. By FY 1980, that expense had risen to slightly over $586 million (28.6 percent of total costs). During recent years the rate of increase has begun to moderate, rising only from 26.7 percent of total costs to 28.6 percent between FY 1976 and FY 1980.

Question: What is your own personal assessment of this trend?

Answer: There are many factors contributing to the rise in indirect costs. The inordinate increase in energy costs in recent years has been a primary contributor. In addition, there are significant costs associated with meeting Federal requirements for civil rights compliance, human subject and animal welfare assurances, cost-sharing, and adjustments in accounting systems to comply with OMB Circular A-21, "Cost Principles for Educational Institutions."

Question: What can or should be done in your view to discourage further escalation of indirect or overhead costs?

Answer: Any change in the current practices for reimbursing indirect costs must be undertaken with extreme caution to avoid serious harm to the biomedical research enterprise. NIH has been giving this question thoughtful consideration in such forums as the

Director's Advisory Committee. We plan to continue such efforts in collaboration with the recipient community and other levels of the Federal Government.

Notwithstanding the complexity of the issue, there are several steps that could be taken to contain indirect costs. For instance, NIH could predetermine an indirect cost allowance at the time of award and discontinue the current practice of allowing upward adjustments (based on final rates) after a budget period terminates. Also, as an interim measure, NIH could award less than the full amount to which an institution is entitled under this current negotiated indirect cost rate agreement. If any steps such as these were to be taken, it would be desirable to make concurrent reductions in some of the administrative requirements currently imposed on award recipients (e.g., establishing and documenting cost-sharing or relaxation of time and effort reporting).

Question: Can NIH provide the Committee with a breakdown of overhead costs as a function of outside services (universities, private foundations, consultants, etc.)?

Answer: The table on the following page provides a breakdown of total contract costs and indirect costs for fiscal years 1978, 1979, and 1980 by type of contractor. Total cost amounts were taken from the NIH IMPAC Contract Data Management System. Indirect cost amounts were taken from percentage data developed through the same IMPAC system, which does not list consultant contractors separately. However, the indirect costs for this type of contractor would be comparable to those for large and small business enterprises, since the majority of our limited number of consultant type contractors are with commercial firms.

Question: To what degree can NIH reduce its reliance on outside services without jeopardizing its research program?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What initiatives will NIH take to avoid waste and abuse of funds?

Answer: Within the existing management structure of program administrators, contract officers, grants management officers, and auditors, NIH will continue to review and monitor recipients' activities and assist them in effecting management improvements wherever indicated.

PEER REVIEW PROCESS

Question: I'm interested in the objectivity of your peer review process. You draw on non-Federal scientists from many institutions to review research applications for merit. How can we be sure that these study groups give objective advice?

Answer: Members of review groups are selected not only for their demonstrated competence and achievement as independent inves-

National Institutes of Health

RESEARCH AND DEVELOPMENT CONTRACTING
TOTAL COSTS AND INDIRECT COSTS BY PERFORMER TYPE

	1978		FY 1979		FY 1980	
	Total Cost	Indirect Cost	Total Cost	Indirect Cost	Total Cost	Indirect Cost
Colleges and Universities	$188,083,000	$40,913,000	$193,509,000	$43,618,000	$156,374,000	$37,277,000
Hospitals	32,243,000	6,029,000	29,665,000	8,200,000	26,647,000	5,123,000
State and Local Governments	11,862,000	1,059,000	11,456,000	1,264,000	9,295,000	1,364,000
Other Nonprofits (including research institutions)	85,707,000	20,381,000	94,505,000	23,502,000	80,288,000	20,771,000
Large and Small Business Enterprises	134,028,000	48,660,000	150,344,000	54,370,000	160,619,000	60,979,000
	$451,923,000	$117,042,000	$479,479,000	$131,954,000	$433,223,000	$125,514,000

tigators in a scientific or clinical discipline or research specialty, but also for their reputation with respect to such personal characteristics as mature judgment, balanced perspective, objectivity, ability to work effectively in a group context, commitment to work assignments, and personal integrity. NIH is extremely careful to select individuals who combine scientific expertise with those personal qualities that produce fairness and objectivity.

Members of application review groups follow detailed guidelines in their review of applications. For example, for research grant applications, the review criteria, as specified in the Public Health Service Scientific Peer Review Regulations, include: scientific, technical, or medical significance and originality of the proposed research; appropriateness and adequacy of the experimental approach and methods to be used; qualifications and experience of the principal investigator and staff in the area of the proposed research; reasonable availability of resources; reasonableness of the proposed budget and duration; and, where application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects. Recommendations emanating from the review groups must be justified in writing.

The peer review system entails a series of checks and balances that ensure a high degree of objectivity. The recommendations of the review groups are examined by national advisory boards or councils, composed of both scientific and lay representatives who are noted for their expertise, interest, or activity in matters related to the mission of the specific awarding component they serve. Council recommendations are based not only on considerations of scientific merit, as judged by the scientific review groups, but also on the relevance of the proposed study to an awarding component's programs and priorities. In addition to this dual review of applications, NIH staff members monitor the review of each application to see that the system has been fair and objective.

Finally, the results of the review group's assessment are recorded in a document called a summary statement, which is sent automatically to the principal investigator upon completion of the review process. The group's evaluation is therefore open to inspection by the principal investigator, who in turn can ask for reconsideration if he or she has reason to believe that there was any significant substantive or procedural shortcoming.

In summary, the NIH believes it has created as effective and equitable a system as possible. Moreover, this system is constantly being modified in response to changing conditions, and it continues to receive the respect and admiration of scientists in the United States and elsewhere in the world.

RESEARCH TRAINING

Question: Is the trend of decreasing the growth in training funds continuing?

Answer: The support of research training in recent years can be seen from the following table:

Year	Dollars in Thousands	Total No. Trainees
1975	$154,875	12,272
1976	119,998	9,654
1977	127,458	10,198
1978	143,926	11,123
1979	143,661	11,197
1980*	176,388	10,664

*Includes stipend increase

Question: To what extent is there danger of an oversupply of PhD's in the biomedical sciences?

Answer: The National Academy of Sciences News Report of June 14, 1978, states that "In the absence of information, reports of underemployment and unemployment among doctorate-holders are dramatic perforce, and sporadic accounts of Ph.D. scientists and engineers unemployed or driving taxicabs get attention. Data in a new report by the staff of the National Research Council Commission on Human Resources suggest such anecdotes may be highly misleading. "The National Research Council report -- Science, Engineering, and Humanities Doctorates in the United States: 1977 Profile -- presents a picture of low unemployment, very low in some instances; an estimate 1.2 percent of a work force of 280,200 holders of science or engineering doctorates..."

The 1979 NRC-CHR survey of doctorate recipients revealed a drop in the unemployment rate for Ph.D.'s in science and engineering to 0.9 percent of the labor force. For the life sciences as a whole it was 1.1 percent. Graduate science enrollment in doctorate-granting institutions leveled off in 1978.

Since then, academic employment of scientists and engineers has increased by 4 percent in doctorate-granting institutions. There appears to be little immediate danger of an oversupply of Ph.D.'s in the biomedical sciences.

Question: What other sources of Federal and non-Federal training funds exist for the biomedical sciences? How do these sources compare in total value with the total NIH training budget?

Answer: Training funds include support of individuals, their tuition, fees, and supplies for their research projects. The major source of Federal training funds in the biomedical sciences are primarily available under the National Research Service Award (NRSA) Act from the NIH, the Alcohol, Drug Abuse, and Mental Health Administration, and the Health Resources Administration. The total program in FY 1980 supported about 12,160 individuals at an approximate program cost of $195 million. Of this, NIH supported 10,664 trainees and fellows, of whom approximately 5,569 were engaged in postdoctoral training and 5,095 were enrolled in predoctoral training at a cost of $176.4 million.

The National Science Foundation (NSF) conducts a $6.2 million predoctoral fellowship program, which supports 1,680 trainees.

Approximately 45% are in the biological sciences. In the postdoctoral research training field, the NSF supports 50 individuals at a cost of $900,000; approximately 25 percent are in the biological sciences.

The Veterans Administration has a program of support for approximately 130 physicians receiving a supervised research experience; the program is estimated at about $6.5 million.

Non-Federal support of predoctoral training, to the best of our knowledge, is rarely comprised of both subsistence and tuition. Students supported with non-Federal funds are, for the most part, unable to devote 100 percent of their time to their studies because they must supplement their incomes. We do know that students with Federal support complete their studies and enter the research work force in less time than do those with non-Federal sources of support.

Non-Federal support of postdoctoral training in structured programs similar to that of the NRSA appears to be minimal. The Hartford Foundation and the Searle Foundation have programs that support perhaps 25 such fellows. The American Heart Association and the American Cancer Society have small programs of support, and the Pharmaceutical Manufacturers Association also supports a group of postdoctoral fellows. It is estimated that approximately 150 individuals at most would receive support under these auspicies.

Question: Has the report we requested last year on the present utilization and future need for training funds been completed and, if so, what are the findings?

Answer: The Committee requested a report on the training levels for all NIH programs designating levels of training support from fiscal year 1978 to the present. That report has been completed, and is being submitted.

CONSENSUS DEVELOPMENT CONFERENCES

Question: How many consensus development conferences does NIH hold yearly? Last year?

Answer: The NIH sponsored 11 consensus development conferences in 1979 and 8 in 1980. In 1981, we estimate that 12 consensus development conferences will be held.

Question: How much did these conferences cost last year?

Answer: Each consensus development conference costs approximately $55,000 to $60,000, depending on the complexity of the subject technology and the number of participants necessary to address the issue fully.

Question: How many do you plan in fiscal 1982? At what cost?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Are there any changes in your research program priorities resulting from these conferences?

Answer: The output of each consensus conference is a series of recommendations that may include suggestions for future clinical trials, potential areas of research emphasis, or -- where consensus cannot be reached -- a list of unresolved issues requiring further study. All these recommendations are fed back into the planning and prioritizing of NIH research programs, in order to optimize attention to crucial issues of public benefit.

Question: Who receives the information developed at a conference?

Answer: The NIH Office for Medical Applications of Research (OMAR) maintains a computerized mailing list of 21,000 persons -- each of whom receives the Consensus Conference Statement (i.e., recommendations) and other relevant materials. The mailing list contains the names of public and interested consumer representatives as well as those from the allied health professions, professional medical societies, practicing physicians, and others. Media representatives are invited to participate in each conference, and are kept apprised of all consensus-related activities. A press conference is held after the reading of the Consensus Conference Statement by the chairman of the consensus panel.

Question: What studies have been conducted to measure the usefulness of such conferences?

Answer: OMAR recently awarded a contract to the University of Michigan to evaluate the consensus development process as a means of technology assessment and transfer of knowledge. In addition, evaluation questionnaires are distributed to the participants at each conference, and the results are analyzed, documented, and used for the planning and improvement of future meetings. Smaller-scale evaluations of conference components, such as representatives, effectiveness of the information dissemination, clarity and usability of the conference recommendations, are also undertaken for specified conferences. OMAR plans to initiate a study of the impact of these consensus conferences during fiscal year 1981.

Question: To what extent have you used -- or do you use -- consultants to set up these conferences?

Answer: The NIH -- through the individual Institutes -- has responsibility for the selection of consensus topics, questions to be addressed, and panelists and speakers for each conference. When appropriate, outside consultants who are expert in the subject technology are used by NIH to lend assistance in planning consensus meetings. To date, consultants have participated in planning associated with approximately one-half the conferences; in each case, only two to three consultants have been involved.

Question: Who coordinates the overall consensus development program?

Answer: The overall coordination of the NIH Consensus Development Program is the responsibility of the Office for Medical Appli-

cations of Research, Office of the Director, NIH. The coordination is accomplished in close cooperation with the individual NIH Institutes having an interest in the subject technology, and with advice and counsel from the OMAR Advisory Committee. All scientific and technical questions are the domain of the responsible Bureaus, Institutes, and Divisions that constitute the NIH.

DUPLICATION OF RESEARCH

Question: A study of the National Tax-Limitation Committee points out that millions of dollars in health research is conducted by Federal agencies other than NIH.

For example, says the report, the Veterans Administration research "involves some obvious duplication of NIH's tasks." The report goes on to list research by VA into: "aging, alcoholism, schizophrenia, tissue regeneration, diabetes, spinal cord injuries, and studies in visual, hearing and speech disorders." Doesn't NIH do research in exactly the same areas?

Answer: Many agencies (such as the Veterans Administration, the Department of Defense, the National Science Foundation, the Alcohol, Drug Abuse, and Mental Health Administration, the National Center for Health Services Research, the Department of Energy, and various PHS agencies) support health research in problem areas that border on or fall within the broad purview of the NIH.

Question: How much of this research by VA and NIH is duplication?

Answer: Differences in missions require different types of research emphases to serve the needs of those missions. This plurality of health research support, provided by the various agencies in support of their generic missions, is desirable and, in the view of the NIH, does not lead to wasteful duplication of effort.

Question: What coordinative arrangements are there among VA, NIH, and other health research agencies to minimize duplication?

Answer: One safeguard against unreproductive duplication is provided by the very nature of the process of scientific inquiry. The vast majority of NIH support of biomedical research is provided through the funding of investigator-initiated research project grants. Each grant proposal represents an individual investigator's own ideas, special skills, training, and perspectives. Consequently, each project represents a novel approach to the research questions that are posed. It is extremely unlikely that actual "duplication" of projects would occur with any significant degree of frequency -- even within specific areas of inquiry.

The possibility of unnecessary duplication of research efforts is minimized by numerous mechanisms, including a central registry of all research projects maintained by the Smithsonian Science Information Exchange. Also, at the administrative level, there are in place a variety of mechanisms, such as interagency agreements, which define the specific responsibilities of those agencies that share a common mission boundary. In addition, to further guard

against the possibility of undesirable program overlap, and to aid in identifying opportunities for fruitful collaboration, the NIH solicits the active participation of other agencies in the work of task forces and coordinating committees to plan programs and provide oversight in specific areas of research. Finally, needless duplication is avoided by continuing informal interchange among Federal program managers concerned with the same or related sectors of science.

CONSULTANTS

Question: The Carter consultant budget for FY 82 for NIH increased by $1.6 million over FY 81 for non-evaluation activities. Why can't you cut back on evaluation studies for which you request $7.6 million?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

INDIRECT COSTS

Question: Indirect cost awards increased from $96 million to $359 million (274%) between 1968 and 1977. The result is that NIH is unable to fund a fair amount of research considered to have scientific merit. What is your recommendation on instituting some form of limitation on indirect cost reimbursement?

Answer: As suggested in response to an earlier question, we believe that several steps could be taken to contain indirect costs. For example, an indirect cost allowance could be determined at the time of award, and the current practice of allowing upward adjustments could be discontinued. Also, as an interim measure, less than the full amount to which an institution is entitled under its current negotiated indirect cost rate agreement could be awarded. We would urge, however, that any change be undertaken with extreme caution to avoid serious harm to the biomedical research enterprise.

Question: Hasn't the GAO suggested some sort of formal ceiling on Federal reimbursement?

Answer: In a report dated July 27, 1979, GAO recommended that, if Federal participation in health research costs is to be limited beyond the present legislative restriction, it should be achieved through some formal ceiling on Federal reimbursement, such as by requiring minimum mandatory grantee participation in total costs, rather than limiting reimbursement on just the indirect cost portion of research.

Question: What about getting the grantees to pick up a portion of these costs - do they participate now?

Answer: For NIH, a statutory requirement exists for grantee cost-sharing, which in practice usually amounts to a minimum of 5 percent of the total cost of research.

Question: Should any limit be placed on total research costs other than indirect costs?

Answer: "Total research costs" means total direct costs of research as distinct from the indirect costs. In the case of some of NIH's large awards, such as program projects and centers, several of the Institutes have already placed an upper limit on the amount of funds that may be requested and awarded. Other Institutes are known to have such limitation under serious consideration. An upper dollar cap for the investigator-initiated individual research project grant is not believed desirable; nor does NIH plan to limit contracts, which appropriately should cover the negotiated full-cost of the proposed procurement. On the other hand, the alterations and renovations cost category is an example of an allowable cost within a grant on which an upper limit has been in place for several years.

INFLATION RATE FOR BIOMEDICAL RESEARCH

Question: The biomedical research deflator factor was last revised in 1977 or 1978. At that time it was calculated that the rate of inflation for research activities was about 9.2 - 9.5%. What is the rate of inflation for research activities in the fiscal year 1981 budget?

Answer: The biomedical deflator is calulated only for actual years. Estimates for future years are based on the OMB-supplied Gross National Product Implicit Price Deflator. The rate of inflation is estimated to be 10.1 percent for FY 1981.

RESEARCH GRANTS TO FOREIGNERS

Question: It is known that a number of foreign scientists receive research grants from NIH. How many foreign countries are recipients of these grants? Who are they?

Answer: In FY 1980 NIH awarded research grants to institutions in 23 foreign countries. Approximately one-third of these grants were to institutions in Canada. Those foreign countries in which NIH awarded grants in 1980 were the following:

Country	Number of Research Grants
Argentina	3
Australia	19
Belgium	7
Canada	65
Columbia	1
Denmark	5
Finland	7
France	4
Germany (Federal Republic)	1
Guatemala	1
Ireland	1
Israel	34

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Italy	6
Japan	3
Mexico	1
Netherlands	3
New Zealand	1
Republic of Africa	1
Spain	1
Sweden	16
Switzerland	6
United Kingdom	20
Yugoslavia	1
Total foreign research grants	207

Question: What is the basis for going outside the U.S. for health research?

Answer: The basis for some of these awards may be found in statutes authorizing international collaboration. Other awards are made in furtherance of the broad charge to NIH and other PHS agencies to conduct and support a broad array of research activities related to human health. In pursuing its research objectives, the NIH recognizes the opportunities for furthering research programs through the use of unusual talents, resources, populations, and environmental conditions in other countries which are not available in the United States or which augment or complement existing resources. To sum up, the NIH recognizes that it can support research in other countries only when such research has important specific relevance to the objectives of the NIH as authorized in the legislative and appropriation acts of the Congress.

Question: Why give grants to foreigners when many of your own scientists complain they can't get to first base with NIH?

Answer: NIH grant awards are based on the scientific excellence and program relevance of the proposed research activity. Thus, it follows that a foreign institution or international organization that meets these criteria should be eligible for support in the interest of improving the health of all people. On the other hand, NIH does not view itself as responsible for enriching the research environment abroad in the same sense as it is charged to do so domestically. Thus foreign institutions are not eligible for grants for program projects, centers, resources, or National Research Service Awards, nor is indirect cost reimbursement provided in the vast majority of cases. Furthermore, grants may not be made to individuals in a foreign country.

Question: What criteria do you use in making awards to foreign scientists?

Answer: All foreign grant applications undergo the same peer review for scientific merit required for domestic awards. National Advisory Councils are directed to consider in their deliberations whether a foreign application is of special importance in fulfilling the mission of the awarding unit. In addition, the application must fall within the upper half of the Council or Board priority score ratings as recommended for approval for that review cycle. These policy requirements are intended to ensure that research supported in foreign countries is of the highest caliber

with significant relevance to problems of human health in the United States and abroad.

DIVISION BETWEEN CURE AND TREATMENT

Question: What percentage of your research budget is devoted to cure of disease - and what percentage to treatment of disease?

Answer: Most NIH research is addressed to finding new knowledge about diseases -- knowledge from which it will be possible to devise diagnostic techniques, therapies that are often curative, and preventive means. The ultimate aim, the aim of all research, is of course prevention -- the only complete "cure" of disease.

The NIH has identified certain areas that can be termed prevention research, representing about 15 percent of NIH research funds. But since research is a continuum, the results of increased understanding of the body and of the causes of disease can lead to the capability of early diagnosis and to treatment as a step along the path. Thus, the research into "cure" vs. "treatment" cannot readily be delineated and distinguished in quantitative terms. For example, it has been shown that early treatment of hypertension leads to a dramatic reduction in stroke incidence. It is the hypertension that is being treated; it is the stroke incidence for which reduction has been found. In a genetic disease such as cystic fibrosis, sufferers can often be kept alive and able to lead relatively normal lives into young adulthood through improved methods of periodic treatment -- yet the research on cystic fibrosis leading to this "half-way technology" is aimed at cure of the disease itself. Because of this organic interrelationship in NIH activities, research cannot readily be allocated as applicable to cure on one hand, and treatment on the other.

Question: What percentage of your budget is for basic research? For applied research?

Answer: In FY 1980, NIH obligations for research and development totalled $3.2 billion. Of this amount, 52 percent was for basic research, 36 percent for applied research, and 12 percent for development.

Question: Do you try to apply a cost-to-benefit analysis to your work? Is it possible?

Answer: Cost-benefit analysis is used for sketching background and developing broad perspectives on selected areas of public policy concern. The issue of whether the Nation is earning a favorable return on the Federal investment in biomedical research is an example of the macropolicy level at which such a tool can be and has been legitimately applied. Its methodology is neither precise nor sufficiently inclusive, however, to be employed in an unqualified manner to reach conclusions and priorities regarding micropolicy issues such as allocation of resources across particular biomedical science and disease alternatives. Its demand for translation of all factors into common dollar measures further complicates and limits its application to the complex issues of health research support.

One element common to both health research support decision-making and cost-benefit analysis is the consideration of need. Measures of the incidence, prevalence, and cost (both "direct" in terms of health care and "indirect" in the sense of loss of earnings and work time due to sickness and premature death) are an important part of cost-benefit analysis. Such measures also provide important insight for NIH regarding varying and competing needs and are factored into judgments regarding resource allocation priorities.

Such a factor, however, cannot and is not employed in isolation. It must be combined and balanced with other equally important considerations. These include an assessment of the state-of-the-art in relevant science areas and the degree to which they are ready for substantial research breakthroughs and progress, the availability of high-quality, peer-reviewed research proposals in concert with trained investigators, and public concern about particular disease areas. Decision-making regarding specific allocation of resource issues demands more than traditional cost-benefit analysis can provide and is a complex undertaking requiring the balancing and blending of a number of science and health considerations.

Question: How would you quantify the benefits received from your research in relation to the amount invested -- 1 to 1, better than 1 to 1, or worse?

Answer: There is substantial evidence regarding the favorable return from investments in biomedical research. A number of studies focusing on particular disease areas and using various approaches have resulted in positive findings. One of the most exhaustive recent studies of the issue looked across the whole range of health and disease. The analysis was conducted by Professor Selma J. Mushkin and published in a book entitled Biomedical Research: Costs and Benefits (Ballinger Publishing Company, 1979).

The major question addressed was the degree to which biomedical research accounted for trends in reduced cost of illness (as measured by reductions in premature death and work-time loss due to sickness) over the period since 1900. Utilizing econometric and statistical tools of inquiry and analysis, Professor Mushkin and her colleagues concluded that 30 to 40 percent of the mortality reduction and about 39 percent of the reduction in the objective sickness rate were attributable to biomedical research. The dollar savings from reduced morbidity and mortality rates compared to investments in biomedical research suggested a net savings to the Nation of $227 to $407 billion since 1900, or a 10-16:1 ratio of benefits to health research and development costs. While such a pioneering study could not incorporate all possible costs and benefits, the final results, even if only the most conservative levels are accepted, show a clear and significant investment return.

NATIONAL TOXICOLOGY PROGRAM

Question: The National Toxicology Program (NTP) has completed its second year. Last year, NIH increased support of that program by $20 million. In 1980, a super-fund bill was passed by Congress to compensate victims of environmental pollution. Thus, the NTP has

assumed greater significance. How was the increased funding for the NTP put to use?

Answer: The FY 1980 budget for the NTP provided an increase of approximately $20 million over FY 1979. This increase enabled the program to initiate 80 new bioassays to be started during FY 1980 and FY 1981; to broaden protocols in the pre-chronic phases of approximately 70 percent of these bioassays to measure toxic effects other than cancer; and to fund the continuation costs of bioassays begun in previous years.

Question: Please summarize the accomplishments of the program over the last year.

Answer: A major accomplishment was to integrate special toxicological studies into the carcinogenesis bioassay system to increase the scientific knowledge base on the toxic effects of the test chemicals. For example, of the 40 chemicals started on test in FY 1980, 70 percent had special studies designed to enable detection of toxicologic effects other than cancer; e.g., damage to certain organs (liver, kidney, lungs), neurological effects, and immunotoxicity.

Efforts were initiated to develop scientific data that, in addition to identifying toxic or carcinogenic properties of a specific chemical, will define the general toxic properties of a chemical class. This approach will provide data in a more timely and cost-effective manner. The NTP initiative on benzidine-derived dyes represents such an approach where integrated testing of 16 dyes in mutagenesis, metabolism, or specific animal bioassays will provide results applicable to several hundred dyes.

Determinations made by an independent audit and by the NTP agreed that the carcinogenesis and toxicological research and testing could be performed best through direct Government management and supervision rather than via the prime contractor mechanism. Thus, bioassays placed under contract in FY 1980 and in the future will be under direct Government management.

During FY 1980 the NTP continued the carcinogenesis bioassay testing of 199 chemicals, started 40 additional chemicals on test, and completed studies on 24 chemicals. Of the 24 chemicals in which tests were completed, 12 were demonstrated to be carcinogenic for experimental animals, 1 had equivocal results, and 11 showed no evidence of carcinogenicity. These results often are of direct relevance to current issues. For example, the 1980 results included TCDD, the contaminant in Agent Orange, which confirmed an earlier report that TCDD was a carcinogen in rats and established its carcinogenicity in a second species, the mouse. Other carcinogenesis bioassay results considered of importance included cinnamyl anthranilate (flavoring agent -- positive), reserpine (antihypertensive drug -- positive), Selsun® (antidandruff shampoo -- negative), di(2-ethylhexyl)phthalate (plasticizer -- positive), dibromochloropropane (soil gumigant -- positive by inhalation).

During FY 1980, 350 mutagenicity tests were begun and 261 completed. Two new mutagenesis systems were developed -- one using cultured mammalian cells and the other using the fruit fly. Test

systems that define the mutagenicity of chemicals are currently being applied to obtain a more comprehensive toxicological profile on chemicals being considered for lifetime cancer studies in rodents.

The NTP expanded activities in the area of reproductive toxicity assessment, began interlaboratory testing of an immunotoxicity test battery, and completed an international collaborative study of short-term testing methods for carcinogenesis.

The NTP continued activities in response to current health problems. Specifically, testing continued on 70 of the 200 or more chemicals found in Love Canal. The NTP took an active role in an interagency work group evaluating potential health effects of Agent Orange; reproductive assessment studies on exposed male mice showed no adverse reproductive effects.

In July 1980 the first NTP Annual Report on Carcinogens was published and distributed. This report, prepared pursuant to the amendment to the Public Health Services Act, commenced the process of listing "all substances which are either known to be carcinogens or which may reasonably be anticipated to be carcinogens and to which a significant number of persons residing in the United States are exposed...." The Report summarizes available human exposure data, evidence for carcinogenicity from human and animal studies, production and use data, and applicable Federal regulations. Future annual reports will expand the chemical list and provide the other relevant data.

To provide the NTP with decision-making guidelines by which to orient its testing activities, the NTP initiated an extensive Testing Needs Study. This study, conducted under contract to the National Academy of Sciences (NAS), will define the universe of chemicals in existence and make judgments as to what proportion of the universe has potential public health implications. The NAS will suggest a system for setting testing priorities among all chemicals submitted to the NTP for toxicological consideration.

The NTP established the NTP Technical Bulletin to disseminate information about NTP test results and program activities on a more frequent basis. Three issues of the NTP Technical Bulletin were published and mailed to 3,000 individuals and organizations who requested the document.

Question: What progress has been made in identifying toxic chemicals in the environment and their potential risk to human health?

Answer: One of the criteria for testing is that the NTP will test chemicals found in the environment for which responsibility for testing cannot be assigned to a single firm or group of firms. Another criterion is that the human exposure to a chemical be such as to indicate that toxicity would be a significant public health concern.

Lacking precise numbers, the extent of human exposure to chemicals can only be estimated -- the number of chemicals, the intensity of exposures, and the number of people exposed being major compo-

nents. Current estimates indicate that nearly 48,000 chemicals are used in commerce in the United States; for approximately 5,000 of these, production exceeds 1 million pounds/year, suggesting the possibility or potential for widespread and intense exposure. There are 5,500 food additives and 4,000 medicinal drugs. Further, humans are exposed to at least 1,200 additional compounds found in household products.

The universe of chemicals to which humans are exposed is therefore so large that the task of preventing human exposure to toxic chemicals might appear impossible. Fortunately, most chemicals are relatively nontoxic and require few if any controls to protect human health. It appears that only a small fraction of these chemicals are highly toxic. Thus, to protect the public health and to prevent disease, this fraction should be accurately identified and rigidly controlled.

The standard tool to do this is the two-sex, two-species lifetime study of experimental animals, usually rats and mice -- beginning at weaning, ending at death -- using multiple dose levels of the chemical being tested. Such a study can provide worthwhile information on the kinds of toxic effects caused by the chemical and the doses or concentrations causing these toxic effects. This standard test determines if a chemical causes cancer and produces damaging effects on certain organ systems -- liver, lung, kidney, endocrine systems, etc. This test is weak at predicting effects on reproductive capacity, pre- and postnatal growth and development, and certain neuro-behavioral functions, and at identifying chemicals that damage genetic information transfer -- mutagens. Further, the study of even a single compound is expensive, costing hundreds of thousands of dollars, taking up to 4 years to complete, and requiring hundreds of hours of scarce professional time.

It is unreasonable even to attempt to study all 48,000 chemicals in this way. Current known world capacity permits the initiation of perhaps 300 such chemical tests each year, and the results published this year are from the tests begun 4 or more years ago. This capacity -- even if financial resources were not limiting -- could be no more than doubled in the next 5-10 years. At this rate, it would take an additional 80 years to study all currently existing chemicals. Further, approximately 500 chemicals are introduced into commerce each year, and this would result in an additional backlog of some 40,000 untested chemicals. Implementation of the Toxic Substances Control Act will impact on the overall issue of testing, yet the final result remains the same -- in the next 80 years the chemical testing backlog would be decreased only moderately.

Therefore, the National Toxicology Program must develop and validate new test methods that will allow us to determine more quickly and less expensively the full toxicologic potential of a compound. To do this, NTP must use advances in basic knowledge of biological processes to design these new methods. NTP is in a unique position to do this because, through its Executive Committee, NTP joins the basic research of the Department to the more immediate needs of the regulatory agencies. The task is difficult, but it is of the highest importance and should result in major improvement in public health.

Question: How many chemicals have been identified and which ones pose the greatest risk to public health?

Answer: The NTP has completed tests through October 1980 on 252 chemicals for carcinogenicity and 206 chemicals for mutagenicity. For teratology, over the FY 1979 and FY 1980 period, 21 tests have been completed. Of the 252 chemicals tested for carcinogenicity, 105 were carcinogenic, 92 not carcinogenic, and 55 were equivocal. Of the 206 chemicals tested for mutagenicity, 46 were mutagenic, 150 not mutagenic, and 10 were equivocal. Of the 21 chemicals tested for teratogenesis, 6 were teratogenic, and 15 were non-teratogenic.

Question: How is NIEHS' intramural program proceeding in this regard?

Answer: The NIEHS/NTP staff have responsibilities for toxicological testing, test development and validation, as well as other program activities such as chemical selection. NIEHS staff collaborate very closely with staff of the NCI Bioassay Program and participate in the design, monitoring, and review of broadened bioassays in that system. The NIEHS manages the Environmental Mutagenesis Test Development Program whose results are cited above. The Director of NIEHS has responsibility for overall coordination and management of the NTP. Basic research at NIEHS contributes to improved understanding of biologic mechanisms and the properties of environmental agents. These data are directly applicable to NTP test development

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

Question: The National Center for Health Care Technology has been in existence for two years. It was established to conduct and coordinate health care technology assessment activities, among other missions. Could you bring us up to date on the activities of the Center over the past year?

Answer: The Center has worked in conjunction with the NIH on several consensus development conferences, specifically "Endoscopy and Its Role in Upper GI Bleeding," "Childbirth by Cesarean Delivery," and "Coronary Artery By-Pass Surgery." The Center has asked that the NIH review specific medical practices and procedures for scientific evaluation, as well as the review of several position papers. Furthermore, the NIH submits annually to the Director, NCHCT, a list of technologies to be considered as candidates for technology assessment.

Question: Which specific activities and agencies within the Department does the Center coordinate?

Answer: The specific activities undertaken by the Center in conjunction with NIH are listed above. In addition, NCHCT interacts with all the Public Health Service agencies, as well as the Health Care Financing Administration and the Assistant Secretary for Health and Surgeon General.

Qustion: Is the Center living up to expectations?

Answer: In terms of its interaction with the National Institutes of Health, the Center is living up to all its expectations.

RECOMBINANT DNA

Question: One company specializing in recombinant DNA research and development made its stock available to the public in October, raising speculation that advances in this field are accelerating and that practical applications of this technology may be close at hand. How fast has recombinant DNA technology research moved over the last year?

Answer: Recombinant DNA research has moved very rapidly over the past year. Important research advances at universities and medical schools have been funded by the NIH, including basic research on gene structure and applied research such as vaccine development.

Question: How close are we to the practical applications of this research, such as in the production of interferon and insulin?

Answer: Important advances have been made by U.S. industry using recombinant DNA techniques, including the production in bacteria of human insulin, human growth hormone, and human interferon, all of which are now being tested in human subjects.

DISSEMINATION OF RESEARCH RESULTS

Question: NIH recently established a program which is designed to improve lines of communication from the health research community to health care providers and the public. The program is known as Consensus Development and is administered by the Offices for Medical Applications of Research. How has the NIH information dissemination program worked during the past year?

Answer: The information derived from NIH consensus development conferences is widely disseminated within 2 weeks following each meeting. This information is supplied by the Offices of Information within the individual Institutes, as well as by the Office for Medical Applications of Research in the Office of Director, and reaches the scientific community and the general public through four primary media: highly recognized medical speciality and subspecialty journals; state medical societies and their journals; popular magazines and journals; and major newspapers and press services throughout the United States.

Question: How can the program be improved in order to better keep the public up to date on the latest medical technologies and innovations?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

FUNDING FOR APPROVED GRANTS

Question: You stated last year that 5,000 new and competing research grants, or about one-third of grant applications approved in FY 1981, would be funded. What evidence can you supply to show that the peer review system is working well?

Answer: The peer review system at the NIH has been examined over the years in no less than 16 different reports by various committees -- mostly non-NIH, chartered by the Congress, the professions, or the Executive Branch. All these studies found the system basically sound and unquestionably deserving continuation. The latest review (May 1980) was by the National Commission on Research, a group constituted by the American Council on Education, the American Council of Learned Societies, the Association of American Universities, the National Academy of Sciences, the National Association of State Universities and Land Grant Colleges, and the Social Science Research Council. This group had no significant criticisms to offer against NIH peer review, but rather cited a number of NIH procedures as examples for improvements in other agencies.

As other advanced nations have attempted to develop scientific capabilities emulating those of this country, most have adopted some form of peer review as the keystone for the selection of science to be supported.

During the approximately 35 years that the system has been operated by the NIH, there has occurred the most explosive advance in the biomedical sciences that the world has ever seen. The United States has far outstripped all other nations in the development of new modalities for the prevention, diagnosis and treatment of diseases, and in the development of new technologies for the useful application of biomedical knowledge. This success is clearly demonstrated by the dominance of this country in the production of work deemed worthy of Nobel Prizes and similar prestigious awards at both the national and international levels. A very large proportion of this brilliant work has been supported by the NIH and has resulted from proposals evaluated and recommended for funding by the peer review process. This is the most eloquent demonstration conceivable of the effectiveness of the process.

FUNDING REQUEST

Question: Over the past five years, how far has the NIH budget lapsed due to inflation?

Answer: Over the period in question, the NIH budget has increased by $27,552,000 in 1977 constant dollars:

	NIH Appropriation	
Fiscal Year	Current Dollars	Constant 1977 Dollars
1977	$2,544,078,000	$2,544,078,000
1978	2,842,936,000	2,645,822,000
1979	3,189,976,000	2,742,885,000
1980	3,428,935,000	2,701,864,000
1981 Carter Budget	3,593,596,000	2,571,630,000

IMPACT OF INFLATION

Question: It's been suggested that inflation may have reached the point where the Government should consider setting an upper limit on the share of a health research project it is willing to fund. What is your comment on this?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HAZARDS OF RESEARCH TRAINING

Question: Would you comment on the quote by Dr. Marianne Legato of Columbia University College of Physicians and Surgeons regarding the financial hazards of research training?: "The realities of research training make it a financially hazardous career choice for the younger doctor . . . In today's climate, the academic physician is a harried investigator who spends a substantial portion of his productive research life trying to extract enough funds from a decreasing pot to keep himself and his laboratory intact..." (Legato, M., Medicines' Threatened. New York Times. Sept. 30, 1980. A-2)

Answer: Dr. Legato's comments appear to capture accurately the attitudes of many present and potential investigators, particularly clinicians. There is no doubt that increasing competition for Federal research funds -- as evidenced by declining award rates -- puts pressure on both the new and established investigator to devote substantial amounts of time and energy to obtaining future support. M.D.'s in particular are likely to be less attracted to research careers in view of other options offering significant professional satisfaction and financial rewards.

Defining the "realities of research training" that make it a financially hazardous career choice for the young doctor as far as income is concerned, one can compare the stipend of the research fellow with the salary of the clinical resident.

Years of Prior Experience	Research Fellow	Clinical Resident
0	$13,380	$16,017
1	14,040	17,141
2	14,736	18,135
3	15,468	19,109
4	16,236	20,058
5	17,040	21,052

Once the young physician's 2- to 3-year investment in research training has been made, there is no guarantee that funds will be available to support his research. Furthermore, it has been shown that the academic physician investigator's income lags by an average of $17,500 per year for the first 10 years of paid faculty employment, and the gap continues to widen thereafter.

Question: Is the Federal funding process and its paperwork discouraging creative research in our universities and private-sector medical institutions?

Answer: NIH recognizes that the application process has become increasingly burdensome in recent years, primarily as a result of the increasing competition for funds. We believe, however, that some relief will be provided by the shorter grant application form now in use. Recent changes in the regulations governing research on human subjects are expected to simplify the process for applicant investigators and institutional review boards as well.

There is little evidence, in our view, that the creative element of science has been stifled by procedural requirements or competition for funds. It is difficult to substantiate charges that innovative ideas fare poorly in the review process. On the other hand, it is comparatively easy to find instances of review groups' willingness to endorse an admittedly risky or unconventional approach, provided the project is well conceived.

Question: Is this developing trend getting out of hand?

Answer: NIH is actively seeking additional ways to relieve the "nonfiscal constraints" on investigators. Discussions have already been held with advisory bodies, and the next step is to solicit a critique from the scientific community on several possible changes in grants policies and procedures. While the specific approach to obtaining this critique has not yet been selected, it probably will include a broadly based and open-minded invitation for comment on the NIH-generated list of possible administrative actions.

Question: What can Congress do to help put a stop to this trend?

Answer: The capacity of either the Congress or the Executive Branch to deal with the situation described by Dr. Legato is limited severely by the nature of the problem. We must continue to stress the importance of clinical investigation and the many research needs and opportunities that are available to prepared minds. We also must continue to make research support as nearly stable as possible from year to year so as to avoid adding further disincentives to the many that already exist. Nevertheless, the intellectual satisfaction and sense of social purpose that accompany a research career will remain the primary magnets attracting clinicians to such endeavors, and the Government can do little more than attempt to facilitate the process for the relatively small numbers of individuals who choose this career over the other alternatives open to them.

CLINICAL INVESTIGATORS

Question: Last year, we noted that a critical problem existed with regard to the supply of clinical investigators in the United States. Could mechanisms be introduced into this year's training budget to help receify any shortage? At what cost?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

CONTRACT MONITORING

Question: We understand several of your Institutes have not followed contract monitoring methods prescribed in HHS and NIH guidelines, particularly in assuring that contractors submit required progress reports and in making site visits to contract facilities. Please identify the Institutes where these problems exist.

Answer: The Inspector General's office in the Department has reported finding weaknesses in certain contract monitoring procedures in the National Cancer Institute. NIH is unaware, however, of any similar reports of deficiencies in contract monitoring in other NIH Institutes.

Question: Why have they been permitted to occur?

Answer: While recognizing the potential adverse consequences of significant deficiencies in contract monitoring, NCI and NIH have disputed many of the weaknesses reported by the Inspector General's office. In some instances, the reviewers failed to note pertinent documents or other aspects of contract files. In other cases, while direct documentation of progress reports or site visits was lacking, other sources of information provided evidence for the accomplishment of those facets of contract monitoring. Any actual weaknesses were rare at most, and clearly not the customary pattern of contract administration. To the small extent that deficiencies occurred, they derived primarily from the fact that the NCI and NIH were placing their primary emphasis on the critical steps in contract initiation; i.e., contract planning, solicitation, evaluation, and negotiation and award. Various advisory reports in the 1970's strongly suggested these as primary targets for improving NIH contracting processes. While additional steps have been taken toward improving overall NIH contract administration, staffing patterns have not always kept up with developing workloads, leading to potential for missed assignments. That these have not occurred with any frequency suggests that contracting and project officers have kept pace for the most part with developing regulations, policies, and procedures.

Question: What steps are you taking to improve contract administration procedures?

Answer: NCI and NIH have taken a number of steps toward improving contract administration procedures. For example, NCI has

- conducted training sessions with contract specialists to discuss directions for stronger contract administration;

- established in the Office of the Chief of the NCI Research Contracts Branch a Contract Administration Review Team to audit contract administration performance of all units in the Research Contract Branch;

- published contract manuals, including the Guide to the Principal Investigator of NCI Contracts, which is issued to principal investigators after contract awards to explain contract functions and processes and the responsibilities of principal investigators, and the NCI Manual for Contract Administra-

tion, which is designed to help project and contracting officers perform contract monitoring responsibilities; and

- centralized the Research Contracts Branch staff in one location, aiming to foster more effective contract administration.

NIH has:

- brought to the attention of senior contracting and program officials, at their periodic meetings, some of the issues raised by the Inspector General's studies of NCI contracting, aiming toward improved sensitivity to contract administration issues by all Institutes;

- required all project officers to take the basic or advanced Project Officers Courses developed by the Department to make project officers more aware of their responsibilities and obligations in contracting, including contract monitoring; and

- initiated a revision of the NIH Project Officers Guide, which includes a section on Post-Award Administration of Contracts and a subsection on Monitoring, with intentions to initiate closer surveillance of the implementation of these procedures.

MUSCULOSEKELETAL DISORDERS

Question: What mechanisms do you employ to coordinate and encourage research activities in the musculoskeletal area among your Institutes?

Answer: The Musculoskeletal Diseases Program of NIAMDD is the major program at the NIH involved in the support of research directed toward an understanding of the structure and function of the musculoskeletal system in normal and diseased states.

The program has taken a lead role in organizing an Interagency Orthopedic Biomechanisms Group in order to provide a forum to understand better the operation and research support of all the agencies involved in the area of musculoskeletal diseases.

Excellent interagency cooperation exists in the sponsorship of a number of conferences and workshops in areas of common interest. These have recently included: Gordon Conference on Bones and Teeth, International Conference on Biomaterials, Hereditary Disorders of Connective Tissue, Gordon Conference on Bio-engineering in Orthopedic Science, Osteoporosis: Recent Advances in Pathogenesis and Treatment, Third International Workshop on Bone Histomorphometry, and Conference on Pathogenesis of Back Disorders.

The Musculoskeletal Disease Program Director, NIAMDD, has established good working relationships with the appropriate representatives of other Institutes (notably the Dental, Aging, General Medical Sciences, and Child Health and Human Development Insti-

tutes) in the exchange and referral of individual research project applications of mutual interest.

Question: One of the major musculoskeletal problems is hip fractures in the elderly -- especially women. What work is NIH doing in this area and what are you doing to interest more investigators to undertake work on this and other musculoskeletal problems?

Answer: NIAMDD supports major research on osteoporosis, a disease of reduced bone mass affecting primarily old individuals (especially women) in which there is an increased susceptibility to bone fracture. To explore the causes of this disease, an NIAMDD grantee at Creighton University, Nebraska, is undertaking a 20-year longitudinal study of calcium and bone metabolism. Investigators are studying the general physical status, dietary history, and hormonal profiles of subjects in an attempt to provide a clearer picture of the natural history of postmenopausal osteoporosis. Similar studies are being supported at other institutions.

Grantees are also studying the effectiveness of various therapeutic agents in the prevention and/or therapy of osteoporosis. These include estrogen/androgen administration, calcium supplementation, and administration of calcitonin, vitamin D and its metabolites, or fluoride. The Musculoskeletal Disease Program has recently released a Request for Applications to support new clinical trials on the efficacy and safety of fluoride for the treatment of osteoporosis. Ten applications have been received for this study and are currently undergoing review.

The Institute is now supporting two grants on the epidemiology of hip fractures and osteoporosis.

Overall, research on osteoporosis and bone mineralization comprises more than one-fourth the total support for all research projects in the Musculoskeletal Diseases Program.

There are also research projects on artificial hip replacements, and a consensus development conference on this important subject is scheduled for early 1982.

In order to stimulate the interdisciplinary attack on osteoporosis and facilitate the identification of areas of research needs, the NIH provided support for a conference entitled, "Osteoporosis: Recent Advances in Pathogenesis and Treatment." This conference was held in June 1980 and was co-sponsored by the National Institute of Arthritis, Metabolism, and Digestive Diseases, the National Institute of Dental Research, the National Institute on Aging, the Fogarty International Center for Advanced Study in the Health Sciences, and the Veterans Administration.

Question: Do you have any data on how much musculoskeletal disorders cost the Medicare and Medicaid programs each year?

Answer: In 1972, the latest year for which exact figures are available, total direct expenditures for musculoskeletal disorders were $5.68 billion, of which $2.915 billion were for hospital care. Interim figures from the Health Care Financing Administration for hospital care of Medicare beneficiaries for musculoskeletal dis-

orders were $481 million for calendar year 1977. Medicaid figures are currently not available.

Question: How much do you propose to spend on research of musculoskeletal disorders in 1981?

Answer: We anticipate expenditures of $17.019 million in FY 1981 on the support of research in this area.

BIOMEDICAL RESEARCH SUPPORT GRANTS

Question: In a recent letter to PHS, the General Accounting Office said that the objectives of the Biomedical Research Support Grant Program, as currently established, "appear too general to permit NIH to effectively measure the extent to which they are being met." The GAO recommended that measurable program objectives be established. Have you developed measurable program objectives in response to the GAO criticism, and if so, what are they?

Answer: As yet, we have not developed what the GAO could call "measurable objectives." However, we have advised the GAO that we intend to continue our efforts to restate the objectives of the Biomedical Research Support Grant Program as more measurable objectives by June 30, 1981. Included in this time frame are meetings of the General Research Support Review Committee and the National Advisory Research Resources Council, both of which will consider this problem and provide staff with advice on restating these objectives. Then, by September 30, 1981, we will have either (1) arrived at a strategy by which to conduct the evaluation against the newly stated objectives, or (2) with the assistance of our advisors and NIH evaluation staff, arrived at the conclusion that existing evaluation methodologies cannot be used to evaluate this program at this time.

Question: If measurable objectives have not been developed, what is the reason for the delay and when can we expect them to be developed?

Answer: As noted above, we intend to have restated the objectives of the Biomedical Research Support Grant Program in as measurable terms as possible by June 30 of this year; however, it is important to note that, during the 19 years of the program's existence, specific measurable and time-bound objectives have not been present. In keeping with the basic intent to help institutional programs to be adaptable, flexible, and able to have the ability of responding to a wide variety of requirements and demands in the biomedical research community which occur with the passage of time, studies by the National Research Council of the National Academy of Sciences in 1965, by two non-Federal consultants in 1969, and by the Research Resources Evaluation Panel in 1976 have all concluded that this program is exceptionally important to research institutions in this country, specifically because of its flexible nature and broad objectives. In summary, there is significant disagreement among knowledgable staff and advisors about whether the development of specific and measurable program objectives can enhance the Biomedical Research Support Program.

EFFECTIVENESS OF TRAINING AWARDS

Question: What evidence is there that the NIH awards for training have actually increased the number of individuals entering the biomedical research field compared to the number that would have entered anyway in the absence of the program?

Answer: There is no hard evidence of the extent to which research training awards have actually increased the number of individuals entering the biomedical research field compared to the number that would have entered in the absence of the program. We do know that by 1968, 50 percent of principal investigators receiving their first NIH research grants had received NIH research training support. From 1973 to 1977 (the last year for which these data are available), this number had increased to 59 percent.

APPROPRIATION CONSOLIDATION

Question: What are the advantages and disadvantages of consolidating all of the NIH appropriations into a single appropriations account?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

EFFECT OF BIOMEDICAL RESEARCH

Question: Despite the vast sums we have spent on biomedical research over the years, the United States still ranks well down the list in life expectancy, infant mortality rates, and other health indicators compared to other countries. If we are number one in spending for research, why aren't we number one in health?

Answer: Several Western European countries and Japan report better life expectancy and infant mortality rates than the United States. All the countries that exceed the United States in these statistics are small and are racially and ethnically homogeneous; most have some form of universal health insurance making medical care available to all regardless of socioeconomic status. In none of these features is the United States comparable. The vast complexity of this country in terms of race, ethnic groups, social and economic status, education, urbanization, and sheer size and geography produces problems that cannot be addressed, much less overcome, by biomedical research. The morbidity and mortality statistics of the United States compared with other highly complex societies is very favorable.

Consideration must also be given to the role of life style in morbidity and mortality statistics. Despite known relationships between smoking and health, and between dietary excesses and health, Americans persist in self-indulgence that is later reflected in poorer health statistics. To these factors can be added failures of individuals to follow therapeutic advice, thus subverting the benefits of scientific achievement that are offered to them.

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It should be noted that infant mortality in the United States is declining at a very fast pace. Between 1965 and 1979, infant mortality declined by 47 percent. Although the decline in infant mortality has been observed in all states, there are wide variations in magnitude from state to state that illustrate the complexity of our society.

Question: What specific evidence do you have that would estimate the contribution of biomedical research to the general decline in mortality and morbidity rates in this country?

Answer: The reduction of morbidity and mortality rates is, of necessity, a long-term goal of biomedical research. The now famous TRACES study demonstrated that innovation and development are often based in part on scientific discoveries that were made more than 30 years previously. Furthermore, at least 80 to 90 percent of many fundamental scientific discoveries that underlie any specific medical advance are made prior to and without insight into the conceptualization of a specific medical application. TRACES and other studies have shown that the average period from conceptualization to innovation is 9 to 10 years. It is further estimated that the lag between science activity and the achievement of a change in health status takes another 10 years. In these terms, the history of Federal biomedical research support is hardly long enough to warrant definitive investigation.

It must be emphasized that medical progress is a sequential, multifaceted process with not one but many contributions to medical knowledge and the new therapies usually involved in long-term reductions in morbidity and mortality. Measles death rates provide a good illustration of this. The National Center for Health Statistics in the Prescription Drug Industry Factbook, '76, presents a chronological sequence of the introduction of such drugs as penicillin and streptomycin superimposed on a measles death rate curve. These and other advances had already been associated with sharp reductions in measles death rates several years before the introduction of measles vaccine. The introduction of the vaccine is then associated with reduction to a near zero death rate by 1975, and a reduction in the sickness rate due to the disease from 204 per 100,000 in 1963 to 23 per 100,000 by 1970.

Two recent NIH evaluation studies have pioneered in investigating the role and the costs of biomedical research in relation to morbidity, mortality, and the costs of illness. In the "Study on Surgical Services for the United States," calculations were made of the number of lives that were saved in a single year as a result of 15 advances in surgical research. The number of lives saved in 1970 to which surgical advances had contributed was calculated to be 78,538. Major contributions to this figure included hemodialysis and kidney transplantation which contributed to saving 31,911 lives; vascular surgery to saving 22,972; and cardiac surgery to saving 16,615. The reduction of direct and indirect costs attributable to these 15 advances was calculated to be $2.8 billion. These gains were assessed against research costs of only $47 million, a benefit-to-cost ratio of 60 to 1.

Dr. Selma Mushkin and her colleagues at the Georgetown Public Services Laboratory undertook an intensive study of the entire

complex problem of assessing economic relationships between research and a broad spectrum of measures of morbidity, mortality, economic and social costs of illness. The Mushkin study covered 75 years from 1900 to 1975. Its finding overall of 20- to 40-percent mortality reduction attributable to research is most conservative. Reduction in objective sickness rate is estimated at 39 percent. The dollar savings from reduced morbidity and mortality rates compared to investments in biomedical research were estimated to be $227 to $407 billion since 1900, or a 10-16:1 ratio of benefits to health research and development costs.

TRAVEL COSTS

Question: What policies does the NIH follow in controlling the travel expenses by the recipients of research grants and contracts?

Answer: For grants, proposed travel is first assessed as part of the peer review process and is recommended for approval as requested, is deleted, or is adjusted. In the post-award setting, an increase in the authorized domestic travel level by way of rebudgeting is subject to local review by the Institutional Prior Approval System. Any proposed foreign travel requires prior approval for the NIH awarding unit.

NIH Manual Issuance 6000-3-15.309-44 states the NIH policy on "Travel of R&D Contractor Personnel." This policy requires that all domestic and foreign travel proposed by contractors must receive the prior review and approval of the NIH. Specific amounts for each category are set forth in the contract and require the Government's approval for expenditures in excess of the specified amounts. (Note: OMB Circular A-21 allows educational institutions to exceed the amount allotted in the contract for domestic travel by "25% or $500 whichever is greater.")

Question: Provide a table for the record showing travel costs incurred by the recipients of research grants and contracts in 1978, 1979 and 1980 and the estimates for 1981 broken down by Institute.

Answer: As a result of OMB directives, NIH is no longer able to obtain detailed categorical expenditure reports from grantees, so we cannot provide any data regarding actual expenditures for travel. The table on the following page reflects authorizations for grantee travel as approved and reflected on award notices.

Annual travel authorizations under NIH grants are relatively constant, and we anticipate that this would continue for FY 1981 at a level of approximately 1.6 percent of total budgeted direct costs.

Travel costs incurred by NIH research contractors are reported on each monthly voucher and quarterly financial report. These vouchers and reports are reviewed by NIH financial, program, and contracting personnel for adherence to approved levels specified in the contract. It would not be possible to provide a table showing total incurred and proposed travel costs in each year by

National Institutes of Health

AMOUNTS BUDGETED FOR TRAVEL (DOMESTIC & FOREIGN) AS A PERCENT
OF TOTAL BUDGETED COSTS FOR RESEARCH GRANTS

BID	FY 1978 Travel	FY 1978 Total Direct Costs Budgeted	FY 1978 Percent	FY 1979 Travel	FY 1979 Total Direct Costs Budgeted	FY 1979 Percent	FY 1980 Travel	FY 1980 Total Direct Costs Budgeted	FY 1980 Percent
Cancer	$5,428,729	$278,881,000	2.0	$6,258,132	$ 321,802,000	1.9	$6,749,576	$ 356,135,000	1.9
Heart	2,797,024	200,154,000	1.4	3,513,406	233,768,000	1.4	3,445,830	244,899,000	1.4
Dental	474,036	24,599,000	1.9	561,491	26,950,000	2.1	453,854	27,224,000	1.7
Arthritis ...	2,088,156	131,433,000	1.6	2,694,158	157,801,000	1.7	3,096,916	175,877,000	1.8
Neurology ...	1,379,591	77,377,000	1.8	1,565,626	96,545,000	1.6	2,100,716	118,025,000	1.8
Allergy	1,066,591	66,946,000	1.6	1,549,064	25,557,000	1.8	1,762,810	97,584,000	1.8
General Medical ..	2,044,802	122,367,000	1.7	2,465,629	154,201,000	1.6	3,011,370	179,909,000	1.7
Child Health	1,228,316	76,339,000	1.6	1,409,612	95,568,000	1.5	1,479,172	98,241,000	1.5
Eye	708,620	45,350,000	1.6	909,163	57,727,000	1.6	924,941	59,782,000	1.6
Environmental Health ...	489,447	23,505,000	2.1	532,197	28,328,000	1.9	515,964	28,129,000	1.8
Aging	295,745	15,613,000	1.9	565,148	25,769,000	2.2	653,620	28,855,000	2.3
Research Resources ..	673,930	13,615,000	0.9	879,757	91,954,000	1.0	863,788	102,808,000	0.8
Library of Medicine ...	64,850	1,664,000	3.9	72,113	2,529,000	2.9	91,811	3,323,000	2.8
TOTAL NIH ..	$18,739,837	$1,077,843,000	1.6	$22,975,496	$1,318,499,000	1.6	$25,150,368	$1,520,791,000	1.7

Institute without reviewing the thousands of individual contracts involved.

OVERHEAD COSTS

Question: What policies does the NIH follow in paying overhead expenses at universities and other research institutions?

Answer: For the most part, NIH pays full overhead under its sponsored programs; exceptions include National Research Service Awards and research career awards, each of which limits recovery to 8 percent of total allowable direct costs, and Biomedical Research Support Grants, foreign grants, and conference grants for which no indirect costs are provided. Indirect costs are provided in accordance with negotiated rates submitted by the recipient institution to the Office of the Regional Comptroller in the region in which the institution is located. Rates are then published for use by all Departmental agencies in order to provide appropriate reimbursement.

Question: Are there any differences on overhead policies among the Institutes, and if so, what are those differences?

Answer: There are no differences on overhead policies among the Institutes.

Question: Provide a table for the record showing overhead costs in 1978, 1979 and 1980 and the estimates for 1981 broken down by Institute.

Answer: Overhead costs for fiscal year 1978-80 are shown below. We estimate that costs for fiscal year 1981 will rise, as has been the trend in recent years.

Research Grants
Percentage of Indirect Cost to Total Dollars Awarded

BID	FY 1978	FY 1979	FY 1980
Cancer	28.1	29.0	29.1
Heart	27.1	27.8	28.6
Dental	28.3	29.5	31.1
Arthritis	28.2	28.5	29.1
Neurology	28.8	28.5	28.9
Allergy	28.2	28.4	30.0
General Medical	28.7	28.1	29.9
Child Health	28.4	28.6	29.6
Eye	28.5	29.3	30.5
Environmental Health	28.6	29.7	30.2
Aging	29.1	29.3	30.1
Research Resources	11.8	14.7	15.5
Library of Medicine	27.3	28.0	29.6
Average Percentage	27.2	27.8	28.6

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

MAINTAINING NEW RESEARCH GRANTS

Question: The fiscal 1982 budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund less than 5,000 grants and put greater emphasis on research contracts or intramural research?

Answer: For the 1982 budget submitted by President Reagan, we estimate funding 4,900 competing research project grants. As shown in the following table, the quality of research proposals has been remarkably stable:

Research Project Grant Applications

Priority Score	1977	1978	1979	1980	1981 Estimate	1982 Estimate
150 or better	1,104	1,284	1,199	1,149	1,431	1,546
200 or better	3,610	4,348	4,087	4,049	5,378	5,804
250 or better	5,870	7,041	6,608	6,222	7,871	8,481
300 or better	7,784	8,926	8,647	8,149	9,951	10,764
Total applications at all scores	9,940	11,489	11,510	11,301	14,042	15,315

Because of this sustained quality, and since we are able to fund only the top one-third of the approved applications, the NIH does not anticipate any problems. However, if any marked decline in the quality of applications were to occur, we would first want to ascertain why the decline had occurred and would then want to consider appropriate corrective action. We would also explore various alternative mechanisms of support, with the aim of selecting those evidencing the greatest likelihood of achieving program objectives. It is possible that the most advantageous approach would be a combination of support mechanisms, such as research and development contracts, research centers, or intramural research. Considerable study would be required to assure that the most promising avenues were chosen.

Question: To what "payline" will you fund new and competing grants in fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: The estimated paylines and award rates for fiscal years 1981 and 1982 are shown in the table on the following page. Also included are the 1980 actuals.

National Institutes of Health

Competing Research Project Grants
Paylines and Award Rates

Institute	1980 Actual			1981 Estimate*			1982 Estimate*		
	Number	Payline	Award Rate	Number	Payline	Award Rate	Number	Payline	Award Rate
Cancer	773	218	39%	726	190	31%	766	190	29%
Heart	589	206	34%	644	180	29%	739	190	31%
Dental	97	230	38%	144	200	36%	119	200	35%
Arthritis	698	221	43%	783	200	39%	655	180	27%
Neurology	503	232	53%	471	200	37%	472	200	29%
Allergy	452	204	38%	430	180	31%	414	170	25%
General Medical	890	219	58%	711	190	40%	835	190	42%
Child	348	200	36%	368	190	31%	378	190	31%
Eye	217	232	52%	296	220	53%	263	210	47%
Environmental Health	87	217	35%	107	260	46%	112	260	46%
Aging	131	227	32%	117	190	18%	146	200	21%
Total NIH	4,785		42%	4,797		34%	4,899		32%

* These are the estimates contained in the 1981 and 1982 budget requests submitted by President Reagan.

INDIRECT COSTS

Question: To what degree can NIH reduce its reliance on outside services without jeopardizing its research program?

Answer: We do not feel that it is feasible or desirable to change the current level of reliance on outside services. It is not possible to produce or furnish all services and materials "in house." Therefore, to sustain the current level of research effort, we must maintain the use of outside services.

Question: If it were decided by Congress to cut the NIH budget, where would you recommend that the cuts be made?

Answer: In making reductions from the budget submitted to you in January, we have attempted to develop a budget that maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities, and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

CONSENSUS DEVELOPMENT CONFERENCES

Question: The NIH Consensus Development Program was implemented in 1977. The process brings together biomedical research scientists, practicing physicians, consumers, and others in an effort to reach a general agreement as to whether a given medical technology is safe and effective. It provides a special kind of technology assessment as a preliminary step before technology transfer. How many consensus development conferences do you plan in fiscal 1982? At what cost?

Answer: We plan to hold 12 to 15 consensus development conferences in FY 1982, at a cost of about $60,000 to $65,000 per conference.

INFLATION RATE FOR BIOMEDICAL RESEARCH

Question: The biomedical research deflator factor was last revised in 1977 or 1978. At that time it was calculated that the rate of inflation for research activities was about 9.2 - 9.5%. What will it be for fiscal 1982?

Answer: The biomedical deflator is calculated only for actual years. Estimates for future years are based on the OMB-supplied Gross National Product Implicit Price Deflator. The OMB inflation rate is estimated to be 9.4 percent for FY 1982.

DISSEMINATION OF RESEARCH RESULTS

Question: NIH recently established a program which is designed to improve lines of communication from the health research community to health care providers and the public. The program is known as Consensus Development and is administered by the Office for Medical

Applications of Research. How can the program be improved in order to better keep the public up to date on the latest medical technologies and innovations?

Answer: The NIH Office for Medical Applications of Research is examining alternatives to the present information dissemination process to optimize the flow of health care information to the practicing physician and the public. Current practices that have proven successful will be expanded. Examples of such practices, as described in the answers to earlier questions, include the following: press conferences after each consensus development conference; transmittal of each Consensus Conference Statement to consumer representatives as well as those from the allied health professions, professional medical societies, practicing physicians, etc.; participation of media representatives in the conferences; dissemination of information stemming from the conferences to medical journals, popular magazines, and major newspapers and press services.

FUNDING REQUEST

Question: Where have you had to cut programs because of fiscal constraint and economic relatities?

Answer: The budget justifications recently submitted to the Congress have attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications show the levels of funding reductions by budget mechanism and major disease category.

IMPACT OF INFLATION

Question: It has been suggested that inflation may have reached the point where the Government should consider setting an upper limit on the share of a health research project it is willing to fund. What is your comment on this?

Answer: Concern has been expressed and discussions undertaken on this subject in various forums such as the NIH Directors' Advisory Committee. Discussions and examination of impact on the scientific enterprise would need to be extensively expanded to include the grantee recipient community as well as other Federal grantors.

CLINICAL INVESTIGATORS

Question: Last year, we noted that a critical problem existed with regard to the supply of clinical investigators in the United States. Could mechanisms be introduced into this year's training budget to help rectify any shortage? At what cost?

Answer: In response to the Subcommittee's request last year, we have prepared a report, Assuring the Supply of Clinical Investigators, which addresses this subject in detail. The report is being submitted to the Committee.

As mentioned in the report, the NIH does have in place, or under development, several programs that are specifically designed to encourage career development in clinical investigation. Included in this category are the following: the Short-Term Training Program for Students in Health Professional Schools, which has been in operation for about a year, is designed to offer a 3-month experience to students in order to expose them to the advantages of a research career; the Medical Scientist Training Program, considered one of the most effective means of developing and retaining clinical investigators, currently supports over 650 students who will earn the combined MD/PhD degree; the Clinical Associates Program, which has considerable expansion potential, provides both the training environment and research development support for physicians with clinical specialty qualifications; and the Program on Special Training for Clinical Investigation, now under development at the NIH, is being designed to provide research training for those already trained to deliver patient care.

Additional funds could be effectively utilized to expand existing programs and to initiate new programs.

APPROPRIATION CONSOLIDATION

Question: What are the advantages and disadvantages of consolidating all the NIH appropriations into a single appropriation account?

Answer: The primary advantages of a single appropriation account are the provision of increased flexibility to shift resources to new areas of exciting research advances, and the facilitation of administering the NIH budget and programs.

Among the disadvantages of consolidating all the NIH appropriations into a single account, the major concern centers on the loss of visibility now accorded each Institute. It is felt that operation within a single appropriation would tend to obscure the needs of the many and varied programs of the Institutes in favor of the more "popular" categorical diseases.

EFFECT OF BIOMEDICAL RESEARCH

Question: Despite the vast sums we have spent on biomedical research over the years, the United States still ranks well down the list in life expectancy, infant mortality rates, and other health indicators compared to other countries. Is there any way you can estimate the effect on the future health of our population of adding or subtracting a half a billion dollars to the NIH research budget?

Answer: As pointed out in response to an earlier question, those countries that exceed the United States in life expectancy, infant mortality rates, and other health indicators are considerably smaller and less complex than the United States. The morbidity

and mortality statistics of the United States do compare favorably with those of other highly complex societies.

With regard to increased/decreased investment in biomedical research, it should be emphasized that at least 80 to 90 percent of many fundamental scientific discoveries that underlie any specific medical advance are made prior to and without insight into the conceptualization of a specific medical application. Therefore, it is not possible to predict with any degree of accuracy what the effect of either increasing or decreasing the research budget would have on the future health of our population. What is clear, however, is that any budget reduction that markedly reduces the development of knowledge about life processes and the breakdown of these processes will undermine the foundation upon which improvements in prevention, diagnosis, treatment and rehabilitation will ultimately depend.

CONSULTANTS

Question: The Carter consultant budget for FY 82 for NIH increased by $1.6 million over FY 81 for non-evaluation activities. Why can't you cut back on evaluation studies for which you request $7.6 million?

Answer: Section 513 of P.L. 91-296, the Public Health Service Act (42 USC 2996), establishes a set-aside of up to 1% of funds appropriated to any program authorized by the PHS and other related acts for program evaluation. The funds are to be used at the discretion of the Secretary, HHS, for the evaluation of health programs. Up to one-half of the set-aside is made directly available to the individual agency to conduct studies. Each year at the direction of the Assistant Secretary for Planning and Evaluation, OS, and of the Assistant Secretary for Health, PHS, a program of studies is planned and conducted by the Bureaus, Institutes, and Divisions of the NIH as well as by the Office of the Director, NIH. The proposed evaluation studies are carefully reviewed at the NIH, PHS and Office of the Secretary levels to assure that the studies are needed and are well designed to meet the objectives.

Evaluation studies assist in program development and management decision making. Program evaluations involve examination of program structure, function, mechanisms, and output to determine how effectively the program mission is being accomplished and to what extent objectives are being realized through policies, procedures, and activities that have been established. Study of agency-wide mechanisms of support, special areas of emphasis, and the development of evaluation methods and data bases are also essential features of the evaluation program.

As the evaluation program is planned for FY 1982, we will assure that only the highest priority studies will be conducted. Those funds not utilized for evaluation studies will be used for the original program purposes.

NATIONAL CANCER INSTITUTE

STATEMENT OF VINCENT T. DEVITA, JR., DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

PHILIP D. AMORUSO, EXECUTIVE OFFICER, ADMINISTRATIVE MANAGEMENT

JOHN P. HARTINGER, BUDGET OFFICER

NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH

ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

RESEARCH HIGHLIGHTS

Senator SCHMITT. We will proceed now to the National Cancer Institute.

Our next witness is Dr. Vincent T. DeVita, Director of the Institute.

The Cancer Institute was established in 1937 and is the primary Federal agency charged with leading the Government's war on cancer.

Dr. DeVita, we welcome you.

In the interests of time, again, we ask that you briefly highlight your opening statement so that we may proceed with questions.

If you wish, you may introduce your associates who have not been previously introduced.

Dr. DEVITA. Thank you, Mr. Chairman.

On my immediate left is John Hartinger, NCI's Budget Officer.

Next to him is Mr. Philip Amoruso, NCI's Executive Officer.

Mr. Chairman, I am pleased to have the opportunity to present the program of the Cancer Institute.

In the interest of time, I will highlight a few points and devote the remaining time to any questions you want answered.

This is the 10th anniversary of the national cancer program, and it is probably worthwhile to strike some contrasts between the state of the art in 1970 and the state of the art in 1981.

I am pleased to say that in the four major areas where the Institute supports research—cause and prevention, detection and diagnosis, treatment, and basic cancer biology—there is a striking difference in the state of the art between 1970 and 1981.

SHIFTS IN RESEARCH PRIORITIES

The Institute made a major shift in its emphasis around 1975 and changed the amount of resources it devoted to cancer prevention. I'd like to just cite some of those figures for you.

The backbone of any prevention program is, again, epidemiology. We have increased our efforts in cancer epidemiology in the last 4 years by 100 percent; and in the study of the chemical causation of cancer, by about 45 percent; while diminishing our efforts in seeking a viral cause of cancer over the same time period by 2½ percent.

In contrast, the resources devoted to treatment research only went up about 25 percent in these 4 years.

So in the last 4 years, there has been a rather striking change in our priorities. There has been good reason for this. We think that if one defines the environment broadly, about 80 percent of all cancers, are related to things that happen in the environment. In 1971, we could only imagine how to prevent cancer. We did not have the information. The switch in the resources supplied by the cancer program has given us a real insight into some of the capabilities we have in preventing cancer.

We're quite excited about the prospects of being able to make some headway in this area in the coming years. This year we have a new initiative in the cancer prevention area within the new division established to deal with the applied side of cancer prevention.

We're in the process of creating a chemoprevention program, to take advantage of and supply some of the new information. For example, derivatives of vitamin A might be used to prevent cancer. Since to determine this will require a large scale, clinical trial, a chemoprevention program is necessary.

Senator SCHMITT. I understand that the vitamin A research has been under your personal supervision; is that correct?

Dr. DEVITA. Well, not directly, Mr. Chairman. But I have taken a personal interest in facilitating it. It's taken some very interesting turns in recent years.

We have some very impressive epidemiologic data that are consistent in one direction. That is, if one looks at a population of people who do not have cancer—16,000 in one recent study draws serum samples and saves those samples, sometime later we can look at people who develop cancer and compare them to matched controls. The data in all studies I know of point consistently in the direction of showing that those that have higher levels of retinol, vitamin A, in fact, have lower incidences of certain kinds of cancer. Many of these happen to be very common cancers, like lung cancer or colon cancer.

This data fits very well with the experimental data developed by the Institute some years ago. These studies looked at the derivatives of vitamin A as a way of preventing cancer in rodents after they've been exposed to a cancer-causing agent. So we're quite excited about the prospects of testing some of the derivatives of vitamin A in clinical trials. These types of trials are logistically very difficult problems to deal with. We have to use large groups of people and follow them over a long period of time, but the trials also provide an opportunity that we have now that we didn't have or didn't even know about during the early 1970's. There are others as well.

CANCER PROMOTERS

There is some suggestive information about colon cancer, which is a very common killer in this country. The incidence of colon cancer is quite different in the Northeastern United States and the Southern United States. It looks like people who migrate from the North to the South of the United States adopt the incidence of the Southern United States. That is a very important observation, for it implies that, over a relatively short period of time, one can change the frequency that one given population gets colon cancer.

This observation fits research data developed on the two-stage process of carcinogenesis, looking at two kinds of cancer-causing agents, initiators and promoters. We feel promoters can be removed from the environment and the incidence of cancer may fall fairly abruptly.

So although we don't have good tests for promoters, we know some of the things fall under the category of promoters. Cigarette smoke, for example, appears to behave much in the manner of a promoter, because we know the mortality of doctors in Britain who stopped smoking has dropped over the past decade from lung cancer.

There are quite a few opportunities we're now exploring while we search for the exact mechanisms of the causation of cancer. We actually know how some cancer-causing viruses may work, something we also didn't know in the early 1970's.

TREATMENT RESEARCH

I would like to mention one thing about treatment, Mr. Chairman—my background, after all, is in treatment research. The investment the Institute made in cancer drug development in the 1960's was widely applied in the 1970's. What we're now seeing as a result is a reduction in cancer mortality under the age of 50.

I brought some materials along with me I can show you, which are also at your desk. This is a reflection of the widespread application of these new chemotherapy tools. In the mid-1970's, we began to develop what we call adjuvant therapy studies and have applied chemotherapy to breast cancer and colorectal cancer in addition to surgery. In 1974, we reported to this committee that we had a positive result in breast cancer.

Now, we have data showing that in premenopausal women national mortality from breast cancer is falling. We also have data from studies in the past year showing a drop in rectal cancer mortality.

Although we are making strides, determining the impact of using these therapies together may take years. A study reported in 1974 needs 5 years of validation and another 5 years to apply the results, and 2 or 3 years to accrue the patient population. This takes about 10 to 15 years. It is difficult in the framework of one decade to see it all, but we're beginning to see it in a very pleasing way.

Dr. Fredrickson alluded to basic biology. Our basic biology program has been responsible, in part, for the revolution in the technology of research that we now have.

We are now able to study in 2 days what we never dreamed we could do at all in 1970.

In fact, the new techniques of DNA sequencing have revolutionized the study of DNA. In treatment and prevention, we can actually look very precisely at where drugs that have been used to treat or drugs that cause cancer actually hit their target.

We can also look precisely at where chemicals that cause cancer work. We can isolate genes of a tumor virus that cause transformation of the cell and the products that those genes produce. It is quite a different situation now than it was in 1970.

These are all challenges for us in the coming years, because they all give us an opportunity for further basic research and transfer to cancer patients in practical terms.

Mr. Chairman, I'd be happy to respond to questions.

[The statement follows:]

STATEMENT OF VINCENT T. DE VITA

I am honored to be here today to report our recent advances in cancer research.

Mr. Chairman, this year will mark the tenth anniversary of the National Cancer Act, and I am pleased to report to this committee that survival for cancer patients has increased. Data published last October by NCI show the five-year survival rate has improved during the 1970's for seven of the 10 major forms of cancer in white Americans and six of the 10 major forms in blacks. At the same time time we have seen the cancer mortality rate decrease for Americans under the age of 55, where cancer is the major cause of death from disease. This decrease reflects the remarkable gains in curing cancers that affect children and young adults. Mr. Chairman, the Institute's coordinated program of fundamental and applied research has played a large part in these encouraging trends.

Still, cancer remains a major killer entailing a tremendous financial and emotional burden. Our best estimates suggest that this year 420,000 people will die of cancer, and the disease will cost Americans approximately $30 billion.

Our program in cancer research has four main thrusts: (1) prevention, (2) detection and diagnosis, (3) treatment, and (4) basic biology. To illustrate how research results apply to common cancers, I will highlight gains made in each area for breast and colorectal cancers.

PREVENTION: In 1980 we completed our reorganization to strengthen the Institute's prevention programs. We increased those programs' funding priorities and organized a new division, built around our cancer centers and control programs, to emphasize research in applied prevention. We now appreciate that cancer causation is often a two-stage process: The first stage -- initiation -- may not result in cancer if the second stage -- promotion -- is interrupted. As we learn more about promotion, we are impressed with the opportunities to interrupt the process and prevent cancer. For example, we have seen a rapid decrease in the incidence of uterine cancer with decreased use of replacement estrogens (a promotor) by postmenopausal women.

Epidemiology studies based on the U.S. maps of cancer mortality we published five years ago have given us a number of clues to environmental factors implicated in cancer. We learned that death rates from colon, rectal and breast cancers are about 50 percent lower in counties in the south compared to those in the northeast and north-central United States. Despite the large number of northerners who retire to Florida, this area retains the low rates of the south, even among older people. Could this lower rate be associated with a change in diet? Consumption of more fiber, vitamin A- and C-rich foods? The water? This finding may be related to other studies that show carcinogens in stools of colon cancer patients are reduced by the use of vitamins E and C. We hope further research will define strategies for preventing cancers of the breast, colon and rectum.

We have new information on how to prevent malignant melanoma, the dread cancer of the common mole. NCI epidemiologists in collaboration with Universtiy of Pennsylvania pathologists have identified a certain type of inherited mole that is definitely a precursor of

malignant melanoma. In its advanced stages this form of skin cancer does not respond to existing treatments. But when treated surgically at the earliest stages, melanoma is curable. The same type of mole now has been linked to the development of over one-third of all melanomas. We are beginning to teach physicians and people with melanoma in their family (who have a 100-fold increased risk of getting the disease) to recognize this particular type of mole and to watch for any subtle changes. This finding has the most important implications for prevention efforts and gives us a tool for early detection of some melanomas equivalent in importance to the Pap smear for detection of cervical cancer.

A major new initiative in applied prevention will begin this year with the development of a program on chemoprevention, the interruption of the cancer causation process with drugs or other agents. This area has developed rapidly, and we are evaluating now the cis-retinoic acids and vitamin C in man.

DETECTION AND DIAGNOSIS: Clinicians are beginning to use tumor markers -- substances shed by cancer cells into the bloodstream -- for screening and early detection of cancer. These materials are already used to track and stage diagnosed patients, to monitor patient response to therapy, and to predict recurrence.

In reference to colon cancer, experts reached consensus this year that the tumor marker CEA is of great help in following colon cancer patients and may be the best method to detect early recurrence. Yet even when a tumor marker such as CEA signals that something is awry, it does not tell clinicians where the cancer is growing. The ability to produce pure antibodies, made possible by fusing cells called hybridoma technology, has extraordinary promise in localizing small amounts of tumor.

In reference to breast cancer, NCI scientists have been able to make monoclonal antibodies to several antigens found uniquely on the surface of human breast cancer cells. They are now able to label the antibody with a special stain that can then be applied to tissue taken from a patient's tumor or lymph node that will aid in determining if it is malignant or benign. They have also linked purified antibody to radioactive iodine and are now conducting studies to determine the value of these specific probes in scanning the body for metastatic sites of breast cancer.

TREATMENT: Our emphasis in treatment has been on the use of several different types of therapy together soon after diagnosis. We call this approach combined modality therapy. The Institute has a major responsibility for refining and developing new tools for combined modality therapy. These include second generation or less toxic anticancer drugs; biologics like interferon; and more sophisticated radiation therapy techniques, including drugs that sensitize cancer cells to and others that protect normal cells from radiation's effects.

The early success of combined modality therapy in increasing survival for women with breast cancer is even more impressive today. We now also have encouraging results from a study of cancer of the rectum. Patients who received radiation, chemotherapy or both in addition to surgery survived free of disease two to five times longer than patients who had only surgery. Colorectal cancer is second only to lung cancer in the number of new cases estimated for 1981.

Last year we established a new program to evaluate biological response modifiers -- agents that exploit the body's natural defense mechanisms. One of these agents is interferon. We have worked closely with the pharmaceutical industry to open up sources for all three types of interferon (leukocyte, lymphoblast and fibroblast) within the United States. Although interferon is still very expensive, the competition generated by our proposal lowered the cost considerably. Our clinical studies are in progress in 7 institutions. The ability to synthesize pure forms of interferon with recombinant DNA techniques may make the product even cheaper. NCI will begin tests this February in conjunction with Hoffman-La Roche, Inc. on one of these pure interferon preparations. Two new biological response modifiers we will evaluate this year are thymosin and MVE-2, a synthetic substance that stimulates the immune system.

BASIC BIOLOGY: A revolution has taken place over the past decade in the field of basic biology. The ability to clone animal DNA in bacteria using recombinant DNA technology and the capacity to sequence and read the genetic code of DNA have opened our eyes to a whole new way of looking at genes and the protein products of genes. We are intrigued by the sensitivity of these new techniques for exploring the subtle differences between normal and cancer cells. Once understood, these differences can be exploited for the prevention, diagnosis and treatment of cancer.

In 1971, the discovery of an enzyme, reverse transcriptase, focused the attention of scientists on a certain class of tumor virus that carries its genetic information in the form of RNA. Some very exciting findings have come from the study of these viruses. Perhaps most exciting is the recent discovery that they appear to be similar to elements called transposons. Transposons are nomadic genes. Due to a special structure, they are able to pop into and out of a cell's chromosome. In bacteria these structures appear to act as switches, turning on genes when they become inserted next to them. Scientists are now using recombinant DNA technology to decipher the genetic code of the RNA tumor viruses. This information may tell us how under certain circumstances these viruses switch on genes that cause cells to grow out of control.

Mr. Chairman, we consider it essential to find ways to preserve the flexibility that allows us to respond to new leads, such as some of those I have presented. Last year through an NCI management initiative we reviewed every contract, one by one. Reductions were made where possible, and savings were redirected to other programs. We will continue this process in the future, phasing out projects that have served their purpose and redirecting funds to promising new areas.

This concludes my statement. I shall be pleased to answer questions and supply additional information for the record.

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 University 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, National Institutes of Health, Bethesda, Maryland

1968-71: Head, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1971-74: Chief, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1974-80: 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- Director, National Cancer Institute, National Cancer Program, National Institutes of Health, Bethesda, Maryland

1981-85: Member, Awards Assembly, General Motors Cancer Research Foundation

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, 1977-81
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, 1979-

Associate Editor, The American Journal of Medicine, 1978-1981
Member, Editorial Advisory Board, Breast Cancer Research and Treatment, 1980-
Member, Editorial Board, Your Patient & Cancer, 1980-

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, 1975-79
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, Treatment 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), 1976-1979

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
Griffuel Prize, Association for the Development of Research on Cancer, Paris, December 1980

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GRIFFUEL PRIZE

Senator SCHMITT. I wonder if Dr. Fredrickson would tell us what the Griffuel prize is and why Dr. DeVita was selected for its presentation by, I believe, the Government of France or the Cancer Research Institute?

Dr. FREDRICKSON. I think it is actually both.

In France this is a distinguished prize. Dr. DeVita earned it, without question, by his important use of a combination of agents to cure people with advanced Hodgkin's disease. We are very proud of him.

Senator SCHMITT. Congratulations.

We're happy to see that.

Dr. DEVITA. Thank you very much.

LIFE EXPECTANCY

Senator SCHMITT. The testimony yesterday was interesting in many respects, dealing with the Centers for Disease Control, in that we once again were brought face to face with the fact that life expectancy, that we think about today as having risen so rapidly, is almost entirely the result of great reductions in infant mortality—that a person who is 50 years old today can expect to live only about 6 or 7 years longer than a person 50 years old at the turn of the century.

Does this in any way bother you, Doctor, that we've put all of this research into other aspects of biomedical activity other than infant mortality, and that we've only gained 6 years in 81 years?

Dr. DEVITA. No; someone has estimated that if we could eliminate cancer, our life expectancy would increase only by about 2½ years.

However, three things should be noted: The number of person-years of life saved from cancer would be something like 8 million person-years of life per year.

And since most people don't die of cancer, although it is a common cause of death the average person who gets cancer loses about 14 years of their life, a bit more for women. And for children, of course, where cancer is, next to accidents, the commonest cause of death, they lose most of their lives. Therefore, the social impact of preventing or curing cancer would be enormous. Quite a lot of years have been added and a lot less suffering occurs, not to mention the savings of the annual $30 billion cost of cancer in the United States alone.

Now, we can cure half of the children with the current techniques we have available. It makes a significant impact, not seen in the overall mortality picture.

It doesn't bother me, I guess, is the answer.

RESEARCH SAVINGS

Senator SCHMITT. Can you translate some of those numbers into costs saved within the medical economy?

Dr. DEVITA. Yes, we've done that. If we just look at the children alone, which is really a rather small group, there are 2,000 children whose lives are saved each year. If you would give them about a $10,000-a-year earning capacity for life each annual cured cohort brings about $0.7 billion a year into this Nation's economy. By curing them

and returning them to society as productive citizens, they are, in fact, making a significant contribution not only to the individual but to the Nation.

Senator SCHMITT. $0.7 million?

Dr. DEVITA. Billion.

Senator SCHMITT. Define that again.

The 2,000 aggregate?

Dr. DEVITA. Each year, about 2,000 children with cancer are cured. Curing, of course, means that a normal lifespan is attained. Although it is not an absolute certainty that their lifespan would be normal, after 15 years of followup it does appear to be so. If one assumes a $10,000-a-year income beginning at age 21 and ending at age 65, each annual cured cohort, they should contribute $0.7 billion in productivity to the Nation's economy.

There is another illustration of the same question. I mentioned before that premenopausal women who get breast cancer in this country now benefit from the use of postoperative chemotherapy if they're treated. We have calculated that if they don't get chemotherapy and recur, and they're treated when they have advanced disease that will ultimately kill them, it costs about $347 million for their care. If, however, they are treated and the disease does not recur, then the cost of the care for the same cadre of women on an annual basis is about $57 million. So there is quite a difference in preventing the more morbid states of cancer from taking over by treating the disease in its very early stages.

These tools work but I'll be the first to admit that the public is very cranky over their side effects. However, much effort is now going into refinement of these tools and developing biological programs using materials like interferon as treatment with fewer side effects.

MONOCLONAL ANTIBODIES

Senator SCHMITT. To what degree are monoclonal antibodies being looked at in cancer treatment?

Dr. DEVITA. Quite a lot. We've estimated we have about $67 million invested in immunology grants, and about half of our grantees are working with monoclonal antibodies in some way. This year we expect to start a trial of monoclonal antibodies as a diagnostic tool in breast cancer.

One of our investigators at the NIH has been able to isolate an antibody from the fused lymphocytes that are around the tumor in the lymph gland of the patient. He has developed a specific antibody that appears to react only with the breast cancer cells. This is probably the newest and best hope we have in diagnosis research, but it also has a potential in therapy.

Years ago we tried to tag therapeutic agents like radioisotopes to antibodies as a way of getting the agent directly to the cancer cell, but the antibodies were not specific enough. Now they're so specific that the whole field has now opened up again. It is quite exciting.

Senator SCHMITT. That is both in terms of the specific cancer cells and in terms of carcinogens; is that correct, antibodies against carcinogens, as well as antibodies against cancer cells?

Dr. DeVita. I was talking about antibodies against the antigens on the surface of cancer cells.

Antibodies have been used in a variety of other ways though. For example, we recently had some work using them to isolate the enzymes that are used to break down carcinogens into nontoxic materials or to convert them into carcinogens.

The genes for these particular enzymes can be taken out of the cell and cloned into the bacteria and studied further. They have very great utility as an experimental tool, as well as potential for diagnosis and treatment. The production of monoclonal antibodies is one of the major breakthroughs in the past decade.

Senator Schmitt. Can you summarize for us the present situation with respect to the actual causable factors of cancer? I'm not talking about carcinogens, but what happens within the cell?

Dr. DeVita. We don't know a lot about these things, Mr. Chairman. But let me give you an example of something that is very exciting and has only occurred in the past few weeks.

When I testified before this committee last year, we had information that one of the viruses known to cause cancer in chickens has a transforming gene. Now we know its sequence. This gene also produces a protein which turns a normal cell into a malignant cell. It is exciting, because even though you can't find out precisely how the genes do this, you can at least work with the protein that is the effective agent. We can now explore various avenues to interrupt and study the function of the protein.

In the past several months, we've learned that the gene of the virus probably came from normal genetic material of chickens and was pulled out by the virus. When the virus infects chickens the extra dose of the gene causes difficulty. The protein itself turns out to be an enzyme that greatly influences the cell membrane.

Senator Schmitt. What?

Dr. DeVita. The cell membrane of the cancer cell. By giving an extra dose of the gene the integrity of the cell membrane is disturbed and probably caused to be "leaky." This changes the internal milieu of the cell and it may be responsible for converting the cell to malignancy.

The interesting part about this research relates to the point of view Dr. Fredickson mentioned earlier, about each Institute nourishing the other, and researchers doing things, but not understanding why necessarily they're doing them. Researchers working on the membrane pump were not thinking they were going to do something useful for cancer, the people who were working with the cancer virus were not thinking about the effect of a virus protein on the sodium pump.

Over the past 2 or 3 months they've bumped into each other with what turns out to be a very exciting story. We will follow it with great interest, because it may be the first cleancut description of how a particular agent can cause cancer in mammals. And presumably there are examples of this in humans.

TREATMENT WITH RADIOTHERAPY

Senator SCHMITT. The Los Alamos Scientific Laboratory's meson facility has had a remarkable success in treating prostate cancer, but at obviously unacceptable costs for general application. Do you have any hope that much lower cost treatments will be possible, based on research and the experimental work that's been done?

As I understand it, that success rate right now is 100 percent.

Dr. DEVITA. It turns out that the best overall single treatment for prostate cancer is radiotherapy. And because of the nature of the prostate gland, where it is located, radiation can be delivered with great precision to the gland only. Pi-mesons happen to be the best way to do it. The Los Alamos facility happens to be our only pi-meson facility.

We had a group of scientists examine the particle radiotherapy program in 1979 and make recommendations regarding our resource allocations. That group suggested that we should evaluate fast neutrons first. Fast neutrons offered the most immediate promise of producing clinical benefits. So we have not expanded research using pi-mesons.

We did invest in developing neutron generators. We have no other plans at the moment for pi-mesons. Cost estimates for pi-mesons, per unit, is quite high. We only pay about $1 million a year at Los Alamos for the use of the facility, which is quite a bit less than the fuel bill of the facility. Pi-meson research is expensive, but we're very grateful for the opportunity to tap in on the resources the facility provides.

Senator SCHMITT. You look at it then, as really not a potential treatment, but as a way of doing research into the effects of radiation?

Dr. DEVITA. It is a potential treatment, too, Mr. Chairman. We're facing several alternatives in radiotherapy.

Just now we're examining potential usefulness for one specific kind of radiotherapy. We have linear accelerators in wide use in this country. In particle radiotherapy, pi-mesons are one example. In the past 5 years we've also been able to develop drugs for clinical use that are referred to as radiosensitizors.

These drugs actually sensitize the tumor, but not the normal cell to radiation effects. We have radioprotectors that protect the normal cell, but not the tumors.

The hypothesis is that a combination of our current equipment, plus radiosensitizors and protectors, might be as effective as particle radiotherapy and certainly a lot cheaper.

Thus, the only particle program we've investigated so far is neutrons as I mentioned before. But we're keeping a handle on the pi-meson generator, just in case we should want to explore pi-mesons as a treatment possibility in the future.

Senator SCHMITT. How much funding will you need in fiscal year 1982, to maintain your share of the NIH goal of 5,000 new competing research grants?

Dr. DEVITA. I believe that our number of grants in both years is the same. The figure is approximately $9 million over the 1981 figure to fund the approximate same number of competing research project grants.

Senator SCHMITT. How many grants is your share?

Dr. DeVita. 778 competing research projects.

Senator Schmitt. Is your inflation impact roughly the same as others?

Dr. DeVita. It varies, Mr. Chairman. In our clinical trials area, for example, where almost everything we do is people oriented, inflation is not necessarily energy-related. The inflationary costs are not as high, but when we get into the drug development area, where people work with solvents, the price of solvents has gone up at a rate faster than the inflation rate.

Overall, I would guess perhaps our inflator may be somewhat higher than the figure previously quoted.

Senator Schmitt. 9.5?

Dr. DeVita. Yes.

Senator Schmitt. Do you think it is important to stabilize new research grants regardless of other budgetary priorities within the NIH?

Dr. DeVita. I believe sincerely that stabilization should be our first priority. It always has been. And until such time that we have information that tells us exactly how to prevent cancer or treat it with very little morbidity, we shall have to deal with halfway technology. To improve it we should be investing in the research; yes.

RESEARCH FACILITIES

Senator Schmitt. Do you see any danger in the effectiveness of new research grants being impaired by deterioration of facilities or lack of investment in new research facilities?

Dr. DeVita. I think there is some, Mr. Chairman. I agree with Dr. Fredrickson. It is a hard figure to get your hands on, but the National Cancer Advisory Board did an independent study of our cancer centers, to see what their estimates were, what they would need to upgrade their facilities. And it does exceed what we had estimated ourselves.

NEW TECHNOLOGY

Senator Schmitt. What do you feel is the most exciting new technology in cancer research, state of the art, not in general applications, just what is the most exciting new technology?

Dr. DeVita. It is a cluster of technology, I believe. Dr. Fredrickson referred to restriction enzymes which were only discovered in the early 1970's. They have given us the ability to take a piece of DNA out of a cell, the ability to sequence it, and the ability to put it in another cell and check the function of that particular piece of DNA.

The whole constellation of events, plus the availability of monoclonal antibodies, which now are being used to precisely track the products of these pieces of DNA is the most exciting new work. It is the most extraordinary revolution in biology I've ever seen, and I have never lived in a period in science that I thought was dull.

Senator Schmitt. How many institutions in this country have that cluster?

Dr. DeVita. Quite a lot. I really can't give you precise figures, but it is not a rare set of skills nowadays.

In our 10 research programs when one considers the amount of grants we fund in each of the programs, we notice increasing support

for grants in the general cancer-biology area, which are largely supporting that kind of research. Genes are being mapped at the rate of three per week using this kind of technology.

Senator SCHMITT. Is it six institutions?

Dr. DEVITA. Many more.

Dr. FREDRICKSON. Scores, because the number of institutions capable of recombinant technology of one sort or another I think exceed 100, Mr. Chairman. There are very few leading research institutions that do not have similar chemical techniques available to them.

The beautiful thing about monoclonal antibodies is that they are relatively cheap, and you can do things, as was mentioned, overnight that you couldn't do for months. I think there are fewer institutions that have the capability for polypeptide or polynucleotide sequencing, but even so, they are not uncommon. These technologies can bear upon the activities of a large cluster.

Senator SCHMITT. You don't think the progress in this particular area is being held back by the lack of facilities, rather it may be held back by the lack of funding to use those facilities?

Dr. FREDRICKSON. I think that is right, for the facilities in general perhaps. But they do not require very specific rules. They are not similar to certain of the larger instruments, for example, or the very large-scale electrophoresis attempts that are being thought about, where we might look at all the proteins of a given tissue. Doubtless we will someday, and will look at the leading forms of those proteins.

There are some construction problems in large instrumentation, but I think not so much bearing on the ones that you described.

ELECTRON MICROSCOPES

Dr. DEVITA. There is another area, Mr. Chairman, which I should mention, because it comes as a close second to the areas I mentioned. It is often referred to as the "new anatomy." Using high-voltage electron microscopes, one can see cells almost at the functional level. These are extraordinary pieces of equipment. We only have two in the United States.

Senator SCHMITT. What does such a piece of equipment cost?

Dr. DEVITA. I can't give you a precise figure, but I believe they're in the range of $3 to $4 million. The instrument itself is expensive, but not outrageously expensive but the facilities to house it are quite expensive since they are 30 to 50 feet tall.

Senator SCHMITT. What would be the effect, if there were 20 of those instead of 2?

Dr. DEVITA. I don't really know, Mr. Chairman.

Senator SCHMITT. You have no feeling as to what would happen if you opened up that area for examination to a broader range of investigators?

Dr. DEVITA. I think there is no doubt the new anatomy, like the old anatomy, has to go through a period of time where everything we own in the body has to be classified and evaluated. I think if we had more, we could do that faster.

These areas provide much in the way of speculation. All I can say is that I'm sure something exciting will be found. I am struck by those

two areas. When I went to medical school, they were the substance of dreams.

RESEARCH FACILITIES

Senator SCHMITT. I don't sense a real concern that we are not hitting the point in terms of our facility availability—that it is going to be a roadblock, or a major constraint to progress in medical research.

The ability to find researchers is far more of a constraint than the ability to find facilities, instruments, and rehabilitation facilities.

Dr. DEVITA. Mr. Chairman, I agree with Dr. Fredrickson. I believe that clearly the need for new buildings is not the highest priority. Certainly the support of research is the highest priority. The renovation of facilities is an answer we can't really give you at the present time. This biology has all happened in the last 4 or 5 years.

Clearly, it has made demands on laboratories some feel they can't meet, so there's a danger of that happening. As I say, we do have some estimates that tell us we need to put more in these areas, but it is a relatively new requirement and something that would be worth paying more attention to in the next 4 or 5 years.

10-PERCENT CUT

Senator SCHMITT. In the February 13 issue of the Cancer Letter, published in Reston, you were quoted, Doctor, as saying that "while a 10-percent cut in the cancer budget would hurt, we can tolerate it. Whatever NIH can tolerate, we can."

Would you want to explain your feelings about that?

Dr. DEVITA. Yes; I was asked a rhetorical question. I meant it is possible for us to take those kinds of cuts. It would not be pleasant, but we are prepared to examine our budget at any time and make the necessary cuts.

The point I made is that we're always a little bit concerned, that because of our size, we are the largest Institute on the NIH campus, we might appear to be an attractive source of cuts that would be disproportionate at NIH.

That was my reason for saying we could if we had to. Certainly we could but we would prefer to be treated equally with the rest of NIH.

Senator SCHMITT. Dr. Fredrickson, do you care to comment on the 10-percent figure?

Dr. FREDRICKSON. Mr. Chairman, the major concern of an organization like NIH and the Nation that supports it has to be the question of whether, in dealing with austerity, you do irreversible damage to an institution—one that is so importantly related to the function of the universities across the country. It is true that reductions in budget tend to impact on certain areas, and they would probably affect most the researchers who are coming back for support. If their capacity to initiate new research grants were diminished, we would do irreparable harm to the system. There are a number of people who would be disenfranchised immediately. And that is a problem, because of the continuity and long-term nature of our activity.

Thus, a reduction of that size, even in a large operation, could do damage far beyond its fractional amount. We don't know in what stage

it would take a reduction to do disproportionate damage to the human and physical capital that is involved. It would be extraordinarily hard to replace it.

RESEARCH EMPHASIS

Senator SCHMITT. Do you see any way, Dr. DeVita, that Congress could technically require a shift in emphasis from treatment to prevention and cure?

Dr. DEVITA. I don't believe it is necessary, Mr. Chairman. I believe we are already making that shift as rapidly as these opportunities present themselves to us.

I am reminded that in the late 1960's we didn't have that much information that would suggest we should make the shift. It was the resources that the Cancer Institute put in the prevention area that provided the data that made everybody so interested in prevention. We are responding to our own data. And we feel that it really should be our highest priority and we give it our highest priority.

Senator SCHMITT. We're going to have to move on. We'll have a number of questions for the record. And, as with other witnesses, we hope that the answers can be provided along with your corrected testimony.

Thank you very much.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

HODGKIN'S DISEASE

Question: You are aware, I believe, of a study by two Harvard researchers indicating that Hodgkin's disease, an often fatal lymph cancer, may have a viral origin. What does this study tell us about the belief that viruses cause - or help cause - some cancers?

Answer: Since many lymphomas and leukemias of animals are caused by viruses, and since Hodgkin's disease is a kind of lymphoma, NCI must seriously consider the possibility that viruses are involved in the cause of this disease. Three kinds of past studies have supported this interpretation. (1) Older pathological studies showed that Hodgkin's tumor tissue was composed of different kinds of cells. This polycellularity is often a manifestation of a viral disease. (2) Epidemiological studies in New York state suggested that cases of Hodgkin's disease in young adults were linked by close interpersonal contact. However, this finding is controversial because in other areas epidemiologists were not able to confirm the observations. (3) The recent Harvard report indicates that Hodgkin's disease in young adults occurs in greater numbers in the higher socioeconomic groups, primarily in individuals with a relatively sheltered early childhood, e.g., few playmates or siblings. This kind of history resembled the model of infectious poliomyelitis and suggests the possibility of a causative role for a common virus causing a rare event. Having said this it is very important to emphasize that no results indicate that patients with Hodgkin's disease are themselves spreading the disease. The recent results suggest, but do not prove, a virus causation, and if they provide a virus role, they suggest delayed infection by a common virus to which large segments of the population are exposed.

Question: Does the study indicate what virus may be involved in causing Hodgkin's disease?

Answer: Neither the recent study nor any other study to date indicates what virus may be involved. The Harvard scientists did suggest that Epstein Barr Virus (EBV) may be involved in some cases, particularly since an increased rise of Hodgkin's disease has been reported in persons with infectious mononucleosis (usually induced by EBV). However, NCI experts commenting on an editorial in the New England Journal indicated that there is some direct evidence against EBV; they suggest that if a virus is involved it may be one not yet well known. The NCI scientists lean to the possibility of a type-C retrovirus. Such viruses have been identified this year in some human lymphomas by Stanford University scientists and by NCI scientists. These viruses are extremely difficult to detect, and how they influence growth of human lymphoid cells is under study. As yet no virus has been clearly associated with Hodgkin's disease, but the clues provided by the Harvard study indicate the need for more intensive experimental investigation.

CANCER CAUSED BY SMOKING AND DIET

Question: A recent report of the President's Toxic Substances Strategy Committee stated that the proportion of cancers attributed to

cigarette smoking and diet has declined. Was NCI involved in this study?

Answer: The NCI was involved in the preparation of the Report of the President's Toxic Substances Strategy Committee and commented on the report during the review process.

Question: Do you concur with the conclusions?

Answer: While some studies suggest a lessened effect on the respiratory system in current smokers, many of whom have switched to filter tips and low tar cigarettes, NCI does not believe that the cancer risk for cigarette smoking can be minimized at this time, or that we can say with absolute certainty that the proportion of cancer from cigarette smoking has declined. With the introduction of the newer low tar/low nicotine cigarettes, the risks of additives and other tobacco products are unknown. In addition, toxic substances and carcinogens occurring in the gaseous phase of cigarette smoke are still present in the low tar cigarette. While other environmental factors, including those occurring in the workplace, are important, they should not obscure the fact that tobacco smoking is the major carcinogenic hazard that has been identified. The relative contribution of diet in the proportion of cancers is not known, but could be substantial.

Question: What influence will this finding have on your research?

Answer: The NCI will continue to support research to determine the impact of newer changing cigarettes on cancer incidence, both through epidemiologic and toxicologic studies. We have increased our efforts devoted to smoking cessation programs, including those directed toward the adolescent. Likewise the research directions on diet and nutrition will continue to examine the role of specific dietary constituents and nutrients on the risk of cancer.

Question: What is NCI's position on the dangers of smoking low tar cigarettes?

Answer: The NCI concurs with findings of the Surgeon General's Report 1981, "The Health Consequences of Smoking: The Changing Cigarette," summarized in the Preface to this report:

- There is no safe cigarette and no safe level of consumption.
- Smoking cigarettes with lower yield of "tar" and nicotine reduces the risk of lung cancer and, to some extent, improves the smoker's chance for longer life, provided there is no compensatory increase in the amount smoked. However, the benefits are minimal in comparison with giving up cigarettes entirely. The single most effective way to reduce hazards of smoking continues to be that of quitting entirely.
- It is not clear what reductions in risk may occur in the case of diseases other than lung cancer. The evidence in the case of cardiovascular disease is too limited to warrant a conclusion, nor is there enough information on which to base a judgment in the case of chronic obstructive lung disease. In the case of smoking's effects on the fetus and the newborn, there is no evidence that changing to a

lower "tar" and nicotine cigarette has any effect at all on reducing risk.

- Carbon monoxide has been impugned as a harmful constituent of cigarette smoking. There is no evidence available, however, that permits a determination of changes in the risk of diseases due to variations in carbon monoxide levels.
- Smokers may increase the number of cigarettes they smoke and inhale more deeply when they switch to lower yield cigarettes. Compensatory behavior may negate any advantage of the lower yield product or even increase the health risk.
- The "tar" and nicotine yields obtained by present testing methods do not correspond to the dosages that the individual smokers receive: in some cases, they may seriously underestimate these dosages.
- A final question is unresolved, whether the new cigarettes being produced today introduce new risks through their design, filtering mechanisms, tobacco ingredients, or additives. One of the chief concerns is additives. The Public Health Service has been unable to assess the relative risks of cigarette additives because information was not made available by manufacturers as to what additives are used.

In view of the unknown risks in new low tar cigarettes related to additives and other tobacco ingredients and changes in the smoking behavior of individuals using such changing cigarettes, NCI's position is that there is no current cigarette which can be regarded as "safe" and that the only means of assuring decreased risk is through cessation of smoking.

CERVICAL CANCER SCREENING

Question: At a recent NCI conference, the panel was divided on the issue of how often women should receive a Pap test. The panel recommended that the examination be given at regular intervals of one to three years. What guidelines has NCI developed to assist women and their doctors in deciding on when to make such a test?

Answer: In July 1980, a Consensus Development Conference on Cervical Cancer Screening: The Pap Smear was sponsored by NCI, the NIA and NICHD in conjunction with the National Center for Health Care Technology as part of the NIH activity on the medical applications of research. The consensus panel represented a broadly based group of individuals, including those knowledgeable in epidemiology, gynecology, oncology, cytology, and consumer opinions. The panel heard evidence related to the development and progression of cervical cancer and its precursors, the risk factors related to cervical cancer, the clinical management of the disease, epidemiologic studies related to screening for cervical cancer, and statements from U.S. and international organizations about policies or approaches for cervical cancer screening. Based on the evidence reviewed, the consensus panel developed a statement which has been distributed widely to physicians and has been reported in the News Section of the Journal of the American Medical Association in August 1980, and in the British Medical Journal. The statement also has been submitted to a widely read medical journal for publication and, finally, the proceedings of the conference are in preparation.

The NCI does not regard this statement as a guideline for U.S. women or doctors. This statement, Cervical Cancer Screening: The Pap Smear, provides an assessment of the state of scientific information by an independent panel of experts.

Question: What is the rationale for not conducting such tests once a year?

Answer: The rationale for suggesting intervals of screening longer than one year is based on several types of evidence. First, the progression of pre-malignant lesions is regarded to be of sufficient length that screening intervals of greater than one year would not compromise screening efficacy. Second, a number of population based studies, mostly carried out in Europe, have utilized screening intervals of greater than one year (e.g., three and five years). The results of these approaches yield about the same results as have been obtained in the U.S. when using one-year intervals. Finally, assessments of cost and benefit of cervical cancer screening indicate that no benefit is lost by lengthening screening intervals to those greater than one year.

FUTURE OF NATIONAL TOXICOLOGY PROGRAM

Question: What is the status of the National Toxicology Program which you recommended be transferred to the Environmental Health Institute?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

BLACK SUSCEPTIBILITY TO CANCER

Question: Recent studies have shown that Blacks are more susceptible to cancer than are Whites. How significant is the difference between the races?

Answer: When considering all cancers combined, the above statement is true only for males. The total age-adjusted cancer incidence rate among Black males is 454.3 per 100,000 males compared with 371.6 for White males. For females, the reverse is true - the overall cancer incidence rate is lower in Black females than in White females (288.7 vs. 301.2 per 100,000 females). Comparing rates for Whites with those for Blacks for all sites combined, however, can be very misleading. The attached table shows the incidence rates for each sex-race group for each of the major anatomical sites. It can be seen that the excess incidence of cancer among Black males over that for White males is accounted for heavily by cancers of the lung and prostate, but also by the esophagus, stomach and pancreas. Among females, Blacks have a lower incidence of breast cancer than White women (72.0 vs. 85.6), twice the risk of cancer of the cervix but only half the risk of cancer of the uterine corpus.

Average annual age-adjusted cancer incidence rates per 100,000 populations for the major anatomical sites, by race and sex, all SEER areas combined*, 1973-1977:

	WHITE		BLACK	
	MALE	FEMALE	MALE	FEMALE
All Sites	371.6	301.2	454.3	288.7
Esophagus	4.8	1.6	16.9	4.5
Stomach	12.7	5.6	22.4	9.9
Colon	36.7	31.0	36.3	30.6
Rectum	19.1	11.5	13.3	10.5
Pancreas	11.9	7.7	17.5	11.9
Lung	76.4	21.8	110.0	24.3
Breast		85.6		72.0
Cervix		10.9		25.7
Corpus		30.6		15.8
Ovary		14.2		9.3
Prostate	66.2		108.9	
Bladder	27.0	7.1	13.6	5.5
Kidney	9.4	4.4	8.7	4.4
Lymphomas	14.3	10.7	10.3	5.8
Leukemia	13.0	7.7	11.1	6.8

*The SEER areas consist of the entire states of Connecticut, Iowa, Utah, New Mexico and Hawaii and the metropolitan areas of Atlanta, Detroit, New Orleans, San Francisco, and Seattle.

Question: What has the Institute done to determine the cause of this difference?

Answer: The NCI has carried out an epidemiologic study of cancer of the esophagus among Black men in the District of Columbia where the rate of esophageal cancer is extremely high and where the rate of alcohol consumption is far above the national average. The study revealed a relationship between esophageal cancer and high alcohol consumption and poor nutrition. As far as lung cancer is concerned, it is known that the proportion of current cigarette smokers is about 10% higher among Blacks than Whites. This undoubtedly accounts for some of the excess lung cancer among Black males. A case-control study of lung cancer in Southern Louisiana is now underway to examine other risk factors, including exposure in the petrochemical industry.

A study of risk factors possibly associated with stomach cancer is being carried out among Blacks and Whites in Southern Louisiana where the rates among Blacks are high.

The NCI is also funding two epidemiologic studies of pancreatic cancer comparing Blacks and Whites. These studies are now underway.

In addition, a subcommittee of the National Cancer Advisory Board, whose members are Dr. Harold Amos, Dr. LaSalle Leffall, and Dr. Irving Selikoff, has been examining the issue of susceptibility and possible differences between the races with regard to cancer cause, prevention and treatment. An NCI task force has also been appointed consisting of Dr. Joseph Fraumeni, Dr. Earl Pollack, Dr. Jan Howard, Ms. Maxine Richardson and Mr. Robert Denniston to interact with the subcommittee to advise it on what research or

administrative steps it should be taking with regard to these differences.

REACHING BLACK POPULATIONS

Question: To what extent does NCI try to reach the Black population with information warning them about the problem?

Answer: The NCI has, in the past several years, undertaken special efforts to reach minority audiences with information about cancer. Minorities, in particular Blacks, are at high risk to some types of cancer, and, in many respects, are hard to reach with information and education programs. Our program, therefore, has been carefully developed to reach these audiences with credible, relevant information that will permit individuals to help reduce their risk of cancer, to recognize early signs of the disease, and to seek prompt treatment if a symptom should become evident.

To develop such a program, NCI contacted existing organizations serving minority populations to establish working relationships. NCI then studied research on minorities' knowledge, attitudes and practices related to cancer, and, with the help of these organizations, determined specific information needs, channels of dissemination, and communication approaches.

Organizations participating have included the National Assocation of Community Health Centers, the National Medical Association, National Newspaper Publishers Association, National Black Network, Mutual Black Network, state health departments and cancer centers.

In this way, a program has been developed to appeal to the target audience, to be interesting and informative, and to be understandable and relevant to day-to-day activities. The program consists of materials and services designed to meet the needs of blacks and the organizations best able to help NCI reach this important audience. Specifically, NCI has:

1. Developed and widely disseminated a booklet and display poster entitled "What Black Americans Should Know About Cancer."
2. Created a series of ten public service announcements which were broadcast by radio stations served by the Mutual Black Network and the National Black Network.
3. Provided a question-and-answer newspaper column to members of the National Newspaper Publishers Association.
4. Disseminated a series of public service print ads to newspapers, magazines, and newsletters serving the Black community.
5. Created an audiovisual program (with supplementary printed materials) on breast cancer, in versions for both Black and Hispanic audiences.
6. Included, in NCI's survey of public knowledge, attitudes, and practices about breast cancer, a special subsample of adult Black women, so that specific information now is available for information program planning and evaluation.
7. Worked with a major cancer center to determine the reasons for under-utilization of a cancer screening program in the inner city.

8. Tested specific cancer information materials, such as TV and radio public service messages, designed for Black audiences to ensure that such messages are appropriate and effective.

In addition, NCI has provided program development information and resources to organizations and health professionals developing their own programs. This includes statistical information, handbooks on reaching minorities, pretesting and message-testing expertise, materials review, and specific searches for materials and audience characteristic information. Such organizations include the American Cancer Society, numerous comprehensive and other regional cancer centers, state health departments and other health and social service agencies.

Question: To what extent do you work with the states to get them to do more to inform their Black citizens about cancer?

Answer: Special efforts to reach groups at high risk to cancer are being made by the cancer communications network, part of the 21 NCI designated comprehensive cancer centers. Such centers, located primarily in urban centers where most of American Blacks live, operate toll-free telephone services to respond to public inquiries about cancer, and provide other information programs. Many of these centers have mounted special efforts to reach out to Blacks. Activities to build awareness of cancer as a health hazard and to increase awareness of cancer-related community resources have been high priorities with many of the programs. More specifically, programs such as the following have been developed:

1. A cervical cancer screening program, carried out in conjunction with state health departments, performs Papanicolau (PAP) tests on low income or indigent women and specifically emphasizes recruitment of Blacks and other minorities. Other screening programs, designed to test the possibility that community-based programs could increase early detection and diagnosis of breast and cervical cancer in Blacks and other minorities, have been supported. Public information campaigns and mobile screening units are used in an attempt to inform these hard to reach populations.
2. Working with local medical associations and community groups to put on "town hall" meetings to focus attention on cancer risks among Blacks and how to reduce risks.
3. Cooperating with screening program to increase awareness of free breast examination center in Harlem.
4. Organizing and developing a cancer curriculum for the public schools.
5. Creating special radio programs about cancer in cooperation with Black radio stations.
6. Working with community health centers and rural health centers to disseminate informational materials to patients.
7. Working with Black media to promote awareness of the toll-free Cancer Information Service.

In addition, NCI has supplied a broad variety of information materials, including those specifically for minority audiences, to state health departments, other state and local government agencies,

and other NCI grantees and contractors for them to disseminate to their constituents.

NUTRITION AND CANCER

Question: In patients who have cancer, to what extent has it been demonstrated that it may be better to feed or starve the cancer?

Answer: From animal studies there appears to be a narrow range of caloric restriction which exerts a beneficial effect in the host. This effect requires careful calibration since exceeding the range leads to negative results. Also the positive effects of calorie restriction are seen only in the early or preclinical stages of tumor growth. In advanced cancers nutritional deprivation negatively affects host animals. With these observations in mind, NCI has undertaken a series of studies to determine the effects of the elimination of certain nutrients and the addition of nutritional supplementation to cancer patients, especially those undergoing therapy.

In the clinical setting, the first step in dietary/nutritional manipulation is the assessment of the nutritional status of cancer patients. NCI is supporting several studies to evaluate new techniques for such assessments. The techniques under examination include metabolic studies, computerized tomography, ultrasound, immunologic testing, determination of body composition using neutron activation and isotopic dilution techniques, and biosteriometrics. The usefulness of these apporoaches is being compared with clinically available methods such as weight, serum albumen, anthropometrics, etc. This research will lead to the precise identification of nutritional changes in cancer patients.

To study the effects of the elimination of nutrients from patients with cancer, a pilot study was carried out comparing the dietary elimination of certain amino acids in patients with brain tumors undergoing treatment with chemotherapy. Patients were treated with dietary elimination alone, dietary elimination plus chemotherapy, and chemotherapy alone. Forty patients entered in this pilot study showed no differences in outcome between treatment groups. Patients treated by elimination diets alone had similar outcome to patients treated in the other regimes. The number of patients in this study is small so it is not possible to draw definitive conclusions. The results have been presented to the Brain Tumor Study group which will consider the initiation of a more definitive study in the future.

The NCI has also funded a number of projects to examine the role of nutritional supplementation by total parenteral nutrition (TPN) for a variety of tumor types in adults and children as an adjunct to cancer treatment. The results to date do not indicate that supplementation with TPN enhances patient response to cancer treatment. Survival of patients in these studies was not increased by the use of TPN. To definitely answer this question, NCI has funded a large prospective randomized clinical trial studying the effects of TPN with chemotherapy and radiation treatment in patients with small cell cancer of the lung. The study involves five collaborating institutions and will be the largest study of nutritional

supplementation thus far carried out. The study is currently accruing patients and results are expected in about eighteen months.

Finally, anorexia (loss of appetite) and cachexia (wasting) accompany the course of cancer in many patients. Studies are underway to determine the physiologic bases of anorexia/cachexia, development of agents to combat these symptoms and the mechanisms of food aversion. Observations from these studies will be used in planning future clinical trials.

In summary, the NCI is in the process of determining the ways diet and nutrition affect cancer patient response to the tumor and/or cancer treatment. These studies will lead to improved strategies of cancer patient management in hospitals across the country.

Question: How much are you spending on nutrition research in fiscal 1982 - and how much do you propose to expend in FY 1982?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

CANCER CONTROL

Question: Are certain activities under the Cancer Control Program being phased out? Which ones?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to these questions.

Question: If so, to what extent can the appropriations for the Cancer Control Program be reduced for FY 82 to reflect the elimination of these activities?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

NCI CONTRACTS

Question: As I'm sure you know, GAO has recommended recovery of $1.1 million for questionable charges from the University of Nebraska's Eppley Institute. What is the current status of the NCI contract with Eppley?

Answer: Contract NO1-CP-33278 entitled "Studies of Environmental Carcinogenesis Research and Bioassay" was originally awarded in May 1973 to the Eppley Institute and was renewed in its original form in November 1977 for a three-year period. In November 1979 NCI chose to separate that single contract into ten individual contracts covering several portions of the original effort. This provided the NCI better control and management of this contract. All

work under the ten was to be completed by November 1980. However, because additional time was necessary to complete pathology work and the preparation of final reports, eight of the ten contracts were extended at no additional cost to the government through June 1981. Eppley is making good progress in completing work under the eight contracts and we anticipate at this point no additional extensions beyond June 1981.

Question: Has the $1.1 million been recovered?

Answer: There were numerous claims against, and criticisms of the University of Nebraska's Eppley Cancer Research Center. It was decided that the Government would conduct an investigation and perform an audit of the contract. As a result of this audit, it was discovered that $1.1 million of unallowable or unsubstantiated claims by Eppley should be recovered. However, as a result of various allegations raised outside of the context of the GAO audit, a Grand Jury was formed to hear the results of a Justice Department investigation. The Department of Health and Human Services (DHHS) Office of General Counsel has not yet received the prosecutorial report concerning the findings of the Grand Jury. This report may have an impact on the recovery of disallowed costs under the Eppley contract. The DHHS Office of General Counsel has requested NCI to withhold further settlement action until after it reviews the Grand Jury report. The Financial Advisory Services Branch (FASB), National Institutes of Health as well as the Cost and Audit Management Branch, Public Health Services, are aware of this deferral and both agree on the importance of having this information in hand before proceeding with any recovery settlement.

Question: The Subcommittee was told in 1979 that NCI's contract with Tracor-Jitco was to be phased out. Has this happened and if not, why not?

Answer: The Tracor-Jitco contract is, in fact, being phased out as we said. It is part of NCI's contribution to the total National Toxicology Program (NTP). The NTP is currently in the final planning stages concerning an earlier phase out of this contract. It is anticipated that the on-going work may be transferred to other parties as soon as this planning can be implemented.

It should be kept in mind that the bioassay testing process is a lengthy one, consuming from two to five years of total effort. Therefore, "phase-out" can be accomplished in one of two ways: on-going tests can be ended prematurely, or additional assignments of chemicals can be withheld while on-going work continues. In conjunction with the Director of the National Toxicology Program, we have primarily adopted the latter method. Since the bulk of tests underway by this contractor was initiated in early 1979, we did not think it prudent to end testing prematurely.

Question: Has the amount of the contract been increased by $13 million and if so, why?

Answer: In June 1979 the Tracor-Jitco contract was extended for a four year phase out period through May 1983 in the amount of $64,495,265 in order to complete the testing of compounds already

entered into test. Each contract year is funded by separate appropriation. The first year of the phase out was funded in the amount of $15 million. We believe that the $13 million referred to in the question represents this first year funding. To date, the current contract has been funded in an amount of $34.7 million which will cover performance through August 1981. This funding has been applied to the completion of chemicals assigned for testing prior to June 1979, and no additional new tests are being performed under this contract. Because of the annual incremental funding, there is an appearance of annual increases in work effort. This is not the case, however, since the increments simply represent payments for that portion of the four year effort which is to occur in the year being funded. We anticipate two additional annual increments, after which Tracor-Jitco will have completed its contract.

Question: What steps have you taken to improve contract administration procedures?

Answer: One of my primary goals as Director of the Institute has been to assure that we are fully accountable for contract management responsibilities. Consequently, I have directed numerous changes to the contracting procedures for all NCI contracts and have strengthened and re-emphasized changes initiated by my predecessor to assure this result.

One of my first steps in this regard was to undertake a 100% review with the Division Directors of every contract in effect in the Cancer Institute. This review was intended to eliminate, reduce, or phase out any contracts which were not fully justifiable. We carefully examined approximately 1,000 contracts and directed terminations and reductions in funding, resulting in the immediate savings of approximately $25 million which was reapplied to other high priority programs. This review also resulted in the identification of numerous contracts under which NCI purchases resources such as chemicals, animals, or viral reagents for use by the contracting or grantee community. In each of those cases, we have required either a user survey to insure that the resources were still needed or a process leading to the determination of which of these resources should be provided only upon reimbursement by the recipients.

Secondly, we have insured that each division with a contracting program has available to it a Board of Scientific Counselors, an advisory body composed of non-federal people, charged with the responsibility of reviewing, at the stage of initial conception, projects proposed for contract funding. Those contracts initiated within organizations of the Office of the Director of the Institute will have their proposed contract activities reviewed at the concept stage by a newly created subcommittee of the National Cancer Advisory Board. No new contracts or recompetitions of existing contracts will be permitted to proceed unless reviewed and approved by a Board of Scientific Counselors or the subcommittee. At the fall meeting of the National Cancer Advisory Board, the Board will be informed of the Board of Scientific Counselors' actions regarding contracts to ensure that all are aware and informed of each Division's programs, thereby avoiding unnecessary duplication. This procedure should provide better advice regarding management of the total Institute.

Thirdly, we have taken a number of initiatives to insure rigorous management of all contracts by NCI staff. For example, all project officers in the Institute are required to attend a course offered by the Department of Health and Human Services to thoroughly acquainf themselves with their responsibilities and obligations as project officers. Contract specialists within the Research Contracts Branch take increased training both through internal seminars and through required attendance at DHHS-sponsored training programs. The Department has a program for the certification of contracting officers, and it is our intention that all contract specialists ultimately will receive such certification. In addition, we have consolidated the Research Contracts Branch staff in one location in order to facilitate day-to-day supervision and management. The Research Contracts Branch has also established a process of internal audit under which a Contract Administration Review Team will periodically examine each contract file to assure that post-award administration is being adequately performed. Contract specialists within the Merit Pay Program are rigorously evaluated on their performance of contract administration responsibilities and will be either rewarded or sanctioned based upon their performance. We have also issued two new manuals, a "Guide to the Principal Investigator of NCI Contracts" and a "Manual for Contract Administration." Principal investigators are those individuals working for contractors who bear primary responsibility for the management and production of work contracted for by the Institute. The guide explains the functioning of the contract and clearly delineates principal investigators' responsibilities. The Contract Administration manual details the various aspects of contract monitoring and is used by project officers and contract specialists and NCI staff as an aid to performing their monitoring responsibilities. I have issued a number of directives to Institute staff with contract management responsibility identifying those areas of concern identified by the General Accounting Office or the Inspector General's Office which require corrective action.

I believe that I have made it abundantly clear to all involved staff that improper and inadequate contract management will not be tolerated. I have also undertaken to strengthen and revise the management of the contract peer review responsibilities within the new Division of Extramural Activities (DEA). Among those changes is a recently agreed to policy under which resource contracts as well as research contracts will be peer reviewed under the auspices of DEA.

Finally, I have been setting aside a portion of each meeting of the National Cancer Advisory Board for the exploration and discussion of Institute contract policies and procedures. These presentations have been summarized in a written document which can be made available to the subcommittee. These are only a few of the specific steps that have been taken to insure that contracts are used only when absolutley necessary and when contracts are essential that they are managed as effectively as possible.

Ouestion: Do you use level-of-effort research contracts which apparently do not require that specific results be achieved? If so, why? How much of your money is invested in these contracts?

Answer: Level-of-effort contracts are generally used for

projects that require the contractor to perform research of a certain nature targeted toward a specific goal or conclusion. In addition, level-of-effort is used where a succession of task orders are issued to the contractor for completion. These latter contracts are where the Government is unable to specify a firm quantity of tests, for instance, that will be required during the contract period.

In the case of a research contract, the use of level-of-effort effectively establishes the margins within which the contractor works on a project. If one were to ask for research on a problem, the potential contractors could propose any number of people to perform, thus causing the Government to receive proposals with a wide range of personnel and dollars. This is unfair to the offerors and makes it difficult to select the successful contractor. The level-of-effort better defines the scope of the project contemplated and assists program staff in the allocation and budgeting of the resources required. In addition, there is the budgetary consideration of a finite amount of dollars to apply to a specific project.

Thus, a level-of-effort contract requires a specific number of labor hours to be applied to work that is described in the contract.

The NCI records do not currently capture contract data that would allow us to determine the amount of dollars associated with active level-of-effort contracts. Two of the classifications available subdivide contracts as either research or research support. Level-of-effort contracts are a significant portion of research contracts. The NCI in 1980 obligated $57 million for research contracts and $151 million for research support contracts.

PROGRESS AGAINST CANCER

Question: Are there any recent developments or clues on how cancer is caused that you can tell us about?

Answer: Cancer cause and prevention research rests on the understanding that most cancer begins with an alteration in the genetic component of a normal cell and progresses through a series of changes before the clinical appearance of the disease. While we are only beginning to understand what the specific changes are, it is nevertheless apparent that the development of cancer is a stepwise process, and prevention may be possible by interfering with any of the steps in this process.

Although what is now the Biological Carcinogenesis Program began with the goal of isolating human cancer viruses, it rapidly brought forth new developments far beyond its anticipated scope of activity, and unforeseen scientific discoveries caused some old ideas to be modified or abandoned entirely. Thus, the primary emphasis in biological carcinogenesis has partly moved away from the search for various human cancer viruses and ultimately a vaccine to the study of genes, gene products, and cellular control mechanisms. Tumor viruses are now increasingly used as tools for deciphering the molecular pathways by which a normal cell becomes malignant. However, there are viruses which apparently are involved in causing human cancer and additional examples will probably be found.

There are several ways in which investigators have capitalized upon the reproducible ways in which tumor viruses transform cells. Molecular biologists have successfully identified the genes, and the protein products coded by those genes, by which certain animal viruses cause cancer. Some of the most potent of these viruses were found to have derived their cancer-causing genes by taking them from normal cells during viral replication. Indeed, normal proteins related to the transforming proteins, coded for by these genes, have been found in all human cells tested thus far, indicating that these genes, or closely related sequences, are present in human cells.

The function of these "viral" genes, which appear in normal tissue and have apparently been conserved throughout millions of years of evolution, is unclear. The fact that genetically transmitted viruses have been isolated from some of man's closest relatives, and that related DNA sequences have been detected in human DNA, suggests that under ordinary conditions, certain of these sequences may serve a normal function but when aberrantly or inappropriately expressed, may cause malignancy. Research on the way in which the cell controls the expression of these sequences, and on the way in which the proteins coded by the sequences act upon the cell, is believed to be of potential use in finding a way to block the transformation process and prevent cancer.

The diversity of the various transforming proteins from dissimilar transforming viruses caused concern that the mechanisms for each type of cancer would be different. However, scientists at Cornell University have recently found that these transforming proteins may all be part of a pathway which transmits high energy phosphate bonds; this process eventually leads to alterations in important membrane components which, in turn, may produce changes in the membrane transport of critical ions. Thus, it is possible that a common metabolic pathway has been found for cancer development and that this will have important future applications to human cancer.

Independent of these developments, NCI scientists have found growth factors that are normal cell proteins which promote growth (when needed) of normal cells by interacting at cell membranes. However, some tumor cells continuously and abnormally secrete those proteins thereby stimulating their own proliferation. Thus, instead of this growth factor protein being regulated and produced only at specific times in the development of a cell, the tumor cell may continuously produce it or may respond excessively to it. Apparently, many diverse causes of cancer can lead to this abnormal development. It is possible that the membrane interaction which occurs, leads to similar biochemical changes, as described above, with the viral transforming proteins. It is likely that the two areas will converge this year. Clearly, understanding at this level should lead to new approaches to controlling abnormal growth.

It is now widely recognized that a large number of chemicals exhibiting carcinogenic properties are, themselves, relatively inert. In order to exert a biological effect, they must be metabolically activated by the target cells. Most cells and tissues examined to date contain enzyme systems which can both activate and detoxify these carcinogens. Important results have been obtained on defining the

various pathways of metabolic activation to the ultimate mutagenic and carcinogenic forms. The enzyme systems responsible have been isolated and characterized from many animal sources. Great progress has been made in the past year on the isolation and characterization of the human enzymes which metabolize polycyclic aromatic hydrocarbons. Furthermore, a program was recently initiated which will focus research efforts on the interspecies comparison of carcinogen metabolism. This research effort should aid in our ability to extrapolate experimental carcinogenicity data to humans.

Many metabolically activated carcinogens have been shown to bind to cellular macromolecules which may explain their biological effect on the target cells. Considerable effort has been expended in the characterization of the various carcinogen-macromolecular complexes and the identification of types of interactions which are biologically important. In particular, it is felt that those interactions of carcinogens which lead to DNA damage are responsible for their ultimate carcinogenic effect. In humans, correlations between DNA damage and carcinogenesis can readily be made in individuals with certain genetic disorders such as xeroderma pigmentosum and ataxia telangiestasia. Cells obtained from these patients are defective in their ability to repair DNA damage due to ultraviolet light and x-rays, respectively. The existence of these repair-deficient cells has made it possible to examine the role of DNA repair in mutagenesis. The data obtained so far indicate that a functional DNA repair system is an important mechanism by which normal cells are protected against potentially carcinogenic molecular lesions. Studies are now underway to develop methods for the identification of carriers of DNA repair disorders since these individuals are thought to have a higher risk of developing cancer.

The two-stage mechanism of carcinogenesis is well established for skin, and evidence is accumulating for its existence in other organs. The first stage, initiation, involves a permanent heritable change in the cell, which is necessary but not sufficient to render the cell malignant. The second stage, promotion, completes the malignant transformation. This mechanism may explain the long latent period between exposure to some carcinogens and the appearance of tumors resulting from this exposure. Known compounds which act as tumor promoters are thought to have certain common characteristics. In principle, they are not carcinogenic when given alone, are not mutagenic, probably have a threshold, do not bind covalently to cellular macromolecules and at given stages their action is reversible. Research on one class of tumor promoters, the phorbol diesters, has shown that they have a wide range of effects on cells. They can cause alterations in cell membrane properties and in the synthesis of the lipid component of membranes. In certain systems, tumor promoters have been shown to inhibit cellular differentiation, while with other cells, the process of terminal differentiation is enhanced. Cell proliferation is also stimulated by tumor promoters. An early event in the action of the phorbol diester tumor promoters on cells is the induction of ornithine decarboxylase (ODC) activity. Several lines of evidence suggest that this induction is an essential component of the mechanism of tumor promotion, at least in skin, and inhibition of ODC induction has been suggested as a screening device for assessing the potential prophylactic activity of new synthetic

retinoids. Indeed, a correlation appears to exist, among the natural vitamin A analogs tested, between the ability to inhibit phorbol diester-induced ODC activity and the ability to inhibit skin tumor promotion.

The synergistic action between other initiators and effectors of tumorigenesis has also been studied. Repeated low dose irradiation influences mammary gland carcinogenesis in estrogenized rats; this demonstrates a synergistic interaction between x-irradiation and estrogen in mammary adenocarcinoma formation. Initial results indicate that repeated low doses of radiation are more carcinogenic than a single high dose and that several estrogen hormones can interact synergistically with radiation.

Several epidemiological studies provide valuable clues on the lifestyle and environmental factors that may be related to cancer causation. We have learned from the U.S. maps of cancer mortality NCI published five years ago that death rates from colon, rectal and breast cancers are about 50 percent lower in counties in the south compared to those in the northeast and north-central United States. Despite the large number of northerners who retire to Florida, this area retains the low rates of the south, even among older people. This observation is of interest because it suggests that the change in rate occurs quickly rather than taking the ten to twenty years we often see with exposure to carcinogens. Some other mechanism, possibly a change in diet, consumption of more fiber, vitamin A- and C-rich foods, could be involved. We don't know, but current studies may provide answers. This epidemiological finding, which is the subject of current studies, may be related to other areas of research. For example, a recent prospective British study confirms others that have shown that persons with low levels of vitamin A in their blood have a higher incidence of cancer. The association was independent of age, smoking habits, and serum-cholesterol levels and was greatest for men who developed lung cancer. Another study, by a group of Canadian scientists, showed that levels of mutagens in stools of normal volunteers are reduced by the use of vitamins E and C. Vitamin C, or ascorbic acid, has also been shown to inhibit the formation of carcinogenic nitrosamines in meats that contain nitrites (bacon, for example). It also prevents the formation of other nitrosamines that may be produced in the stomach from nitrites and amines that occur naturally.

Retinoids, which are natural and synthetic analogs of vitamin A, have shown great promise in the inhibition of the carcinogenic process. Several studies have demonstrated that these substances inhibit or delay the development of invasive malignancy in well-defined animal models of epithelial carcinogenesis and that they suppress malignant and phenotypic transformation in culture by chemicals or ionizing radiation. Since natural vitamin A is toxic to animals in large doses, the NCI has supported the synthesis of many new retinoids with modifications in all parts of the molecule in order to develop compounds which exhibit the desired properties. Although not all of these retinoids have been thoroughly tested, various synthetic analogs have been found to exhibit less toxicity while retaining equal or greater effectiveness in the suppression of tumorigenesis.

10% CUT

Question: The February 13 issue of The Cancer Letter, published in Reston, Virginia, quotes you, Dr. DeVita, as saying that while a 10% cut in the cancer budget "would hurt...we can tolerate it. Whatever NIH can tolerate, we can." Does this mean that NCI could tolerate about a $100 million cut from its billion dollar budget? Please explain.

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: What research and other activities would be affected by such a reduction?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Dr. DeVita, you also are quoted as saying: "My fear is being asked to take a bigger cut than NIH." Would you explain what you meant by this?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: I gather from the same article that some members of the National Cancer Advisory Board are in mood to fight any proposals to cut the NCI budget. One is quoted as saying? "We should say now that no cuts are tolerable." What's your comment?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is fowarded to the Congress, we will provide an appropriate answer to this question.

PHASING OUT CONTRACTS

Question: Dr. DeVita, you told a news conference last July 14 that you will move to phase-out the use of research contracts in favor of grants. Is this still your intention? How much money would be saved?

Answer: NCI never intended to completely phase-out research contracts in favor of grants. The contracts vehicle has been and continues to be a useful mechanism needed to support NCI programs. The Institute has used and should continue to use contracts as the mechanism best suited to stimulate major new initiatives, including such efforts as the Biological Response Modifier Program and the Chemoprevention Program. When contracts are used to support basic

research there often comes a time when the effort should be shifted to grants as the field expands. Until recently, the Institute had no good way of monitoring the shifts. There have been considerable reductions in selected areas, most notably reductions in viral carcinogenesis contracts. The phasing down of the research contract efforts has provided the Institute with the ability to redirect the dollars into research supported by the grant mechanism and its peer review system. Through a management initiative in 1980, the Institute has reviewed its contracts - one by one - and determined which ones could no longer be maintained during these times of increased fiscal restraint. This initiative resulted in approximately $25 million worth of effort being redirected within the cancer program.

Question: What prompted your press conference statement on contract phase-outs?

Answer: NCI contracts have over the recent past been a subject of considerable discussion and comment by the community. During this press conference the question concerning NCI contracts again arose. As previously indicated, the Institute determined that some of the contract supported efforts could and must, be converted to grants since further stimulation of certain fields is not necessary.

It was at that time, and continues to be, my belief that certain programs of the Institute had historically placed too much reliance on the contract mechanism for the conduct of basic research, which in my view is more appropriately funded by way of the grant mechanism. This view was buttressed by comments and recommendations made by many advisors and observors both within and outside the Institute. Three factors were perhaps most influential in leading to this judgment. First, when the need is for the conduct of very basic research it is important to be open to the broadest possible source of ideas and approaches. This goal is best met when the entire eligible research community is free to suggest and propose, by way of grant applications, whatever ideas and approaches they feel will best address the problem. This process is in my view unduly restricted when the contract mechanism is employed. Secondly, the dual peer review process through which grant applications are evaluated is a well established, accepted and highly effective method for judging research proposals. Although procedures and policies for the peer review of contract proposals are also highly effective, there has historically been a lower degree of confidence in the outcome of that approach. Thirdly, the monitoring of research conducted under contract is more labor intensive on the part of government than is monitoring grant research, and consequently there is an increase of productivity which has become ever more important as the personnel resources available to us have decreased.

It should be noted that the circumstances that led to the creation of major contract-supported research programs in the early 1960's in many cases has changed and this, too, has strengthed my resolve to make necessary adjustments. I might briefly mention two of those circumstances that have changed. A decade ago Institute management made the judgment that there was inadequate research activity addressing such matters as the role of immunology or viruses in carcinogenesis. The contract mechanism was viewed at that time as

a good means of stimulating research in these fields. After ten years of development, however, there seems to be more than adequate activity and a substantial flow of high quality applications for grant support in those fields. Consequently, one of the primary rationales for contract supported basic research no longer exists. Another factor that led to substantial use of the contract mechanism in the past was the fact that major initiatives could be undertaken very rapidly under applicable contract procedures. This is no longer the case, however, and new program initiatives can now be undertaken no more quickly using the contract mechanism than by using the grants or cooperative agreement mechanisms. So the underlying rationale for basic research contracts is no longer present.

Question: Which programs will have to be modified if you proceed with phase-outs?

Answer: We are already well along in adjusting both the Immunology Program and the former Viral Oncology Program by terminating use of research contracts as work on existing contracts is completed and by utilizing the funds made available from this phase-out to fund grant applications which address similar research needs. Even within major program areas, such as Cause and Prevention Research, there has been significant shifts in emphasis. For example, epidemiology is increasing and biological carcinogenesis is decreasing.

Question: Why drop research contracts - why not simply deal with the weaknesses in contracting procedures, which seem to be at the root of the problem?

Answer: We have taken major strides to address any real or perceived weaknesses in our contracting procedures. Even so, the phase down of the research contract in some areas is necessary. We have initiated major improvements in our planning and review procedures to increase objectivity and to assure the necessity and appropriateness of both new contracts and renewals. We have also greatly accelerated our training programs for contract specialists and project officers and are well along in assuring that all Institute staff with responsibilities in contract management know what is expected of them. To supplement these training programs we have issued instruction manuals for project officers, for the principal investigators who are on the staff of contracting organizations, and for members of contract peer review groups. We have also taken a number of actions to intensify and improve internal audit and monitoring of those employees with contracts management responsibilities. I am confident that as these steps to strengthen our contracting procedures take effect, we will be able to continue using the contract mechanism wherever it is necessary and useful in Institute programs.

There remain major needs for use of the contract mechanism and we intend to use that mechanism for the foreseeable future whenever it is appropriate. For example, the contract mechanism is essential in acquiring services and resources and in the conduct of certain well defined and less basic forms of research. It is also the mechanism of choice when the capabilities and resources of the industrial sector

are required. In our drug development program, for example, the contract is the mechanism of choice for the refinement, development, packaging and distribution of chemicals or biological products that we wish to evaluate for potential anticancer effects. Contracts are also useful in that program for preclinical testing of potential anticancer agents. Another, more visible, need for the contract is in the operation and maintenance of the Frederick Cancer Research Center. There are many other needs for contracts and I expect that we will always use them.

FREDERICK CANCER RESEARCH CENTER

Question: You were quoted in your July press conference as saying that the Frederick Cancer Research Center "is a sore point and a problem we have to deal with." What is the "problem" you refer to?

Answer: I used the word "problem" regarding the Frederick Cancer Research Center (FCRC) in a special way. There are no longer major operating problems at FCRC - it is well run and managed by the contractor. There are no major problems with the research conducted at FCRC - successive peer reviews of the science have resulted in praise for both the quality and innovativeness of the work. The "problem" I referred to is strictly one of how - in the face of tight budgets - can we best utilize a Federal facility that costs approximately $25 million per year to operate under contract. In 1979, this question was addressed by a committee appointed by the Director, NCI. The major recommendation of the committee was to gradually (over a period of five to ten years) change the facility from a predominately contractor to a predominately Federal operation. A special ad hoc subcommittee on FCRC appointed by the National Cancer Advisory Board and the full Board concurred with the NCI decision to move in this direction. The entire Laboratory of Viral Carcinogenesis (approximately 100 plus people) has already moved from off site facilities in the Washington area to Frederick and plans are underway to move additional intramural staff to the facility. In the future recompetition of the FCRC contract effort will be reduced by about 20%. In the immediate future NCI will centralize the direct management of the FCRC - I plan to assign this responsibility within my office under the direct purview of the NCI Deputy Director. Previously each Division separately managed their individual FCRC located program. We believe these changes will bring the FCRC in line with our need for high quality science and fiscal restraint.

Question: What is the status of the Litton Bionetics contract for operating the center?

Answer: The current contract with Litton Bionetics, Inc. will expire in September 1982. The general plan for recompeting this contract has been reviewed by the senior NCI staff, the special NCAB subcommittee on Frederick, and by the full NCAB. The general features of the recompetition are:

(1) With the exception of one component of the contract which will be set-aside for small business, interested contractors will have the option of bidding on the remaining components as one contract or as several contracts.

(2) It is planned to negotiate the total amount of the contract(s) at an appreciably lower level than the current cost.

CANCER CONTROL CONTRACT PROCEDURES

Question: The GAO has criticized the management of four cancer control contracts, saying that NCI did not award the contracts in accordance with departmental contracting procedures or sound management practices. What actions have you taken in response to the GAO's criticisms?

Answer: The General Accounting Office reviewed five selected contracts, or approxiately 1.5% of the contracts of the former Division of Cancer Control and Rehabilitation and cited certain shortcomings in our management of those five contracts. Although we don't believe that the shortcomings cited occurred in many other contracting programs of the Division or of the Institute, nonetheless we have done a number of things to strengthen contracting practices throughout the Institute. As regards cancer control activities in particular, two very major and significant changes have been made. The first was the recent creation of the Division of Resources, Centers and Community Activities (DRCCA), which places cancer control activities in a more appropriate management context, i.e., since cancer control correlates to technology transfer it was decided that these efforts needed to be more closely aligned with the cancer centers program. Both of these activities are now within the same new division. Second is the establishment of a new board of scientific counselors to provide a more rigorous advisory input at both the concept stage and throughout the life of all contracts managed by DRCCA. In addition, we have instituted procedures across the board in the Institute designed to insure more careful attention to the recommendations of peer review committees in the negotiation of contracts and more rigorous monitoring by both contract officers and project officers to give early warning of any shortcomings in the progress of contractors and to make sure that corrective action is taken immediately. As is the case at any time that changes in policies or procedures are instituted, positive results may not be immediately evident. I feel confident, however, that there will be improvement. I should also mention that we have had underway for several months a nationwide search for a permanent Director of the Division of Resources, Centers and Community Activities. A permanent director should be named shortly and I anticipate continuation of the steady improvement in division management following that selection.

Question: What are you doing to make certain that problems are corrected promptly and that the contractors perform the tasks specified in the contracts?

Answer: As mentioned earlier, we have instituted new procedures that will require closer monitoring by contract officers and project officers, more careful attention to evaluating work performance by contractors to assure that effective corrective action is taken in a timely manner. I believe that we are fully aware of the weaknesses in our previous practices and look forward to steady improvement in current and future activities.

PROGRESS ON INTERFERON

Question: In the recent past, there was a good deal of speculation that interferon might be the "magic bullet" to control or cure cancer. Is there still reason to believe that interferon will be as effective as some people think?

Answer: Since the range of opinion as to the effectiveness of interferons is very wide, this question is extremely difficult to answer. It seems best to restrict consideration to the level of effectiveness expected by most scientists and physicians active in interferon research. There is good reason to believe that interferons will have some degree of activity against certain cancers. The preliminary results to date would substantiate that belief since somewhere between one-fourth to one-half of the patients with breast cancer, multiple myeloma and lymphoma have demonstrated some shrinkage in the size of their tumors in response to interferon therapy. Most of these responses have been of short duration (a few months) and have not resulted in complete disappearances of the cancers. However, most of the patients had previously treated malignancies that were unresponsive to standard therapy. Therefore, these initial responses are of interest and are a clear indication of the need to proceed with further studies to define the level of efficacy for the interferons. It should be remembered that the interferons used thus far have been relatively impure preparations. More purified preparations are becoming available and it is hoped that they will be more effective.

Question: Are the results of using interferon any better than using conventional therapy?

Answer: The interferon studies are still very early. Most of the studies that have been done, have been to investigate what the appropriate dose of the interferon preparation might be and to investigate in a preliminary way which kinds of cancer seem to be responding to these preparations. Therefore, it is too early to compare interferon with conventional therapy since it is being used in these preliminary studies primarily in patients resistant to conventional therapy. After the most effective dose of interferon has been identified, then further clinical trials comparing interferon preparations to conventional therapy will be carried out and combination treatment regimes utilizing interferon in addition to conventional therapy as compared to conventional therapy alone will also be initiated.

Question: Should the public temper its expectations for interferon - and should NCI help to cool down expectations?

Answer: The response to this question depends on how one views the level of public expectations. If one believes that the public expects interferon to be a drug with tremendous curative powers, then clearly some tempering of expectations is needed and the NCI should help temper those expectations. However, there is evidence that public expectations have already cooled as more and more clinical data from the interferon trials become available. At this point it appears that the scientific community and the lay community are both waiting and watching to see what the results of further interferon trials will bring. It would be important for the NCI to evaluate carefully and scientifically all the information available on interferon as it becomes available and to inform the public in as straightforward a manner as possible regarding the results of these trials and the expectations for future trials. There does not seem to be any need for the NCI to initiate a dedicated campaign to cool down public expectations at this point.

Question: What is the budget just for interferon research in FY 1981?

Answer: The NCI anticipates that it will spend approximately $5.6 million in research for various types of interferon during FY 1981. Included in this estimate is approximately $1.6 million for the purchase of a sufficient quantity of lymphoblast interferon to initiate clinical trials to evaluate the toxicity and efficacy of this type of interferon. It is expected that about $2.7 million of investigator-initiated research grants involving interferon will also be awarded.

Question: To what extent do you coordinate your interferon research with other NIH Institutes also working with the drug?

Answer: Since the establishment of the Interferon Coordinating Committee, there has been considerable coordination and communication between the different institutes at the National Institutes of Health with respect to interferon research and clinical trials. This committee has been very helpful with regard to keeping each institute informed of the others' activities in the area of grant-supported interferon research and it has provided a forum for the identification of high priority projects to be supported by new grants and contracts. In particular, the cooperation between NIAID and the NCI with respect to the purchase of interferons for clinical trials and with respect to the acquisition of interferon standards (standard preparations of interferon to allow for comparison between laboratories) has been excellent. Continued coordination of efforts between the institutes is anticipated in FY 1982 to avoid any unnecessary duplication of effort and to insure the careful, coordinated use of resources supporting interferon research in clinical trials.

Question: Interferon is known as a "Biological Response Modifier" which alters the body's response to cancer. Are there other such modifiers - and are they proving to be more or less effective than interferon?

Answer: Yes, there are many Biological Response Modifiers in addition to interferon. Currently we know there are over 20 molecular types of interferon alone. in addition, there are many stimulators of immunity, some of which are pharmaceutical agents (drugs), some agents from natural sources (plants, etc.) and others from natural biological sources (cell products). For example, one class of cell products would be the cytokines. There are known to be at least 100 such substances made by our normal cells which can regulate and stimulate the body's immune response. There are other cytokines which may regulate the growth of cancer directly and these "growth factors" may be very useful as anticancer agents. Many other substances such as monoclonal antibodies are Biological Response Modifiers and are increasingly viewed as potential anticancer agents. These cells, which are specifically targeted to kill cancer cells are now potential therapuetic Biological Response Modifiers.

Although there are hundreds of Biological Response Modifying agents in addition to interferon, comparisons have not yet been made as to their effectiveness as anticancer agents in man. The major

focus of the Biological Response Modifiers Program is to investigate these many agents and to compare their relative efficacy as anticancer agents in man.

DRUG DEVELOPMENT

Question: We understand that NCI has incurred substantial costs for testing and developing anticancer drugs that later were marketed by the drug companies which held the patents to the compounds used. To what extent do you have agreements that would require these firms to reimburse NCI for some or all of the expense the Institute incurred for testing the compounds?

Answer: At the present time the NCI does not have agreements with drug companies involving reimbursement for development costs on compounds owned by the companies. Agreements whereby the companies underwrite certain developmental costs, thereby relieving the NCI of a proportion of such costs, have been utilized in the case of drugs developed by the NCI and its contractors. Such agreements also include negotiated sales prices of these marketed drugs, thus insuring a reasonable price to the cancer patient for the first five years of marketing. In addition, the contracts with pharmaceutical companies for development of fermentation products include substantial cost sharing (30-50 percent).

Question: Why don't you arrange for reimbursement?

Answer: The expectation of profit on the part of drug companies for anticancer drugs for years has been so bleak that no reimbursement policy appeared to be worth considering. In recent years, however, as new drugs have been developed that have demonstrated greater sales potential, it becomes more feasible to consider a reimbursement policy as a part of the NCI Drug Development Program and discussions with internal NCI staff and with GAO have been carried out regarding the appropriate procedures whereby such a policy could be implemented.

Question: How much could you recoup from this arrangement?

Answer: If one considers those anticancer drugs in which the NCI played a significant role in terms of testing and development, total sales for 1979 are estimated at approximately $70 million. This compares with total anticancer drug sales of about $140 million and total drug sales of $9.6 billion. Using the normal royalty for patents as a reasonable guidepost, one would expect that recoupment might involve $2 to 3 million, not considering the cost that the management and auditing of such an arrangement might involve. It should be pointed out that half of the total U.S. sales of $70 million is represented by one drug, Adriamycin, while the majority of the balance of drugs had sales of $1 million or less.

Question: Why not encourage the drug companies to do the testing and development themselves?

Answer: The NCI does, indeed, encourage drug companies to carry out as much of the development of anticancer drugs as possible.

The NCI program was initiated in 1955 because of the need to develop new anticancer drugs and the unwillingness of the pharmaceutical industry to pursue the problem aggressively because of the relatively poor profit potential. As new drugs are developed and the overall progress in chemotherapy improves, we believe that companies will be more willing to underwrite more of the development costs. However, the initial "risk capital" needed to discover and carry out the early developmental work on anticancer drugs will probably not be an area companies will be willing to underwrite at any time in the foreseeable future. Once a drug has been demonstrated to have some preliminary utility, the companies are certainly eager and willing to participate. The NCI staff makes every effort to encourage that participation on both financial as well as other bases.

THE ISSUE OF PRUDENT DIET

Question: There seems to be a difference between NCI and the National Academy of Sciences as to what constitutes a prudent or healthful diet. You both agree on maintenance of ideal body weight and reduction in total fat. But while you suggest increasing fiber intake, the Academy does not mention this. It talks instead about reducing the intake of saturated fats, salt and alcohol. What is your comment on this? Who's right?

Answer: The NCI statement presented to the Subcommittee on Nutrition, Senate Committee on Agriculture, Nutrition and Forestry on October 2, 1979 carefully points out that although there are many interesting associations no direct cause and effect relationship has been observed for diet and nutrition as related to cancer in humans. The Report of the National Academy of Sciences (NAS) entitled, Toward Healthful Diets, also reaches this conclusion and points out NCI's acknowledgment of this state of scientific knowledge. The NCI statement proceeds to point out that even with the incomplete evidence at hand, it appeared prudent to provide certain advice related to diet and nutrition and the incidence of cancer.

This advice included the following points:

- maintenance of ideal body weight
- decrease in total fat intake
- increase in dietary fiber
- intake of a well-balanced diet should not require supplementation with vitamins and minerals
- moderation in alcohol intake

These principles are consistent with a nutritious well-balanced diet.

The Report of the NAS concludes its section on cancer by saying, "Clearly a nutritious diet providing adequate amounts of all nutrients and the proper energy content to achieve desirable weight is important for general health and for rigorous defense mechanisms against cancer as well as other diseases." The final conclusions and recommendations of the NAS report are quite similar to NCI's principles and advice. Therefore, we do not believe the statements of the NAS and the NCI are significantly divergent. Both stress the incomplete scientific evidence currently at hand related to diet,

nutrition and cancer incidence, and the need for a nutritious, well-balanced diet to maintain ideal body weight. Salt intake is related to hypertension and its role in cancer is unproven.

Question: Have you considered any changes in your prudent diet principles in light of the Academy's recommendations?

Answer: At present, the NCI does not intend to change its October 2 statement. However, it has requested an independent, indepth state-of-the-art assessment by the NAS Assembly of Life Sciences to examine the broad question of the role of diet and nutrition on the incidence of cancer. The report of this extensive study will be available in about eighteen months. Appropriate changes in our current statement will be made upon receipt of that report or significant new information generated from research studies now underway.

Question: How important is fiber intake to preventing cancer?

Answer: There is preliminary evidence that low fiber intake may increase the risk of colorectal cancer, but the precise relationships are unclear. The fiber may act through various mechanisms including dilution of fecal contents, alterations in intestinal flora or increase in transit time of intestinal contents through the colon. Some investigators have noted that foods high in fiber, such as fruits and vegetables, also contain high levels of certain micronutrients (e.g., Vitamin A) or indole compounds that can inhibit carcinogenesis in laboratory animals. The risk of eating diets with high fiber content, at present, would appear to be negligible. Therefore, while we have no definitive information on the role of fiber in preventing cancer of the colon, it appears prudent to have diets contain generous amounts of fiber-containing foods. The NAS also recommends appropriate amounts of vegetables, fruits, cereals and breads (foods which are high in fiber content) similar to NCI's advice.

Question: What research priorities have been identified for NCI in regard to diet and cancer in the coming year?

Answer: The research priorities for the NCI in diet and cancer for the coming year are:

- Epidemiologic and multidisciplinary studies to clarify the role of dietary fat, fiber, micronutrients, trace elements, caloric excess, food additives, alcohol and contaminants of drinking water.
- Continuation of studies to determine the chemical and molecular mechanisms of cancer induction by a variety of dietary constituents, e.g., mycotoxins, nitroso compounds, fiber, fat, protein, alcohol, compounds associated with the gut including bile acids/fecal steroids and the influence of fecal microflora.
- Studies of the mutagenicity of various diets including the influence of food processing and cooking.
- Studies of the carcinogenicity or inhibition of carcinogenesis in naturally occurring food products.
- Studies of the bioavailability of micronutrients and their role in diet, nutrition and cancer.

- Increased efforts in metabolic epidemiology to characterize differences in dietary habits and life style which may alter physiologic patterns.
- Examination of the influence of nutrients on carcinogenesis and cancer prevention, i.e., vitamin A, vitamin C, vitamin E, selenium.
- Effects of nutrition on immune function.
- Studies to identify biological markers that accurately reflect past dietary intake.
- Studies on the assessment of nutritional status of the cancer patient.
- Studies on the mechanisms of anorexia/cachexia of cancer patients.
- Studies of the role of nutritional supplementation in the treatment of cancer patients.

CANCER IN BLACKS

Question: We see statistics indicating that while some 42% of white males survive cancer of the rectum for at least five years after diagnosis, the comparable figure for blacks is only 19%. Why the disparity between the races? Why can't we do better for black people?

Answer: Part of the disparity in survival rates between black males and white males with cancer of the rectum is accounted for by a lower proportion of blacks being diagnosed while the disease is localized (34% for black males vs. 48% for white males). Those whose rectal cancer is diagnosed while the disease is localized have a better prognosis than those whose disease is more advanced. For localized disease, the five-year survival rate is 69% for white males vs. 51% for black males. Part of this difference is undoubtedly due to a lower socio-economic level among the black males for whom these survival rates were derived compared with that of the white males.

HOSPICE CARE

Question: Under Cancer Control you have been evaluating care for those dying of cancer - care through hospices and other means. What do your evaluations indicate are the best forms of care for the terminally ill?

Answer: NCI has carried out a study of three hospices designed to describe the physiological and psychosocial functioning of patients and family members, to document the utilization of services by the patient, to estimate costs and services in each of three hospice settings, and to characterize the paid and volunteer staff who provided hospice care to the patients and family members. A report on the results of this study should be available by late summer or early fall 1981.

Question: Do terminally ill cancer patients do better at home or in a hospice?

Answer: There is no clear cut answer to this question. If patients' care is kept comfortable they prefer home care if not, they

often prefer to take the burden of care off their family and be admitted to a hospital. The NCI study involved three hospices that provided a combination of home and inpatient care. The results, therefore, do not bear on this question.

Of the 128 established U.S. hospices, who are members of the national Hospice Organization, 125 provide hospice services in the home. Sixty-seven hospices also provide a combination of home care and inpatient hospice services in either a free-standing facility, a hospital or in an extended care facility. Fifty-eight hospices provide only home care services and three hospices provide only inpatient care.

Question: How much are you devoting to hospice evaluation and research?

Answer: From FY 1977 to FY 1980, NCI spent about $4.5 million on hospice evaluation and research. These projects are now completed, and the data are in the process of being analyzed.

TRAINING SUPPORT FUNDS

Question: Dr. DeVita, you are quoted in U.S. Medicine of last August as saying that the 1981 training budget level threatens cancer and other biomedical research and you warn against a policy in 1982 providing for no new training starts. In fiscal 1981 Congress provided some $183 million for all NIH training. In the Carter budget for FY 1982 this increases to $192 million, but with an increase for individual awards of less than $5 million. What is your appraisal of the current and proposed funding for research training?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Are you as concerned today as you were last August?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

TREATMENT OF NAUSEA

Question: Last summer, the Food and Drug Administration agreed to permit THC - the active ingredient in marijuana - to be used for treating the nausea associated with chemotherapy. What has been the result of this step?

Answer: The NCI's distribution of THC to assist in ameliorating the nausea and vomiting resulting from cancer treatment has been carried out as a part of its Group C drug distribution program. This portion of the NCI's distribution scheme rests on a memorandum of understanding between NCI and the FDA which states that drugs which show a clear and reproducible pattern of efficacy in the

treatment of cancer, or its related symptoms, are made widely accessible under the scope of general guidelines. Those who request the drug are required to be registered with the NCI and are obligated to report any adverse reactions resulting from the drug's use. The NCI, in turn, must notify the FDA of the adverse reactions and take appropriate actions, but the NCI is not required to supply further efficacy data for individuals or groups of patients. This mechanism has served the objective of making available to the general public of cancer patients important advances in the treatment of cancer as rapidly as possible. This mechanism bridges the gap until a new drug application (NDA) is approved and the drug is placed on the market.

Question: To what extent can doctors get THC for the treatment of their patients?

Answer: Unlike the anticancer drug Group C program, the THC program has some unique differences. Because THC remains in Schedule I, the NCI chose to distribute the THC to hospital pharmacies rather than individual physicians. Hospital pharmacies generally have the necessary security and record-keeping facilities to handle scheduled compounds. Each pharmacy participating in the program must have a Schedule I license. Obtaining the licenses for the participating pharmacies has been greatly expedited by the cooperation of Drug Enforcement Administration officials. Under the Group C program at the current time, there are in excess of 1,000 registered physicians and 500 pharmacies participating. As of February 6, 1981, the NCI had shipped or authorized for shipment in excess of 180,000 capsules of THC.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier reponses.]

FUTURE OF NATIONAL TOXICOLOGY PROGRAM

Question: What is the status of the National Toxicology Program which you recommended be transferred to the Environmental Health Institute?

Answer: The National Toxicology Program is actually an inter-agency organization to which the NCI, NIEHS, FDA, and NIOSH contribute resources. The Executive Committee which consists of the heads of NIH, NCI, EPA, FDA, CPSC, OSHA, NIOSH, and NIEHS, provides guidance to the Director of the NTP, Dr. David Rall, who also serves as Director of the NIEHS. The Executive Committee is also responsible for approving the NTP Annual Plan, as well as the chemicals to be tested by the Program. The contributing agencies have identified programmatic resources which include facilities, personnel, and funding all of which are subject to oversight and direction by the Director, NTP. Total funding in FY 1979 was $40.9 million and in FY 1980 was $68.8 million. In both years the contribution by the National Cancer Institute has been by far the largest of all agencies, totalling nearly $22 million in FY 1979 and $43 million in 1980. Early last year NCI concluded that it would be more effective to consolidate these resources and the management responsibilities of NTP within NIEHS. Following approval by Dr. Fredrickson, discussion and endorsement by the National Cancer Advisory Board, the two Institutes undertook negotiations leading to agreement on the parameters of the organizational consolidation. It is my understanding that the necessary paperwork to effect the organizational transfer has been

presented to the Public Health Service and upon approval will be forwarded to the Secretary for final decision. Upon approval by the Secretary, we would anticipate that the transfer could be completed before the start of FY 1982. NCI will continue to be represented on the Executive Committee and provide advice on the evolving Federal role in chemical testing.

NUTRITION AND CANCER

Question: How much are you spending on nutrition research in fiscal 1981 - and how much do you propose to expend in FY 82?

Answer: In FY 1981 the Institute will obligate approximately $15.2 million for nutrition research. Nutrition related research in carcinogenesis, tumor biology, epidemiology and rehabilitation as well as nutrition-related training increase the estimated obligations to $28.4 million. For FY 1982, the levels are $19.6 million and $29.0 respectively.

CANCER CONTROL

Question: Are certain activities under the cancer control program being phased out? Which ones?

Answer: In 1982, no programs are being phased out. However, increased emphasis will be placed on applied prevention activities. For example, the Breast Cancer Detection and Screening program supported in previous years as a treatment activity will move into the follow up phase as a prevention activity.

Question: If so, to what extent can the appropriations for the cancer control program be reduced for FY 82 to reflect the elimination of these activities?

Answer: The FY 1982 request is a slight increase over the FY 1981 level. These funds are deemed necessary in order to enhance the redirection of the program toward the planning and implementation of applied prevention activities. Elimination of additional activities are not included in the FY 1982 request.

10% Cut

Question: The February 13 issue of the Cancer Letter published in Reston, Virginia, quotes you, Dr. DeVita, as saying that while a 10% cut in the cancer budget "would hurt...we can tolerate it. Whatever NIH can tolerate, we can." Does this mean that NCI could tolerate about a $100 million cut from its billion dollar budget? Please explain.

Answer: The quote referred to was in response to a rhetorical question. It is possible that NCI could sustain a reduction of such magnitude, however I do not mean to imply that it would be a pleasant task, but if the economic situation dictates it, we are prepared to further examine the budget at any time and make the necessary reductions.

Question: What research and other activities would be affected by such a reduction?

Answer: If we had to absorb a $100 million reduction, the reductions would include existing cancer centers, some of which would be terminated; the organ site program would be cancelled; a radical reduction in research programs would be required, including a major portion which is supported through investigator-initiated research grants; and resource contracts that provide materials to the scientific community would be reduced. Funds allocated to the National Toxicology Program would also be eliminated or drastically reduced.

Question: Dr. DeVita, you also are quoted as saying: "My fear is being asked to take a bigger cut than NIH." Would you explain what you meant by this?

Answer: The point I made is that we're always a little bit concerned that because we are the largest Institute on the NIH campus, we might appear to be an attractive source of reductions that may be disproportionate to the rest of NIH. The percentage of the NCI budget relative to the total NIH budget has already been decreasing since 1976.

Question: I gather from the same article that some members of the National Cancer Advisory Board are in the mood to fight any proposals to cut the NCI budget. One is quoted as saying: "We should say now that no cuts are tolerable." What's your comment?

Answer: This, I think, is a normal response from the community - both lay and scientific - that is interested in cancer research. They recognize that scientific opportunities exist for exploitation and feel a need to be sure that the appropriate constituency is aware of these opportunities. The Institute recognizes that inflation impacts on the biomedical research community just as much as it does on the rest of the nation's economy. If the inflation trend is reversed and we do see a declining rate, the biomedical community will profit also. Based on the current economic situation we feel that the Cancer Program has been given a fair share of available government resources.

TRAINING SUPPORT FUNDS

Question: Dr. DeVita, you are quoted in U.S. Medicine of last August as saying that the 1981 training budget level threatens cancer and other biomedical research and you warn against a policy in 1982 providing for new training starts.

In fiscal 1981 Congress provided some $183 million for all NIH training. In the Carter budget for FY 1982 this increases to $192 million, but with an increase for individual awards of less than $5 million. What is your appraisal of the current and proposed funding for research training?

Answer: Support for biomedical research training must be considered in the larger context of support for biomedical research. There should be a linkage between support for training and support for research. It would not be prudent to train large numbers of researchers if sufficient funding to support their investigations after they are trained is not anticipated. If research support is to decrease, training support should also decrease. Fluctuations in the level of training support, however, should not be so abrupt as to discourage potential trainees or eliminate the pipeline of new people entering the system.

Effective training programs cannot be sustained in the absence of new trainees. Once disbanded, the critical elements for a good training program are not readily reassembled, and I therefore am still concerned about any policy that does not provide for new training starts. The revised budget request contains funds sufficient to support 1,358 full time equivalent trainees, only a slight reduction from preceding years.

Question: Are you as concerned today as you were last August?

Answer: Yes, the same concerns exist today regarding the training issue as last August.

MAINTAINING NEW RESEARCH GRANTS

Question: The fiscal 1982 budget continues to emphasize the stabilization of new, investigator-initiated research grants for NIH at 5,000. How much funding will you need in fiscal 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NCI share of that amount is $104,751,000 and 766 grants.

Question: How is inflation impacting -- or how will it impact -- this goal? What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new research grants regardless of other budget priorities within NIH?

Answer: The stabilization of research projects has always been one of our highest priorities. The best way to foster investigations in basic science is to assure some degree of stability. Until we know enough about the disease process we are forced to continue dealing with halfway technology. Therefore it is essential to maintain our investment in basic research. While stabilization is important there must be some flexibility allowed so that a fixed number of grants does not become sacrosanct. As the total budget level for the Institute fluctuates that level of support provided to research project grants must also be allowed to fluctuate, while still maintaining research project grants as one of the highest priorities.

Question: What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: The Institute would be very concerned and cautious to ensure that only the highest quality research is supported. In a given year the priority score through which the Institute is capable of funding can fluctuate depending on available funds and

scientific merit. We must always be conscious that a proper program balance is maintained.

Question: To what "payline" will you fund new and competing grants in fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: In FY 1981 the Institute projects funding research project grants to a priority score of approximately 190. This will provide for funding of 31% of approved competing research projects. FY 1982 estimates a priority score of 190 with a funding rate of 29%.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January, we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities, research and development contracts, cancer control, construction, and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justification recently submitted to the Congress have attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major activity.

National Heart, Lung, and Blood Institute

STATEMENT OF DR. ROBERT I. LEVY, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. PETER L. FROMMER, DEPUTY DIRECTOR,
JOHN H. REEDER, BUDGET OFFICER
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

INTRODUCTION OF ASSOCIATES AND PREPARED STATEMENT

Senator SCHMITT. Our next witness is Dr. Robert I. Levy, Director of the National Heart, Lung, and Blood Institute.

The Institute has the responsibility for coordination of research in heart, blood vessel, lung, and blood diseases in the United States.

Dr. Levy, we welcome you and ask, in the interests of time again, that you highlight your opening statement, and we can proceed to questions.

Please introduce your associates.

Dr. LEVY. Thank you, Mr. Chairman.

On my left is my Deputy Director, Dr. Peter Frommer.

To his left is my Budget Officer, Mr. John Reeder.

I am pleased to submit my statement for the record.

[The statement follows:]

STATEMENT OF DR. ROBERT I. LEVY

I appreciate the privilege of appearing before you once again to discuss the status of heart, lung, and blood diseases in the United States. We meet at a time when cardiovascular diseases are the leading cause of death in our country. However, we also meet during a period which has been characterized by a dramatic decline in the number of deaths caused by heart attack and stroke.

The activities of the past year have been encouraging in that continued progress has been amply evident. They have also been challenging, in that they have underscored the magnitude of the problems we face.

Magnitude of the Problem

Diseases of the heart and blood vessels account for more than 50 percent of all deaths in the nation each year. There are over 600,000 deaths from heart attacks every year and 175,000 stroke deaths. Chronic obstructive pulmonary diseases, emphysema, and bronchitis accounted for almost 50,000 deaths last year. While deaths attributed to blood diseases are considerably smaller in number, blood related problems affect all processes of the body. Sickle cell anemia, one blood disease of particular concern, affects nearly 50,000 Black Americans.

In terms of economic costs, the diseases addressed by the Institute total more than $72 billion annually, with diseases of the heart and blood vessels representing.over $50 billion.*

Progress is being made, however. During the past decade, we have seen a decline of 25 percent in the number of heart attack deaths and a 37 percent drop in the number of stroke deaths. On the other hand, during this time, chronic obstructive pulmonary disease deaths have increased by 22 percent, thereby representing the most rapidly increasing of the top ten causes of death.

Let me share some of the highlights of the past year with you.

Hypertension

During the past year, the Institute was given the Albert Lasker Special Public Health Award for our Hypertension Detection and Follow-up Program, or HDFP, a clinical trial involving 11,000 volunteer patients. HDFP demonstrated that through vigorous, systematic treatment of high blood pressure, premature death could be reduced among hypertensives by 17 percent. It also demonstrated--for the first time--that individuals with so-called "mild" high blood pressure could have 20 percent lower mortality if they received the type of care given in the clinical trial. In its citation, the Lasker Award said that HDFP "is a demonstration of the most dramatic reduction in the national death rate since the introduction of penicillin, and shows that the treatment of mild hypertension should become universal throughout the world."

* Public Services Laboratory, Georgetown University, Costs of Illness, FY 1975.

Another major finding of HDFP was that Blacks--who are much more susceptible to high blood pressure--could benefit at least as much as Whites when receiving effective treatment and control.

The cost of this multi-year major clinical trial was approximately $70 million, authorities agree that as its lessons are applied there will be a return, based on lives saved and illness averted, that will be measurable in the billions. Estimates have already been made that from 60 to 80 thousand additional lives may be saved each year if the lessons of HDFP are applied. However, applying the lessons of HDFP will also likely mean millions more Americans on daily medication, which further underscores the need to pursue research into the basic causes of hypertension and to conduct studies to determine the role of non-drug therapy, such as weight reduction, salt restriction and exercise, in the control of high blood pressure.

Arteriosclerosis

Another major clinical trial of the Institute is the Lipid Research Clinics Coronary Primary Prevention Trial, which is designed to answer an extremely important question: does lowering blood cholesterol levels actually help prevent heart disease. Begun in the early 1970's, this program, at a cost of over $10 million a year, will be concluded between 1982 and 1983.

Most of the questions concerning cholesterol and heart disease have focused on low density lipoprotein-cholesterol or LDL-cholesterol. Relatively little attention has been given high-density lipoprotein cholesterol, referred to as HDL. During the past year, studies from our lipid research program have provided new evidence regarding HDL, evidence which confirms that lower levels of HDL are associated with more heart disease while higher levels of HDL are associated with less heart disease. These studies also demonstrated that moderate amounts of alcohol and physical activity tend to raise HDL levels while smoking and obesity tend to lower such levels. We still have to learn, however, about how HDL works in the body and whether changes that raise HDL levels actually lower a person's risk of cardiovascular disease or heart attack. Indeed, there are a number of questions concerning heart disease and cholesterol which remain unanswered. For example, epidemiological studies sponsored by the Institute have suggested that very low levels of cholesterol may be associated with an increased risk of noncardiovascular disease, particularly cancer. At this time, however, this evidence is not anywhere as strong as the evidence which suggests that high levels of cholesterol are associated with an increased incidence of heart disease.

Coronary Artery Bypass Surgery

The Coronary Artery Surgery Study is another clinical trial of the Institute, this one designed to compare surgery with medical (non-surgical) management of patients with coronary heart disease. The importance of this trial, due to conclude in 1983, was illustrated at a recent NIH Consensus Conference. This type of conference involves biomedical researchers and medical practitioners who come together to assess and reach agreement, when possible, on specific methodologies. Specialists from around the country concluded that more factual information is still needed to provide physicians more accurate and useful guidance in order for them to determine when a patient is a likely candidate for bypass surgery,

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i.e., when it will extend and/or improve his or her life. The information to be derived from the Coronary Artery Surgery Study will be of significant help in making this determination.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

A new technique called percutaneous transluminal coronary angioplasty (PTCA) represents a potential alternative to bypass surgery in approximately five percent of surgical candidates. In this procedure, a balloon tipped catheter is passed through the blood vessels to the site of the obstruction in the artery. The balloon is then inflated to compress the obstruction against the blood vessel wall, allowing the blood to flow at an increased rate. This procedure may lead to a less hazardous and less expensive method of treating patients who would otherwise be surgical candidates. Our experience with this technique is limited, and its long term benefits still need to be assessed. NHLBI has established a registry to facilitate further evaluation of this procedure.

Other highlights in the area of cardiovascular diseases for the past year include the continued progress in the development of new calcium channel blocking drugs like Nifedipine and Verapamil which show great promise in the treatment of arrhythmias (any variation from the normal rhythm of the heartbeat), coronary artery vasospasm (spasm of the coronary artery), cardiomyopathies (diseases of the heart muscle), and high blood pressure. Also, dramatic advancement was noted in noninvasive diagnostic techniques with the use of computer technology, ultrasound (echocardiography) and radionuclide procedures, which provide safer, more economical, and more sophisticated means of detecting and following congenital, rheumatic, and coronary artery disease.

Lung Diseases

As indicated earlier, the incidence of chronic lung disease is on the rise and respiratory diseases today represent the most frequent reason why people seek a physician's attention. They also account for more lost workdays than any other illness. However, even in this area, there is promise.

Emphysema

After ten years of fundamental lung research, we now have a much better understanding of the mechanisms of lung damage which cause emphysema. The disease is characterized by the destruction of elastin, a major structural protein of the lung. Essentially, the imbalance of two groups of enzymes, the proteases which break down elastin and the antiproteases which inhibit this breakdown is responsible for this dread disease. Recent research by the Institute indicates that inhalation of tobacco smoke exacerbates this situation. The Institute is now supporting investigations attempting to increase lung protection against these proteases. One area of promise is the intravenous adminstration of concentrated alpha-1-antitrypsin, a natural antiprotease obtained from normal plasma. This approach has allowed the maintenance of "protective" levels of antiprotease activity in individuals who have a genetic alpha-1-antitrypsin deficiency.

Oxygen Therapy

Victims of chronic obstructive lung disease usually have an oxygen deficiency leading to such complications as lung irritability, an increase in the number of red blood cells, and elevated pressures in the pulmonary artery. These complications can often be overcome to some extent by utilizing oxygen therapy. Until the completion of an Institute clinical trial this past year, there was a growing belief that 12hour night-time oxygen therapy could be as effective as continuous oxygen therapy. The clinical trial demonstrated that the life of patients was extended if continuous oxygen therapy was applied rather than 12-hours of oxygen daily. These findings hold considerable significance for the approximately 500,000 Americans suffering from chronic obstructive lung disease.

Blood Diseases

Last year, I discussed the etiology and regulatory aspects of certain anemias. This year, I would like to stress some treatment accomplishments in the area of blood diseases.

Pulmonary Embolism

Two thromboembolic complications of heart and blood vessel diseases are deep-vein thrombosis (clotting) and pulmonary embolism (blockage) which are usually treated with anticoagulants, such as heparin. It has now been noted that the fibrinolytic drugs urokinase or streptokinase are safe and effective if the patients are properly chosen (specifically, when the patients are treated shortly after the thromboembolic episode) and when the drugs are used in conjunction with anticoagulants. Properly used, fibrinoloytic therapy represents a significant advance in the management of proximal deep-vein thrombosis and the more severe forms of pulmonary embolism. In addition, these agents may allow for the more effective treatment of acute coronary artery occlusions.

Blood Substitutes

Blood transfusion is frequently required to maintain adequate oxygen transport and to restore blood volume following hemorrhage from trauma or disease. At times when donor blood stores are depleted or when larger quantities of typed or cross-matched bloods are needed, the availability of nonantigenic blood substitutes would be of great value. While different fluids have been used successfully in the past for plasma volume expansion, restoration of oxygen transport by these substances has been unsuccessful. Two years ago, I reported to this Committee the development of synthetic "perfluorochemicals" for use as blood substitutes. Recent studies of isolated organ systems have shown that normal or near normal brain, heart, lung, and kidney function can be maintained with the use of these substitutes. Intact animal studies have shown these perfluorochemicals can support life under conditions of partial or complete blood replacement. More recent use of these perfluoro-chemicals as artificial blood substitutes in human patients has been very encouraging. These substances have the potential for improving the efficacy and efficiency of blood replacement programs while improving the cost effectiveness of patient care.

Cooley's Anemia

Patients with severe forms of anemia require frequent blood transfusions to replace depleted red blood cells. These repeated transfusions, however, cause iron to accumulate, thereby damaging vital organs. Recently, iron binding drugs have been administered to reduce this deleterious effect. New techniques have now been found to safely increase the dosage of these iron chelators and a new technique involving the transfusion of only the youngest red cells from donor blood has been tested. The use of neocytes (or young red blood cells) prolongs the effect of each transfusion and thereby decreases transfusion frequency and iron accumulation. This, in turn, can result in less damage to vital organs and prolongation of life. The central tool in this procedure is a continuous flow cell separator, standard equipment in blood banks performing plasmapheresis.

Prevention, Education and Control

Progress continues to be made in the Institute's commitment to effectively translate and transfer the fruits of our research to both the practicing medical community and to the public. One area which has been given considerable attention during the past year is disease prevention and health promotion at the worksite. The Institute has provided data, technical assistance and/or educational materials to a growing number of businesses and unions. As a result of collaborative efforts, many companies have implemented or are planning to implement new initiatives, such as high blood pressure control programs for their employees. Among the companies the Institute has worked with are General Motors, Boeing Aircraft, Bethlehem Steel Corporation, Ford Motor Company, and the Westinghouse Corporation. Many insurance companies, including Blue Cross/Blue Shield and Travelers, are not only initiating programs for their own employees but, with assistance from the Institute, are developing disease prevention programs for their group subscribers as well.

In conclusion, Mr. Chairman, I have provided some highlights and accomplishments, discussed a few issues, and outlined some questions that still need to be answered as we continue to pursue the Institute's ultimate goal of: the prevention of heart, lung, and blood diseases in the United States.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute

NAME: Robert I. Levy, M. D.

POSITION: Director, National Heart, Lung, and Blood Institute

BIRTHPLACE AND DATE: Bronx, New York - May 3, 1937

MARITAL STATUS: Married, 4 children

EDUCATION: June 1953 - Graduated from Bronx High School of Science; 1957 - B. A., Cornell University - highest honors and distinction in Zoology; 1961 - M. D., Yale University - cum laude

EXPERIENCE:

1961 - 1962	Intern in Medicine, Yale - New Haven Medical Center, New Haven
1962 - 1963	Assistant Resident in Medicine, Yale - New Haven Medical Center
1963 - 1966	Clinical Associate, Section on Molecular Diseases
1965 - 1966	Chief Resident, National Heart Institute
1965 - present	Attending Physician, Molecular Disease Branch
1966 - 1968	Attending Physician, Georgetown University Medical Division, District of Columbia General Hospital, Washington, D. C.
1966 - present	Head, Section on Lipoprotein Metabolism and Intervention, Molecular Disease Branch
1969 - 1973	Chief, Clinical Service, Molecular Disease Branch
1970 - 1974	Chief, Lipid Metabolism Branch, DHVD
1973 - 1975	Director, Division of Heart and Vascular Diseases
1975 - present	Director, National Heart, Lung, and Blood Institute
1975 - present	Coordinator for cardiovascular portion of US/USSR Agreement in Health and Medical Sciences
1975 - present	Chairman, National High Blood Pressure Education Program Coordinating Committee
1975 - present	Chairman, Interagency Technical Committee
1978 - present	Member, Advisory Council on Education for Health, Clearinghouse on Corporate Social Responsibility
1978 - present	Panel Member of the WHO Advisory Panel on Cardiovascular Diseases (World Health Organization)
1979 - present	Member, Advisory Committee for the Division of Health Promotion and Disease Prevention, Institute of Medicine

ASSOCIATION MEMBERSHIPS:	American Society for Clinical Investigation; American Institute of Nutrition; American Federation for Clinical Research; American Heart Association Council on Arteriosclerosis; New York Academy of Sciences; American Society for Clinical Nutrition; American College of Cardiology; American Society for Clinical Pharmacology and Therapeutics; Association of American Physicians; Academy of Behavioral Medicine; Institute of Medicine of the National Academy of Sciences.
SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS:	Kees Prize Research Thesis, Yale University, 1961; Alpha Epsilon Delta (premedical); Alpha Omega Alpha; Phi Beta Kappa; Sigma Xi; Arthur Flemming Award, 1975; DHEW Superior Service Award, 1975; Humanitarian Award, Associated Health Foundation, 1976; American Association for Clinical Chemistry Award, 1979; Donald D. Van Slyke Award for Clinical Chemistry, 1980; Author or Co-Author of approximately 225 publications; Editorial Board, Dialogues in Nutrition, and the American Heart Journal.

HEART, LUNG, AND BLOOD DISEASES RESEARCH SPECTRUM

Dr. LEVY. Perhaps for the sake of time I will highlight some of the accomplishments in the areas for which we have responsibility—heart, lung, blood diseases, and research into the management of our blood resources. We view our activities as part of a broad spectrum of continuous biomedical research activities from knowledge acquisition—the traditional and basic concern of NIH—to knowledge validation—clinical trials to validate research hypotheses—to a third part of the spectrum which was mandated by the National Heart, Lung, and Blood Act of 1972, that of transferring validated knowledge as expeditiously as possible to the health care community.

In fact, Mr. Chairman, we think of all of this as an ordered process, designed to ultimately reach our overall goal of preventing disease.

Now, you asked Dr. Fredrickson a question earlier about targeting or evaluating the impact of our efforts. When it comes to basic knowledge acquisition, the outcome of research grants—which we support as a major endeavor—is often so speculative that it is difficult to use the kinds of evaluative factors that we can more readily apply when looking at validation and dissemination activities.

Before we consider initiating any clinical trial, we consider issues like the state of the science and how rapidly it's developing. We consider issues like the potential impact of the results of that trial, the impact on research, and the impact on health care. We consider ethical issues as well as the issue of feasibility along with strategies for effective dissemination.

When it comes to knowledge transfer, the number of people one can affect by the transmission of particular data or information obviously plays a large role in our considerations.

KNOWLEDGE ACQUISITION

Now, as an example, in the time we have remaining, let me just highlight one example of knowledge acquisition, another example of knowledge validation, and a third example dealing with dissemination and transfer.

For knowledge acquisition, let me turn to the example of chronic obstructive lung disease. Some 9 million are affected—2 million with emphysema, 7 million with chronic bronchitis. The disease is now the fifth leading cause of death, causing up to 50,000 deaths a year, and increasing almost more rapidly than any other substantial cause of death.

Through basic research, we've learned the basic mechanism and causation of this disease. We've learned that it appears to be an imbalance between the enzymes that break down the elastic skeleton of the lung and enzymes that break down or inactivate these destructive ones.

This information now allows us to explain why the disease emphysema occurs so commonly in smokers. We now tend to understand why smokers have this problem and how cigarette smoking affects this delicate enzyme balance.

We can also understand why a rare familial disease, alpha-1 antitrypsin deficiency, results so often in emphysema.

Not only does this new knowledge give us information as to basic causation, it gives us promise for new approaches to the detection, diagnosis, and treatment of the disorder. We can now measure breakdown products, demosine, in the urine, in the sputum, and in the blood of individuals at risk for emphysema and determine the activity of the disorder.

In the area of knowledge validation and knowledge transfer, I'd like to highlight just one of our activities: a clinical trial, which was completed a year ago, the hypertension detection and followup program. For that trial, the Institute received the Lasker Foundation public service award this past November.

KNOWLEDGE VALIDATION

This is a trial, Mr. Chairman, that cost some $65 million over the previous 8 years. Before that trial was begun, we knew of the benefit of treating moderate and severe hypertension in middle-aged men in a hospital setting. We did not know that treatment of mild hypertension in a community setting provided more benefit than risk, or whether blacks could be treated as effectively as whites, women as well as men, young as well as old.

The findings of that trial, which were released last year, gave us the information of the benefits of treating mild hypertension. There was a 20 percent reduction in mortality for those with mild hypertension who were treated systematically, compared to those receiving typical or routine care.

And, Mr. Chairman, some 40 million Americans have mild hypertension. There was a 45-percent reduction in stroke, and a 46-percent reduction in acute heart attack mortality among those receving systematic care.

Mortality in blacks from this study was reduced by 24 percent, destroying the myth that hypertension in blacks is somehow more difficult to control than in whites.

Through aggressive treatment and followup, the incidence of stroke, new stroke, was decreased by some 50 percent. There was also a significant decrease in the amount of left ventricular enlargement that occurred among those receiving systematic care.

In other words, Mr. Chairman, this study showed that we could increase the quality as well as the length of life. And it's been estimated that this trial, which cost us some $65 million over 8 years, will more than repay itself in the number of lives saved as well as the billions of dollars saved in the next several years.

KNOWLEDGE TRANSFER

Now, going on to knowledge transfer. In 1972, while this trial—the hypertension detection and followup program—was just getting underway, we were given the charge from the then-Secretary of Health, Education, and Welfare, Elliot Richardson, to coordinate the national high blood pressure education program. This program was designed to get out to the practicing physician, the health professional, and the public, the information that was available then about the treatment of moderate and severe hypertension.

We coordinate this program, but it is a program in which the private as well as the Federal sector actively participate.

We coordinate the private sector through our National High Blood Pressure Coordinating Committee that I chair and which includes such private sector organizations as Citizens for the Treatment of High Blood Pressure, the American Heart Association, the National Kidney Foundation, and others who are in a position to impact on the problem.

We also interact with Federal agencies through an interagency technical committee, created by the National Heart, Lung, and Blood Act of 1972, to enable us to exchange and coordinate all information related to heart, lung, and blood diseases.

Through the National High Blood Pressure Education Program Coordinating Committee, primarily through the private sector participants on the committee, we've been able to leverage a huge number of dollars from a relatively small Federal investment to develop a comprehensive effort to increase the knowledge of the American public and health professional, and to change their attitudes and habits regarding high blood pressure.

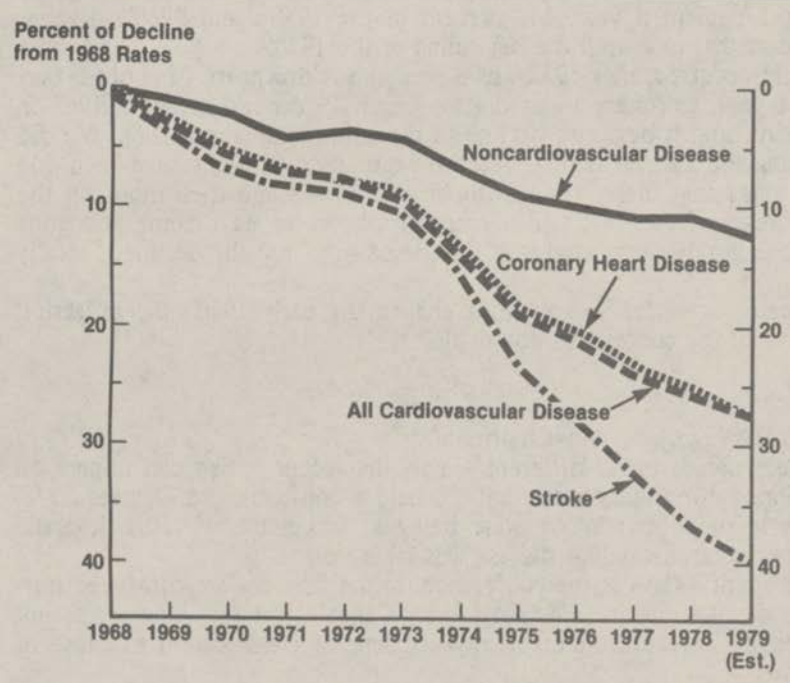
Consequently, we have seen, as this national education program developed, a tremendous increase in patient visits for hypertension control.

DECLINE IN CARDIOVASCULAR DEATHS

And perhaps the bottom line, Mr. Chairman, as you can see on the chart provided, is that since 1972 when the program began we have seen a precipitous decline in stroke and coronary heart death in this country.

[The chart follows:]

Trends in Cardiovascular Disease and Noncardiovascular Disease: Decline by Age-Adjusted Death Rates, 1968–1979



HYPERTENSION CONTROL

Dr. LEVY. Now, we have a long way to go. We can now surely say that we can control hypertension; but in 95 percent of the patients with hypertension, we don't know its cause.

Clearly, we can talk about treatment for a lifetime to prevent heart attack and stroke. That's beneficial. But, if we knew the cause of hypertension and could prevent it from occurring at all, it would be even more cost effective.

We're making headway in terms of the decline in cardiovascular mortality, but cardiovascular diseases still account for 51 percent of all deaths. Thus the effort is being waged successfully, but it is really only through continued exploration of the research questions present today that we will be able to prevent disease tomorrow.

Senator SCHMITT. Thank you.

Was there anything unusual about 1971 and 1972 that caused that inflection in the curve.

Dr. LEVY. In terms of noncardiovascular mortality?

Senator SCHMITT. There seems to be a reflection even in the cardiovascular curve.

Dr. LEVY. We are sometimes hit by what we call flu epidemics. Flu tends to take the most vulnerable of our citizens.

Dr. LEVY. We are sometimes hit by what we call flu epidemics. Flu tends to take the most vulnerable of our citizens.

Let's look at the decline in cardiovascular mortality in terms of both stroke mortality and coronary heart disease mortality, as seen on the chart. The stroke mortality component had been decreasing slowly, by about 1 percent a year, 1½ percent in the 1950's and 1960's. It continued at that rate until the beginning of the 1970's.

What occurred after 1972 was a precipitous downturn of about 5 percent a year. Coronary heart disease began to decline in about 1963 in the nonwhite; it began to decline in the white male about 1968. We did not note the decline at first, because we thought it might have been due to the fact that there was less flu in late 1960's and then more flu the early years of the 1970's. Flu epidemics however have come and gone over the last 10 years, and it is clear to us now that the decline is totally real.

Senator SCHMITT. So you think that in the early 1970's the inflection upward of the curves was due to flu?

CAUSES OF THE DECLINE

Dr. LEVY. In part, Mr. Chairman.

There are so many different events that occur which can impact on the national mortality rates that we held a conference in October 1978, to try to pinpoint why we were being so successful, why the dramatic decline in cardiovascular disease was taking place.

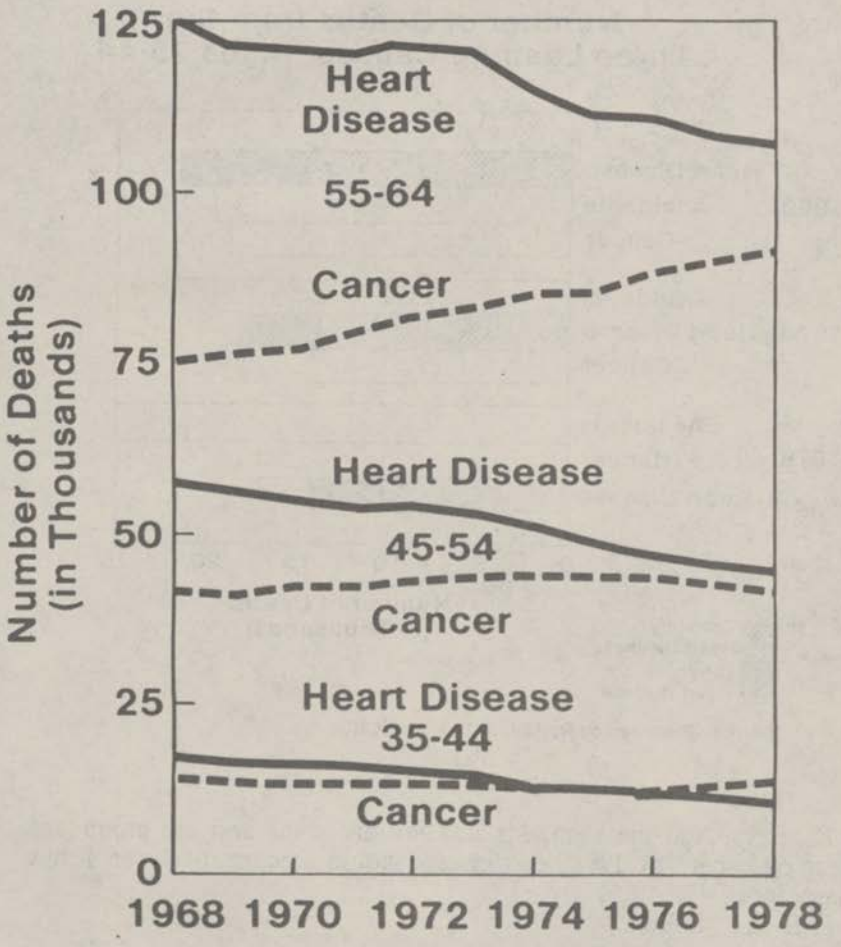
We spent 3 days at the conference. In the first day we convinced ourselves that the decline was not artificial, that it was real, that it was not caused by age adjustment or any accident of classification in cause of death.

In the next 2 days we tried to look and see what caused the decline in the United States. We noted that the coronary heart disease rate was increasing in many countries. In Eastern Europe, in some Western European countries, and in many of the developing countries there were increases. Some countries also had a decline but none had a decline as spectacular as ours.

In our country and a few others, attention to factors like hypertension is most preeminent. The decline, I might say, is also striking in that it is seen in all age groups, both men and women, both in our majority and minority populations.

[The chart follows:]

Number of Deaths from Heart Disease and Cancer Among Three Age Groups: U.S., 1968/1978



YOUNG AGE GROUP

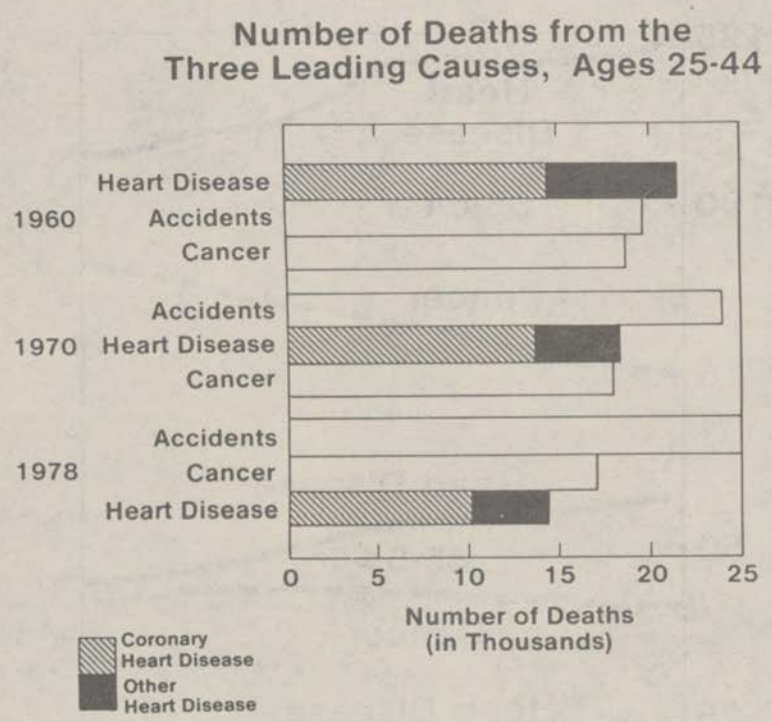
Dr. LEVY. One result is that in the younger age group—between the ages of 35 and 45—whereas heart disease was responsible for the majority of all deaths two decades ago, now we have seen a precipitous change in cardiovascular death in this age group.

Now, cancer deaths have declined some in this age group. Heart deaths have declined even more. In every age group, heart disease is responsible for less death than before. Below age 65, it used to be quoted that there was 77 percent more heart deaths than cancer deaths.

I'm delighted to say that below age 65 now, the difference between cancer and heart deaths is down to about 6 percent. It's not so much a matter of increased cancer deaths. It is related to this dramatic fall in cardiovascular deaths.

You have a chart that shows whereas in 1960 heart disease ranked No. 1 in the age group 25 to 44, it now ranks No. 3.

[The chart follows:]



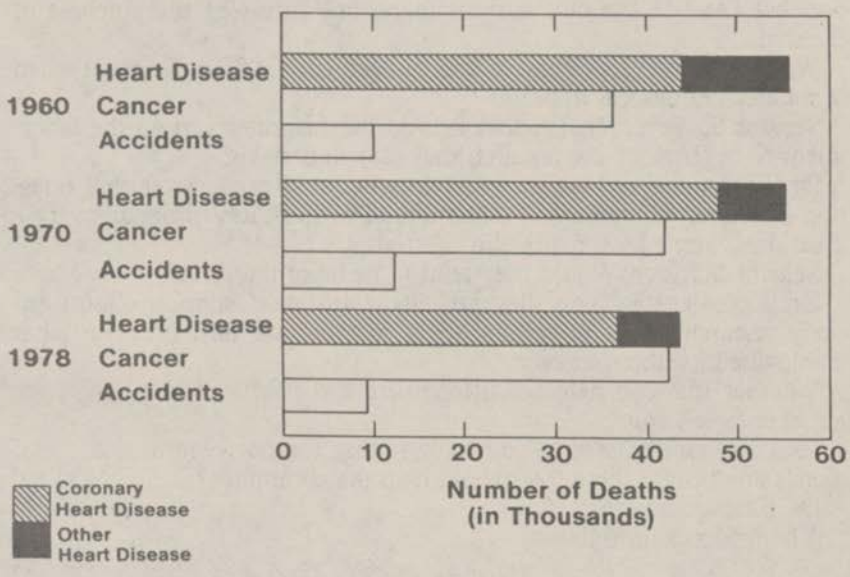
Source: Prepared by NHLBI; data from NCHS.

AGE GROUP 45 TO 54

Dr. LEVY. And this change is also obvious in the next age group, age 45 to 54, where by 1981 heart disease should account for fewer deaths than cancer.

[The chart follows:]

Number of Deaths from the Three Leading Causes, Ages 45-54



Source: Prepared by NHLBI; data from NCHS.

RESEARCH RESULTS

Dr. LEVY. The data is quite striking in terms of what has occurred. It's real. And clearly prevention, the application of the research results that came out of the epidemiologic field studies, like that in Framingham of the 1950's and 1960's, is paying dividends in terms of what we can do today.

RESEARCH PROJECT GRANTS

Senator SCHMITT. How many of the 5,000 new, competing research project grants are in your Institute?

Dr. LEVY. Some 750, for a little over $102 million.

Senator SCHMITT. We have a misstatement.

Dr. DeVita said, I believe, that $10 million was for about the same number of grants.

Dr. FREDRICKSON. Dr. DeVita meant to say $106 million.

INFLATION

Senator SCHMITT. Is inflation impacting your figures any differently than the average?

Dr. LEVY. We're all hit by inflation.

Senator SCHMITT. I know.

Is there anything unique about your institute, where inflation is higher or lower than the average?

Dr. LEVY. No; I would not say unique, except that perhaps in the large multicenter clinical trials that we support, it is very difficult to cut corners. When you're supporting a clinical trial, the motivation of the investigators and of the patients that are participating is of great importance. And if one cuts corners there, one threatens the outcome of the trial.

We have over 12 percent of our budget—over $55 million—invested in multicenter clinical trials.

Senator SCHMITT. Dr. Fredrickson, do the Institutes vary in the labor-intensity in terms of the research that they undertake?

Dr. FREDRICKSON. I am not certain whether I can answer that question effectively for you, Mr. Chairman. The Institutes' programs vary a great deal. Some have many clinical trials.

Senator SCHMITT. Would they tend to be labor-intensive?

Dr. FREDRICKSON. Yes, they are. Some Institutes support almost entirely research grants in certain areas, so there are differences in labor employment, without question.

Whether that can help us differentiate the effects of inflation, I am not able to tell you.

Senator SCHMITT. Could you look at that for our record, and see if there's any insight there that would help the committee?

Dr. FREDRICKSON. Yes, I will.

[The information follows:]

LABOR INTENSITY IN RESEARCH

Variability between Institutes in terms of the labor intensiveness of the research they fund results from the different requirements of different kinds of research. Research centers, clinical trials, and research and development contracts tend to be much more labor intensive than investigator-initiated research projects. Therefore, the labor intensiveness of the research supported by different Institutes will vary in proportion to the different research mechanisms utilized.

PRIORITIES FOR PROGRAM CUTBACKS

Senator SCHMITT. If you, Dr. Levy, were faced with a major budget cutback within your program, where would you place your priorities?

Dr. LEVY. I would agree with what the first two speakers have said. Clearly, the acquisition of knowledge, the research project grant must be protected. However, we have to maintain balance. We have to have activities in the validation area and in dissemination as well.

We have to have activities going on to make sure that the research results are validated and then disseminated so that they can be appropriately and as rapidly as possible applied in the health care community. I would emphasize the importance of balance between the activities that we support. Any one at the expense of the others would have a drastic effect on our long-term, sought-for outcome, the prevention of disease.

DECREASE IN CLINICAL INVESTIGATORS

Senator SCHMITT. I understand that there were 630 clinical investigators in the Institutes' training programs in 1972, but in 1979 this figure was 295. What is the reason for that change?

Dr. LEVY. We're very concerned about the falloff in the number of clinical investigators in training. Training is indeed a priority area for the Institute because this is the only way to guarantee the next decade's productive research. The reason why the downturn is occurring is complex. It deals with the differential in terms of salary that one can look forward to in medical research as compared to in practice. It deals with the pressures that the young investigators see or feel now in terms of the difficulties in their peers being funded. It deals with changing role models. It deals with a whole constellation of issues.

We are trying to address this problem because, as Dr. Fredrickson said, we feel that the clinical investigator is a very important endangered species. We've created what we call clinical investigator awards, awards designed to try to increase the support or stability of the young investigator after he's completed training. We try to provide him or her with the salary so that he can do research and not be diverted into more income-producing areas. This is a great problem that we are addressing.

And perhaps the most important thing, Mr. Chairman, is that both the university community and the NIH recognize the problem. And we're both trying to do all we can to increase the flow of investigators into the clinical research area. That will require providing, obviously, more stability for the clinical investigator.

Senator SCHMITT. I'm told that last year late report language or record language asked that you evaluate this in some detail. Are you planning to provide the subcommittee with a specific report on this, Dr. Fredrickson?

Dr. FREDRICKSON. We are, Mr. Chairman. I have a copy of that with me. I thought it had been provided to you.

Senator SCHMITT. Apparently not.

Dr. FREDRICKSON. You will certainly receive it today.

Senator SCHMITT. Thank you.

We'll receive that for our files.

To what extent, Dr. Levy—and I would certainly appreciate Dr. Fredrickson's answer to this—to what extent is the Institute and the NIH encouraging States to participate in funding research training and, in particular, clinical training?

STATE PARTICIPATION IN TRAINING

Dr. LEVY. We do not have information about the States and their funding for training. It would be my impression that there is relatively little going on in terms of the funding of training by the states. Training has been cut back in the NIH budget. This has led to training being picked up, in part, by hospital administrators.

But what has occurred has been a change in the nature of training. In the cardiologic area, we've seen a change from a focus on research and on research questions, to one of providing patient care. Now, that's appropriate in a hospital setting.

But in terms of wanting to maintain a cadre of young investigators who will provide us new insights for tomorrow, we're very concerned about this trend, because we feel there must be a certain number of investigators who are prepared for this increasingly sophisticated area of biomedical research.

Dr. FREDRICKSON. Mr. Chairman, if I might add just a comment, there are certain types of training programs, more than others, where Federal participation is far more effective than a State effort. For example, we feel that it is important to have a uniformity of quality, a certain required or minimum breadth of training. We can get this through institutional training grants, asking teachers to conform to a certain level of curriculum, and so forth. It is very difficult for the States to do this alone. This is particularly true of the medical science training program, where we have M.D.-Ph. D. training going on, often in parallel. It would be very difficult to do this as a State effort.

Where the States may provide a great deal more opportunity for training is at the predoctoral level, bringing people up to the stage where the programs then become more effective at the Federal level.

Senator SCHMITT. Do you make any specific effort to encourage the States to do this? Do you have any program of communication and consultation with the States?

Dr. FREDRICKSON. We do not specifically do so. Doubtless, as our training budget decreases, the States are indirectly encouraged. But we have had no program. In fact, I would find it difficult for us to lay out a separate set of training requirements that the States might follow as a kind of uniform code. It would be difficult.

I think that there is a natural equilibrium between the State and Federal support in this area, as I have just described.

Dr. LEVY. Our most aggressive area with the States is in the area of health promotion and disease prevention, where we have tried to provide them with the expertise and a hookup between the private sector groups like the Heart Association and the Kidney Foundation and the State and territorial health officers, to try to, as best we can, coordinate efforts within the State to bring the facts that we have on hand about the prevention and control of diseases like hypertension into practice in terms of the care of the patient and the public at large. This has been most aggressive and most effective I think in the high blood pressure area.

Senator SCHMITT. Have you ever approached States individually or collectively to contribute funds to the programs operating under your guidance?

Dr. FREDRICKSON. Mr. Chairman, I answered the question earlier, largely in the context of training. In the broader sense, we have not sought State programs because, outside of the agencies for disease prevention and certain State health department relationships, the effective organization with the State is the university. And of course there we play a great role.

Senator SCHMITT. But they're funded through the State appropriations.

Dr. FREDRICKSON. That's right. But there are not enough State organizations, for example, for the training of students or for many of the

other research activities. There are no State research organizations that provide an effective network.

Senator SCHMITT. I am thinking, for example, have you ever considered a conference of State legislators from committees within the State legislature that have jurisdiction over funding of university training.

Dr. FREDRICKSON. We have not considered that.

Senator SCHMITT. Have you discussed the issue with them, informing them of what you're doing and what they might do, and the short- and long-term value it would have to their State.

Dr. FREDRICKSON. We have not done so with the legislators. Of course, we have done that with the educators. But, except for certain specific problems where we wanted to inform the States about special problems of concern to them in Federal research activities related to them, such as radiation development, we have not discussed the matter with State legislators. It's a good idea. We will think about it. Perhaps we can make an effective move in that direction.

Senator SCHMITT. I think it would be very helpful—your educators, as they will, I'm sure, tell you, do not control State funding very well; legislators do.

Once again, if we're going to get through this hearing, we're going to have to submit questions for the record. But I would like to ask something slightly more personal.

During the late 1960's and early 1970's, there was a considerable body of data collected on the reaction of the cardiovascular system to weightlessness as a result of the Apollo program, but more importantly as a result of some long duration flights of Skylab.

To what degree has that information been of use and available to the institute or to the medical community as a whole?

INFORMATION FROM THE SKYLAB PROGRAM

Dr. LEVY. The information I think, you know, Mr. Chairman, has been published in a very large document entitled, "Biomedical Results From Skylab." The National Heart, Lung, and Blood Institute actually participated in some of that work. It gave us a chance to demonstrate the effectiveness of some of the noninvasive diagnostic techniques that were then developing. They have developed in quantum jumps since that time.

Dr. Whedon may comment later about the problems of calcium demineralization in space. In terms of the changes seen in the cardiovascular and pulmonary system, many of the changes in heart size, rate, and pressures seem to be explained by deconditioning.

We can look at these things in a much more sophisticated degree than we could then. All the changes that were seen in terms of decreasing heart size, in terms of the total fluid redistribution in the body, are probably explained by conditioning and deconditioning. And we suggest that even more vigorous exercise programs than were participated in, in the past, can control them. But we have methods and techniques today that will allow us an even more sophisticated view of the changes that can and do occur with space flight.

Senator SCHMITT. Doctor, what I'm getting at is not the deconditioning aspects of it, because some of these effects took place, I believe, far more rapidly than any deconditioning.

For example, red cell count began to drop precipitously right from the first day. Apparently the body ceased to produce red cells until it hit a new concentration level, somewhere—as I recall about 10 percent lower.

There were other chemical changes I believe that at least were inferred by examination of urine and other means.

It is my recollection that a lot of these reactions were finally determined to be very similar to bed-rest reactions, except at that time we didn't have data on healthy bed-rest patients. Has that deficiency been taken care of since? Are we now—is this a reaction comparable to what was found in bed-rest patients?

Dr. LEVY. The changes in the cardiovascular and pulmonary system—that's why I called it deconditioning—can be reproduced in large part by bed rest. However, the changes in body mass and fluid redistribution that occurs in the state of zero gravity, of course, can't be reproduced by the resting state.

To understand the issue of the changes in red cell mass, we would need more information. It isn't clear, as we review that data, how much could be explained by very rapid redistribution of fluids from the lower limbs and the changing in the size of the liver and spleen and their activities, as compared to a termination for the period of time of new erthyrocyte formation. Those questions can only be answered by more studies in space.

In our interagency technical committee—where NASA is well represented—we have discussed these kinds of studies, the kinds of things that we could and should do when the new space lab is in place.

I might say, as I guess I've said already, that our ability to noninvasively look at the cardiovascular system and the pulmonary system has advanced tremendously in these 10 years, and we can learn a tremendous amount more now from the same number of studies as we could then.

Then we looked at general global functions of the heart like the overall decrease in heart size. Now we have the capacity noninvasively to look almost at the level of the individual muscle cell and its function.

Senator SCHMITT. Thank you very much.

We will submit questions for the record and appreciate the answers along with your revised testimony.

Thank you very much.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

BEHAVIORAL MEDICINE

Question: The Committee has become aware that various "behavioral medicine" initiatives seem to have demonstrated considerable promise especially in prevention and facilitating rehabilitation efforts in response to hypertension and heart attacks. Accordingly, the Committee would appreciate learning of the number of professional staff members assigned to this particular effort and the extent of their research budget projected for FY 1982.

Answer: The NHLBI has been instrumental in the development of the field of behavioral medicine; the formation of the behavioral Medicine Branch within the Division of Heart and Vascular Diseases in 1977 was the first such program within the Federal government.

An interdisciplinary field concerned with the integration and application of behavioral and biomedical science knowledge and techniques to the problems of health and illness, behavioral medicine has encouraged the development of a "biobehavioral" perspective concerning the prevention and control of hypertension and coronary heart disease. For example, we are currently targetting "biobehavioral approaches to the treatment of hypertension" based upon preliminary but consistent evidence that combinations of pharmacologic and non-pharmacologic therapies may be more effective in reducing and maintaining normotensive blood pressures than either approach alone. Most importantly non-pharmacologic therapies may also permit the reduction and, in selected cases, the elimination of anti-hypertensive medication once proper blood pressure control has been established.

Although typically associated with stress-related disorders, behavioral medicine is also concerned with research in the development, change, and maintenance of health behavior related to diseases prevention and health promotion. We currently support experimental studies in health behavior (e.g., smoking prevention in adolescents) as well as large scale community demonstration programs designed to modify cardiovascular risk factor behaviors (smoking, diet, stress, exercise, blood pressure) of entire communities in health-enhancing directions.

The funding for the Behavioral Medicine Branch, currently staffed by two permanent full-time employees, has increased since its inception three years ago, with FY '80 expenditures of approximately $6 million in grant-supported extramural research. Continued support in FY 81 is anticipated at approximately $9 million.

While the Behavior Medicine Branch has the lead role for behavioral research and demonstration programs within the Institute, behavior modification is part of our strategy in several of our educational programs and clinical trials. For example, messages developed for our National High Blood Pressure Education Program are tested via the Health Message Testing Service (operated jointly by NHLBI and the National Cancer Institute) to make sure that they achieve the intended effect on the target audience. The thrust of many of our high blood pressure messages is aimed at some form of behavior modification, e.g., convincing hypertensives to stay on their daily treatment regimen. In addition, such clinical trials as the Hypertension Detection and Follow-up Program involved health pro-

fessionals who employed a number of behavioral techniques to keep hypertensive patients on a sustained treatment program. We are currently analyzing those techniques and trying to determine which were most effective and should be applied generally within the community.

The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

HYPERTENSION--PRIVATE RESEARCH

Question: We hear much about government research to control hypertension. What is the private sector doing in this regard?

Answer: Hypertension research is conducted by such private organizations as the American Heart Association and the National Kidney Foundation.

Question: To what extent are the pharmaceutical houses involved?

Answer: Many pharmaceutical houses are indeed involved in hypertension related research and much of this, as one would imagine, is related to improving the effectiveness of drugs to treat hypertension. It is difficult to set certain percentages regarding the amount of research conducted by the federal government as compared with the non-profit and/or profit-making private sectors. Due to the proprietary nature of the pharmaceutical industry, figures regarding hypertensive-research by pharmaceutical companies are not easy to come by. Nevertheless, it is safe to say that the bulk of research in the area of hypertension is conducted by or supported by the National Heart, Lung, and Blood Institute.

It should be added, however, that much of NHLBI's research would be more costly to the taxpayer if it weren't for the fact that the pharmaceutical industry furnishes drugs at no or reduced cost. Also, the pharmaceutical industry is quite aggressive in disseminating research findings regarding hypertension to the physician, albeit very often on a somewhat selective basis.

It is worth noting that the pharmaceutical industry has also been supportive of our National High Blood Pressure Education Program. In fact, the American Heart Association, the National Kidney Foundation, the American Red Cross, Citizens for the Treatment of High Blood Pressure, the American Medical Association and the National Medical Association, along with a number of other health-oriented organizations and associations, are actively involved in that program and have contributed in aggregate consideraly more dollars and resources than the NHLBI to this national education program. Large industries, the insurance industry in particular, unions, civic groups, and many other organizations also participate in the national effort to control high blood pressure.

The significance of the contributions these groups have made in the progress to date in controlling high blood pressure should be underscored. Although the National Heart, Lung, and Blood Institute may claim the lion's share of responsibility for hypertension research, transferring the knowledge of this research into detection, treatment, and follow-up programs for hypertensives through-

out the country would be impossible without the active participation of the groups and organizations which have been named, as well as many others. This particular effort truly represents an effective public-private sector partnership which has proved very beneficial for the American public.

EMPHYSEMA AND CHRONIC BRONCHITIS THERAPY

Question: The Institute has previously reported funding of a clinical study of the use of continuous oxygen therapy versus 12-hour oxygen therapy in patients with chronic bronchitis and emphysema. Has that study been completed?

Answer: The Nocturnal Oxygen Therapy Trial, which compared 12-hour, nighttime oxygen therapy with continuous oxygen therapy in patients with chronic obstructive lung disease was completed in June 1980.

Question: If so, what are the results?

Answer: The results were disseminated to the medical community in an article published in the Annals of Internal Medicine in September and at the national meeting of the American College of Chest Physicians in October. The general public was informed of the results by means of a press release to the national wire services and selected newspapers.

The study, which involved six medical centers and 203 volunteer patients, was undertaken because there was some preliminary evidence indicating that administration of oxygen for 12 hours at night was as effective as continuous oxygen in preventing complications arising from oxygen deficiency; a condition which is commonly found in the advanced stages of emphysema and chronic bronchitis. The results indicated that mortality was twice as great among patients in the nighttime oxygen therapy group as among those in continuous therapy.

The patients who agreed to participate in the study were randomly assigned in either the continuous or the nocturnal oxygen therapy therapy program. Because the patients did not begin the study at same time, results at the end of the first year were not statistically significant. But after the patients had received 12 months of therapy, mortality was 11.9 percent in the continuous oxygen group and 20.6 percent for those receiving the nighttime therapy. For those patients followed for two years, mortality was 22.4 percent and 40.2 percent respectively. Thus, continuous oxygen therapy is the therapy of choice, at least in those patients suffering severe respiratory impairment. Approximately 500,000 out of the roughly nine million individuals with chronic obstructive pulmonary disease have severe respiratory impairment.

Question: Would you recommend that 12-hour oxygen therapy be used generally as a treatment for chronic bronchitis and emphysema, or only in the worst cases?

Answer: The use of oxygen therapy is quite expensive; it can cost as much as $500 per month to provide continuous oxygen therapy to a patient. If methods can be developed to detect and treat the disease at an earlier stage, the number of individuals who would develop severe respiratory impairment would decrease as would the need

for expensive oxygen therapies. The NHLBI is currently supporting investigators who are developing an immunologically-based method which may provide an inexpensive means for physicians to screen individuals for the first signs of the development of this disease.

ROLE OF SALT AND WATER

Question: What studies has the Institute conducted to determine the role of salt and water balances in hypertension?

Answer: Much of the early research examined sodium as an isolated, independent factor in blood pressure regulation. It is now known that the issue is more complex. The apparent effects of sodium on fluid balance and blood pressure are probably not related solely to the absolute amount of sodium taken into the body.

Several formal randomized clinical trials are underway in which the roles of salt and water balance in hypertension are being addressed through a systematic control of the diet. In one trial hypertension prone individuals (defined as having consistently high normal blood pressure readings) will undertake to lose weight and restrict high sodium intake to see whether a significant reduction in high normal blood pressure will occur. A second project will determine whether hypertensive patients under drug treatment can be weaned from the drug or require less drug under weight control and salt restriction. A third study also seeks the control of hypertension by non-pharmacologic means, i.e., weight loss and sodium resriction. The fourth project will study identical twins to ascertain whether salt restriction in one twin of each pair will result in a lower blood pressure response.

Question: What information have you developed on this?

Answer: The ratio of sodium and potassium seems important. There is some evidence that needs to be confirmed, that blacks and whites handle potassium differently, and that this, rather than a high sodium intake, may better explain the high hypertension prevalence among blacks. We would hasten to add that this is probably not the only reason for the high prevalence of high blood pressure among our black citizens.

There is also some evidence that obese and slim people may handle sodium differently. Again, this needs more confirmation. This question is compounded by the fact that obesity is not necessarily a single condition. Sodium metabolism and transport may be different in people who are obese due to very large fat cells than it is in people who are obese due to larger numbers of fat cells.

Epidemiological studies have found that extremes of salt in the native diet will protect against hypertension when very low and promote hypertension when very high. There is a strong genetic component to hypertension and there is emerging preliminary evidence that there may be salt-hypertension reactive families. At the level of animal research, selective breeding of rats has established strains of dietary salt-sensitive and salt-resistant rats that are studied by many investigators. The Institute maintains these colonies of animals.

Epidemiological studies have been somewhat hampered by the fact that it is hard to measure accurately salt intake and excretion. Part of this difficulty has now been shown to occur because it takes 9 to 12 sequential daily measurements to get a dependable average since we all vary our salt intake greatly from day to day. Another difficulty has been that measurement methods have been imprecise and demanding. The Institute now has requested and funded an ongoing study specifically to improve methodology.

It is now many years since it was shown that the very low salt "rice" diet would lower blood pressure in many hypertensives. The advent of sodium excreting diuretic drugs has been the modern substitution in the treatment of high blood pressure. Currently there are clinical investigations that are studying the effect of salt loading or salt restriction of intermediate level on hypertensive patients. As yet the results do not allow a simple interpretation since studies with and without effect have been reported. Nevertheless, there are preliminary indications that different patients may be affected differently by salt restriction or load in these acute studies. It remains to confirm these data, to ascertain the role of other ions such as potassium, to recognize the characteristics of patients that will predict response and to assess the therapeutic or public health significance of the research.

The Institute is very interested and is continuing to explore recent findings by both French and American investigators of differences between normal and hypertensive patients in red blood cell handling of sodium. It is relatively certain that some individuals are more sensitive to sodium (as it affects blood pressure) than others. We cannot, at this time, clearly identify who these people are until they have hypertension and are found by trial and error to respond well to sodium restriction. If this red blood cell phenomenon can be proved valid as a clinical indicator of sodium sensitivity, we will have a tool that may be useful not only for improved treatment decisions but also as a possible step to prevent hypertension. If we could early on detect people at high risk, we could counsel them to alter their diet and perhaps avoid a need ever to treat them for hypertension. It would be nice to project for you when all this will be possible, but we cannot. It can only be said that this is an interesting lead we intend to follow.

Sodium is not the only factor influencing how the body handles water. It may surprise you to learn that there are quite a few mysteries still remaining about <u>where water is</u> in the body. We know it is in the circulatory system, that it is in body cells and it is in fluid that surrounds body cells. Because we still lack technology to measure accurately some of these "compartments," as they are called, we still have much to learn about how, where and when water moves within us and how any of these factors <u>interact</u> to affect blood pressure.

The research area of sodium and water balance (and the associated questions just described) were strongly highlighted in a nine-volume report on hypertension research recently developed by a special Institute sponsored committee as well as by the Black Health Providers Task Force. The Institute has been responsive to--and even anticipated--this emphasis by supporting a number of investigators in pursuit of these issues.

ALTERNATIVE TREATMENT METHODS

Question: A prescription drug regimen is the primary method of treatment used to control mild hypertension found in 40-60 million Americans. Since this regimen could last for the rest of the patient's life, what alternative treatment methods, such as behavior modification, are you looking for?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

MINORITY HYPERTENSION PROBLEMS

Question: The National High Blood Pressure Education Program has been successful in providing information and treatment programs for people suffering from hypertension. Success in the control of hyertension has led to a 36 percent decline in deaths from strokes between 1970 and 1979, according to the Department of Health and Human Services. Does this overall percentage decrease in deaths from strokes take into account age, race, and sex?

Answer: We are very pleased to have observed a decline in stroke death rates which is time associated with our hypertension education activity. The National High Blood Pressure Education Program (NHBPEP) does provide information and technical assistance. Although we try to stimulate treatment programs, the NHBPEP does not directly provide treatment services. It is, as its name implies, solely a coordinative educational effort.

As to your core question on stroke deaths, the 36 percent decline from 1970 to 1979 is of age adjusted, i.e., adjusting for the changing age-structure of the population, stroke mortality. However, although our population is larger and older, there has even been a decline in the absolute number of stroke deaths from 207,166 in 1970 to 175,629 in 1978--a 15 percent decline.

The outstanding risk factor for stroke is high blood pressure, and it is over the past decade that the significance of hypertension and the resultant public education, screening, and treatment programs have been initiated. Indeed, although a decline in stroke mortality had begun earlier--antihypertensives have been used increasingly since the early fifties--it has been since the development of the National High Blood Pressure Education Program in 1972 that the dramatic decline in stroke mortality has occured at a rate of over 5 percent per year. This represents not only a major savings of life, but it is accompanied by a major decrease in the disability and financial burden that so often accompanies nonfatal stroke.

Question: If not, do you have rates of decline in deaths from stroke by race, age, and sex? What are they?

Answer: The decline in age, race, and sex specific stroke death rates is shown in the following table. It shows that both men and women, young and old, white and non-white experienced declines in stroke mortality of very similar magnitudes. Non-white females and persons under age 65 experienced the steepest declines. Breakout data are not yet available to us for 1979 so the table is from 1970 to 1978.

STROKE MORTALITY * DECLINE,
UNITED STATES, 1970 to 1978,
BY AGE, SEX, AND RACE

	Rate 1970	Rate 1978	Percent Decline
Total Population	66.3	45.3	31.7
Age 24-64	34.2	22.0	35.7
Age 65 and Older	710.2	494.4	30.4
All Males	73.3	49.8	32.1
All Females	60.8	41.8	31.2
White Males	68.8	46.8	32.0
White Females	56.2	39.3	30.1
Non-white Males	113.6	76.5	32.7
Non-white Females	101.4	63.4	37.5

* Rates per 100,000 popoulation, age-adjusted within each group listed

Question: Do blacks have a higher incidence of hypertension than whites? If so, has a special effort been made to educate black people about hypertension and its effects under the National High Blood Pressure Education Program?

Answer: A higher proportion, approximately twice as many of the black population in the U.S., has hypertension than do whites. We have only scant information on Asian-American, Native American, and Hispanic populations at this time. It is important to note that the poor and uneducated, regardless of race, also have a higher prevalence of hypertension. For example, affluent and well-educated black people are more likely to have hypertension than their white counterparts, but they are less likely to be hypertensive than poor, uneducated black people.

The NHBPEP has long recognized a need for and has pursued greater efforts to promote high blood pressure control among blacks. Since the NHBPEP inception in 1972, we have produced and disseminated educational materials especially developed for the needs of the black population: brochures, posters, television and radio announcements, etc. Further, we have always strongly urged state and local efforts to plan for and develop their own targeted efforts for this important group.

To increase our own knowledge and to aid in coordinating the efforts of appropriate organizations, the Committee on Hypertension in Minority Populations of the NHBPEP was formed and has sponsored teaching and fact gathering workshops for each of the several minority populations. Among blacks, because much was already known about the epidemiology of hypertension in this population, the concentration has been on three areas:

1. interdisciplinary roles among black health professionals were thoroughly examined by the Black Health Providers Task Force, which was commissioned by the NHLBI;

2. economic issues related to hypertension control among blacks were examined in a special workshop; and

3. issues related to diffusion of health information among minority populations, so we can do a better job of communicating with these groups, are currently being identified and clarified by a special task force.

The results of these three efforts have influenced and/or will influence the manner in which we pursue high blood pressure control in the black community. We hope to have in place this fiscal year, a five-year demonstration project in five sites (four of which most serve predominately black populations) to test the practicality of bringing the recommendations of the Black Health Providers Task Force and findings of our successful Hypertension Detection and Follow-up Program into operational reality at the community level. This demonstration is jointly funded and administered by our Institute and the Bureau of Community Health Services of the Health Services Administration. The projected budget for this five-year program is $2.5 million, to be shared equally by the two agencies.

We have actively tried to help black and other minority communities to initiate and improve high blood pressure control programs. We provide technical assistance consultation. We provide quantities of the educational materials mentioned earlier. We are widely disseminating the Report of the Black Health Providers Task Force. We have supported for several years a minority hypertension summer research training program. This program, operated in conjunction with minority professional schools and colleges, offers learning opportunities not only in biomedical research but also in education and health services delivery research, questions of vital and practical interest in minority communities.

We have also invited black health provider organizations to serve on the Coordinating Committee of the National High Blood Pressure Education Program. Some groups, such as the National Medical Association and the Black National Nursing Association, are already serving on the Coordinating Committee.

We realize our work on this task is far from complete. We can, however, report some signs of significant progress. We are pleased to see that the age-adjusted stroke death rates for black men and women have declined at a greater rate than for white men and women. Further evidence of progress is shown by a 24.5 percent drop in the percent of blacks with blood pressures at or above 160/95 from 1971-72 to 1974-75. Although not current, this is the latest data we have from the National Center for Health Statistics. We can reasonably infer that this indicates an increase in the number of blacks achieving hypertension control.

And, from 1971-72 to 1974-75 the percent of blacks with blood pressure above 160/95 (but not diagnosed as hypertension) dropped almost 13 percent. The percent above a diastolic pressure of 105 (but not diagnosed) dropped a sizeable 44 percent.

These figures indicate that high blood pressure control programs in our black communities are paying dividends. At the same time, however, the Hypertension Detection and Follow-up Program clearly demonstrated that with intensified effort we can further reduce the hypertension related death rate that now exists in the black population.

HYPERTENSION RESEARCH

Question: What percent of the Institute's budget is used for hypertension research, clinical programs, training programs, and investigator awards?

Answer: Approximately 15% of the Institute's budget is devoted to hypertension research, which encompasses the entire range of research activities within the Institute's mandate. These activities include: basic and clinical research into the etiology and pathogenesis of hypertension as well as treatment and behavioral modalities; clinical trials to assess the efficacy of nonpharmacologic therapy on blood pressure control; the training and development of both new and experienced investigators in this field; education and demonstation programs which serve as models for community, state, and industrial hypertension prevention and control efforts.

EMPHYSEMA ETIOLOGY AND TREATMENT

Question: Emphysema is a disease characterized by loss of lung elasticity and breakdown of alveolar walls. Researchers have found that emphysema is caused by an imbalance of two proteins: an enzyme called elastase that breaks down the elastin network of the lung and an enzyme inhibitor (alpha-1-antitrypsin) that blocks the action of elastase. In the past five years the incidence of emphysema has increased and these current studies appear to be promising in trying to eludicate the factors involved in the disease.

You told us last year that some emphysema victims are genetically deficient in an inhibitor called alpha-1-antitrypsin.

Is the Institute currently funding research to develop a synthetic elastase inhibitor to use for replacement therapy in such individuals?

Answer: The NHLBI is currently funding basic research to develop synthetic inhibitors which will be effective in arresting the development of emphysema and some of the results appear promising.

Question: If so, what is the status of the research?

Answer: One group of compounds, the chloromethylketones, have been tested in various animal models of emphysema to study their short-term effects. When given either orally, by injection, or down the airway, the compounds were effective in preventing the development of an emphysematous lesion if given prior to the disease initiating event, instillation of elastase. However, as of yet, long-term experiments on the effects of these compounds have not been carried out. If these studies prove promising, it would still be necessary to perform the testing required by the FDA to prove safety and efficacy before any compounds are available for public use. In order to further the development and testing of synthetic inhibitors, the NHLBI is sponsoring a workshop to be held this summer which will bring together investigators from both academia and industry to discuss the state of synthetic inhibitor development; to identify potential stumbling blocks toward the development of a safe and effective inhibitor; and possible ways to get around them.

In addition to trying to develop a synthetic inhibitor which may be useful for the general treatment of emphysema, the NHLBI is also sponsoring research which may allow individuals with alpha-1-anti-trypsin deficiency to augment their levels with alpha-1-antitrypsin isolated from the blood of normal individuals. Several groups are developing blood fractionation techniques which are capable of isolating the protein from a blood fraction which is currently discarded during commercial fractionation procedures. However, the isolated alpha-1-antitrypsin still has to be tested for its safety and efficacy.

Question: Are physicians able to detect whether people are deficient in alpha-1-antitrypsin? If so, how?

Answer: Alpha-1-antitrypsin deficiency can be detected by taking a small blood sample and using a technique called gel electrophoresis, which separates the blood proteins by the speed with which they move in an electrical field. Since the alpha-1-antitrypsin from genetically deficient individuals moves more slowly than that from normal individuals, it is easy to tell if it is present. It is also possible to determine, by various techniques, the actual amount of alpha-1-antitrypsin which is present in the blood.

RESEARCH TRAINING

Question: We understand there were 630 clinical investigators in the Institute's training programs in 1972, but this number dropped to 295 in 1979. Why this drop-off?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Is there sufficient money available to you this year to maintain your training effort? If not, what do you recommend?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: What evidence is there that your training programs work and produce results?

Answer: There is no question that our training programs have been highly successful, both in terms of attracting qualified individuals to the fields of heart, lung, and blood and in terms of providing them with excellent quality training. The excellence and productivity of our cardiovascular and pulmonary researchers today is the result of our effective training programs of the past two decades.

Training program directors report that postdoctoral positions are nearly fully subscribed, and the majority of their trainees remain in academic research after the training period. Former postdoctoral trainees form a large proportion of our applicants for more advanced grants, such as Research Career Development Awards, and fare quite well in the review process. Finally, a number of NHLBI special manpower development initiatives, such as the Young

Investigator Research Grant and the Pulmonary Academic Award, have been perceived as so successful that they have inspired the creation of similar programs throughout NIH.

Question: To what degree could the states assist in funding research training?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

CAUSES OF HYPERTENSION

Question: Although several effective treatments exist to control hypertension, a cure for the disease has not been found and its cause is not known. What progress has been made in trying to determine the cause or causes of hypertension and its cure?

Answer: For a small percentage of hypertensives the cause and the cure are known. Examples include hypertension secondary to a narrowed renal artery cured by repair of the vessel or hypertension secondary to a tumor of the adrenal gland cured by its removal.

But for the great majority of patients the cause of their hypertension is not known and, consequently, it cannot be cured even though the high blood pressure can be treated and its complications prevented.

The blood pressure, both normal and elevated, is maintained by a multitude of mechanisms that are interactive and compensatory. The word "mosaic" has been used by some investigators to express this complexity of mechanisms. In this circumstance, one is probably dealing with a number of different "hypertensions" rather than a single one, with a number of different "causes" rather than just one, and thus, with a variety of possible cures.

There are some very promising leads that indicate good progress in trying to find the causes and the cures for hypertension. There is a strong family or genetic component that underlies the disorder. Genetically hypertensive strains of rats have been developed by breeding. Children with higher blood pressures tend to "track" or maintain that higher level as they mature. Hypertension is more often expressed in the socio-economically depressed segments of society. It is more prevalent among blacks than whites. It is related to obesity and losing weight will often revert a mild hypertension to normal. In some isolated populations a native diet that is grossly excessive in salt is accompanied by hypertension. In others where the native diet is remarkable low in salt hypertension does not occur. Genetically salt-sensitive and salt-resistant strains of rats have been bred. Clinical investigation indicates that salt may affect different patients' blood pressure differently although this remains an area of active research. Other preliminary experiments suggest that membranes of cells from hypertensives may handle sodium abnormally. There is some evidence that potassium may protect against hypertension and that the sodium potassium dietary ratio may be significant. Among the many mechanisms that are involved in blood pressure there is growing evidence that the central nervous system and its signaling or neurotransmitter mechanisms may play prominent roles. Other studies suggest imbalances in body

made hormones bradykinin, renin, and prostaglandins; others suggest abnormalities in the blood vessels themselves and their intrinsic contractility, still others suggest that the problem may rest with heart or kidney dsyfunction.

These and other findings offer valuable leads to domains of research that are under active study. They also indicate by their variety that hypertension is not biologically simple. Not only must we understand the many basic mechanisms better, but we must also learn to attribute them to the appropriate patient. Then we shall have an understanding of both causes and suitable cures as we now have for secondary hypertension. And, most importantly, we will be better able to primarily prevent the disease. Steady progress is being made in this combined process of analysis and synthesis of complex fundamental mechanisms, their perturbation by causal phenomena, and the implications for cures and prevention.

Question: How much funding will you need in FY 1982 for basic research on its causes and cures?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

HYPERTENSION DETECTION AND FOLLOW-UP PROGRAM

Question: Last year, the Institute testified that the Hypertension Detection and Follow-Up Program was able to provide the evidence required to demonstrate that a systematic method of treatment could be effective regardless of age, sex, and race in controlling hypertension and prolonging life. Has the Institute made any efforts to ensure that the regimens that were used in these trials are being applied by community health programs, private physicians, clinics, and hospitals?

Answer: We can enthusiastically report that not only our Institute, but also many of the organizations participating on our National High Blood Pressure Education Program (NHBPEP) Coordinating Committee, have made and continue to make substantial efforts to disseminate Hypertension Detection and Follow-Up Program findings.

The results have had wide exposure in both the lay and professional literature. Institute staff have made, collectively, over 150 presentations to professional groups. NHBPEP newsletters and exhibits have carried the information to hundreds of thousands of people. A NHBPEP document, widely received and respected by practitioners, "The Report of the Joint National Committee on Detection, Evaluation and Treatment of Hypertension," was recently revised and contains much information based upon this study. We are developing a teaching kit on this report which will contain even more details. We even refer to the study in public education radio spot messages that are now being produced. The American Heart Association, the American College of Cardiology, the drug industry and many others are also helping to disseminate the findings of the Hypertension Detection and Follow-up Program (HDFP) in a variety of ways.

The implications of this study go beyond the finding that hypertension control is life-extending. It is the first clinical

trial by our Institute in which patient participation and response increased rather than decreased as the study progressed. This suggests that the procedures used to identify, track, retain, and counsel patients were good procedures and of value to the nation. But the study was on the pharmacologic treatment aspects, not the health service delivery aspects of hypertension control, and thus many questions people are now asking cannot be answered directly from the study data.

We are taking two clear steps to move further ahead. One step is to hold a major workshop on the implications of this study--economic, organizational and social--for health planners and policy setters. We hope to conduct the workshop this June to clarify questions that should be examined from a policy perspective and to seek recommendations on how and by whom additional questions should be pursued.

The second step is the five-site demonstration mentioned in the discussion of minority hypertension concerns. Those of us associated with the HDFP believe it is very likely that at least some of the systems approaches used are adaptable in usual community health care settings. But we don't know which are more useful or the extent to which the adaption can be made. This demonstration project--conducted at five sites over five years--should provide us with some crucial answers regarding the adoptability of the HDFP model in minority communities. This demonstration project is being supported jointly by NHLBI and the Health Services Administration at a total cost of $2.5 million, to be shared equally.

HEART ATTACK MORBIDITY AND MORTALITY

Question: The precipitous decline in deaths due to heart attacks has been established. What role has improved treatment of heart attack patients played in the decrease in the death rate?

Answer: Both primary prevention and improved therapy for heart attack victims undoubtedly are playing major roles in the recent mortality decline. However, their relative contributions remain unknown.

The treatment of heart attacks has been improved through earlier hospitalization and improved overall hospital care, including in particular a better control of rhythm disturbances. Prehospital cardiac arrest has become increasingly well treated in a number of communities through improved emergency medical systems and cardiopulmonary resuscitation initiated by members of the general public. Coronary artery bypass surgery, which has its major benefit in improving the quality of life, yields an increase in life expectancy in some selected patient groups. The everyday management of persons with heart disease has been aided by new drugs for the management of angina pectoris, congestive heart failure and rhythm disturbance, which may in varying degrees impact upon mortality, and certainly impact upon the quality of life.

Question: To what extent has heart attack prevention by early detection and physician monitoring contributed to this decrease?

Answer: Public awareness of heart disease risk factors has caused changes in lifestyle which may have contributed to a lesser

incidence of heart disease, although national statistics are not available to assess such a decrease. For example, smoking has de-decreased in all segments of the population except young women; dietary changes have taken place in the nation as a whole which could be expected to decrease blood cholesterol (and indeed a decrement of average blood cholesterol has been observed nationally); exercise is more widely practiced. All in all, health consciousness has become important in the American lifestyle, and health education programs have played a signifcant role in this. High blood pressure is now much more widely and effectively treated, and this has a proven impact upon stroke and heart disease mortality.

In the past decade the death rate from heart and vascular disease has declined dramatically. For example, the age-corrected mortality rate for coronary heart disease has declined more than 25 per cent. If the death rates of ten years ago were in effect today, more than 200,000 additional deaths from heart attack and 375,000 additional deaths from all forms of heart and vascular disease would have been recorded in 1980. This decrease in the cardiovascular death rate has been more than twice that for other diseases. We will analyze this new data thoroughly as it becomes available. Examination of state trends during the past decade reveals geographic patterns in the mortality decline. Western states continue to have the lowest mortality rates, while states in and around the Appalachian region are now those with the highest rates. Finally it should be noted that preliminary figures for 1980 unfortunately suggest that, for the first time since the 1960's, the crude cardiovascular death rate may have increased slightly (2.5 per cent) although the increase is less than that seen for other diseases.

TRENDS IN MORBIDITY AND MORTALITY

Question: Have any studies been funded by the Institute to determine trends in morbidity (number of heart attacks) and mortality (number of heart attack deaths)?

Answer: There are considerable data which provide a clear picture of the downward trend in deaths due to heart attack and cardiovascular diseases in general. Understanding the cause or causes for this dramatic decline in deaths is more difficult, largely due to the paucity of morbidity data on the number of heart attacks per se.

In October, 1978, NHLBI sponsored a major conference bringing together outstanding experts in the field to analyze the decline in cardiovascular deaths. Their charge was to determine whether the decline was real and not a statistical quirk or related to any change in death coding; to determine what were the principal causes of this striking decline, and to identify new areas of research which would be needed to provide as accurate a picture as possible so that we can effectively build on the progress represented by the mortality decline.

In brief, the conference was in agreement that the decline was genuine. It also agreed that research advances leading to better detection and treatment of heart disease were clearly one area contributing to the decline. Likewise, the conferees agreed that the changes in American lifestyles, i.e., reduced smoking among adult males, better control of high blood pressure, and a drop in serum cholesterol levels represented a major contributor to the mortality

decline. The conference participants felt, however, that data on morbidity was much too inadequate to accurately assess which of these factors was primarily responsible for the decline. If the number of heart attacks were decreasing along with heart attack deaths, it was postulated that the changes in lifestyles were playing the predominant role. If the number of heart attacks were not decreasing along with heart attack deaths, then improved treatment and detection would probably represent the major factor. The conferees felt it crucial that more morbidity data be gathered.

In January, NHLBI issued a Request for a Proposal (RFP), one of the first steps in funding a feasibility study for tracking trends in morbidity. It is anticipated that four projects will be launched in this study by August, 1981. If feasibility is established and funding is available, these community-based population studies should provide important new information on the changing patterns of heart disease mortality and morbidity in the United States which, in turn, will enable us to focus more aggressively on those areas with the most promise for further decline in heart attack deaths.

DIETARY GUIDELINES

Question: In June, 1980, the National Academy of Sciences (NAS) released its report, "Toward Healthful Diets," which reviewed the latest recommendations on how the American public should eat. Comparing its recommendations to those in the "Dietary Guidelines" released in February, 1980, by the Departments of HHS and Agriculture, some similarities and some differences are noted. Does the Institute embrace the recommendations of either or both of these reports?

Answer: There is much in both reports which can be endorsed and supported by available scientific facts. It is important to analyze the basis of the recommendations in each case as well as the context in which they were made. "Nutrition and Your Health--Dietary Guidelines for Americans" represents a brochure directed at the general population. The recommendations within have been described as representing "prudent advice", based on suggestive evidence rather than indisputed fact, as well as the opinions of some expert groups. On the cover, there are seven general recommendations including the following two: "avoid too much fat, saturated fat, and cholesterol" and "avoid too much sodium." In the brief chapter addressing the recommendation on cholesterol, the DHHS-DOA booklet cites epidemiological evidence linking high levels of serum cholesterol in populations with higher incidence of heart disease. It notes that, on the basis of this evidence, healthy Americans as well as those at risk, e.g., smokers or those with high blood pressure, should "avoid too much fat, saturated fat, and cholesterol." It also notes that controversy exists about what recommendations are appropriate for healthy Americans and adds: "But for the U.S. population as a whole, reduction in our current intake of total fat and cholesterol is sensible." In the chapter on salt, it notes that populations with low-sodium intakes have less incidence of high blood pressure than populations with high-sodium intake. It states: "If people with high blood pressure severely restrict their sodium intake, their blood pressures will usually fall--although not always to normal levels." It adds "Since most Americans eat more sodium than is needed, consider reducing your sodium intake."

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In its report, "Toward Healthful Diets", the Food and Nutrition Board of the National Academy of Sciences also noted existing epidemiological evidence regarding high levels of serum cholesterol and higher incidence of heart disease. However, it contended that "no significant correlation between cholesterol intake and serum cholesterol concentration has been shown in free-living persons in this country." Therefore, it made no specific recommendations about dietary cholesterol for the healthy person. For persons with a positive family history of heart disease, and other risk factors, such as obesity, hypertension, and diabetes, the report said: "concentrations of blood lipids and liprotein fractions should be determined and, if they are abnormal, therapy should be undertaken under a physician's guidance."

On sodium, the Food and Nutrition Board had this to say: "The Board believes that sodium choloride intake of many people in this country is excessive, particularly in that 15 percent of the American population at risk for hypertension. There is no reason to believe that reduction of sodium choloride intake to levels of 3 grams per day would be harmful for healthy persons, and it may be helpful for the prevention of hypertension in susceptible individuals for whom salt is a permissive factor." In short, the recommendation on sodium made by the Food and Nutrition Board had a similar premise to the recommendation on cholesterol made by the Departments of Agriculture, and Health and Human Services.

On one hand, the Food and Nutrition Board made a strong recommendation regarding sodium intake, largely on the basis of epidemiological evidence. On the other hand, it decided not to make recommendations regarding cholesterol intake, despite the fact that there exists an impressive amount of epidemiological evidence linking high levels of cholesterol with increased risk of heart disease. This struck us as inconsistent. It is important to note that the data serving as the basis for the Food and Nutrition Board report was available data, not new data. We would also point out that the panel of experts reviewing and assessing this data did not include a cardiologist or an epidemiologist, which we felt to be serious omissions in the makeup of the panel.

The two reports were unfortunately pitted against one another in press accounts and public statements which followed the release of the Food and Nutrition Board report. We are sure many citizens felt that one governmental body was saying that high levels of cholesterol were bad for you and another was saying that such levels really didn't matter, which distorts the respective recommendations in each report.

Question: To what extent do your research findings support the recommendations of these reports?

Answer: The NHLBI can support the premise that sodium intake is excessively high in this country and that, for those with hypertension, sodium intake should be curtailed or reduced significantly as <u>one</u> means of helping to reduce blood pressures.

The issue of cholesterol and heart disease is more complex. There is indeed a large body of epidemiological evidence linking high levels of serum cholesterol with higher incidence of heart disease. The evidence is far from conclusive, however, that lower-

ing cholesterol levels will help prevent heart disease. There is also insufficient evidence to say to the public at large that we know the ideal cholesterol level towards which everyone should strive. However, we can agree with the recommendation of the DHHS/DOA that, based on existing evidence, it would be prudent for the general public to "avoid too much fat, saturated fat, and cholesterol." Excessive cholesterol should be of concern to the American public, and it is encouraging to note the trend of the past few years which shows a decrease of cholesterol in the American diet. It would be unfortunate if the cholesterol controversy of the past year reversed that trend.

We have two major clinical trials underway which, hopefully, will provide us with new data and shed considerable light on the cholesterol/heart disease hypothesis. One is the Lipid Research Clinics' Coronary Primary Prevention Trial. This 10-year study, scheduled for completion in 1983, involves 4,000 men between the ages of 35 and 59 who are essentially normal, except for the fact that they have elevated cholesterol levels. One of the primary objectives of this clinical trial is to determine whether lowering cholesterol levels will reduce or slow the development of coronary heart disease. Another clinical trial -- the Multiple Risk Factor Intervention Trial or MRFIT -- involves 12,000 men between the ages of 35-55. With this trial, we are attempting to see if we can affect a significant reduction in coronary heart disease deaths by lowering serum cholesterol levels, reducing elevated blood pressure and eliminating smoking. This trial is scheduled for completion in 1982.

We anticipate that the findings of these two trials will help us immeasurably in understanding the association between cholesterol and heart disease. However, when one realizes that there remain today a few scientists who still challenge the link between smoking and heart disease and smoking and lung cancer, we cannot give assurances that any new data provided by these clinical trials will resolve the cholesterol controversy completely.

Question: Has there been a change in the research priorities of the Institute in the past year as a result of these reports and, if so, please explain?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: In light of the amount of dietary information being provided to the American public, what is the Institute doing to reduce the confusion of conflicting information and provide a coherent message to the American people?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

HEART TRANSPLANT SURGERY

Question: Is heart transplant surgery still considered a viable form of treatment for heart disease?

Answer: Patients who meet the criteria for heart transplantation utilized by Stanford Medical Center have less than a 10% likelihood of living one year unless they receive a heart transplant. For them the procedure is the only hope of therapeutic benefit and for them it is an effective and beneficial procedure. Heart transplantation, however, is certainly not the answer to the problem of heart disease.

Question: How many heart transplants are performed each year in the United States?

Answer: We estimate that about 40 heart transplants were performed in the United States in 1980.

Question: What is the current survival rate of heart transplant patients?

Answer: The only survival data that are based upon sufficiently large numbers of patients followed for a long enough period of time and utilizing current practice are those from the Stanford University Medical Center. Based upon data from patients operated upon since January 1, 1974, there is about a 70% one-year survival and a 50% five-year survival.

Question: Do heart transplants actually increase longevity?

Answer: In the very carefully selected patients that Stanford accepts for the procedure there is no question that heart transplantation increases longevity very substantially. The patients accepted are truly moribund. Between one-fourth and one-third die before a donor heart becomes available, and the average time of such deaths is only about four or five weeks. Of those accepted for transplantation by Stanford, life expectancy without surgery would be less than 10% survival for one year, whereas those who receive the transplant have about a 50% survival for five years.

Question: Are other forms of heart disease treatment more cost-effective?

Answer: For the group of patients who meet the Stanford patient criteria (i.e., those with severe preterminal disease), there is no alternate therapy which begins to compare in effectiveness. For these patients there is no alternate form of treatment at this time which is more cost effective.

There is no question, however, that the most cost effective "treatment" of heart disease lies in its prevention, and this is the fundamental thrust of the Institute's efforts. Often early treatment of a disease or another precursor disease can postpone or prevent serious disease. This is dramatically demonstrated in the treatment of hypertension, and the resultant substantial decrease in disability or death from such consequences of untreated hypertension as stroke and heart attack. Of course, this is cost effective.

CORONARY ARTERY BY-PASS SURGERY

Question: Seventy to eighty thousand coronary artery by-pass operations are performed each year at a total cost of more than $1 billion, we're told. How effective is this treatment?

Answer: Our estimates are that in the United States today there are actually 100,000 to 110,000 coronary by-pass procedures annually with an aggregate cost, all things considered, probably closer to $2 billion than to one. The procedure is certainly effective in relieving or ameliorating the symptoms of angina pectoris in 80 or 90% of the patients in whom the procedure is undertaken. However, medical therapy and change in lifestyle is also an effective therapy in many patients. Proven effectiveness in increasing life expectancy is limited to only that group of patients who have severe disease of the left main coronary artery. There is also evidence, which a consensus group judges needs further corroboration, that it may be effective in improving life expectancy of patients who have significant disease of the two major branches of the left main coronary as well as involvement of the right main coronary artery; in other words, in patients who have three-vessel disease. Full understanding and quantitation of effectiveness and comparison to alternate (non-surgical) therapies, which have demonstrated value are not yet available; but we clearly have much better information than we had several years ago. The conclusions of our Coronary Artery Surgery Study (CASS) one of our major clinical trials, should provide us with even more information when it concludes in 1983.

Question: What studies have you conducted on effectiveness? What do they show?

Answer: The Institute has sponsored a number of studies on coronary artery by-pass surgery to assess the effectiveness of the procedure. One major study involved 10 collaborating institutions and examined whether emergency coronary by-pass surgery would improve the survival of patients admitted to the hospital with symptoms suggestive of heart attack but turning out not to have heart attack; the patients had the kind of coronary artery disease in which surgery might be of benefit. In 288 patients randomized between emergency surgery and maintenance of medical therapy (unless and until chronic symptoms dictated surgery) there was no improvement in life expectancy with surgery, even after several years of followup. A substantial fraction of patients did undergo late by-pass surgery, typically 12 or more months after the original episode, but a significant fraction of patients have needed no surgery whatever and have not had serious problems with angina pectoris.

The Institute has and continues to support a variety of other studies to assess the effectiveness of coronary by-pass surgery. These address the quality of life and indices thereof. These show, for example, that the procedure has reduced the subsequent number of cardiac related events, the amount of medication required, and the frequency of hospitalization. The majority of patients have been able to increase their exercise capacity and improve their New York Heart Association functional class after operation. This observation has been documented by improvements in functional exercise testing, angina threshold, left ventricular wall motion, left ventricular ejection fraction during exercises, indices of myocardial oxygen consumption during exercise and lactate extraction across the myocardium. Studies also show that contrary to expectations, although the symptoms and functional capacity following by-pass surgery should enable most patients to resume gainful employment, the results are quite mixed. Such factors as preoperative work status, availability of other income, perception of health, age, level of education, and

employer attitudes, all appear to influence the postooperative employment status.

The improvements cited should not be considered a justification for operation in and of themselves. The correct interpretation of these observations is that for persons whose quality of life is significantly impaired by their symptoms and who have coronary artery disease suitable to amelioration by surgery, can look forward to benefit from the procedure. Studies have also shown dramatic improvements in the quality of life from advances in nonsurgical or purely medical forms of therapy. Thus, surgery to improve the quality of life should be restricted to those persons whose quality of life is significantly impaired despite a full, carefully prepared, and individualized medical regimen. As noted above, there are patient groups in whom life expectancy can be improved by surgery and this, of course, must also be considered.

We are now in the follow-up phase of one of our largest clinical trials, the Coronary Artery Surgery Study. In 14 participating institutions all patients undergoing coronary angiography--the definitive diagnostic procedure immediately preceding by-pass surgery--have their clinical angiographic and other characteristics recorded in a central data registry. About 24,975 patients--over 99.9% of those undergoing angiography at these institutions--have entered the study, and we have 99.4% complete long-term survival data on these patients. Of these patients over 5,000 underwent by-pass surgery and the balance received medical management or turned out to have no significant coronary disease. This study is providing an invaluable resource encompassing the complete spectrum of severity of coronary heart disease. Perhaps the most valuable part of this study is the randomized clinical trial involving 780 of these patients. These patients, who are in one of three groups sharply defined by history, symptomology, and coronary anatomy, do not have symptoms or angiographic findings which would dictate surgery. Thus randomized allocation between surgical or exclusively medical treatment was not only ethically justified but accepted by the patients and their physicians. The recruitment in these studies was completed in May 1979, and the follow-up is scheduled to May 1983. The followup data are being monitored regularly, but the outcome results are presently known only to the data monitoring committee. The results will be made known when the follow-up is complete or earlier if definitive results are achieved earlier.

Although the results of the randomized studies in the Coronary Artery Surgery Study will not be available for some time, significant reports have already appeared in the scientific literature and before numberous audiences based upon the data from the 25,000 patient data base. These have included the quantification and description of the relatively low rate of complications associated with diagnostic coronary angiography, refinement of the diagnostic significance of the exercise test in assessing the severity of coronary lesions in persons with and without symptoms of coronary heart disease, and further establishing and refining the prognosis of patients with disease of the left main coronary artery managed by medical or operative therapy. Numerous other studies are coming out of this rich resource even prior to the major study from the randomized patients.

Question: What advice or information have you passed on to the medical profession?

Answer: The results of the clincical trial in patients with angina pectoris mimicking myocardial infarction was very quickly disseminated to the medical community through numerous presentations at major scientific meetings, the first time within two and a half months of the one-year follow-up. Significant press coverage was insured. What at that time was a new and somewhat controversial finding has now become almost universally accepted practice in the community.

In December 1980, the Institute played the lead role in a three-day NIH Consensus Development Meeting on the topic of coronary artery by-pass surgery. Twenty-five invited speakers presented the most up-to-date information relevant to the clinical use of coronary artery by-pass surgery. A group of 12 experts assessed these presentations and discussions from the general public, and prepared a consensus statement. That statement has been summarized and paraphrased in a variety of medical and lay journals and newspapers, and the full text of that consensus statement will appear in the widely read New England Journal of Medicine on March 12 and shortly thereafter in the Journal of Cardiovascular Medicine.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Question: In 1963, chronic emphysema, asthma, and chronic bronchitis ranked eighth on the list of diseases known to be leading causes of death in the U.S. In 1976, these diseases moved up to sixth in ranking. What accounts for the reported increase in deaths from chronic obstructive lung disease?

Answer: The most important factor in the increase in deaths from chronic obstructive pulmonary disease is thought to be the increase in cigarette smoking over the past 40 years. The combined diseases, chronic obstructive pulmonary disease, emphysema, and bronchitis, accounted for about 52,000 deaths in 1978, showing a 24 percent increase in the age-adjusted rate from 1968.

The greater relative increase in death rates from these causes in women (40 percent) than in men (9 percent) during the period 1969-1977, is consistent with changes in lung cancer death rates and smoking habits in women.

The long-term upward trend is further indicated by the 66 percent increase in the death rate which occurred between 1959 and 1967. This is in contrast to the death rate for all causes, which declined 3 percent during this period. The continuation in the long-term increase in a number of important respiratory diseases through 1977 has been somewhat obscured because physicians use different diagnostic labels for similar conditions. When the categories "bronchitis", "emphysema", and "asthma" are combined with the complementary category--chronic obstructive lung disease without mention of asthma, bronchitis, or emphysema, the upward trend in these rates becomes apparent.

Question: Could it be the combination of exposure to pollution, earlier detection, and better diagnostic techniques, smoking, etc.?

Answer: The effect of chronic exposure to air pollution on mortality from chronic obstructive lung disease is extremely diffi-

cult to determine. It has been studied by numerous investigators with somewhat variable results. These studies do not show consistent mortality gradients. Although air pollution is an important factor in pulmonary disease, it does not seem to be a major factor in producing the upward mortality trend in COPD between 1963 and 1976. Changes in nomenclature have affected the mortality rates as mentioned above. Perhaps heightened awareness among physicians about chronic obstructive pulmonary disease also contributes to its more frequent identification as the cause of death. However, earlier detection and better diagnostic techniques, although they may increase the statistical prevalence of COPD, should not have had much influence on mortality rates in the time period 1963 to 1976 because the rates reflect only people who have died of their far advanced lung disease. Techniques for detecting far advanced disease were available in the 1960s as well as in the 1970s.

Question: What is the status of a collaborative study of the efficacy of intermittent positive pressure breathing therapy for chronic obstructive lung disease?

Answer: The Intermittent Positive Pressure Breathing or IPPB trial is comparing the efficacy of this modality when used as an adjunct to the overall long-term care of ambulatory patients with chronic obstructive lung disease. The study which involves five medical centers will compare the effect of IPPB with that of a simple powered nebulizer in 985 volunteer patients for three years. Recruitment for the study was completed in October 1980 and the baseline data are currently being analyzed. The variables being measured include lung physiology parameters, quality of life, neuropsychologic and socioeconomic indices.

Question: What research is the Institute doing on byssinosis, or brown lung, whose signs, we're told, are quite similar to asthma?

Answer: Research on byssinosis or brown lung is being supported by the Institute. While it has long been known that the difficulty in breathing experienced by cotton products' workers upon exposure to cotton dust results from constriction or narrowing of the airways, a condition similar to an asthmatic attack, only recently have investigators begun to establish how inhalation of dust brings about this effect. Two substances have been discovered on cotton fibers which can stimulate the contraction of smooth muscles lining airways, one substance by acting directly on smooth muscle cells and the other by causing release of an agent from blood platelets which then causes smooth muscle cells to contract. The end result of either event is narrowing of the airways, which is precisely the effect seen in an acute attack of byssinosis. It is expected that knowledge of this mechanism will now help researchers develop methods for therapeutic agents which will prevent or alleviate such attacks.

Another facet of the disease for which plans have been proposed is the chronic, long-term debilitating effects of brown lung. There are suggestions that immune responses are responsible for at least some of these effects, and studies involving cotton mill workers as well as animal experiments have been proposed to address this issue.

PERCENT OF INSTITUTE BUDGET FOR BLOOD RESEARCH

Question: What percent of the Institute's budget is spent on blood research?

Answer: In 1980 15.8 percent of the Institute's extramural research and training budget was obligated in programs related to blood diseases. The budget estimate for 1981 includes 16.2 percent for research on blood diseases and blood resources.

COOPERATION WITH OTHER INSTITUTIONS

Question: How much of the blood research is done in cooperation with studies funded by other institutions?

Answer: Organizations throughout the Federal government conduct or sponsor blood research. Their activities are combined with the efforts of private charitable organizations, the industrial and financial sectors of the economy, and groups in private health care delivery settings.

In view of the vastness and complexity of the National Program and the number of agencies involved in supporting related efforts, the Institute utilizes a range of formal and informal mechanisms to foster coordination of blood research. One of the most important of these formal mechanisms is the congressionally mandated Interagency Technical Committee (IATC) on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources. Established in 1972, the IATC plays a crucial role through the collection and classification of program information, exchange of programmatic knowledge, provision of technical expertise, and promotion of collaboration among its member agencies.

Twelve components of the National Institutes of Health and sixteen other agencies, including ten within the Department of Health and Human Services, are involved in interagency projects relating to several areas of the National Heart, Lung, and Blood Program. Twenty-one of these twenty-six organizations support blood research. The number of active research projects and funding for these projects in fiscal year 1979 are shown on the next page:

Fiscal Year 1979 Federal grants and contracts in blood research (does not include amounts for manpower and training) 1/

Federal Agencies	Blood Diseases and Resources Number of Awards	Funding ($000)
National Heart, Lung, and Blood Institute	526	$ 71,294
Other NIH		
National Cancer Institute	138	18,094
National Eye Institute	0	--
National Institute of Allergy and Infectious Diseases	17	1,882
National Institute of Arthritis, Metabolism, and Digestive Diseases	110	9,103
National Institute of Child Health and Human Development	9	795
National Institute of Dental Research	4	241
National Institute of Environmental Health Sciences*	23	2,337
National Institute of General Medical Sciences	55	3,449
National Institute of Neurological and Communicative Disorders and Stroke	5	450
National Institute on Aging	0	--
Division of Research Resources	713	6,540
Total: Other NIH	1,074	42,891
Other Federal		
Alcohol, Drug Abuse, and Mental Health Administration	32	5,084
Center for Disease Control	0	--
Department of Agriculture	26	**
Department of Defense	95	3,485
Department of Energy	14	2,519
Department of Transportation	0	
Environmental Protection Agency	8	526
Food and Drug Administration	20	1,426
Health Resources Administration	0	--
Health Services Administration	43	690
National Aeronautics and Space Administration	0	--
National Center for Health Services Research	1	--
National Science Foundation	29	1,272
Rehabilitation Services Administration/ National Institute for Handicapped Research	0	--
Veterans Administration	211	**
Total: Other Federal	479	$ 20,703
TOTAL FEDERAL:	2,079	$134,888

* Includes intramural research projects
** Data not reported

1/ Research Pathways to Modern Medicine: Eighth Report of the Director, National Heart, Lung, and Blood Institute, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health (Unpublished).

In addition to this coordination of activities within the Federal government, the NHLBI works with industry to meet shared goals in the interest of the American public. Recently, the NHLBI has cooperated with pharmaceutical manufacturers (for example, Ciba-Geigy) that have provided drugs for clinical studies; with the Merck Institute in the testing of a type B hepatitis vaccine; and with the United States Department of Agriculture and Meloy Laboratories in support of a study relating to diet and platelet function.

ACCOMPLISHMENTS IN BLOOD RESEARCH OVER PAST TEN YEARS

Question: What progress has been made in blood research during the past ten years?

Answer: This information is available to the Congress in the annual Reports of the Director, NHLBI, and the annual Reports of the NHLBI Advisory Council. Some of the highlights from these reports are listed below.

BLOOD DISEASES

Hemophilia. Better procedures were developed for isolation of anti-hemophilic factor (AHF) from human plasma, and availability of a dry concentrate has made home care the preferred treatment program for hemophiliacs.

Patients with inhibitors to AHF can now be treated with new plasma fractions which apparently bypass the AHF step in the clotting process. New techniques for assaying AHF (or factor VIII) have made it possible both to identify female carriers of hemophilia and to diagnose the disease prenatally. Work at the basic level has led to a better understanding of the nature of the complex factor VIII molecule.

Fibrinolytic Therapy. As a result of NHLBI-sponsored trials, two agents are now licensed by the FDA for use in dissolving clots in the lungs or the peripheral veins. These agents are now being used experimentally in the treatment of acute myocardial infarction.

Prevention of Venous Thrombosis. Certain groups of patients have been identified as being at high risk for developing venous thrombosis. Aspirin has been shown to be effective prophylactically in some of these groups, while low-dose heparin or other drugs such as dextran are effective in other groups.

Mechanism of Aspirin as an Antithrombotic Agent. It is now known that aspirin inhibits the production of two important substances found in blood. One of these, thromboxane A_2, causes blood vessels to constrict and blood platelets to aggregate, so to make blood clotting more likely. The other substance, prostacyclin, has the opposite effect of widening blood vessels and causing platelets to loose their stickiness. However, the processes by which these two are synthesized have differing sensitivities to aspirin and the challenge is to find the optimal dose to inhibit thromboxane A_2 production while interfering minimally with prostacyclin formation.

Understanding the Mechanism of the Coagulation Process. Significant advances have been made in elucidating the structure of several key clotting factors, in identification and characterization of inhibi-

tors of clotting which regulate the process, and in understanding the molecular interactions and enzymatic processes which ultimately result in the formation of a clot or thrombus.

Noninvasive Techniques for the Diagnosis of Venous Thrombosis. ^{125}Iodine labeled fibrinogen has been shown to be effective in localization of intravascular thrombi and has been licensed for general use in the past ten years. Newer methods of thrombus localization include ^{111}Indium labeled platelets, which may be a sensitive indicator of arterial thrombi. Laboratory tests have also been developed to assay blood samples for products of the clotting process, which may be indicative of intravascular clotting.

Contributions of Platelets to Atherogenesis. It is now recognized that platelets adhere to damaged blood vessels and release substances that initiate some of the early events in the formation of an atherosclerotic lesion. Inhibition of the platelet response may be a way of preventing or reducing atherosclerosis.

Gene-Mapping Techniques for the Diagnosis of Thalassemia. Through advances in molecular biology and restriction enzyme techniques to excise specific portions of DNA (the gene), diagnosis of thalassemia and other hemoglobin disorders is now possible. Further research using these techniques may provide information which will allow treatment of these inherited disorders at the gene level.

Treatment of Thalassemia. The iron-overload experienced as a result of treatment of thalassemia by repeated blood transfusions can now be treated with iron chelators which bind iron and facilitate its removal from the body. Other new treatment methods involving transfusion of only young red cells, thereby reducing the frequency of transfusion, are now being used. It is hoped that these methods will prolong the lives of those people with thalassemia.

Purification and Assay of Erythropoietin. For the first time, erythropoietin, a prime regulator of red blood cell production, has been purified to homogeneity. The availability of the pure material has made possible the development of a sensitive radioimmunoassay which offers the promise of being a reliable diagnostic aid and a research tool.

National Blood Policy.

NHLBI collaborated with the Bureau of Biologics of the Food and Drug Administration (FDA) and the private sector of the blood banking community to develop the National Blood Policy and help establish an American Blood Commission (ABC) through which the private sector in blood banking will develop plans for implementation of the National Blood Policy.

In addition to assisting in the creation of the ABC, the Institute has supported research conducted by ABC task forces in the following areas: the Regionalization of Blood Bank Services; the National Blood Data Center; the Committee on Commonality (development of standard and machine-readable labels for blood products and of other automated methods); and donor recruitment.

A three-year analysis of the complex and fragmented blood supply system led to the design and initiation of a national blood re-

source information system based on standardized reporting applicable to the blood banking community. Information collected under this program will be integrated with the National Blood Data Center.

BLOOD RESOURCES

Posttransfusion Hepatitis

The discovery of an antigen (Australian antigen) in the blood of some individuals and the demonstration of its relationship to human type B hepatitis have led to the development of sensitive tests for the diagnosis of type B hepatitis and to the development of a vaccine against this form of hepatitis.

Institute support for research in hepatitis detection has culminated in the characterization of the "e" antigen, a recently discovered soluble antigen that appears to be a better marker for infectivity than is the Australian (type B) antigen.

A cooperative study on transfusion-transmitted viruses has shown that type B hepatitis as a transfusion complication has been largely controlled. Sensitive techniques to identify the hepatitis viruses allowed scientists to discover so-called non-A,non-B hepatitis. This form, previously masked by the high incidence of type A and type B hepatitis, is now known to be as common as the other two were before their incidence was significantly reduced. No method to control non-A,non-B hepatitis is presently available, even though the Institute is supporting studies to develop a sensitive assay system to detect non-A,non-B hepatitis.

An NHLBI-supported chimpanzee colony is now fully operational and provides an invaluable resource for the advancement of hepatitis research. The chimpanzee is the only known animal model that develops clinical type B hepatitis or non-A,non-B hepatitis.

Histocompatibility of Cellular Elements.

Advances that occurred in the past five years make it possible to type and match blood platelets in much the same way as red blood cells. Matching platelets by histocompatibility testing has resulted in improved response in patients who have become resistant to unmatched platelets.

Blood Bag Labelling.

Standardized human- and machine-readable labels and codes for blood bank containers and equipment have been developed and are now being fieldtested. This automated system could eliminate human error in identifying the donor, blood unit, and recipient.

Storage of Cellular Components of Blood.

Platelets can now be stored for extended periods of time in the liquid state and retain their viability and effectiveness. This advance could greatly aid in the treatment of patients with acute leukemia, aplastic anemia, and cancer patients receiving chemotherapy and radiation therapy.

For 20 to 30 years, granulocytes have been thought to be of great therapeutic value. Due to their fragility, however, it has been impossible to separate and store an adequate supply for clinical use. New methods of fractionation (modifications in continuous-flow centrifugation) have significantly improved granulocyte yield and allow their increased use in treating infections, especially in patients with acute leukemia, aplastic anemia, and neutropenia.

Progress in the preservation of red blood cells has been marked. Two advances are of special importance: the use of adenine in preserving solutions and the development of a new closed system docking device. Adenine can extend the useful life of blood from 21 to 35 days and improve its quality. It also increases the opportunity for better inventory management and reduced shortages of blood. Red blood cells can be maintained for many years without loss of quality when stored frozen. Present FDA regulations, however, require it to be used within 24 hours after thawing. The new closed system docking device will make it possible for blood bank personnel to thaw red blood cells and selectively remove fractions while maintaining sterility. This process increases the safe storage time of all red blood cell products and reduces waste due to outdating of products.

Derivatives of Plasma.

The use of serum albumin (the major plasma protein) has dictated the amount of plasma that is collected and processed. The Institute has developed guidelines for the appropriate clinical use of albumin in order to reduce unnecessary demand.

A recent finding is that fibronectin, a protein found in blood plasma, assists some of the body's immune defense systems in the destruction of invading bacteria. Fibronectin levels have been shown to decrease with sepsis and other pathological conditions.

The low level of fibronectin, which may contribute to organ failure in severely ill patients, has been raised in a group of trauma patients who had developed postoperative infections. They were treated with infusions of cryoprecipitate, a blood plasma fraction rich in fibronectin. This infusion of fibronectin in the form of an easily obtainable plasma fraction may offer a new approach to treatment and prevention of multiple organ failure, especially in injuries involving sepsis.

Although interferon's antiviral properties have been known for more than two decades, evidence is just beginning to accumulate demonstrating its clinical usefulness in man. Interferon has been shown to be quite effective in the treatment of certain viral infections. Similarly, the observation that interferon also suppresses cell division has led to the suggestion that it may be effective in the treatment of certain cancers. Because interferon is in most instances species-specific, interferon used to treat humans must be derived from a human cell source. Human interferon is most commonly obtained from three major cell types: human fibroblasts, human lymphoblastoid cells, and human leukocytes. Human leukocyte interferon is by far the most effective therapeutic interferon. The recent cloning of the human leukocyte interferon gene is an exciting achievement. However, the critical question now confronting investigators is whether the interferon-like protein (which differs in

molecular weight and is devoid of a polysaccharide residue) will be therapeutically useful in humans. Approximately 99% of the interferon clinical trials have been performed with human leukocyte interferon. A great deal of knowledge and experience has accumulated in this area over the years. It is generally agreed that human leukocyte interferon is the standard against which all other interferons are measured. Scientists generally agree, however, that current methods of producing and purifying human leukocyte interferon can be improved to give far greater yields of interferon from human leukocytes than is currently possible.

The Institute is presently sponsoring research on the production and purification of human leukocyte interferon to improve the overall efficiency of the process. By increasing interferon yields per unit of leukocytes, costs, which over the years have been a major impediment to clinical investigation and basic research, may be reduced.

A completely closed, continuous-flow plasmapheresis system (or system for separating blood components) has been developed. The system, a form of automated plasmapheresis which employs microporous membrane filtration technology, will probably be the most significant technological development in blood banking over the next few years. The automated device is designed to reduce plasma collection time from 1-1/2 hours currently required to perform a manual plasmapheresis procedure to 30 minutes. It is predicted that this device, which will make plasmapheresis more convenient for donors, will significantly increase the number of volunteer plasma donors and reduce dependence on commercial plasma.

A chromatographic procedure for the purification of factor VIII, prothrombin complex, albumin, and gamma globulin has been developed. The yield and purity of the fractions it produces are at least equal to those of commercially available plasma fractions. This new method offers a less expensive, more efficient method which can be fully automated and yield high-quality products.

Blood Substitutes.

Animal transfusion studies with blood substitutes (fluorocarbons) have been highly encouraging. In the foreseeable future, blood substitutes may be used as a blood replacement in emergencies and are a valuable tool for biomedical research.

SICKLE CELL DISEASE

Basic Research.

By use of x-ray crystallography, electron microscopy, and nuclear magnetic resonance, scientists have determined the structure of the normal and sickle hemoglobin molecules. This allows for more sophisticated techniques to be applied to the characterization of the hemoglobin S aggregation. A better understanding of the physical-chemical nature of the sickling process may provide ways of modifying the reaction at the molecular level, which would afford effective therapy for the sickle cell anemia patient.

A major concept in sickle cell disease research has been that partial inhibition of intracellular hemoglobin S polymerization

should result in decreased clinical severity, while complete inhibition should produce a "cure." For the past several years, many significant advances in our understanding of the polymerization process have occurred. Currently there exists a variety of techniques to study hemoglobin S polymerization, as well as quantitative criteria to assess the therapeutic potential of inhibition.

Among the various strategies that have been proposed to inhibit intracellular polymerization, the most exciting and straightforward is the use of small molecules that can bind the regions of the hemoglobin S molecular surface that are involved in an intermolecular bone in the polymer. An essential requirement for a systematic approach to the design of stereospecific inhibitors, then, is a detailed knowledge of the regions of the hemoglobin S molecular surface that are involved in intermolecular bonding. Significant advances have been made in this area of research, and much of this information has recently become available.

It now appears from a combination of gelation polymerization data on hemoglobin mutants, fiber diffraction and electron microscope data that the double strand of molecules found in the deoxyhemoglobin S single crystal lattice is also a basic element of the polymer structure that occurs inside sickled erythrocytes. B. Magdoff-Fairchild has recently shown that x-ray diffraction patterns of fibers of deoxygenated sickle hemoglobin and of the needles that appear at the expense of fibers are strikingly similar to rotation of diagrams of single crystals grown according to the methods of Wishner and Love. The degree of similarity suggests that the crystal structure can serve as a model for the fiber, although some differences between fibrous and crystalline patterns exist. Therefore, it may be possible to design inhibitors which bind stereospecifically to the regions of the hemoglobin S molecule that form bonds in the crystal and expect that such molecules will inhibit polymerization.

Treatment of Sickle Cell Disease.

A notable accomplishment has been the finding that, of all antisickling drugs investigated, cyanate is the most promising. In vitro studies of the effect of cyanate in sickling have shown that it most likely increases the oxygen affinity of hemoglobin S, thus preventing deoxygenation and consequent aggregation and sickling. Since studies to date indicate that cyanate has serious toxic side effects, techniques are now being developed by which cyanate can be administered by extracorporeal techniques. Some of the patient's blood is withdrawn and treated with cyanate outside the body and then reinfused into the patient after free cyanate has been removed. Preliminary data suggest that this treatment may reduce the severity of anemia and the frequency of crises without significant side effects.

Significant technical and scientific progress has been achieved toward determining whether continuous extracorporeal carbamylation in patients with severe sickle cell anemia may be associated with significant improvement in the disease. Three centers, the University of Kansas, Ohio State University, and the University of Washington, evaluated the safety of the method in a small number of sickle cell patients. Safety of therapy was measured by observing whether it changed 1) the frequency, severity, and duration of painful episodes; 2) the functional status of the patient; and 3)

hematologic measurements such as red cell survival, red cell mass, and hemoglobin concentration.

Diagnosis of Sickle Cell Disease.

It is now possible through improved diagnostic techniques to accurately diagnose sickle cell disease at birth. Although the major type of hemoglobin present at birth is fetal hemoglobin, there is also a small percentage of adult hemoglobin present. Despite the presence of large amounts of fetal hemoglobin, hemoglobin S can now be detected in the small amount of adult hemoglobin present in cord blood of newborns. Detection of sickle cell anemia in the newborn has tremendous advantages for the clinical management of the disease. The alerted physician is then able to closely monitor the child for early symptoms of often life-threatening infections.

The diagnosis of sickle cell disease can be made from fetal blood in utero, but current methods of obtaining fetal blood have considerable risks. The development of a flexible fetoscope will make it possible to obtain fetal blood under direct visualization, thereby increasing the accuracy and safety of the procedure. The capability of prenatal diagnosis will greatly increase the options genetic counselors can offer couples at risk.

A recent breakthrough in the prenatal diagnosis of sickle cell disease has been reported by DNA analysis of amniotic fluid cells. Using the restriction endonuclease HpaI, polymorphism in a DNA sequence adjacent to the human B-globin genes was detected. Cleavage of normal DNA produces a 7.6 kilobase (kb) restriction fragment containing the B-globin structural gene. Two variants have been found in people of African origin of 7.0 kb and 13.0 kb in length and 87% of individuals studied with hemoglobin S had the 13.0 kb fragment. Additionally, this fragment has not been found in Asians or Caucasians and family studies indicated that these variants were inherited in a Mendelian manner. This finding has been applied successfully to prenatal diagnosis in an "at risk" pregnancy for sickle cell disease. The Beta S gene was linked to the 13.0 kb fragment and used as a genetic marker for linkage analysis. In this case, there was also a 7.6 fragment (found in HbA) indicating the prenatal diagnosis of sickle cell trait. This diagnosis was later confirmed using fetal blood.

It is currently estimated that this method may be applicable to approximately 60% of the pregnancies at risk, thereby avoiding the problems with fetal sampling. In addition, this represents a new class of genetic markers that could provide an approach to other genetic disorders.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

MAINTAINING NEW RESEARCH GRANTS

Question: The fiscal 1982 budget continues to emphasize the stabilization of new, investigator-initiated research grants for NIH at 5,000. How much funding will you need in fiscal 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NHLBI share of that amount is $101,092,000 and 739 grants.

Question: How is inflation impacting--or how will it impact--on this goal? What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new research grants regardless of other budget priorities within NIH?

Answer: The National Heart, Lung, and Blood Institute places its highest priority toward furthering scientific understanding of fundamental life processes as they relate to heart, lung, and blood disease. In fact, the Institute devotes the largest share of its resources to the support of basic and clinical investigator-initiated research with laboratory-based research serving as the foundation of the Institute's strategy. Indeed, such research is the first step or keystone of the entire biomedical research continuum which consists of the ordered sequence of acquiring new fundamental knowledge, testing and evalulating promising hypotheses in the clinical setting, and disseminating new and existing medical knowledge. The Institute believes that fostering a strong, steady support of the search for fundamental knowledge through the science base is the primary means of providing stability and predictable support of laboratory and clinical research investigations.

While we must continue to have balance in our attack upon disease and our attempt to prevent disease, new research grants do have the highest priority because they include not only the development of the most promising current approaches, but also the most promising new ideas. They include the seed from which our harvest of continuing future health benefits will be reaped. Further cutbacks in this area would delay the acquisition of fundamental new knowledge. It would further retard the necessary influx of creative new investigators. It would accelerate the departure of established investigators because they also depend upon new and renewal grants as their current grants expire, typically on a 3 to 5 year cycle.

Question: What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: The NIH goal of approximately 5,000 new and renewal research grants was established not as a goal but as a floor. The NHLBI share of 739 for 1982 is actually significantly lower than the 3-year average of the 810 new and renewal awards made annually in the years 1977-1979. Since that date the number of highly meritorious research proposals has increased rather than decreased. We are nowhere near being able to fund all of our research proposals of extremely high merit and promise.

We put a high priority upon a balanced portfolio of activities. Our intramural research program is indeed of comparable priority to our research grant activity. Research contracts are the primary mechanism by which the Institute can undertake validation of promising results from small scale studies on a sufficiently large scale to be definitive. Contracts also provide the only mechanism whereby the Institute can take an active and directive role in research, for example, in the development and validation of instrumentation for the noninvasive assessment of heart and lung disease. Our balanced portfolio of activities also utilizes research centers and other research, as well as research training activities. All of these are important elements in the discharge of the Institute's responsibilities.

The NHLBI cannot overemphasize the fact that the number, and cost, of research grant applications has grown markedly and, because of factors such as inflation and additional Institute mandates, the growth of funds has not kept pace. The quality of new research proposals would have to decline to a large extent before it would have an impact on the Institute's ability to only fund high quality proposals.

If, however, the situation should occur, the Institute would place its greatest emphasis on renewing the resource of physician and academic investigators to assure that we can capitalize on the opportunities that are now available and related to potential breakthroughs in the early and noninvasive diagnosis, prevention, and treatment of heart, lung, and blood disease and assure higher quality research in the future.

Second to revitalizing and assuring a sufficient number of well trained, dedicated health research professionals, the Institute would place emphasis on clinical trials which are best supported by contracts. The clinical trial is the key evaluation tool that bridges the validation gap between basic research developments and achievements of health practice. The need for new evaluation efforts is pressing. The following efforts have been proposed for initiation.

Systolic Hypertension in the Elderly Program (SHEP) - to determine whether treatment of isolated systolic hypertension in 4,200 patients, 60 years of age or older and randomized to treatment and control, will reduce the incidence of stroke. Secondary aims are to evaluate the effect of treatment on total morbidity, fatal and nonfatal myocardial infarction, congestive heart failure and renal insufficiency, and cognitive impairment and psychiatric morbidity.

Platelet Active Drugs and Myocardial Infarction - 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.

Percutaneous Transluminal Coronary Angioplasty (PTCA) - 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 and a more effective therapy than nonsurgical management.

Prevention of Pulmonary Emphysema in Patients with Alpha-1-Antitrypsin Deficiency - to develop and test synthetic low molecular weight elastase inhibitors for the treatment of patients with the genetic deficiency of alpha-1-antitrypsin.

Validation of Noninvasive Assessment of Large Vessel Atherosclerosis - the progress that has been made in noninvasive techniques to assess large vessel atherosclerosis could significantly enhance the likelihood of safe, inexpensive, early detection of progressive atherosclerosis. This trial would validate the new techniques against the existing invasive methods, a necessary step before widespread application of the techniques.

Effect of Dietary Modification in Blood Pressure Control - 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 males and females, currently controlled hypertensives, and 240 patients with uncontrolled blood pressure would be included in the study.

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.

Prevention of Sudden Death in High Risk Populations - to evaluate the detection of strategies for individuals at high risk for sudden cardiac death and to evaluate device and drug-oriented preventive regimens. The trial would include the evaluation of implantable defibrillation devices as well as antiarrhythmic drugs.

Clinical Efficacy of Human Serum Albumin - to establish the extent of effectiveness of serum albumin used in the treatment of patients.

Feasibility of the Development of Markers to be Used as Adherence Measures in Clinical Trials of Pharmacologic Agents - to develop safe, stable, and noninterfering, nonradioactive 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.

Modified Hemoglobin - to test various forms of modified hemoglobin as blood replacement preparations.

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.

Effectiveness and Long-Term Results of Bronchial Drainage - to 1) evaluate the different bronchial drainage procedures during short intervals of time, and 2) examine the long-term consequences of drainage procedures. The determination of the effectivenss of these procedures would be evaluated with objective criteria including spirometry, and arterial blood gas and sputum volume determinations before and after treatment and over an appropriate time interval.

Question: To what "payline" will you fund new and competing grants in fiscal 1981--and if you can estimate it--in FY 1982? What percentage of grants will you fund in both years?

Answer: The payline for new and competing grants for fiscal year 1981 will be 190. This will allow the NHLBI to support 29% of the applications which are approved research project grants and eligible for funding. The estimate for FY 1982 is a payline of 190 and an award rate of 31%.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justifications recently submitted to the Congress have attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

ALTERNATIVE TREATMENT METHODS

Question: A prescription drug regimen is the primary method of treatment used to control mild hypertension found in 40-60 million Americans.

Since this regimen could last for the rest of the patient's life, what alternative treatment methods, such as behavior modification, are you looking into?

Answer: The National Heart, Lung, and Blood Institute is aware of both the costs and risks associated with the life long use of pharmacological agents in the treatment of hypertension. We have, therefore, placed the search for alternative non-pharmacological treatments high on our priority list.

Our interest in this area was presented to the scientific and medical communities in a program announcement entitled, "Biobehavioral Approaches to the Treatment of Hypertension". The response has been gratifying and clearly indicates a recognition of the needs.

The recently completed Hypertension Detection and Follow-up Program has demonstrated the benefits derived from treatment of mild hypertension and has created an even greater need to develop alternative treatment strategies. It is now estimated that 60,000,000 Americans will benefit from research in the hypertension area.

Modification of diet is one non-drug modality that we are fully exploring. We know now that, in some patients, restricting the amount of sodium consumed (usually as salt) can help lower blood pressure. In some patients, weight loss can bring the pressure down. We cannot now tell in advance whether a given patient will be helped by these approaches, nor are we certain (although it seems very likely) that this way of lowering blood pressure also lowers risk. We do not now fully understand what physiological mechanisms are altered by these approaches. For example, in at least some persons, the ratio of sodium and potassium eaten may be more important than the absolute amounts consumed. The way the body handles sodium may be different in obese people and slim people. Recent research has detected differences in sodium movement into and out of red blood cells in hypertensive and normal persons. We are not yet sure, however, whether or not this is an important clinical indicator. The Institute is supporting a large number of investigations examining these and other related questions.

Exercise is another modality of interest. Some hypertensive patients experience a modest blood pressure reduction when they exercise regularly. A portion of this effect may be due to weight loss, but some patients end up with lower pressure even though their weight stays the same. The role of exercise in lowering blood pressure is also under study.

Perhaps the most talked about non-drug treatments are the psychological approaches: relaxation training, stress reduction, biofeedback, yoga, and similar methods. Although these are being investigated, it is important to note that they are exceedingly complex research questions to explore because it is so difficult to separate out the so-called placebo effect.

Our interest in these alternatives is great for several reasons. Each alternative offers a different view on the causes of hypertension and, therefore, relates to our ultimate goal of preventing rather than treating hypertension. Secondly, no drug is totally free from risk. If we can treat hypertension effectively through non-drug therapy, everyone benefits. And, we are certainly very sensitive to cost issues. If a diet program can have the same outcome as using a drug, we certainly have more cost effectiveness, provided the benefit is the same or better.

That brings us to the most cogent questions on this issue. First, we must answer the question of whether an alternative treatment to drug therapy can sustain a significant lowering of blood pressure. Secondly, we must be sure that blood pressure lowering by way of an alternative treatment also lowers the risk of death and disease as effectively as currently used treatments.

We do not have answers to all these questions as yet. Therefore, all these alternatives must be considered experimental, especially as primary therapy for moderate and severe hypertension. In these two cases, we must continue to use medication in high risk subjects until we have very clear evidence that alternate approaches can result in the same benefit.

RESEARCH TRAINING

Question: We understand there were 630 clinical investigators in the Institute's training programs in 1972, but this number dropped to 295 in 1979. Why this drop-off?

Answer: Factors playing a role in the decreasing number of clinical investigators include:

. the fluctuation of the level of available training funds in the 1970s.

. research support decreased in some institutions resulting in considerable concern about suport of active investigators. Clinicians considering the possibility of research careers would be discouraged by the general concern about the national goals relating to biomedical research.

. debts resulting from the escalating cost of medical education continue to increase and are added to the expenses of living, which often includes a family in the case of the young physician. Research training delays the payback of debts which increase because of the interest accumulation. Pressures from family and lending agency strongly discourage continued postponement of the debt retirement.

. payback obligations built into the NRSA training programs require a period equal to the months of stipend support in full-time research and/or teaching. Individuals who do not obtain acceptable positions are subject to financial payback unless alternative payback is justified and granted.

. stipends were unchanged between 1974 and 1980, despite the continued inflation. Stipends are not competitive with other options available to physicians.

Question: Is there sufficient money available to you this year to maintain your training effort? If not, what do you recommend?

Answer: The budget as originally approved by Congress for 1981 provides sufficient funds for research training to adequately fund the most meritorious submitted applications. However, the possibility of a rescission proposal which would reduce the number of trainees by 8% (131) and delete traditional institutional support and indirect costs, leaves the future of these training programs in question.

Question: To what degree could the states assist in funding research training?

Answer: The states already provide the major support for facilities, faculty, and personnel salaries and indirect costs in the state institutions. Over three-quarters of institutional research training support is currently being borne by local institutions, particularly state university medical schools.

CAUSES OF HYPERTENSION

Question: How much funding will you need in FY 1982 for basic research on its (hypertension's) causes and cures?

Answer: In FY 1980 approximately $26 million was available to support fundamental research in hypertension. A level of $50 million in FY 1982 would permit not only the support of additional investigators to work on this important topic and pursuit of additional promising new areas of basic research but would also permit the support of multidisciplinary collaborative fundamental efforts which could advance the state of the science in this complex area of research to a greater degree.

DIETARY RECOMMENDATIONS

Question: In June, 1980, the National Academy of Sciences (NAS) released its report, "Toward Healthful Diets," which reviewed the latest recommendations on how the American public should eat. Comparing its recommendations to those in the "Dietary Guidelines" released in February, 1980 by the Departments of HHS and Agriculture, some similarities and some differences are noted. Has there been a change in the research priorities of the Institute in the past year as a result of these reports and, if so, please explain?

Answer: There really has been no change in NHLBI research priorities resulting from the cholesterol controversy of the past year. However, there has been a feeling of reinforcement for our efforts to seek answers to crucial questions about cholesterol and heart disease, as well as for our policy of making factual information available to the professions and the public, based on what is known, what is suggested, and what is not known.

Question: In light of the amount of dietary information being provided to the American public, what is the Institute doing to reduce the confusion of conflicting information and provide a coherent message to the American people?

Answer: We have two major clinical trials underway which, hopefully, will provide us with new data and shed considerable light on the cholesterol/heart disease hypothesis. One is the Lipid Research Clinics' Coronary Primary Prevention Trial. This 10-year study, scheduled for completion in 1983, involves 4,000 men between the ages of 35 and 59 who are essentially normal, except for the fact that they have elevated cholesterol levels. One of the primary objectives of this clinical trial is to determine whether lowering cholesterol levels will reduce or slow the development of coronary heart disease. Another clinical trial--the Multiple Risk Factor Intervention Trial or MRFIT--involves 12,000 men between the ages of 35-55. With this trial, we are attempting to see if we can affect a significant reduction in coronary heart disease deaths by lowering serum choles-

terol levels, reducing elevated blood pressure, and eliminating smoking. This trial is scheduled for completion in 1982.

We anticipate that the findings of these two trials will help us immeasurably in understanding the association between cholesterol and heart disease. However, when one realizes that there remain today a few scientists who still challenge the link between smoking and heart disease and smoking and lung cancer, we cannot give assurances that any new data provided by these clinical trials will resolve the cholesterol controversy completely.

Cholesterol and its impact on heart disease is a relatively complicated issue and one which prohibits a general public educational approach on a national scale. We do not know what is a desirable level for cholesterol as we know with blood pressure. We cannot assure people, at this time, that lowering their cholesterol level will help prevent a heart attack.

Our approach to countering confusion and giving perspective to the issue is to make available to the health professions and the public information based on what we know, what is suggested, and what we don't know. We do this in a number of ways. Let us give you some examples. For the physician, we have the Dietary Management of Hyperlipoproteinemia, a series of patient education pamphlets and a physician manual which have been distributed in the millions and are used widely in daily practice. These guides deal with specific lipid disorders. For those engaged in nutrition counselling, we, together with the American Heart Association, have staged a series of workshops around the country which will result in a "workshop package" to be further used by many others involved in training nutrition counselors. For the public, we have developed a number of projects and have disseminated a variety of informational materials. Together with Giant Foods, we developed the "Foods for Health" program which provided consumers with basic nutritional information at the point of purchase. The American Heart Association is developing a model based on this experimental project for national distribution through its chapters. Other food chains and businesses have adapted the program for community or employee educational purposes. Our widely distributed booklet on heart attacks, being promoted by tennis star Arthur Ashe, carries a section on cholesterol as one of the risk factors associated with heart attacks, and we have just completed a project with U.S. Air, whereby we provided a column on nutrition and heart disease each month for their inflight magazine.

We are hopeful that in the not too distant future we will have the scientific base upon which to aggresively build a more comprehensive educational program directed at altering dietary behavior and extending life among our citizens. On the basis of available data, we cannot yet aggressively pursue that course of action.

BEHAVIORAL MEDICINE

Question: The Committee would appreciate learning of the extent of the NHLBI "behavioral medicine" budget projected for FY 1982?

Answer: The funding for the Behavioral Medicine Branch will be approximately $9 million in both 1981 and 1982 for grant-supported extramural research.

National Institute of Dental Research

STATEMENT OF DR. DAVID B. SCOTT, DIRECTOR

ACCOMPANIED BY:

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ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

DENTAL RESEARCH

Senator SCHMITT. Our next witness is Dr. David B. Scott, Director the National Institute of Dental Research.

NIDR, as it is called, is the Nation's focal point for dental research and related training, aimed at the oral diseases, probably the most universal afflictions of mankind.

Dr. Scott, welcome.

And if you'll introduce your colleagues, I would appreciate it, and then summarize your testimony. The entire testimony will be included in the record.

Dr. SCOTT. Thank you, Mr. Chairman.

To my immediate left is Mr. Gilbert Press, our Budget Officer.

Next to him is Dr. Richard Christiansen, our Associate Director for Extramural Programs.

As you heard Dr. Fredrickson mention, our Institute is responsible for about 80 percent of the dental research that is done in this country. There was essentially none done at the time the Institute was founded some 30 years ago. So, starting from ground zero, we had to stimulate the growth in research and the training of scientists to carry it out.

Last year, before this committee, I mentioned that we have finally reached the point at which we are beginning to make clinical applications in almost all of our problem areas. This year, I am indeed pleased to tell you that we have important new information. The prevalence of one of our most devastating diseases, tooth decay, is on the decline.

CARIES PREVENTION

Over the years, quite a large number of preventive methods have been developed, and they have really been quite well accepted by the profession and by the community. During the last year we have conducted a large survey of 6- to 18-year-old individuals in a population

sample which permits a comparison to be made with data from the national health and nutrition survey of about 10 years ago.

It appears abundantly safe to say that during the last decade the overall dental caries prevalence has been reduced by at least 25 percent, which I think is a long step in the right direction, considering that there already had been some changes in the pattern before this.

We shall, of course, continue to refine the data, to learn the subtle messages that can be derived, such as regional differences and the like. We still have farther to go in our research on various chemopreventive agents, vaccines, diet modification, and behavioral science. This will all continue.

PERIODONTAL DISEASE

We are also making progress in our efforts to develop some means of controlling periodontal disease, which is the major problem in adults. We estimate that some 94 million people are afflicted with this group of diseases. They are the principal cause of tooth loss in adults.

In this case, we have not advanced as far with caries prevention, but we are getting together the required base of information and moving into clinical investigation.

One of the main advances in the last 1 or 2 years is an increase in our potential to see if and when periodontal disease is actually active. These diseases are slow and insidious, and turn on and off, so that it is very difficult to tell activity.

The four new techniques that have been worked out are all quite sophisticated, but we think they will give us the information we need. One involves analysis of minute samples of fluid from the periodontal pockets around the teeth for the presence of prostaglandin, a molecule which indicates tissue breakdown. Another involves assaying the same fluid for antibodies against a major causative microorganism which bespeak infection. A third system utilizes, in the dental office, a phase microscopic survey of the bacterial population of the pockets. The fourth involves an ingenious system of computer reproduction and enhancement of extremely minute differences in X-ray pictures of bone around teeth at intervals during attacks of the disease or during treatment.

So, contributions are being made at all levels of science. This bears a little bit on what you have been asking. Recently, from benefits of the space age in computer science, and from areas of medical science, such as the immune response, we have been quick to exploit any means at hand to improve our information.

ORAL HEALTH RESEARCH

We are moving along in most of the other fields of oral health research similarly, including craniofacial anomalies, development of restorative materials, and in the soft tissue diseases, such as the ulcerative diseases that plague a large number of our population at any one time, mainly fever blisters and canker sores. We are into the clinical stages in those investigations. Still, time will be required for definitive information.

I think this gives you a thumbnail sketch of where we are. Certainly a most exciting development is in the fight against dental caries, because this is an extremely costly disease. To see a reduction like this is really quite rewarding. I should add there are a couple of other studies available which show that the effect has been seen in adults as well as in children.

I shall be happy to answer any questions.

[The statement follows:]

STATEMENT OF DR. DAVID B. SCOTT

This Institute is concerned with research to improve treatments, find eventual cures, and achieve ultimate prevention of the many dental and oral diseases and disorders afflicting millions of Americans. We have already made inroads in basic research that have broad application to almost all fields of medicine and dentistry. The fruits of recent research have impelled the continuation of current projects and initiated new studies that build on the exciting knowledge thus gained.

Dental Caries

The National Caries Program (NCP) continues to explore avenues of research to elucidate the tooth decay process and methods of controlling and preventing caries.

Water fluoridation remains the most effective measure against caries. The NCP is evaluating alternative methods of delivering fluoride protection to people living in areas without community water fluoridation. The Program is comparing techniques under carefully controlled conditions, disseminating information on their relative effectiveness, and promoting those with high potential value. The recent school-based fluoride mouthrinse demonstration program for children in lower grades achieved 35% prevention of new cavities, and current clinical trials are examining alternative fluoride programs for children in upper grade levels. In addition, the Program plans to begin a demonstration of the cost-effectivness of combining adhesive sealants painted on the chewing surfaces of teeth with topical fluoride applied to the other surfaces in order to prevent caries.

A 3-year clinical trial will evaluate the effectiveness of a miniature appliance, cemented to the outside of a tooth, that will continuously release appropriate amounts of fluoride over a period of several months. This type of fluoride delivery could greatly help people in non-fluoridated communities, patients with special problems such as severe decay, the physically or mentally handicapped, and children who wear braces.

Preliminary work with animals has proved the feasibility of vaccination against decay. Limited studies in humans have shown that ingestion of an oral vaccine of killed Streptococcus mutans, the principal organism implicated in decay, produces antibodies in blood and saliva and promotes elimination of the bacteria. Still to be determined is what portions of the killed bacteria are most effective. The NCP will continue to isolate and purify potential immunogens from decay-causing organisms and to evaluate the vaccines in animals. Our hope is to develop a simply administered vaccine that produces a long lasting immunity.

Another area of caries prevention is concerned with decreasing the cariogenic potential of the national diet. We are using our w test to evaluate the cariogenicity of snack foods. A variation of the same test method has shown that some foods, such as cheese, may actually inhibit the decay process, and we plan to explore the possible mechanisms involved. In addition, the Caries Program will survey national snacking patterns to establish what types of snacks are consumed, the typical frequency of snacking, and the associated incidence of caries.

Periodontal Diseases

Research continues on periodontal diseases, which attack the gums and supporting structures of the teeth, and affect an estimated 94 million Americans. They are the chief cause of tooth loss in adults and are responsible for total loss of teeth in nearly 23 million people.

The goal of the Periodontal Diseases Program is to develop preventive measures that can be started at an early age and continued throughout life to maintain natural teeth. Crucial to this effort is the development of sensitive diagnostic methods for early detection of active disease.

Several sophisticated new diagnostic methods seem promising. Controlled experiments that use image enhancement by successively recorded x-ray images and digital computer manipulation have achieved earlier detection of periodontal lesions with lower radiation doses than possible with conventional radiographic methods. This new technique will permit not only early detection, but also earlier and more accurate assessment of treatment effects as well.

Scientists at one of our clinical research centers have devised two sensitive assays of periodontal pocket fluid to detect disease in specific sites. One method detects minute amounts of prostaglandins, substances associated with tissue breakdown. The second measures the antibody to a strain of A. actinomycetemcomitans, one of the bacteria suspected of causing periodontal disease. Research will continue in this area.

Investigators have established that periodontal infections are associated with host immune responses which vary in patients with different types of periodontal disease. In patients with localized juvenile periodontitis, neutrophils--certain infection-fighting white blood cells--are less able to mobilize at the site of an infection. This deficiency may explain why these patients are susceptible to breakdown of the gum tissue. Impaired neutrophils also occur in patients with diabetes mellitus, who are believed to be more susceptible to periodontal destruction than nondiabetics. Investigators have begun studies of the relation between neutrophil function, periodontal disease, and diabetes.

Phase contrast microscopy of the bacteria in peridontal pockets to assess the status of periodontal disease has generated much interest in recent years. We plan field studies of the reliability of this procedure in determining the level of disease activity and its usefulness as a diagnostic and prognostic tool. We will also examine its potential for self-care motivation: patients will see video pictures of their oral bacteria at intervals, thereby witnessing their progress. The study will also compare the relative value of conventional home treatment--brushing and flossing--with a combined regimen of flossing, irrigation, and application of a salt and hydrogen peroxide mixture.

Soft Tissue Diseases and Nutrition

A common cause of oral infection is herpes simplex virus type I. It causes painful recurrent sores of the lips and mouth, and severe infections of the eyes and brain may threaten vision and life itself. In addition, research findings have suggested that the virus could be associated with oral and upper digestive tract cancers.

New drugs afford some protection against herpes virus infections but to date, none are effective against fever blisters. Laboratory studies of ara-A aroused hope because it killed the virus in animals with skin infections. The drug proved ineffective for human use, however, because it failed to penetrate the skin. Use of a weak electrical current to transport the drug through the skin has been sucessful in a small clinical investigation and this and other methods of application will be studied.

Early vaccines against the herpes virus have produced encouraging results in animals. Investigators at an NIDR research center isolated a protein located on the surface of the virus and produced antibodies to it, which they then injected into mice. The mice were rendered immune to lethal doses of the virus. Work with this and other viral components will continue.

Our studies of salivary glands and oral viral infections are providing leads for studying diseases of other similar secretory glands, such as virus-induced diabetes. Previous research suggests that the most severe form of diabetes may represent a complex interaction between the patient's genetic heritage, abnormalities of the immune defense system, and damage caused by a virus infection or environmental toxin.

A study of 36 diabetics who required insulin injections showed that most of these patients produced antibodies against their insulin- producing cells. In some cases, these antibodies might have resulted from viral infection or chemical damage to the cells.

A new animal model has shown that cumulative insults from viruses and chemicals can produce diabetes in mice. This raises the question whether repeated exposures to such agents might also damage human insulin-producing cells sufficiently to cause clinical disease.

Restorative Materials

In the physical sciences, our efforts to improve materials for the restoration of diseased teeth and supporting tissues continue. The physical properties and natural appearance of plastic composites render them appropriate for fillings in anterior teeth. Investigators are evaluating whether, with modifications to increase durability, some of these composites might be made suitable for posterior fillings as well. Investigators have developed a laboratory device to analyze and measure the wear of composites and silver amalgams. This will be helpful in testing the strength of new experimental materials.

The design and compostition of tooth implants, and improved materials for endodontic and prosthodontic therapy are being evaluated.

Craniofacial Anomalies

Another area of NIDR research is craniofacial anomalies, especially cleft lip and palate. We hope that studies of the mechanisms responsible for palatal closure will eventually enable scientists to predict the types of drugs and other agents that interfere with normal development and thus to prevent abnormalities.

Approximately 10.5 million Americans sustain injuries to the head and orafacial region each year. The NIDR is committed to improving methods of treating these injuries as well as developmental malformations.

The success of surgery to correct malformations depends on proper repositioning of muscles to insure function. Our investigations on the relationship of nerve and muscle activity to bone restructuring will continue.

Improved orthodontic treatments may result from insights into the effects of mechanical stimulation of bone-forming cells. Studies have shown that mechanical forces applied to these cells activate enzymes associated with cell growth. A better understanding of this process may lead to improved ways to move teeth.

Pain Control and Behavioral Studies

Research on pain control has included exploration of the brain's pain suppression system and has yielded fascinating information about pain transmission and modification of pain signals by opiate-like chemicals (endorphins) produced by nerve cells. After oral surgery patients often have increased levels of endorphins and experience a reduction in pain. However, if patients are given a drug that blocks the action of endorphins, they have more postsurgical pain than do patients who are given a placebo. Additional basic knowledge of inherent pain suppression could have far-reaching clinical applications.

Our behavioral studies continue to probe the reasons for fear of dental treatment and to develop techniques for assuaging that fear. Biofeedback training helps reduce muscle tension and allays dental anxiety. Tape-recorded relaxation instructions before treatment procedures also reduce anxiety. Approaches such as these could be applied in dental practice and further studies of this sort will continue to be emphasized.

Dissemination of Information

The Institute vigorously pursues its mandate to inform the public of research findings. We reach professional audiences through exhibits, demonstrations, journal articles, proceedings of workshops and conferences, our publications, "NIDR Research News" and "NIDR Abstracts" and staff presentations at scientific and clinical meetings as well as professional schools.

We continue to disseminate information on the protective benefits of fluoride and to implement new school-based fluoride programs in areas without community water fluoridation, and new educational materials are being developed.

To increase public awareness of the effects of diet on teeth, we released a TV spot this year that generated thousands of requests for information. We will soon air twelve radio public service announcements of varying lengths to promote non-cariogenic snack foods. Additional informational and promotional materials are in preparation. I shall be pleased to answer any questions.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service, National Institutes of Health

Biographical Sketch

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Electron Microscopy Society of America
Washington Academy of Science (Fellow)
American Academy of Forensic Sciences (Fellow)
American Association for the Advancement of Science (Fellow)
Ohio Academy of Science
Society of the Sigma XI
Northeastern Ohio Society for Electron Microscopy
Ohio Dental Association
Cleveland Dental Society
American Board of Forensic Odontology (Certified)

SPECIAL AWARDS CITATIONS, OR PUBLICATIONS: Honorary Membership, Finnish Dental Association, 1952
Fellow, American College of Dentists, 1953
Arthur S. Flemming Award (given annually to "ten outstanding young men in the Federal Service" by the U.S. Junior Chamber of Commerce), 1955
Honorary Lecturer, Tokyo Dental College, 1959
Award for Basic Research in Mineralization, International Association for Dental Research, 1968
Fellow, International College of Dentists, 1969

Annual Achievement Award, Sigma Epsilon Delta Dental Fraternity, 1976
Honorary Member, Section of Odontology, Royal Society of Medicine (England), 1977
Massachusetts Dental Society International Award for the Advancement of Dental Research, 1978
Fred Birnberg Research Medal Award of the Association of Dental Alumni of Columbia University (New York), 1978
Doctor of Science, Honoris Causa, College of Medicine and Dentistry of New Jersey, 1979
Doctor of Science, Honoris Causa, Louis Pasteur University, Strasbourg, France, 1981
Award in Forensic Odontology, American Academy of Forensic Sciences, 1981
Author of some 80 publications.

COMPUTER SCIENTISTS

Senator SCHMITT. Thank you, sir. I intended to ask this earlier, and I'll ask Dr. Fredrickson now, since you brought up the computer. Is there a deficiency in computer scientists available to the Institute programs?

Dr. FREDRICKSON. We do not have precise data, but there is no question that there are some shortages of computer people, particularly, throughout the whole country, and they exist in biomedical research.

Senator SCHMITT. You have no hard data on how expensive it is?

Dr. FREDRICKSON. We do not. I will attempt to get the best we have and provide it for the record.

Senator SCHMITT. I suspect they're comparable with the rest of the country?

Dr. FREDRICKSON. Yes; I believe that is correct.

[The information follows:]

SHORTAGE OF COMPUTER SCIENTISTS

There is a serious nationwide shortage of computer scientists. Recent advances in the technology have made computer hardware relatively cheap and available. This has created opportunities for the application of this hardware and has thus created an increased demand for computer scientists to develop software to take advantage of these opportunities. A recent issue of Johns Hopkins magazine states, "There's no such thing as an unemployed computer science graduate. For evidence, one has only to check the number of classified ads for computer professionals in any newspaper, or leaf through page after page of industry offers in a computer journal. IBM and Bell Labs alone have more openings each year, for computer scientists, than the annual Ph. D. production." The shortage of computer science professionals nationwide is well known: the same article says that Bureau of Labor estimates are showing that the computer industry needs 8 times the number of B.S. graduates currently graduating and 11 times the number of M.S. graduates.

This shortage has pushed salary levels to previously unheard-of highs. According to the January 9, 1981, issue of Science magazine computer science graduates with baccalaureate degrees are being offered $30,000 as starting salaries in entry-level positions.

The overall shortage of available personnel and the high salaries offered have put the NIH at a severe competitive disadvantage in recruitment of qualified people. In fact, we have also advertised in newspapers and trade journals without any responses or results. Federal salary levels are not attractive enough in this area for us to compete with large computer firms and the fast growing software production firms.

This shortage of computer scientists is especially distressing in biomedical science because of the sheer complexity of the subject matter which requires specialized software. It is almost impossible to attract computer scientists with the requisite background or interest in the biomedical specialties.

FUNDING

Senator SCHMITT. Dr. Scott, how much funding will you need for fiscal year 1982, to maintain your share of the 5,000 new competing grants, and what is that share?

Dr. SCOTT. Our share is 126. We estimate about $12 million.

INFLATION

Senator SCHMITT. Do you have any special inflation characteristics within your programs?

Dr. SCOTT. I think not more special than any of the others. I think what everyone else has said is applicable here too. We feel that the inflator that is used, 9½ percent, whatever is used, is pretty accurate for us too. It's labor-intensive.

CLINICAL RESEARCH

Senator SCHMITT. Your work is largely clinical?

Dr. SCOTT. No; our work is largely in the basic sciences, and it is just getting into the clinical. We have a bit of epidemiological and a certain percentage of clinical work, but if you are thinking of dental offices and that kind of thing, no, that is not the type of clinical we are involved in.

Senator SCHMITT. I meant clinical research in the same way that it was used previously.

Dr. SCOTT. Considered in the same way that it was used previously, yes; we have a fair amount of investment in clincial studies.

Senator SCHMITT. Is that increasing?

Dr. SCOTT. Yes; it is.

Senator SCHMITT. So presumably your work will get more labor-intensive with time, if that trend continues.

Dr. SCOTT. I would think so; yes, sir. As it stands now, personnel costs comprise about 70 percent of our grant budgets or in-house budgets.

RESEARCH GRANTS

Senator SCHMITT. Do you agree that your first priority is to maintain your basic research grant program?

Dr. SCOTT. I think so; yes. Very much so, in our case, because we started from ground zero 30 years ago, and have still not acquired all the needed basic facts.

CONTRACTS

Senator SCHMITT. Dr. Fredrickson, is there a deemphasis in contract research by the Institutes with a priority being placed on grant research?

Dr. FREDRICKSON. There is and, in fact, it has been a matter we have been dealing with for a matter of the last 5 or so years, Mr. Chairman.

Senator SCHMITT. Can you give me some kind of quantitative measure of that deemphasis?

Dr. FREDRICKSON. I would say that we have reduced contracts quite significantly. In 1979, for example, we had $427 million in contracts. In 1981, we have $355 million, but the percentages show that drop in

more than just the 2 years. It is, of course, an area that is impinged upon when we emphasize research grants.

Senator SCHMITT. What is the effect of that change of emphasis?

Dr. FREDRICKSON. There are different effects in different Institutes. We watch it very carefully, because there are some Institutes who will appear before you who cannot mount certain development programs, particularly in the area of vaccines, or obtain certain items, because they are being forced to maintain an emphasis on grants. We realize that. In some Institutes, it is quite an impingement, particularly in the area of clinical trials. We have a number of clinical trials we would like to start. We have an inventory of waiting ships out there.

But again, this is too expensive, in terms of an emphasis on grants. It is a deliberate choice, but we are on a very narrow line with some of the Institutes in their ability to do some contract work. I appreciate their sense of anxiety and attention on individual cases.

Senator SCHMITT. Are there any priorities that you set within contract work where you feel that damage is being done to the overall program, because of your inability to let a research contract?

Dr. FREDRICKSON. I think we are under a good deal of pressure to find financing for certain clinical trials that stand before us. That is very important. It is also true for certain questions regarding the development of vaccines and antiviral compounds. We are, and have been this last year, examining with great care the question of whether we must lower the number of grants in the stabilization objective just enough to see if we can't get one or two of these contract programs going. I think that is a very important balance point.

Senator SCHMITT. Are there any other research contracts besides those two types?

Dr. FREDRICKSON. There are many other contracts that are for procurement, particularly for various supplies, or for contracts to make use of animals. There are a whole host of uses for contracts, but I would say that the ones I have described may be among the most important.

Senator SCHMITT. In order to preserve the grant program, would you reduce the nonclinical, nonvaccine-related research contracts?

Dr. FREDRICKSON. I think that for most programs and most Institutes, we have gone as far as we can in a balancing of grants against contracts. We have watched that very carefully, Mr. Chairman, and I think it is a decision that is of great importance for most Institutes, perhaps all, that we have come down as far as we can come down in terms of reducing contract capabilities.

VACCINES

Senator SCHMITT. How soon, Dr. Scott, can we expect to see vaccines that will be of an anticaries nature or other oral disease nature?

Dr. SCOTT. There are three general areas in which we're considering vaccines. One is in the area of caries prevention. Periodontal disease promises to give us more problems, but we are learning now that it is an infectious process, purely and simply, and that there are specific microorganisms involved. There is some hope there, but strictly on the drawing board at this point. In collaboration with the Allergy and Infectious Disease Institute and others, we are also interested in vaccines that will affect the herpes virus, which causes a prevalent infection in the mouth, and also, of course, is a cause of venereal disease.

Where we are most advanced—I would not want to give you a timetable—small studies are now going on in human volunteers with vaccines made from killed streptococcus mutans, which is the principal offender in dental caries. We have had good luck in the first small studies, in that the antibody titer has risen and been maintained for quite a long time. It is possible through an orally ingested preparation, to raise the antibody titer to a respectable level and maintain it.

There are many problems in making a streptococcal vaccine, so it is not going to be tomorrow. Some of our grantees estimate somewhere in the order of a decade, perhaps, 15 years, before all of the trials that have to be done are finished, and also to satisfy all of the requirements of manufacturing regulations, such as safety and efficacy, and the like. So it is going to be some while before we get a vaccine, but we are very encouraged by the basic success in animals and the beginnings of clinical applications that have already been made.

Senator SCHMITT. Are we in a position where money is not the issue, where it's just time for all the steps to be taken?

Dr. SCOTT. Well, I suppose one can never say that money is not in the picture, but the main thing is, as you say, time to develop the principles and to carry out the studies. And if more money were available, obviously, some of this would be done at a quicker rate. But we are still talking in terms of quite a few years.

DENTAL COSTS

Senator SCHMITT. What proportion of dental costs are caries-related?

Dr. SCOTT. That is hard to say precisely. If you wish to talk about the first cost, repairing initial caries lesions, then we would say about $4 billion out of the $15 or $16 billion that are spent on dental care in the country. If you wish to carry the considerations to the point where restoration has to be remade, or bridges or replacements have to be constructed, then the cost escalates. I think probably what you were after was the first cost.

Senator SCHMITT. I'm trying to determine the effect of a broadly utilized caries vaccine on the annual cost of dental care. What would you expect to see if there were a caries vaccine today that was marketable as of right now? How long would it take before it was in general use?

Dr. SCOTT. If it were available right now, I think it would probably go into general use immediately, but you must remember that whether or not the uptake by the population, the public health people and so on, would be as great as it would be with a vaccine for a lethal disease, is an open question. Also, you must remember that we have already gone a long way in prevention. So, whether a vaccine will be more useful for those who have acute fulminating cases of dental caries or are resistant to other preventive methods, or whether it should be considered in terms of a national vaccination program, will eventually have to be the subject of some kind of a consensus conference.

I see it as saving a great deal of money, certainly, because the cost of vaccine injections should nowhere near approach the cost of restoring the teeth.

Senator SCHMITT. Thank you. We'll have some more questions for the record, Dr. Scott, and we appreciate those answers with your corrected testimony.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

DENTAL CARIES

Question: Dr. Scott, I understand that this country is experiencing a substantial reduction in dental caries. What factors have contributed to this reduction: fluoride, diet, improved dental hygiene? Is there any one thing you can point to?

Answer: Fluoride is the major contributing factor in the national decline in the prevalence of dental caries in school children. Greater numbers of children are growing up in areas with optimal levels of fluoride in the water supplies, and those who have lived in these areas since birth have 50-65% less caries.

Also, large numbers of children have participated in school-based fluoride programs. Fluoride is provided in tablet or mouthrinse form, or is being added to the school water supply. Where school programs do not exist, dentists are prescribing fluorides for home use. Our best estimate is that about 14,000,000 children now are using some form of self-applied fluoride. Though the benefit they will receive is only about half that received from municipal water fluoridation, the result is contributing nationally to the reduction in caries. Also, the near-universal use of fluoride-containing dentifrices adds to the reduction in caries.

Other factors probably contributing to the reduction in caries are improved diet practices (including use of sugar-substituted foods and beverages and prudent consumption of snack foods) and greater awareness of the value of effective oral hygiene care. The Institute has been exceedingly active in the last few years in informing the public in these areas.

PERIODONTAL DISEASES

Question: Although the Dental Institute seems to be making some progress in preventing dental caries, what progress are you making in preventing periodontal diseases?

Answer: During the past few years, the NIDR has initiated three research centers where basic and clinical scientists are working in concert to learn more about the clinical nature of periodontal diseases, their microbial causes and the human host response to the causative organisms. It is anticipated that these efforts will lead to easily-applied methods for prevention based on accurate understanding of the disease process.

Such methods include new antibacterial agents as well as improved delivery systems. However, since none of these approaches has yet reached the stage of clinical testing, we must still rely on mechanical methods of oral hygiene, particularly frequent professional cleaning of subgingival plaque from the teeth. Optimal frequency of such cleaning, as well as the effect of cleaning in combination with new preventive agents, will be investigated.

Question: What do you have to report about your work in this area and, roughly, what percentage of our population is afflicted with this disease?

Answer: Periodontal diseases constitute a major health problem throughout the world. Millions of Americans have already lost their teeth because of these diseases and many more will become edentulous

unless effective prevention and treatment measures can be developed. The steadily increasing longevity of the population makes the control and prevention of periodontal diseases even more urgent. In the U.S., more than 65% of the adult population (94 million) are afflicted by periodontal diseases and one-third (32 million) have a severe form. In addition, more than 11% of the population (22 million) have already lost all of their natural teeth, primarily because of periodontal diseases suffered earlier in life. In view of this situation, the NIDR has accelerated research to control these diseases so that in the future our citizens can retain their natural teeth throughout life.

The NIDR can report a good deal of progress in this area. Scientists now believe that some forms of periodontal diseases are cyclical, being characterized by periods of activity and remission. Current efforts are concentrating on methods to determine exactly when the disease is active. Two sensitive laboratory methods to be used in conjunction with X-rays promise to aid clinical scientists in learning the exact pattern of the disease in humans. In studies on the causative organisms, scientists have been able to show that a particular species is implicated in adult periodontitis, whereas a different organism is implicated in a specific form of severe juvenile periodontal disease. Studies of the human host response show that the affected individuals make antibodies to the organisms which are apparently causing the disease. Other studies have indicated that three different types of periodontal diseases may be diagnosable in the future by simply testing the immune reactions of the blood and white blood cells. Studies of this type indicate that some patients may be more susceptible to disease because their white cells are defective and do not function normally. Other diagnostic methods, using biochemical analysis, microscopic evaluation, and special computer-based X-ray procedures are under study. It is hoped that continued research will reveal ways to identify high-risk patients and reduce the impact of these diseases by early intervention.

Question: How has the Institute moved to apply the body of basic dental science information toward the management of orofacial disease?

Answer: The Institute has utilized a number of mechanisms to transfer the information obtained from its basic science activities to the application phase. One of the primary goals of the Dental Research Centers supported by the NIDR is to place the basic scientists in the same environment with the clinical investigators in order to facilitate the exchange of information. In addition, the NIDR continues to support conferences, including consensus development conferences (implants and third molar removal) to foster the free and open discussion of clinical practices in the light of current research findings. Recent long-range planning efforts include consideration of the best and most efficient means of transferring the products of basic research to application through applied research, clinical trials and projects related to technology transfer.

CLINICAL RESEARCH PROJECTS

Question: What clinical research projects will you support in 1981 in order to hasten the application of your dental research findings?

Answer: Examples of clinical research projects to be supported in 1981 are:

- Development of improved methods of treating herpes virus infections.
- Studies of rapid identification of oral bacteria.
- Radiographic evaluation of the temporomandibular joint changes in young adults.
- Psychosocial evaluation of craniofacial surgery patients.
- Studies of treatment for dental patients at risk for endocarditis.
- Examination of tarnish and corrosion of new restorative materials in humans.
- Efficacy testing of bacteriocidal agents in treatment of adult periodontal disease.
- Development of improved clinical record systems for orthognathic surgery patients.

DENTAL MATERIALS

Question: With the increasing cost of gold, what research are you supporting in order to develop new and less expensive dental materials?

Answer: The NIDR is supporting projects ranging from basic metallurgical studies to clinical evaluation of such materials in an effort to develop new and less expensive dental materials to replace the use of gold. Investigators are studying the oxidation chemistry and oxidation rates of nickel-base alloys used for porcelain fused to metal restorations. Other investigators are studying 81 experimental alloys in in vitro and in vivo tests. Additional clinical studies are designed to evaluate tarnish and corrosion of experimental and commercially available low-gold and base-metal alloys.

CONSUMER FOOD ITEMS

Question: Last year, you said that you were working out a system to screen consumer food items for their decay-causing potential. It was hoped that the results of studies on this subject would offer information useful both to consumers and food manufacturers. Has a list of foods most harmful to dental health been compiled for the consumer?

Answer: The National Caries Program recently developed a method of testing various foodstuffs for cariogenic potential in animals. These studies will be adapted for extension to humans. In our initial animal tests, several representative food products were evaluated, including sugar, presweetened and unsweetened cereals, sugar-coated chocolate candy, caramel, potato chips, chocolate bars, fortified cereal, and chocolate cookies with a soft filling. The results showed that the relative cariogenicity of a food cannot be assessed simply on the basis of concentration of sugar, although clearly, all foods tested that contained sugar were to some degree

cariogenic. Other ingredients added to foods can influence their decay-causing potential by either retarding or enhancing the effect of sugar. Furthermore, an important finding of this study and previous supported research is that the frequency of eating sugars, not just the amount consumed, affects how much decay occurs. That is, the more often sugar is eaten, the more tooth decay results.

Question: When will such a list be made generally available?

Answer: At this time it is not possible to predict the availability of a list of cariogenic foods. It would be impractical to test all food items available for consumption. However, the animal test method provides a means of screening for cariogenic potential. Researchers, regulatory agencies, food manufacturers, and consumers can gain information from use of these tests on which foods may pose the greatest hazards in the humans.

Question: To what extent would dental costs be reduced by such information?

Answer: Americans spent nearly $15 billion last year on dental care, much of it to repair damage done by dental caries. Modified dietary habits of the public would reduce the prevalence, and thus the cost, of dental caries treatment.

ANTI-CARIES VACCINE

Question: It was recently revealed in the press that a new anti-caries vaccine is in advanced stages of development. Such a vaccine could constitute a revolutionary contribution to dentistry, to say nothing of the nation's general health. How soon can we expect to see the anti-caries vaccine introduced into general use? Can the effort be accelerated?

Answer: Results from studies in a small number of human volunteers who swallowed capsules containing Streptococcus mutans have also shown that an infecting strain of S. mutans is rapidly cleaned from the mouth following vaccination. This study was not designed to determine the effect on the prevalence of dental caries.

Long-term studies are now underway in primates to determine the effect of administering an oral vaccine on the prevalence of caries. Very early results appear to be promising although it will be several years before complete results are available. Assuming that no untoward effects are observed and that the vaccine is shown to be effective, it would then take a minimum of 3 years to carry out a clinical trial to determine its efficacy in humans. It would appear therefore, assuming that everything goes well, that we are not less than a decade away from a vaccine which would be suitable for general use in humans.

The expense of carrying out this research is a matter of continuing concern. Primates are by far the most suitable experimental animal model. Their initial cost, in addition to their maintenance costs are rising at an alarming rate, and their availability is declining.

Question: How does the vaccine work?

Answer: The vaccine is believed to exert its effects by inducing the production of antibodies in the oral cavity which prevent colonization of tooth surfaces by S. mutans.

Question: What impacts will the vaccine have on the Nation's dental and health care programs? On health costs?

Answer: A vaccine against dental caries should not be viewed as an alternative to existing methods of prevention. All the available evidence suggests that although a vaccine could be effective on its own it could act as an adjunct with those preventive methods currently available, each rendering the others more effective when used together. More widespread use of preventive methods could greatly contribute to the health of the nation and reduce the country's current 14.7 billion bill for dental treatment.

GUM DISEASE

Question: Last year, you said that progress was being made in identifying organisms which contribute to gum disease. Is a vaccine specific to organisms that are harmful to the gums feasible or being developed?

Answer: The feasibility of a vaccine for periodontal diseases has yet to be determined, because not enough is known about the specific causative organisms. When we achieve better understanding of the etiologic factors, we will be in a better position to make recommendations on vaccine development.

VACCINE

Question: To what extent will the new anti-caries vaccine be helpful in this regard?

Answer: The expertise gained by numerous scientists in developing a caries vaccine will be of distinct aid in future attempts to develop a vaccine for periodontal disease. However, the vaccine is specifically directed against the bacterium Streptococcus mutans, which is the main causative organism for dental caries. Since S. mutans is not one of the main organisms responsible for periodontal diseases, we do not believe that the new anti-caries vaccine will be directly helpful in preventing periodontal diseases.

NUTRITION

Question: What about the role of nutrition in gum disease; has any progress been made in this area?

Answer: There is a general consensus among scientists that nutritional deficiencies do not initiate periodontal diseases. Animal studies, however, have shown that dietary and nutritional factors may exacerbate the disease. For example it is evident that the periodontal disease status in animals with acute protein deprivation and Vitamin C and Vitamin B deficiencies is often more severe than in nondeficient animals. Moreover, a recent study showed that monkeys with a subclinical Vitamin C deficiency exhibited more severe experimentally-induced periodontal disease than did nondeficient animals. It is intended that the leads from these animal studies will be followed up in humans.

FLUORIDATION

Question: Certain groups, such as the National Health Federation, continue to maintain that fluoridation of public water supplies is damaging to public health. Is resistance to fluoridation of public water supplies growing or declining?

Answer: Although opinion polls indicate that 50 to 70 percent of the American public continues to approve of fluoridation, the small minority that actively opposes fluoridation has become increasingly visible and vocal. Opponents have, in the last few years, filed lawsuits against the initiation or continuation of fluoridation in several areas. Although no court of last resort has ever ruled against fluoridation, the multiple lawsuits have delayed the implementation of some administrative decisions for fluoridation, discouraged some local governments from making such decisions, and created negative publicity. Organizations opposed to water fluoridation have become more active in lobbying Congress by mass mail and personal contacts to eliminate Federal budget support of fluoridation programs and are attempting to reverse the positions of proponent organizations.

Question: Is there any new evidence to implicate fluoridation as a cause of cancer?

Answer: New evidence continues to support the safety of water fluoridation in that there is no association indicated between fluorides in water and the incidence of cancer. In 1980, publications from the National Health Statistics Center of New Zealand and a Committee of Inquiry appointed by the Premier of the Australian State of Victoria reported their negative findings, which are in full agreement with previous evaluations by the National Cancer Institute; National Heart, Lung, and Blood Institute; the U.S. National Academy of Sciences; National Health and Welfare of Canada; the Royal Statistical Society (London); and other similar organizations in the U.S. and overseas.

Question: Is there any new information that indicates that fluoridation is beneficial to the general health of the public?

Answer: The benefits to dental health provided by fluoridation include: (1) as much as two-thirds less tooth decay in children; (2) a six-fold increase in the number of decay-free teenagers; (3) fewer extractions of primary and permanent teeth; (4) fewer and less complex restorative dental service needs; and (5) fewer decay-related treatment needs and decreased loss of teeth in adults. The latest reconfirmation of these benefits has come from several U.S. and foreign studies during 1980 (Omaha, Nebraska; East Germany; England; and Australia).

MOUTH RINSES

Question: What new developments have there been in the development and application of fluoridated mouth rinses?

Answer: An important development has been the over-the-counter marketing of fluoride mouthrinses for home use. These mouthrinses, based on either sodium or stannous fluoride and intended for daily use, are now widely available and, we believe, will become widely used. Conscientious daily rinsing should achieve about a 35 percent

reduction in caries prevalence of children. This is a particularly important mode of prevention for children residing in non-fluoridated areas and attending schools without self-applied fluoride programs for older children graduating from such programs, and, of course, for adults with teeth at high risk for caries.

SUBSTITUTE SWEETENERS

Question: Your Institute continues to search for substitute sweeteners that are acceptable and noncariogenic. Last year, you did not sound very hopeful about short-term solution and said it would take 5-7 years for a new substance to meet regulatory requirements. Are there any sweeteners that are good substitutes for sugar?

Answer: Several sweeteners appear to be good substitutes for limited use. These include the sugar alcohols, sorbitol and xylitol, which are now being used to sweeten dietetic candies and much of the chewing gum consumed in the U.S. Neohesperidine dihydrochalcone, derived from citrus rind, also may be in this category and is being studied by the FDA. A number of other sweeteners, about which information is incomplete, have potential for fairly widespread use as sugar substitutes. For example, an extremely sweet protein, monellin, and an equally sweet protein glycoside, thaumatin, both found in berries of African plants, have attracted some commercial interest. In addition, a very sweet terpene glycoside, stevioside, can be isolated from leaves of a Paraguayan plant. This plant is now being cultivated extensively in Japan for the sweetener. Food chemists, particularly in Japan, have developed several starch derivatives that are highly sweet and reputedly non-cariogenic. Aspartame and saccharin are still being reviewed by the FDA.

Question: How much are you spending on this effort?

Answer: In FY 81, the NIDR will spend approximtely $400,000 in contracts for research on substitute sweeteners.

DISSEMINATION OF INFORMATION

Question: Last year you provided some very encouraging indications that the dissemination of information from the Institute was being expanded. In view of recent developments such as the new dental vaccine, we would hope this trend would continue. What new initiatives in information dissemination will you undertake in Fiscal Year 1981?

Answer: The Institute plans to expand its efforts to inform the dental and medical professions, as well as the public, about our new research findings on diet and caries. We are preparing two films on this subject--one for health professionals and one for the general public.

New publications are also planned to advise health professionals and cancer patients of the adverse effects of radiation therapy and chemotherapy on the teeth and the soft tissues of the mouth, and to outline steps to prevent and alleviate these effects.

Question: How wide is the dissemination of dental care information to the nation's school system?

Answer: The National Caries Program recently produced three films describing self-applied fluoride tablet and mouthrinse programs in schools. Last year, these films were seen by over 16,000 viewers. Almost 140,000 pamphlets on the same subject were distributed to school children. In addition, the NCP has distributed more than 200,000 posters designed to emphasize the importance of fluorides in caries prevention.

The National Caries Program also consults with community groups and school personnel about setting up school-based fluoride programs and works closely with other government agencies and offices involved in these efforts. A new exhibit on self-applied fluorides was shown at the annual meeting of the American School Health Association and the Association of Teacher/Educators. Other exhibits, developed for distribution on a free-loan basis, were sent on request to meetings of state PTAs and school board associations.

The Institute received requests for more that one-quarter million NIDR publications last year on tooth decay, oral hygiene, and snacking. Many of these requests were from students, their parents, and their teachers.

DIABETES

Question: Your Institute reported that you have been able to associate experimentally a cause and effect relationship between viruses, early-onset diabetes, and oral cancer. What follow-up has there been on this matter over the past year?

Answer: Our Institute reported an association between viruses and early onset diabetes mellitus. Over the past year, another case has been reported in the literature showing a link between coxsackie viruses and diabetes in the human. In our Institute, additional evidence has been obtained from autopsies showing that certain viruses can damage insulin-producing beta cells in the pancreas. A number of important new leads also have been obtained from studies on virus-induced diabetes in animals.

Question: How good is our understanding of the relationship between viruses and diabetes or oral cancer?

Answer: A great deal of information has accumulated from experiments in animals showing that several viruses can infect and destroy beta cells in the pancreas and produce diabetes. However, at the human level, it still remains to be determined whether viruses are only a minor cause of diabetes or whether viruses are one of the more important causes of this disease. As testified last year, there is still no clear relationship between herpes viruses and oral cancer.

PREVENTION

Question: How will this knowledge be applied to prevention and patient care?

Answer: If a virus or viruses can be shown to be a major cause of diabetes, then it might be possible to develop a vaccine to prevent this disease.

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan provided for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NIDR share of that amount is $11,399,000 and 119 grants.

Question: How is inflation impacting -- or how will it impact -- on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new research grants regardless of other budget priorities within NIH?

Answer: While the largest proportion of scientific activity related to oral health problems is currently in the basic research domain, this prominent function is implemented primarily by means of the investigator-initiated grant mechanism. The current state-of-the-science in oral health research is still largely in the basic area, and most of the research capacity is to be found in university and other related research institutions. To lessen the support for research grants to these institutions would seriously diminish U.S. capability to pursue basic science investigations relevant to oral health. Alternative sources of support from the private sector cannot be expected because these sources focus on the more clinically relevant investigations of technologies closer to potential market development and production. Thus, stabilization of new research grants is essential to maintain a steady stream of knowledge development concerning the etiologic aspects of oral diseases and conditions which can lead to new or improved diagnosis, prevention and therapy.

Question: What happens if, in a particular year, the quality of new research proposals declines: To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: Never in the history of the NIDR has there been an insufficient pool of quality research proposals. It is unlikely that a decline in quality will occur in the near future since with the advent of a diminishing funding capacity, only the highest scoring applications will be supported. An extreme level of competition might ultimately precipitate a decline in ability to attract the brightest potential investigators to careers in biomedical research in general and this would limit the nation's capacity to pursue productive research through any mechanism, whether it be grants, contracts or intramural research.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: In FY 1981 and 1982 the NIDR plans to fund to the 200 "Payline", representing 36 percent and 35 percent respectively of all approved grants.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: The Institute will continue to emphasize the importance of basic and applied research by supporting research grants in its six categorical program areas: dental caries; periodontal diseases; soft tissue stomatology and nutrition; craniofacial anomalies; restorative materials; and pain control and behavioral studies. In order to accommodate to a major cutback, the Institute would need to decrease the investment in research training; decrease applied research through the contract program; decrease the effort in intramural research; and decrease information/dissemination activities in the Institute's Office of Scientific and Health Reports.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: Because of the hiring freeze imposed during FY 81, savings were incurred in personnel costs. Additional reductions were made in travel, consultant services and procurement contracts. During FY 82 consultant services were cut further but reductions in other areas could not be absorbed without seriously affecting essential research activity.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justifications recently submitted to the Congress have attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

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National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

STATEMENT OF DR. G. DONALD WHEDON, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
L. EARL LAURENCE, EXECUTIVE OFFICER
DONALD F. CYPHERS, FINANCIAL MANAGEMENT OFFICER
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator Schmitt. We move to the next witness, who is Dr. G. Donald Whedon, Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. This Institute is one of the most complex of the Institutes, as we heard earlier. It is responsible for 10 major research areas. Its research encompasses most of the serious chronic diseases being studied at present.

Doctor, we welcome you. We ask you to introduce your colleagues and summarize your statement. Your prepared statement will be included in the record in its entirety.

[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, Diabetes, and Digestive and Kidney Diseases (NIADDK). During 1980 the Institute began its fourth decade of serving the American people through the conduct and support of biomedical research. The programs of NIADDK deal with a wide range of chronic diseases, as exemplified by the recent passage of legislation (P.L. 96-538), which expanded the name of the Institute to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

I would like to describe some of the ways in which this Institute is meeting its responsibilities to the American people and to give you a brief overview of research planned for the coming year.

Arthritis and Related Diseases

Research advances are developing rapidly in the study of arthritis and rheumatic diseases. Recent research has shown that systemic lupus erythematosus, a potentially fatal connective tissue disease, tends to run in families, involves abnormalities of the immune system, and that certain blood cells are defective in lupus patients. New findings also have established the influence of sex hormones in lupus.

Penicillin therapy has been shown to alleviate the initial skin rash characteristic of Lyme disease (an infectious form of arthritis) and may prevent or lessen the severity of the arthritis that develops later. In patients with scleroderma, life saving drug treatment has been successful in improving kidney function, lowering blood pressure, reducing ulcers on the fingers and even softening of hardened skin, problems characteristic of the disease.

New hope for an effective treatment for the debilitating and incurable skin disease, epidermolysis bullosa, has been reported. Young patients with this uncommon inherited disorder experience severe scarring, deformities, and malnutrition. Phenytoin, an anticonvulsant drug, was found to reduce significantly the blistering of skin and mucous membranes that characterizes this rare skin disease, a major advance for its victims.

Diabetes and Other Metabolic Diseases

NIADDK will continue to emphasize diabetes research. During the past year, Institute-supported investigators successfully transplanted the insulin-producing cells of the pancreas across animal species without immune rejection, a major advance in the continuing search for better methods of treating diabetics whose lives depend on insulin injections. We will capitalize on the progress that has been made in the development of insulin infusion systems ("artificial pancreas") to normalize elevated blood sugar levels in humans and animals.

Other promising research is taking advantage of the significant advances that have been made in recombinant DNA biology. Basic research by NIADDK grantees using recombinant DNA techniques has laid the foundation for the bacterial production of human insulin. Research on the bacterial production of other peptide hormones is receiving special emphasis, following the completion of the Congressionally-mandated evaluation of research needs in endocrinology and metabolic diseases, the "Ingbar Report." The Institute plans to undertake clinical trials of human growth hormone produced in bacteria by

recombinant DNA techniques. This research represents a major advance in overcoming hypopituitary dwarfism, since previously the only source of human growth hormone has been that extracted from human pituitaries collected at autopsy.

Research on cystic fibrosis (CF) represents a special focus for the Institute. It is the most common lethal inborn error of metabolism among Caucasian children. Institute grantees have recently reported the development of tests that may make it possible to identify people who carry the gene for CF and to predict the condition before birth.

Digestive Diseases

NIADDK-supported research has demonstrated successfully that "monooctanoin"--an emulsifying agent derived from digested fat--is an excellent solvent for cholesterol gallstones. This effective and inexpensive agent appears to be a satisfactory treatment for removing gallstones that remain in patients after biliary tract operations.

Over the past 20 years, the detection of disease responsible for life threatening gastrointestinal bleeding has been improved by the introduction of endoscopy--the use of flexible, fiberoptic instruments to view the inside of the upper portion of the GI tract. NIADDK grantees are studying the control of GI bleeding by endoscopic systems involving laser coagulation, electrocoagulation, suture clips, and tissue glues. They have found that these techniques offer new hope for the safe and effective control of massive bleeding.

Kidney and Blood Disease

NIADDK research efforts in kidney disease are focusing on the development of new methods of preventive therapy, earlier diagnosis, and more effective treatment through understanding of the basic mechanisms and causes. Such efforts provide hope that the numbers of patients dependent on artificial substitutes for normal kidney function will be reduced in the future.

NIADDK research has recently shown that the success of cadaver kidney transplants increases in proportion to the number of blood transfusions given before transplantation. Patients receiving many transfusions, surprisingly, had much better graft survival than nontransfused recipients. Accordingly, investigators recommend more liberal transfusions and frequent antibody screening for transplant candidates in order to ensure the most effective cadaver kidney transplants.

The Institute will continue its support of research into basic mechanisms of normal blood cell function and blood diseases. For example, NIADDK-supported research has led to the development of a highly safe and sensitive method for prenatal diagnosis of sickle cell disease, proven useful in 70 percent of pregnancies at risk for this potentially fatal blood disorder. A major advantage of this method is that it does not require a fetal blood sample, but rather tests amniotic fluid surrounding the fetus. This advance has stimulated activity in the research community in the effort to duplicate this type of testing in a variety of genetic diseases.

Intramural Research

The Institute's intramural scientists continue outstanding research in basic and clinical sciences. Our staff scientists have made major contributions in arthritis, diabetes and many other areas of our research responsibility and have attained international renown.

Institute scientists in the Diabetes Branch have found evidence that nearly every cell in the human body makes insulin--not just the islet cells of the pancreas, as was previously thought. New studies now suggest that cells may regularly produce all the proteins encoded in their genetic material--but at a low rate--throughout their lives.

In the area of genetics, NIADDK scientists have provided the foundation for understanding inborn errors of metabolism, which can cause physical deformities, mental retardation, and a shortened life span. Knowledge gained from these studies is now routinely used to provide diagnosis and prenatal and genetic counseling to families afflicted with these disorders.

A study of glucose tolerance and its relationship to pregnancy in the Pima Indians, in whom diabetes is 10 times more prevalent than the national average, has resulted in description of the risks associated with various degrees of glucose intolerance before, during and after pregnancy.

Mr. Chairman and Members of the Committee, this concludes my statement. I shall be glad to answer questions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Biographical Sketch

NAME: Dr. G. Donald Whedon

POSITION: Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK)

BIRTHPLACE AND DATE: Geneva, New York, July 4, 1915

EDUCATION : A.B., 1936, Hobart College; M.D., 1941, University of Rochester School of Medicine; Sc.D. (Hon.), 1967, Hobart College; Sc.D. (Hon.), 1978, University of Rochester

EXPERIENCE: Director, NIADDK, 1962-present; Assistant Director, NIADDK, 1956-1962; Chief, Metabolic Diseases Branch, NIADDK, NIH 1952-1965; (Organizer for DCMS program of General Clinical Research Centers Program, now in DRR, 1959-1961); Physician, Outpatient Dept., New York Hospital, 1947-1952; Assistant Physician, Outpatient Dept., New York Hospital, 1944-1947; Assistant Professor of Medicine, Cornell University Medical College 1950-1952; Instructor of Medicine, Cornell University Medical College 1944-1950; Assistant in Medicine, University of Rochester School of Medicine, and Assistant Resident Physician in Medicine, Strong Memorial Hospital, 1942-1944; Intern in Medicine, Mary Imogene Bassett Hospital, Cooperstown, New York, 1941-1942.

ASSOCIATION MEMBERSHIPS: Association of American Physicians; The Endocrine Society (Postgraduate Committee, 1962-1965); American Rheumatism Association; American Diabetes Association (Board of Directors, 1970-1976, Postgraduate Education Committee, 1971); American Federation for Clinical Research; New York Academy of Sciences; American Association for the Advancement of Sciences; American Physiological Society; The Gerontological Society; American Institute of Nutrition; Pan American Medical Association; American Gastroenterological Association; Aerospace Medical Association; Orthopaedic Research Society; American Academy of Orthopaedic Surgeons (Honorary Member); Dermatology Foundation, American Astronautical Society; The American Society for Bone and Mineral Research.

SPECIAL AWARDS, CITATIONS, PUBLICATIONS, OR ACTIVITIES: PHS Superior Service Award, 1967; Citation to Alumni Award, University of Rochester, 1971; NASA Exceptional Scientific Achievement Medal, 1974; Endocrine Society Ayerst Award, 1974; Arnold D. Tuttle Memorial Award of Aerospace Medical Association, 1978; Certified American Board of Internal Medicine, 1950; Certified, American Board of Nutrition, 1968· Special Postdoctoral PHS Fellowship, New York Hospital-Cornell Medical Center, January 1 - June 30, 1951; Subcommittee on Calcium Committee on Dietary Allowance, Food and Nutrition Board, National Research Council, 1959-1964; Editorial Board, Journal of Clinical Endocrinology and Metabolism, 1960-1967; Editorial Board,

Calcified Tissue Research, 1967-1976: Scientific Council of the Maryland Academy of Sciences, March 1965-1971; Council, National Program for Dermatology, 1971-1975; Principal Investigator of Calcium-Nitrogen Metabolic Balance Study on NASA Gemini-VII Space Flight, December, 1965, and for similar studies on Skylab series of NASA space flights, 1973-1974; Consultant to Space Medicine Division, Office of Manned Space Flight, NASA, 1963-present; University of Rochester University Medical Alumni Council, 1971-1976; University of Rochester Trustees' Council 1971-1976; Chairman, 1974-1975; American Institute of Biological Sciences Medical Program Advisory Panel to NASA, Chairman, 1971-1975; Chairman, Life Sciences Committee, NASA, 1974-1978; Member, Space Program Advisory Council, NASA, 1974-1978; Board of Trustees, Dermatology Foundation, 1978-present: Consultant, Endocrinology and Metabolism Advisory Committee, Bureau of Drugs, Food and Drug Administration, 1977-present.

Dr. Whedon is the author of over 70 scientific papers on metabolic and physiologic studies of convalescence, immobilization, paralytic poliomyelitis, diseases of bone particularly including osteoporosis, human energy metabolism and space medicine.

INTRODUCTION OF ASSOCIATES

Dr. WHEDON. Thank you, Mr. Chairman.

On my immediate left is my Executive Officer, Mr. Earl Laurence. On his left, my Budget Officer, Dr. Donald F. Cyphers.

I'd like to begin with a few general descriptive remarks about the Institute. It was renamed by very recent legislation, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. We actually began in 1948 as the Experimental Biology and Medicine Institute, and as one of the older Institutes, have a sizable intramural research operation in Bethesda, strong in fundamental biochemistry, physiology, and pathology, also in clinical research, carried on with about 15 percent of our total resources. Of the various extramural mechanisms for support of research, 75 percent of the total Institute's funding is in research grants, and five-sixths of that is in the individual research project grants, the so-called RO1 grants.

As our new name indicates, among our 10 extramural programs, 4 have our highest priority: arthritis, diabetes, digestive diseases, and kidney diseases. Since 1977, diabetes has been the lead program. As our name implies, we have broad disease research responsibilities. Nonetheless, about two-thirds of the research we support is of a fundamental laboratory nature and indicates dedication to the principle that solution of disease problems and their ultimate prevention is most likely to be obtained through determining causes and mechanisms of development of disease.

I shall give some examples from just four of our programs of the sorts of research we support. In the arthritis area, research on rheumatoid arthritis, the great crippler with which we are concerned, has yielded much evidence that some agent or substance, possibly a virus or other microbe, after invading the body, ultimately disrupts the body's

supposedly protective immune systems in such a way that inflamed, swollen, and later crippled joints result. Much effort is being devoted by many investigators to increasing our understanding of this immunologic phenomenon and to modifying and suppressing it.

In diabetes, the most notable recent advances have been: one, the discovery of receptors on the surface of cells as the principal system through which the hormone insulin acts to activate the metabolism of glucose; and, two, an advance in transplantation research, so that the insulin-producing pancreatic islet cells of one species, rats, can be given to another, mice, and can be not only accepted but remain viable and effective. This latter development is a very significant step toward possible control of human diabetes, eventually, through transplantation of normal islet cells to diabetic patients.

In digestive diseases, investigators are taking advantage of the recent development of long, flexible fiberoptic instruments called endoscopes, to view the inside of the intestinal tract and to study various methods of controlling intestinal bleeding. But in this disease area, as well, there are many basic studies of normal and diseased bowel function and of pancreatic, gall bladder, and liver diseases.

In the kidney diseases area, we have supported much of the progress in artificial kidney and kidney transplantation technology, but the emphasis of our support is progressively more on fundamental studies of kidney stone formation and of the acute and chronic kidney diseases that lead to end-stage renal deterioration. Here's a prime example of attacking causation of a disease for the purpose of ultimate prevention. Throughout all 10 of our programs of extramurally supported research, there is a balance between clinical- or disease-related studies and fundamental studies needed for ultimate cure and prevention, but with emphasis on the latter.

I shall be happy to answer any questions, Mr. Chairman.

PROSTAGLANDIN RESEARCH

Senator SCHMITT. What is the status of prostaglandin research with respect to arthritis?

Dr. WHEDON. Prostaglandin research really runs through many of our programs. It is a set of complex substances derived from certain fatty acids which are made by many cells throughout the body. They were initially mainly of interest to endocrinologists for their effect on the actions of other hormones. Even in gastroenterology at the present time, there's considerable interest because of the discovery that certain prostaglandins appear to have the ability to protect the mucous membranes of the intestinal tract and, therefore, might be of some advantage in the treatment of ulcers, or at least in their management. This has come about through the finding that certain drugs, which are antiprostaglandin in nature, do seem to provoke or worsen peptic ulcer disease. Studies are now underway to try to find out the extent to which the direct application of prostaglandins will be effective in the treatment of ulcers.

You mentioned arthritis. I don't know the specific studies at the moment, but prostaglandins are intimately involved in the inflammatory process. I would be pleased to supply further information for the record.

[The information follows:]

PROSTAGLANDIN RESEARCH IN ARTHRITIS

The prostaglandins are a group of unsaturated fatty acid derivatives with potent physiologic effects in most of the organs of the body. Recent research has indicated that certain prostaglandins promote inflammatory reactions, and in this manner, play an important role in the cause of inflammatory types of arthritis.

There is much evidence that prostaglandins of the E type, e.g., PGE2 and PG12, prostacyclin, are mediators of inflammation when injected. The E prostaglandins cause inflammation: they potentiate other mediators of inflammation: and their concentrations in inflammatory fluids are elevated.

Most nonsteroidal anti-inflammatory drugs, such as aspirin, indomethacin, and phenylbutazone, which are widely used in the treatment of many types of arthritis, have been discovered to be powerful inhibitors of the synthesis of prostaglandins. This is also true for newer nonsteroidal anti-inflammatory drugs, such as motrin or naprosen. There is a good correlation between the potency of these drugs' ability to combat inflammation and their potency to inhibit prostaglandin synthesis. Indeed, many scientists think that most, if not all, of the important pharmacologic effects of these drugs can be ascribed to their inhibition of prostaglandin synthesis.

There is also evidence that prostaglandin E2 mediates the resorption of bone in rheumatoid arthritis, causing the bony erosions that are characteristic of this disease. Inflamed joint lining cells from rheumatoid arthritis patients grown in tissue culture release large amounts of PGE2 with a capacity to resorb bone. Therefore, adequate suppression of PGE2 synthesis by anti-inflammatory drugs may prevent or reduce bone destruction in this crippling disease.

In addition, it has been very recently demonstrated that when monocytes, white blood cells, are exposed to uric acid crystals, the cells phagocytize, eat the crystals, and in doing so, produce large amounts of prostaglandins. Thus, the mechanism by which uric acid crystals produce the extremely painful acute attacks of arthritis in gout is now explained.

IMMUNE PROCESS

Senator SCHMITT. You did not include this in your testimony. Does this mean that you think this is one of the less promising areas of research, or one you just didn't choose to highlight?

Dr. WHEDON. No, Mr. Chairman; I just didn't pick it. We have, as I said, 10 areas, and many, many things to talk about. And I thought I would just hit the general matter of the affected or altered immune process in talking about arthritis. It is easier to emphasize.

Senator SCHMITT. Prostaglandin research in arthritis was one area of research that I ran across, along with many others, where there seems to be an increasing focus on trying to duplicate what the body has evolved to do by itself, but sometimes does not do sufficiently, to protect against the more virulent or chronic forms of disease.

I haven't asked this question, but is that your summation of the current thrust of much research throughout the Institutes, Dr. Fredrickson, particularly this one, to try to understand more what the body does for itself—recognizing that it's had a lot longer to do research than we have?

Dr. FREDRICKSON. Yes; I think just trying to understand nature's secrets has been our principal preoccupation since we started. But you are right—we have got to understand the normal mechanisms, how the body does it, and where it goes wrong, and how we are able to facilitate that process.

Senator SCHMITT. In addition, the treatment that more closely duplicates natural body functions will tend to have less after effects or side effects.

Dr. FREDRICKSON. It would also be less costly; yes.

Senator SCHMITT. Particularly the new techniques for production of natural body chemicals that appear to be coming out of DNA research.

Dr. FREDRICKSON. That is absolutely true.

DIABETES RESEARCH

Senator SCHMITT. In that regard, we discussed yesterday with the Center for Disease Control the issue of trying to duplicate natural body release of insulin.

Doctor, would you care to comment on that? You mentioned very briefly in your statement, are we putting sufficient priority on that area of diabetes research.

Dr. WHEDON. Yes; we are very interested in that area, and of course, many of our investigators are, as well. I mentioned briefly in my remarks some recent progress in transplantation research with respect to islet cells in the pancreas. Of course, if that can be achieved in human beings, that would go a very long way toward putting the diabetic patient back in link with the natural system of insulin supply and utilization which occurs in the normal human being.

There's another approach to this process of trying to get back to normal function. That has to do with artificial assistance to provide the diabetic patient with insulin, so-called insulin pumps. We are supporting studies of that sort.

The situation at the present time is that there are studies of the use of insulin reservoirs and pumps which can be worn attached to the waist of the patient. Most are about the size of a small hand calculator. There is a needle which is inserted in the subcutaneous tissue of the abdomen, and then, as a part of this whole package, there is a set of electronic controls in the apparatus which enable one to preprogram the rate at which insulin should be supplied to the patient during a 24-hour period. So, there would be a constant insulin infusion level with increasing amounts of insulin delivered just before meals. And I understand that these devices also have an arrangement whereby if there are any special requirements, these can be adjusted by the patient. So, these apparatuses are becoming more sophisticated and usable. Just how far they will go, and how far investigators will go in being able to apply this very broadly among diabetic patients has yet to be determined.

Senator SCHMITT. Wouldn't it be less expensive to use the brain as a computer, rather than one worn around the waist?

Dr. WHEDON. Except we don't know enough about how the brain works.

Senator SCHMITT. I mean, let the patient determine how much insulin he or she needs.

Dr. WHEDON. I think I understand what you mean. But the patient may not be able to tell by his own brain or otherwise exactly how much more insulin he needs at any one time so the approach at the moment is to have intensive study of the patient, for what his particular needs are in relation to his exercise and in relation to his food intake, and then program that into the device.

There are not many diabetic patients who can tell in advance exactly how much insulin they need for their particular problem. I know that

diabetic patients do get pretty wise and canny with experience, but I think we're inclined, at least at this stage of attempting to learn about these machines, to test, as far as we can, the ability of computerized technology to cover that.

NEW AND COMPETING GRANTS

Senator SCHMITT. What proportion of the 5,000 new research grants, will be allocated to you, and what is your share of the budget?

Dr. WHEDON. Our share is 690 grants, at a funding level of $69 million. To reach this level in 1982, we would need an increase in total research grants of approximately $10 million over the 1981 level.

Senator SCHMITT. That 690 is down from 816 in fiscal year 1981.

Dr. WHEDON. That's correct.

Senator SCHMITT. Why?

Dr. WHEDON. It's generally a matter of, in part, the growing expense of individual grants. As we estimated, there will be a greater man-load, and also, a greater equipment load, which makes the individual grant more expensive.

Senator SCHMITT. So it's inflation; is that what you're saying?

Dr. WHEDON. Excuse me. Mr. Laurence?

Mr. LAURENCE. There is also the cycle factor in our research grants program. From year to year there will be a change in the proportion of competing and noncompeting, so that the total number of grants that the Institute would be supporting would be approximately constant. Our competing number goes down when our noncompeting number increases.

Senator SCHMITT. Has inflation had any special effects on the activities of the Institute?

Dr. WHEDON. I'm not aware of any special ones for us. We certainly support research that requires very talented manpower and very sophisticated instrumentation, but I don't think that this is vastly different from the situation at other Institutes.

VIRAL TRIGGERS

Senator SCHMITT. There has been some suspicion that there are viral triggers of the juvenile onset of diabetes. Is there any new information in that regard?

Dr. WHEDON. The situation there is that since the early descriptions of an association between a viral infection and the onset of juvenile diabetes, notably by Dr. Notkins, of the National Institute of Dental Research, there have been some reports of additional cases over the past year which have confirmed this. So I think it is a real factor among the various etiologies of diabetes. I think one has to bear in mind, though, that it is very likely that the finding of specific viruses which bring this about is going to be quite difficult. And it's rather unlikely, in our present stage of knowledge, that a virus etiology for onset will be exclusive or even very extensive.

In other words—to put the whole situation another way, certain individuals by their genetic background probably have a predisposition to develop diabetes when something happens, something invades the body,

or some trauma occurs—some immune phenomenon or noxious environmental factor—of kinds that we do not fully understand. One of these factors could be an unusual virus infection.

Senator SCHMITT. Do you feel you're maintaining the momentum of your diabetes program with your fiscal year 1982 request as it now stands?

Dr. WHEDON. We will do our best to maintain our diabetes program, but in a situation where there has been limitation in our total funding, there is the possibility that the lead which diabetes has had over other programs will not be as great.

We're very anxious to maintain as much of a good balance as we possibly can among our various programs. When we occasionally see the situation, as we do this year, for example, in our hematologic diseases program, where the priority score pay levels are extremely low, then we have to come to the rescue of some of these poorer programs.

ARTHRITIS

Senator SCHMITT. My mother, like many others, has received relief from arthritic pain by wearing a copper bracelet. Have you figured out why that happens?

Dr. WHEDON. If there were time, Mr. Chairman, I could tell you a humorous story. But the gist of it is that patients believe in whatever they feel has caused an improvement, like the patient with a copper bracelet whose doctor gave him various regular treatments, and finally gave him one which did result in improvement. The patient congratulated the doctor for having found something that would finally make his bracelet work.

Senator SCHMITT. My mother receives no other treatment. [Laughter.] And never has.

Dr. WHEDON. She's very fortunate.

Senator SCHMITT. You don't believe in copper bracelets, other than the psychological effect?

Dr. WHEDON. In a hearing before the House some years ago, one of the members of the House committee, a very lovely lady, held up her arm, showed me her copper bracelet and asked for comment. I turned to her, and said, "On you, madam, it's very charming."

Senator SCHMITT. Well, I'll tell you, I have known an awful lot of cases, including golfers, that couldn't play golf, and then put on the bracelets and then went back to playing golf.

Copper is a trace element. As we're finding with many other trace elements, I believe it probably plays a very important part in bodily functions.

Dr. WHEDON. I think the various kinds of arthritis, particularly rheumatoid arthritis, are typical of many diseases in which the etiology, the causation, and the development, is so complex, that it's very difficult to know exactly what's going on. Many of these diseases have a tendency to wax and wane. In fact, they can even go away entirely. And if that coincides with the wearing of a copper bracelet, or coincides with any other event, the patient is likely to credit that event with having caused a marvelous cure. Also, these diseases can stay away for a long time, and if you're wearing a bracelet all that time, or if you're wearing a green dress all that time, or whatever——

Senator SCHMITT. Well, I don't think my friend is going to be satisfied with that answer at all. Certainly, my mother won't be.

Dr. WHEDON. I would like to followup on this for the record.

[The information follows:]

COPPER BRACELETS

Many intelligent people wear copper bracelets in the belief that it helps their arthritis. It may be that many of them fortunately have a mild form of arthritis. In other cases, the lessening of symptoms may be due to a placebo effect. Some patients may be in the improvement stage of their arthritis when they start to use the copper bracelet. Arthritis specialists in general do not think that copper bracelets are effective, having seen many patients coming to them for help for their active arthritis who had worn copper bracelets for long periods of time. On the other hand, there seems to be little, if any, risk in wearing them, so long as it does not prevent persons with active arthirits from seeking and obtaining treatment that is appropriate and effective for their particular type of arthritis.

There have been studies of copper levels in arthritis. Investigators have found that joint fluid copper concentrations were raised in patients with rheumatoid arthritis; 75 percent of the copper was present as ceruloplasmin, a copper-containing serum protein. However, the free copper and ceruloplasmin concentrations in the blood were no different in these patients with rheumatoid arthritis than in controls. Other investigators have found increased blood levels of ceruloplasmin in rheumatoid arthritis, reflecting in their opinion, nonspecific inflammatory activity.

Copper is, indeed, an important trace element in human metabolism and nutrition, being an important part of certain enzymes, particularly in relation to blood formation. None of the observations above suggest that any form of arthritis is copper-deficiency disease.

MALROTATED INTESTINAL TRACT

Senator SCHMITT. What is the status of early diagnosis of malrotated intestinal tract?

Dr. WHEDON. I have no special information on that situation. I don't know of any particular advances. You're talking about infants born with that?

Senator SCHMITT. Yes: having been born with one, and later having it diagnosed very late, relatively late in life. I'm just curious how you're doing.

Dr. WHEDON. I can give you no specific information, but I'd be glad to go into it.

Senator SCHMITT. Are we still waiting for symptoms to occur later in life for diagnosis? Has there been any systematic evaluation technique for newborn infants?

Dr. WHEDON. I think in order to diagnose that situation, the doctor would have to decide whether to take X-rays of the intestinal tract. And I think—obviously, the vast majority of infants being born normal, I would hesitate to do such a procedure as a normal, routine matter. So, as you know, in most medicine, most diseases, the doctor waits until the patient comes to him with a complaint.

Dr. FREDRICKSON. Dr. Whedon will check and provide a response for the record. [Laughter.]

Dr. WHEDON. I shall be happy to.

[The information follows:]

CONGENITAL MALROTATION OF THE INTESTINE

Congenital malrotation is one of many minor and usually asymptomatic aberrations in embryological development of vital organ systems. In this instance there is a developmental failure of the right side of the colon and the caecum to rotate into their proper position with the caecum and the appendix in the right lower quadrant of the abdomen. It is a rare abnormality present at birth. In most cases congenital malrotation is compatible with normal intestinal function and its presence remains undetected during the lifetime of the patient. When it is detected, it is usually when a symptomatic intestinal malfunction, which may even be unrelated to the malrotation itself, arises, and is followed by radiography or surgical opening of the abdomen. One example is the failure to recognize acute appendicitis, in later life, because the appendix is not in its usual location. The general level of knowledge among physicians, concerning congenital malrotation and its treatment, is much more advanced today than in the past. Since congenital anomalies of this general type are so diverse, individually so relatively rare and are so seldom associated with significant disease states, it has not been a part of good medical practice to screen intensively for all such possibilities. The more serious abnormalities are usually detected in early infancy.

SUBMITTED QUESTIONS

Senator SCHMITT. I'm sympathetic with your answer. I'm just curious as to whether there was any progress. When I was involved in this in 1960, it seemed to be pretty much a hit-or-miss affair. You got some symptoms, and you happened to be near a good hospital, and you survived. If you didn't, and you were somewhere away from a good hospital, you didn't survive.

Dr. WHEDON. I'll look into it, sir.

Senator SCHMITT. Thank you. Gentlemen, we will have additional questions for the record. And we'd appreciate those answers with your revised testimony.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

Clinical Nutrition Research Units

Question: How many Clinical Nutrition Research Units are currently operational?

Answer: There are currently seven clinical nutrition units (CNRU's) being supported by the NIH. Five of these are supported by the National Institute for Arthritis, Metabolism, and Digestive Diseases, and two are supported by the National Cancer Institute.

Question: How many are in the developmental stage?

Answer: Applications for two new centers have been reviewed and approved for support, but have not been funded.

Inquiries have been made by six additional groups of investigators who would be interested in developing an application for such a center.

Question: What do you envision to be the optimum number?

Answer: The CNRU serves as the focal point for multidisciplinary research in clinical nutrition and the standards used in the review of applications for this program have been high. The existing centers are relatively new and more experience is needed in evaluating their development. Professional judgment would be that support of between 12 to 15 centers across the country would be sufficient to carry out the goals of stimulating high quality research, strengthen training, and improve nutrition education for professionals and the general public.

Question: Are they cost-effective?

Answer: The existing centers were initiated in FY 1979 and FY 1980, so that it is too early to assess any questions of their cost effectiveness in meeting the goals of the program. However, it is clear, even at this stage in their development, that some of the programs developed by these centers will generate activities that can be considered beneficial in terms of cost.

For example, because of one of the programs run at the CNRU program at Vanderbilt University, there has been a marked increase in the awareness of the possibility of malnutrition in patients who are hospitalized. In this study, 4800 adults who were admitted to the hospital were screened and, as a consequence, 123 of these patients were judged to be suffering from unrecognized and potentially rectifiable protein-calorie malnutrition. The cost to identify these cases turned out to be only 24 cents per patient.

Question: How many individuals are currently being trained in nutrition under the units and other training programs that NIH has established in nutrition?

Answer: In each of the currently funded CNRU's there is specific provision for the support of a young investigator in order to encourage the development of his/her interest in nutrition research. While there are no other directed training funds associated with the CNRU's, most centers have developed programs in clinical nutrition which

enhance the education of various health professionals.

In FY 1979, the year for which the most complete data is available, the NIH supported under the auspices of its various extramural training programs related to nutrition, 297 trainees, as well as awarding 30 individual Research Career Development Awards (RCDA's) and 18 new Young Investigator Awards. Forty-one additional individuals were being trained in the intramural programs of the NIH.

DIABETES MOMENTUM

Question: What are the plans of the Institute to maintain a fiscal year 1982 the momentum developed in the past 5 years for diabetes research?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Would you supply for the record at the appropriate time, material showing spending for diabetes research in FY 1982?

Answer: The budget amount for this program is currently under discussion with the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

CHRONIC COMPLICATIONS OF DIABETES

Question: What are your plans for studying the effects of insulin in relation to the chronic complications of diabetes?

Answer: An example of the progress of the past few years in diabetes research is the opportunity to undertake a meaningful study of the most important clinical issue in diabetes today: the long-term relationship between the control of blood glucose concentration and the chronic complications of diabetes. As a result of the technological progress of the past few years we are now finally in the position to address this crucial question.

The NIAMDD has just announced to the scientific community a solicitation for applications to undertake a controlled clinical trial to assess whether and to what extent "strict" control of blood glucose (intensive therapy) may be an important factor in the prevention or amelioration of the vascular complications of insulin-dependent diabetes mellitus. The clinical trial is planned to consist of four sequential phases including those of planning, limited feasibility testing, conduct of the full-scale collaborative trial and data analysis and reporting. Phase I is expected to begin in the fall of 1981.

CHANGES IN EATING PATTERNS

Question: Has there been any change in the food consumption patterns of the American public in the last decade?

Answer: Based on the preliminary information released by the

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U.S. Department of Agriculture (USDA) concerning the 1977 National Consumption Study as compared with the results obtained in the 1965 study, it appears that changes in consumption of certain foods and nutrients, as detailed below, have occurred during the past twelve years. The significance of these changes must await more detailed analysis of the findings.

- Decrease in milk and milk products, except for cheese which increased 60% (mean calcium intakes dropped 11-24% for infants and children but not for adults).
- Decrease in eggs consumed.
- Decrease in legumes for all ages under 35 years.
- Decrease in fats and oils except among women and older teenagers.
- Increase in consumption of dark green vegetables, especially in older adults.
- Household consumption of meat did not change, but meat consumed away from home increased.
- Vitamin A intake decreased except in older adults.
- Thiamine intake increased.
- Magnesium intake decreased.
- Dietary iron increased.
- Vitamin C intake increased 20-50%.
- The mean total per capita per day energy intake (total calories) has declined somewhat.
- Although the absolute amounts of energy from protein and fats were lower in 1977, both had increased when expressed as a percent of total calories (16.6% protein calories, 40.3% calories from fat). Calories from carbohydrates have decreased to 42.8%.

Question: Has the research done by the Institute concurred with the results of the most recent USDA Household Consumption Study?

Answer: NIAMDD does not support national food consumption studies because this type of study is already being supported by USDA and the National Center for Health Statistics, HHS. The latter's Health and Nutrition Examination Survey (HANES) collected food consumption information in the 1971-72 and 1976-80 survey, but the dietary data are not yet available from the 1976-80 study.

Question: If there has been a change in food consumption, how has this affected nutritional status?

Answer: One can only postulate as to the effects these recent

changes in food consumption may have had on nutritional status. First, the USDA release on its 1977 Food Consumption Study is still preliminary, and more detailed information by age groups is needed, as well as further information on the variability and significance of the data.

Once the HANES (II) data on health and nutritional status are available for the 1976-80 period, a comparison of it with the HANES (I) data (1971-72) should provide detailed information relevant to this question.

Based on the significant positive relationship between dietary iron intake and blood hemoglobin levels as well as hemotocrits, the increase in dietary iron levels observed in the recent USDA survey is encouraging. The reported reductions in calcium, magnesium and vitamin A intakes, however, as well as an increase in dietary energy from fat give rise to concern. The apparent reduction in mean caloric intake level may be offset and balanced by similar reductions in the daily energy expenditures in many population groups.

Question: To what can this change be attributed?

Answer: One can only postulate that these apparent changes in food consumption patterns are due to the same social and economic factors that have changed dietary patterns over the last 30 years. These include changes in life styles, an increase in number and availability of processed foods, increased consumption of convenience foods, snacks and soft drinks, enrichment of some processed foods with essential nutrients, and a reaction to nutrition information linking saturated fats and cholesterol to heart disease.

CHANGES UNDER NEW LAW

Question: A law passed last year made a number of changes in the Institute, including changes in its name. How will these changes affect your activities? To what extent will the kidney diseases program get more emphasis? How will you implement the recommendation by the conferees that training of allied health professionals be given special attention in the centers programs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

DERMATOLOGY

Question: Last year Dr. Whedon, head of the Institute, reported that the Institute had 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. Did publication of the Odland Report stimulate a substantial increase in applications for research in skin diseases, as you said you expected last year?

Answer: A two-year contract awarded to the University of Washington School of Medicine to do an analysis of the needs and priorities for dermatologic research was completed and submitted to the NIAMDD in July 1979. This report was published in the November 1979

issue of the Journal of Investigative Dermatology. The objective of the project was to provide a comprehensive basis for support of research and an increased understanding of the major dermatologic problems that beset Americans.

Since publication and broad dissemination of the "Odland Report," there has been a significant increase in research grant applications to the Skin Diseases Program.

In addition to this trend for an increased number of applications for research in skin diseases there has been a concommitant improvement in the average priority score for these applications, which reflects the increased scientific merit of these applications.

Question: Which diseases or areas of dermatologic research are being emphasized in your program?

Answer: The Skin Diseases Program supports clinical and laboratory research of both normal and diseased skin to obtain a better understanding of the causes and processes of various skin diseases. The goal is to provide means of prevention, treatment, and cure of these diseases. Basic and clinical research areas relevant to program goals are:

1. Disorders of keratinization, including psoriasis and ichthyosis

2. Eczematous and immunologic diseases, including atopic dermatitis and other chronic inflammatory diseases of the skin

3. The vesiculobullous (blistering) diseases, including pemphigus, bullous pemphigoid, erythema multiforme, dermatitis herpetiformis, and epidermolysis bullosa

4. Disorders of the pilo-sebaceous (hair and oil glands) apparatus, including common acne

5. Disorders of connective tissue, including scleroderma, keloid scars, and cutis laxa

6. Disorders of pigmentation, especially vitiligo

7. Photobiology, including phototoxic and photo-allergic (light sensitive) diseases and reactions to internal and external agents.

COORDINATION WITHIN INSTITUTE

Question: We are interested in how you achieve cooperation among overlapping programs within your Institute. For example, what exchange of information occurs between your obesity center at St. Luke's Hospital in New York City which is a part of the Digestive Diseases and Nutrition Program and the researchers in the Diabetes, Endocrinology and Metabolic Diseases Program?

Answer: We make every effort to keep the definitional boundaries between our programs as flexible as possible and there is significant transfer of information and, where needed, of resources between them. Many of our programs have significant nutrition related components,

particularly diabetes, metabolism, kidney and hematology. Of the 25.4 million dollars of extramural nutrition research and training support by NIAMDD in FY80, 14.7 million was actually budgeted to the Nutrition Program. The Institute reviews its support each year to determine the total amount and nature of nutrition research and training in all programs. This is part of a trans-NIH effort to exchange information and prepare an annual report on the biomedical and behavioral nutrition research and training at the NIH through the Interinstitute Nutrition Coordinating Committee.

With respect to the specific question about the obesity center, because of the high relevance of its research activities to diabetes, this center grant has utilized funds budgeted for diabetes and is administered by the Nutrition Program, as are several other obesity-diabetes related research grants. There is frequent and continuing information exchange among the staff of these programs. Moreover, Dr. Lester Salans is a leading obesity research scientist in his own right as well as our Associate Director for Diabetes, Endocrine and Metabolic Diseases. He is regularly involved as a resource person in the development of any new program thrust in obesity research.

Question: Wouldn't investigators involved in kidney diseases be interested in new information on the physiology of obesity?

Answer: The role of obesity as a risk factor for hypertension and for non-insulin dependent diabetes ("maturity onset diabetes") is reasonably well established. Other conditions including gall bladder disease, gout, kidney and digestive diseases appear to be associated with obesity. Despite considerable effort, it has been difficult to establish definitely the etiology of obesity or its casual role in such diseases although progress is being made. The NIH and NIAMDD facilitate the exchange of information in multi-disciplinary areas through workshops, advisory group meetings, coordinating committees, and by direct inter- and intra- institute communication by technical staff. Of course, scientific publications and multidisciplinary national meetings (both encouraged and supported by the NIH) are primary means of prompt information exchanges among researchers in the fields of obesity and kidney disease.

Question: Some forms of arthritis can also cause serious kidney disease. How do you coordinate research between the two program areas?

Answer: The most important and widespread example is the disease systemic lupus erythematosus (SLE), a rheumatic disease which damages many body systems, including the kidneys and joints. Kidney failure is the ultimate cause of death in about half the patients with this disease. Another example is scleroderma, a rheumatic or "connective tissue" disease characterized by progressive rigidity and thickening of the skin and underlying tissues and by frequent progressive involvement of internal organs, including the kidneys. Here, too, renal insufficiency, hypertension, and eventual kidney failure can be a cause of major disability and mortality in such patients.

In our Institute, the program staff responsible for the Arthritis Program and for the Kidney Disease Program, respectively, cooperate very closely and continuously exchange information about the respective program activities and research results, as a matter of routine

working practice.

LOW BACK PAIN

Question: We understand that your Institute recently conducted and supported a workshop on low back pain. Why would you undertake such a project?

Answer: While some causes of low back pain are clearly diagnosable (e.g., herniated disc), most cases are of unknown specific origin. Research on the complex spinal structures and nerve pathways require investigators from diverse backgrounds. Therefore, researchers from several clinical and basic science disciplines were gathered to discuss the knowns, unknowns, and research directions for future studies. In light of the tremendous incidence and large economic impact of back pain, this workshop provided stimulation to generate new research ideas and applications and a clearer definition of the relevant problems to be addressed.

Question: Is this a major problem?

Answer: The workshop chairman opened this research conference by identifying low back pain as a very frequent and important problem. The following facts indicate the major medical and socio-economic impacts of back disorders:

- Several studies have indicated that four out of five individuals will have a significant complaint of back pain at one time or another in their lives.

- Impairments of the spine are the most frequent causes of activity limitations in persons 18 to 44 years of age, according to surveys performed by the National Center for Health Statistics.

- Back pain is second only to the common cold as a cause of time lost from work.

Question: What did you learn from this workshop and how will the outcome affect your research activities for the 1982 budget year?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

JOINT DISORDERS

Question: It is our understanding that approximately 20% of the U.S. population suffers from some form of joint disorder. We also understand that as our population grows older, we can expect this problem to become more severe. What research work are you supporting in order to ultimately prevent this problem?

Answer: Research activity is being continued to relate degenerative joint disease to the effect of aging and trauma on joint cartilage. Studies that have led to the structural and metabolic characterization of cartilage have also demonstrated biochemical

abnormalities in this tissue that are unique to the disease. Several enzymes with tissue-eroding or dissolving potential have been isolated from cartilage and the changes observed in joint disorders may be related to the release or activation of some or all of these enzymes. Extension of the enzyme studies could provide the means for inhibiting the destructive changes that attend the disease.

The injurious effects of inflammation on joint structures are now better understood. Bone and cartilage can be destroyed by the production of enzymes such as collagenase by specialized cells in joint tissue and the process is influenced by a variety of mediators. More detailed knowledge of the process is being obtained which will provide a better understanding of the stimulus required to initiate the inflammatory process. This better understanding may lead to more selective and effective intervention for these disorders.

Question: At the present time, the medical community uses a number of artificial joints (hip, knee, ankle, etc.) to help restore those individuals afflicted with joint diseases to productive life. What success have we had with these devices? Or failures? What major problems have you found?

Answer: Joint replacements have provided improved quality of life, return to the workplace, and pain-free motion to hundreds of thousands of patients. In the United States, over 100,000 hip joint replacements are performed each year. The short-term (up to 8 years) success rate is estimated at over 90%. The long-term results vary significantly in several studies. It is reasonable to expect that with current surgical procedures many years of painless joint motion may be gained by hip joint replacements. Over the past few years, knee joint replacements have evolved into a semi-constrained form that promises improved long-term results.

The major causes of failure of various joint replacements are loosening, infection, dislocation, component breaking, and toxic biomaterial reaction. Because a revision procedure for an initial failure presents greater surgical difficulties, it is important to reduce all failures to an absolute minimum. The Musculoskeletal Diseases Program supports about 23 grants in this area at the cost of about $1.6 million. Additionally, an NIH Consensus Conference on Artificial Hip Joints is scheduled for March 1982.

POLICY ON GRANT AWARDS

Question: We have been advised that in recent years the Institute has followed a policy of awarding research grants in certain areas to applicants whose priority scores were higher, and thus represented lower quality than those in other areas of the Institute, particularly by the Arthritis "Cluster." We now understand that you intend to try to eliminate this inequity by henceforth basing the awarding of research grants solely upon the quality of the application as reflected by the priority score accorded it in the peer review process. Would you please comment on this apparent change of policy?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

JUVENILE RHEUMATOID ARTHRITIS

Question: This committee has for the last several years expressed a specific interest in an expansion of research in the field of arthritis in children. What avenues is the Institute pursuing in this area?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

EPIDEMIOLOGICAL STUDIES

Question: Do you intend to initiate epidemiology studies in arthritis to try to identify the precipitating environmental factor?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

VIRUSES, GENETICS AND DIABETES

Question: Viral triggers of juvenile-onset diabetes have been suspected for several years. However, there is apparently a great difference in susceptibility of individuals to infection by the various viruses that may be agents in causing diabetes. The role of heredity in maturity-onset diabetes has likewise not been explained. Has any further information been developed concerning viral causes of diabetes?

Answer: During the past few years a considerable body of indirect evidence has accumulated concerning the relationship between viral infections and insulin dependent diabetes (juvenile diabetes). This form of diabetes has been induced in laboratory animals using several human viruses; certain strains of laboratory animals appear to be especially susceptible to these viruses while other strains do not, apparently on a genetic basis. There is an increasing body of epidemiologic evidence suggesting an association of virus infection with insulin dependent diabetes in human subjects. Recently, a virus has been isolated from the pancreas of a young patient which induced diabetes when injected into laboratory animals. The results of this study strongly suggest that the virus was responsible for producing diabetes in this child. This is the first direct evidence that viral infections may cause diabetes in man. It is, however, unlikely that viral infections are responsible for a large number of cases of insulin dependent diabetes in man. Nevertheless, some individuals may be genetically predisposed or hypersensitive to the destructive action of pancreatic viral infection and thus to insulin dependent diabetes mellitus.

Question: What is known about the genetic component of susceptibility to diabetes?

Answer: During the past several years our knowledge about genetic factors in diabetes mellitus has increased enormously. It is clear that genetic factors are important and probably primary in the genesis of both insulin dependent and non-insulin dependent diabetes mellitus. It has been learned that the genetics of insulin dependent

diabetes differ from the genetics of non-insulin dependent diabetes mellitus. Within insulin dependent diabetes there is considerable genetic heterogeneity. Thus, insulin dependent diabetes may be associated with different genetically determined histocompatibility tissue types (HLA). In insulin dependent diabetes genetic factors confer increased susceptibility to certain factors in the environment, for example to certain viruses capable of destroying the pancreatic islets (the cells which produce insulin). An autoimmune component to insulin dependent diabetes (self-destructive antibodies to insulin secreting cells), has been recently recognized and found to be under genetic control.

Genetic factors are also important in non-insulin dependent diabetes mellitus. Genetic studies in identical twins demonstrate that if one twin has this form of the disease, it is nearly certain that the other twin will eventually develop the same form of diabetes. Genetic factors impart increase susceptibility to environmental factors in this form of the disease as well, for example overnutrition and obesity. Not all obese patients develop non-insulin dependent diabetes; only those who are genetically predisposed suffer the disease. Our continuing intensive studies of the Pima Indian community, through our research activities in Phoenix, have contributed significantly to understanding of the influence of genetics and obesity as predisposing factors in diabetes.

DIABETES CENTERS

Question: Would your research proceed faster if you could expand your centers programs? What additional areas could the various centers profitably investigate?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

SYNTHETIC INSULIN

Question: The news media seem to be full of articles on recombinant DNA technology and its potential for producing large quantities of synthetic human insulin. What is the status of that research at present?

Answer: Remarkable progress has been made in this area. The insulin gene and its initial translation product, pre-proinsulin, has been identified and isolated. DNA copies of the messenger RNAs for insulin have been cloned and sequenced. Human insulin has been produced by bacteria using recombinant DNA techniques. This synthetic insulin has been demonstrated to be biologically active in both laboratory animals and in man. Six research centers in the United States are initiating clinical studies to test in man the efficacy of recombinant DNA-synthesized human insulin.

DIABETES TRAINING

Question: Are there particular areas of diabetes research which suffer from a shortage of trained investigators?

Answer: The remarkable progress made in diabetes biomedical research during the past few years reflects, in large part, the contributions of established investigators in diabetes. Increased support of diabetes research during the past several years has enabled the Institute to increase opportunities for, and to attract new investigators into, diabetes research. Continued and future advances in diabetes research, however, will be highly dependent upon an influx of additional and new research scientists. The body of highly qualified investigators, particularly clinical investigators with an in-depth background in both basic science and clinical medicine, declines with time and requires replenishment. There is a need for new and highly trusted investigators for the broad-based innovative approaches needed to unraveling the fundamental processes of the nature, and the pathological events causing disease, and the evolution of rational approaches to prevention, treatment, and cure of diabetes. There is a shortage in the total manpower pool, particularly severe in important diabetes-related aspects of biochemistry, metabolism, immunology, epidemiology, virology, pathology, pediatrics, obstetrics, neurology and renal physiology.

Question: If so, what is the Institute doing to correct the situation?

Answer: The Institute has been and is continuing to stimulate interest in the broad biomedical research community through various mechanisms including program announcements, workshops and symposia, and by working closely with the appropriate individuals, organizations and institutions in the scientific field. This vigorous approach is generating greatly increased interest and opportunities in research and training support, at times beyond available resources. We have undertaken several new focused efforts of manpower development in the diabetes area with particular emphasis on the support of new investigators with particular interest in a diabetes-related research career.

One of these, the Special Emphasis Research Career Award (SERCA), has been developed by NIAMDD to address (currently) three interdisciplinary areas, in conjunction with other Institutes. They are: 1) cardiovascular complications of diabetes (with the National Heart, Lung and Blood Institute), 2) obstetric, perinatal and pediatric complications of diabetes (with the National Institute of Child Health and Human Development) and 3) diabetes in the elderly (with the National Institute on Aging). We are currently looking for other interdisciplinary areas that could be funded with the SERCA mechanism.

AUTOIMMUNE PROCESS

Question: There are more than 100 different disorders of the joints and connective tissues that are included in the term "Arthritis." The most common form, osteoarthritis, is a "wear-and-tear" breakdown, but other forms seem to involve a derangement of the body's immune system that results in self-destruction of tissue. Have any advances been made in understanding the autoimmune processes that seem to be a part of certain types of arthritis?

Answer: Arthritis research has enhanced and in large part developed a number of the modern concepts of immunology. These include the biology of immune complexes, autoimmunity, the complex regulation

of immune reactions, the genetic control of immune responses, and others such as the mediation of inflammation and "complement" chemistry. In addition, there is great need to identify the antigens that initiate these autoimmune processes. There is some evidence that Epstein-Barr virus may be implicated in rheumatoid arthritis and that hepatitis virus is involved in many cases of polyarteritis. Much more needs to be done in these causal aspects of autoimmune diseases.

Question: What preventive measures can the public take to guard against arthritis?

Answer: Much more needs to be known about the underlying causes for the various types of arthritis before definitive preventive measures can be planned and undertaken. Epidemiological studies are needed to identify risk factors for the development of osteoarthritis, similar to the productive research that has been carried on in other major chronic diseases such as arteriosclerosis. In addition, physical fitness programs may be helpful in minimizing the disability caused by arthritis.

Question: What is the status of research on plasmapheresis as a possible treatment for rheumatoid arthritis?

Answer: Therapeutic pheresis (removal of potentially deleterious blood components with replacement of the "purified" residual blood) is now under considerable study but its potential value for treating and investigating rheumatoid arthritis and certain other rheumatic diseases is not at all clear at the present time. Technology has been developed for removal of abnormal immune lymphocytes as well as of abnormal protein components from the blood. The small number of clinical trials that have been performed to date indicate that this new form of treatment may be promising - however, there are also clinical trials, notably one carried out in Canada, that showed that plasmapheresis was not effective in rheumatoid arthritis. Therefore, there is great need for additional very well controlled trials in order to determine both the efficacy and safety of this new treatment. Intramural scientists in the Arthritis and Rheumatism Branch of the NIAMDD at the Clinical Center are currently carrying out such carefully controlled clinical investigations.

CYSTIC FIBROSIS

Question: Cystic Fibrosis is a hereditary metabolic disorder of unknown cause. Pancreatic function is abnormal and excess mucus is produced, especially in the lungs. Victims rarely survive beyond adolescence. What research are you pursuing on cystic fibrosis, and how does it relate to that carried on in the Heart and General Medical Sciences Institutes?

Answer: The NIAMDD supports research on the full range of factors concerned with and involved in cystic fibrosis, including research on the etiology, pathogenesis, natural history, diagnosis and treatment of this disorder. Some areas of particular emphasis in the Institute's research program include studies on exocrine function in cystic fibrosis, the digestive complications of cystic fibrosis, detection of the carriers of cystic fibrosis and basic studies of the metabolic dysfunctions observed in this disorder. The National Heart, Lung and Blood Institute supports research on cystic fibrosis as it

effects structure and function of the lung. The National Institute of General Medical Sciences (NIGMS) supports studies which focus on basic aspects of protein and mucopolysaccharide structure, basic genetics and ion transports which may be relevant to cystic fibrosis. NIGMS also supports the Human Genetic Mutant Cell Repository which supplies 36 different CF cell lines to investigators on a worldwide basis to aid in cystic fibrosis research.

NUTRITION RESEARCH

Question: Since 1977 a number of reports have been released by both Government agencies and private organizations making recommendations on how the American public should eat. The recommendations of some reports have not always been in agreement with those made in others. In light of the proliferation of reports since 1977 recommending how Americans should eat, what is your Institute doing to help resolve the controversy over the relationship of diet and disease?

Answer: Many of the questions raised about the possible relationship of diet to disease are based largely on epidemiological studies, and work with experimental animals. Diet appears to influence the incidence of cardiovascular disease, gallbladder disease, maturity-onset diabetes, and, of course, obesity and its complications. But despite this, there is remarkably little definitive information on the etiology of a number of diet-related conditions which constitute major health problems in the U.S. Accordingly, in 1978, NIAMDD contracted with the National Academy of Sciences (Food and Nutrition Board) to evaluate the available information on this subject and to identify priorities for research in nutrition, identifying new information needed for the development of dietary recommendations for the public. This report, "Research Needs for Establishing Dietary Guidelines for the US Population", was published in 1979. This report is expected to stimulate research in these areas.

NIAMDD also provided a clinical nutritionist to the NIH Nutrition Coordinating Committee in 1979 and to the Office of the Assistant Secretary of Health, HHS, to work on the "Dietary Guidelines for Americans".

NIAMDD, in conjunction with other Institutes and the Nutrition Coordinating Committee, issued in November, 1978 an announcement of research support on "Studies on Nutrition and Obesity".

A special workshop is planned in FY 82 to identify Methodologies for characterizing Human Obesity. Also a consensus workshop on the health significance and safe ranges of body weight is presently being planned in collaboration with the National Institute on Aging and other Institutes.

Question: What, if any, research has been funded on the appropriate proportion of macronutrients (carbohydrate, fat and protein) in the diet?

Answer: Energy balance, in terms of the appropriate proportion of the macronutrients in the diet as it relates to various diseases continues to be a major area of research supported by the NIAMDD primarily through its nutrition, diabetes and kidney diseases

programs.

A sampling of the types of research supported in this area includes:

- o "Composition energy and weight maintenance" - to learn how the proportions of carbohydrate and fat in the fuel mixture which is being oxidized are influenced by the amount and composition of the food mixture and by physical activity.

- o "Metabolic aspects of obesity". The study of effects of maternal diets composed of either high fat or high carbohydrate on the subsequent development of fat cells in the infant.

- o "Dietary obesity: Consequences of overfeeding" - study of the relationship between the macronutrient composition of the diet and proportion of brown adipose tissue in rats.

- o "Optimal Diets for Treatment of Obesity: Metabolic Basis" - attempts to determine the optimal diet composition for the treatment of obesity as well as the role of exercise and techniques of behavior modification.

- o "Utilization of Protein and Energy" - measurement of the effects of energy intake on the utilization and retention of protein.

- o "High Carbohydrate and High Fiber Diets for Diabetics" - Study of the dietary control of patients with diabetic hyperglycemia.

Question: The traditional recommendations made about diet have been based on a ratio of 50/15/35 per cent of total calories being provided by carbohydrate, protein, and fat respectively. Now recommendations are being made to change the traditional ratio of calorie sources. Such changes in the recommended levels of macronutrients could have a profound effect on the dietary requirement for vitamins and minerals. Some proponents claim that these alterations will not hurt anyone. In reality there has been a dearth of literature on the subject, because little or no research has been done. What, if any, investigation is being made of the requirements for trace minerals and vitamins which might be affected by the changes being advocated in the macronutrients?

Answer: For many years, the NIAMDD has contracted with the National Academy of Sciences (Food and Nutrition Board) to revise and update periodically the current "Recommended Dietary Allowances (RDA)". This involves critical evaluation of all available information on factors which may affect nutritional needs, as well as the research data in this area. Part of this continuous effort is a reconciliation of the daily human requirements for essential micronutrients (vitamins and trace minerals) with the quantities of macronutrients likely to be consumed by the average healthy person living in a moderate climate in the United States.

In addition, NIAMDD, in collaboration with the National Institute of Child Health and Human Development, the National Cancer Institute,

and the National Institute of Allergy and Infectious Diseases, is preparing an announcement of intended grant support for the study of environmental and host factors that affect nutritional requirements. This is a part of the program of the US Malnutrition Panel, US-Japan Cooperative Medical Science Program (administered by NIAMDD). Such studies in countries consuming markedly lower levels of protein and fat but higher levels of complex carbohydrates is expected to yield valuable information about requirements of some trace of minerals and vitamins with changed proportions of the macronutrients.

Some of the projects which NIAMDD has funded relating to trace mineral or vitamin requirement affected by changes in macronutrient composition of the diet include:

- "Effect of Meal Pattern and Diet on Energy Metabolism" - The results of this study indicate that obese mice require more dietary vitamin E than lean mice.

- "Bioavailability and Kinetics of Ingested Molybdenum" - This study includes experiments on the influence of gastric and intestinal environments (including amino acids, etc.) on absorption of molybdenum (a possible essential trace mineral).

- "Studies of Human Nutrition - Trace Element Needs for Maintenance and Reproduction"- The overall objectives include determination of human requirements for zinc, copper, and selenium from various mixed diets, and a study of the interaction of zinc with protein and calcium in the diet.

- "Dietary Lysine and Carnitine Formation" - This work indicates that rats and man consuming diets low in protein or lysine have lower levels of carnitine, an essential metabolite normally synthesized by the body if the diet is adequate.

- "Effect of Ethanol and Other Drugs on Folate Metabolism" - This study involves a study of the effect of increasing the calories from alcohol on the requirement for folic acid.

- "Metabolism and Function of Carotenoids and Vitamin A" - This investigation has obtained data suggesting that there is a relationship between the serum vitamin A level and serum taurine level in rats and people fed low-protein diets.

- "Dietary Fiber and Bioavailability of Macronutrients" - This investigation has found that certain food fiber sources, but not others, increase the excretion and decrease the absorption of dietary Vitamin B_{12}.

DIETARY FIBER

Question: How strong is the evidence which suggests that the American public would benefit from an increase in dietary fiber?

Answer: Essentially all of the evidence suggesting possible

relationships between dietary "fiber" levels and diseases or disorders is based on epidemiological studies and therefore indirect. A direct link has, therefore, not been proven.

Question: To what extent have any diseases been linked to fiber content of the diet?

Answer: Eating foods high in "fiber" tends to reduce the symptoms of chronic constipation, diverticulosis and some types of "irritable bowel." There also is concern (as yet unconfirmed) that low fiber diets may increase the risk of developing colon cancer.

It has been postulated that a high dietary fiber intake would reduce intake of excessive calories and thus help prevent obesity. Diets high in fiber and complex carbohydrates tend to lower (the otherwise elevated) blood glucose levels in individuals with "maturity onset diabetes" who do not require daily insulin for control of their disease. This effect is thought to be the result of a generally slower intestinal digestion of complex carbohydrates mixed with fiber in the gut which consequently delays the absorption of glucose into the bloodstream.

Question: How do changes in dietary fiber alter other nutrient needs?

Answer: Increased levels of some sources of dietary fiber have been found to decrease the bioavailability of certain trace minerals (zinc, copper, iron), to increase the fecal excretion of vitamin B_{12} and to impair the action of lipolytic digestive enzymes, thus reducing fat digestion.

BLOOD PROGRAMS

Question: Research in hematology is intended to increase fundamental and applied knowledge about blood and blood diseases. How do the activities of the Blood Diseases component of your Institute mesh with the programs of the National Heart, Lung and Blood Institute?

Answer: The Hematology Program of the NIAMDD supports extramural research into basic mechanisms of both normal blood cell function and disease pathogenesis, ranging from studies using blood cells as models, to studies aimed at development of new therapy or preventative measures for selected diseases within the mission of the Institute. Because of its accessibility and ease of handling, the red blood cell has proven to be a useful model for studies of biological membranes and their transport properties, and the hemoglobin molecule as a tool for studying molecular and genetic diseases. The use of recombinant DNA technology has intensified research in the latter area, and promise now exists for the prevention or cure of certain genetic diseases, based on studies of this intensely studied protein, hemoglobin. Primary areas of clinical interest within the mission of the NIAMDD Hematology Program are the origin and pathogenesis of the anemia of chronic renal failure and of other chronic diseases; hereditary anemias; development of therapeutic modalities such as bone marrow transplantation and factors such as erythropoietin involved in regulation of stem cell differentiation; metabolic abnormalities related to iron overload and deficiency or the interaction of various nutrients.

The NIAMDD Hematology Program activities are complementary to the blood research activities of the NHLBI, and guidelines for the assignment of grant applications are carefully negotiated to avoid duplication of effort. The closest areas of interaction are: first, in research on erythropoietin, where the NIAMDD support studies of erythropoietin in blood cell population and physiological function, while the NHLBI supports efforts to collect, purify, and distribute erythropoietin to investigators; second, in hemoglobin research, where the NIAMDD supports basic studies on the genetics and biosynthesis of a wide variety of hemoglobin types, often as a model protein, while the NHLBI is interested in the hemoglobinopathies such as sickle cell disease and the thalassemias; lastly, the red blood cell is of mutual interest. NIAMDD supports research on the red blood cell as a model for metabolic studies or in anemias of chronic disease, while the NHLBI supports research on red blood cell disorders in certain defined diseases.

The NIAMDD is committed to coordination of research activities in blood, and Institute staff are assigned to the NIH Coordinating Committee for Blood-Related Activities and to the Interagency Technical Committee Working Group on Blood and its Substitutes.

A three-year project is entering its completion which is evaluating the state of the art and research needs in hematology. This should provide NIAMDD, as well as NHLBI, the National Cancer Institute, and other concerned Institutes a better understanding of the current status of research in hematology and the promising directions for future investigations--especially those whose neglect would delay progress in the understanding, diagnosis and treatment of human disease. This is being done through a contract between NIAMDD and the Albert Einstein College of Medicine of Yeshiva University. This major effort involves a central coordinating committee and ten subspecialty working committees of experts in the field of blood diseases and hematology.

NATIONAL COMMISSIONS

Question: During the past decade, several National Commissions were created to study the state-of-the-art on various diseases and to make recommendations for further research. In each case, increased research emphasis has followed. Do you foresee the need for any more National Commissions such as the ones that studied diabetes, arthritis, and digestive diseases? Would kidney diseases be a logical candidate?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NIADDK share of that amount is $66,022,000 and 655 grants.

Question: How is inflation impacting -- or how will it impact -- on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new research grants regardless of other budget priorities within NIH?

Answer: The success and effectiveness of biomedical research depends completely on constantly emerging new research advances and findings so that new knowledge is constantly being acquired and, based on it, new methods of diagnosis, treatment, and prevention of diseases can be developed. Without research activities based on the latest new ideas and new findings, there is no progress toward the National priority of more effective treatment, prevention, or recognition of disease. Ordinarily, research grants are awarded by NIH for a period of three to four years. Therefore, each Institute at the NIH carries over from one year to the next an obligation of continued funding of a large number of research projects which must be honored if ongoing research is to continue productively. Thus, about 75 to 80 percent of the budget of a new year is "spoken for"; the remaining percentage of available funds must be secured for meritorious, new research proposals since without them, new progress will cease.

For this reason, it is extremely important to stabilize the number of new research grants and to build a floor below which this number is not permitted to decrease.

Question: What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: Based on the experience of many previous years, the fluctuation in quality of new research proposals is quite minor. The emergence of new ideas in some fields, or individual facets thereof, tends to counterbalance the occasional loss of momentum which may occur in other facets of related research where unexpected difficulties arrest, temporarily, forward movement. Because of this compensatory action in which progress in different facets of biomedical research tends to undergird other, temporarily

less active areas, it has usually not been necessary--except for the attainment of specific developmental goals -- to place greater emphasis on research contracts or to make major changes in the ordinarily very productive intramural research of this Institute.

Question: To what "payline" will you fund new and competing grants in Fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: We project a "pay line" of 200 and a funding rate of 39 percent in 1981 and a "pay line" of 180 and a funding rate of 27 percent in 1982.

DIABETES MOMENTUM

Question: What are the plans of the Institute to maintain in Fiscal Year 1982 the momentum developed in the past five years for diabetes research?

Answer: The Institute intends to maintain the momentum developed in diabetes research during recent years by funding this effort to the limits of its resources and by capitalizing with new research grants on a vast fund of new knowledge which was developed during the rapid expansion of diabetes research during the past five years.

Question: Would you supply for the record at the appropriate time, material showing spending for diabetes research in FY 1982?

Answer: In 1982 we have allocated $79,475,000 for diabetes, an increase of $3,488,000 over 1981. Diabetes will receive the same proportion of the total funds available to the Institute as it did in 1981.

POLICY ON GRANT AWARDS

Question: We have been advised that in recent years the Institute has followed a policy of awarding research grants in certain areas to applicants whose priority scores were higher, and thus represented lower quality than those in other areas of the Institute, particularly by the arthritis "cluster." We now understand that you intend to try to eliminate this inequity by henceforth basing the awarding of research grants solely upon the quality of the application as reflected by the priority score accorded it in the peer review process.

Answer: For a number of years the Institute has developed separate budgets for its ten categorical disease programs. These "program budgets" result in the programs having research grant "paylines" that vary by as much as 50 points. The priorities reflected by these "paylines" have been developed with the advice and recommendations of three national advisory commissions, two national advisory boards, the Institute's national advisory council and most importantly, the reports of the Senate and House appropriations committees. We would anticipate that our program budgets will continue to result in different "paylines".

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justifications recently submitted to the Congress have attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

NATIONAL COMMISSIONS

Question: During the past decade, several National Commissions were created to study the state-of-the-art on various diseases and to make recommendations for further research. In each case, increased research emphasis has followed. Do you foresee the need for any more National Commissions such as the ones that studied diabetes, arthritis, and digestive diseases?

Answer: The reports generated by the three national commissions have been of major benefit to the Institute's programs. It is reasonable to expect that commissions studying the state-of-the-art of our other categorical disease areas would be equally beneficial.

Question: Would kidney diseases be a logical candidate?

Answer: Yes. As one of our major programs, kidney disease would be a logical candidate for study by a national commission.

CHANGES UNDER NEW LAW

Question: A law passed last year made a number of changes in the Institute, including changes in its name. How will these changes affect your activities?

Answer: The new law will strengthen the Institute organization by formalizing organizational changes which our Institute has

undertaken administratively over the course of recent years in order to be able to carry out its rapidly expanding mission.

Question: To what extent will the Kidney Diseases Program get more emphasis?

Answer: We expect the kidney disease program to maintain its current proportional share of the Institute's budget.

Question: How will you implement the recommendation by the conferees that training of allied health professionals be given special attention in the centers programs?

Answer: The Institute will include the proper wording concerning the availability of stipends for health professionals enrolled in arthritis and diabetes multipurpose center training programs in all future center program announcements and in application directions for renewal of existing centers and for the creation of new ones. It is to be expected that the extent of such training will vary from center to center, depending on the local need and on the resources available to each center. Because of the budgetary constraints already at work, most centers must choose their priorities very carefully and the magnitude of their respective activities reflects this reality.

JUVENILE RHEUMATOID ARTHRITIS

Question: This committee has for the last several years expressed a specific interest in an expansion of research in the field of arthritis in children. What avenues are being pursued by the Institute in this area?

Answer: The Institute has included arthritis in children in its program announcements to the research community as a special area deserving research emphasis. Meetings have been held with the leaders in pediatric rheumatology research to inform them of our special interest in this field and of the various mechanisms available for support of research training and development. In addition, several interesting projects on arthritis in children are being supported in the Multipurpose Arthritis Centers. These include long-term follow-up studies into adult life, basic immunology research, and the initiation of an epidemiology study.

DIABETES CENTERS PROGRAM

Question: Would your research proceed faster if you could expand your centers programs?

Answer: The ability to take advantage of the many new and exciting opportunities for sufficient and rapid advancement in diabetes requires the use of all mechanisms of support of research which are available: investigator-initiated research, centers programs, training and research contracts. Centers provide a unique opportunity to bring together in a concentrated environment scientists and physicians from multiple and diverse scientific disciplines to conduct multifaceted and integrated research which bears upon diabetes mellitus. The centers environment also provides the unique opportunity to integrate multidisciplinary research with training,

information transfer and health care activities. Expansion of the centers program will stimulate the overall effort against diabetes. Expansion of all mechanisms of diabetes research will allow faster progress in diabetes research.

Question: What additional areas could the various centers profitably investigate?

Answer: The diabetes centers environment provides a particularly good opportunity to investigate many aspects of diabetes from a multidisciplinary approach. Thus, questions concerning the etiology of diabetes can be addressed in a single setting by virologists, geneticists, immunologists, epidemiologists, pediatricians and internists. Investigations regarding the mechanisms by which hormones act, particularly insulin, can be conducted in an integrated fashion by biochemists, physiologists, molecular biologists and internists. These are but a few of the many areas of research on diabetes that could be profitably investigated within the diabetes centers. The diabetes centers also provide an excellent environment in which to conduct clinical investigation, for example, to study in man the relationship between the metabolic abnormalities of diabetes and the development of the chronic complications of this disease.

LOW BACK PAIN

Question: What did you learn from this workshop and how will the outcome affect your research activities for the 1982 budget year?

Answer: The workshop on low back pain was divided into 5 sections: Epidemiology and Natural Course; Anatomy and Ultrastructure; Biomechanics; Neural Mechanisms; and Biochemistry of Supporting Structure. Each section prepared a summary paper of the major findings to date and a list of promising questions for future research. In many such areas, investigators from more than one discipline would collaborate to produce a more clinically and scientifically significant study.

The forthcoming book based on the proceedings of the workshop and a summary to be published in the journal Spine should serve to stimulate interest in the area by the general academic community. New grant applications for projects in research in this area may therefore be anticipated during the 1982 budget year.

SUBCOMMITTEE RECESS

Senator SCHMITT. The subcommittee will stand in recess until 2 p.m., when we will hear further budget requests.

[Whereupon, at 1:30 p.m., Wednesday, February 18, the subcommittee was recessed, to reconvene at 2 p.m. this same day.]

(AFTERNOON SESSION, 2:05 P.M., WEDNESDAY, FEBRUARY 18, 1981)

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

STATEMENT OF DR. MURRAY GOLDSTEIN, ACTING DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. KATHERINE BICK, ACTING DEPUTY DIRECTOR
WILLIAM B. MATTHEWS, JR., BUDGET OFFICER
NORMAN MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

SUBCOMMITTEE PROCEDURE

Senator ANDREWS [presiding]. The subcommittee will come to order. This afternoon we're going to resume our hearings on the National Institutes of Health. Our first witness is Dr. Murray Goldstein, Acting Director, National Institute of Neurological and Communicative Disorders and Stroke. As I understand it, the Institute's mission is to support and conduct research into disorders of the nervous system, including the brain, spinal cord, nerves, and muscles, as well as research into problems of hearing and communication.

Doctor, we welcome you, and ask that in the interest of time—and I'm sure your colleagues have told you about the extensive hearings we had this morning—that you very briefly highlight your opening statement so that we may quickly get to questions. And I would appreciate it if you would introduce your colleagues. And then you may proceed.

[The statement follows:]

Statement of Dr. Murray Goldstein

Fiscal year 1981 has been a year of both success and difficulty in our nation's research effort to prevent and treat the devastating effects of disorders of the brain, the spinal cord, the nerve-muscle apparatus, hearing and that uniquely human attribute of speech and language.

The brain tells us what we are, who we are, where we are and controls our relationships to the environment by means of thought, memory, speech, movement and the coordination of every organ of the body. Malfunctions of this amazingly sensitive and complex system can easily, and often do, lead to death. However, perhaps even more ominous to the individual and society, these disorders if not fatal, inevitably lead to a significant decrease in the quality of life characterized by severe disabilities such as paralysis, dementia, convulsions, deafness or intractable pain.

Despite impressive advances in the prevention and treatment of stroke, it remains the third leading cause of death and a major cause of long-term disability. Our success against the results of accidental injury to the brain and spinal cord--the nation's leading cause of death in persons under 45 years of age--remains poor and establishes head and spinal cord injury as a modern epidemic of continuingly increasing proportions rivaling even heart disease, cancer, and stroke. Dementia--the loss of intellectual function due to brain degeneration--in itself does not cause death, but the disease--and it is a disease and not a normal phenomenon of the aging brain--accounts for more institutionalized or hospitalized patients in the U.S. in any single day than all other diseases combined. When one adds to these examples the consequences of the developmental disorders of the nervous system of children (e.g., Tay-Sachs disease, spina bifida), infectious disorders of the brain or its covering (e.g., Reye's syndrome, meningitis), epilepsy, the still unknown causes and ineffective treatment of multiple sclerosis and of amyotrophic lateral sclerosis (Lou Gehrig's disease), the muscular dystrophies, and hearing loss due to childhood diseases and environmental trauma, the aggregate adds up to a total of 600 known diseases of the nervous system and of human communication for which the NINCDS has primary research responsibility.

Every Institute is pleased to be able to report on successful accomplishments. On behalf of the NINCDS, I have selected five (5) achievements which are representative of research progress made this past year.

The first is the unprecedented explosion of new knowledge about the basic functioning of the brain and nervous system. A very large proportion of disorders for which the NINCDS is responsible is characterized by unknown causes and therefore the availability of only symptomatic therapy and inadequate methods of prevention; thus, the need for the priority given to basic research in the neurosciences and communicative sciences. As a result of this research, more has been learned about the way the nervous system works in the past few years than in the total of the previous fifty years. Methods are now available to probe how the nerve cell functions, how it communicates with other cells

and how it reacts to signals from the environment. We now recognize that the nervous system is not only a series of finely balanced electrical-like relay stations but is also a complex chemical factory that modulates the activity of every body tissue by means of the production of peptides, neurotransmitters and neuroendocrine agents.

Another success involves an innovative research approach which the NINCDS was able to initiate just one year ago--positron emission tomography (PETT). Last year, our recently retired Director, Dr. Donald Tower, described for you the excitement surrounding a technological breakthrough for studying in human beings the metabolism of the brain in health and disease. Seven PETT research centers and a center at the NIH were established to apply the use of this advanced space-age methodology to the study of the human brain. The early success of this investment has already provided completely new insights on the reaction of the brain cell to stroke, the metabolic activity of the brain in epileptics and the site of pathology in Huntington's disease.

The third area of success I would like to comment upon is that of replacement therapy for enzyme deficiency disorders of infancy and childhood. These are a class of disorders characterized by the pathological accumulation of metabolic materials in brain and other tissues because of the lack of a genetically controlled enzyme necessary for their disposal. This enzymatic deficiency leading to excessive storage causes the cells to degenerate, failure of the brain and body to develop, and ultimately death. To date, there has been no treatment for these genetic disorders. An example of this type of disorder is Tay-Sachs disease, an inevitably fatal genetic disease of infancy and childhood. NINCDS and other NIH scientists and grantees have untangled the complicated enzyme stories underlying this condition and other similar disorders. The NINCDS Developmental and Metabolic Neurology Branch is providing experimental enzyme replacement to a few children with a related disorder known as Gaucher's disease to see if we can overcome the deficiency. I am pleased to report that the treatment appears to be effective and children under study are apparently developing normally, the genetic defect having been overcome. On the basis of these preliminary findings, the NINCDS hopes to develop methods to produce larger quantities of the needed enzyme so that more patients can be helped, develop animal models to test the safety and efficacy of new enzymes, and launch carefully controlled clinical trials of treatment for this and other enzyme-deficiency diseases.

The fourth area concerns progress against the principal fatal disorder of the nervous system, stroke. As a result of the joint research effort of the NINCDS and the NHLBI, stroke as a major health problem is gradually coming under control as indicated by the significant decrease in stroke incidence and stroke mortality. Our success against stroke is not the result of a single dramatic scientific breakthrough but rather the cumulative effect of a series of contributions over time. A most important consequence is the decline of the hemorrhagic aspects of stroke for which improved methods of hypertension control and advances in neuro-surgical therapy have substantially diminished the impact of this great killer which previously was 80 percent fatal. However, we now recognize that if all

hypertension were adequately controlled, half the strokes currently occurring in this country would still occur and the stroke mortality rate would decrease by 19 percent. Thus, the very large aspect of the nation's stroke problem which is not associated with high blood pressure demands our continuing research attention. An example is the joint NINCDS-industrial effort for the development of anti-platelet agglutination agents to diminish clots in cerebral blood vessels and prevent cerebral infarction, the most common type of stroke. Also, this year the NINCDS will complete Phase II of a three phase controlled clinical trial of the efficacy of a surgical procedure to by-pass an obstruction of a brain blood vessel to prevent stroke. This much publicized procedure (EC/IC anastomosis) is under study in 65 clinics around the world to evaluate whether the procedure in fact does all that individual reports claim.

Finally, I would like to comment on a new initiative the NINCDS has developed with the cooperation of the NCI, a targeted effort against brain tumors. The results of tumor growth in the brain are disastrous in two respects: one is the obvious effect of destruction of brain centers by the tumor; in addition, even a non-malignant tumor inside the skull is life threatening because of the increasing amount of space the growing tumor occupies within the limited confines of the bony skull. In the past, only surgery and radiation have been available to combat these tumors and diminish their invasive and space occupying characteristics. More recently chemical and immunological therapies, at first singly but now in combination, have become available. In our neurosurgical laboratory in Bethesda and in grant supported laboratories around the country, tissue culture methods are being developed by which a prescription for the individual patient's specific type of brain tumor can be ordered, thus tailoring therapy to the patient's tumor. We must temper our enthusiasm for the potential results of this approach, but can report with conservative enthusiasm that a specific and effective approach to brain tumor therapy may well be within our grasp.

I must balance these research successes with reports of areas in which we have not been as productive. Despite a continuing nationwide scientific effort, clinically applicable results for the treatment of head and spinal cord injury are still very meager. That unique loss of ability of tissue of the central nervous system to heal itself, still confounds us. We have made significant advances against several of the complications of such injuries and have improved the duration and quality of life resulting from them, but we have not yet been able to reverse the process and restore normal brain and spinal cord function. A small but dedicated group of skilled investigators is providing the stimulus necessary for attention to this most difficult of problems.

Another area for emphasis is amyotrophic lateral sclerosis (Lou Gehrig's disease). This fatal disorder results from the death of motor nerve cells in selected areas of the brain and the anterior portion of the spinal cord. The muscles dependent upon these cells wither, and the functions they control become increasingly impaired, leading eventually to death. But why are these specific nerve cells affected and not adjacent cells? Why their unique susceptibility to the process causing the disorder?

Despite our focused attention utilizing genetic, immunologic, viral and metabolic studies, we still do not have the answers to these questions. However, I can assure the Committee that we are hard at work addressing these problems and will continue our efforts until we resolve them.

Mr. Chairman, I could continue to describe the other significant research issues faced by the NINCDS. I have not discussed multiple sclerosis and the progress immunological studies are offering us, the exciting epidemiological and pharmacological studies initiated for the study of Huntington's disease and the leap forward being initiated against disorders of speech. A series of controlled clinical trials have been started in the areas of hearing impairment and we are exploring approaches to those troubling and common characteristics of modern life--headache and backache. Basic neuroscientists are doing an excellent job in providing the fundamental information upon which to build. A small but highly skilled cadre of clinical investigators are exploring methods for translating this core of information into clinically applicable methods of prevention and therapy. There are no easy roads to a better understanding of the brain and its disorders, but the programs of the NINCDS are moving ahead steadily and soundly towards the achievement of this goal through research.

I am pleased to share this information with you and will try to answer any questions you may have about these matters. Thank you.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
Biographical Sketch

NAME: Murray Goldstein, D.O., M.P.H.

POSITION: Acting Director, NINCDS

BIRTHPLACE & DATE: New York, New York; October 13, 1925

EDUCATION:
B.A., New York University, 1947
D.O., Des Moines Still College of Osteopathic Medicine, 1950
M.P.H., University of California, School of Public Health, 1959

EXPERIENCE:
Acting Director, NINCDS, 1981-present
Deputy Director, NINCDS, 1978-1981
Medical Officer, Commissioned Corps, PHS (Assistant Surgeon General), 1953-present
Director, Stroke and Trauma Program, NINCDS, 1976-1978
Director, Extramural Programs, NINCDS, 1961-1976
Visiting Scientist, Mayo Clinic and Graduate School, Rochester, Minnesota, 1967-1968
Chief, Special Projects Branch, NINCDS, 1960-1961
Asst Chief, Research Grants Review Branch, DRG, 1959-1960
Actg Chief, Section on Virus Diseases of the CNS, Bureau of Acute Communicable Disease, Calif. State Dept of Public Health, 1958

Director, Epidemiology and Biometry Training Grant Program, DRG, 1956-1958
Asst Chief, Grants and Training Branch, NHI, 1953-1958

ASSOCIATION MEMBERSHIPS

American Academy of Neurology
American Association for the Advancement of Science
American Heart Association, Council on Stroke
American Neurological Association
American Osteopathic Association
Association for Research in Nervous and Mental Disease
Society for Neuroscience
The American Parkinson Disease Association, Medical Advisory Board
Eisenhower Institute for Stroke Research
United Cerebral Palsy Research & Educational Foundation Board of Directors
Consultant, World Health Organization Program on Neurosciences
Commission on Alternative Health Care, U.S. Olympic Council on Sports Medicine

SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS

Beta Alpha Epsilon; Biology National Honor Society, N.Y.U.
Psi Chi; Psychology National Honor Society, NYU
Sigmi Alpha; Osteopathic Scholarship National Honor Society; College of Osteopathic Medicine
Delta Omega; P.H. National Honor Society; Univ of California
Doctor of Science (Hon); Kirksville College of Osteopathic Medicine
Certificate of Merit; ANA
Silver Star; Purple Heart, U.S. Army
Meritorious Service Medal; PHS
Associate Editor, Stroke, A Journal of Cerebral Circulation, AHA
Editorial Board, Osteopathic Annals
Editorial Board, International Journal of Neurology
Author of over 20 scientific papers and monographs

INTRODUCTION OF ASSOCIATES

Dr. GOLDSTEIN. Thank you Senator. May I introduce Dr. Katherine Bick, on my far left. Dr. Bick is the Acting Deputy Director of the Institute. And on my immediate left is Mr. William Matthews, Budget Officer of the Institute.

Thank you for the opportunity to present the programs of the National Institute of Neurological and Communicative Disorders and Stroke.

As you indicated, the scope of the Institute's program is very broad-based, affecting the entire nervous system and muscular system, hearing, and the very human attribute of speech and language. Because of the innumerable responsibilities of the Institute, we cover many areas. In the written presentation, sir, I have pointed out five examples of successful results of our research activities this past year.

Senator ANDREWS. Doctor, before you proceed, I notice that you are a graduate of the Still College of Osteopathic Medicine. One of my

family's great friends is an osteopath in Fargo, N. Dak., Hal Hanson, and Hal's daughter, Beverly, who was my age, became the women's national amateur golf champion—I am sure because she had the proper adjustment along the way.

Dr. GOLDSTEIN. I am glad it was helpful. I wish it would help my golf.

Senator ANDREWS. You can still play a lot better golf than I can.

Go on. Continue.

BASIC RESEARCH

Dr. GOLDSTEIN. Thank you, sir. The Institute supports a very extensive program of basic research. One of the primary reasons for this is the brain has been truly called "the last frontier." We understand so very little about how it works, and, even more important, so little about how it goes wrong. And for this reason, since for most of the disorders we deal with we still do not know the etiology or cause, we must invest in basic research. I am delighted to say that over the past 10 years, we have learned more about how the brain and nervous system works than in the preceding cumulative 50 years.

POSITRON EMISSION TOMOGRAPHY

A second important area is the use of modern technology in research and an example of this is a program that we call our positron emission tomography program. This provides us for the first time with the opportunity to actually look inside the human brain and see how it works, and watch it working, with no ill effect at all on the patient. So, now, without opening the skull, we can actually look inside that brain and watch its activities, and identify where and how things go wrong.

This is primarily done through the use of very short-lived isotopes. With the support of the Congress, sir, we have been able to establish seven research centers in the United States, and one at the National Institutes of Health.

ENZYME DEFICIENCY DISORDERS

A third and very important area which has been spearheaded at our center in Bethesda in the intramural program is a group of disorders known as the enzyme deficiency disorders. These are errors of metabolism that children are born with, and because of these errors of metabolism usually due to a deficient enzyme, the children do not develop properly. Quite often, they die at a very early age—it is the problems of these kinds of children that have been associated with genetic counseling. We are now able in one disorder, Gaucher's disease, to give the child the needed enzyme replacement, and for the first time, we have a small group of children with this deficiency who appear to be developing normally.

This gives us a wonderful alternative and an opportunity to be looking at other alternatives for genetic counselors to offer.

STROKE

The fourth area I would like to mention is stroke. Stroke remains the third leading cause of death in the United States. There have been remarkable advances against both the incidence of stroke and its mortality. In a joint effort with our colleagues in the National Heart, Lung, and Blood Institute, research programs have been launched the results of which have cut both mortality and incidence tremendously. This is true particularly in those types of stroke associated with high blood pressure.

Yet on the other hand, a substantial proportion of people who do have a stroke do not have high blood pressure. And so, high blood pressure research, as important as it is, and one in which we need to continue our activity, is not the ultimate answer to stroke or to the complete story of stroke. Therefore, we need to continue our research efforts with vigor.

HEAD AND SPINAL CORD INJURY

Another very important area, sir, is the issue of head and spinal cord injury, and regeneration of the nervous system following these events.

In some respects, head and spinal cord injury due to trauma such as automobile accidents, is a plague of modern American society. Most of the people who die in these horrible accidents die because their brain and spinal cord have been injured. This is a very, very difficult problem to solve, because we are dealing quite often with research problems the results of which affect life and death at the time of the accident or shortly thereafter.

To help those who do survive, we have started a very concerted research effort to see if it is possible to help the brain and the spinal cord to regenerate those damaged neurons, the nerve cells that have been injured.

We have had a tremendous breakthrough in this area, and the breakthrough is that for the first time we are not asking, "Can regeneration occur?" but we are now asking, "How can we make it occur?" It can occur. It does occur in lower organisms. For one reason or another, as we have evolved to the human state, we seem to have either lost or arrested that ability of nerve cell regeneration in the brain and spinal cord. We have hope. It is a very conservative hope, but we do have hope that we might be able to solve this problem.

INSTITUTE OF 600 DISEASES

Well, sir, we are truly called the "Institute of 600 diseases," because of all the things that can go wrong in the nervous system and in hearing and human communication. It is a very large task, but we are working hard at it, and hope that with your support we can continue to do so successfully.

Thank you, sir.

Senator ANDREWS. Well, I appreciate your most intriguing, very interesting opening remarks. Certainly, an investment in this area is really an investment in the future of this country, and could well result in savings down the line, in the cost of medical care for those people who have thus been brought back to full or nearly full health.

FISCAL YEAR 1982 BUDGET

To get down to the budget figures that we have to look at, how much funding do you need in fiscal year 1982, to maintain your share of the overall NIH goal for new and competing research grants? I understand the overall goal is some 5,000. How much funding does the Institute need to keep up that proportion?

Dr. GOLDSTEIN. The President's budget for 1982 for our Institute proposes a budget of $281,181,000. This, sir, will permit us to continue our program at the present level of activities.

Senator ANDREWS. That maintains the program at the present level?

Dr. GOLDSTEIN. That's correct, sir.

Senator ANDREWS. Now, how does inflation impact, or how will it impact, on this goal?

Dr. GOLDSTEIN. An estimate for inflation has been built into that figure, sir. Of course, it is a little hard for us to predict exactly what the inflation level will be next year.

Senator ANDREWS. What figure did you use?

Dr. GOLDSTEIN. I believe the figure that we used was 8 percent. Am I correct, Dr. Fredrickson?

Dr. FREDRICKSON. No; it was 9.2 for 1982, Mr. Chairman.

Senator ANDREWS. Do you have any special problems in your shop, related to these inflators and the additional cost of maintaining this level of research?

Dr. GOLDSTEIN. No very special problem, sir. There is a general problem that the entire NIH will face in terms of inflation and the high cost of technology.

STABILIZATION OF RESEARCH GRANTS

Senator ANDREWS. For the record, because we have to know to carry this bill to the floor to gain the support of our colleagues, why is it important to stabilize new research grants, regardless of other priorities that there may be in the NIH?

Dr. GOLDSTEIN. First, new research grants provide us with the opportunity to capitalize rapidly on new information as it evolves out of the ongoing program. By not having this opportunity for initiating new projects, we would cut off the new leads.

Second, and perhaps of equal importance, is that there is a continuing group of bright, young people with new ideas and new technology arriving on the scene.

It is to these young people that we often have to look for new ideas. If they feel they have no way to compete because the people already in the horse race have consumed all of the funds, then we find a situation that results in their seeking other kinds of opportunities for careers.

And, therefore, by stabilization, by seeing to it that there will always be at least a specified number of new grants available for which the young people can compete, or people from other disciplines who wish to enter research on the problems of the nervous and communicative systems, we provide, if I might use the phrase, the carrot, the stimulus for them to try to succeed in the competition for funds.

Senator ANDREWS. In other words, years ago, I recall debate on the House floor when we had this bill up, and it was always very popular

to add some for cancer research, because that was the thing that was attracting attention. We finally got the input from people in the NIH at that point in time that additional funding wouldn't really gain much, because the researchers weren't in place.

I then gather from your comments just now that the importance of maintaining this level of new research grants is to make sure that these young and qualified researchers do in fact stay in place, and are encouraged to be there.

Dr. GOLDSTEIN. Exactly, Senator, exactly.

Senator ANDREWS. And without that, our Nation loses not just that current year's opportunity, but loses the opportunity for valuable ongoing research in years to come.

Dr. GOLDSTEIN. Sir, you have said it beautifully. That is exactly the situation.

PROGRAM PRIORITIES

Senator ANDREWS. If you were faced with a major budget cutback, what are your priorities, in other words, let's say when we sit around the table and have to finally put this back together—what is your idea of priority? You certainly can speak to this far better than we can. We are lay people.

Dr. GOLDSTEIN. Sir, I would have three equal first-order priorities to suggest. The first of these three would be our research project grant system. This system provides the means by which an independent investigator can apply for support for pursuing his research idea, working in his laboratory on an important problem, in open competition with his peers. It is one of our top three priorities.

A second of the top three priorities is the support of our intramural research program. There, we have a stable group of established and productive investigators who are able to take on those very difficult problems which will require at least 5 to 10 years of hard work to answer. The intramural research program provides a stable and productive research resource for our Nation.

The third is our research training program, because this is our future. This is the future of research 5 years hence. These three, in terms of the best ways to invest the moneys of the people, I suggest should be our first priorities.

MORE EFFICIENT MANAGEMENT

Senator ANDREWS. Can your shop save some money through more efficient management, and less official travel, and fewer consultant contracts? That's always the story we read about in the newspapers, you know. How tight a ship are you running out there?

Dr. GOLDSTEIN. Well, sir, I think we are running a very tight ship, but it's a little hard for me to have a completely unbiased perspective. Perhaps this is not the proper moment to say it, but I think the best way we can be efficient is to be provided with the greatest degree of flexibility.

When, as managers, we are locked into very specific line item kinds of budgets and administrative inflexibilities, it does not provide us with the means to be able to seize opportunities as they come down the pike, opportunities which are very hard to predict in advance. Permis-

sion seeking is a long and time-consuming process. And so, as an administrator, I suggest, if we had greater flexibility linked to accountability we would have more efficiency.

STROKE

Senator ANDREWS. Well put. You mentioned stroke in your initial testimony. Between 1950 and 1978, the incidence of mortality from stroke declined 50 percent, from about 89 per 100,000, to 44 per 100,000 population, with most of the decrease, really, in the past decade. Now, is the incidence of stroke still on the decline, or have we reached a leveling-off point in our ability to lower the occurrence of this third leading cause of death in the United States?

Dr. GOLDSTEIN. The incidence of stroke, the third leading cause of death, continues to decline. Data which we have developed about the last few years shows the decline is continuing. We are now beginning to find that the decline is also occurring in some of the most difficult parts of the stroke problem.

This has to do with deaths due to cerebral hemorrhage. Cerebral hemorrhage in the past has had an 80-percent mortality rate. This rate is now dropping both because of improved methods of prevention due to hypertension control and because of the new methods of therapy available, particularly neurosurgical methods in which either the clot is able to be evacuated without damaging the patient or the leaking blood vessel repaired, preventing future hemorrhage.

And so, we look forward to a continuing decline in both incidence and mortality. We are not certain yet when this decline will level off.

Senator ANDREWS. You don't have a projection for that curve?

Dr. GOLDSTEIN. I'm afraid not, sir.

Senator ANDREWS. How much in additional health costs would you estimate that this trend, this decline, could save the American people? Can you give us a hard figure? Or for the record, a figure that $1 million spent in this type of research eliminates some number of dollars of health care cost 10 years hence?

Dr. GOLDSTEIN. We have just completed a national survey of stroke, information from which I would be glad to submit for the record. In the survey, we document the economic burden of stroke.

I would have to do some projections from our data because our figures are for 1976. I could project those data to the mid-1980's and I would be glad to provide that information for the record.

Senator ANDREWS. But if you could document, for the record, say, what the investment in this type of research in the decade of the 1970's saved in projected health care costs, in the decade of the 1980's—or a similar figure that you could get pretty sharp substantiation for. I think it would be quite valuable to us in our ability on the floor to say that this is not so much an expenditure of Federal tax dollars as it is an investment and a savings in the long run.

Do you understand what I am saying?

Dr. GOLDSTEIN. I understand what you're asking, sir, and I will see to it that that material is provided.

[The information follows:]

STROKE HEALTH CARE COST SAVINGS

The prevention of stroke saves patients and the community the direct cost of hospitalization, diagnosis, and treatement for their disease. The NINCDS supported a national stroke survey for the period 1977 to 1980 to gather data on incidence and cost of stroke in the United States. According to this survey, based on constant 1977 dollars, the estimated savings in direct health care costs due to reduced rates of stroke incidence in the United States during 1978 through 1980 was $233 million. For this same period, also based on constant 1977 dollars, the cost of NINCDS stroke-related research was $43,500,000. This establishes a ratio of $5.36 in savings for each $1 of stroke research costs during this period.

Based on the amount of NINCDS supported research of $100,514,000 for the period of 1970 to 1979, it is projected that $538 million of direct health care costs were saved due to the declining incidence of stroke. The results of stroke research in the 1980's can be expected to provide for a continuing decline in stroke incidence and a resultant proportional decrease in stroke health costs during this decade.

SYNOPSIS

Senator ANDREWS. If you can come up with the hard figures in a brief synopsis, but include enough detail so that the press, looking at the record, or the skeptics, looking at the record, aren't going to say, "You just picked that thing out of the wild blue yonder."

Dr. GOLDSTEIN. We will look at the data which we have obtained over the last several years, and try to make reasonable projections on the basis of them. They will be conservative projections.

Senator ANDREWS. Now, with the gains that you have made against stroke, can we look forward to reducing the cost of research in this particular area, in fiscal year 1982 and beyond; in other words, have we gotten to the point where we have learned as much as we need to learn, or is there a demonstrated need for additional research?

Dr. GOLDSTEIN. Sir, I can predict with a great deal of certainty that over the next 5-year period it would be an economic waste to cut back on the stroke research effort. We are on the verge of understanding so much more, for example, in the area, as I'm sure my colleagues mentioned this morning, of prostaglandins and platelet adhesiveness.

We are looking beyond the prevention aspect of stroke since there is a reasonable probability that even when we do know more about prevention, some strokes will continue to occur. We are trying to learn how we can safeguard that threatened brain cell during the period when the acute stroke is going on, so that it has the opportunity to recover when recirculation once again is reestablished.

The answer to this problem of protecting the cell during a loss of oxygen is one of the basic issues in neurobiology, and it would be very foolhardy for us to predict that we will have the answer to that in the next 2 to 3 years. Certainly, it should be a 5-year goal.

Senator ANDREWS. In other words, your research of the past decade or two has brought you up to the threshold of a new breakthrough that needs continued application of research?

Dr. GOLDSTEIN. We are now at the point, sir, where, because of what we've learned and because of the availability of technology, we are able to ask the intelligent questions for really the first time. Answers to the kinds of questions which are now approachable will not only describe how to prevent stroke, but for those people who have had a stroke, they will address how we diminish that terrible loss of quality of life so

that our citizens are able to reenter society and rejoin their fami-lies as contributing human beings.

In nervous system research, the quality of life is as important an endpoint as is survival.

POSITRON EMISSION TRANSVERSE TOMOGRAPHY

Senator ANDREWS. One of the projects you have going out there is your so-called PETT project, beyond—an ongoing project following on the heels of the CAT scanner. I got better acquainted with the CAT scanner in the past year than I ever really thought I would or even wanted to be.

Was the intramural PETT program initiated last year at your Bethesda facility?

Dr. GOLDSTEIN. Yes, sir.

Senator ANDREWS. Could you provide the cost figures for those intramural programs, specifically the cost of hardware involved? We've got a fight going on out in North Dakota. One hospital of mine wanted to have a CAT scanner and the powers that be said, "No, you can't have a CAT scanner." And we got into all kinds of interesting things about the costs.

Dr. GOLDSTEIN. Yes, sir; the intramural activity at the present time is being initiated in two phases. The investment in the scanner—this is the instrument which one applies to the head and measures the emission of the short-lived isotope—is approximately $150,000 in 1980, for a total of $450,000 over a 2-year period. The second phase will be a new cyclotron which we are presently preparing to install next year. This is the source for the needed short-lived isotopes. It will cost approximately $1.5 to $2 million by the time it is installed.

Senator ANDREWS. Is this program still experimental, or have you reached the phase where these devices can be used clinically in diagnostic purposes?

Dr. GOLDSTEIN. At the present time, this is a research instrument. It is not an instrument for clinical use. It is not paralleling the development or use of the CAT scanner. Since it is often used in a clinical research situation, there are some clinical situations of a very specialized research variety that are heavily dependent upon this kind of capability. But it is a research instrument.

Senator ANDREWS. It's nothing that is going to be put into position in the hospitals or in medical treatment centers around the country?

Dr. GOLDSTEIN. No, sir.

Dr. FREDRICKSON. Mr. Chairman, I do not think that will ever happen. The instrument is extraordinarily useful for research in answering biological questions, but it does not have the accuracy that would be required to diagnose tumors or other conditions clinically, so I think we are not creating something that you can expect to overload the cost containment problem.

Senator ANDREWS. Along those lines, the basic CAT scanner has proved its worth, but this is for research.

Dr. GOLDSTEIN. This is a research instrument.

Senator ANDREWS. To see how the brain works, as I understand it.

Dr. GOLDSTEIN. That is correct.

Senator ANDREWS. You can actually watch the living brain function and get a little more insight?

Dr. GOLDSTEIN. That's correct.

REGENERATION RESEARCH

Senator ANDREWS. On another matter, you touched on how the Health Programs Extension Act of 1980 directs the Secretary to enter into a contract for a review of past and ongoing neurological research, including central nervous system regeneration research. The 5-year plan is also to be developed.

To what extent would you be increasing your emphasis in this area in the next few years?

Dr. GOLDSTEIN. On regeneration research?

Senator ANDREWS. Yes.

Dr. GOLDSTEIN. Our plan at the present time is that we will increase the effort by approximately $1 million, sir.

Senator ANDREWS. What about the supply of trained investigators in this field?

Dr. GOLDSTEIN. This is a major problem. It is a brand new field of research, and there are relatively few people with the skills necessary who are prepared to enter the field. And so our research training effort has this as a specific target.

Senator ANDREWS. Isn't that a pretty low amount for a very important area?

Dr. GOLDSTEIN. That $1 million figure is an increase, sir, on a base of approximately $9.5 million at the present time.

Senator ANDREWS. I thought you said $1 million?

Dr. GOLDSTEIN. That's a $1 million increase, sir.

Senator ANDREWS. What we heard back here was it was $1 million for this field.

Dr. GOLDSTEIN. No; we propose to go from $9.6 to $10.6 million in 1982.

Senator ANDREWS. Well, we will clean up the record on that.

Can you tell us about some of the promising avenues of research on regeneration of the spinal cord?

Dr. GOLDSTEIN. There are two major problems. The first is when the spinal cord is injured and its processes die back. The injured nerve cell attempts to regrow by sending out a bud. For reasons that no one has yet completely understood, that bud when it is on a nerve cell in the brain or spinal cord shrivels up and dies. And so the injured nerve cell is actually trying to repair itself and regrow.

There are two elements to this. The first element is intrinsic in the cell itself, and this has a great deal to do with the development of proteins by the cell body and their transfer down the cell to its growing end.

The second element of this is the outside factors, such as trophic factors, elements which, in fact, we know cause no nerve cells to grow. And these are called nerve growth factors.

These are the two elements of one of the major problems in regeneration that we are investigating. There has been some success in lower

animals. We have now been able successfully to encourage the growth of what we call the long track, the nerve that starts in the brain and goes all the way down the spinal cord to a receptor organ. This has now been successfully accomplished in lower animals.

The second and equally important major problem is how will the redeveloping long track nerve know where to go? When it is growing, how will it make the right connection? If the nerve is supposed to go, for an example, to the bladder and goes instead to the big toe, we are in serious trouble.

And so investigators, for example, at Harvard and at the University of Toronto, are trying to give the nerve something to grow along to the appropriate target. These are very active areas of investigation at this time.

Senator ANDREWS. Doctor, I appreciate that. It has been most interesting, and I have a number of other questions that I would like to submit to you to answer for the record so we will have them available to the committee before we mark up.

BUDGET REDUCTIONS

Senator ANDREWS. In the meantime, I would like to present my colleague from Pennsylvania for any questions he might have.

Senator SPECTER. Thank you, Mr. Chairman.

Dr. Goldstein, what is your sense as to whether the National Institute of Neurological and Communicative Disorders and Stroke ought to base at least some reductions in line with the general attitude about budget reductions this year for fiscal year 1982 and perhaps for 1981 as well?

Dr. GOLDSTEIN. I'm sorry, Mr. Specter, I seem to have lost the thrust of your question. Senator, would you mind repeating it?

Senator SPECTER. Yes. In the light of the prevailing mood on budget cuts, what is your sense as to the budget cut for your Institute?

Dr. GOLDSTEIN. A budget cut that would be geared to our Institute will have its primary effect, if we have such, on, first, our center grant program; and second, on the contract program, a small element of which is in the intramural research program.

Senator SPECTER. Well, you have identified where the cuts would be felt.

Dr. GOLDSTEIN. Yes, sir.

Senator SPECTER. My question to you is: What is your opinion as to whether your Institute ought to be cut, in the light of proposed cuts which may exceed the $40 billion mark for the budget as a whole?

Dr. GOLDSTEIN. The NIH, as a whole—and it needs to be considered as a whole—has a great number of interrelated programs. The cuts that will be or that are being suggested to be put against our own Institute, the Neurological Disease Institute, are in proportion to the cuts in the other Institutes. Obviously, whatever funds we receive, we will try to use to the best of our ability. I don't know specifically what information about cuts the President will share with us tonight.

Senator SPECTER. What I'm driving at is you're not suggesting that if there are major cuts in the budget that your particular Institute be exempt from cuts?

Dr. GOLDSTEIN. No, sir; I'm not suggesting that.

Senator SPECTER. Have you been consulted by anybody from Mr. Stockman's agency about possible areas of cuts within your own Institute?

Dr. GOLDSTEIN. No, sir; no one from Mr. Stockman's agency has discussed that with me.

Senator SPECTER. Have you been consulted by anyone within the Department of Health and Human Services about possible cuts?

Dr. GOLDSTEIN. All of my discussions, sir, have been with the Director of the National Institutes of Health.

Senator SPECTER. Have those discussions involved any talks about areas of possible cuts within your own Institute?

Dr. GOLDSTEIN. Yes, sir; the question was asked about competing priorities in terms of what priorities do we have as an institute, both in terms of mechanisms such as grants and contracts, and in terms of research priority areas; also what is the listing order of competing priorities.

Senator SPECTER. Did anybody come to you and say, "If we were to have a 2-percent cut within your Institute, where would those cuts be made?"

Dr. GOLDSTEIN. Yes, sir.

Senator SPECTER. What was said?

Dr. GOLDSTEIN. We were given several different potential levels of cuts.

Senator SPECTER. What were those potential levels of cuts?

Dr. GOLDSTEIN. I believe, sir, they were at the level of the operating 1981 budget, at the level of President Carter's rescission budget, at the level of President Carter's 1982 budget, and then at 1-, 2-, 3-, and 4-percent reductions below that; also where would we place our program priorities. Is that a fair statement, Dr. Fredrickson?

Dr. FREDRICKSON. That is a fair statement. We used a whole array of possible reductions, Mr. Specter, in examining, with all of the Institutes together, how those reductions, if they were experienced, would be absorbed. We have had a number of exercises, probably from the very beginning, when the announcement was made that there might be some reductions in the budget. I think NIH has had an opportunity to be consulted and certainly to consult itself about how it would absorb almost any possible reductions.

Senator SPECTER. Do you think it is possible to make, say, a 2-percent cut in the NIH budget without—and this is important—materially or significantly reducing your effectiveness?

Dr. FREDRICKSON. I think if we measured that effectiveness in terms of the level of activity and the height of activity, it must be diminished somewhat. It is clearly almost thermodynamically impossible. I can honestly say that we will still have a very strong and vigorous research program, but it will be 2 percent less than it would be if the budget were not cut.

Senator SPECTER. Dr. Goldstein, I asked a question this morning about the areas of cancer and heart, and would repeat the same question to you as to whether, if funding were of no problem at all—and this is contrary to what I have been asking you—if you could make gigantic strides in the fields of neurological disorders?

Dr. GOLDSTEIN. Sir; there are research opportunities that are available that we would implement if there were no issue of funding particularly in the areas of cerebral vascular disease, trauma, hearing, and epilepsy.

LOU GEHRIG'S DISEASE

Senator SPECTER. I have one other question about a specific ailment which I have an interest in, from the famous athlete, Lou Gehrig—had an affliction, at least as reported, within the area of your specialty. What progress, if any, has been made in the cure of so-called Lou Gehrig's disease?

Dr. GOLDSTEIN. Lou Gehrig's disease or amyotrophic lateral sclerosis, is a disorder, Senator Specter, of what we call the motor neuron, the nerve that goes from the spinal cord to the end organ—as an example, a muscle. For yet mysterious reasons, the nerve cell body dies.

We have learned a number of things. One important thing is that we are probably not dealing with a single disease. This disorder is what in medical language we call a syndrome. It is highly probable it is a collection of several diseases, all of which express themselves in the death of that neuron.

We are exploring two major aspects of this. One, the viral aspect—in other words, is there a viral infection? This is an intriguing possibility, because the disorder has some of the kinds of characteristics that poliomyelitis has had, and therefore there are a group of investigators exploring that probability.

I must say we have found no evidence to date that there is a viral infection. However, the possibility of it being a viral infection or an improper immunological response to an infection has not been eliminated.

The second and more intriguing possibility at the moment is that it is a metabolic disorder which is triggered by an environmental stimulus. Wherever there is a population of people who develop this disease at a very high incidence, practically in epidemic proportions, such as on the island of Guam or on the Kei Peninsula in Japan, we have investigated why these people have a great deal more of this disease than anywhere else in the world. We find one intriguing thing that we can't explain yet and that is a very large accumulation of trace metals or minerals in the soil.

Senator SPECTER. Trace metals where?

Dr. GOLDSTEIN. In the soil.

Senator SPECTER. And what are they?

Dr. GOLDSTEIN. For example, aluminum is a trace metal. These are materials we take into our bodies in very, very minute quantities.

Now, most people in these communities seem to be able to handle that trace material with no difficulty at all. But yet, some segments of the population, for some reason, perhaps because of a metabolic defect, are not able to handle the increases in these trace metals.

This is an intriguing hypothesis which is being followed. Again, the problem we have in A.L.S. is probably a number of disorders, all of which express themselves in the same way. One of the dangers is that the metabolic defect, if true, may be a very peculiar form of the disease.

The syndrome, as we would like to call it, may exist in these particular localities—and perhaps information about it can't be extrapolated to a more general population, where we don't have epidemic sites, such as in the United States.

And so, we are looking at the virus hypothesis and with that to a possible viral-immunological interaction and, second, for a possible metabolic defect, particularly as it may relate to external factors.

Senator SPECTER. So active research is being conducted at the present time on this disease?

Dr. GOLDSTEIN. Yes, sir; it is an active research program.

It is not a burgeoning program with a great number of investigators flowing into the field, because we still don't have the very specific leads on which to capitalize.

Senator SPECTER. On a research project like that, is it possible to express any opinon or judgment as to the possibility of success within any timeframe?

Dr. GOLDSTEIN. No, sir; I could not do that.

Senator SPECTER. Thank you.

Thank you, Mr. Chairman.

Senator ANDREWS. Thank you, Senator Specter.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

BUDGET

Question: Will you give us some idea of how your Institute plans to adjust to the overriding demands of the inflationary economy that we are currently burdened with?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: To what extent will you have to make substantial cuts in various programs in order to fund others of a higher priority?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

EPILEPSY

Question: The establishment of the sixth Comprehensive Epilepsy Center was to be announced in mid-1980. There was support for such a center in the FY 1980 appropriation for NINCDS and a funding level set the following year in the FY 1981 budget. What is the status?

Answer: NINCDS awarded a contract for a Comprehensive Epilepsy Program in June 1980 to the University of California, Los Angeles, School of Medicine. The Comprehensive Epilepsy Program has components at the King/Drew Medical Center, the Hubert H. Humphrey Comprehensive Health Center, the Harbor General Hospital, and the Wadsworth and Sepulveda Veterans Administration Hospitals. This clinical epilepsy research program will emphasize the special problems of epilepsy in ethnic and racial minorities in a large urban setting.

Question: In the area of epilepsy research you have an ongoing Drug Development Program. On what basis are grants awarded to stimulate development of new drugs to treat epilepsy?

Answer: All grant and contract awards in the NINCDS Anti-epileptic Drug Development Program are made on the basis of staff plans reviewed and approved by the Epilepsy Advisory Committee and then the scientific and technical merit of applications as determined by the NIH peer review mechanism. A Request for Grant Applications (RFA) was issued in 1979 and resulted in the award of 13 grants to academic medicinal chemists to synthesize novel chemicals. These chemicals are being screened in the NINCDS Drug Development Program.

Question: Where are these grants awarded in the private sector?

Answer: Grant-in-aid awards have been made to academic medicinal chemists in universities and research institutes in thirteen states. Southern Research Institute, a non-profit, non-governmental organization has been awarded a contract to evaluate the chronic toxicity of the most promising antiepileptic drugs.

In a cooperative effort between industry and the NINCDS Antiepileptic Drug Development Program, one of the two FDA-required toxicology studies is performed by the government supported contractor and the other by industry.

Question: Are the large research-intensive drug manufacturers actively seeking these grants?

Answer: Recently the Antiepileptic Drug Development Program of NINCDS solicited proposals to study clinical pharmacology and to conduct clinical trials of antiepileptic drugs. In addition to the academic medical center responses, approximately 50-60 profit-making organizations have expressed written interest in this project, including both small companies and large pharmaceutical firms. The scientific merit of these proposals will be determined in a few months by review groups of experts in the field.

Question: What is the status of implementation of the recommendation of the Epilepsy Commission, and has the Institute submitted a report to the Committee?

Answer: The status of implementation of the recommendations of the Epilepsy Commission has been detailed in a report submitted to the House Appropriations Committee. The following highlights and tabulations present a picture of the current status of the implementation effort:

The Commission recommended that the NINCDS combine clinical research with an attack on the problems of total management of persons with epilepsy, with particular emphasis on the problems of members of minority groups. In the past year, NINCDS funded an Urban Comprehensive Epilepsy Program addressing this issue.

The Commission placed strong emphasis on the need for better drugs for epilepsy. NINCDS continues to promote drug development and to study any toxic effects of antiepileptic drugs. Examples of this effort are:

a) Proceedings of a symposium on the Mechanisms of Action of Anticonvulsant Drugs were published in 1980. More fundamental research on the action of anticonvulsant drugs will continue to be conducted through the grant mechanism.

b) The NINCDS continues to inform professional and lay persons about its drug development program through symposia and workshops.

c) Synthesis of new compounds for the antiepileptic drug development program has been supported directly through the grant mechanism; grantees are now working on synthesizing novel antiepileptic compounds and submitting these to NINCDS.

d) A contract for animal screening for anticonvulsant activity of new drugs has been renewed by NINCDS and modest plans to expand this program are under consideration. New animal models of epilepsy are also needed to identify potential antiepileptic drugs; some potential models are now under study through the grant and contract mechanisms.

e) The pharmacologic evaluation of new drugs is proceeding at the Veterans Administration Epilepsy Centers, at the Clinical Center, NIH, and at the comprehensive epilepsy centers. Such pharmacologic studies will allow greater insight into the clinical efficacy and usefulness of these compounds as well as studying phenomena such as drug-drug interaction. The Epilepsy Branch, NINCDS, has expressed its intent to fund future clinical trials of promising antiepileptic drugs.

f) The NINCDS Epilepsy Advisory Committee and the staff of the Institute's Epilepsy Branch have collaborated in the modification and updating of the Food and Drug Administration guidelines for testing efficacy and safety of anticonvulsant drugs in children. These guidelines will be published in their revised form and will be disseminated.

g) NINCDS has set up a committee to evaluate specifically the problem of producing new drugs with limited commercial value. This will have direct implications on the development of drugs for epilepsy. Further collaboration with the FDA is anticipated.

The Commission recommended a workshop on status epilepticus, a condition in which epileptic attacks occur in rapid succession and the patient does not regain consciousness during the interval. NINCDS sponsored an international workshop on status epilepticus which was held in November 1980, in Santa Monica, California. The proceedings will be published promptly for widespread distribution.

The Commission called for a study of prophylactic medications in febrile convulsions. NINCDS has sponsored a consensus development conference on prophylactic medication for febrile seizures. The Developmental Neurology Branch is planning further clinical investigations in this area.

NEURAL PROSTHESIS

Question: Under an NINCDS contract an electrode has been developed which is capable of exciting small populations of neurons without producing the potentially toxic electrochemical reaction products that can accompany neural tissue stimulation with conventional metal electrodes. What is the potential range for use of this electrode?

Answer: This new electrode is capable of safely stimulating small groups of nerve cells; it is known as a capacitor electrode. NINCDS contractors are continuing their work to shrink the dimensions of the capacitor electrode to the size of individual nerve cells. This will improve the selectivity of neural excitation and permit more precise control of nervous system function. The electrode in its present size is being considered for use by NINCDS investigators who are developing auditory prostheses for the deaf. Such an electrode would not only be safer than current prototype electrodes but would also permit reduction in the size of the accompanying electronic implant that is used to produce the stimulation pulses. Another potential application of the capacitor electrode is in a prosthesis for the blind. Several years ago NINCDS completed a feasibility study of such a prosthesis based on rather large electrodes placed on the surface of the brain. The conclusion

was that such a prosthesis would not be practical until electrodes could be developed which were much smaller and safer. The capacitor electrode has these properties and should permit further studies of methods of restoring visual information to totally blind individuals. In fact, this electrode should prove useful in all neural prosthetic applications that require electrical stimulation of delicate nerves. At the present time, the capacitor electrode is being successfully used as a new tool in basic studies concerning how the nervous system operates.

Question: For many years this Institute has been using dogs to test and develop a prosthesis for the paralyzed urinary bladder. Have you finally gone into human trials using this device?

Answer: The feasibility of a prosthesis for emptying the paralyzed urinary bladder (neurogenic bladder) has been successfully demonstrated in paralyzed dogs. At this time last year, all apparent problems except for electrode lead breakage had been solved. Since then the electrode and its attached lead wire have been completely redesigned. This new system has been implanted in dogs and has provided bladder evacuation on command for five months without a single failure. Based on this new reliability data, fabrication of electrodes, radio receivers and transmitters for human trials has been initiated. Assuming the prosthesis receives a favorable review from the Medical Devices Bureau of the Food and Drug Administration and an Investigational Device Exemption is granted, human trials are being considered for implementation in fiscal year 1982. It is anticipated that four paralyzed patients would be implanted initially and if the system functions as anticipated, expanded clinical evaluation will follow.

STROKE

Question: Between 1950 and 1978 the age-adjusted mortality from stroke declined 50 percent from about 89 per 100,000 population to 44 per 100,000, with most of the decrease in the past decade. Is the incidence of stroke still on the decline or have we reached a leveling-off point in our ability to lower the occurrence of the third leading cause of death in the United States?

Answer: The incidence of stroke continues to decline. The stroke incidence for 1977 was 137 cases per 100,000 population. Projections from the NINCDS National Stroke Survey indicate in 1980 it was 130 per 100,000. The expected rate of stroke incidence for 1986 is expected to be 118 per 100,000.

Question: If we are to witness a continued decline in stroke incidence as we have over the past decade, what specific course of action should be followed to achieve such dramatic results?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How much in additional health costs would you estimate this fortunate trend has saved the American people?

Answer: The prevention of stroke saves patients and the community the direct cost of hospitalization, diagnosis and treatment for their disease. The NINCDS supported a National Stroke Survey for the period 1977 to 1980 to gather data on incidence and cost of stroke in the United States. According to this survey, based on constant 1977 dollars, the estimated savings in direct health care costs due to reduced rates of stroke incidence in the U.S. during 1978 through 1980 was $233,000,000. For this same period, also based on constant 1977 dollars, the cost of NINCDS stroke-related research was $43,500,000. This establishes a ratio of 5.36 dollars in savings for each one dollar of stroke research costs during this period.

Based on the amount of NINCDS supported research of $100,514,000 for the period 1970 to 1979, it is projected that $538 million of direct health care costs were saved due to the declining incidence of stroke. The results of stroke research in the 1980's can be expected to provide for a continuing decline in stroke incidence and a resultant proportional decrease in stroke health costs during this decade.

Question: To what extent can we look forward to reducing the cost of research as a result of our gains against stroke in fiscal 1982 and beyond?

Answer: There are three important goals of stroke research: better prevention, improved acute care to decrease mortality and diminish infirmity, and improved care for those with permanent disabilities. The NINCDS is giving highest priority to research on prevention and improved acute care and is sharing responsibility with the National Institute of Handicapped Research for research on handicapping neuromuscular and brain disabilities. Prevention is the ultimate goal of stroke research. Success will decrease the need in the future for a major stroke research effort from both the financial and public health viewpoints. We are pleased to report that important progress has been made in the prevention of some types of stroke, particularly those associated with hypertension. However, progress for the prevention of other types of stroke, which are still major problems as measured by either incidence or mortality, remains relatively limited. There are a number of exciting findings which may lead to improved prevention of those types of stroke in the relatively near future.

For the patient undergoing a stroke, the critical issues are (1) the development of improved methods of early diagnosis both to recognize the stroke and to identify its specific cause and (2) improved methods of therapy to prevent brain damage. Great progress has been made in both these areas leading to a remarkable decrease in stroke mortality and morbidity. Even greater improvements are in the offing, but stroke is still the third leading cause of death in the U.S.

In summary, if the stroke research program of the NINCDS continues to make the progress anticipated for it, the need for research funds in the future in the areas of stroke prevention and acute therapy will be substantially reduced.

"PETT" PROJECT

Question: The so-called Positron Emission Transverse Tomography (PETT) technology follows on the heels of the CAT Scanner which was developed over the past decade. Was the Intramural PETT program initiated last year at your Bethesda facility?

Answer: A program of biological, immunological and chemotherapeutic investigation of human brain tumors was initiated last year. The installation and operation of the Positron Emission Transverse Tomography methodology will provide for the noninvasive examination of the human brain for the study of tumors and of damage to the brain seen in Alzheimer's disease, epilepsy, Huntington's disease and Tourette's syndrome.

Question: Could you provide the cost figures for this Intramural program and specifically the cost of the "hardware" involved:

Answer: The cyclotron for the NIH Intramural research program including PETT was purchased for $1.7 million in 1980. Future installation costs associated with the cyclotron are approximately $600,000 for the partial equipping of a radiation chemistry laboratory. Costs associated with the PETT program for salaries, supplies, and isotopes are $107,000 in 1980 and an estimated $332,000 in 1981. Additionally, the cost of the PETT scanner in 1980 is $150,000, and an estimated $20,000 in 1981.

In summary, a total of $1.9 million including the cyclotron and PETT scanner purchases in 1980 and an estimated $560,000 in 1981 reflect the costs associated with the intramural PETT program.

Question: Is this program experimental or have you reached the stage where these devices can be used clinically for diagnostic purposes?

Answer: PETT is a research methodology utilized to unravel the complex biochemical mechanisms of diseases. The research information gained concerning specific diseases through studies utilizing PETT will lead to modification in the treatment and diagnosis of disease and will result in improved care of the patient.

Question: When these PETT scanners are in full operational use at various locations throughout the country, won't their extremely high cost of purchase and operation eventually be passed on to patients under treatment at hospitals or clinical centers?

Answer: There are no indications that PETT technology will be introduced into many medical centers nor that it will become an important clinical tool at any time in the near future, but it is very important as a research methodology.

STROKE IN THE "SUN BELT"

Question: Apparently there is a higher incidence of stroke reported from the warmer climates of the United States, specifically in the "Sun Belt" and southeast region of the country. Is this still true, and if so, have plausible explanations been given for this?

Answer: There are several reports of community studies made in selected areas suggesting a higher occurrence of stroke in the southeast portion of the "Sun Belt." However, these studies may not be representative of the larger regions in which they are located and are ambiguous with regard to their implications. There is also a marked geographic variation in stroke mortality by region of the U.S. with higher mortality rates being reported in the southeast. These differences in mortality rate may be explained only in part by differences in the usual risk factors including age and high blood pressure. No other comprehensive explanations have become apparent although dietary factors such as salt intake are being explored as well as the availability and impact of modern medical methodology in diminishing the consequences of stroke as these relate to mortality and quality of life.

Question: What information or data has been generated by the Comprehensive Stroke Center that is funded by NINCDS at Chapel Hill, North Carolina?

Answer: The Comprehensive Stroke Center funded by NINCDS at Chapel Hill, North Carolina in conjunction with the Cerebrovascular Research Center funded by NINCDS at Bowman Gray School of Medicine is developing a patient oriented data system to provide longitudinal information on stroke patients from time of admission to the hospital through a series of followup visits for six months. The information includes demographic, social and stroke related factors as well as indices of disability and neurologic status. Specific data collected over the past two and one-half years are expected to include the exact diagnosis by type of stroke, average length of stay in the hospital, presence of risk factors, stroke severity, death due to stroke, discharge status and effect of community education programs on these factors.

These data will be evaluated to determine the effect of the program on the outcome of stroke in North Carolina as well as compared with two other Comprehensive Stroke Centers, one in Monroe County, New York and the other in Oregon.

Question: Is it hoped that this center may play a significant role in reversing the upsurge of reported stroke incidence in that region of the country?

Answer: The Comprehensive Stroke Center activity at Chapel Hill, North Carolina should be able to provide information concerning the usual outcome and effects of stroke in the population and the results of treatment. The most promising and favorable approach to the reduction of stroke incidence and severity is through reducing or avoiding those risk factors which contribute to stroke. Health professionals in North Carolina are developing community support for the stroke prevention programs directed toward reduction of risk factors, such as hypertension and atherosclerosis through activities which reinforce and stimulate particular types of behavior, i.e., reduction of weight, dietary improvement and physical exercise. In addition, programs geared to public education on the warning signs of stroke are being evaluated. Such stroke prevention activities may be encouraged through a variety of mechanisms and extended to other communities.

REGENERATION

Question: The Health Programs Extension Act of 1980 directs the Secretary of HHS to enter into a contract for a review of past and on-going neurological research, including central nervous system regeneration research. A five-year plan is also to be developed. To what extent will you be increasing your emphasis on this area in the next few years?

Answer: NINCDS over the course of the last several years has placed considerable emphasis upon developing additional research on the problem of regeneration of the central nervous system and will continue to do so in the future. New research leads continue to evolve as a result of the efforts of investigators directly addressing the problems associated with nerve tissue regeneration and studying parallel biologic mechanisms. As new promising investigative areas appear, these are transmitted to the scientific community by the NINCDS in order to exploit these promising new avenues. This program effort is one identified for high priority by the staff and National Advisory Council of the NINCDS.

Question: What are you doing to overcome the shortage of trained investigators in this field?

Answer: The NINCDS supports a variety of training programs intended to encourage new talent to address the problems of nervous system regeneration. These programs, i.e., individual fellowships, institutional fellowships, Research Career Development Awards and Teacher-Investigator Development Awards, contribute to the development of new investigators. Additional investigators are also introduced to the field of regeneration through their exposure as research associates in the laboratories of established researchers with interests in the area. The Institute attempts to recruit both basic scientists and clinical investigators to assure the broadest possible approach to a perplexing, fundamental biological dilemma and a most compelling physical, socio-economic medical problem.

Question: What are you doing to get researchers in related disciplines to go into regeneration research?

Answer: Investigators from a variety of disciplines (e.g., chemistry, physiology, anatomy, biophysics, biology, materials science, medicine, etc.) are encouraged by the NINCDS to engage in research on regeneration of the nervous system. Diverse and interdisciplinary approaches are necessary to unravel these extremely intricate and complicated biological processes. The Institute uses a variety of mechanisms to mobilize the appropriate manpower and expertise, including published announcements, discussions at national scientific meetings and conferences and workshops.

Question: Can you tell us about some of the promising avenues of research on regeneration of the spinal cord?

Answer: A multifaceted research approach is underway to delineate the many factors which either facilitate or inhibit nervous system regeneration. All of the relevant studies are not

confined to the spinal cord, since findings derived from the brain and peripheral nervous system contribute extensive knowledge and new concepts applicable to the spinal cord as well. There is a growing body of knowledge to suggest that remodelling of the nervous system occurs following injury. This remodelling occurs in the spinal cord and elsewhere and is due to the collateral sprouting of surviving nerve cells and the ingrowth of nerve processes from other locales. The varied types of neurons and their individual propensities for regrowth are currently being characterized. Random intrusion of inappropriate nerve processes and early non-specific contact and synapse formation may account for the known abortive regrowth following injury. Thus investigators are carefully defining, particularly in the developing animal, those guidance and trophic factors responsible for the well integrated outgrowth and development of nerve processes, as well as the means whereby proper selectivity in nerve-to-nerve connections is attained. Other studies suggest that a number of post-injury tissue responses, including gliosis, may play a lesser role in the inhibition of nerve regeneration than previously supposed. Such findings may permit a rechanneling of effort into studies aimed at promoting more purposeful regeneration, and thereby functional recovery.

HUNTINGTON'S DISEASE

Question: What progress are you making against such killing and crippling diseases as Huntington's disease?

Answer: A focused program of basic research is aimed at understanding the underlying defect in Huntington's disease by studies of cell metabolism and cell membranes. The newly developed technique of positron emission tomography has demonstrated early (pre-clinical) metabolic changes in brain centers. In addition, a promising study using recombinant DNA techniques to identify the Huntington's disease gene may permit a presymptomatic diagnosis. Other investigations of chemical markers in tissues outside the brain are also being pursued.

An international collaborative project with Venezuelan scientists to study a unique population of Huntington's disease families in Venezuela is in progress. This study provides scientists with an opportunity to study an isolated population with unique genetic characteristics of importance to understanding Huntington's disease.

Two interdisciplinary Huntington's disease research Centers Without Walls have been funded.

EPILEPSY

Question: What progress are you making against such killing and crippling diseases as epilepsy?

Answer: The progress in epilepsy research is both at the basic and the clinical level. The basic studies are primarily aimed at identifying the various causes of seizures so that prevention may eventually be possible. The clinical studies are an effort to find improved methods of seizure control for the two million Americans who have epilepsy, particularly for those whose seizures are presently uncontrolled.

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Basic studies are involved in such investigations as evaluating the oxygen consumption of epileptic nerve cells, in studying how seizure discharges spread throughout the brain and how the inhibitory mechanisms of the brain interact with the seizure and eventually stop it.

Clinical studies include clinical epilepsy research for the diagnosis, treatment, prognosis, and prevention of epilepsy. A new technique, positron emission tomography, is providing new understanding of the metabolic events which occur in patients with partial (local, focal) epilepsy. In addition, a modest effort in technology transfer demonstrates to physicians and other professionals the newest advances in epilepsy research and treatment and establishes a pilot program for public education.

A major investigative effort is devoted to the development of new antiepileptic drugs. This includes synthesis, screening, toxicology, and clinical trials of promising compounds.

MULTIPLE SCLEROSIS

Question: What progress are you making against such killing and crippling diseases as multiple sclerosis?

Answer: Progress is being made in studies exploring the cause, improving the accuracy of diagnosis, and the efficacy of treatment. Perhaps the most significant recent development in understanding the disorder is the discovery of changes in the immune system in the MS patient. Investigators in the Intramural Program have developed a model of a disease state much like MS in mice, which may lead to better understanding of the human disease. Also, intramural scientists have developed a unique program to study twins, one or both of whom have MS. Newly developed diagnostic strategies have the potential to reduce significantly the time needed to reach an accurate diagnosis for the MS patient. NINCDS supports clinical trials of various promising treatments in MS, primarily based on modifying the abnormal immune responses of MS patients. Basic electrophysiological studies are uncovering pharmacological means which offer hope of restoring normal conduction to demyelinated pathways.

AMYOTROPHIC LATERAL SCLEROSIS

Question: What progress are you making against such killing and crippling diseases as ALS?

Answer: In May 1980, the Neurological Disorders Program issued a Program Announcement to encourage biomedical investigators to submit grant applications for study of promising leads in amyotrophic lateral sclerosis (ALS). Responses to this Announcement in the form of applications are presently undergoing review under the NIH peer review system. Recently the NINCDS Intramural Program uncovered a focus of very high incidence of ALS in western New Guinea where the wells and garden soil show very low levels of calcium and magnesium and high levels of manganese, iron and aluminum. These and other observations have encouraged a renewed search for metabolic abnormalities in ALS influenced by an exogenous stimulus such as high levels of trace metals. An ALS-like syndrome in dogs has been identified and studies of its pathology, clinical

course and genetics are progressing. In addition, research into possible viral causes of ALS continues as well as into the immunological response of ALS patients to infection.

HUNTINGTON'S DISEASE CENTERS

Question: Have you opened any Centers Without Walls for those suffering from Huntington's?

Answer: Research grants to support two Huntington's Disease Research Centers Without Walls were awarded in July 1980, one to Johns Hopkins University and one to a consortium of investigators in the Boston area with administrative focus at the Massachusetts General Hospital.

REYE'S SYNDROME

Question: What progress are you making against Reye's Syndrome, a frequently fatal disease in children?

Answer: The NINCDS, in co-sponsorship with other NIH institutes, published a Program Announcement requesting research grant applications related to Reye's Syndrome on May 16, 1980 in the NIH Guide to Grants and Contracts, Vol. 9, No. 7. Responses to this Announcement in the form of applications are presently undergoing NIH peer review. The NINCDS is the lead institute in sponsoring a Consensus Development Conference on the "Diagnosis and Treatment of Reye's Syndrome" to be held March 2-4, 1981 at the National Institutes of Health. Currently the NINCDS is supporting research on metabolic profiles and amino acid disorders in Reye's syndrome and on its neuropsychological consequences. Over the last several years, mortality rates for Reye's Syndrome reported by medical centers treating the syndrome have dropped considerably. This change is due in part to earlier detection and treatment, increased knowledge and experience, and more aggressive treatment. Most of the surviving children seem to have full recovery, but there is suggestive evidence of emotional and personality changes in some survivors, short-term memory problems in others, and in some of the most severe cases clear evidence of varying degrees of brain damage.

Question: How much is in the Carter budget for Reye's research?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

AUTISM

Question: What advances have you made against autism, a complex learning and personality disorder in children?

Answer: Research on intonation and timing of speech production has shown characteristic differences between autistic and normal children. These findings suggest new approaches for speech training in autistic children. Research continues on the acquisition of language and communicative skills by speech and sign in autistic children. A search for early predictive signs

of autism in neonates and infants is underway. As autism is a complex disorder of unknown etiology and pathology and as there as yet have been no major research leads, emphasis continues to be placed on basic neuroscience research in order to identify approaches for targeted studies.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NINCDS share of that amount is $52,837,000 and 472 grants.

Question: How is inflation impacting--or how will it impact--on this goal? What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new Research Grants regardless of other budget priorities within NIH?

Answer: The award of new grants provides the opportunity to capitalize on new information as it evolves from the research. It also provides for the support of a continuing group of bright, young investigators and investigators from other fields with new ideas and new technology relevent to NINCDS areas of responsibility.

Question: What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: Past and present experience demonstrates it is highly improbable that this would occur. However, if it should occur, the funds would be utilized in meeting additional needs in other areas of priority which have been restrained because of fiscal constraints, such as support of clinical trials and full utilization of intramural research opportunities.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981--and if you can estimate it--in FY 1982?

Answer: We estimate that new and competing research project grants will be funded through a priority score payline of 200 for 1981 and 200 for 1982.

Question: What percentage of grants will you fund in both years?

Answer: In 1981, we estimate that 37 percent of approved new and competing research project grants will be funded. In 1982, the estimate is 39 percent of approved grants.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justification recently submitted to the Congress has attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications show the levels of funding reductions by budget mechanism and major disease category.

BUDGET

Question: Will you give us some idea of how your Institute plans to adjust to the overriding demands of the inflationary economy that we are currently burdened with?

Answer: The NINCDS is reevaluating the competing priorities among its several research responsibilities and adjusting the emphasis to be given to its targeted efforts in relation to public need and research opportunity. In addition, both its personnel needs and procedural methods are being reviewed to assure even greater economies and efficiencies commensurate with program adequacy.

Question: To what extent will you have to make substantial cuts in various programs in order to fund others of higher priority?

Answer: The NINCDS will continue to give primary emphasis to its research project grant program, intramural research program and research training and career development programs. This will decrease the resources to be made available to other activities.

STROKE

Question: If we are to witness a continued decline in stroke incidence as we have over the past decade, what specific course of action should be followed to achieve such dramatic results?

Answer: A continued decline in the incidence of stroke will depend in part upon the widespread understanding and control of the all-important risk factors related to stroke. Additional impact on stroke incidence and mortality will be accomplished by current stroke research which is addressing itself to more specific diagnosis of stroke type (hemorrhage vs. arterial occlusion), more aggressive management of stroke, therapeutic trials to determine the efficacy of new treatments and a multidisciplinary understanding of the biochemical and physiologic mechanisms which precede and follow a stroke.

REYE'S SYNDROME

Question: How much is in the Carter budget for Reye's research?

Answer: The NINCDS budget for research directly related to Reye's syndrome is estimated for FY 1981 at $360,000 and for FY 1982 at $400,000. This includes $15,000 for intramural research projects in each year. President Reagan's revised budget provides for the same level of funding for Reye's syndrome as the Carter budget. In addition, the NINCDS supports a broad program of research on the consequences of infectious and metabolic insults to the nervous system and neuroimmunological responses to these factors. These studies provide for the basic research necessary to identify specific factors which will be of importance to understanding the basis of Reye's syndrome.

National Institute of Allergy and Infectious Diseases

STATEMENT OF DR. RICHARD M. KRAUSE, DIRECTOR

ACCOMPANIED BY:

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ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator ANDREWS. Our next witness is Dr. Richard M. Krause, Director of the National Institute of Allergy and Infectious Diseases.

I understand, Dr. Krause, the mission of your Institute is to conduct and support research on all infectious diseases of men and on diseases caused by disorders of the immune system, such as asthma and other allergies. And we welcome you and would ask that you very briefly highlight your opening statement, which will be printed in full in the record so that we can move quickly to questions from the subcommittee.

And I would appreciate it if you could, first, introduce your associates and then proceed.

[The statement follows:]

STATEMENT OF DR. RICHARD M. KRAUSE

Just a little more than a century ago, Pasteur proved that bacteria were the cause of infectious diseases as well as of other biological processes such as decay, putrefaction, and fermentation. In short, Pasteur developed a common explanation for a diverse array of biological processes that puzzled mankind for centuries. Blown away were such age-old notions that diseases were caused by spontaneous generation, infectious night air, and foul humors. The years since these early discoveries can be described as Pasteur's Century -- a century in which the recognition that microbes cause disease would change for all time the way medicine had been practiced for 2,000 years.

We now enter a second century since Pateur's first discoveries. Already there are signs that the achievements of this second century will surpass, beyond all expectation, those of the first. Antibiotics have repelled ancient scourges, including tuberculosis and pneumonias; vaccines now prevent polio, measles, and other childhood diseases. But Pasteur's legacy, we should remember, is not just vaccines and wonder drugs. The crowning achievements were the birth of microbiology and immunology. From these twin sciences spring the clinical discoveries of this Institute.

In the last 30 years these two sciences have literally burst with ingenuity, energy, and enthusiasm. Bacteria have been used to trace the intricate metabolic pathways in all living cells and to decipher the chemical basis of heredity. In a word, knowledge of microbes spawned a new science, molecular biology, and new methods such as recombinant DNA technology. And a new immunology is exploring for the first time the internal machinery of the immune system. This past year the importance of immunology was noted when three scientists with long-standing ties to NIAID received the Nobel Prize for their work on the genetic control of immunity. One of the laureates, Dr. Baruj Benacerraf, formerly served as Chief of our Laboratory of Immunology in Bethesda.

Through immunological research we are learning, on the one hand, to enhance the protective powers of the immune system and, on the other, to regulate the destructive processes that lead to immunologic diseases and allergies. A major advance in this work has been the discovery and application of hybridoma cell fusion, a new technique to produce pure antibodies. This method is already as widely used in science and medicine as is recombinant DNA technology. As a consequence of these new discoveries, we can probe more deeply than ever before into the innermost secrets of disease processes and acquire the knowledge needed to develop new methods for diagnosis, treatment, and prevention. The opportunities are at hand. These are the omens for optimism as we enter the second century after Pasteur.

Infectious Diseases -- Worldwide, infections are the single most common cause of both illness and death. Even in the United States -- 40 years after the introduction of antibiotics and despite the widespread use of new vaccines -- nearly one-fourth of all patients who seek medical care do so because of an infection. Infection acquired in the hospital prolongs the stay of one out of every 20 patients. Why do the microbes that cause these infections elude our efforts to contain them? There are two reasons: first, their extraordinary diversity -- there are an incredibly large number of different microbes; and second, their ability to mutate, to change and to escape our

methods of treatment and prevention. Diversity and mutability -- these are the formidable qualities of the microbial sea in which we exist. For this reason we are caught on the restless tide of microbial evolution. Because nature adapts to circumvent the barriers that we erect in her path, we must be alert to the stream of change in the biological world. New problems emerge and old problems persist, often clothed in new garments. Examples of this include the discovery of new viruses and other unexpected pathogens that produce Legionnaire's disease or toxic shock syndrome, as well as the emergence of antibiotic-resistant pneumococci and gonococci. Unusual bacteria that seldom produced disease in previous years are now known to cause life-threatening infections in the elderly and in patients undergoing intensive immunosuppressive therapy for cancer and arthritis. Strange and highly lethal virus infections are emerging from Africa and elsewhere.

And we are not oblivious to the persistent threat of infections among the very young. Infants may die or become mentally retarded for life because of infections of the central nervous system. Reye's syndrome is a tragic consequence in some children following influenza. So every effort is being made to improve flu vaccine.

Prevention is still the most cost-effective way to diminish the burden of infectious diseases in our society. And yet, over 100 years after the first discoveries of Pasteur, barely a dozen infections have been controlled by vaccines. There are over 50 common as well as severe life-threatening infections that can be neither treated nor prevented. For this reason, vaccine development is being pursued. And we believe the new technologies that I mentioned earlier will be helpful in this endeavor.

Vaccines recommended for accelerated development include those for gonococcal infections, bacterial meningitis, Pseudomonas aeruginosa infections in cystic fibrosis patients, genital herpes simplex infections, hepatitis, and infections causing infant bronchiolitis, croup, and diarrhea.

With few exceptions, there is no treatment for virus infections, the single most common cause of all illness in the United States. Hazards from viruses to the health of the young and old alike have stimulated targeted research toward the development and testing of better antiviral drugs, including interferon. Clinical studies, now under way, will determine the effectiveness of interferon in treating a severe form of chickenpox in patients who are afflicted with other chronic illnesses. And acyclovir is being tested in similar patients who are especially susceptible to certain herpesvirus infections. A small number of children with herpes encephalitis were successfully treated with a new drug, ara A.

The last decade has seen an epidemic of sexually transmitted diseases (STD's), including the traditional ones, such as gonorrhea, and a growing number of other diseases that can be called the "new generation" of STD's, such as genital herpes. Many factors have contributed to this epidemic, but the outlook for control is optimistic. Investigators at the University of Washington, for example, are using the new technologies to develop a gonococcal vaccine.

Genital herpes has emerged as the most prominent STD in the past decade. It is estimated that nearly 500,000 new cases occur annually. This genital infection is chronic and can recur frequently throughout life. In addition to the serious intermittent discomfort,

there are the possible dangers of malignancy of the cervix and infection to a newborn child. Currently, there is no effective therapy or vaccine. Research is needed on new methods of treatment and prevention as well as identification of the factors that have influenced the rapid spread of this infection.

Tropical medicine research focuses on the most widespread of the world's health problems. Parasitic diseases rage out of control in much of the developing world. For this reason they are a potential threat to the health of Americans both at home and abroad. Malaria, the "King of Diseases," once under control in much of the world, is again on the march because of drug-resistant parasites and insecticide-resistant mosquitoes. Research is closing in on a possible malaria vaccine, and new methods are being explored to control mosquitoes by altering their breeding habits, fertility, and behavior.

The Immune System and Its Diseases -- An estimated 35 million Americans have allergies, including 9 million with asthma. These illnesses account for 5 to 10 percent of all patient visits to physicians, with a direct medical care cost of $1.5 billion in 1975 and other socioeconomic costs in excess of $800 million per year. In adults, asthma alone accounts for at least 90 million days of restricted activity and absence from work. Among children, it is the most common chronic disease causing school absenteeism. Looking beyond the allergies, a major, but as yet unmeasurable proportion of chronic diseases -- such as rheumatoid arthritis, systemic lupus erythematosus, and probably juvenile diabetes -- may be due to a complex interplay between immunity and an unrecognized infection.

We are moving to implement the recommendations of the Task Force on Asthma and Other Allergic Diseases. The strategy includes: (1) basic research on the immunologic and chemical mechanisms that are responsible for asthma and other allergic reactions; (2) basic and clinical research on improved immunotherapy (allergy shots) for the treatment of specific allergies; and (3) development of new drugs to combat the destructive inflammation that occurs in the tissues that are affected by allergic reactions.

One of the most frightening and life-threatening events is an adverse "allergic" reaction to drugs. Drugs as commonly used as aspirin and penicillin can trigger these severe reactions in a sizable group of the general population. Research is in progress to identify susceptible individuals so that they can take precautions to avoid those drugs that might trigger such a reaction.

Research on the immune system is flourishing today as never before. This system includes approximately 1 trillion specialized cells called lymphocytes. These cells are divided into many different sets and subsets, each with a different job to do -- some enhance and some suppress immunity. As these different sets of lymphocytes work together within the body, they serve as checks and balances to regulate immune processes. Disease occurs when there is an imbalance in the interrelationship among the lymphocytes. A principal aim is to learn how to restore this balance to a healthy state by a process called immunoregulation. Already this research has led to practical approaches for treating chronic diseases such as lupus erythematosus.

Progress in immunology will touch nearly every field of medicine in the coming decade. New technologies and opportunities will lead to the development of new and improved vaccines for infections of all

kinds, new diagnostic reagents, and novel drugs and new strategies for treatment. In short, we are entering a new era.

A special word must be said about immunogenetics, the area of research of the three immunologists who received the 1980 Nobel Prize. Immunogenetics is the study of the genetic factors that control the beneficial as well as the detrimental immune responses that occur after exposure to microbes, allergic substances, and to environmental factors including industrial products.

Transplantation biology is one important aspect of immunogenetics. We now know that the outcome of an organ transplant is under genetic control. Its success or failure is related to "transplantation" antigens that are on the surfaces of all the cells of our bodies, including those of organs to be transplanted, such as kidneys, skin, and bone marrow. Each individual inherits from his parents a set of transplantation antigens that differs from the sets of antigens of most other unrelated people. This becomes an important consideration in the clinical use of transplantation. Organ transplants are rejected by the immune system of the patient when there is a mismatch between the transplantation antigens of the donor and the patient. Therefore, prior to kidney transplantation, for example, a search is made to "match" the transplantation antigens. The closer the match between the antigens of the patient and the donor, the more likely will the kidney transplant "take" and not be rejected by the immune system of the recipient.

One of the most intriguing outgrowths of this basic research on immunogenetics has been the recognition that patients with certain chronic diseases, such as juvenile diabetes and various forms of arthritis, are more likely to possess one special type of transplantation antigen than is the case for the general population. This observation has become a fascinating clue to the possible causes of these debilitating diseases. It is obvious from these considerations why "transplantation" antigens and the genetics that control the immune response to them are subjects of intense investigation.

This concludes my prepared statement. I would be pleased to answer any questions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institute of Allergy and Infectious Diseases

Biographical Sketch

NAME: Richard M. Krause, M.D., D.Sc.

POSITION: Director, National Institute of Allergy and Infectious Diseases

BIRTHPLACE AND DATE: Marietta, Ohio
January 4, 1925

EDUCATION: B.A., Marietta College, 1947
M.D., Case Western University School of Medicine, 1952

EXPERIENCE: Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 1975 to present

(Assistant Surgeon General, U.S.P.H.S. Commissioned Corps, 1977 to present)
(Surgeon, U.S.P.H.S. Commissioned Corps, 1975-1977)
Professor, Rockefeller University, and Senior Physician to the Hospital, 1968-1975
Associate Professor, Rockefeller University, and Physician to the Hospital, 1966-1968
Professor of Epidemiology and Professor of Medicine, Washington University School of Medicine, 1965-1966
Professor of Epidemiology and Associate Professor of Medicine, Washington University School of Medicine, 1962-1965
Associate Professor, Rockefeller Institute, and Associate Physician to the Hospital, 1961-1962
Assistant Professor, Rockefeller Institute, and Associate Physician to the Hospital, 1957-1961
Assistant, Rockefeller Institute, and Assistant Resident Physician to the Hospital, 1954-1957
Internship and Residency Training, Internal Medicine, Barnes Hospital, 1952-1954
Research Fellow, Department of Preventive Medicine, Case Western University School of Medicine, 1950-1951

ASSOCIATION MEMBERSHIPS:

National Academy of Sciences of the United States of America, Chairman, Section 43, Medical Microbiology and Immunology 1980-83
Institute of Medicine, National Academy of Sciences
Association of American Physicians
American Academy of Allergy
American College of Allergists
American Society for Clinical Investigation
American Society for Microbiology
Infectious Diseases Society of America
American Association of Immunologists
Royal Society of Medicine
Practitioner's Society of New York
American Rheumatism Association
American Thoracic Society
American Academy of Microbiology
American Epidemiological Society
New England Society of Allergy
American Society of Biological Chemists
The Harvey Society
Sigma Xi
American Association for the Advancement of Science
American Venereal Diseases Association
The Albert Lasker Medical Research Awards Jury, 1977
Member, Steering Committee of the Biomedical Sciences Scientific Working Group, World Health Organization, 1978
Member, Board of Directors, Lupus Foundation of America, 1977
Member, Board of Directors, Allergy Foundation of America,1976-1977
Member, Infectious Disease Advisory Committee, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 1970-1974
Board of Directors, Royal Society of Medicine Foundation, Inc., 1971-1977 (Treasurer 1973-1975)

Consultant and Member, Coccal Expert Committee, World Health Organization, 1967 to present
Directors Council, New York Heart Association, 1973-1975
Chairman, Allergy and Immunology Study Section, National Institutes of Health, 1966-1970
Commission on Streptococcal and Staphylococcal Diseases, United States Armed Forces Epidemiological Board (Deputy Director, 1968-1972), 1963-1972
Chairman, Research Study Committee and Member, Executive Committee, Council on Rheumatic Fever and Congenital Heart Disease, American Heart Association, 1963-1966
Member, Policy Committee, American Heart Association, 1966-1970
Board of Directors, New York Heart Association, 1967-1973
Chairman, Advisory Council on Research, New York Heart Association, 1969-1971
Chairman, Research Study Committee, Council on Rheumatic Fever and Congenital Heart Disease, American Heart Association, 1963-1966
Member, Executive Committee, Council on Rheumatic Fever, American Heart Association, 1963-1966
Member, Board of Trustees, Marietta College

EDITORSHIPS: Section Editor, Journal of Immunology, 1974-1975
Editor, Journal of Experimental Medicine, 1973-1975
Editorial Board, Immunochemistry, 1973 to present
Editorial Board, Bacteriological Review, 1969-1973
Editorial Board, Infection and Immunity, 1970-1978
Associate Editor, Journal of Immunology, 1963-1971
Editorial Board, Clinical Immunology and Immunopathology, 1976-1978
Advisory Editor, Journal of Experimental Medicine, 1976 to present

AUTHOR: Publications of more than 125 papers on research in infectious diseases and immunology

AWARDS AND HONORS: Honorary Doctor of Science Degree, Marietta College, Ohio, 1978
DHEW, Distinguished Service Award, 1979
Honorary Doctor of Science Degree, University of Rochester, New York, 1979
Republic of Egypt Order of Gumhuria Award, 1980

INTRODUCTION OF ASSOCIATES

Dr. KRAUSE. Thank you. Senator Andrews.

First, Dr. John Seal, Deputy Director of the Institute.

And Mr. Charles Leasure, Executive Officer.

Perhaps in just a moment or two it would be helpful if I were to give you an example of what we have done that has made a difference to the health of the American people and in the prevention of disease, and then give you a glimpse of what we think we may be able to do in the future.

Despite the widespread use of antibiotics such as penicillin, infections are still with us, meningitis, hepatitis. One hears about the sexually transmitted diseases, Legionnaire's disease and, yes, even the common cold.

And sudden and unexpected outbreaks of fatal infections still make the news these days and alarm the public, even right here in the United States.

And so it is no surprise that recent outbreaks of meningitis in schools in Houston and Miami have been widely reported in the national press. And I have some of those clippings here.

In the last 2 weeks there have been at least 10 deaths among children in schools, and a number of other patients have been hospitalized with this potentially fatal illness.

MENINGITIS OUTBREAKS

Senator ANDREWS. Is that viral meningitis?

Dr. KRAUSE. This is bacterial meningitis. It is an infection of the membranes, as you know, covering the brain.

And even with penicillin treatment, those that recover oftentimes have permanent brain damage and have neurological and mental symptoms for the rest of their life.

So for these reasons, the public health officials have wisely begun a vaccination program in the schools afflicted to stop the outbreaks from spreading.

We are fortunate that they have a vaccine to use. It is a vaccine which has been developed with the research of the past decade.

And development of this vaccine—and I have a vial of it here, which I'm going to ask Mr. Leasure to take up to you—I might say was something of a breakthrough, because there were probably at least 50 efforts in the past, earlier attempts to prepare that vaccine.

If you hold it upside down, you will see that it is a white powder and looks very much, in fact, like sugar beet sugar extracted from sugar beets.

In fact, it is——

Senator ANDREWS. You really know how to appeal to an old sugar beet farmer. [Laughter.]

Is this a different vaccine from the pneumococcal vaccine that we used?

Dr. KRAUSE. Yes; the pneumococcal vaccine is designed on the same principle, but this is a different vaccine.

Senator ANDREWS. But this is a different bacteria?

Dr. KRAUSE. Yes, sir.

Now, that is, in fact, sugar. But it is in a high molecular weight form, like starch. It is extracted from the bacteria, from the meningococcus that produces this disease, and it is a very high molecular weight form, therefore when injected produces antibodies.

Just—that is a 50-dose vial, but to put it in perspective, 1 ounce of the powder is the equivalent to 60,000 doses of vaccine.

Senator ANDREWS. Is this development of the research facility at the pharmaceutical companies, or is this a development of the research facilities of NIH?

Dr. KRAUSE. It is a development of the research effort initially at Walter Reed; second then, with extensive developments supported by the National Institute of Allergy and Infectious Diseases; and third, with the basic research that was done on the development of this vac-

cine, as well as clinical trials taken over by the drug industry. And the developmental research was then done by them for the marketing and the use throughout the country.

RELATIONSHIP BETWEEN NIH AND DRUG INDUSTRY

Senator ANDREWS. Now, in some of this, one of the issues that we face is NIH getting compounds from the drug industry which it then tests for the drug industry. As I understand it——

Dr. KRAUSE. Excuse me, sir?

Senator ANDREWS. You get compounds from the drug industry, not only in this but in other fields, and you then test those compounds for efficacy and safety, as I understand.

Maybe we ought to have the Director address that, because that has to do with not just your own shop.

Is that not essentially true?

Dr. FREDRICKSON. Mr. Chairman, on occasion we do get study materials from the drug industry. Generally speaking, we do not use those in extensive clinical trials except when we have a major scientific question to be answered and where those materials will provide a mechanism for doing so.

I think that what you are getting at basically is what is the direction of movement, or the interaction between industry and the Government and NIH.

Senator ANDREWS. We've gotten into that classically in a whole lot of fields, not only clinical drugs, but agricultural herbicides and pesticides. Where do we draw the line, really? Is it the obligation of the Government to do the testing to make sure the products are safe? Or is it the obligation of private industry? Or should there be a mix?

And when this question ran across me, I remembered some of the extensive testimony we've had in the herbicide-pesticide field.

And of course the follow-on question would be: If you cooperate with the drug industry in doing part of this testing because it helps your program, do they then compensate you for that share that they would otherwise have to do on their own? Is there any payment involved, quid pro quo?

Dr. FREDRICKSON. Quite frequently, that is correct, Mr. Chairman. In fact, sometimes it is highly desirable that the public sector—underwrite these trials to avoid conflicts of interest that could make a difference in interpretation of the results. Thus, I think we must do a certain amount of clinical trials in the public sector. When we do so, we attempt to get the drug houses to supply the material. Sometimes they do it free.

We put every pressure we can upon them to make sure that it is possible. At the same time, we are trying to answer the basic scientific questions, not just relative to the safety and efficacy of that product alone. I think we rarely do that simply to prove that one product might be better than another. In that case, they must underwrite that sort of trial.

Senator ANDREWS. I'm not worrying about one product—better than the other. I am thinking about one product is safe.

Do you, in fact, given a new material from the drug industry in your testing program, provide part of the function of assuring that it is safe, indeed, to use on American patients?

Dr. FREDRICKSON. We do not, if it is just to see if the product is safe for American patients as opposed to something they have picked up abroad on a license. We do not do that kind of developmental work for them. But if it is the first time a vaccine has been developed, it may be that we would be the first to test it and then pass the results on in larger scale to the industry.

The development of drugs, however, is the second question. And that is: Do we develop drugs that the industry ought to be developing?

Senator ANDREWS. But the drug companies make a profit from the sale of this.

Do you get any reimbursement for the testing and discovering whether or not the product is safe?

Dr. FREDRICKSON. At the present time, we do not get any direct reimbursement from the drug houses, or from any of our patents that are held by institutions, on inventions whose development we may have helped underwrite.

Senator ANDREWS. Have you ever looked, and could you supply for the record——

I don't want to prolong this, but this is my first year on this subcommittee, and a lot of things tie in from other subcommittees that I've been privileged to serve on, in the past.

Have you ever looked at the possibility of this type of interrelationship, so to speak?

We keep hearing reports of fantastic medicines that are available in Europe, that aren't available here, because we aren't sure that they're safe. We then hear about medicines such as thalidomide, which went on the market here without adequate testing.

How do we assure the public that they do have access to new developments in the field of medicine, as rapidly as is safely possible, and at the same time protect them?

Could we move toward a more balanced program of cooperation between the Federal Government and the private firms?

Have you got any ideas on this?

Dr. FREDRICKSON. Yes, I do; and I will just take 1 second of your time at this moment.

The relationship between industry and NIH, the biomedical research establishment supported by the public, is a key one for examination at the present.

On March 16 and 17, in fact, we are going to do that by having representatives from industry and from the Government, and various other people, look at exactly some of the problems you have raised. Dr. Krause will present some of his own possibilities for drug development, and we will examine those from several sides. We have an active program ready, and we will send you the agenda. Certainly, the results of that program will be made available to the public.

Senator ANDREWS. Could you provide also, for the record at this point, so we don't prolong the hearing right now, your ideas on how such an interrelationship might work out?

Dr. FREDRICKSON. Yes; I would be happy to do that, for the record.

[The information follows:]

National Institutes of Health—Industry Relationships

The National Institutes of Health has responded to the need for a more balanced program of collaboration between the Federal Government and private industry. This matter is being actively explored by the Advisory Committee to the Director, NIH.

Undergirding current relations with industry is the widespread and continuous communication in the biomedical research and development process. This arises from the open publication of research findings by scientists being supported by Federal research grants. Often these published results have led to the marketing of useful products by commercial manufacturers. In almost all cases, the product of research ultimately is manufactured and sold to users by an industrial corporation.

More specific relationships usually involve drug or vaccine development and in no case result in flow of funds back to NIH. The benefits to the Government and the public are most often social ones resulting from the reduction or elimination of disease. Monetary benefits accrue to the firm involved in marketing the final product. Several examples from the National Institute of Allergy and Infectious Diseases will serve to demonstrate some of the involvement between the NIH and industry.

A typical case is that involving both a diagnostic test and the vaccine for hepatitis B. In this example, the NIH supported the necessary basic research from which industry now profits. Following the Federal effort, Abbott Laboratories developed the Ausria test, a diagnostic test that has virtually eliminated the transmission of hepatitis B by blood transfusions. Additionally, Merck developed a hepatitis B vaccine, which recently published data have shown to be effective in reducing disease in a high-incidence group of individuals. The significance of the gain to the public from both of these developments, which have roots in federally supported research, is unquestionable.

Another example involves a more direct relationship between NIH and a particular private concern. Often it is necessary for NIH to foster the development of a drug when industry finds the research investment too costly. Taking on this responsibility has the effect of reducing both the development cost to the private concern and the time needed for completion of clinical testing. In such a case, the NIAID has been conducting the clinical trials for a drug for herpes encephalitis, which was originally development by Parke-Davis. Again, great social benefit will be more quickly derived, and industry is sustained and fostered.

In a different category from the first two examples is the birth of the recombinant DNA research industry. This industry has sprung directly from the work of two scientists supported by NIH who have received a patent for the process involved in this type of research. These scientists have since turned the patent over to two academic institutions, who will receive royalties from private concerns using this process. These funds, above and beyond administrative costs, must then be funneled back into research and education. It is expected that the work of these two NIH grantees in recombinant DNA technologies will lead to a significant flow of funds back into research. In an indirect way, this should lessen the burden on the Federal Government as private capital is invested in this growing field of research.

Another approach under active consideration at NIH is the creation of joint Federal, industrial, and academic programs for development of classes of drugs or vaccines. In one proposed program, the NIAID would competitively award cooperative grants to academic institutions with major programs in virology, immunology, and pharmacology. These institutions would, in turn, cooperate with industry and Government scientists to define needed drugs and develop specifications for their manufacture and testing. Contracts would then be let to industry for drug development.

The benefit to industry would be the creation of a new technology for the development of biologically active pharmaceuticals that might have only a limited market. The effort would also create a cadre of scientists trained in this technology in both universities and industry. The public would benefit by earlier and wide availability of drugs for prevention or treatment of certain diseases.

As noted above, NIH has been actively exploring several facets of the Federal-university-industry relationship at meetings of the Advisory Committee to the Director, NIH. Thus at its March 16–17 meeting, the committee explored in some depth such issues as: (1) the patenting of biological inventions; (2) royalty income from federally held patents; (3) industry support for basic and developmental health research; and (4) certain policy recommendations contained in the report of the National Commission on Research on the development of cooperative research relationships with industry. Subsequent meetings of the advisory committee will consider the policy options raised

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at the March 16–17 meeting. This will establish how the NIH and the Government generally might work with the academic/industrial sectors in light of congressional and administration initiatives in this area.

PROMISE OF IMMUNOLOGY

Senator ANDREWS. Would you proceed, Doctor?

Dr. KRAUSE. Yes, sir; let me go on, now.

I said that we would talk about what we have done that has made a difference. Let me very briefly talk about what we think we might do in the future that might make a difference in the health of the people.

We have used immunology in a major way, to develop these new vaccines. But there is more to immunology than vaccine development. Immunology is now touching nearly every aspect of medicine: allergies, arthritis, diabetes, cancer, organ transplantation.

And, in recognition of this promise that immunology holds, three immunologists, including two Americans, received the 1980 Nobel Prize in medicine. And what did these three men do? They recognized the importance of the barrier that usually prevents successful transplantation of organs from one individual to another.

And yet, because of their work, we have learned how this transplantation barrier may be overcome.

Let me explain, just in a second, what that transplantation barrier is. Without special procedures, we can't transplant organs from one individual to another, just as blood can't be transfused from one individual to another. The body has defense mechanisms against the transfusion or against an organ transplantation.

But we have learned to overcome, in the past, the barrier against blood transfusions, and there are some 7 or 8 million performed each year in the United States, following surgery and for other medical reasons.

Now, when there is a perfect match through this matching process, the blood can be transfused. But, in a similar fashion, what these Nobel Prize winners discovered is: They have suggested how this transplantation barrier of organs, which is much, much more complex and technically very much more difficult, how that can be overcome; and the transplantation can be done with success.

If a close match is achieved between the donor and the recipient of the organ, that insures success. If there is a mismatch, the result is failure.

Well, now, is this just putting in old organs, or putting organs into individuals that may be worn out anyway?

The fact is, I think not. The future is much brighter than that. What they have taught us is that it may be possible, for example, to take bits of a normal pancreas—just normal bits of normal pancreas—and transplant those into patients with diabetes; and have that transplant produce insulin, as if they had their own normal pancreas.

And this past year, immunologists collaborating with diabetes specialists have done just that, and succeeded to do just that in animals.

And I think this represents an example of collaboration between institutes, because the diabetes people are supported by the Arthritis Institute. And I take personal pride in mentioning the immunologist, because he trained in my own laboratory.

And, working together, he—receiving considerable support from this Institute—and the diabetes people from the Arthritis Institute have, in fact, successfully transferred a pancreas from a rat to a mouse, and cured the mouse, which had been made diabetic.

The bottom line, then, is: 5 years ago, a report of this would have been condemned to the area of science fiction. But there is now, to my mind, reason for optimism that transplantation can be employed in the future for diseases as common as diabetes.

Such, then, is the promise of immunology. A diverse group of common diseases—the allergies, arthritis, some of the anemias—have as a root cause an abnormality of the immune system. We are learning to control these diseases by devising ways to master these abnormalities.

Those are the remarks I wanted to make, Senator, in a preliminary way.

RESEARCH PRIORITIES

Senator ANDREWS. Thank you, Doctor.

I take it that the funding that is in the budget allows you to continue your share of 5,000 competing research grants, within NIH?

Dr. KRAUSE. Yes, sir.

In the 1982 budget, that is 420 grants.

Senator ANDREWS. What inflator are you using? Or, I would assume you are using the same for the entire Institute?

Dr. KRAUSE. Yes, sir.

Senator ANDREWS. We have heard a lot, lately—well, let me put this one in right now. Faced with a major budget cutback, what are your priorities?

Dr. KRAUSE. If there were a major cutback, I would first of all maintain a strong core of individual research grants; and this would mean that we would not be able, perhaps, to fund as many as we would do. But we would fund as many as we could.

Second, we would continue to support as much applied research, contract research, as possible. Because it is that research which translates the basic findings into the vaccines, such as I've showed you earlier, as well as the work leading to practical application of transplantation.

We would try to balance both of those efforts. But, clearly, we would not be able to do as much in either one as we are doing, were there a budget cut.

Senator ANDREWS. Would you provide, for the record, as I asked your colleague who proceeded you, what medical cost savings we could expect in the decade of the 1980's, per dollar of, or for, a given research expenditure that took place in your shop, in the decade of the 1970's?

Dr. KRAUSE. Yes, sir.

There are several examples, such as prevention of hepatitis and meningitis, and so forth.

[The information follows:]

MEDICAL COST SAVINGS FROM PREVENTION OF HEPATITIS

The general question of national medical care savings attributable to the cost of a specific NIH research program is a very complex one. It is difficult to give a precise answer based on current methodology for estimating cost benefits or cost effectiveness.

Current methodologies for estimating cost benefits or cost effectiveness require a series of assumptions and estimates for the important variables. The final answer is sensitive to different degrees by the assumptions for each variable. And while the final answer arrived at by a standard method for a set of diseases may provide useful comparisons, such purely arithmetic values do not convey the importance from a human, or humane, point of view. Disability, suffering, and death are not describable by an accounting procedure.

The realized benefits of hepatitis research and the opportunities perceived for future benefits are impressive. Basic research in hepatitis by a variety of organizations and substantially funded and expedited by NIAID support has resulted in marked reduction of the disease caused by hepatitis virus which is associated with the commonplace blood transfusion. Development of sensitive, highly specific blood tests for hepatitis B virus have nearly eliminated the danger of transmission from blood donors with an otherwise unsuspected carrier infection. This was achieved essentially by 1977 after the expenditure of an estimated $17 million in the NIAID hepatitis program.

The careful study by one State health department revealed graphic proof of the benefits. Only transfusion associated hepatitis serious enough to require hospitalization was considered. If the 1970 risk had still applied in 1976, 507 rather than 60 patients would have been hospitalized for an average of 20.7 days, rather than 16.2 days, and an additional $1.5 million in direct hospital costs would have been incurred.

The national situation, as opposed to a single-State experience, must necessarily be more loosely estimated. The estimated gross savings in hospitalization costs alone in the 1980 decade would be $560 million, 1978 dollars. This estimate is derived from the following assumptions:

Number of hepatitis cases serious enough to be hospitalized in an average year (1973) before general application of a specific hepatitis B test	44,800
Of this number, about 50% were transfusion associated hepatitis type B as viewed retrospectively with benefit of accurate sensitive tests	22,400
Average hospitalization 10.9 days at $250 per day—1978	$56,000,000
Accumulated for the 10 years 1980–89:	
Hospitalization costs saved in 1978 dollars	$560,000,000
Hepatitis type B hospitalized cases prevented	224,000
Including chronic cases—10%	22,000
Deaths—2%	4,500

This simplistic, but easily, grasped projection gives a crude ratio of $1 research for $33 in hospital costs saved.

The full story of possible savings can only be guessed at. Some $23 million was spent during 1970 to 1979 on the NIAID hepatitis program. This activity in cooperation with others, including a large industry involvement, has resulted in an inactivated vaccine for hepatitis B. A controlled clinical trial in a specific population which is about 10 times more likely to contract hepatitis than a population of normal healthy blood donors has shown the vaccine to be about 92 percent effective in preventing infection.

Although formal cost effectiveness analysis cannot yet be performed, it appears unlikely that the vaccine will be used for universal vaccination because of both economic and health care delivery constraints. Two sophisticated techniques which should markedly reduce the cost of vaccine are promising. The high-risk population—of which the clinical trials group above is representative—has been estimated at 7,500,000. If it becomes feasible to deliver an inexpensive vaccine to this group, substantial health care benefits can be expected.

INTERFERON RESEARCH

Senator ANDREWS. What is the status of your research on interferon? That seemed to be a cure-all, be-all, end-all. And then, it kind of fell from grace. And now it seems to be coming back—at least that's the way a layman looks at it, from what he reads in the paper.

Dr. KRAUSE. There is a special report on interferon, which was requested and which has been submitted, from the NIH as a whole. But let me make one or two comments.

Interferon is a substance which the body generates naturally, during a virus infection. And this substance appears to be a natural antiviral compound that the body produces, that is involved in some way with the body's self-cure of the virus infection.

There is still, however, very, very much more to learn about how this substance works. And that is basic research, which is still proceeding.

Senator ANDREWS. Is this research that is going on in your shop, or in the National Cancer Institute?

Dr. KRAUSE. It goes on in both Institutes. A great share of it goes on in universities across the country, and is supported by research grants.

I think it is probably fair to say that the basic research that is done is of two sorts: That that we support is primarily directed at learning how interferon works in curing the body of virus infections. Whereas, the research that the Cancer Institute is pursuing is to try to determine how interferon might help the body destroy cancer cells.

Senator ANDREWS. Is there total communication between the researchers?

Dr. KRAUSE. I think there is very good communication between the researchers, because this is a subject of considerable interest in scientific meetings. The researchers supported by us, as well as supported by the Cancer Institute, intermingle at scientific conferences.

Furthermore, at the administrative level, we have set up a committee at the NIH, in which the advances in the area are cataloged, are identified, and priorities are set.

Senator ANDREWS. Could you provide, or could Dr. Fredrickson provide, for the record a short statement on what steps have been taken in the past, and are being taken now, to make sure that the research that is going on in the various research centers around this country is tied together, so we don't have two shops 1,000 miles apart, doing the same work on the same disease, and at the same basic time?

Dr. FREDRICKSON. We have a number of devices, and I would be glad to describe them.

Senator ANDREWS. I would appreciate it if you would provide that for the record.

[The information follows:]

DUPLICATION OF RESEARCH

The National Institutes of Health employs several devices to prevent the duplication of research efforts. The primary safeguard against unproductive duplication is provided by the very nature of the process of scientific inquiry. The vast majority of NIH support of biomedical research is provided through the funding of investigator-initiated research project grants. Each grant proposal represents an individual investigator's own ideas, special skills, training, and perspectives. Consequently, each project represents a novel approach to the research questions that are posed. It is extremely unlikely that actual duplication of projects would occur with any significant degree of frequency—even within specific areas of inquiry, such as aging, diabetes, et cetera.

Applications for grants undergo rigorous scrutiny for originality at several points in the funding process. Applicants are required to indicate any support being sought from another agency. In addition, NIH participates in the Smithsonian science information exchange, which lists support provided by other agencies. Both intramural and extra-

mural projects are listed in this index. At the initial stage of evaluation, scientists in the relevant fields assess the originality of each application. Any that needlessly duplicate previous efforts are not recommended for approval. Apparent overlaps are brought to the attention of advisory councils and this is an important factor in funding decisions. Before final funding decisions are made, the program staff at NIH again reviews the types of research proposed for funding in terms of their originality.

Nonetheless, the most effective means of preventing duplication of research lies outside NIH, in the effort of members of the scientific community to keep themselves abreast of recent developments through journals, conferences, and peer interaction. Since needless duplication neither advances careers nor provides professional satisfaction, scientists serve their own interests by avoiding it.

INTERNATIONAL BIOMEDICAL RESEARCH

Senator ANDREWS. We're hearing a lot of talk lately on what there might be in international biomedical research. And I understand that you have been making some efforts with Japan and the Soviet Union.

To what extent has that international biomedical research effort with Japan and the Soviet Union been fruitful?

Dr. KRAUSE. I think, in our own case, as far as the research with the Soviet Union is concerned, it has been useful for us to have exchange of materials with them, as well as information in regard to major worldwide pandemics.

As you know, when influenza and other infections sweep over the world, we need to have as much advance information as we can, not only on the disease, but also samples of the infecting organisms.

When a new wave of influenza starts, for example, the more advance notice we have of that, and the sooner we get the strains of the virus—the new strains of the virus—that are causing the epidemic, the better prepared we can be.

Senator ANDREWS. Is this research in cooperation with Japan and the Soviet Union been confined to worldwide epidemics? Or do you also exchange information on basic research, and some of the other subjects that we've been talking about here today?

Dr. KRAUSE. In our case, most of our attention is on influenza, as far as our work with Russia is concerned.

In addition, what is important, of course, is that—I will come to Japan in just a moment—in addition, with Russia, we also have exchanged a good deal of information with them, to be sure that we are following similar laboratory practices.

In regard to Japan, the cooperation is much more extensive.

The Japanese are a highly developed, and technical country, as you know. Their research on hepatitis is first-rate. Their research on interferon is far advanced. Their research in a number of other areas is extensive. And we are cooperating with them on those.

Our scientists have found it very useful, for example, to keep abreast of what the Japanese are doing in hepatitis vaccine development, and in the manufacture of interferon with recombinant DNA technology.

Senator ANDREWS. Now, you're saying, in the case of Japan, you are finding that their basic research in medicine is significantly far ahead, or sufficiently far enough advanced, so that you are interfacing with them, bringing some new ideas and concepts to us.

Yet, in the case of the Soviets—is this because you are not examining similar types of research with them, rather we are limiting our interchange with them solely to epidemics?

Dr. KRAUSE. I think that perhaps Dr. Fredrickson would want to expand the remarks in regard to our relationship with the Soviet Union. Because, certainly, the National Heart, Lung, and Blood Institute, and the Cancer Institute, have a number of programs, I believe, with the Soviet Union.

Senator ANDREWS. Well, I was looking at this new one, specifically in interferon, which you just said. And again, you stimulate my imagination every time you bring one of these up, and undoubtedly prolong the hearings, unfortunately.

But, you mentioned what you are finding out with interferon through the Japanese. And you also, in your justifications, make two rather startling statements.

You say that the mastery of the immune system is at hand. And you also say that we are entering a new era.

I would think, if you are that caught up in the magic of these new breakthroughs and new findings, we would be exploring at this field with the Soviets, as well. Or is Soviet medicine that far back that there is nothing there to pick up?

Dr. KRAUSE. I think that it is probably—it may not be fair to say—it may not be correct to say—but for a variety of reasons, which probably include the level of science in the Soviet Union, there is less fruitful exchange between our scientists and their scientists, than there is between our scientists, for example, and those in Japan. Or elsewhere in Europe.

I think there are probably reasons that extend beyond just the level of their science.

There are also problems in terms of communication. It is true, however, that every effort is made to learn what the Soviet Union is doing. We have an extensive service, in terms of translation of their periodicals; that is, not only in the translation of their periodicals, but the survey of what is in them.

But, it is clear that our scientists do not have as close a relationship with their colleagues in Russia as they do with other countries.

INTERFACE WITH CHINESE MEDICINE

Senator ANDREWS. Well, let me go to another nation that has been totally isolated from the Western World for a long time, and has developed a fantastic heritage of accomplishing, being out front—you know, in the livestock industry, we say they've got "fantastic genes"—because of what they've accomplished over the years, in their own way.

And that is the People's Republic of China. They have a medicine that is totally different from ours: acupuncture, and the use of herbs, and the rest.

What kind of interface do we have with the Chinese medicine?

Now, I've made a couple of trips to the People's Republic of China and watched the barefoot doctors at work, and they seem to violate everything that we have been told is a necessity in modern medical practice.

But the results seem to be pretty credible.

What type of interface do we have with them?

Dr. KRAUSE. Well, Dr. Fredrickson may want to speak to this for the NIH as a whole, because he pioneered—if I may put it that way—the beginning of the NIH exchange and interface with China.

I personally was there for several weeks in September, and we set up a cooperative program between the two countries, in various areas of immunology, as well as diseases where immune reactions are abnormal, such as in arthritis, and many other areas of clinical immunology.

Clearly, the Chinese today are traveling on two tracks: On the one hand, they are going to examine the useful aspects and retain those of traditional medicine, and of the barefoot doctors, as primary health care providers.

On the other hand, it seems to me that they have every intention of building up, as rapidly as they can, the strong points of Western medicine.

Senator ANDREWS. I'm not interested in what they're doing. I'm interested in what we're going to benefit from being in a position to share some of the techniques that they have developed over the centuries.

What are we finding that we can fold into our system of medicine, from them?

Dr. KRAUSE. Well, I think that in the first place, we will need to be alert, and are, to what they have found in their pharmacopoeia that is useful. Some of those things have already come in, in the past. When one finds them, and they are there, they in fact do get brought in.

Senator ANDREWS. Let me get down to a specific, Doctor.

What if suddenly, out of the blue, comes a Chinese development and hits us square on the forehead; a development we may want to pick up.

What organized procedures have you, in the biggest medical research center in the United States, to systematically explore and examine and profit from the developments that this great people have brought up, totally separate, totally isolated, totally insulated from the Western World for some 30 years?

It looks to me as though we are missing a bit, if we don't have some systematic way of analyzing what they have to offer, and determining what might be of benefit, in bringing it into our structure of medicine.

Dr. FREDRICKSON. Mr. Chairman, let me add to that, speaking for all of NIH.

We have an American-Chinese agreement and a relationship that is very close. Just last week, we had two separate visits by two separate subdelegations. Not a month goes by that we do not have some exchange, at both official and unofficial levels, with them.

We have broken that down into various sectors of activity. Within those sectors, the experts of the United States have really quite excellent access to the Chinese developments, to their opportunities, including going back to some of their ancient medicine, as it might bear on our own diseases.

This is true, also, in providing us some interesting laboratory opportunities in China. There are certain kinds of cancer we do not have. There are certain cardiovascular differences, and the comparisons in epidemiology should be very instructive. Indeed, in hepatitis and certain other infectious diseases, we will also have special opportunities.

I think what you say is very true. I should add, just for the record, the following: We are in a new revolution in biology, and there are a number of nations around the world, including the People's Republic of China, just coming to the fore, who are in positions to compete very

strongly with the United States. I think we have a narrow advantage there. One thing that we have to do is to continue a vigorous level of exchange and information as to what they are doing, and cooperate as much as we can.

But we have to expect the exploitation, in even very economically profitable ways, of the new biology, which, in a sense, is primarily an American development in many ways. I speak not only for biomedicine, but also for other industrial applications and agriculture.

Senator ANDREWS. But that exchange has been systematized? It is not haphazard? And it has been developed to get the maximum benefit, both for the Chinese people and for us?

Dr. KRAUSE. I think it has. And we are exchanging scholars; not only on just visits, but people are actually going and——

Senator ANDREWS. If you could provide a little for the record. And, again, I'm looking for what we've got, when we go to the floor.

Dr. FREDRICKSON. I would be glad to do that.

Senator ANDREWS. If you would provide for the record what this amounts to, and what, in your mind, might be accomplished by this facet of the NIH, I think it might be quite helpful.

[The information follows:]

UNITED STATES-PEOPLE'S REPUBLIC OF CHINA BILATERAL PROGRAM

Though the National Institutes of Health involvement in this government-to-government program is extremely modest, it serves as a catalyst for considerable private sector scientific exhange. In addition, NIH involvement makes possible unique training opportunities for Chinese scientists, and enables U.S. scientists in private institutions to continue to benefit from collaborative efforts with their Chinese counterparts. Five of the NIH Institutes—NCI, NIAID, NHLBI, NICHD, NIEHS, plus NLM—are collaborating with their scientific counterparts on areas of mutual concern.

There are 10 areas of cooperation between the United States and the People's Republic of China: infectious and parasitic diseases, cancer, cardiovascular disease, public health and health services research, biomedical information sciences, immunology, human genetics, reproductive physiology and family planning techniques, mental health, and food and drugs. Progress has been notable in the 18 months since the health protocol was signed in June 1979. At a recent session of the United States-People's Republic of China Joint Health Committee held in China in November 1980, progress was reviewed by eight working groups. Papers and discussion focused on research activities and findings resulting from the numerous exhanges of delegations during the past year.

Plans were developed to collaborate in the epidemiology, detection, diagnosis, and treatment of cancer; cardiovascular epidemiology, including risk factors, biochemical, and human studies of atherosclerosis, hypertension, and nutrition. Environmental issues are being explored in the area of epidemiology and toxicology of pesticides, asbestos, and metals. The National Library of Medicine is cataloging publications dealing with Chinese traditional medicine. The Child Health Institute is exhanging information on human genetics, nutrition, and child development. Numerous exhange visits are planned in the coming year to continue cooperative efforts in these areas.

At the time of the first meeting of the United States-People's Republic of China joint committee in June 1979, the National Institute of Allergy and Infectious Diseases was asssigned lead responsibility for immunology and secondary responsibility with the Centers for Disease Control, in parasitology and infectious diseases. NIAID subsequently assumed the lead role in recombinant DNA research. In May 1980 the Chinese coordinator in immunology spent 1 week at the NIH campus. The Director of NIAID led a four-person delegation of U.S. immunologists on a 2-week visit to China in September 1980. As a result of the exhange visits, the protocol for cooperation in immunology was modified to include infectious and parasitic diseases; cancer; diseases of the immune system, including primary immune deficiency diseases; autoimmunity and

allergy and skin and organ transplantation. The research approaches will involve: (1) immunobiology; (2) immunogenetics; (3) molecular immunology; (4) immunopharmacology; and (5) clinical immunology. The Chinese and U.S. immunology groups subsequently developed a work plan for fiscal years 1981 and 1982 in the context of the revised protocol which provides for scientific exchange, research training, working groups, and collaborative research in immunogenetics and clinical immunology.

Parasitic and infectious diseases emphasized in the bilateral health protocol are: (1) malaria; (2) schistosomiasis; (3) hepatitis; and (4) influenza. During fiscal year 1980 the Chinese coordinators for these four diseases visited CDC and NIH to develop work plans and protocols. Malaria and hepatitis were singled out for special emphasis in the first full year of the program. Malaria activities to date have been control-oriented and primarily of interest to CDC. Following a visit by the NIAID and the CDC scientists responsible for hepatitis to China in February and a return visit by their Chinese counterpart in May 1980, a protocol was signed for cooperative studies on the efficacy of inactivated hepatitis B vaccine in the prevention of hepatitis B virus from hepatitis B surface antigen carrier mothers to their infants.

HERPES SIMPLEX VIRUS

Senator ANDREWS. Finally, Doctor, I have one last question. Herpes simplex is a disease that people are talking about more and more. How serious a problem is it in the United States today, and without a cure or treatment, how much worse will the situation get in the next 2 years?

Dr. KRAUSE. Herpes simplex is of two sorts. It is one which frequently causes the common cold sore which recurs over and over again in many people, and it is a major discomfort, but it is not as serious in many ways as the problem of the herpes which is transmitted by sexual activity. And that is becoming a much more serious sexually transmitted disease than it had ever been previously and indeed more serious than many of the other traditional, if I may call them that, venereal diseases such as gonorrhea.

There are up to 10 million episodes of genital herpes in the United States today with perhaps 500,000 new cases every year. The problem, of course, is that once the infection is acquired, it persists.

Now the lesions on the genital organs may disappear for some weeks or months, then, under periods of stress, recur. Of course, not only is it an infection of discomfort, but it also is one which causes psychological and emotional problems.

Finally, of course, these infections are a risk to the child at the time that it is born and passes through the birth canal, because it is that time at which a newborn infant is susceptible to these herpes infections, and one of the serious complications is herpes encephalitis.

Senator ANDREWS. Thank you, Doctor. I appreciate your candor, and we will look forward to the inserts. I also have a list of questions that the clerk will provide your shop to be answered for the record so that we will have a complete hearing record.

Dr. KRAUSE. Thank you very much. Let me just say that you can believe it; it is a new era.

Senator ANDREWS. Well, I certainly hope so for a whole host of reasons. We've got a daughter who just graduated in biochemistry from a school up in Massachusetts, and she's now going to medical school. Who knows, we may have another doctor in the family yet. But it's fascinating, what you are doing, and the whole world really is waiting for these new breakthroughs and sharing with you the enthusiasm that you pursue in your day-by-day tasks. It sometimes seems pretty tedious, I'm sure, but there is so much hope for mankind.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

TOBACCO ALLERGY

Question: The sensitivity to tobacco smoke experienced by some people is reportedly related to a specific protein that is released in the burning of tobacco. Is there a tobacco allergen for persons sensitive to cigarette and other tobacco smoke?

Answer: Existing commercial preparations to test for tobacco allergy are heterogeneous mixtures of extracts of fresh and/or cured tobacco leaves. The actual components responsible for tobacco allergy are unknown. However, two promising substances, now available to researchers, have been isolated and partially characterized, one a glycoprotein common to both tobacco extracts and smoke, and the other a proteinaceous material from green and cured tobacco.

Question: How widespread is this particular form of allergic response?

Answer: It appears that an allergic response to tobacco smoke is extremely uncommon or nonexistent and that most complaints from individuals are related to the smoke's irritant effect. On the other hand, many tobacco workers react to extracts of tobacco leaf. The significance of this observation in the general population remains to be determined because large survey studies have not been performed.

SEXUALLY TRANSMITTED DISEASES

Question: The Institute sponsored a Study Group on Sexually Transmitted Diseases in January, 1980. What changes, if any, did the Institute Council make in the recommendations of the Study Group?

Answer: The National Advisory Allergy and Infectious Diseases Council highly commended the Sexually Transmitted Diseases (STD) Study Group on the excellence of its effort and agreed with the substance of the report. The major modifications of the report recommended by the Council were concerned with the following: a) strategies for implementing the training of physicians and scientists urgently required to meet our national needs for STD research; b) the level of funding for this purpose; and c) the level of funding for each category of disease considered in the STD Study Group report.

Question: Were the recommendations for budget needs virtually cut in half? If so, why?

Answer: The STD Study Group recommended that all STD categories and training be supported to the level of $41,165,000 in fiscal year 1981. This compares to an investment in the same area of just under $8,000,000 in fiscal year 1979. Thus the STD Study Group recommended more than a fivefold increase over a two-year period. The Advisory Council considered this level of increase unrealistic; the major reason is that not enough physicians and scientists are trained in STD research to be able to accommodate such an increase in effort. An indication of the shortage of trained investigators is the fact that, in 1979, the NIAID received only seven approved research grant applications, totaling $626,000, to study genital herpes type 2. In 1980, again only seven applications were approved for $481,000 to study herpes type 2. The STD Study Group recognized this need for

more scientists and physicians trained in STD and, in fact, gave training the highest priority in its list of recommendations. The Advisory Council agreed wholeheartedly with the Study Group's conclusions and priorities and recommended what it felt to be a more realistic funding level--at least $28,140,000 (1980 dollars) invested by 1985.

RECOMBINANT DNA RESEARCH

Question: NIAID has actively conducted and supported a variety of risk assessment experiments. What are the results of your risk assessment studies of the recombinant DNA research techniques?

Answer: Special experiments have been conducted to assess the potential risks associated with recombinant DNA research. These experiments were designed to determine the probability of the occurrence of such events as the escape of an organism containing recombinant DNA into the environment, the likelihood of its survival and the possibility of a change in its natural biology so that it becomes a danger to some higher organism.

The NIH Risk Assessment Plan requires that an annual update be prepared and the first proposed report has been published in the Federal Register, Vol. 45, No. 182, 61874 (attached). A lengthy discussion of all past results and future plans is contained in that document. In summary, no risks of recombinant DNA research have been identified that are not inherent in the microbiological and biochemical methodology used in such research because recombinant DNA technology does not endow the laboratory research system with new hazardous properties not present in the starting materials. Therefore, it is now widely accepted that research performed in accordance with the NIH Guidelines for Recombinant DNA Research poses no threat to the investigator, the community or the environment.

Question: How do you cooperate with other Institutes in this regard?

Answer: Responsibility for coordination and implementation of the risk assessment plan was assigned by the Director, NIH, to the Director, National Institute of Allergy and Infectious Diseases (NIAID). The Office of Recombinant DNA Activities (ORDA), located in NIAID, interacts with designated representatives of other NIH Institutes to coordinate current NIH policies and procedures for the conduct of recombinant DNA research. Cooperation among different Federal agencies is achieved through the Federal Interagency Advisory Committee and through direct contact by ORDA staff with Federal agencies involved in the support of recombinant DNA research.

FOOD ALLERGY

Question: Avoidance is reported to be the preferable approach to managing food allergies, rather than using desensitizing techniques. To what extent can an individual's sensitivity to certain foods change over time?

Answer: Young children, who appear to experience many more allergic or adverse reactions to foods than adults, usually outgrow their reactivity by the time they are five to six years old. Among adults who experience such reactions, persistence of symptoms tends to be the rule. Some individuals face the lifelong hazard of severe,

even life-threatening, reactions.

Question: How many people are affected by food allergies?

Answer: Without the availability of precise diagnostic tests and procedures, it is impossible to state, at present, how many people are affected by food allergies. However, it is estimated that 1-4 percent of children under age five suffer from food allergy, with lessening incidence noted with advancing age.

IMMUNOLOGIC INFERTILITY

Question: Dr. Gilbert G. Haas, Jr., and his associates at the University of Pennsylvania have developed a test to identify those men and women who are infertile because they produce antibodies to sperm. Have there been further breakthroughs in the area of immunologic infertility since the September 1980 report of an antibody test being developed to aid infertile couples?

Answer: The test developed by Dr. Haas and his associates appears to be more accurate than tests used previously for the detection of anti-sperm antibodies. To our knowledge, no further information has been reported since their publication. We are aware, however, that several groups are now examining the usefulness of Dr. Haas' test in their patient populations.

INTERFERON RESEARCH

Question: What is the status of your research on interferon?

Answer: NIAID supports investigator-initiated research grants for basic research on interferon. Most of these grants deal with mode of action, immune modulatory effects, and properties of the various interferons. Also supported are a wide variety of contract activities ranging from clinical trials of interferon in several types of virus infections, to studies of its effects on the immune system, to projects providing reagents and the support of basic research. The NIAID supported clinical trials that demonstrated the efficacy of interferon against herpes zoster (shingles). Interferon has also been given to patients undergoing trigeminal nerve resection for the painful "tic douloureux syndrome" and it was found to prevent reactivation of latent herpes simplex, a frequent complication. As we learn more about treatment of cancer patients, transplant patients, and others who need to be put on immunosuppressive drugs (which reduces their natural resistance), viral infections become an increasingly important problem. Therefore, the role of interferon against viral infections such as chickenpox and cytomegalovirus is currently being investigated. Its role in chronic active hepatitis is also being evaluated.

Question: Have there been any promising results in clinical trials in the past year?

Answer: Interferon does indeed seem to have a role in the control of orofacial herpes (Pittsburgh study), zoster or shingles (Stanford) and perhaps in the treatment of chronic active hepatitis B in conjunction with adenine arabinoside (Stanford). A double-blind, placebo-controlled trial is being planned to determine efficacy against chronic hepatitis; a study is currently under way with primary genital herpes. Reports from several countries in the past

year noted encouraging results in the treatment of laryngeal papilloma and other wart-like growths; depending on availability of funds, a study to demonstrate efficacy in this area will be undertaken.

Question: To what extent are you cooperating with the National Cancer Institute in this research?

Answer: In FY 1980 NCI provided $1.145 million to the NIAID to support some contracts of mutual interest (related to interferon) as part of a collaborative effort on this subject between the two Institutes. We have proposed additional projects for a similar collaborative effort in FY 1981 that are under consideration by NCI. In particular, the cooperation between NIAID and the NCI with respect to the purchase of interferons for clinical trials and with respect to the acquisition of interferon standards (standard preparations of interferon to allow for comparison between laboratories) has been excellent. Continued coordination of efforts between the Institutes is anticipated in FY 1982 to avoid a duplication of effort and to insure the careful, coordinated use of resources supporting interferon research in clinical trials.

The NIAID and NCI will continue their collaboration through exchange of information and resources wherever possible. In addition, this Institute is responsible for an informal interagency information exchange committee to assure that all involved organizations have the opportunity to keep abreast of each other's activities and to jointly plan new activities.

Question: How effective is interferon in the treatment of cancers?

Answer: This is best answered by the National Cancer Institute which is currently investigating this question. From the worldwide publications to date, it appears that interferon will have a positive role in the treatment of cancer, but is by no means a cure for many forms of the disease. It will probably be most effective in conjunction with other treatment modalities in selected cancers.

SEXUALLY TRANSMITTED DISEASES

Question: Gonorrhea has been classified as a national epidemic, with an estimated 2.5 million new cases occurring annually in the U.S. Other sexually transmitted diseases are also appearing more frequently. What progress has been made in treatment of such diseases and prevention of their spread?

Answer: In March 1976, penicillin-resistant strains of gonococci were identified in this country. Fortunately, this new type of gonorrhea has not spread rapidly and it is treatable with other antibiotics such as spectinomycin and tetracycline. However, the appearance of these strains made clear to everyone that drug treatment of gonorrhea is not the ultimate answer to its control. The search for gonococcal vaccine has accelerated and the prospects appear promising. Vaccines are now being tested that inhibit attachment of gonococci to human cells and that stimulate antibodies that kill the bacteria.

Chlamydial infections respond well to antibiotics, but there is a need for simple and inexpensive diagnostic tests. Recent progress

in developing ways to study these infections in animal models will facilitate future research and development of these tests. Other studies have shown the feasibility of treating pregnant women who have chlamydial infections in order to protect their newborn infants. Treatment of the newborn's eyes with erythromycin ointment has prevented chlamydial conjunctivitis. This study lays the groundwork for possible changes in neonatal prophylaxis that will protect infants from both chlamydial and gonococcal infections of the eye.

Several antiviral drugs are being evaluated for their effectiveness against herpes simplex virus, the cause of genital herpes. One of the most promising drugs is acyclovir. The recurrent aspect of herpes infections complicates the search for effective treatments and preventive measures. A scientist recently reported that recurrent lesions are due to a defect in the regulation of virus-specific cell-mediated immunity. The lesions recur in those individuals who suffer from a defect that prevents their immune memory from initiating rapid responses capable of curtailing virus growth and cell-to-cell spread. Perhaps vaccines can be designed to modulate the regulatory aspects of the immune reaction in such a way as to protect from reinfection.

Question: Which of those diseases are presenting the greatest problem at this time?

Answer: Genital herpes, caused by the herpes simplex virus (HSV), is one of the most serious sexually transmitted diseases. It is estimated that 300,000 to 500,000 new cases occur each year in this country. Since most patients with genital herpes have recurrences, some authorities estimate that between five and ten million episodes of genital herpes occur yearly. This infection also has serious implications for pregnant women and their unborn and newborn babies. The first occurrence of the disease early in pregnancy can result in spontaneous abortion. If the infection occurs later in pregnancy and virus is present in the birth canal during delivery, the baby may develop disseminated HSV infection which is frequently a fatal or crippling disease. It is entirely possible that some mothers of infected babies may show no obvious symptoms of genital herpes; that is, they may have at the time of delivery a subclinical or inapparent infection.

Another major health problem is caused by chlamydial infections. Out of an estimated one million cases of nongonococcal urethritis (NGU) each year in the U.S., 30 to 50 percent are caused by chlamydia. This organism is also an important cause of postgonococcal urethritis, epididymitis, and prostatitis in men. In women, chlamydial infections cause inflammation of the fallopian tubes, the cervix, and the uterus. In newborns, it is the most common cause of conjunctivitis and of pneumonia, affecting more than 100,000 babies each year.

HERPES SIMPLEX

Question: How serious is the problem of herpes simplex type 2 in the U.S. today?

Answer: Genital herpes, which is caused primarily by herpes simplex virus (HSV) type 1 or type 2, is a very serious problem today. It is estimated that 300,000 to 500,000 new cases occur each year in this country. Since most patients with genital herpes have

recurrences, some authorities estimate that between five and ten million episodes of genital herpes occur yearly. The morbidity of the acute illness, its frequent recurrence rate, its occasional complications such as meningitis, its devastating effect on the newborn, and its epidemiologic association with cervical carcinoma have made this disease a major public health problem.

Question: What are the medical consequences?

Answer: Painful, prolonged ulcerations associated with fever, burning, and swelling of the genitalia occur during the first episode of infection. The sores may last about three weeks before healing, but then may recur at monthly intervals. Added to this physical burden is the concern that years later the infected mother will carry an increased risk of delivering a premature or stillborn infant or that the virus will be transmitted to the infant during birth, with potential death or neurologic damage to the child. In addition, the risk of the mother developing cervical cancer may be increased. The psychologic-sexual disruption that accompanies this infection often causes strained relationships, severe depression, broken marriages, and lifelong alterations in social and sexual behavior.

Question: What is the association with higher risk of cervical cancer for women with herpes?

Answer: Several studies have shown that antibodies against HSV are more common in patients with cervical cancer than in women without cancer. A recent study has shown that some cervical carcinoma tissue contains HSV genetic material and protein. These studies show only an association and not any cause-and-effect between HSV and cancer. Much research is now under way to try to answer this question definitively.

Question: Without a cure or treatment, how much worse will the situation get in the next few years?

Answer: Several factors are expected to increase the magnitude of the entire STD problem in the next few years. The projected composition of the U.S. population indicates that the number of young adults in the 18- to 29-year age group, which experiences the highest rates of STD's, will continue to increase until the middle of the 1980's. An increasing proportion of teenagers and young adults are having premarital sex with multiple partners, thereby increasing their risk of contracting STD. The chronic, recurrent nature of genital herpes indicates that the prevalence of this disease, in particular, is likely to increase tremendously.

Question: What are the research needs to help people live with the disease and prevent its transmission until a treatment is found?

Answer: Viral latency is still a mystery; still unknown is what happens to the virus between obvious episodes of the disease, and how many people shed the virus without being aware of any sores. Several questions concerning the impact of genital herpes on the newborn also must be answered. Scientists need a better understanding of how and why the infection persists and the factors involved in reactivation. They are testing experimental drugs that are effective in stopping active infections, but the infection does recur. There is a need to identify the role of the immune system in recurrent infections. Investigators are also concerned about drug resistance developing after recurrent infections are treated.

ENTERING A NEW ERA

Question: In your FY 82 justifications, you make two rather startling statements. You say that "mastery of the immune system...is at hand." You also say that "we are entering a new era." This all sounds like the coming of a "Golden Age of Medicine." Please explain.

Answer: Although earlier research has curbed the major epidemic diseases, many common infections caused by viruses and parasites as well as many chronic diseases have resisted attack. And hazards once controlled have reemerged with the changing fortunes of evolution.

These formidable problems, but new applications of research developments, which have emerged in the past 20 years on the physiology of the immune system and the molecular biology of microbes are opening new strategies for treatment and prevention.

Clinical immunologists are applying our increasing knowledge of the immune system to regulate, in novel ways, the destructive processes in patients with diseases such as lupus erythematosus and asthma.

The programming of bacteria to produce medically useful substances using recombinant DNA technology is creating unanticipated opportunities to improve old vaccines and develop new ones as well as to manufacture other substances such as hormones and the antiviral agent interferon.

Using hybridoma cell fusion techniques it is possible to produce in the laboratory, at will and in a predictable fashion, antibodies with exquisite purity and of the highest quality. Never before has this been possible. These products will facilitate the development of vaccines, enhance immunotherapy of infections and malignant diseases, improve diagnostic tests, and serve as new probes to examine the innermost secrets of living processes.

The use of hybridoma cell fusion in conjunction with recombinant DNA technology will have an extremely powerful, potentiating effect on the pace of biomedical research. Together, the two technologies will multiply the pace of research rather than double the effort. Already they are being used in branches of medicine as diverse as rheumatology, cardiology, oncology, endocrinology, neurology as well as specialities concerned with infectious and genetic diseases.

For these reasons I have said we are entering a new era, a new "golden age of medicine" that will equal or surpass the last century of achievements.

Question: In the face of this statement of hope, you propose to cut back on your new research by reducing new and competing research grants from 268 to 250. Why?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

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IMMUNOLOGIC DISEASES

Question: In 1978, the Institute established four centers to accelerate clinical application of new knowledge on the immune system. What type of research areas are under investigation at the Centers for Interdisciplinary Research on Immunologic Diseases?

Answer: A variety of efforts are now under way. Studies in asthma range from approaches to teach asthmatic children how to manage their illness to studies of why children who experience respiratory syncytial virus infections subsequently develop asthma. Representative studies of hypersensitive reactions include approaches to improve methods for evaluating patients having adverse reactions to therapeutic drugs and, for example, methods for oral desensitization of patients who are allergic to penicillin. Other studies are designed to develop the capability for early diagnosis of serious fungal infections in immunologically compromised patients and to develop a safe bacterial vaccine against Haemophilus influenzae, a common and potentially serious infection of infants.

Question: Have you been recruiting and training clinical investigators for these centers? Where do you stand on this?

Answer: We strongly believe that the centers provide an excellent training environment. However, the center awards are limited to support of research; and support for training on a formal basis is prohibited by the conditions of the award. Nevertheless, the senior staff investigators at the four currently funded centers informally provide guidance and training for their younger clinical and laboratory associates during the course of the research studies. Support for these individuals generally is provided by some type of training grant or fellowship award from this Institute or others under the provisions of the National Research Service Awards Act. Our position has been, and will remain, one of encouraging the senior investigators at these centers to continue their informal efforts and to develop formal training programs.

ALLERGY AND ASTHMA

Question: What progress has been made during the past year in research on asthma and allergic diseases?

Answer: The chemical structures of several substances (called mediators) that cause inflammation and allergic reactions in man have been clarified. This new information is expected to permit the rapid development of drugs that will offset these reactions. Similarly, progress in identifying substances in serum that will either increase or diminish allergic reactions should permit development of new ways to treat allergies on a general, broad scale, as opposed to treatment for a specific allergen thought to be causing a reaction.

Question: Have the Asthma and Allergic Disease Centers provided any new insights into the cause, treatment, or prevention of these conditions?

Answer: Studies on the role of bronchoprovocation tests to diagnose asthma have been extended to include family members of asthmatic persons. Results show that these tests can be used to predict which family members will contract asthma within the next 3 to 5 years. It is hoped that detection and prevention programs can

then be developed. The cause of asthma in some children appears to be related to prior infection with respiratory syncytial virus. When this finding has been fully confirmed, a vaccine could be developed that may prevent asthma in such children.

In addition, significant progress has been made in both the diagnosis and treatment of allergic reactions to penicillin. Both skin tests and certain laboratory tests can identify penicillin allergy with a high degree of accuracy, and treatment regimens have been developed that permit rapid oral desensitization so that this life-saving drug can be used if needed.

Question: Can an individual "outgrow" allergies?

Answer: Usually, after the ability to react to a particular allergen has developed, it remains for life. This is especially the case in adults and where airborne inhalant allergens are concerned. However, tolerance may occur to some extent with time. In as many as 10 percent of cases, acute allergic reactions may disappear, with no allergic reactions of consequence resulting on future exposure.

Question: Is there a genetic predisposition to certain allergies?

Answer: Some investigators believe that there appears to be a genetic predisposition to hay fever as well as a familial--and therefore probably genetic--tendency to develop asthma. Certain types of skin allergies are believed also to be influenced by genetic factors.

INTERNATIONAL BIOMEDICAL RESEARCH

Question: The Institute's International Biomedical Research Program conducts research and scientific training on infectious diseases important to the health of the world's developing countries. The ultimate goal is improved technology for preventing, diagnosing and treating these diseases. In what areas of research are you cooperating with other countries?

Answer: NIAID conducts international research "to advance the status of the health sciences in the United States and thereby the health of the American people through cooperative endeavors with other countries in health research, and research training." This collaboration is carried out by intramural NIAID staff, awards to U.S. universities to conduct research overseas, and exchange research fellowships or direct grants to foreign scientists. Bilateral science and technology agreements between the U.S. and host governments frequently provide a formal basis for collaborative activities in tropical medicine, microbiology and immunology.

During FY 1980 NIAID launched a new program of awards for U.S. scientists for International Collaboration in Infectious Disease Research (ICIDR) in developing countries. These awards were made to universities to work in parasitic diseases or leprosy with counterparts in seven developing countries (Brazil, Colombia, India, Mexico, Nigeria, Sudan, and Thailand).

At the present time NIAID intramural scientists are involved in collaborative work in West Africa on the mechanisms of immunity to malaria, in India on the pathogenesis of tropical pulmonary

eosinophilia, and in Brazil and Argentina on the reasons why certain patients develop chronic heart and intestinal disease following infection with American trypanosomiasis (Chagas' Disease) while others do not. Current efforts are directed towards epidemiological studies of non-A, non-B hepatitis in India and field trials of hepatitis B vaccine in the Peoples Republic of China to prevent transmission of hepatitis B from the mother to the newborn. NIAID scientists have carried out a collabaorative project involving more than 20 countries to isolate viral agents which produce diarrhea.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

MAINTAINING NEW RESEARCH GRANTS

Question: The fiscal 1982 budget continues to emphasize the stabilization of new, investigator-initiated research grants for NIH at 5,000. How much funding will you need in fiscal 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan, provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NIAID share of that amount is $44,804,000 and 414 grants.

Question: How is inflation impacting -- or how will it impact -- on this goal? What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new research grants regardless of other budget priorities within NIH?

Answer: "Stabilization" is important both to the government and to the scientists. For the government it means that a reasonable number of research projects deemed by peers to be of high scientific merit and relevance can be funded. This is the likely source of the new knowledge and technology we need to solve health problems that are now approachable with, at best, what has been termed halfway technology. For the scientist it means that he knows there is a reasonable chance of getting research ideas funded and encourages him to stay in research rather than earn a living elsewhere.

Question: What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: This has to be regarded as a hypothetical question since funds have never permitted payment of more than about 40 percent of approved applications; in most years paying a third or fewer. If a drop in the number of applications gaining approval made it possible to fund more than half, the Institute would seek reprogramming authority to divert funds to research contracts. While an individual application judged to be of intermediate merit (priority score 230-270) might be funded because of program relevance, the funding of research contracts, career development

awards, and training would take precedence. Progress in new vaccines and antiviral drugs depends on research contracts.

Question: To what "payline" will you fund new and competing grants in fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: In FY 1981 and 1982 under the revised budget request we would fund competing research projects to a payline of about 180 and 170, respectively. The revised budget would permit funding of approximately 31 percent of eligible competing research projects in FY 1981 and 25 percent in FY 1982.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

ENTERING A NEW ERA

Question: In the face of this statement of hope, you propose to cut back on your new research by reducing new and competing research grants from 268 to 250. Why?

Answer: The figures cited represent only the numbers of competing renewal grants requested in the 1982 revised budget request. The total number of competing grants (new, competing renewal and supplemental) requested in the 1982 revised budget decreases from 430 in FY 1981 to 414 in FY 1982.

It should be noted that the Institute is requesting an increase in funding for competing grants but tempered the amount in order to maintain program balance between its several funding mechanisms. Rapidly increasing costs in grantee institutions, particularly indirect costs such as fuel or plastic laboratory ware derived from petrochemicals, suggests that the dollar increase we have requested will pay fewer grants. Despite this decrease, we expect the number of grants related to the new thrusts in research that I have mentioned to increase since applications in these areas have the highest priority.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF DR. RUTH L. KIRSCHSTEIN, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDERICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. LEO H. VON EULER, DEPUTY DIRECTOR
WILLIAM T. FITZSIMMONS, EXECUTIVE OFFICER
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator ANDREWS. Our next witness is Dr. Ruth Kirschstein, Director of the National Institute of General Medical Sciences. NIGMS is the basic research institute of the National Institutes of Health, and the mission of the Institute is not to study a specific disease or groups of diseases, but rather to develop new knowledge of the human body and how it works. NIGMS focuses on the cell and chromosomes and genes.

I am intrigued with this. Back in my previous reincarnation on the House Appropriations Committee, we were proud that we directed a good deal of research through the Department of Agriculture in human nutrition labs. We found that we knew far more about pig nutrition than we did about people nutrition in this country. Tragically, I think that is still true, but in discovering more in basic human nutrition, we're finding out how to address a whole host of problems, and I'm sure in the work that you're doing, you are finding out how to address a host of problems, and we certainly welcome you here.

And again, in the interest of time, we would appreciate it if you would briefly highlight your opening statement which will appear in full in the record and in the meantime introduce your associates and proceed with your statement.

[The statement follows:]

STATEMENT OF DR. RUTH L. KIRSCHSTEIN

Many years ago, Louis Pasteur observed that "the secrets of the infinite will be found in the infinitely small."

In the past few years, the virtual explosion of knowledge about the hereditary material contained within the cell has made it plain that Pasteur was right in more ways than he knew. If anything is certain in our time, it is that many of the most exciting advances in our knowledge about human life will flow from basic studies about the "infinitely small": the human cell, its internal structures, and the molecular and genetic materials that direct and control fundamental life processes.

The research and research training programs of the National Institute of General Medical Sciences (NIGMS) support studies in the sciences basic to medicine, which are fundamental to the activities of the other Institutes.

The major share of research supported by NIGMS comprises studies of cell structure and function and of basic genetics that seek clearer insights into the molecular mechanisms of human inheritance in health and disease. Other areas of research inquiry are closely related--for example, studies of the effects of drugs within the body, focusing on events at the cellular and molecular levels; studies of intricate responses of many body systems to severe burns and trauma; and development of new, increasingly sophisticated technology to advance this work.

Though the research supported by NIGMS is not targeted toward a specific disease or category of diseases, it provides the fundamental understanding of body processes that is the sine qua non for a truly effective attack on the broad range of illnesses which afflict mankind.

Often, these basic studies find their way quickly and dramatically to clinical application. For example, just a few years ago, experiments involving the insertion of foreign genetic material into loops of bacterial DNA, or plasmids, fascinated molecular biologists--and few others. Who would have guessed that, by 1981, the development of recombinant DNA technology would make possible the manufacture, in bacteria, of large quantities of important biological substances needed for biomedical research, such as human insulin, growth hormone, and interferon--or that this technology could be used, as is now being done, for prenatal diagnosis of certain genetic disorders.

This year, again, as in all previous six years that I have appeared before you, I am pleased to report that NIGMS grantees have been the recipients of national and international recognition for their research achievements. Drs. Paul Berg, of Stanford University, and Walter Gilbert, of Harvard, were co-winners of the 1980 Nobel Prize in Chemistry; and Dr. Berg and three other grantees-Drs. Stanley Cohen, A. Dale Kaiser, and Herbert Boyer--won the prestigious Lasker Award for Basic Research, all for studies involving recombinant DNA technology.

Genetics

The use of recombinant DNA technology has permitted rapid and far-reaching progress in our basic understanding of the genetic makeup of a wide variety of organisms from bacteria to man. It has recently been shown that the pneumococcus bacterium that causes lobar pneumonia has become resistant to penicillin, formerly the antibiotic of choice in treating this disease. However, Dr. Walter Guild, an NIGMS grantee at Duke University, has shown that the type of resistance of these bacteria is clearly different from that of others. Antibiotic resistance in this particular organism can be transferred when the chromosome of one resistant bacterial cell passes into an adjacent bacterium. As far as is now known, the transfer of such antibiotic resistance by this process--known as "conjugation"--is unique for the pneumococcus, since, in other bacteria, antibiotic resistance is transferred by bacterial plasmids, which are free within the cell and which, up to now, have always been found separate from the bacterial chromosome. Dr. Guild has shown that the antibiotic-resistant genes of the pneumococcus are present as large chromosomal insertions of extra DNA, as though the plasmids had become part of the bacterial chromosome. Thus, this new discovery uses the most advanced techniques of molecular biology to explore the important and growing clinical problem of resistance to antibiotics.

Cellular and Molecular Basis of Disease

Studies supported by the Cellular and Molecular Basis of Disease Program are designed to elucidate the normal and abnormal structure and function of the fundamental unit of the body, the cell--a "small universe" that has turned out to be immeasurably more complicated than had been anticipated. Researchers are just beginning, in fact, to nibble at the edges of this complexity. They have found, for example, that the membrane which covers a cell is a dynamic structure through which essential chemicals enter and leave the cell. As seen by high-powered electron microscopy, this membrane has depressions lined internally by a specific protein. These so-called "coated pits" are the locations of the membrane receptors which permit the uptake into cells of such important substances as low-density lipoproteins (which play a role in coronary artery disease) and epidermal growth factor (which is essential for growth of many of the body's cells to form tissues and organs). Detailed chemical studies regarding these membrane receptors may seem far removed from clinical interests but hold the key to an understanding of many serious health problems, such as heart disease, diabetes, and arthritis.

Burn and Trauma Research

Studies at the cellular level are still needed to enable us to understand the body's response to trauma and burn injury. In order to consolidate the knowledge that is available and to assure that physicians are using the most up-to-date methods of caring for burn patients, in November, 1980, NIGMS held a two-day follow-up conference to the Consensus Development meeting held two years ago, and about which we reported to this Committee in the past. Several recommendations from the previous meeting were modified, based on new research developments. Most important, however, was the report of the results of a survey among physicians caring for burn patients which indicated that the widely disseminated recommendations of the first meeting are now well known and have had a real impact on the care of such patients throughout the nation.

Pharmacological Sciences

As part of the care of severely burned patients, skin grafting is essential. If the grafted skin is from another donor, the patient's immune system must be suppressed to allow the graft to "take." A grantee of the Institute's Pharmacological Sciences Program is studying the correlation between the action of certain immunosuppressive drugs and their rate of metabolic breakdown. Dr. Leslie Benet, of the University of California, has shown that the immunosuppressive activity of these drugs can be better correlated with the amount of drug circulating free in the blood than with the level of drug bound to blood proteins. These findings will enable burn surgeons, as well as those doing kidney transplants, to more accurately calculate the dosage needed to provide immunosuppression and yet avoid the severe secondary infections that sometimes result.

Shared Instrumentation

Behind these remarkable new insights lie not only brilliant and creative minds, but also the availability of new, highly sophisticated instrumentation that now makes possible a wide variety of technical procedures, ranging from visualization of large molecules to physical and chemical analyses of minute particles. Modern instruments of these kinds are, not surprisingly, extremely expensive and often beyond the provisions of the normal budgets of research project grants. In order to provide as wide an availability as possible of this new instrumentation, NIGMS is offering a shared instrumentation program. Under this program three or more NIH grantees (at least two of whom must be grantees of NIGMS) may apply for funds to purchase a major piece of equipment on the basis of a plan for sharing it not only among themselves, but also, on a limited basis, with younger investigators who may not be fully acquainted with the potential uses of the instrument.

Research Training

To maintain the momentum of such research advances, a continuing supply of well-trained basic biomedical scientists is vital. To ensure that these highly qualified investigators will continue to be available, NIGMS provides research training through institutional awards and individual fellowships.

Minority Access to Research Careers

The Minority Access to Research Careers (MARC) Program is a unique research training program designed to increase the number of minority scientists in biomedical research. Encouraged by this Committee's interest in the MARC Program, NIGMS has just established a new predoctoral individual fellowship for graduates of the MARC Honors Undergraduate Program. Its purpose is to assure support for the very best students to attend the finest biomedical graduate programs in the country. It is anticipated that several such awards will be made this year.

Mr. Chairman, I shall be pleased to try to answer any questions and supply any additional information desired.

CURRICULUM VITAE

RUTH L. KIRSCHSTEIN, M.D.

POSITION: Director, National Institute of General Medical Sciences

BIRTHPLACE and DATE: Brooklyn, New York
October 12, 1926

EDUCATION:
A.B., magna cum laude, Long Island University, 1947
M.D., Tulane University School of Medicine, 1951

EXPERIENCE:
Director, National Institute of General Medical Sciences, September 1974-present
Deputy Associate Commissioner for Science, FDA, 1973-1974
Acting Deputy Director, Bureau of Biologics, FDA, 1972-1973
Assistant Director, Division of Biologics Standards, NIH, 1971-1972
Chief, Laboratory of Pathology, DBS, NIH, 1965-1972
Acting Chief, Laboratory of Pathology, DBS, NIH, 1964-1965
Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH, 1962-1964
Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH, 1960-1962
Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH, 1957-1960
Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH, 1956-1957
Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine, 1954-1955
Resident, Pathology, Providence Hospital, Detroit, Mich., 1952-1954
Assistant Resident, Pathology, Veterans Administration Hospital, Chamblee, Ga., 1952
Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y., 1951-1952

ASSOCIATION MEMBERSHIPS:
American Association of Immunologists
American Association of Pathologists
American Society of Microbiology

SPECIAL AWARDS or CITATIONS:
DHEW Superior Service Award, 1971
PHS Superior Service Award, 1978
Presidential Meritorious Executive Award, 1980

COMMITTEE MEMBERSHIPS:
Invited member of World Health Organization Expert Group on International Requirements for Biological Substances, Geneva, Switzerland, 1965 and 1971

COMMITTEE MEMBERSHIPS: (continued)

Invited consultant to World Health Organization concerning problems related to the use of Poliovirus Vaccine, Live, Oral. Geneva, Switzerland, 1967
Member, Board of Consultants, Journal of Medical Pathology
Member, Primate Research Centers Advisory Committee, Division of Research Resources, NIH, 1971-1975
Member, National Commission on Diabetes, 1975
Member, National Commission on Arthritis and Related Musculoskeletal Diseases, 1975
Member, Ad Hoc Committee on Reserpine and Breast Cancer, 1974-1977
Chairperson, NIH Grants Peer Review Study Team, 1975-1976
Member, Editorial Board, Journal of Toxicology and Environmental Health
Member, Scholars-in-Residence Advisory Committee, 1977-present
Member, NIH Coordinating Committee on Manpower, 1978-present

BASIC RESEARCH

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman. To my left is Mr. William Fitzsimmons, the Executive Officer of the Institute, and to his left Dr. Leo von Euler, who is the Deputy Director of the Institute.

The National Institute of General Medical Sciences has a unique place within the constellation of Institutes that comprise NIH as demonstrated in this chart. It is the role of NIGMS to support studies in biomedical sciences which are basic to and form the underpinnings of the activities of all the other—the categorical institutes.

To accomplish the objectives of NIH requires, among other things, support of fundamental untargeted investigations that generate knowledge and new concepts which, while not immediately relevant to any particular disease, will ultimately have importance to any number of human disorders. Such concepts form the foundation for subsequent research strategies developed at more disease-oriented levels.

The major share, about 70 percent, of the research supported by NIGMS comprises studies of cell structure and function and of basic genetics, studies that seek clearer insights into the molecular mechanisms that maintain human health, mechanisms which, if they go awry, can cause disease.

RECOMBINANT DNA TECHNOLOGY

Sometimes the results of these basic studies find their way very quickly and very dramatically into practical application, and the best recent example of such a success story is that of the recombinant DNA technology. Fundamental research in molecular genetics and biochemistry in the 1970's has provided the basis for, and led directly to, the development of this technology, and the vast part of such research was—and still is—supported by NIGMS. Indeed, it was for such undifferentiated studies in genetics and biochemistry of simple organisms that Drs. Paul Berg of Stanford University and Walter Gilbert of Harvard, both long-time NIGMS grantees, were named corecipients of

the 1980 Nobel Prize in chemistry. And Dr. Berg and three other NIGMS grantees—Drs. Herbert Boyer, Stanley Cohen, and A. Dale Kaiser—also this year won the prestigious Lasker Award for basic research.

Parenthetically, I might say that our Institute, NIGMS, has supported 42 Nobel laureates, and again this year, as for the past 6 years that I've presented before this committee, we have had Nobel laureates.

Now, scientists in this country have very quickly seen the potential of the recombinant DNA technology, and small companies, as well as large drug manufacturers, are attempting to exploit this, as I noted on the chart, for the production of rare and expensive therapeutic agents including insulin, growth hormone, and interferon, which was mentioned by Dr. KRAUSE. Just last week, the first clinical trials of synthetic insulin manufactured by use of this technology were begun, and clinical trials of interferon so produced are currently in progress.

Senator ANDREWS. Don't use the word "exploit"; use "utilize." It sounds a lot better. Otherwise, it sounds like there is some unholy alliance between those of you who discover these new breakthroughs and those who are able to pass it on to the public.

Dr. KIRSCHSTEIN. You are correct, sir. In order, though, to take full advantage of this enormous thrust made by the recombinant DNA technology, we must also continue to expand our knowledge concerning the fundamental unit of the body, the cell, a small universe which has turned out to be much more complicated than we had anticipated.

For example, the effectiveness of this new synthetic insulin is dependent on the ability of it to interact at the targeted cell. NIGMS grantees are actively studying membrane receptors which are the special areas on the cell surface which allow such interaction to take place. The detailed chemical studies of such membrane receptors hold the key to an understanding of many serious health problems such as heart disease, diabetes, and arthritis.

Now usually it is the nature of this untargeted research, supported by NIGMS, to gradually evolve and become specifically focused on categorical problems, and when this occurs, the support is transferred to the more appropriate categorical Institute. Thus the NIGMS programs feed those of the other Institutes and function like a breeder of scientific concepts.

ROLE OF HEREDITY IN HYPERTENSION

A number of examples of this come to mind. I will give you only one. Scientists at Harvard University, supported by NIGMS, have been investigating the movement of essential, but very simple chemicals across the membrane into and out of the cell. In the course of this work, they have found that the rate of transport of certain chemicals such as sodium or salt and a related element, lithium, correlates with whether or not the person whose cells are being studied has that common and very serious disease known as essential hypertension or high blood pressure of unknown cause. Upon further investigation, it was found that not only is the rate of transport increased twofold through the cells of persons with this disease, but also through cells from their close relatives, whereas transport across the membrane of cells from normal individuals is twofold lower.

The usefulness of these findings to elucidate the role of heredity in the development of essential hypertension and also as a diagnostic tool prior to the onset of the high blood pressure has been recognized by the National Heart, Lung, and Blood Institute, which is currently providing support for these investigators to continue their studies. This is but one of a number of such examples of how basic concepts developed through research funded by NIGMS can lead to information relevant to disease.

SHARED INSTRUMENTATION

But in order to maintain the momentum of these remarkable achievements, there is need for highly skilled, creative scientists and for the availability of highly sophisticated, expensive, modern instrumentation to replace equipment which is now obsolete.

To provide these essentials, NIGMS has established a research training program, including the provision of support for medical scientist training, as well as a shared instrumentation initiative. In the shared instrumentation initiative, three or more grantees may apply for funds to purchase a major piece of equipment on the basis of a plan for optimizing its use and for sharing it, not only among themselves but also with young beginning investigators who are the future scientific leaders of this country.

I hope I have shown you that basic undifferentiated research is absolutely essential to provide a foundation for much of the successful clinically oriented research. Our experience abundantly indicates that the basic research NIGMS supports now will form the backbone of future medical progress.

I would be pleased to answer questions, sir.

NEW AND COMPETING RESEARCH GRANTS

Senator ANDREWS. I appreciate your statement, Doctor. I noted with interest that you are a graduate of Tulane. My nephew is now at the Tulane Medical School. I'm surrounded by medical students in the rest of my family.

I assume that you are getting the same amount of the program that other areas in NIH are getting. In other words, the funding that you now have in the budget is sufficient to maintain your share of NIH's goal of 5000 new and competing research grants.

Dr. KIRSCHSTEIN. Yes, sir. Mr. Chairman. In President Carter's 1982 budget presentation, our share of the 5,000 competing grants is 838 grants, or 16 percent, for a total amount of $89 million.

Senator ANDREWS. Does that maintain your level?

Dr. KIRSCHSTEIN. Yes, it does.

RESEARCH TRAINING AWARDS

Senator ANDREWS. Then how do we tie that in with the fact that your budget request for fiscal year 1982 proposes better than a 200-percent increase in new and competing training awards? You would go, as I understand it, from 58 to 198, or is this some other category?

Dr. KIRSCHSTEIN. No, sir; the budget of the National Institute of General Medical Sciences, like that of all other Institutes, is divided

into two portions—a portion to support research through the award of research grants, and a portion to support research training. The National Institute of General Medical Sciences, besides supporting basic fundamental research, is also, in a sense, the research training institute for NIH. One-third of all the research training that is done by all of the Institutes at NIH is supported by the National Institute of General Medical Sciences.

Senator ANDREWS. You are the farm club, then, supplying the heavy hitters for the other Institutes?

Dr. KIRSCHSTEIN. That is correct.

Senator ANDREWS. Why, then, again, the increase? Are we bringing on board more researchers for the future, even though the level of research seems to be maintained, as we developed earlier on in questions about the same level?

Dr. KIRSCHSTEIN. No, sir; the number of awards that you are looking at are for new individual fellowships. These are for training individuals who have received either the M.D. degree or the Ph. D. degree for a postdoctoral period which usually lasts from 1 to 3 years. These are nonrenewable. And at the end of that period of time, there would be a——

Senator ANDREWS. That is totally correct, but my question goes back to why the increase? You're the farm team supplying these researchers. We developed earlier on that these researchers are extremely important because it doesn't do much good to throw dollars into cancer research or stroke research or whatever else if you don't have the researchers to do the job.

We have also maintained, in the portion of the hearings that I've been privileged to chair, the concept that the budget allows us to proceed at about the same level in terms of man- and woman-hours of research that we have had in the past. Yet in yours, we run into this 200-percent increase in training the researchers. And I just kind of want to get back to why.

Dr. KIRSCHSTEIN. It is not a 200-percent increase in total numbers of trainees. The overall number of trainees for NIGMS is decreasing by approximately 60, and for NIH as a whole is also decreasing.

Senator ANDREWS. Well, the figures that I have is that these awards go from 58 to 198.

Dr. KIRSCHSTEIN. Those are the number of individual fellowships; that is correct.

Senator ANDREWS. That's right. And the number of individual fellowships is what gives you the pool of researchers for the future. So how come quadrupling almost—certainly tripling——

Dr. KIRSCHSTEIN. In 1980, we supported 182 individual fellowships. The budget constraints for 1981 allow us only to have 58 fellows, and this increases to 198, therefore, would provide the return of stability to the 1980 figures.

Senator ANDREWS. In other words, you had a shortfall that you are trying to recoup?

Dr. KIRSCHSTEIN. Exactly.

Senator ANDREWS. Well, I remember years ago, a fellow by the name of John Rooney, who was my first committee chairman, funded the State Department, and he was a delightful guy. He was a former district attorney, and he said, "Mark, as long as you're on my committee, just remember one thing. Know the answer before you ask the question, and be sure that you know what you're trying to develop."

And what I was really inviting you to say—and I don't want to coach the witness; I wouldn't do that, because I'm not an attorney; I'm an agronomist, so I think I'm close to this other discipline—but the thing I was trying to find out was whether there had, in fact, been a shortfall or whether you had a dropout in researchers because of the pay scale or the funding for the researchers wasn't adequate to keep these people in that discipline.

Now that I've prompted you, do you have a falling out of the pool of researchers, or is this simply to make up the dropout that you had because of restraints in the fiscal year 1981 budget?

Dr. KIRSCHSTEIN. Overall, there is a decrease in the number of trainees that we have been supporting for the last 4 to 5 years. It was a particular shortfall, and there will be a particular shortfall during this current fiscal year, which we will try to make up next year if possible.

Senator ANDREWS. But is there a dropping out of the people—in other words, the career researcher? Are they staying in the field, or have they been dropping out of the field at a greater rate during the last 4 or 5 years than in the prior 5-year period? And if you don't have those figures, you could take a guess at them now and correct them for the record.

Dr. KIRSCHSTEIN. Well, we can say several things, and we may want to amplify for the record.

There are, of course, two types of individuals who are in research in the biomedical area, Ph. D. scientists and physicians. The number of physicians who are engaging in research has decreased rather markedly. And the number of physicians who are in research training has also decreased. This, for example, is one of the reasons for the NIGMS medical scientists training program, the program which strives to change that decrease by providing support for individuals who are planning to become researchers to earn the combined M.D./Ph. D. degree.

The number of Ph. D. scientists has remained approximately steady.

Senator ANDREWS. Well, the concern of the committee—and I just gained the information that this has been an ongoing concern and not one that I just stumbled on this afternoon—but the concern of the Committee is maintaining a stable research pool, and you mentioned that you are seeing dropouts of trained researchers at this period of time.

Can you give us for the record the reason for this dropping out. And can you, for the record, expand on what has happened in this to-be-sought-for goal, really, of a stable trained cadre of researchers who should be attracted into this subprofession of the medical profession and should be kept there? Isn't it a lot like the army? If you get them to reenlist, you can save a whale of a lot and have a much more effective army on down the line than if they keep dropping out on you. So

if you could provide some of those figures, it might give the subcommittee some better insight than we would have otherwise.

[The information follows:]

MAINTENANCE OF STABLE POOL OF RESEARCH SCIENTISTS

The dominant position of American science in today's world, and the truly excellent quality of the biomedical research being conducted in this country, is nowhere more vividly demonstrated than in the yearly distribution of Nobel Prizes in the various science categories. Indeed, the NIGMS alone has, over the years, provided support to 42 investigators who have won recognition from the Nobel Prize committees. Our ability, as a nation, to maintain this level of excellence is necessarily dependent on the ability to maintain an adequate pool of talented and dedicated researchers, trained in a broad range of subject matter areas.

A number of difficulties must be overcome to achieve this goal. First and foremost is the fact that the "half-life" of a grantee is only about 5 years; i.e., only half of the scientists who received research project grants from NIH in 1980 can be expected to still be grantees in 1985: experience shows that by 1990 this figure will drop to about 35 percent. Second, between 1966 and 1977, the percentage of NIH grantees who are physicians dropped from 43 percent of the total to only 28 percent—a serious decline, highlighted in a special article published a year ago in the New England Journal of Medicine, by Dr. James A. Wyngaarden of Duke University, entitled "The Clinical Investigator as an Endangered Species." Third, it has proven difficult to entice medically trained individuals to commit themselves to careers in certain important areas of research. For example, critical shortages of trained investigators exist in such areas as clinical pharmacology and trauma and burn research.

This problem of the growing shortage of physician-researchers is perhaps the most acute and has been the subject of considerable study and debate. Some important reasons for the decline, according to Dr. Wyngaarden, include the instability of Federal support to biomedical research and research training, curriculum revisions in the medical schools, and the disincentives contained in the payback provisions of the National Research Service Act awards. One impact of the payback provision, Dr. Wyngaarden argues, is to help "* * * make a tentative research training decision a very difficult step to take"—making it impossible to sample the research life without incurring, what he calls, "unwarranted economic or professional penalties."

At the request of the Congress, the National Academy of Sciences has been carefully studying these and other issues related to the role of the Federal Government in the training of biomedical research scientists. Three recommendations emanating from the Academy's studies are particularly significant: (1) that the NIH should provide funding support for a total of 4,250 predoctoral trainees each year; (2) that, through its medical scientist training program, the NIGMS should specifically provide support each year for 725 individuals enrolled in combined M.D.-Ph. D. degree granting programs; and (3) that an attempt should be made to encourage research training of a broad, multidisciplinary nature.

As the principal source of support for research training at NIH, the NIGMS has played a vital role in the maintenance of the Nation's pool of high-quality biomedical research scientists—providing support for two-thirds of the predoctoral trainees funded by NIH and roughly 40 percent of all the NIH-funded trainees. Coordinating its efforts with those of other components of the NIH, the NIGMS has followed the NAS guidelines regarding the number of predoctoral trainees to be supported and has strongly emphasized broad, multidisciplinary training. In addition, the Institute has provided support for the full number of M.D.-Ph. D. trainees recommended by the Academy. Through its minority access to research careers program, the NIGMS has also expanded opportunities for minority group members—long underrepresented in the field of biomedical research—to enter careers in scientific research.

Roughly 10 percent of the trainees supported by the NIGMS are the recipients of individual NRSA fellowship awards. The remainder receive support for research training under institutional fellowship awards provided by the Institute to various university training programs throughout the country. Typically, these awards are made for a 5-year period, during which the programs are gradually brought up to full strength in terms of the number of classes and number of trainees permitted on the award. At the end of this period, the schools must recompete if they wish continued support, on the

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basis of the quality of their programs. Because NRSA awards were started in fiscal year 1975, a large part of the research training budget has a 5-year cycle. This was reflected in the Institute's training budget for fiscal year 1980, with its large proportion of competing awards, and can be expected again in fiscal year 1985.

It is the hope of the NIGMS, and the NIH generally, that efforts to stabilize the yearly funding of competing research projects will encourage physicians and scientists to enter research, and thus maintain an adequate national pool of highly qualified researchers. But, as the Director of NIH has indicated in a recent article, scientific research is a profession with a naturally "high metabolic rate," and as many as 2,000 principal investigators are lost every year. Because of the critical importance of attracting, and retraining, the best young minds available to biomedical research, the NIGMS is committed, through such mechanisms as the medical scientist training program, to do what is possible to overcome the obstacles which may prevent maintenance of a stable pool of highly qualified research scientists.

SUBMITTED QUESTIONS

Senator ANDREWS. I have, as I'm sure you know, a whole host of questions, but in the interest of time, we will let you answer them for the record and go on to our next witness.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

Pharmacological Sciences

Question: Last year you described for us investigations involving prostaglandins that were part of a research program being supported by your Institute through the Pharmacology Research Center at Vanderbilt University.

Have these investigations shed further light on our knowledge of these substances and their involvement in certain diseases?

Answer: Prostaglandins are naturally occurring substances found in almost every cell in the body. Researchers are still only beginning to discover the various roles that these substances play in the normal and abnormal functioning of body tissues; but, it is already clear that a knowledge of how prostaglandins are formed and released within the body is critical to an understanding of a variety of diseases and disorders.

Dr. John Oates, director of an NIGMS funded research team working at Vanderbilt University, has been among the leaders in prostaglandin-related research. His most recent report, in the December 11, 1980, issue of the New England Journal of Medicine, describes a newly discovered prostaglandin and indicates that there is a marked overproduction of this prostaglandin-D_2 in patients with a rare, often fatal disorder called systemic mastocytosis. This is a condition characterized by episodic attacks of flushing, the precipitous lowering of blood pressure, and rapid heartbeat--all of which can result in life threatening shock.

Analyzing the urine from one patient suffering from systemic mastocytosis, Dr. Oates noted this overproduction of the prostaglandin-D_2, and decided to treat another such patient with aspirin, which acts to inhibit prostaglandin production. This second patient has now fully recovered, and has been disease-free for over eight (8) months.

While it has been known that a prostaglandin of one type or another is involved in many clinical conditions, this is one situation in which a specific prostaglandin has been associated with a specific disorder. As a result, not only did Dr. Oates save at least one life, he and his colleagues have opened up studies aimed at one day using pharmacologic agents aimed at inhibiting the production of or antagonizing the action of only a specific prostaglandin, without disturbing other bodily functions. Aspirin and other nonsteroidal anti-inflammatory agents which are used today are not selective in terms of their action.

Other aspects of prostaglandin pharmacology and physiology are being studied at the Medical University of South Carolina. In studies in which endotoxic shock is produced in rats, NIGMS grantees have discovered that administration of certain nonsteroidal, anti-inflammatory drugs can significantly improve survival by inhibiting the synthesis or activity of thromboxane, another prostaglandin. (Thromboxane has been implicated in the aggregation of platelets, a contributing factor to endotoxic shock.) These observations are consistent with the hypothesis that thromboxanes play an important pathophysiological role in endotoxic shock and provide a basis for the design of therapeutic agents which may be useful in treating endotoxic

shock in man. These findings are also significant because of their potential value in understanding various toxic shock syndromes.

These two examples are indicative of the types of research in the prostaglandin area supported by the NIGMS Pharmacological Sciences Program.

Question: How might these findings be applied to our understanding of the disease processes involved in arthritis?

Answer: It is already known that inflammation, in a joint or elsewhere, results in increased prostaglandin production in the affected tissues, and that prostaglandins, in turn, tend to contribute to the inflammatory process and increase pain. But, additional basic research focused on the structure, synthesis, and release of the various prostaglandins (as well as their metabolites or by-products) is necessary before we can understand their role in a specific disease like arthritis.

Question: Do you support any research to investigate the possible role of these substances in producing menstrual cramps?

Answer: The NIGMS does not support investigations related to the possible role of prostaglandins in producing menstrual cramps, since such research would be supported by the National Institute of Child Health and Human Development. However, the work of Dr. Oates and other NIGMS grantees on prostaglandins will have importance for and influence studies of individual disorders, such as menstrual cramps.

GENETIC SCREENING AND COUNSELING

Question: Do you support research in genetic screening and counseling?

Answer: The NIGMS is not directly involved in the areas of screening and counseling. Research on the development of screening methodologies for particular genetic diseases is the responsibility of the various categorical institutes at NIH--the NHLBI, for example, has a sickle cell disease program. Research on the delivery of genetic services, including studies of the effects or effectiveness of genetic screening and counseling, on the other hand, is a responsibility of the Health Services Administration.

Nevertheless, screening and counseling programs are necessarily dependent upon an understanding of fundamental genetic structures and processes, as well as on techniques, developed through basic, untargeted genetic research; and support of such research is one of the primary functions of the NIGMS. Indeed, it should be noted that one of the newest techniques now being used to screen individuals for sickle cell disease grew out of recombinant DNA technology developed, in large measure, by NIGMS grantees.

Question: Have any new diagnostic techniques been developed to detect the presence of genetic disease, either prenatally or in other affected individuals?

Answer: The pace of advances in modern genetics is such that techniques and concepts developed in research laboratories are becoming assimilated into the practice of genetic diagnosis and counseling at an ever-increasing rate. One such advance, already alluded to, relates to observations regarding the sizes of fragments of DNA obtained from fetal cells in amniotic fluids. From such observations, and using recombinant DNA technology, clinical geneticists are now able to detect differences between normal individuals and those that have sickle cell disease or thalassemia.

Question: What plans do you have for the coming year with regard to coordination with the Bureau of Community Health Services in the area of genetic counseling?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

BASIC RESEARCH IN GENETICS

Question: What progress has been made in the area of basic research in genetics?

Answer: Basic research in genetics has been one of the fastest moving fields of research in recent years. The dramatic increase in the pace of genetics research can be attributed to the invention of two powerful new research tools, namely, recombinant DNA technology and rapid methods for determining DNA sequences. Both techniques are considered so important that Nobel prizes have been awarded to the inventors of each. The availability of these new methods has allowed scientists to apply the approaches that were used so successfully, for many years, in studies of bacteria and viruses to research on the much more complex genetic material of higher organisms, including man.

Three significant discoveries, with potentially far-reaching implications, have already resulted from research on genes in higher organisms. First, scientists have discovered that many genes exist in pieces rather than continuous stretches of coded information. These pieces are separated by intervening sequences of DNA, called introns, which do not themselves get translated into the proteins essential for the body's growth and functions. However, since these intervening sequences are present during a part of the process by which genetic information leads to protein synthesis, but are cut out at another stage, it seems clear that they play an important role in controlling gene activity. Further research on the nature and function of "introns" may be critical to understanding the control mechanisms of normal development and the loss of such control which results in developmental abnormalities and certain diseases.

A second significant discovery is that pieces of genetic information frequently move around or are transposed on the chromosomes. Awareness of the importance of these "transposable elements" or "jumping genes" continues to increase. New evidence suggests that transposition of genetic elements plays a role in mutation (hereditary change) and differentiation or maturation as well as in other phenomena. For example, the genes responsible for the synthesis of antibodies are assembled from several pieces of genetic information

which move into close proximity when such synthesis occurs. Evidence suggests that such gene transposition may explain how the human body can make the millions of different kinds of antibodies which are responsible for eliminating invading viruses and bacteria from the body and are involved in such phenomena as allergy and graft rejection.

Other significant studies indicate that "transposable elements" or "transposons" may have some bearing on malignancy. Some viruses that can transmit cancer genes in laboratory animals have been found to be specialized "transposons" which carry a normal cellular gene to a new location. This leads to changes in the cell that transform it into a cancer cell.

A third significant finding concerns gene amplification, a phenomenon occurring when genes make many copies of themselves in order to respond to a need in the cells for the production of large amounts of certain substances. This normal process can also be called into play in abnormal circumstances. For example, when cancer patients are treated with the chemotherapeutic agent, methotrexate, they may become resistant to the effects of the drug. This resistance is brought about by multiplication of the gene that makes the protein which is inhibited by methotrexate. As a result, the methotrexate becomes less effective in combating the patient's cancer.

These are just a few examples of the kind of knowledge being gained through research in basic genetics. We expect that the rapid pace of new discoveries in this area will continue for some time and that the impact on medicine will be profound.

Question: Are there any new insights into the genetic components of such diseases, as diabetes, atherosclerosis, hypertension, etc.?

Answer: Approximately forty diseases, including such common diseases as certain variants of diabetes and arthritis, as well as other conditions such as psoriasis and celiac disease, have been shown to be strongly associated with one or another variant of a gene complex, known as HLA (Human Leucocyte Antigen). However, relationships between this gene complex and a predisposition to certain diseases are far from clear, and are currently a topic of intensive study in many laboratories. During the past two decades, susceptibility to mental disorders such as mania, depression, and schizophrenia has also been shown to be associated with genetic factors.

Question: How much does the Carter budget allow for the continued support of basic research in this field?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: How do you interact with the other institutes in terms of sharing the knowledge gained from basic research supported by your Institute?

Answer: The Genetics Program, like all of NIGMS, considers itself to be a generator of concepts which often, unexpectedly, become relevant to disease conditions which are of major program interest to the more categorical NIH institutes. Research projects, which because of their fundamental, noncategorical significance originally were supported, are often transferred to categorical institutes when their emergent relevance to conditions such as atherosclerosis, cancer, and infectious disease become apparent.

Furthermore, the Genetics Program currently is developing other means of interacting with other NIH institutes. In recent years, we have held workshops in collaboration with other institutes in regard to: (1) common diseases which have strong genetic components such as hypertension, diabetes, and atherosclerosis, (2) how a data bank might be developed to take advantage of the proliferation of information on nucleotide sequences in nucleic acids and to serve the needs of research supported by all institutes, and (3) new possibilities for developing mouse models of human genetic disease, as well as mouse strains for use in research on the mutagenicity of chemicals.

Recently, NIGMS has undertaken a survey to determine the extent of the overall support of genetics at NIH. Since nearly all human disease has some genetic component, this determination will lead to an increase of common interests and continued interaction with other NIH components.

One activity supported by the NIGMS that has a great effect on the more categorical programs is a Cell Bank which develops and distributes cell lines representing human genetic disease. Such cell lines are distributed to grantees of all the institutes, as well as to members of the intramural research staff of NIH. We have received much favorable comment on this cell bank and these cell lines are generally recognized to be of high quality. Furthermore, it is a cost-effective enterprise. Since its existence avoids repetition of the development of particular types of cell lines by individual investigators, research can be performed which would otherwise not be readily possible.

Question: What evidence can you provide indicating the effectiveness of your work?

Answer: The effectiveness of the NIGMS Genetics Program can be demonstrated in a variety of ways. Most simply, it can be readily measured by the recognition of the work of grantees of the Program by the scientific community. For example, two of the three recipients of the 1980 Nobel Prize in Chemistry were American scientists supported by the Genetics Program: Dr. Paul Berg (supported by NIGMS since 1960) and Dr. Walter Gilbert (supported by NIGMS since 1969.)

However, the more intangible effects of the Program are probably even more profound. The NIGMS Genetics Program supported a major portion of the research that led, in the 1970's, to the development of recombinant DNA technology. This technology is now a major tool in biology, and it is being applied successfully to areas as diverse as: (1) cancer research, (2) investigations of organisms infectious for man, (3) research related to the basic cause and the diagnosis of genetic disease, (4) the manufacture of rare and expensive chemicals such as insulin, growth hormones, interferon, and safer vaccines,

(5) the improvement of plants which provide food, and (6) research on energy resources. In very specific ways, then, the Genetics Program has provided concepts needed to stimulate several segments of the U. S. economy.

CELLULAR AND MOLECULAR BASIS OF DISEASE

Question: Has research supported under the Cellular and Molecular Basis of Disease Program yielded any new insight into the cause and possible treatment of cancers or other diseases?

Answer: Research supported by the Cellular and Molecular Basis of Disease (CMBD) Program has provided many new insights regarding the cause and possible treatment of cancers and other diseases, while also developing information regarding the structure and function of the cell and its components. Just as the human body is composed of organs--the brain, heart, liver, muscles, and so on--each with its own unique and special function, each of the cells--of which all organs and tissues are composed--also has its own array of tiny organs, or organelles: a nucleus that contains the genetic instructions by which the proteins of each cell are synthesized, microsomes that carry out protein synthesis according to the instructions sent on genetic messages from the nucleus, mitochrondria that provide the energy required for life processes, microtubules and microfilaments that provide structure and motility, membranes that divide the cell into compartments and protect it from its external environment, and so on.

One of the most important research areas in modern cell biology, the study of cell membranes, has direct applicability to learning more about cancer. Cancer is clearly a cellular disease, in which growth, motility, and shape of cells, as well as cell-cell interactions are no longer normal. All these properties are intimately tied up with changes in the cell membrane since it is this organelle which must mediate cell-cell interactions, and change shape for any form of cellular motion. The membrane and its underlying cellular skeleton are known to be altered in cancer and what is being learned about normal cell membranes is rapidly being used to elucidate the abnormalities of the membrane of a cancer cell.

We now visualize membranes as islands of protein floating in a "sea of lipid." Membranes consist of:

Channels for the entry and exit of sodium, potassium, and other ions, and for glucose, amino acids, and other nutrients needed to maintain the life of a cell.

Receptors for essential chemicals and hormones such as insulin or growth hormones which send signals into the cell to alter their metabolic activity.

Glycoproteins that have on their outer surface complex branching structures made of sugars that serve to communicate with other cells and to give the cell a specific identity--these are important in organ transplantations.

Gap junctions that serve as communicating portals between adjacent cells to let small molecules and electrical impulses pass directly from one cell to another.

Tight junctions that form tight seals between cells--such as those lining the intestines--so that nothing can pass between. Thus, nutrients absorbed from the gastrointestinal tract must pass through the cells lining the intestines; they cannot go between. This prevents the bacteria in the intestine from invading the body directly through spaces between the cells.

Cancer researchers are now studying whether one or more, or all of these parts of the membrane are altered when a cell becomes malignant. They are also trying to understand the fundamental changes in the cell that remove it from its normal state. Is it in the glycoproteins that appear to give the normal cell its identity or through the branching sugar moeities that stand out from the cell surface? Are the glycoproteins normal in cancer, or are they modified in some way so that the cell is no longer identified as belonging to that organ or tissue? Or, is the significant change in the gap functions that normally provide direct portals of communication between the cytoplasm of adjacent cells? Is this communication altered in cancer cells? Whereas normal cells normally remain in place within their respective tissues and carry out their normal function, malignant cancerous cells pry themselves loose from their moorings, become motile, move around, and metastasize to other locations in the body. What are the normal control mechanisms by which cells are prevented from entering the motile state--or on other occasions are instructed to do so? Such studies are possible because work supported by the CMBD Program has clarified so much about the normal cell.

Examples of the relationship of NIGMS supported studies to cancer research can be illustrated by the following:

1. Dr. S. Jonathan Singer of the University of California, San Diego, one of the early pioneers in research in membrane structure, proposed the "fluid-mosaic" model for cell membranes in which proteins may be compared to "icebergs floating in a sea of lipids." This is still the predominant theory of membrane structure. Supported for many years by NIGMS for fundamental research on membrane structure and function, he began to receive support from the National Cancer Institute in 1977 for research on mechanisms of transmembrane control in malignant cells contrasted to normal cells.

2. Dr. Werner Loewenstein of the University of Miami is one of the pioneers on research on intercellular communication through gap junctions. In 1973 he began to direct his study toward gap junctions as to their possible role in the etiology of cancer.

3. Dr. Albert Lehninger of Johns Hopkins University first discovered the role of mitochondria in the production of the chemical energy needed for life processes. Long a grantee of NIGMS on the structure and functions of mitochondria, he recently began a research program on respiration coupled transport in tumor cells under support from the National Cancer Institute.

4. Dr. Raymond Blakely of the University of Iowa has been supported by the NIGMS for a number of years for his study

of the processes by which enzymes are regulated and controlled. Recently, he has undertaken structural studies of the enzyme, dihydrofolate reductase, the enzyme acted upon and inhibited by a potent drug (amethopterin) used for the treatment of acute leukemia. Support for this research has therefore been taken over by the National Cancer Institute.

Question: Does your proposed budget allow for adequate funding of basic research in this area?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

TRAUMA AND BURN RESEARCH

Question: What breakthroughs in the area of trauma and burn research have been made in the past year?

Answer: Information obtained from fundamental investigations at the molecular, cellular, and organ levels is beginning to have a substantial effect on reducing the mortality and morbidity of severe injury and burns.

For example, much progress has been made in characterizing the total body's metabolic response to acute injury, and the study of the dynamics of this response at the organ/cellular level has begun. Recognition that protein malnutrition is a significant problem in these patients, possibly even a major cause of death, has resulted in the administration, to severely traumatized patients, of resuscitation fluids containing amino acids. This is associated with an increase in the survival rates of the severely injured. In addition, a study of the metabolic processes occurring in the liver and muscle of the injured patient, which are much accelerated over normal, has revealed that the infusion of glucose above that needed to meet the caloric needs of the patient is detrimental. Infusion of glucose in excess of 4 mg/kg body weight/day accelerates skeletal muscle protein breakdown and is associated with an increased conversion of carbohydrate to fat by the liver. The latter process results in the disposition of fat in the liver, probably impairing liver function, and can precipitate respiratory collapse in those patients whose cardiopulmonary system is insufficient to clear the increased amounts of carbon dioxide formed in the conversion of carbohydrate to fat.

A second area where progress has been made is in the prevention of scar formation and skin contractures. In theory, the solution of the burn problem is simple. The burned patient, after removal of the injured tissue and replacement with normal skin, would no longer have a burn injury. The problem for the extensively burned patient is that there is not enough unburned skin to use as grafts to cover the burned areas. The result of delayed grafting is that large areas of the body which are normally protected by the skin are left open to easy invasion by bacteria, healing is delayed, and the incidence of scar formation is increased. Dr. Yannas and associates, of MIT, and

Dr. Burke, of Harvard University, have collaborated in an attempt to design an artificial skin that would reduce the possibility of infection and serve as a matrix to encourage new skin formation. After years of testing in animals, an artificial skin developed by Drs. Burke and Yannas is now beginning to be used to treat severely burned patients, with exciting results. After excision of the burned area, a composite, made up of collagen in the form of glycoaminoglycans covered with a thin silastic sheet is applied to the surface of the wound. Cells then grow into the applied material, along with blood vessels. After several weeks, the silastic sheet is removed and a thin layer of the patient's epidermis from another part of the body is applied to the wound.

During this year, Dr. Burke has applied this composite to 22 patients ranging in age from 2 years to 68 years. Ten patients (6 adults and 4 children) had large burns ranging from 60-95% of their total body surface. None have died, but two are still at risk because of the severity of the burns involved. One child had 60% of his body surface covered and part of the coverage remained intact for 56 days. This child has returned home and is doing well.

Such complications as life-threatening infections and graft rejections have not occurred. The number of surgical procedures has been reduced by approximately 1/3, but depends on the size of the wound. The length of each procedure has been cut from approximately 5 hours to 2 hours as a result of the artificial skin. Also, the layer of epidermis taken from the patient's healthy skin is such a thin layer, that new "crops" can be harvested more frequently, which speeds up the wound closure.

Future work will involve attempts to refine the composite and the techniques of its application as well as to reduce the contractures and scar formation which cause such severe disfigurement on burn patients.

Question: You mentioned last year that a researcher at the Massachusetts General Hospital was studying the basic mechanism of the formation of collagen in the hope that some insight might be gained as to the prevention of disfiguring scars. What progress has been made in this research area?

Answer: In the continuing studies of burn wounds and their healing, Drs. Robert Trelstad and Paul Ehrlich have noted that third-degree burns initiate a series of pathologic alterations, some of which are not caused by direct thermal injury but are more properly defined as an extension of the initial burn lesion. These studies, which initially focused on the fact that these secondary changes could be halted by transplantation of the burned area to a new site, suggested that, in addition to changes in the vascularity of the wound, factors released from the burned skin play a role in the subsequent inflammatory reaction and resultant skin contraction and scar formation. In the past year, an improved experimental model for the study of this process has been developed. It contrasts the degradation of skin matrix and wound contraction in skin which has been frozen (moderate matrix breakdown, no contraction) with that of burned skin (extensive matrix breakdown, prominent contraction). The breakdown of collagen in the matrix of burned skin has been found to be much more extensive than that of frozen skin.

In addition, it has been found that the collagen from hypertrophic scars contains less hydroxyproline, thereby lowering the thermal stability of collagen. A working hypothesis for the mechanism of scar contracture has been developed which argues that a less stable collagen would produce an unstable connective tissue matrix. More frequent turnover of the matrix would facilitate cell movement through a physical barrier which otherwise keeps cells confined, and this could account for increased scar formation and contracture. Although the hypothesis does not deal with the entire question of what causes scarring, it may dissect out an important mechanism controlling scar formation and contracture.

EFFECTS OF DRUGS ON CHILDREN AND THE AGED

Question: The effects of drugs on children and the elderly are known to be different than the effects of the same pharmacologic agents on young and middle aged adults. These were identified as important areas of research by the Institute in previous years.

What research do you support in the area of pediatric pharmacology?

Answer: The NIGMS currently supports seven (7) research projects concerned with pediatric pharmacology. An illustrative example is the work being done by Dr. Gerhard Levy and his colleagues at the State University of New York, Buffalo. Dr. Levy's group is studying drug action in pregnant women and in their newborn infants. They have discovered that, in pregnant women, there are differences in the degree to which some drugs circulate freely or are bound to plasma proteins in the blood. This distinction is critical since the level of the drug's pharmacological effect is related to the "free" fraction. Such drugs as aspirin, the anticonvulsant, phenytoxin, and the tranquilizer, diazepam, are more active because they are not as frequently "bound" to the blood proteins. However, in newborn infants, the same drugs are "bound" more extensively, reducing their pharmacological activity. Dr. Levy's group is now extending its studies to elucidate the role of the placenta in the transfer of drugs from the mother's blood to the fetus.

Question: Do you support any studies involving the effects of pharmacologic agents on the elderly and aging population?

Answer: During the first few years after the establishment of the National Institute on Aging (NIA), the Pharmacological Sciences Program of NIGMS worked to help the NIA develop its efforts to support research on the effects of increasing age on pharmacological action, and on the toxicity of pharmacological agents. For the past year, the NIA has administered a more formal program in pharmacology to which are referred all individual pharmacological grant proposals with a primary emphasis on the effects of drugs in the aging population. However, under the aegis of two of the research center grants supported by the NIGMS Pharmacological Sciences Program, age is being studied, among other factors which can affect therapeutic drug safety and efficacy. Dr. Gerhard Levy and his colleagues at SUNY-Buffalo are studying the effect of age on alterations in the pharmacokinetics (studies of absorption, distribution, and elimination) of therapeutic drugs. As a member of the research center grant at Vanderbilt University, Dr. Grant Wilkinson started research on the effects of

age on the pharmacokinetics of drugs. This has now developed into an individual project grant supported by the NIA.

In addition, Dr. Richard Ross, a post-M.D. fellow in the NIGMS intramural Pharmacology Research Associate Training Program, is studying the relationship of age to the pharmacokinetic and pharmacodynamic mechanisms of action of the tricyclic antidepressants--drugs much used in the elderly. Dr. Ross is working in the laboratory of Dr. Frederick Goodwin of the National Institute of Mental Health.

MINORITY ACCESS TO RESEARCH CAREERS (MARC) PROGRAM

Question: The Minority Access to Research Careers (MARC) Program is a special training program of your Institute.

How many special fellowships were provided under the MARC Program during the past year?

Answer: A total of thirteen (13) new institutional fellowship awards were made under the MARC Honors Undergraduate Research Training Program in fiscal year 1980, bringing the total level of support for this activity to 35 awards and $3.3 million. The Honors Program is designed to provide support to minority institutions to teach and provide research training to honors undergraduates (237 currently), who are in their third or fourth year of college, and who plan to obtain their doctorate (Ph.D.) degree in the biomedical sciences.

Question: What other awards were granted under this Program?

Answer: In addition to the new awards made under the Honors Program, eight (8) new MARC Faculty Fellowship awards were funded by the NIGMS in 1980, for a total of $185,000. Three (3) other awards, administered through the MARC Program, were funded by other institutes--two by NHLBI and one by NIAID--at a cost of $68,200.

Faculty Fellowship awards provide opportunities for advanced research training to selected faculty members of minority institutions to strengthen the teaching and research training program of these institutions.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier reponses.]

BASIC RESEARCH IN GENETICS

Question: How much does the budget allow for the continued support of basic research in this field?

Answer: The Reagan Budget allows $130,624,000 for support of the NIGMS Genetics Program. This includes $115,761,000 for investigator-initiated research grants, $4,000,000 for Genetics centers, $270,000 for Research Career Program awards, $15,000 for Research conferences, $9,288,000 for National Research Service Awards, and $1,290,000 for Research Contracts.

CELLULAR AND MOLECULAR OF DISEASE

Question: Does your proposed budget allow for adequate funding of basic research in this area?

Answer: The Reagan Budget allows for $114,861,000 for the NIGMS Cellular and Molecular Basis of Disease Program. This includes $93,825,000 for all investigator-initiated research grants which would allow for the funding of approximately 42% of the approved competing applications, $600,000 for a Molecular Pathology center, $272,000 for Research Career Program awards, $16,000 for Research conferences, $20,113,000 for National Research Service Awards, and $35,000 for a Research contract.

GENETIC SCREENING AND COUNSELING

Question: What plans do you have for the coming year with regard to coordination with the Bureau of Community Health Services in the area of Genetic counseling?

Answer: The NIGMS has traditionally worked together with the Bureau of Community Health Services of the HSA (which has the primary responsibility for genetic counseling) on a report that is submitted to Congress annually in response to the requirements of the Genetic Diseases Act. The Institute provides the portion of the report related to developmental aspects and research on genetic diseases.

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request proposed by President Reagan provides for the funding of approximately 4,900 new and competing renewal research project grants at a cost of $571,621,000. The NIGMS share of this amount is 835 awards for $89,399,000.

Question: How is inflation impacting--or how will it impact--on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new Research Grants regardless of other budget priorities within NIH?

Answer: Over the years, it has become apparent that the individual, investigator-initiated research project is the life blood of NIH extramural activities and of biomedical research in this country. Without a steady influx of new ideas and the testing of them, biomedical science will lose its vitality and go stale. Without stability of support from year to year, universities and their scientists cannot plan their future activities in the most efficient

way, and are discouraged from seeking solutions to important but complex problems that require sustained efforts lasting many years. Stability of support reflects a steady commitment by the Government, and this is a very significant factor in attracting bright college graduates into careers in science.

Question: What happens if, in a particular year, the quality of new research proposals declines: To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: The quality of research proposals submitted to NIH is dependent on the innate talents of the investigators and on the quality of their training for research. Reflecting past Federal investments in research training and great enthusiasm for the many opportunities to make new discoveries in biomedicine, the quality of research proposals in the recent past has been generally very high, as indicated by the substantial numbers of approved proposals that go unfunded for lack of funds. A dramatic decline in quality, therefore, seems highly unlikely, and NIGMS would expect to continue its emphasis on the individual, investigator-initiated research project as most appropriate to its mission. NIGMS supports very little intramural NIH research and has only a small research contract program.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981--and if you estimate it--in FY 1982? What percentage of grants will you fund in both years?

Answer: Under the revised budgets proposed by President Reagan, NIGMS expects to reach a "payline" of approximately 190 in fiscal year 1981 and 190 in fiscal year 1982.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: The essential mission of NIGMS is the support of fundamental, undifferentiated biomedical research. In our experience, this is best accomplished through the mechanism of individual, investigator-initiated research project grants (ROIs). In making reductions from the budget submitted to you in January, we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: The NIGMS management staff has worked hard to be as efficient as possible; and in the last few years has been successful, through carefully planned reorganizations and tight management controls, to streamline the Institute's operations and reduce unnecessary expenditures. Overtime, for example, has been cut dramatically.

In 1981 cuts were made in travel, consultant services, procurement contracts, and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982.

Additional cuts in these areas in FY 1982 could not be absorbed without affecting such essential activities as project site visits, which are used to assist in evaluating requests for research and research training support.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF NORMAN KRETCHMER, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
BETTY H. PICKETT, DEPUTY DIRECTOR
JOEL R. HEDETNIEMI, EXECUTIVE OFFICER
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator ANDREWS. Next we have the National Institute of Child Health and Human Development. Our next witness is Dr. Norman Kretchmer, Director of the National Institute of Child Health and Human Development. And the Institute is a principal agency of the Federal Government for research on the special health problems of mothers, children, and families. That certainly encompasses all of us because I think we fathers are part of the family.

Doctor, we welcome you to our hearings, and would ask that in the interest of time you briefly highlight your opening statement which will be presented in full in the record, and, of course, before you begin, please introduce your colleagues and then proceed with your statement.

[The statement follows:]

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STATEMENT OF NORMAN KRETCHMER

Each year more than 45,000 infants die in the U.S., most of them from birth defects or infections, or because they are of low birth weight. Seven of every 100 infants born alive have physical or mental handicaps that will last a lifetime. Moreover, one in every 7 pregnancies, some 500,000 births each year, is not planned and 2 million couples who want to have children are unable to have them. Such problems, originating early in life or occurring during the reproductive years, are an economic burden on society. The cost of birth defects is at minimum $2.5 billion a year for hospitalization, physicians' fees, and services. Intensive care for low birth weight babies is estimated to cost $6.5 billion each year.

The mission of the National Institute of Child Health and Human Development (NICHD) is to support and conduct biomedical and behavioral research, with the goal of increasing scientific knowledge and applying it to prevent and cure these costly problems.

Much of the work of the NICHD is aimed at understanding normal human development and processes--the transformation of a fertilized egg into an infant; the growth of an infant into a productive, healthy adolescent and adult; and the complexities involved in contraception, childbearing, and childrearing. Elucidation of human development is an intriguing and profound challenge of modern science. Moreover, concentration on early development, when many diseases and disorders originate, places the NICHD in a prime position to contribute to preventive medicine.

In the remainder of my statement I will give examples where gains have been made in the areas of pregnancy, fetal medicine, mental retardation, child development, contraception, and reproduction.

Pregnancy

The infant death rate in the U.S. has dropped dramatically since the 1950's because research has shown us how to save more babies of very low birth weight. But decreases have not been achieved in all weight categories, and 15 countries still have lower infant mortality rates than the U.S. Moreover, there has not been a parallel decrease in the number of low birth weight babies. Low birth weight babies account for nearly 11 percent of all births. This is of concern since 75 percent of infant mortality is linked to low birth weight, and even more important, 30 percent of very low birth weight babies who live have neurologic problems that last a lifetime.

Clearly, our record for infant mortality and morbidity would improve if we could solve the problem of prematurity and the problem of babies born on time, but too small. Scientists supported by the NICHD are learning how to prevent prematurity and low birthweight by studying why labor begins and how the mother, via the placenta, nourishes the fetus. Understanding the complex interactions that take place between the mother and the fetus during pregnancy and labor forms the basis for improving medical management of pregnancy and examining new drugs to delay early labor.

Fetal Medicine

Advances in the past decade in understanding the developing embryo and fetus have been paralleled by breakthroughs in the technology used in prenatal diagnosis. These gains give us the

knowledge needed to begin correcting problems in utero and preventing many disorders before birth. At present, the practice of fetal medicine involves treating the pregnant woman to affect the health of the fetus in utero. For example, it is now possible to prevent respiratory distress syndrome by giving steroids to the mother prior to delivery to hasten maturation of the fetus's lungs. Dietary restriction of galactose during pregnancy can prevent cataracts in children with a particular enzyme deficiency, and treatment with large doses of vitamin B 12 during the last 9 weeks of pregnancy can correct a specific enzyme deficiency in the fetus and prevent death and mental retardation.

Diabetic pregnancy is an area which demonstrates how understanding fetal development contributes to prevention of death and disease. Just a decade ago, women with diabetes were cautioned about becoming pregnant because of the risks to themselves and to their infants. Now, because of research advances, the risks to the diabetic mother are very low, and the number of diabetic women whose babies die before birth has dropped to about the rate in uncomplicated pregnancy. However, this improvement has not yet been matched by a decrease in birth defects associated with maternal diabetes. A new study sponsored by the Institute aimed at reducing the risk of birth defects--a risk 3 times higher than that for normal pregnancies--will carefully monitor the diet and insulin therapy of diabetic women in the very early weeks of pregnancy, based on the hypothesis that the defects are due to some disturbance in the maternal milieu rather than exposure to insulin itself.

With advances in technology offering safer direct access to the fetus, comes the hope that more problems can be prevented before birth. In animal models, for example, it is now possible to prevent by drug therapy or hormone replacement certain defects of the eye, the palate, and the genitals. The ability to treat the embryo or fetus in utero depends upon a fundamental understanding of the mechanisms and timing of developmental processes.

Mental Retardation

About 6.6 million people in the U.S. are mentally retarded and the number increases by 126,000 new cases each year, occurring in 5 percent of all births. This disorder, which lasts a lifetime and costs at least $10 billion per year in public funds, is caused by biologic, social, or psychologic factors or is due to a combination of factors. Whatever its causes, it is clear that the roots of mental retardation lie in the faulty development early in life or neurobiologic mechanisms. Therefore, some of the most important research supported by the NICHD is the study of the maturation, migration, and interconnection of the 200 billion neurons that generate during the first 3 months of fetal existence. These studies hold great promise for answering some of the most important questions relating to brain development. As these questions are answered, scientists will begin to understand more about preventing mental retardation whether it is caused by genetic factors, environmental pollutants, infections, or a deprived social environment.

Studies in Children

As a result of Institute-supported research since 1972, significant progress has been made in understanding the sudden infant death syndrome (SIDS)--the leading cause of death among infants between the ages of 1 and 12 months. Data from a current

NICHD study make a genetic origin for SIDS seem unlikely, providing strong support for continuing research on environmental and developmental causes of SIDS.

Children with dwarfism because their pituitary glands produce insufficient human growth hormone, will be the first beneficiaries of DNA recombination technology, a technology pioneered by NICHD scientists and investigators working elsewhere. This technique allows large quantities of the growth hormone to be harvested from bacteria, and overcomes the severe shortage of the hormone, previously available only from human cadavers.

The NICHD is also concerned with preventing learning problems which affect millions of American school children. Technologic advances have caused a burgeoning of research in the area of infant capabilities. Based on such measures as heart rate, eye fixation, and brain activity, it is now recognized that even very young infants are amazingly capable of hearing, seeing, tasting, smelling, and interacting with people around them. This understanding permits better diagnostic tests to distinguish between normal infants and those who might later develop serious physical and learning problems. Early diagnosis makes possible early application of remedial programs and the hope of preventing learning problems. An active program studying how children learn, perceive, pay attention, and remember, from infancy through adolescence, is continuing.

Contraception and Reproduction

The NICHD supports the largest program in the world for the synthesis of modified copies, or analogs, of luteinizing hormone releasing hormone (LHRH). LHRH, produced in the brain, enters the bloodstream and is carried to the pituitary gland which is stimulated to secrete other hormones that regulate the functions of the ovary in women and the testis in men. These analogs could herald the development of a new generation of contraceptives that are effective and safe for both men and women. They have already been used successfully to treat infertility in women, and may be useful for male infertility as well. These compounds also have been used by NICHD scientists for treating precocious puberty, a condition affecting children as young as 9 months old who begin physical sexual development normally associated with puberty. In addition, LHRH analogs hold promise for treating certain hormone-dependent cancers.

Because of widely-publicized reports on the possible association between the use of oral contraceptives and heart attack, stroke, and certain benign tumors, many women have stopped taking the pill and are turning to barrier methods of contraception. Therefore, the Institute is supporting clinical trials on the cervical cap, a barrier method of contraception currently unavailable in this country.

Improved drug delivery systems are also being sought. Oral contraceptives are currently taken in a pill form that results in rapid absorption of the drug. The rapid absorption produces levels of drugs in the blood higher than necessary for contraception. Methods that would release these drugs into the blood in a slower, more sustained fashion should improve safety of available drugs.

A ten-year study on the health risks of taking oral contraceptives, the Walnut Creek Contraceptive Drug Study, has just been completed and widely reported. The study did not reveal any new health hazards of the pill except for the possible relationship to skin cancer. This finding will be examined further. This and other studies confirm that for some women, particularly women who smoke, the pill may not be the drug of choice because of increased risk of heart attack and other serious side effects.

The Institute has continued its efforts in the area of infertility. An NICHD investigator working with monkeys recently developed

a procedure that permits pregnancy in females with blocked fallopian tubes. A number of studies will concentrate on infertility in the male. For example, one research team is working on a sophisticated assay for recognizing abnormal sperm, making possible more accurate diagnosis of male infertility. Other studies will focus on the effects of toxins and drugs on sperm production.

As I stated earlier, the problems addressed by the NICHD are among the most significant and costly health problems of our society. Answers to these problems can be found in research, research directed toward the fundamental questions in human development and reproduction. The NICHD research program could have great impact on health care expenses in this country because the diseases and disorders we seek to prevent are lifelong problems, some of the most costly to the Nation.

Mr. Chairman, I would be glad to answer questions or to supply additional information for the record.

NORMAN KRETCHMER, M.D., Ph.D.

Date & Place of Birth: January 20, 1923, New York City
Residence: 8 North Drive, Bethesda, Maryland 20014
Married, 3 children
Social Security Number: 090-14-1489

Education:

1940-44	Cornell University	B.S.	Animal Physiology
1944-47	University of Minnesota	M.S. (1945) Ph.D. (1947)	Physiological Chemistry
1948-52	State University of New York, College of Medicine, New York City	M.D.	

Fellowships & Honors:

1952-53	Commonwealth Fund Fellow, Montefiore Hospital
1955-56	Henry L. Moses Alumni Prize in Basic Research, Montefiore Hospital
1957	Commonwealth Fund Traveling Fellowship, St. Mary's Hospital, London and University of Paris
1958	E. Mead Johnson Award for Research in Pediatrics, American Academy of Pediatrics
1965	Alpha Omega Alpha (Faculty)
1965	Honorary Member, Faculty of Medicine, University of Chile
1965-66	Commonwealth Fund Fellow, Atomic Energy Laboratory, Saclay, Paris
1969	Alumni Medallion for Distinguished Service to American Medicine, College of Medicine, Downstate Medical Center, New York
1969	Borden Award, American Academy of Pediatrics
1971-76	Harold K. Faber Professor of Pediatrics, Stanford University
1973-74	Guggenheim Fellowship in Human Development
1975	Honorary Degree, Doctor of Science, Medical College of Ohio at Toledo
1977	Public Health Service Superior Service Award, U.S. Department of Health, Education, and Welfare
1978	Doctorat Honoris Causa, University of Bern, Switzerland

Positions:

1944-47	Teaching Asst. and Jr. Scientist	University of Minnesota
1947-48	Asst Prof. of Pathology & Biochemistry	University of Vermont
1948-52	Fellow and Research Associate of Pathology	Long Island College of Medicine
1950-55	Lecturer of Biology	Brooklyn College
1953-56	Asst. Professor of Biochemistry in Pediatrics	Cornell University
1956-58	Asst. Professor of Pediatrics	Cornell University
1958-59	Assoc. Professor of Pediatrics	Cornell University
1959-69	Professor & Executive Head, Pediatrics	Stanford University
1969-78	Chief, Division of Developmental Biology	Stanford University
1969-74	Chairman, Program in Human Biology	Stanford University
1969-78	Professor of Pediatrics	Stanford University
1970	Visiting Professor	University of Lagos Lagos, Nigeria
1972-78	Chief, Section of Developmental Medicine	Stanford University
1974-	Clinical Professor of Pediatrics	Howard University
1974-	Consultant/Lecturer, National Naval Medical Center	Bethesda, Maryland
1974-75	Acting Director, National Institute on Aging	Bethesda, Maryland
1974-	Director, National Institute of Child Health and Human Development	Bethesda, Maryland

Clinical Training & Appointments:

1952-53	Intern, Montefiore Hospital	New York City
1953-55	Asst. Resident, Pediatrics (6 mo/yr)	New York Hospital
1953-54	Asst. Pediatrician to Outpatients	New York Hospital
1954-55	Pediatrician to Outpatients	New York Hospital
1955-59	Asst. Attending Pediatrician to Outpatients	New York Hospital
1959-69	Physician-in-Chief, Pediatrics	Stanford Univ. Hospital
1969-76	Pediatrician	

Military Service:

1942-43	Air Force, U.S. Air Force
1968-71	Pilot, Civil Air Patrol

Memberships & Appointments:

1960-63	Ross Laboratory Research Award Committee, Western Society for Pediatric Research
1960-64	Special Consultant, National Institute of Arthritis and Metabolic Diseases, Hematology Training Committee, U.S.P.H.S.
1960-64	Member, Scientific Advisory Board, National Cystic Fibrosis Research Foundation
1961-67	Member, Advisory Committee, Maternal & Child Health Bureau, State of California
1962-65	Consultant, U.S. Naval Hospital, Oakland, California
1962-66	Member, Medical Advisory Board, Foundation for International Child Health
1963	Member, Medical Advisory Board, San Francisco Chapter, National Foundation
1964-68	Member, Medical Advisory Council, Food and Drug Administration
1964-67	Member, Committee on Medical Education, American Academy of Pediatrics Chairman, District X
1964-68	Member, Study Section on Human Embryology & Development, U.S.P.H.S.
1965	Chairman, Delegation on Developmental Physiology, USSR, for the Department of Health, Education, and Welfare
1965-66	Medecin Attache, U.S. Embassy Paris, Office for International Research-NIH
1966-71	Chairman, Medical Advisory Board, Foundation for International Child Health
1967-68	Member, panel 15, Committee on Research in the Life Sciences, National Academy of Sciences
1967-69	Special Consultant, World Health Organization
1967-68	Member, Joint Council of National Pediatric Societies
1969-71	Board of Scientific Counselors, NICHD, National Institutes of Health
1970-73	Committee on Undergraduate Studies, Stanford University
1971-74	Chairman, Scientific Advisory Board, Fel Institute for Human Development, Yellow Springs, Ohio
1974-	Member Executive Committee, International Pediatric Association
1974-	Member, Scientific Council, Institut de la Vie, Paris
1974-75	Consultant, Office of the Director, NIH
1974-	Temporary Advisor, Maternal and Child Health, World Health Organization, Geneva
1974-	Member of the Board, USA-Israel Science Foundation
1979-	Member, National Board Ben Gurion University of the Negev (American Associates)
1979-	Member, Board of Scientific Counselors, Children's Nutrition Research Center, Baylor University
1979-	Board of Trustees, Heart International Foundation, Great Neck, N.Y.
1980-	Consultant, National Science Foundation, Division of Problem Focused Research
1980-	Member, International Scientific Council, Foundation Pediatrique Princesse Marie-Christine, Belguim

Editorial Board Memberships:

1958-64	PEDIATRICS
1959-63	ANNALES PEDIATRICI--EDITOR
1961	BIOLOGIA NEONATORUM
	EXCERPTA MEDICA, Human Developmental Biology, 21st Edition
	STANFORD MEDICAL BULLETIN, Advisory Board
1967-75	ADVANCES IN PEDIATRICS
1971	ARCHIVES DE PEDIATRIE
1971-	MONOGRAPHS IN PEDIATRICS, Basel, Switzerland
1973	Editor, SERIES IN CLINICAL PEDIATRICS, John Wiley & Sons
1980	JOURNAL OF PEDIATRIC NEPHROLOGY AND UROLOGY

Society Memberships:

American Academy of Pediatrics (Fellow)
American Association for the Advancement of Science (Fellow-1963)
American Association of University Professors
American Board of Pediatrics (Licentiate-1957)
American Chemical Society
American Institute of Biological Sciences
American Pediatric Society (Vice President, 1977; President, 1978)
American Society for Biological Chemists
American Society for Clinical Investigation (Member of Council, 1964-67)
American Society for Clinical Nutrition
American Society for Human Genetics
Association of American Medical Colleges
Harvey Society
Histochemical Society
International Organization for the Study of Human Development (President, 1970-81)
International Pediatric Association (Member, Executive Committee, 1974-80)
Perinatal Research Society
Salt and Water Club
Sigma Xi
Society of Growth and Development
Society for Pediatric Research (President, 1967-1968)
Society for Research in Child Development
Western Society in Child Development
Western Society for Pediatric Research (President 1966-67)

Honorary Memberships in Societies:

Chilean Society of Biology
Chilean Society of Endocrinology
Chilean Pediatric Society
Czechoslovakian Society of Pediatrics
Finnish Pediatric Association
Italian Pediatric Society
Nigerian Pediatric Society
Societe Francaise de Pediatrie de Paris
Argentine Pediatric Society
Dominican Pediatric Society
British Paediatric Association

INTRODUCTION OF ASSOCIATES

Dr. KRETCHMER. Thank you, Mr. Chairman.

To my immediate left is Dr. Betty Pickett, the Deputy Director of the National Institute of Child Health and Human Development. To my far left is Mr. Joel Hedetniemi, the Executive Officer of the Institute.

Each year, Mr. Chairman, more than 45,000 infants die in the United States. Most of them die from birth defects or infections or because they are of low birth weight. Seven of every 100 infants born alive have physical or mental handicaps that will last a lifetime. One in every 7 pregnancies, some 500,000 each year, is not planned, and 2 million couples who want to have children are unable to have them.

Such problems, originating early in life or occurring during the reproductive years, are an economic burden on society. The cost of birth defects is at minimum $2.5 billion a year for hospitalization, physicians' fees, and various services. The most amazing figure is that intensive care for low birth-weight babies will cost an estimated $6.5 billion this year, and this cost is increasing each year.

INSTITUTE MISSION

The mission of the National Institute of Child Health and Human Development is to support and conduct biomedical and behavioral research, with the goal of increasing scientific knowledge and applying it to prevent and cure these costly problems as well as many others.

Much of the work of the Institute is aimed at understanding normal human development and processes—the fertilization of an egg; the transformation of that fertilized egg into an infant; the growth of an infant into a productive, healthy adolescent and adult; and the complexities involved in contraception, childbearing, and childrearing, as well as relationships within a family.

Elucidation of human development is an intriguing and profound challenge of modern science. Moreover, concentration on early development, when many diseases and disorders originate, places the NICHD in a prime position to contribute to preventive medicine.

RESEARCH HIGHLIGHTS

I would like to share with you today, if I may, some of the gains that have been made in particular areas; namely, pregnancy, fetal medicine, mental retardation, child development, contraception, and reproduction. I will just mention them as highlights.

The infant death rate in the United States has dropped dramatically since the 1950's because research has shown us how to save more babies of very low birth weight. Still, 75 percent of infant mortality is linked to low birth weight.

Scientists supported by the NICHD are learning to prevent prematurity and low birth weight by studying how labor begins and how the mother nourishes the fetus.

Advances in the past decade in understanding the developing embryo and fetus have been paralleled by new knowledge needed to begin detecting and correcting many disorders before birth. With advances in technology offering a direct access to the fetus comes the hope that more problems can be prevented before birth. This is fetal medicine.

In animal models it is now possible to prevent, by drug therapy or hormone replacement, certain congenital defects of the eye, the palate, or the genitals.

More than 6 million people in the United States are mentally retarded, and the number increases by at least 126,000 new cases each year. Mental retardation costs approximately $10 billion per year in public funds, and is caused by biological, sociological, psychological, or environmental factors. Therefore, some of the most important research supported by the NICHD is directed toward answering basic questions related to brain development. As these questions are answered, scientists will begin to understand more about mental retardation.

The NICHD supports the largest program in the world for the synthesis of modified copies of a substance called luteinizing hormone-releasing hormone. The modified copies of this hormone could herald a new generation of contraceptives that are safe and effective for both men and women. These compounds have been used successfully to treat specific problems associated with infertility and a particular gynecologi-

cal disorder in children. They also hold promise for treating certain hormone-dependent cancers.

As I stated earlier, the problems addressed by the National Institute of Child Health and Human Development are among the most significant and costly problems of our society. The NICHD program could have a great impact on health care expenses in this country, because the diseases and disorders we seek to prevent are costly lifelong problems.

Mr. Chairman, I would be glad to answer any questions or to supply any additional data for the record.

Senator ANDREWS. Thank you, Doctor, for a most interesting presentation. I notice you got your B.S. in animal physiology at Cornell. That's not bad.

Dr. KRETCHMER. I listed animal physiology because many people do not understand animal husbandry, which is what I really studied.

Senator ANDREWS. It sounds so much more impressive. I'm glad to see you carried on with that interest. My grandfather graduated in the first graduating class from Cornell in 1870.

Dr. KRETCHMER. That was before my time. [Laughter.]

Senator ANDREWS. He went out to Nebraska. He graduated in agriculture and went to Nebraska and started farming. And the grasshoppers got him one year and the drought got him the next year. And he chased cattle up and down the Chisholm trail to make enough money to go back home, which was the town of Prairie Center, N.Y., upstate New York, not too far from Cornell.

Dr. KRETCHMER. My son has his Ph. D. from Cornell, in vegetable crops.

Senator ANDREWS. He came into town with his pony and his six-guns and he figured it would be better to go back to school again, so they sent him to the University of Michigan to study medicine, which is where he got his M.D. degree. He came out to North Dakota after first going to New York City. I guess they didn't have any type of women's rights in New York City for women physicians in the 1870's, so my grandmother, who was also a physician and classmate of his, said let's abandon New York City. So they went out to the Dakota Territory just 3 years after Custer got his in the Battle of Little Big Horn and they set up a medical practice, and a whole host of other things. My grandfather died in 1904.

And there was a fellow on the farm just south of us who was not quite right, but he could function, and my grandfather had to sew up a hole in his head from being kicked in the head by a horse. So those early day physicians were pretty darn competent.

I saw that Cornell thing and that brought back some old memories. We've been there to the campus, and my daughter was interested in veterinary science and was thinking of going to Cornell at one point but decided that she would go into human medicine.

One of the old windows in that chapel is dedicated to my great aunt and one to my great uncle. It's a beautiful spot. But that's taking up too much time.

I assume that you are getting the proportional amount of funding that will keep you up to the NIH goal of 5,000 new and competing research grants. Is that correct? You are not being discriminated against?

Dr. KRETCHMER. No; in President Carter's 1982 budget we were expecting to pay 373 new and competing grants for a total amount of approximately $41 million, which is our share of that stabilization.

PROGRAM PRIORITIES

Senator ANDREWS. Now faced with a major budget cutback, what would your priorities be?

Dr. KRETCHMER. My priorities are similar to those of witnesses who preceded me. My first priority would be research grants, because they pay investigators at the grassroots. And my second priority would be our research centers program. The reason is that we think the centers address particularly important problems. For example, population research, perinatology and infancy, and mental retardation.

The third priority would be training, because there has to be an influx of new people or the field will wither.

The fourth priority would be our own intramural program, which we consider very important. It is the program that is based at Bethesda.

SUDDEN INFANT DEATH SYNDROME

Senator ANDREWS. In the field of ongoing programs in crib death, sudden infant death syndrome, what is the status of your research on this?

Dr. KRETCHMER. Well, each year over the past few years we have increased the fiscal support of research on sudden infant death syndrome.

Senator ANDREWS. You have been doing it for just 3 years? That is the length of time you have been doing this research?

Dr. KRETCHMER. No; I referred only to the past few years in which we have been increasing the fiscal support of the program. It has been a very interesting field. When I first came to the Institute 7 years ago, it was estimated that approximately 10,000 infants died of crib death each year. Now we estimate the number at about 6,000. The lower number may be because we have better statistics, or because we have made people more aware. It is very hard to say.

The type of research that has evolved has shown that these babies are not well babies to begin with. They are really not. A good number of the sudden infant death babies come from the group of premature infants.

We have raised questions as to possible genetic causes.

Further, we have been able to show over the years that there is a relationship to the breathing apparatus and that some of these babies, to put it bluntly, probably suffocate.

We now have a major study which involves six research centers looking into the epidemiologic aspects of sudden infant death syndrome. Data from these centers are now being analyzed. We expect results from this study by the end of this year.

Senator ANDREWS. How long have you been doing this research?

Dr. KRETCHMER. Sudden infant death?

Senator ANDREWS. Yes.

Dr. KRETCHMER. The Institute actually started, if I remember, in the middle 1960's. So it has been about 15 years.

Senator ANDREWS. And how much money have you spent to date on this research? Could you provide that for the record?

Dr. KRETCHMER. I could provide that for the record.

[The information follows:]

FUNDING FOR SUDDEN INFANT DEATH SYNDROME RESEARCH

From fiscal years 1964 through 1980, the NICHD obligated a total of $104,983,000 for support of research on sudden infant death syndrome. Cumulative amounts for 1964–77 include obligations for primary and subsidiary research only. Starting in fiscal year 1978, an additional amount has been included for a tertiary category—research in high-risk pregnancy—indirectly related to sudden infant death syndrome.

PREVENTING SIDS

Senator ANDREWS. And you would be indicating to the committee, if I understand you properly, that the outlook for controlling this syndrome probably lies more with thorough examination of the infant at the time of birth than any other one thing, if in fact it is the weakened infant, the subpar infant who is coming to this sudden infant death syndrome. You think you found that there isn't any new—well, not new, but any lurking type of strange disease that has been striking out of the blue.

Dr. KRETCHMER. You are absolutely correct, Mr. Chairman. I think that we would make the greatest impact on sudden infant death if we could reduce prematurity. It is exactly what you said. If we could reduce the number of weaker babies by preventing prematurity then we would reduce the number of sudden infant death syndrome babies.

Senator ANDREWS. What percentage of these babies that succumb to the syndrome are premature?

Dr. KRETCHMER. Many of them are.

Senator ANDREWS. I know. But what percentage?

Dr. KRETCHMER. I don't know the percentage offhand.

Senator ANDREWS. Could you provide that for the record?

Dr. KRETCHMER. Certainly.

[The information follows:]

SUDDEN INFANT DEATH SYNDROME

Based on data obtained in two studies, it has been determined that 25 percent of babies who died of sudden infant death syndrome were premature.

ORAL CONTRACEPTIVES

Senator ANDREWS. In the news lately, of course—in fact, the Washington Post over the weekend had a big article about oral contraceptives, and there still seems to be a good deal of uncertainty about the health risk associated with them. Where do we stand on this?

Dr. KRETCHMER. I don't know if you had an opportunity to read the articles that came out, about a week ago, in the Washington Post.

Senator ANDREWS. I thought I saw it last weekend.

Dr. KRETCHMER. That's right, this past weekend. Those articles really didn't describe, for the most part, quite fairly what is going on in the Institute. Over the past 12 years, we have supported a study at the Kaiser-Permanente Medical Center in Walnut Creek, Calif., more than 16,000

women of various ages were studied. Within the group were women who were currently using an oral contraceptive, women who had never used an oral contraceptive, and women who had used oral contraceptives in the past.

The articles that you have seen in the newspapers over the past couple of years came primarily from that Walnut Creek study. The study showed that the pill, in certain women, was associated with thrombophlebitis, which is an inflammation of the veins, and that it was associated with an increase of stroke in certain women. In addition, women more than 35 years of age who took the pill and who smoked, had something like a fortyfold increased chance of having stroke or heart failure than women who don't take the pill and who don't smoke.

The results from Walnut Creek are now being analyzed more thoroughly, but I think one point of caution has to be made that was not in the newspapers. Millions of women have taken millions of pills over the past 13 years, but only a few women have suffered adverse side effects. So, you probably have to consider a genetic susceptibility also.

The analysis of the Walnut Creek data probably will be finished this year. Two volumes have already been published and the third and final volume is in preparation.

RISK VERSUS BENEFIT OF ORAL CONTRACEPTIVES

Senator ANDREWS. How do you analyze this risk, which gets into pretty basic stuff? I remember the Food and Drug Administration came before another subcommittee that I was on back when Dr. Edwards was the head of that several years ago, and they had done some work in morning-after contraceptives, and it was at exactly the same time that they banned the use of stilbesterol—to go back to yours and mine agricultural training—as a part of the cattle fattening ration which, as you know, lowered the price or the cost of fattening a steer by about 20 percent. And I asked the doctor, because I was intrigued, why they had banned the use of stilbesterol in feeding livestock in the same week that they had OK'd the use of stilbesterol in the morning-after birth control pill. And we got into quite an interesting discussion.

And, of course, we developed through the questioning period the fact that the only place they ever found residues of stilbesterol in the beef animal was not in the skeletal tissue but only in the liver and in the kidney, which is not a big factor in the American diet at all.

And then I asked the people in the third row, and we haven't had that experience here today, but over there we would see what you had in the front row, and then backup people in the second row who did all the whispering to the people at the table who never seemed to have the answers. You guys are just great. We haven't had too much of that today. But then back in the third or fourth row were the people who could actually answer the question. And my question was, what is the most grossly contaminated case of beef liver you've ever found?

And they came up with a figure. And I said how much of that liver would a woman have to ingest to equal one of these morning-after birth control pills. And, of course, the answer came back, 35. And I said, a woman would have to have 35 pounds of the most grossly contaminated beef liver you have ever found to ingest the same amount of stilbesterol she would get in one of these pills?

And from the second row came up, "No, Congressman, not 35 pounds, 35 tons." And then there was some laughter in the fourth or fifth row back where they had the sliderules going, and I said there must be more to this than we've developed so far. And I said what's the laughter all about?

And then came the answer back from the back that, you know, you only asked part of the question. It is not one pill, it is one pill a day for 5 days.

And I said it is 5 times 35 or 175 tons?

And the answer came back, "Yes."

So one agency of the Government says it is unsafe to feed livestock something that lowers your cost of production by 20 percent, but the residue in the most grossly contaminated form ever found a woman would have to eat 175 tons of beef liver to equal one course of 5-day treatment.

Where do we draw the line? Where do we find out in the case of birth control pills and oral contraceptives what is safe and what type of figures can we, who sit on this side of the hearing table, and I will admit that we've got some basic law to look at, the Delaney amendment and a host of other things, but in medical judgment, where do the risks outweigh the benefits? Have you got any insights that you can give us briefly on that and perhaps expand for the record?

Dr. KRETCHMER. The point that you make about the risks versus benefits is a very important one. I think that the risks may be relative to age of the individual. There is no increase in heart disease in women 20 or 25 years old who are taking the pill. The risk is to the older group of women. The risk has been well reported to the general public over the past 2 or 3 years via the newspapers.

The pill is a very effective agent, but the number of pills that are being consumed has fallen off appreciably in the past year. So what is happening is that women in the general public are making their own decision.

SAFETY OF ORAL CONTRACEPTIVES

Senator ANDREWS. But in your capacity as head of this arm of NIH, is there cause for alarm, given the benefits versus the detriments of this particular type of birth control?

Dr. KRETCHMER. We have stated, Mr. Chairman, in the foreword to the most recent volume of the Walnut Creek study, the indication that there are some risks in taking the pill. The risks are well stated. We can't say with certainty whether a given woman who takes the pill at a particular age, with or without heavy smoking, would develop thrombophlebitis. We just don't know. All we can say is there are some risks, just as with any other drug.

With the thalidomide situation that you mentioned earlier there was a risk. And the risk was well stated, that if a pregnant woman took thalidomide, which was a very good sedative, between 20 and 40 days of pregnancy, then the odds on having a baby with abnormalities were very high.

I would say offhand, to paraphrase what you said, I don't think that there is a cause for alarm. A person must be aware that there are certain risks attached to a drug. These are the risks attached to the pill.

There are risks attached to aspirin, which most physicians know. You can certainly get gastrointestinal trouble from aspirin.

Senator ANDREWS. In other words, you would suggest to your daughter that there is nothing wrong with such a course of birth control? That's the best way of getting it down to the basics?

Dr. KRETCHMER. If my married daughter were over 35, I would probably tell her to be careful and use other means of contraceptives.

Senator ANDREWS. But up to 35, you'd suggest that she use that?

Dr. KRETCHMER. But then she would be aware of the potential problems.

Senator ANDREWS. Senator Hollings?

NUTRITION PROGRAMS

Senator HOLLINGS. Thank you, Mr. Chairman.

Dr. Kretchmer, is there any coordination whatever between nutrition programs in our Government, feeding for children, for example, women, infants, and child feeding, nutrition programs, and the National Institute on Child Health and Human Development? Is there any coordination, whatsoever?

Dr. KRETCHMER. Yes, Senator Hollings, there is a good deal of coordination. Let me describe the coordinative levels. We have a coordinating committee within the NIH that relates to a coordinating committee within the Department. There is also an interdepartmental coordinating committee. But I would rather speak about the Child Health Institute itself. The Child Health Institute has a very close relationship with the people in the Department of Agriculture, particularly those in the Agricultural Research Division, not so much the WIC program, but the programs that are dealing with nutritional research in the Department of Agriculture.

Also I sit on the Scientific Board of the Infant Nutrition Center, established at Baylor University, which is a U.S. Department of Agriculture center.

I also relate to the new center being built up by the Department of Agriculture at Letterman Hospital, which is supposed to be a surveillance center, and which will be involved peripherally in the WIC program because it is supposed to look at nutritional status. That center involves the University of California, as well as the Department of Agriculture.

So there are coordinating activities among the Institute, the Department of Agriculture, and the Bureau of Foods of the Food and Drug Administration.

Senator HOLLINGS. And that is administrative. Now medically speaking, with respect to—I will get right into the nutrition programs or WIC, women, infants, and children. Medically speaking, I take it, you consider this to be a program supported by Child Health, or don't you?

Dr. KRETCHMER. It is a program that certainly relates to child health and the health of women. It is a program, however, administered by the Department of Agriculture, and it relates to our type of research activities.

Senator HOLLINGS. Let me get to the specifics of what I'm trying to get to. I'm trying to see if, whether when we make cuts, and we all are going to make certain cuts, whether we are really solving a problem or, in essence, creating a problem. You and I both have 13 billion brain cells, I understand from various brain doctors, and there have been many of us who have done research in this field that say that 10 of the 13 billion are developed in the first 5 months in the woman's womb, and a lack of the proper nutrition can cause as much as 20 percent brain cell development in that first 5 months.

Now if you lose 20 percent or 2 billion of those cells, George Wallace will tell you, they will never repair, can never repair injury or loss of that particular thing. And there's a definite connection between retardation and the ability, what you might call inorganic brain damage, generalized damage, to concentrate or to assimilate educable children.

I'm told that if, back as a Governor, for example, that if I cut that, and I look at my mentally retarded in the Institutes of Health there, and I'm paying out for every mentally retarded child, $787,000, and they're living longer. Longevity is extending. So if I cut out my feeding program, I've saved a few million here, but I might be wasting billions on the other end of the spectrum.

You know, the greatest subject discussed in this regard would be an expectant mother who can't identify the father and violated all of the welfare rules and every other thing, so we can, administratively, governmentally, give her nothing, but economically, other than healthwise, we really by giving her nothing, are cutting our nose off to spite our face, aren't we? I mean, medically speaking, isn't a wise thing to make sure not just that the mother gets nutrition, but that the child does, early on in the pregnancy?

Dr. KRETCHMER. I agree with you completely, Senator Hollings. I think what you have described is preventive medicine. I don't think we even need think in terms as seriously as mental retardation, but how the individual is going to perform in school. Whether that child is going to be a person who might fall asleep in school, and, therefore, won't make the social contribution that the child might have the potentiality for. There's no question that nutrition has always been one of the basic elements in our development. And it relates not only to the development of the brain, but also to the development of the whole organism and the ability of the organism to perform in whatever environment it must function, as a schoolchild, or eventually in the workplace.

I think the point you've made in terms of looking at one end of the spectrum and seeing what's going to happen at the other end of the spectrum is the credo of preventive medicine.

Senator HOLLINGS. Thank you very much, Mr. Chairman.

Senator ANDREWS. Thank you, Senator Hollings.

I have a number of other questions that I will put in, and you may answer for the record, Doctor, and I appreciate your contribution to the committee hearings, and wish you well.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

BIRTH DEFECTS

Question: How common are birth defects involving the musculoskeletal system? (Note: Included in this category of disease are congenital dislocation of the hip, abnormalities of the arm and hand, brittle bone disease, etc.)

Answer: Birth defects involving the musculoskeletal system occur often but it is difficult to state their specific incidence. They are exceeded in frequency only by anomalies of the central nervous system and cardiovascular system. Musculoskeletal defects are represented by such entities as abnormalities of the arm and hand, congenital dislocation of the hip, clubfoot, osteogenesis imperfecta (Brittle Bone Disease), and many others.

The following examples can be offered. Approximately 45,000 of the 3,000,000 babies born each year have defects of the hand and upper extremity and about 20% of these are related to genetic factors that may be transmitted to their own children. Approximately two out of every thousand babies have a congenital dislocation of the hip which may have an associated anomaly of the joint as well. Clubfoot is twice as common in males as in females and occurs in two out of every 1,000 live births. Approximately 20% of these defects are believed to result from some genetic component. Brittle Bone Disease, a metabolic disorder of bone development, results in multiple fractures producing severe deformities. The cause is still unknown.

Question: Do you currently support a research program in growth disorders involving the musculoskeletal system? If so, how big a program -- in terms of dollars?

Answer: Since its inception the NICHD has supported research on physical growth and the musculoskeletal development of infants, children and adolescents. Currently the Institute is funding a group of studies which include skeletal development, human cartilage, and the effects of growth hormone on musculoskeletal development.

This program included 15 projects funded at the level of $1,250,000 in FY 1980.

Question: It is our understanding that scoliosis is a major problem affecting young females. What is the incidence of this disorder and what research are you supporting in this area? (Note: Scoliosis is a lateral curvature of the spine. Most children live their adolescent life in a cast or brace to attempt straightening of the spine.)

Answer: Scoliosis is a lateral curvature of the spine that occurs in otherwise normal children, but is also found associated with some diseases of the central nervous system. Milder forms of scoliosis occur as often in young males as in females. However, the curvature of the spine in females frequently results in a more severe deformity that in males. Routine school screening for scoliosis now allows earlier detection and provision of brace treatment to prevent development of more severe conditions. This has resulted in a decreased need for surgical correction. It is estimated that approximately two percent of teenagers will need close observation or treatment for scoliosis based on its present incidence and the current detection methods.

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The NICHD is currently funding various studies concerned with cartilage and muscle development both for normal and abnormal conditions. In addition, studies of tissue interaction involving muscle, bone and nervous tissue are directed toward better understanding of tissue and cellular interactions. These basic approaches to health problems are important to improved understanding of underlying causes of these defects.

TEST TUBE FERTILIZATION

Question: We understand you have been working on test tube fertilization in regard to laboratory animals. Can you bring us up to date on this undertaking?

Answer: NICHD supported 40 projects in FY 1980 for a total of approximately $2.7 million in the area of in vitro (test tube) fertilization in a variety of animal species. There has been an increase in the number of projects using the primate model for this type of research. The studies cover a broad range of research interests, including the biochemistry of the maturing sperm, the interactions of the sperm and egg at the molecular level, immunologic factors involved in fertilization, analysis and characterization of sperm and egg surface components, and the biochemistry and physiology of sperm motility.

To varying degrees, success has been obtained in virtually every animal species in which in vitro fertilization has been attempted. It should be noted, however, that this technique may lead to an increased incidence of genetic defects in early embryos. Because most, if not all, such embryos either do not implant or fail to survive to term in utero, there is no convincing evidence that in vitro fertilization leads to any significant increase in the number of abnormal offspring.

Question: You are banned, are you not, from doing any of this testing on humans?

Answer: Yes. Since 1974, the Department of Health and Human Services (formerly the Department of Health, Education, and Welfare) has withheld support for research on human in vitro fertilization.

ADOLESCENT NUTRITION

Question: What is the Institute doing to make more information available on adolescent nutritional status?

Answer: The NICHD program on adolescent nutrition, initiated in 1972, emphasizes three important areas of adolescent nutrition: (1) nutrition and the adolescent growth spurt, (2) obesity in adolescence, and (3) nutrition of the pregnant adolescent. In 1973 the NICHD sponsored a conference on nutrient requirements in adolescence, the proceedings of which were later published as a book. The NICHD has also published a pamphlet on adolescent nutrient requirements for distribution to the general public. This pamphlet has gone through two printings, and 30,000 copies have been distributed.

Recently, the NICHD has sought to stimulate more research on adolescent nutrition, especially in the area of eating habits during adolescence. A program announcement which emphasized this aspect of

adolescent nutrition was published in January, 1980. Research applications dealing with adolescent obesity, iron intake of adolescents, and the development of anorexia nervosa have already been received in response to this announcement.

Question: Does a separate program exist in this area?

Answer: No, the adolescent nutrition program is part of the general program in Nutrition and Endocrinology administered under the Center for Research for Mothers and Children of the NICHD. In FY 1980 the adolescent nutrition program consisted of 12 extramural research projects funded at the level of $1,032,000, and one intramural project on obesity in childhood and adolescence, funded at the level of $153,000.

Question: Is the research funding adequate?

Answer: Yes, considering the balance of the entire nutrition research activity, although it is smaller than other nutrition programs of the NICHD. Fewer applications are received in this area than in other areas of nutrition. This situation is caused by the difficulty of the research area since it is much easier to ascertain accurately the total daily nutrient intake of an infant than that of an adolescent.

MENTAL RETARDATION

Question: NICHHD invests a portion of its total annual budget in the general area of mental retardation. This amount comes to approximately $31 million in the FY 1982 budget. What do the statistical figures tell us about the incidence of mental retardation in the general U.S. population?

Answer: Different estimates have been made of the prevalence of mental retardation. The traditional method, based upon the normal distribution of intelligence test scores, places the number of mentally retarded in 1979 at an estimated 6.6 million Americans, or 3% of the general population. Some authorities, employing adaptive behavior criteria in addition to measures of intelligence, estimate the frequency to 1 to 2 percent of the population. Still other authorities expand the estimated number of retarded individuals by including the less severely affected--that is, persons with I.Q.s up to 80 and with problems in social adaptation.

Question: Is the number of retarded children born each year on the decline?

Answer: A precise answer to this question is possible only for discrete disease entities associated with mental retardation. Evidence does exist that the numbers of children born who have Down syndrome and mental retardation consequent to phenylketonuria (PKU) have declined.

The observed reduction in the incidence of Down syndrome has been attributed mainly to prenatal diagnosis and selective pregnancy termination, and a progressively smaller proportion of women 35 years of age or older who are having babies.

The widespread newborn screening programs for PKU have detected a large number of children with the disorder. Early intro-

duction of a special diet which maintains the level of phenylalanine within normal limits has prevented the occurrence of brain damage which is invariably observed in untreated infants with PKU. A 1974 survey of 117 institutions for the mentally retarded in the United States and Canada showed no admissions of children with PKU in states and provinces where newborn screening for PKU was being performed at the time of birth.

Question: What research advances are being made or are in the offing?

Answer: In order to study how infants learn and perceive their worlds, researchers have devised special new techniques. One of the important benefits of this research is the possibility of applying these new techniques to screen infants soon after birth to identify those who are at risk for mental retardation. Development of these new screening methods will allow early enrollment in treatment programs designed to prevent retardation in learning and language abilities which otherwise would result. In addition, some of these learning techniques will be used to treat infants who are at risk for mental retardation.

A number of behavioral scientists, some in the mental retardation centers, have been making great strides in improving the learning abilities of mentally retarded children and adults. These scientists have found that providing the retarded with training in how to remember enhances their ability to learn and remember material.

Research advances in genetics with special emphasis on the genetic aspects of the Down and Fragile X syndromes are being made and have good prospects for making future progress toward our understanding of these and other genetically-based disorders.

Down syndrome, with an incidence of 1 per 800 live births, is the most common and readily identifiable genetic condition associated with mental retardation. Five percent of mentally retarded males with I.Q.s within the range of 30-55 are estimated to have the Fragile X syndrome. This condition results from the apparent instability of a segment on the X chromosome producing a clinical picture characterized by mental retardation, enlarged head, and malformed ears among other features. The condition is the most frequent genetic cause of mental retardation in males.

A research contract currently supported by NICHD deals with the development of a mouse model for the chromosomal abnormality exemplified by Down syndrome. This project has demonstrated that, based on the products that are known to be generated by the genes on human chromosome 21, the genetic material of mouse chromosome 16 possesses an homologous relationship to the human chromosome 21. Morphological, histological, developmental, molecular, and biochemical studies of the mouse model will help us understand the basic mechanism involved in the faulty arrangement of chromosomes. The mouse model will enable investigators to initiate studies that are difficult to carry out on human subjects for scientific or ethical reasons.

Cells from the skin of males with the Fragile X syndrome and from females carrying the abnormal X chromosome have been cultured successfully. In addition, the tissue culture conditions which

will optimize detection of the marker X chromosome are currently being studied. These studies will help in the development of cytogenetic techniques which will lead to the prenatal detection of the Fragile X syndrome, reliable diagnosis of carriers, and a more complete characterization of the clinical manifestations of the syndrome. The eventual goal of these projects is to prevent the occurrence of the syndrome.

INFANT MORTALITY

Question: Where does the United States rank compared to the rest of the world in the area of infant mortality?

Answer: The last year for which reasonably complete figures have been published is 1978. Based on final and provisional international data for that year, it appears that the final U.S. rate of 13.8 infant deaths per 1,000 live births will rank about 16th among countries with a population of 2 million or more. Preliminary and provisional data for 1979 indicate that our rate of 13.0 will rank about 13th.

Question: In 1977 the Institute estimated that the U.S. ranked 12th with a mortality of 14.1 deaths per 1,000 live births. Have we improved throughout the remainder of the decade?

Answer: Yes. The provisional 1979 rate of 13.0 deaths per 1,000 live births represents a 7.8% improvement in two years. Final data for 1980 are not yet available, but provisional monthly analysis shows continued improvement and indicates that the 1980 rate will be below 13.0. Although international rankings fluctuate slightly from year to year, the overall recent trend is steady progress in all the leading countries in infant mortality.

Question: Have we made any progress in lowering the infant mortality rate in some of our States and cities that are more troubled by this problem? Our National Capital, for example?

Answer: The States with the highest infant mortality rate and the District of Columbia have made varying amounts of progress. This table documents the changes, based on place of occurrence, for the five areas having the highest rates in 1977.

	1977	1978	1979 Provisional
District of Columbia	23.9	24.7	19.3
Louisiana	18.0	17.7	14.8
South Carolina	17.8	18.6	17.2
Mississippi	17.3	17.9	17.8
Alabama	17.0	16.0	14.4

INFANT FORMULA

Question: As a follow-up to the problems discovered last year with infant formulas determined to be deficient in chloride, what research has the Institute initiated to increase our knowledge of the appropriate levels of nutrients in infant formulas?

Answer: The occurrence of hypochloremic metabolic alkalosis among some infants fed formula deficient in chloride pointed out

the need for increasing our knowledge on the appropriate levels of nutrients in infant formulas and other foods fed during infancy. These research needs have been recognized by the NICHD since the early days of the Institute and were, in fact, highlighted again in 1978 with a Request for Grant Applications entitled "Infant Nutrition." Since that time, the Institute program has grown to over 60 projects funded at a level of $5.1 million. Included in the program are a variety of projects designed to elucidate metabolic needs and tolerances throughout infancy. Other studies focus on human milk to understand better how specific factors of this unique fluid function to maintain health and to sustain rapid growth rates during infancy. Another important aspect of the infant nutrition research program is to understand better how certain foods or food components cause strong adverse reactions in the infant and how to prevent these reactions. An integral part of knowing what to feed infants is learning how the intestinal tract of the newborn digests food, accommodates new foods, and resists invasion by foreign proteins and infective agents. This aspect of the nutrition program of the NICHD currently supports an additional 11 projects that account for over $1 million.

These projects and those that have gone before have lead us to the current state of knowledge that permits the establishment of nutrient levels for infant formula promulgated in the Infant Formula Act of 1980. Present and future studies are critical to refining these nutrient levels and establishing nutrient levels where the present state of knowledge does not permit establishing safe ranges.

CAFFEINE AND ALCOHOL IN PREGNANCY

Question: An increasing body of evidence has suggested that the consumption of alcohol and caffeine by pregnant women contributes to birth defects. While definitive evidence is still lacking, some attempts to warn the public have already appeared. To what extent is your Institute investigating the effects of caffeine and alcohol on the outcome of pregnancy?

Answer: The NICHD supports a limited program for specific studies on the effects of caffeine and alcohol on the outcome of pregnancy. With reference to effects of alcohol on pregnancy, NICHD funded four extramural grants ($213,148) and one intramural project ($39,653) in FY 1980. The only study NICHD is supporting in effects of caffeine upon outcome of pregnancy is a minor part of an epidemiological surveillance examining uses and consequences of a great number of foreign compounds.

DOWN SYNDROME

Question: According to your statistics, surveys have shown that the incidence of Down syndrome is one per 800 live births. Where do we stand on research into this condition?

Answer: Application of staining techniques, which produce distinct alternating light-and-dark banding patterns on each chromosome, has enabled investigators to delineate precisely that segment of chromosome 21 which is responsible for the clinical manifestations of Down syndrome. Down syndrome is attributable to trisomy, i.e., the presence of three instead of two segments on chromosome 21. With the advent of newer techniques it may now be possible to assign a specific sequence of trisomic segments on chromosome 21 to indivi-

dual clinical manifestations of Down syndrome.

The previously held assumption that all cases of Down syndrome originated from a defect in the ovum is refuted by recent research findings. Investigators have now shown that the chromosomal defect in 20-25% of cases of Down syndrome is of paternal origin. This observation has a major effect on genetic counseling and in determining the factors that might contribute to the birth of a baby with Down syndrome.

In FY 1980, NICHD supported 17 projects with a primary emphasis on Down syndrome for the total amount of $1,423,728. These projects included five research grants, four program projects, four center grants, two research fellowships, one research contract, and one project which was conducted by a member of the NICHD intramural staff.

Question: What is the status of the animal model you are developing for use in research on Down syndrome?

Answer: Restraints placed upon research using human subjects, particularly those involving minors, mentally retarded individuals, or those who cannot provide informed consent, have made it necessary to develop alternatives such as animal models. Animal models enable the conduct of research projects which cannot be carried out on human subjects for ethical and scientific reasons.

By selectively breeding a mouse with a specific chromosomal abnormality with a normal mouse, it is now possible to produce litters that have three, instead of two chromosomes of a given type. The investigators have demonstrated that two of the three genes that are present on human chromosome 21 (the chromosome involved in Down syndrome) are located on mouse chromosome 16.

Techniques are being developed to maintain mouse embryos in a state capable of being reimplanted at a future time. These embryos will be distributed to research investigators, thus facilitating research on Down syndrome using this animal model.

CONTRACEPTIVE RESEARCH

Question: According to your own justifications, one in every seven births is unwanted and about 17% of all births yearly are to girls between the ages of 15 and 19. Don't these statistics tell us that research has been inadequate to the task of finding a contraceptive that is safe and will be widely used?

Answer: It is true that during the past decade there has not been a major breakthrough in terms of marketed contraceptives. Also, acceptability and continuation rates for the major fertility regulation methods currently in use are not high and contribute to unplanned pregnancies. Additionally, concerns over the safety of oral contraceptives and intrauterine devices have decreased their overall utilization.

Research programs supported by NICHD focus on the development of safe, efficacious and acceptable methods of fertility regulation. The purpose is to develop an array of methods that can be used successfully by different couples under various circumstances. This

program, which is necessarily broad in scope, includes research in progress that is likely to lead to safer fertility regulating drugs, improved barrier methods of contraception, as well as improved methods of drug administration. Many of these studies have progressed to the stage of clinical testing. We have also shown that natural family planning methods, if used correctly, are effective. Research in the area of fertility regulation is a lengthy and complex process. In general, we are dealing with healthy people and consequently must observe very strict guidelines for safety. Progress is definitely being made and new contraceptives will become available in the future if the carefully planned sequence of developmental efforts continues. Since it is unlikely that any single contraceptive approach will satisfy the needs of all of the people who desire to limit their fertility, a variety of methods will continue to be explored.

A new approach to fertility regulation using derivatives of brain hormones offers exceptional opportunity for research progress leading to a new generation of contraceptives for both men and women. The NICHD has started a major program of clinical trials to assess the use of certain of these derivatives. The development of modified copies, or analogs, of luteinizing hormone releasing hormone (LHRH) is the direct result of the basic research on brain hormones by Drs. Andrew Schally and Roger Guillemin, both supported by NICHD, which won them the 1977 Nobel Prize in Medicine and Physiology. LHRH, produced in the brain, enters the bloodstream and is carried to the pituitary gland where it stimulates the pituitary to secrete other hormones that regulate the functions of the ovary in women and the testis in men. If proven successful as fertility regulators, the derivatives in men will suppress sperm formation and in women will suppress ovulation on a regular basis with minimal side effects and be more advantageous than the currently used oral contraceptives.

Question: Why should we appropriate $16 million for contraceptive development and evaluation?

Answer: Much of the research involved is too long-range and uncertain of early payoff to be undertaken by industry. Continuing research efforts are planned for FY 1982 toward the achievement of NICHD program goals in the areas of contraceptive development and evaluation which require the requested level of funding. These program plans include the following examples:

Contraceptive Development

1. LHRH Analogs - Clinical trials will be continued of synthetic copies of the hypothalamic releasing hormone (luteinizing hormone releasing hormone agonist). Preliminary results in female subjects indicate that ovulation can be inhibited with the timely injection of these drugs.

2. Barrier Methods - Efficacy studies on the cervical cap will be continued, involving large scale trials which are intended to provide sufficient data to make an improved cap available to the general public. A clinical trial of a contraceptive sponge diaphragm will also be continued to obtain information on the acceptability and efficacy of the sponge diaphragm in comparison to the currently available ones.

3. Long-Acting Injectables - Clinical trials of the long-acting injectable female contraceptive, norethindrone enanthate, will be con-

tinued for the purpose of obtaining sufficient information on the efficacy and safety of this preparation. The NICHD effort will compliment the efforts of the World Health Organization (WHO) and will help provide information sufficient to make a decision on marketing of the product.

4. Natural Family Planning (NFP) - Although NFP depends on abstinence during the fertile period, current methods of ascertaining the woman's fertile period are rather crude. A more objective method of defining the fertile period is needed and will be pursued.

Contraceptive Evaluation

1. Variations in steroid blood levels in women taking oral contraceptives. Studies will be initiated to determine whether there is substantial variation among women in the levels of the drugs which they maintain in their blood after taking a standard dose of the pill. If differences in blood levels of the drug are associated with differential risks of adverse effects, a simple screening method would be available to identify women at high risk, permitting them to use other methods of contraception.

2. Reversibility of vasectomy and tubal ligation. A clinical study will be undertaken to investigate the reversibility of vasectomy and the factors involved in restoration of fertility. Research will also be supported on the factors that influence reversibility of tubal ligation. As increasing numbers of men and women elect sterilization as a method of contraception, requests for reversal are increasing, in part due to changes in family circumstances.

3. Mechanisms of post-vasectomy atherosclerosis. Studies will be initiated to identify the mechanism involved in the marked increase in atherosclerosis which occurs in vasectomized monkeys. Studies will determine whether vasectomy increases the risk of cardiovascular disease in man.

4. Mechanisms of adverse effects of oral contraceptives. Research will be started to identify the biochemical mechanisms involved in the various adverse effects of the pill, particularly cardiovascular diseases. Studies have established that cardiovascular disease is the most serious risk of oral contraceptives. Data from these studies can be used to identify drug formulations which offer the least risk of cardiovascular side effects and to guide the development of new formulations.

FUNDING FOR POPULATION RESEARCH

Question: Last year you were projecting a downward trend in the funding of population research by private foundations such as the Ford Foundation, Rockefeller Foundation, and The Population Council. Has the decline continued? If so, why?

Answer: The total funding of population research by these private foundations has remained about constant, although two of the three of these organizations have continued to experience a decline in funding. Information available to the NICHD indicates that the decline is generally due to decreasing income and also to changing priorities that reflect new areas in which they are providing "seed" money.

Question: What are your plans for increasing this funding so as to reduce the financial burden on the Federal government?

Answer: The NICHD maintains its liaison and coordination of activities with the foundations, including the identification of research areas where support by non-Federal sources could be used most effectively. However, the Institute has no means by which to otherwise influence the foundations' allocations for population research.

Question: What, if anything, are the States doing in this area?

Answer: Numerous State universities and State research foundations are engaged in a variety of population research activities in the biomedical and social sciences.

Question: Do you coordinate with them?

Answer: Yes, as a part of our responsibility for keeping totally aware of research in our fields of activity, through reading the scientific literature and through communication with scientists at national conferences and professional meetings.

THE PILL

Question: There still seems to be uncertainty about health risks associated with oral contraceptives - The Pill. What reevaluations of this risk have there been?

Answer: It has long been established that oral contraceptive (OC) use increases the risk of cardiovascular disease, primarily the risk of venous thromboembolism (blood clots in veins), myocardial infarction (heart attack), and stroke. Until recently, it has been thought that this increased risk is present only among current OC users. However, there is now growing evidence that some increase in the risk of certain cardiovascular diseases, especially myocardial infarction and stroke, does persist among long-term past users of the pill. Several research projects are under way or being formulated to clarify this potentially serious problem. These include studies of how OCs influence blood lipids (the fat content of blood) and whether OCs increase the risk of diabetes mellitus, which is a risk factor for cardiovascular disease.

Recent data suggest that OC use decreases the risk of cancer of the endometrium (uterine lining) and ovary, while the effect of OC use on the occurrence of breast cancer remains uncertain. A large scale investigation of the relationship between OC used and the occurrence of cancer of the breast, endometrium, and ovary is currently under way and is expected to provide extensive data in this important area within 2-3 years.

It has been suggested that OC use may increase the risk of malignant melanoma (a form of skin cancer) and pituitary adenoma (a technically benign but dangerous tumor at the base of the brain). Detailed studies are under way to investigate these issues.

Question: Is race a factor in risk?

Answer: Because most research concerning the effects of OC

use on the health of women has been carried out among white women in the U.S., Britain, and Northern Europe, information concerning the extent to which race or ethnicity may modify the effects of OC use on health is limited. However, in one NICHD-supported study of OCs and blood pressure that was carried out in a Black population, it was found that: (1) the incidence and prevalence of hypertension is not different for users and non-users of OCs; (2) family history of hypertension does not differ between users and non-users with essential hypertension; and (3) the clinical and laboratory features of hypertension in users are not different from essential hypertension seen in non-users.

Question: What role, if any, does smoking play?

Answer: Findings from NICHD-supported research indicate that OC use multiplies the effect of smoking on the risk of myocardial infarction and stroke. For example, it has been found that the risk of myocardial infarction among OC users who do not smoke is increased 4-6-fold. Among women who smoke heavily but do not use OCs, the risk is increased about 7-fold. However, among women who both use OCs and smoke heavily, the risk is increased nearly 40 times.

INFERTILITY RESEARCH

Question: What advances have been made in attempting to overcome infertility?

Answer: NICHD-supported research has contributed to the following recent advances in the alleviation of infertility in women and men:

1. Induction of ovulation. The development of highly effective measures for the induction of ovulation is perhaps the most significant recent advance in scientific efforts aimed at the alleviation of human infertility. Physicians can now choose from among three classes of substances that have recently become available for administration, singly or in combination, to infertile women in order to stimulate the release of eggs from their ovaries.

2. Tubal repair by microsurgery. Recent advances in our knowledge of tubal physiology have led to the development of microsurgical and, more recently, laser beam techniques for the correction of blocked tubes and other tubal defects in order to permit or to facilitate egg transport in the Fallopian tube. In addition to the development of these techniques, advances in our knowledge of tubal physiology have contributed significantly to markedly improved accuracy in the prognosis available for the correction of infertility due to tubal defects. Physicians can now make reasonably accurate predictions of the likely outcome of laser beam or microsurgical procedures for the correction of tubal defects.

3. Analysis of cervical mucus. Recent advances in our knowledge of the structure and function of cervical mucus have led to greatly improved measures for the diagnosis and treatment of certain forms of cervically related infertility. It has been clearly shown that sperm transport through the cervix can be almost totally impeded or markedly facilitated by the physical condition of the cervical mucus. In addition, these advances continue to contribute to the improvement of techniques for use by women in the determination of their fertile periods through self-examination of their cervical mucus.

4. Improved pregnancy tests. Highly precise procedures for the very early diagnosis of pregnancy have been developed. These tests have special significance for women who are at high risk for ectopic pregnancy or pregnancy outside the uterus. Through the use of newly developed pregnancy tests based on highly specific antibodies to a hormone formed during pregnancy, physicians can now treat patients at high risk for ectopic pregnancies without resorting to surgery which itself may lead to infertility.

5. Alleviation of endometriosis. Endometriosis is one of the most frequently occurring serious reproductive disorders in women. It is often associated with infertility. Recent advances in reproductive endocrinology have led to the development of a treatment modality involving the use of Danazol, a synthetic steroid, for the successful reduction of the painful symptoms of endometriosis.

6. Evaluation of the sperm quality. It is often quite difficult to determine the cause of apparent infertility in men with "normal" sperm counts. Included among the causes of such infertility are swimming defects in sperm and the inability of sperm to penetrate the egg for fertilization. New techniques of sperm swimming ability that involve the use of TV cameras or laser light beams promise to replace the present highly subjective techniques that involve direct observation of sperm through the microscope. In addition, new methods involving egg membrane penetration have been devised for the evaluation of sperm fertilizing capacity.

Question: Is there any evidence from ongoing human studies that long-term infertility can be reversed?

Answer: There is abundant evidence from clinical research that certain types of long-term infertility can be reversed by appropriate endocrinologic or surgical treatment.

GENETIC TRANSFER EXPERIMENTS IN MICE

Question: Successful experimentation involving the transfer of mammalian genetic material has been recently reported in the press. (Washington Post, January 5, 1981.) Can you comment on this area of research?

Answer: This research involves the transfer of genetic material for the purpose of studying mammalian development. The mammalian developmental process is still incompletely understood and needs further study through a variety of approaches, one of which is the technique in question. Briefly, genes are transferred from cells of developing mouse embryos to fertilized eggs of another mouse strain from which the chromosomes have been removed. The recipient fertilized eggs develop into mice with the characteristics of the donor. Such experimentation leads to a more thorough understanding of the interaction between male and female reproductive cells at the time of fertilization, and also provides new insights into the biological consequences of gene modification during development.

Question: Does your Institute support research involving "cloning" in animals?

Answer: The NICHD does not support research involving "cloning" in animals. The investigation of Dr. Peter Hoppe of Jackson Laboratory in Bar Harbor, Maine, is not a study of "cloning"

but rather a study of nuclear transplantation (the original nucleus is removed from the cell and replaced by a nucleus taken from the cell of a different mouse strain). Dr. Hoppes work is the only study of this type currently being funded by the NICHD.

Question: Please comment on the potential bioethical implications of the research.

Answer: Research applications submitted to NIH which would propose the transfer of genetic material between humans are subject to screening by review boards at the applicant institutions as well as by NIH offices, as a safeguard to prevent misuse of the gene transfer technology. These regulations would be utilized to assure consideration of the bioethical implications.

At present, the mouse is the highest animal in which cloning technology has been successful. There has been much discussion about the bioethical implications of possible future applications of this technology in man, without consensus. These discussions are continuing and will be of value to review boards in the future, if and when they are asked to review proposed research involving cloning of human material.

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan, provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NICHD share of that amount is $41,560,000 and 378 grants.

Question: How is inflation impacting--or how will it impact--on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new Research Grants regardless of other budget priorities within NIH?

Answer: Research project grants have been the dominant form of NICHD support of research. They continue to have the highest priority because these grants fund investigator-initiated projects at the grass roots. In order to sustain superior quality research, all research investigators periodically must compete for available funds. Similarly, these researchers need an indication that the government is committed to support their research. It is important that reasonable levels of support be established and protected to the extent possible by giving it the highest priority. In this way gifted researchers will continue to be motivated to accept the challenge, and the risks, of cyclical competition for research grants.

Question: What happens if, in a particular year, the quality of new research proposals declines? To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: It is indeed a remote possibility that the quality of new research proposals would decline to the extent that the NICHD would fund fewer new grants. The NICHD is already funding fewer grants than it did in prior years. The Institute is anticipating funding 31% of approved competing research project grant applications in FY 1981 and FY 1982. Clearly, we are far from being able to fund all the highly meritorious applications which have been approved.

If, however, the situation of lower quality research project grant applications should occur, the NICHD would propose to increase the funding of its research center grants. These grants provide research resources for investigator-initiated projects, and their unique multi-disciplinary approaches to solving complex research problems in the areas of mothers and children and in population provide special opportunities not possible under other mechanisms of support.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: The NICHD estimates that the payline for 1981 and 1982 will be approximately 190 and that 31% of approved competing grant applications will be funded each year.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January, we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in the estimate for 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justification recently submitted to the Congress has attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

NATIONAL EYE INSTITUTE

STATEMENT OF DR. CARL KUPFER, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. RONALD G. GELLER, ASSOCIATE DIRECTOR
EDWARD H. McMANUS, EXECUTIVE OFFICER
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator ANDREWS. Our next witness is Dr. Kupfer, Director of the National Eye Institute.

Research supported by the National Eye Institute is aimed at reducing or preventing the physical, emotional, and economic hardship caused by eye diseases which impair the vision of one out of every 20 Americans.

Dr. Kupfer, you are most welcome to our hearings. We ask that you very briefly highlight your opening statement, so that we may move on to questions from the subcommittee. and I first hope you will introduce your colleagues, and then you may proceed with your statement.

[The statement follows:]

STATEMENT OF DR. CARL KUPFER

Americans fear blindness more than any other disability except cancer. It is a handicap that can have a profound effect on one's life. And no one knows that better than the ten million people in the United States who suffer from visual impairment and blindness. That is one in every twenty Americans. The toll in human terms is, of course, incalculable; the costs to society of treating these eye disorders and caring for affected individuals is nearly so. According to figures from a 1976 study updated for inflation, the annual bill totals at least seven billion dollars a year. We at the National Eye Institute are committed to reducing these costs to society--as well as human suffering--by supporting research aimed at improving our ability to prevent, diagnose, and treat blinding and disabling eye disease.

This research can take two primary forms: studies conducted in the laboratory, or clinical research conducted on human subjects. I would like to discuss today the synergistic relationship between laboratory and clinical research and give you some examples of the interplay between these two.

One of the most exciting examples is the story of diabetes-associated cataracts. Usually, human cataracts develop slowly, as a function of the aging process. But in people with diabetes, this process seems to be accelerated; and, as a result, cataracts are more common in diabetics than in nondiabetics.

In laboratory animals treated to make them diabetic, cataracts appear so quickly their development can be easily followed by investigators interested in the developmental process of these so-called sugar cataracts. It is now known that the process begins with a rise in the level of sugar in the blood and in the lens cells. An enzyme called aldose reductase, which is present within the lens cells, then becomes active and converts these large amounts of sugar into a product which draws water into the lens cells and eventually causes them to burst, thus destroying the clarity of the lens and producing a cataract.

After having identified aldose reductase as the key to the formation of sugar cataracts, investigators at the National Eye Institute tested chemicals until they found inhibitors potent enough to block the activitiy of aldose reductase and halt the progression of sugar cataract in the diabetic animals.

Now aldose reductase inhibitors are emerging from the laboratory and are ready to be tested in human diabetics to discover if they can block one of the minor ocular complications of diabetes--the swelling of the lens that occurs in many juvenile diabetics and often causes blurring of vision. A clinical trial of aldose reductase inhibitors in diabetics with incipient cataract is also in the planning stages. In addition, these agents will be tested to determine if they can improve wound healing in diabetic patients who have to undergo eye surgery. Surgeons have observed that the ability to replace the outer layer of the cornea is impaired in diabetics. Recent studies in diabetic laboratory animals indicate that eye drops containing aldose reductase inhibitors may speed corneal healing and reduce the likelihood of post-surgical complications.

But this is not the limit of our hopes for aldose reductase inhibitors. We are beginning to suspect that cataract researchers

may have uncovered one of the basic mechanisms responsible for other, even more serious, complications of diabetes. It has been suggested, for example, that aldose reductase inhibitors may also be effective in treating the peripheral nerve disease and small blood vessel disease that is associated with diabetes.

The story of how laboratory scientists and clinicians cooperated on the investigation of aldose reductase inhibitors would not be complete without mention of another type of collaboration on this project--between the scientific community, the Federal Government, and private industry. Development and testing of aldose reductase inhibitors have been supported over the years by both the Federal Government and by companies interested in the commercial potential of these agents. In fact, at least 12 companies are now testing a variety of aldose reductase inhibitors in the United States, England, and Japan.

The series of studies I have just described is one example of how tightly interwoven are laboratory and clinical research, but let me give you another. It concerns research on diseases of the retina, the eye's light-sensitive, innermost layer. Retinal diseases account for nearly one half of all cases of severe visual impairment and blindness in the United States. Of all these diseases, the most frustrating to the clinician are the ones which are inherited. Many of these strike in childhood, adolescence or young adulthood, and unfortunately, there is no known way to prevent most of them.

Because of the difficulty in obtaining living human retinal tissue to examine, scientists interested in studying hereditary retinal disease have turned increasingly to animal models. For example, studies of certain mice and Irish setter dogs with inherited retinal degenerations resembling retinitis pigmentosa have shown that a specific biochemical defect may be responsible for the breakdown of retinal tissue. Now that the defect responsible for the breakdown is known, it is possible to devise an approach to treatment. In fact, studies are now underway to test a treatment aimed at correcting the defect chemically, thereby slowing down or preventing retinal damage. This approach to treatment in animals offers hope that it may be possible to intervene biochemically in the course of hereditary retinal degenerations in people.

In fact, that is exactly what some investigators have been doing with the human retinal degenerative disorder called gyrate atrophy, which is similar in many ways to retinitis pigmentosa. Working closely together, laboratory scientists and clinicians have discovered that people with gyrate atrophy have an enzyme defect which causes the amino acid ornithine to accumulate in their blood. This is the first demonstration of a specific inborn error of metabolism associated with a human retinal degeneration. In the last year, two people with gyrate atrophy who were put on special diets to correct this metabolic imbalance have shown objective evidence of improvement. Furthermore, scientists in the laboratory have discovered that ornithine is toxic to retinal tissue. Thus, there is a clear and direct connection between the metabolic problem and the retinal damage that leads to blindness. This is a very interesting laboratory finding which complements and confirms the preliminary clinical results.

Cooperation between laboratory and clinic has been the key to success in developing a treatment for another eye problem called uveitis, which is the name given to a group of inflammatory diseases

affecting the inner eye. Because questions about uveitis could not be answered by experimenting on people with this disease, investigators first developed an animal model for uveitis. Research in the laboratory subsequently revealed that many of these diseases arise because the immune system, which is responsible for protecting the body from invading organisms, has somehow mistaken the tissues of the inner eye for invaders and appears to attack them. Following this discovery, tests were conducted in animals to determine if drugs known to destroy attacking immune cells might be helpful in uveitis. The results were encouraging, and investigators are now planning a clinical trial to evaluate these drugs as a treatment for appropriate patients whose sight is threatened by uveitis. Included in the study will be patients who did not respond to the medications ordinarily used to treat uveitis or those who were unable to tolerate the side-effects of the medications.

Another exciting development in vision research laboratories over the past few years has been the great strides made in our ability to culture normal and diseased cells from ocular tissue. 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. One new tissue culture technique, for example, has enabled NEI scientists to find the biochemical defect responsible for the clouding of the cornea that occurs in a disease called macular corneal dystrophy. It may also be possible one day to use corneal cells grown in the laboratory to replace clouded corneal tissue, thereby freeing us from dependence on the availability of donor tissue.

Although new tissue culture techniques have not solved the problem of damaged corneas or macular corneal dystrophy, they have released eye research from its long dependence on the intact eye as a source of living material for study. I believe that quiet laboratory revolutions of this sort are the ones that eventually lead to major breakthroughs in treatment.

In addition to giving you a progress report on scientific advances, I would also like to bring you up-to-date on the NEI's program planning process. Program planning is the foundation upon which all research programs of the NEI are built. Periodically, our National Advisory Eye Council consults with many of the nation's leading experts in the visual sciences for help in developing a five-year plan for vision research. The Council and its consultants examine categorical areas of vision research support, reassess program goals and objectives, review recent accomplishments in vision research, describe research needs and opportunities, and then establish priorities in basic and applied research. The Council is now in the process of producing its third five-year national plan. When completed late in this year, it will be used by the Council and the staff of NEI to make rational decisions about funding priorities and areas of research to encourage. I would be pleased to answer any questions from the committee.

Department of Health and Human Services

National Institutes of Health

Biographical Sketch

NAME:	Carl Kupfer, M.D.
POSITION:	Director, National Eye Institute
BIRTHPLACE AND DATE:	New York, New York, February 9, 1928
EDUCATION:	A.B., Yale University, 1948; M.D., the Johns Hopkins Medical School, 1952
EXPERIENCE PRESENT:	Director, National Eye Institute, National Institutes of Health
1966-1970:	Professor and Chairman in Ophthalmology, University of Washington School of Medicine
1962-1966:	Assistant Professor in Ophthalmology, Harvard Medical School
1960-1962:	Instructor in Ophthalmology, Harvard Medical School
1958-1960:	Research Fellow in Ophthalmology, Harvard Medical School
1957-1958:	Research Fellow in Ophthalmology, Wilmer Eye Institute, the Johns Hopkins Medical School; Laboratory Assistant, Biostatistics, the Johns Hopkins Medical School
1953-1954:	Laboratory Assistant, Biostatistics, the Johns Hopkins Medical School
1952-1954:	Internship and Assistant Residency, Wilmer Eye Institute, the Johns Hopkins Hospital
ASSOCIATION MEMBERSHIPS:	American Physiological Society Association for Research in Vision and Ophthalmology American Academy of Ophthalmology and Otolaryngology American Ophthalmological Society Pan American Ophthalmological Society
PUBLICATIONS:	Author or coauthor of over 70 publications in clinical ophthalmology and the anatomy, physiology and biochemistry of the visual system

INTRODUCTION OF ASSOCIATES

Dr. KUPFER. Yes; to my immediate left is Mr. Edward McManus, who is the Executive Officer of the National Eye Institute. and to his left is Dr. Ronald Geller, the Associate Director.

DIABETIC CATARACT

I would like to make some brief comments concerning discoveries that are first made in the laboratory and then are translated into new clinical techniques and methods that add to the ophthalmologist's ability either to prevent an eye disease, improve its diagnosis, or even treat it better. Several examples of this are given in my prepared statement. One that I would like to elaborate on starts with some very interesting laboratory developments over the last 10 years in research related to the ocular effects of diabetes, specifically, to the development of senile cata-

ract which occurs in diabetics at a much earlier age than in nondiabetics.

It has been shown conclusively that if one induces diabetes in laboratory animals they develop cataracts fairly rapidly. This has been shown to be due to the presence of an enzyme in the lens of these animals. As glucose, the sugar in the blood, increases because of the diabetes, it also increases in the eye. The sugar goes into the lens where it is converted by this enzyme into a substance which cannot get out of the lens. This causes fluid to move into the lens, causing the lens fibers to swell and burst, and a cataract results.

Now these observations have been well-documented in diabetic laboratory animals, and they have led to initial therapeutic applications in human diabetics. For once the enzyme that causes cataract was identified, emphasis was placed on the development of drugs which inhibit this enzyme, so that the cataract in the experimental animal would not develop. This is the type of drug that we are beginning to use in clinical testing to see if we can slow down the development of cataract in humans with diabetes, so that they will not require cataract surgery.

DIABETIC RETINOPATHY

Now there is another aspect to using this inhibitor of the enzyme, and that is that it may also slow down the development of another complication of diabetes, diabetic retinopathy. That is the blinding disease that occurs in some diabetics, especially those that have had diabetes for a rather long period of time. Again, we are in the planning phase of trying to prevent the development of diabetic retinopathy by using potent enzyme inhibitors.

A third aspect of this, which I think is particularly interesting is that after a series of enzyme inhibitors was developed by scientists in various universities and in our intramural program, private industry became very much interested in this. Pharmaceutical companies took the initiative in developing at least 20 or 30 other inhibitors in an effort to find one safe and effective enough to use in humans.

So I think we are on the verge of being able to decrease significantly the incidence of blindness from diabetes preventing diabetic retinopathy. We have been successful in treating diabetics who have retinopathy with the laser, but this is really not getting to the basic problem of prevention. I think that these newer developments coming from the laboratory will enable us to do that sort of thing.

Senator HOLLINGS [presiding]. How do you diagnose the cataract? Is it suggested that you find first that the patient does have diabetes, or you could look at a cataract, and say this is caused by trauma, this is caused by age, or this is caused by diabetes?

Dr. KUPFER. Actually, a combination of the two. Most commonly, cataracts develop with age, but with diabetics they occur at a younger age than in nondiabetics. So, in the future, if we have a patient whom we know is a diabetic, and he's developing a cataract, it may be possible that we will be able to slow that down to a considerable extent.

Senator HOLLINGS. Can a person have a diabetes cataract and not have diabetes?

Dr. KUPFER. No, sir; the cataract occurring in a young person with uncontrolled diabetes is a very specific type.

IMMUNOLOGY

A second field of active development is immunology, and we've heard some discussion about this previously today. The area of immunology I would like to highlight, is the basic research that has been undertaken to understand the cause of uveitis, which is an inflammation of the back part of the eye, a major cause of blindness and visual disability in the United States. As a result of improved understanding of the immune mechanisms underlying uveitis, new drugs have been developed which can treat this disease specifically. Again we are at the point of clinically testing drugs to prevent the loss of vision in several types of uveitis.

PROGRAM PLANNING ACTIVITIES

Finally, I would like to give you a status report on our program planning activities. The National Advisory Eye Council is in its third cycle of program planning activities, in which there is a reassessment of our program goals and objectives, a review of recent accomplishments in vision research, an analysis of the needs and research opportunities that are present and, most important, an establishment of priorities. And this is done, of course, in conjunction with the vision research community itself.

I think our program planning activities are at the very basis of our research program, and they have enabled us to make maximal use of our resources.

I would be happy to answer any questions.

CONSTRUCTION FUNDS

Senator HOLLINGS. Dr. Kupfer, you know, last year with the supplemental, we found that the critical factor limiting essential growth in eye research was the lack of laboratory space, and on the Senate side we provided an additional $1 million appropriation be allocated for vision research, facility renovation, and construction. In this 1982 budget, what is it? Do you put that $1 million in there, or what is planned for construction, if anything?

Dr. KUPFER. Yes, sir; I would like to ask Dr. Geller to bring you up to date on this. This was money that was appropriated without needing to be spent in a particular period of time. So we have been working to allocate these funds, and perhaps Dr. Geller would like to comment on this.

Dr. GELLER. In fiscal year 1980, $3 million was appropriated for the project you described. The deadline for receiving applications for construction grants is May 1, 1981. To date, we have mailed out about 70 application kits and have discussed proposals with about 50 different institutions throughout the country. Our guess, and it's only a guess, is that there may be as many as 35 applications, competing for this $3 million construction fund.

We plan to have these applications reviewed some time this summer and early fall. The first awards possibly could be made as early as January 1982, after a review by the National Eye Advisory Council.

Senator HOLLINGS. Is that construction affected in any way by the proposed cuts by the administration, do you know?

Dr. GELLER. To date, it has not.

Senator HOLLINGS. You haven't met David Stockman yet?

Dr. GELLER. No.

Dr. KUPFER. As far as we know, Senator, they haven't been affected.

Senator HOLLINGS. Didn't we ask for an additional $1 million, though, to that $3 million?

Dr. KUPFER. Yes; that was requested in the Senate, but I don't believe it finally appeared in the appropriation.

Senator HOLLINGS. Are you requesting it now?

Dr. KUPFER. No, sir; it is not in the 1982 appropriation request.

Senator HOLLINGS. You're not telling me we don't need it?

Dr. KUPFER. No, sir; we definitely need it, especially, to increase our activity in clinical research.

BUDGET ESTIMATES

Senator HOLLINGS. All right, sir. The fiscal year 1982 budget continues to emphasize the stabilization of new investigator-initiated research grants for NIH of 5,000. How much funding will you need in fiscal year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Dr. KUPFER. We have estimated that we would require $29,715,000 to maintain our share of that research grant stabilization.

Senator HOLLINGS. Is that in your budget? Is it included in this request?

Dr. KUPFER. Yes, sir.

Senator HOLLINGS. What is the overall budget? $134 million?

Dr. KUPFER. $134,401,000.

Senator HOLLINGS. And what was it in 1980—what is it in the present fiscal year?

That would be from $118 million?

Dr. KUPFER. The 1981 estimate is $118,555,000. The 1980 appropriation was $113 million.

Senator HOLLINGS. So you would go to $134 million?

Dr. KUPFER. Yes, sir; that is our request for fiscal year 1982.

Senator HOLLINGS. And you haven't heard anything about cutting back that particular budget from OMB?

Dr. KUPFER. There were discussions, sir, but I don't think any decision has been reached.

Senator HOLLINGS. Is that coordinated? Does the Office of Management and Budget know that you are up making presentations on budget requests now of the Congress?

Dr. KUPFER. Perhaps Dr. Fredrickson would want to comment.

Senator HOLLINGS. Dr. Fredrickson, is this coordinated, is this supported by Stockman or not, or do you know?

Dr. FREDRICKSON. We are not able to comment on what may happen tonight or thereafter, Senator Hollings, but we have been consulted by OMB, in the sense of determining the impact of the reductions or the potential reductions in the budget.

Perhaps Mr. Itteilag would like to comment.

Senator HOLLINGS. Would you like to comment? I'm not trying to probe where I shouldn't, but I would like to get an idea for the committee where we are. I just don't know myself. But I'm confident that President Reagan is not going to address the Eye Institute budget in his talk tonight, but they've got a big, thick book. Have you looked through that to find out where you are?

Mr. ITTEILAG. Yes, sir, we have.

Senator HOLLINGS. And where is this? Is it at the $134 million level?

Mr. ITTEILAG. Senator, my sense is that there will be some level of reduction to the National Institutes of Health in total, but I am also certain that the specific breakdown by Institute has not yet been determined.

The other comment I would make is that the administration and Secretary Schweiker are aware that we are testifying, at the request of the committee. We are happy to be here. But, everyone agrees that these amounts are subject to change, and when they do change, we will provide the details for the committee.

Senator HOLLINGS. Well, I'm a disciple of Senator Schweiker. He was always asking for more, and I don't want to be disloyal. I want to be sure to ask for enough at least and maybe more.

The overall—Dr. Fredrickson, do you have any idea when you say "cut some" to the NIH budget?

Dr. FREDRICKSON. No; I am not sure what is going to happen, Senator Hollings, but I think that we may expect some reduction.

Senator HOLLINGS. But you just don't have any idea?

Dr. FREDRICKSON. I am just not prepared to comment on it.

Senator HOLLINGS. How is inflation impacting upon the goals of 5,000 new and competing research grants?

Dr. FREDRICKSON. Would you like me to answer that, Senator Hollings?

Senator HOLLINGS. Yes.

Dr. FREDRICKSON. I think that——

Senator HOLLINGS. What inflator are you using, Dr. Fredrickson?

Dr. FREDRICKSON. We are using figures of approximately 10.1 percent for 1981 and 9.5 percent for 1982. This is a general deflator used across the Department. There is no question but that inflation impacts upon the awarding of 5,000 grants, because our estimated costs are rising each of the years for the last 4 that we have available data. If we are to fund 5,000 research project grants, we will clearly have to remove funds from other parts of the program if we are at a constant level.

Senator HOLLINGS. What happens if in a particular year the quality of new research proposals declines? In other words, to what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Dr. FREDRICKSON. I would say at the current level of operation, Senator Hollings, we know that we can probably fund only on the average of about 33 percent of approved grants, and those are very high-priority grants. Therefore, I do not think that we are going to have any problem of funding low-quality research with a floor of 5,000. We clearly have not entered that era.

Senator HOLLINGS. You will be funding 33 percent then for 1981 or 1982?

Dr. FREDRICKSON. That is the estimate for the overall NIH, with some variation among the Institutes.

Senator HOLLINGS. Well, then, let me ask Dr. Kupfer, in the negative sense now, if you did have to face a cutback, what are your priorities?

Dr. KUPFER. Well, Senator Hollings, I think through our program planning efforts, we have identified areas that are a major public health problem, and in which there are opportunities to move rather rapidly, and I think they would be protected. In the area of retinal diseases, for example, I think the opportunities we have to learn more about inherited retinal degenerations, especially retinitis pigmentosa have been identified. I think we would maintain our support there. As I have said, immunology is a very rapidly expanding field for us, in understanding uveitis and its treatment, so we would protect that. And research in the field of diabetic retinopathy, which is the major cause of new adult blindness, would be very much protected. In fact, it's expanding, and I think that expansion would also be maintained.

In corneal diseases there are some very exciting new developments in transplantation which will not only have an impact on ophthalmology but on the general field of transplantation and graft rejection.

We are expanding our activities in ocular herpes simplex viral infections, which is the main cause of painful eye disability. In glaucoma, we will continue a clinical trial on the use of the laser in the treatment of glaucoma, because if this treatment is successful it will have a major impact, not only in terms of treating the disease, but in economic terms, because it can be done as an outpatient procedure.

In cataract, we are rapidly moving toward understanding more about the risk factors that predispose people to cataract and the biochemistry underlying this disease. Finally, in the sensory motor area, we want to test therapies of cross-eye, and understand better the amblyopia or lazy eye that occurs in childhood.

So these are the areas we would protect, and to do it we would have to slow down research in some of the other programs.

Senator HOLLINGS. On the matter of travel, Dr. Kupfer, and consultant contracts, you know we're looking at every one of the budgets. Have you looked at your own budget to see if you could minimize the travel and make some savings relative to consulting contracts?

Dr. KUPFER. Sir, we have looked at travel very, very closely because the resources are very limited. We do reserve travel primarily for the close monitoring of extramural projects that require visits by our staff. Most of our clinical trials, for instance, are supported by contracts, and they require very careful on-site surveillance on the part of staff. It's very important that we do maintain this.

On the other hand, we are gradually reducing our use of consultant contracts as it becomes possible to utilize our own staff instead of consultants for some activities. We will continue to restrict the use of consulting contracts because funds are limited. And in the long run, although it is very tempting to use consultants, we have found that our staff is often able to do the work itself, and that the high quality can be better monitored and maintained.

Senator HOLLINGS. I'm sure the chairman of the committee would like to have from both Dr. Kupfer and particularly Dr. Fredrickson any amounts as you hear further for any of these NIH budgets, any policy that would restrict or in any way limit the request that you are presenting to the committee this afternoon. Would you please send that up in detail as to how you expect to cope with it—your amended figures, in other words?

Dr. FREDRICKSON. We will do so, Senator.

Senator ANDREWS [presiding]. I thank my colleague for his contribution, and I have a series of questions that I will put in the record that you might answer for the record, and I appreciate the testimony that you gentlemen have made today.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

CLINICAL TRIALS

Question: In what fields of research are you currently conducting clinical trials? How much is this costing?

Answer: The National Eye Institute supports clinical trials in each of its five programs: Retinal and Choroidal Diseases, Corneal Diseases, Cataract, Glaucoma, and Sensory and Motor Disorders of Vision. The Early Treatment Diabetic Retinopathy Study is a nationwide clinical trial of laser treatment for this ocular complication of diabetes which is a leading cause of blindness in the United States. The study seeks to determine whether treatment at earlier stages of diabetic retinopathy would be more effective in reducing the risk of blindness than treatment at later stages, as is now the standard practice. The study must also address the issue of whether a reduction in the risk of blindness outweighs the risk of adverse effects from the treatment itself. Investigators also hope to find out whether photocoagulation may be effective against macular edema, a condition which frequently accompanies diabetic retinopathy and which may cause blurred central vision. A third objective is to determine whether aspirin, alone or in combination with photocoagulation, may be useful in treating diabetic retinopathy by preventing the clumping of blood platelets in retinal vessels. This study began in late 1979; therefore, no results are yet available.

The NEI is also supporting a clinical trial to evaluate the effect of intraocular lenses on the inner layer of the cornea, the endothelium, following cataract surgery. This study is aimed at determining the significance of the observation that endothelial cells of the cornea appear larger and fewer in number after a cataract extraction with intraocular lens implantation than after conventional cataract surgery. This controlled, prospective trial is expected to provide more definitive information concerning the effects of intraocular lenses on the human corneal endothelium. It may also provide information that will help ophthalmologists predict preoperatively whether complications may occur postoperatively and/or aid them in selecting patients for various types of cataract extraction.

Another NEI-supported clinical trial designed to evaluate the safety and effectiveness of timolol, epinephrine, and carbonic anhydrase inhibitors, used separately and in combination, in the treatment of various types of secondary glaucoma. The study encompasses seven individual protocols. Protocols I and II are short-term studies to examine drug interaction and effects on intraocular pressure. Protocols III and IV are long-term clinical trials to examine the efficacy of drug therapy on the disease process. Protocols V and VI are aimed at determining whether it is possible to reduce the side effects associated with carbonic anhydrase inhibitor therapy. In Protocol VII, the long-term safety of timolol will be monitored in patients for whom timolol has been added to other antiglaucoma therapy.

Yet another clinical trial is studying the effects of purposeful overcorrecting myopia (nearsightedness) with lenses in children ages

5 to 15 to determine whether or not this will slow down the rate of myopia change. Typically, myopia is expected to progress rapidly until the middle or late teens and then stabilize.

In FY 1980, the National Eye Institute supported 25 clinical trials costing $8,421,000.

FUTURE CLINICAL TRIALS

Question: What new ones do you have planned for the future?

Answer: The National Eye Institute has plans for three additional clinical trials. One will evaluate the benefits and risks of the surgical procedure laser trabeculotomy in treating glaucoma. Current treatment for this condition consists of topical application of one or more drugs, often with side effects. The advantage of this surgical procedure is that it can be done quickly and easily on an outpatient basis in about 15 minutes. The problems associated with drug treatment could be eliminated.

A multicenter collaborative study of ocular melanoma is also planned. The proper treatment of ocular melanomas (malignant tumor of the eye) remains controversial among ophthalmologists. Before proper treatment can be determined, knowledge about the natural history of this disease is essential. A study aimed at gaining this knowledge is a first phase of a project that is expected to result ultimately in randomized treatment trials.

The third planned clinical trial will try to determine the optimum age for strabismus surgery. Misalignment of the eyes (crosseye or wall eye) is a major ophthalmological disorder, affecting between 2 and 4 percent of the population. There were 83,000 eye muscle operations in 1976 to correct strabismus, the majority in children. Recent research has suggested that there is a critical period after which normal visual input can no longer reverse the effects of strabismic suppression. The goal of the clinical trial is to identify the optimum age for performing the corrective surgery and preventing the development of amblyopia and lack of scopic vision.

Question: What kind of time frame do such trials require before results are available which can be used by practicing ophthalmologists?

Answer: The amount of time required to complete a study and evaluate the results depends upon a number of variables including the number of patients who must be enrolled, as determined by statisticians who calculate in advance the number required to achieve an unambiguous result. In the case of relatively uncommon disorders, it may take one center or several centers working together years to accumulate enough patients so that a valid comparison can be made between treatment groups or between treated patients and the untreated control subjects.

When the correct number of patients have been enrolled, treated, and followed for the prescribed amount of time, the data is analyzed,

interpreted, and reported to practicing ophthalmologists and other physicians when appropriate.

In some clinical trials, however, the data and safety monitoring committee responsible for continuous analysis of patient data may find a compelling reason to release preliminary results long before scheduled completion of the study. This happened in the NEI's Diabetic Retinopathy Study. After only two years, careful monitoring of data from the first patients revealed that laser treatment of advanced diabetic retinopathy was so effective in reducing the risk of blindness in treated eyes that treatment should be offered to all eligible eyes. The protocol was changed and the preliminary results announced. The results of the DRS have since been reported in personal letters sent to every ophthalmologist in the country; articles have been published in medical journals and medical news publications; scientific papers have been presented and exhibits displayed at medical meetings, and information materials summarizing the result have been prepared and distributed. In addition, courses on the treatment of diabetic retinopathy have been conducted by NEI staff members and others involved in the trial.

In a study as significant as this one, information dissemination efforts may continue for years. This is to ensure that the entire ophthalmological community is aware of the results, to enlist the cooperation of other physicians who should be referring all diabetic patients for eye examinations in an effort to prevent blindness from diabetic retinopathy in as many people as possible, to alert the general public to the ocular complications of diabetes and the need for periodic eye examinations, and to ensure that the results are incorporated in to textbooks, ophthalmology courses, and speciality board examinations.

TRAINING OF INVESTIGATORS

Question: Are there any fields of vision research where progress is hampered by a shortage of trained researchers?

Answer: Yes, in addition to the general need for more clinical researchers, there are specific needs within each of the five major programs of the Institute. There is a tremendous need for cell biologists skilled in recombinant DNA technology to perform basic research in the Retinal and Choroidal Diseases Program, Corneal Diseases Program and the Cataract Program. Physiologists with training to work on small blood vessel studies are needed in the Cataract and Retinal and Choroidal Diseases Program. Biochemists are needed to carry out connective tissue studies in the Corneal Diseases Program. Cell biologists specializing in tissue culture techniques and clinical pharmacologists are needed in the Glaucoma Program. In the Sensory and Motor Disorders of Vision Program, clinicians who specialize in strabismus and amblyopia with expertise in clinical trial methodology and psychophysical procedures are needed.

Question: Does the vision research community include sufficient technical expertise in all areas that you think have promise for new development?

Answer: In addition to the specialities I have mentioned above, we have a shortage of biomedical engineers and epidemiologists in our programs.

Question: What efforts does NEI make to train new investigators or to encourage researchers to pursue lines of study where more new blood is needed?

Answer: The National Research Service Act (NRSA) mechanisms are used to train investigators. The National Advisory Eye Council's national plan that outlines five-year program priorities is widely disseminated within the biomedical research community. In addition, program announcements, conferences, task forces, workshops, and publications of the proceedings represent mechanisms by which specific program needs are described to the vision and other research communities. Individual contacts by NEI staff with scientists not currently working in vision research have also met with some success.

PROGRAM PLANNING

Question: The National Advisory Eye Council's program plan makes recommendations for the future development of the Institute's programs. What were the Council's recommendations derived from?

Answer: The Council's recommendations concerning areas of program emphasis and program priorities were derived from expert assessments of the current state of research in each of the National Eye Institute's five programs and scientific judgments concerning the most important research needs and opportunities in these fields. Five panels of scientists, one for each program, advised the Council and presented reports which, for each major disease or basic science area within their purview, described the area's importance, defined program goals and objectives, reviewed recent accomplishments and their significance, considered current research needs and opportunities, and, outlined program priorities. These priorities were based on a consensus of the panel on what kinds of research had the greatest probability of advancing the field and meeting program objectives over the next five years. In addition to the scientific recommendations derived from the advice of the expert panels, the Council's Program Planning Subcommittee also made recommendations concerning general National Eye Institute policy and administrative issues. These recommendations were based on an extensive review of program data and conclusions reached after consultations with the NEI staff.

SHIFTS IN RESEARCH EMPHASIS

Question: Do you anticipate any major shifts in research emphasis in the next few years?

Answer: The Council's current plan, begun in 1977, covers the five-year period ending in FY 1982. At present, the Council is nearing completion of a new plan for the years 1983-1987, in which each of the National Eye Institute's five programs is being assessed in greater detail than ever before. Although work on the

new plan is still under way, several areas of research have already been identified in which recent advances and the availability of new research techniques portend significant shifts in research emphasis over the next few years. An example is in the field of ocular tissue culture, where recently developed methods for growing cells from various kinds of eye tissue in the laboratory will permit much greater emphasis on experimental studies with human tissue than would be possible in the intact living eye. By growing normal and diseased cells in culture, cellular and molecular mechanisms which form the basis of disease processes can be studied and various forms of therapy may be tried and tested without any risk to patients.

Another shift in emphasis will be in the area of clinical trials, an appreciation for which has been steadily growing within the ophthalmological community ever since the successful completion of the NEI-initiated Diabetic Retinopathy Study in the late 1970s. A number of opportunities for new clinical trials are expected to be identified in the Council's new plan, and the NEI will make strong efforts to implement those trials considered to be of the greatest importance and for which there is widespread support among scientists and practitioners.

A third major shift will be in the broadened search for specific biochemical defects in a variety of inherited and developmental eye disorders which have thus far eluded all efforts at prevention or control. Recent advances in understanding the biochemical basis for a few hereditary degenerations in animals and for one form of human retinal degenerative disease offer hope that similar defects can be found in other ocular disorders, indicating the way to specific therapies.

Still another trend is evident in the NEI's successful sponsorship this year of scientific workshops on immunology and ocular melanoma in which scientists from fields of biomedical research other than vision have become acquainted with opportunities for conducting studies in the visual system. At such workshops, vision scientists also have the opportunity to learn how new developments outside their field can have an important bearing on learning more about the eye in health and disease. We expect that continuing developments in immunology, genetics, cell biology, biophysics, and other basic and applied disciplines will open up whole new areas of eye disease research.

Finally, the neurosciences are one of the most rapidly advancing disciplines in all of biomedicine, and neurobiologic investigators working in the visual system are among the leaders in this field. Studies of the effects of sensory deprivation and investigation of the role of neurotransmitters in the visual system are just two of many areas of research which may lead to improved treatment of a variety of neurologically based eye and visual disorders.

CHANGES IN FUNDING NEEDS

Question: Will your funding needs change?

Answer: Undoubtedly, if we are to capitalize fully upon new research opportunities as they are identified through our planning process and evaluated in terms of their potential to improve visual health, additional resources will be required. Much of today's research requires expensive, sophisticated equipment and facilities, and even if the current rate of inflation is slowed, we expect that the costs of doing such research will increase over the next few years. However, it is important to note that both the National Advisory Eye Council and the NEI staff will be determining funding needs on the basis of a continuing analysis of the ongoing program and rational assessments of future needs and opportunities through our comprehensive planning and evaluation process Whether the institue in fact realizes additional funding depends on the policies of the Administration and the action of the Congress.

Question: Have you been successful thus far in carrying out the recommendations of the plan?

Answer: In terms of increased funding in those areas of research identified as high priority in the plan, we have been quite successful. The Council made detailed recommendations for increased funding for three support mechanisms: research projects, specialized clinical research centers, and research contracts. In our tracking of the implementation of the Council's recommendations we have taken into account career awards in addition to project grants and centers. Contracts are tracked separately, and since they fund NEI-initiated multicenter clinical trials exclusively they are excluded from the following analysis.

In FY 1977, the year in which the plan was prepared, the NEI funded 587 grants (research projects, specialized center grants, and career awards). Of these, approximately 38 percent were in areas the Council judged to be of high program relevance and priority. In FY 1980, 990 grants of type listed above were funded, of which 50 percent were in areas designated as being of high priority. Thus, the percentage of these grants in priority areas has increased by 12 percent during this three-year period, and the absolute number of these grants in priority areas has also increased.

Considering that these are primarily investigator-initiated research projects, this may be viewed as a significant response by the scientific community to the Council's priority recommendations. It should be pointed out, however, that the Council had envisioned a total budget of $126,692,000 for 1,554 for research projects by FY 1980. In actuality, $80,617,000 was available for the 990 grants noted above.

IMMUNOLOGY OF THE EYE

Question: The field of immunology offers many potential applications to research on difficult ocular diseases, particularly inflammations and infections. Last year, Dr. Kupfer described a series of workshops being sponsored by NEI and the National Institute of Allergy and Infectious Diseases (NIAID) to acquaint

immunologists with promising opportunities for research on the eye. What new aspects of eye immunology were discussed in the workshops you held with NIAID during 1980?

Answer: The first workshop, held in December 1979, identified recent advances in immunogenetics and transplantation immunology that might be productively applied to eye research. In particular, workshop participants discussed:

--mechanisms for attracting immunologists to departments of ophthalmology and training them to carry out vision research.

--need and opportunity for research relevant to corneal transplantation.

--attempts to define individual antigens responsible for ocular autoimmune diseases.

--the derivation of white blood cells (lymphocytes) associated with malignant lymphoid tumors of the eye.

--the association of HLA antigens with ocular disease.

--chemical and physical factors leading to vascularization of corneal transplants and resultant rejection.

A second workshop, held in March 1980, identified promising avenues for additional research on the immunological mechanisms which govern autoimmunity in relation to specific ocular diseases. Some of the recommendations made were:

--specific ocular antigens from animals and humans should be isolated, characterized, and identified.

--animal models should be developed, particularly those which represent spontaneous ocular autoimmune diseases.

--longitudinal clinical studies should be conducted to establish the abnormal features through all phases of various ocular autoimmune diseases.

--new approaches to immune modulation, such as the use of immunosuppressive agents, suppressor cells and their products, and specific anti-idiotype immunity, should be applied to ocular immune diseases.

The third workshop was held in June 1980 and provided a forum for discussion of promising approaches to minimizing the destructive effects of inflammation associated with ocular disease while maximizing the protective effects of the inflammatory process. The recommendations dealth with:

--delineation of the events in the inflammatory process and response, so that destructive components may be avoided,

--investigations to determine which cellular events lead to inflammation and ultimate structural damage,

--evaluation of interferon, alone and in combination with antiviral drugs, for the treatment of stromal herpes keratitis, herpes zoster and adenovirus infections,

--the urgent need for drug delivery systems which increase the penetration or permeability of drugs through topical application to the eye,

--the need to develop new antiviral drugs,

--evaluation of new antibiotics and antifungals for treatment of ocular disease.

Question: Can you report any progress in developing treatments for herpes simplex infections of the cornea or other ocular infections?

Answer: Many advances in determining the pathogenesis and therapy of herpes simplex disease states have been made by vision research scientists during the past two decades. The first successful application of a drug in the control of human viral infection was the introduction of idoxuridine for therapy of ocular herpes. So successful was this drug for treating ocular herpes, it is now approved by FDA for use systemically in treatment of human herpetic encephalitis.

Much of the damage created by herpes is due to its chronic recurrent pattern of producing disease. Each attack may result in more permanent damage. One important, far-reaching discovery is that latent herpetic reservoirs in the deep-seated neuronal tissues are the source of recurrent viral infections. Latent neuronal virus is beyond the reach of topical drugs, but recent studies have shown that systemically administered medications may reduce the levels of latent virus in the neurons. Studies have also indicated that some herpes strains are more prone to recurrent and severe disease while others are rarely recurrent and cause little disease after the primary infection. The possibility that derivatives of these mild strains or a recombinant DNA altered strain may be used as a vaccine to block subsequent infection by a more severe herpes strain is raised by these findings.

In addition, the National Eye Institute is funding a clinical trial on ocular herpes simplex which will study new drugs that are specific for the virus-infected cells.

The National Advisory Eye Council also believes improved treatment of viral infections of the eye is a high priority. In its recently updated, report Vision Research--A National Plan, a high priority of the Corneal Diseases Panel will be to promote the development of more effective, specific, and safe, drugs to prevent recurrent viral infections.

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GLAUCOMA

Question: To what extent, if any, did the research proposals to study the effects of marihuana and its derivatives on glaucoma receive funding?

Answer: To date, five such proposals have been funded. In two of the projects investigators are studying the effects of marihuana cigarettes and delta-9-tetrahydro-cannabinol (THC) drops or capsules on intraocular pressure in normal and glaucomatous humans and animals.

One project is concerned with the pharmacologic effects of drugs, including marihuana and some derivatives, in animals. Perhaps 15% of the effort is devoted to marihuana research.

Two projects are concerned with extracting substances which lower intraocular pressure (other than THC) from the marihuana plant. One project deals with water soluble substances, the other with cannabinoids. The isolation of promising substances could be the basis for developing new drugs free of the behavioral and physiological effects of marihuana. The total cost for these projects in FY 1980 was $457,000.

Question: Has anything further been learned thus far about the effectiveness of such treatments?

Answer: Smoked marihuana does lower intraocular pressure in some people with and without glaucoma. However, some people cannot tolerate smoking marihuana and some have deleterious side effects. THC eye drops irritate the cornea and do not appear to penetrate into the eye well or to lower intraocular pressure significantly and reliably. We do not yet know whether more effective formulations of drops could be more beneficial.

Preliminary investigations using laboratory animals have indicated that an aqueous extract of marihuana leaf--not containing cannabionids--is a potent agent in lowering intraocular pressure. Much work remains to be done to determine if this material will be clinically useful. Certain cannabinoids--not legally restricted substances and devoid of the undesirable effects of THC--also lower intraocular pressure in animals, and evaluation of their clinical potential must await further experimental studies.

Question: Are you any closer to discovering the underlying causes of glaucoma, or developing new drugs or treatment methods to prevent blindness from this disease?

Answer: Primary open-angle glaucoma is the most prevalent form of this disease. Studies have shown that blockage of the outflow of fluid from the anterior chamber of the eye causes the increase in intraocular pressure. Recently, it has become possible to grow in the laboratory cells from small samples of tissues from the blocked area making it possible for the first time to study how they differ in normal eyes and eyes with glaucoma, and to study experimentally the effects of drugs on these cells.

Laser surgery is being used to treat different types of glaucoma, and it has been reported to be quite effective in treating a serious type of the disease, angle-closure or narrow-angle glaucoma. Investigations are also under way to determine the best means of using laser energy to treat primary open-angle glaucoma, a procedure now coming into clinical use. Also, laser photocoagulation is being tested for its value in arresting the progress of yet another serious type of glaucoma, neovascular glaucoma.

Timolol is a drug introduced into general medical use about two years ago and is now widely used to treat glaucoma. Clinical research investigators are conducting studies to determine the optimum conditions for its use (patients most likely to benefit, dosage and dosage schedules, long-term safety and efficacy). Also, since many glaucoma patients eventually need more than one drug to control their intraocular pressure, studies are under way to define the best ways to use timolol in combination with other anti-glaucoma drugs.

EYE INJURIES

Question: We have heard that next to cataracts, injury is the most common cause of visual impairment. To what extent is this true?

Answer: Approximately 1.3 million persons suffer eye injuries each year. Next to cataracts an injury is the most common cause of visual impairment. Four types of eye injuries account for an estimated total of 2.4 million cases per year. Thirty-five percent of the cases involve a foreign body in the eye. Open wounds and contusions each account for about 25 percent and the remainder are burns. Almost one-half of all eye injuries occur in and around the home and are product related.

Question: How many people are visually impaired due to injury?

Answer: About one million American citizens have partial sight due to injuries. Injuries account for 40,000 cases of impaired vision each year.

Question: Does NEI have any activities relating to eye injuries, either treatment or prevention?

Answer: Much information gleaned from NEI-supported research on specific eye diseases or disorders of vision has applicability to the treatment of eye injuries. This is because eye injuries may trigger ocular problems which require the same treatment as conditions resulting from diseases of the eye. For example, cataracts may develop after ocular trauma, as can retinal detachment. The onset of glaucoma also may be related to an eye injury. Thus research directed primarily at slowing down, preventing, treating, or ameliorating these conditions when they result from disease may also be relevant when the conditions occur as a result of eye injury. Research on corneal transplantation and corneal wound healing is also of direct relevance to the treatment of eye injury since this clear outer covering of the eye is the most exposed part

of the eye and thus quite vulnerable to damage. Corneal transplantation is, by the way, one of the most successful of all tissue transplant procedures.

Question: To what extent do you participate in efforts to develop standards for protective eyewear, such as is used in industry and in sports?

Answer: The NEI has no role in developing standards for protective eyewear, but we are supportive of the efforts of other Federal agencies charged with this responsibility and of the voluntary organizations which are engaged in such activities. We consult with these organizations on the development and implementation of prevention of blindness campaigns, provide them with background information and information materials on our own programs for their distribution, and channel requests for additional information on protective eyewear from the media, the general public, and from the medical community as well.

CLINICAL INVESTIGATORS

Question: We understand that you are experiencing some difficulty in getting medical school graduates to go into clinical research. What is the problem and how bad is the shortage?

Answer: Prior to 1975, significant numbers of ophthalmologists expressed interest in research careers by participating in research training programs. This may be responsible for the significant increase in the number of ophthalmologists serving as principal investigators of research project grants which was observed in the period, 1977-80. In spite of this increase, however, the percentage of principal investigators who are ophthalmologists has declined. Furthermore, the number of ophthalmologists is lower than that needed to address all of the clinical research issues identified in Vision Research--A National Plan.

Question: What are you doing to reverse the trend?

Answer: The NEI is attempting to promote clinical research in several ways. Our major emphasis on clinical trials is apparently attracting the participation of many ophthalmologists. Meetings have been held with the professional societies to seek their advice. Guidelines developed for clinical trials have been helpful to many ophthalmologists interested in preparing research grant applications. The NEI has sponsored meetings, workshops, and courses on clinical trial/clinical research methodology. Several new research grant mechanisms have been proposed: 1) a special competition for New Investigator Research Awards open only to ophthalmologists, 2) a program to provide support to initiate needed clinical trials, 3) a pilot study grant program to encourage young clinicians to attempt a research project, and 4) incorporation of medical student training on institutional training awards.

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NEI share of that amount is $27,663,000 and 263 grants.

Question: How is inflation impacting--or how will it impact--on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new Research Grants regardless of other budget priorities within NIH?

Answer: Stabilization of research grants is necessary if we expect men and women with an interest in science to make a commitment to biomedical research and young doctors to choose research over full time private practice. With a constantly fluctuating budget for research grants, even longtime, dedicated investigators who continue to propose worthwhile and scientifically meritorious research projects cannot depend on continued support in their own field.

Stabilization also provides a foundation on which to base long-range planning of a research program. Building on such a foundation, it is possible to plan carefully and rationally for the appropriate allocation of resources. At the same time, stabilization still provides the considerable flexibility needed to insure that the NEI remains responsive to developments in the field of vision research. This may mean reducing funding in certain areas when appropriate, or taking advantage of unexpected research opportunities which offer hope of improving the treatment of eye disease or prevention of visual impairment.

Question: What happens if, in a particular year, the quality of new research proposals declines: To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: The study of the visual system offers a unique opportunity to apply the concepts and methods of many scientific disciplines, and new scientific knowledge often generates as many questions as it answers. For these reasons, and also because there is very active communication between NEI staff and the research community through the Institute planning process, hundreds of innovative, scientifically meritorious, potentially fruitful research proposals are submitted and approved each year. Given the number of applications eligible for funding, it is therefore unlikely that a lack of high quality grant applications would lead

us to put greater emphasis on other mechanisms at the expense of research projects. Furthermore, the distribution of Institute funds is based on conscious decisions to maintain a balanced program of complementary research activities.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981--and if you can estimate it--in FY 1982? What percentage of grants will you fund in both years?

Answer: In FY 1981 the NEI would fund approximately 53 percent of the new and competing grants eligible for award; the payline funded would be 220. We estimate that the payline funded in FY 1982 would be 210 and that the award rate would be approximately 47 percent.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submited to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts:

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts, and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF DR. DAVID P. RALL, DIRECTOR

ACCOMPANIED BY:

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PREPARED STATEMENT

Senator ANDREWS. Our next witness is Dr. David P. Rall, Director of the National Institute of Environmental Health Sciences. NIEHS was established in 1966 to deal with the growing seriousness and complexity of environmental health issues. The Institute is located in Research Triangle Park, N.C. You recall the suggestion of my colleague from Macon for 20 years to move some of this stuff a little further from Washington—the only Institute of NIH that is outside of the Washington area.

Dr. Rall, we welcome you to our hearings and ask that in the interest of time you briefly highlight your opening statement so that we may quickly move on to questions. And first, of course, I would like to have you introduce your associates and then proceed with your statement. Your complete statement will be placed in the record in full at this point.

[The statement follows:]

STATEMENT OF DR. DAVID P. RALL

Mr. Chairman and Members of the Committee, it is a pleasure to be here today to discuss the role the National Institute of Environmental Health Sciences (NIEHS) and its research programs play in identifying and in resolving issues which affect the health of the American people.

Prior to the '60s, a few people understood the impact of environmental agents on human health. It was Rachel Carson's book, Silent Spring, published in 1962, that awakened us to the fact that many manmade chemicals are persistent in the environment. Because of their structure, they do not break down naturally in the water or air into harmless components. They accumulate in our tissues only to cause disease years after we are exposed.

We now know that even low-level exposure to some environmental agents-substances in our air, water, food and drugs - can cause cancer, heart and lung disease and birth defects. Some of these toxic agents have become so widespread that they touch us all. I would like to cite a few examples:

Both the Congressional Research Service and the House Government Operations Committee have recently documented repeated cases of contamination of our ground and surface water supplies by toxic chemicals. Many of our great rivers - the Shenandoah, Susquehanna, Housatonic, Mobile, Tombigbee, and Hudson - have been closed to fishing. The Great Lakes contain PCBs, Mirex, DDT, mercury and asbestos.

Increasingly, we are dependent on underground sources for water. Our use of this vital supply has increased by 170 percent between 1950 and 1975. And yet, well closings have been reported in New Jersey, Long Island (two million residents affected), Massachusetts (a third of the communities affected), and Michigan (268 sites identified as contaminated). In California, both the San Gabriel and the San Joaquin Valleys have lost vital water supplies to industrial chemicals.

Our food supplies have been repeatedly affected as well. In a well-known 1973 incident in Michigan, cattle feed was contaminated by PBBs, a fire retardant chemical. As a result, virtually everyone in Michigan carries PBB residues in his or her body. And PCBs, used as transformer coolants, have caused major incidents in dozens of states including New York, Maine, Mississippi, and recently in Montana, where an accidental spill affected food supplies in 19 states.

The research conducted at and supported by the NIEHS is based upon the premise that by gaining new knowledge, prudent disease prevention strategies can be developed which will substantially reduce the burden of environmentally-induced diseases. NIEHS' goal is to identify toxic substances, learn their mode of action within the body, determine at what level they are toxic to humans, and make this information available to the public and other government agencies. The end product of this research is an enhanced quality of life for ourselves, our children, and our children's children.

I would like to touch on a few areas in which NIEHS has been particularly active recently.

Health problems associated with exposure to chemicals stored at hazardous waste sites such as the dramatic example of Love Canal may be the most important public health issue of the '80s. Some of the problems at these sites may arise from direct exposure to hazardous chemicals from waste dumps such as at the Love Canal which I discussed last year. A more serious consequence could be the effect of these chemicals percolating downward and contaminating our Nation's ground water sources. The House Government Operations Committee last year found that in 41 states hazardous waste sites are located within one mile of a major water supply.

Exposure to many chemicals are known to cause genetic changes in human cells. These changes can become manifest as cancer 20 to 40 years after exposure or as inherited traits, diseases or malformations, that may occur in the children or grandchildren of those exposed.

The need for better methods of assessing genetic effects of chemicals is a high priority at NIEHS. Scientists in the NIEHS intramural program are studying the mechanism whereby chemicals interact with the genetic composition of cells. Their goal is to devise a method to detect these changes before disease occurs. This would allow scientists to identify those at risk from exposure to certain chemicals and to devise techniques for preventing these diseases after exposure.

The most effective public health program is prevention - one that controls human exposure to chemicals based on knowledge of potential adverse health effects. Since effects in humans may demonstrate a long latency period, 20 years or more for cancer, an effective predictive toxicology program must be based on information obtained from experimental models other than man.

Animal bioassays are currently the best surrogate for human studies. Given this, there is critical need to develop a reliable methodology that will allow us to extrapolate from the high dosage used to produce an effect in a very limited number of animals to the low dose normally experienced by humans in order to estimate risk to human health.

The NIEHS Biometry and Risk Assessment Program's basic research is aimed at developing risk assessment methodologies. Information in this form is needed by policy makers in developing prudent public health strategies and regulations effective for human populations.

Love Canal also poses the question of whether exposure to certain chemicals causes effects on the nervous system. Efforts to measure nerve conduction have been equivocal. Although behavioral changes are suspected, efforts to substantiate them so far have been complicated by numerous uncertainties.

Scientists in the NIEHS Laboratory of Behavioral and Neurological Toxicology have developed a battery of tests to assess subtle neurotoxicities using laboratory animals. These tests are now undergoing validation in comparative trials in other laboratories. Nine neurotoxins are under test in these trials.

As Love Canal occupied the headlines, another saga began unfolding, that of the possible adverse health effects on Vietnam veterans due to exposure to the herbicide Agent Orange. NIEHS has been conducting studies on the long-term health effects of Agent

Orange and other phenoxy herbicides and Dr. John A. Moore, Deputy Director of the National Toxicology Program (NTP), is chairing the Scientific Panel of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Their Contaminants.

Vietnam veterans are concerned about the risk of having children with birth defects even years after their exposure to Agent Orange. In order to assess adequately this effect, simulated Agent Orange was given to male laboratory animals. NIEHS scientists examined their sperm and their ability to fertilize untreated females and then examined their offspring to determine if there was any harmful effect.

This study was recently completed. It does not show any evidence of germ cell toxicity or adverse effects in the development or survival of offspring as a result of paternal exposure to simulated Agent Orange. That is good news for the veterans.

The veterans are also concerned about the increased risk of cancer from their exposure. According to a recent study by the National Toxicology Program and an earlier study conducted by the National Cancer Institute, the dioxin contaminant of Agent Orange is a potent carcinogen in rats. However, while these studies suggest an increased risk of cancer for humans, a quantitative risk of cancer to the veterans cannot be determined because it is difficult to make an exact prediction based upon the results in laboratory animals and because the exposure levels experienced in Vietnam are unknown.

Another area of concern is the emerging problem of indoor air quality. Two phenomena that are contributing to this increasing concern about air quality in the home and workplace are: first, the effort to tighten buildings in order to conserve fuel by reducing air exchanges; and second, the increasing use of products which emit chemicals.

One such problem chemical is formaldehyde. The United States produces seven billion pounds of this ubiquitous chemical each year. It is used in formaldehyde foam insulation and as adhesives used in wall board, kitchen cabinetry, some newer forms of furniture, and carpeting.

Formaldehyde is particularly irritating to the eyes, ears, nose and throat. Some people who have been exposed, particularly those living in the tight quarters of mobile homes, have found that it causes respiratory problems, nausea and dizziness which seem to increase with the duration of exposure.

Of even greater concern is the possibility that formaldehyde is carcinogenic. A recent study by the Chemical Industry Institute of Toxicology suggests that inhalation causes nasal tumors in mice and rats.

Formaldehyde is currently being evaluated for mutagenic and teratogenic effects by the NTP.

Finally, I would like to say a word about the National Toxicology Program. I have touched somewhat on NTP efforts because many of the NIEHS efforts are integral to NTP.

Consider these facts: Since 1943, the production of synthetic organic chemicals has increased ten-fold, from 32 billion to 321

billion pounds. There are some 60,000 different chemicals in use today and unfortunately, very few of these have been adequately tested for safety.

The NTP, which was established in November 1978, is two related programs - a testing program and a test methods development program. The two are integrally related because developing new test methods requires validating these tests against results using established methods.

The NTP's test methods development efforts are critical to both industry - as it carries out its responsibilities for testing under the Toxic Substances Control Act - and to government - as it implements important public health protection programs that require the development of new toxicological methodologies in order to be effective.

A major part of the NTP is the continuation of the cancer bioassay program of the National Cancer Institute. In addition, the NTP is incorporating other kinds of studies into each bioassay so that we can test for other toxic endpoints at the same time. Substances being bioassayed are also tested in various short-term test systems in an effort to validate these quicker and far less expensive systems.

Another NTP effort, the NTP's Environmental Mutagenesis Test Development Program (EMTDP), has two aims: It tests chemicals using these short-term systems to determine if they produce genetic damage. It also aims to develop and validate new short-term test methods, to understand their limitations in the detection of toxic agents and to assure their reproducibility.

The NTP also tests chemicals for teratogenic effects - that is, the ability to induce birth defects - and tests a variety of chemicals including halogenated organics, metals and estrogenic compounds for neurobehavioral effects.

We at NIEHS are proud of the Institute's role in promoting the health of Americans by seeking new knowledge and understanding about how the environmental agents can affect their health. We believe this knowledge is critical to the prevention of diseases.

I shall be pleased to reply to any questions of the Committee.

Thank you.

CURRICULUM VITAE

David Platt Rall

Birthplace and Date:	Aurora, Illinois; August 3, 1926
Marital Status:	Married; two children
Education:	Public Schools, Naperville, Illinois B.S., North Central College, Naperville (1946) M.S. (Pharmacology), Northwestern University (1948)

Ph.D. (Pharmacology), Northwestern University (1951)
M.D., Northwestern University School of Medicine (1951)

Professional Training:

Internship; Second (Cornell) Medical Division Bellevue Hospital, 1952-53

Experience:

Director, National Institute of Environmental Health Sciences, NIH, 1971-present
Director, National Toxicology Program, November 1978 to present
Assistant Surgeon General, USPHS, 1971-present
Associate Scientific Director for Experimental Therapeutics, National Cancer Institute, 1966-71
Medical Director, USPHS, 1963-71
Chief, Laboratory of Chemical Pharmacology, National Cancer Institute, 1963-69
Senior Surgeon, USPHS, 1959-69
Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute, 1958-63
Surgeon, USPHS, 1955-59
Scientist, Laboratory of Chemical Pharmacology, National Cancer Institute, 1953-55
Research Associate in Pharmacology, Northwestern University, 1950
Assistant in Pharmacology, Northwestern University, 1949-50
Baxter Fellow in Pharmacology, Northwestern University, 1947-49

Association Memberships:

American Association for the Advancement of Science
American Association for Cancer Research
American College of Preventive Medicine
American Society for Clinical Investigation
American Society of Pharmacology and Experimental Therapeutics
Society for Experimental Biology and Medicine
Society of Occupational Environmental Health
Society of Toxicology

Honors and Other Special Scientific Recognition:

Member, Institute of Medicine, National Academy of Sciences, 1979
Nellie Fox Lecturer, Northwestern University Medical School, April 1978
Chairman, Committee on Health and Environmental Effects of Increased Coal Utilization, 1977-78
Harrington Lecturer, University of Buffalo, April 1976
Member, NAS Safe Drinking Water Committee, 1975-77
Member, Secretary's Review Panel on New Drug Regulation, 1975-76
Associate Editor, Journal of Toxicology and Environmental Health, 1974-78

Editoral Board, Archives of Environmental Health, 1973-76
Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-present
US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present
US Coordinator, Biological and Genetic Consequences Project, US-USSR Environmental Protection Agreement, 1972-present
US Coordinator, US-UK Cooperative Program in Environmental Health Sciences, 1972
Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present
Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72
Associate Editor, Cancer Research, 1970-74
Chairman, HEW Departmental Committee on Drug Research and Regulations, 1970
Editorial Board, Pharmacological Reviews, 1969-72
Chairman, National Institute of General Medical Science Pharmacology-Toxicology Review Committee, 1967-69
Member, National Institutes of Health Chemotherapy Study Section, 1965-67
Editorial Board, Cancer Research, 1964-present
Member, Graduate Council, George Washington University, 1962-71
Editorial Board, Proceedings of the Society for Experimental Biology and Medicine, 1962-65
Lecturer in Physiology, Medical School, George Washington University, 1958-62
PHS Meritorious Service Medal
DHEW Distinguished Service Medal, April 1975

Research Interests: Dr. Rall has authored and co-authored over 100 published papers relating to comparative pharmacology, cancer chemotherapy, blood-brain barrier, blood CSF barrier, pesticide toxicology, and drug research and regulation.

INTRODUCTION OF ASSOCIATES

Dr. RALL. Thank you, Mr. Chairman. On my immediate left is Mr. Paul Waugaman, our Executive Officer, and on his left, Mr. Bob Patrick, our Budget Officer.

I am very pleased to be here this afternoon to describe NIEHS, its missions, programs, and accomplishments. Although established as a division in 1966, NIEHS became an Institute in 1969 to undertake the conduct and support of research and training aimed at the development of knowledge basic to an understanding of the processes by which man's health is adversely affected by his environment. Thus, emphasis in NIEHS is on research and on knowledge development.

This is, I think, particularly important in the area of environmental health since this is an enormously broad field, and it deals with the effects of—potentially harmful environmental chemicals on human health. But, it is a relatively new area for scientific investigation. Probably the publication of "Silent Spring" by Rachel Carson in 1962 gave impetus to an area of environmental health research which previously had been essentially ignored.

This is, let me emphasize, a particularly complex field of scientific endeavor. Environmental chemicals cause almost the whole spectrum of human diseases. Kepone and methylbutylketone produce neurological diseases. Lead and methylmercury can cause brain damage. Kepone and dibromochloropropane can cause male sterility, and asbestos and vinyl chloride cause cancer. So environmental health research must deal with a whole variety of endpoints or manifestations of disease, and unfortunately many of these endpoints, these diseases, appear only years to decades after the initial insult or the initial exposure to the chemical, so there is a long timelag between exposure to chemicals and development of disease.

In addition, there are hundreds and hundreds of chemicals to which we are exposed. We don't know how many. There are about 50,000 chemicals in commercial production today, and in addition hundreds of medicines and food additives. So clearly this is scientifically and technically a very large and difficult problem, socially and economically. In terms of the potential effects on public health, it is also a very important problem.

To regulate too strictly a chemical that is unlikely to damage health is wasteful, costly, and inefficient. But on the other hand, to fail to regulate a chemical that is likely to cause human disease will cause human suffering and be costly and damaging to the public health. Bad regulation, either too strict or too lenient, is very often based on faulty information and/or too little information. One of NIEHS' main tasks is to provide the best possible research for providing the best possible foundation for regulation.

EXAMPLES OF NIEHS RESEARCH

Now let me just briefly touch on two or three examples of NIEHS research before we go on to questions. I think one of the more serious controversies over the past few years has been Agent Orange, the herbicide used in Vietnam, composed of 2,4,5-T and 2,4-D and contaminated with the extraordinarily toxic tetrachlorodibenzodioxin. The Vietnam veterans have claimed that they are sterile and their children have suffered birth defects because of exposure to Agent Orange.

At NIEHS, we set up an experiment using laboratory mice, exposed them to Agent Orange at very large doses, and studied the ability of the males to mate with fertile female mice. We studied the sperm of the males, and we found that there was no effect produced by exposure to Agent Orange on the mouse sperm, on fertility, or on the offspring.

Thus, this is the sort of toxicological research that is rarely reported in the literature. It is negative, but it is a very important result; and we think this ability to show it was unlikely that Agent Orange or dioxin caused problems with male fertility was an important observation.

And finally we are concerned about better and more rapid test methods. The classic tests to see whether compounds are toxic are very long, very expensive, and very cumbersome. And in our research, again, one of the most important items is to develop a variety of new tests, new techniques, to make judgments more rapidly and more precisely about whether or not chemicals are toxic.

Thank you. I would be delighted to answer questions.

AGENT ORANGE

Senator ANDREWS. Doctor, I appreciate your testimony. You again know how to stimulate my interest by talking about herbicides and Agent Orange. And I hesitate to correct or suggest corrections to a person who is the head of a noted research group, but you start on page 4 saying, "As Love Canal occupied the headlines and other sagas began unfolding, that of the possible adverse health effects on Vietnam veterans due to exposure to the herbicide Agent Orange," and then you talk about the long-term health effects of Agent Orange, and then you said, "After their exposure to Agent Orange," and then you said "simulated Agent Orange," and then finally down at the bottom you came up pointing out that the dioxin contaminant of Agent Orange is a potent carcinogen, which it is.

Now if there is anything wrong with 2,4,5-T or 2,4-D, my growth would have been stunted way back when, because I probably darn near have taken baths in that stuff, standing under old sprayers for our crops. But the tragedy of the whole thing is that we now have a situation where 2,4,5-T has been banned, and the superenvironmentalists are trying to ban 2,4-D, yet your own studies have pointed out—and I'm sure other studies will conclude—that there is no problem with 2,4-D or 2,4,5-T being a carcinogen.

The problem came about, as I understand it, during the Vietnamese war when they wanted to defoliate trees so they could see what was underneath, and they went to the county agent types and found out what would work, and they said, "Heck, use 2,4,5-T and 2,4-D." They did, but they had to manufacture tons of the material on a crash basis from the low bidder, as the Government always goes out there, and, boy, they got a product, but they had a contaminated dioxin which is not in well-manufactured herbicides.

Even now it can be controlled or should be controlled much greater than what we found in 2,4-D and 2,4,5-T. You found no danger from the pure herbicide, as I understand it?

Dr. RALL. No; we called it "Mock Agent Orange" because we put in the same amount of 2,4-D and 2,4,5-T it had, and we added the maximum amount of dioxin contamination.

Senator ANDREWS. In other words, you added the maximum amount of dioxin found in the worst possible case?

Dr. RALL. We were creating the worst possible case, and we found out that was negative. So we think that is significant and important.

Senator ANDREWS. Did you go on any further to take a look at the types of 2,4,5-T and 2,4-D that are being manufactured commercially and what type of contamination of dioxin they might contain?

Dr. RALL. Well, that is basically known. The 2,4-D has no dioxin in it. The 2,4,5-T that is currently manufactured by Dow—and I cannot speak for the other manufacturers—has less than one-tenth of 1 part per million. To put that in perspective, the maximum contaminated Agent Orange has dioxin at 30 parts per million in its 2,4,5-T.

Senator ANDREWS. But your 2,4,5-T had less than one-tenth of 1 part per million, and the 2,4-D that you examined had no dioxin?

Dr. RALL. That's right.

DIOXIN

Senator ANDREWS. Again, I hate to regress into another field, but this is so darned important. It is so darned important for us sometimes to make sure we're zeroing in on the proper target. I think the proper target was undoubtedly dioxin, and I appreciate your testimony to that effect. That is what your findings, in a sense then, confirm.

Dr. RALL. That is correct. We are also testing for neurobehavioral effects using pure 2,4-D and 2,4,5-T. There have been some reports, particularly with 2,4-D, that there may be some muscle weakness after heavy exposure. Those studies are not completed yet, but we will keep you informed.

Senator ANDREWS. Permanent or transitory?

Dr. RALL. Not totally permanent, but they lasted years.

FUNDING OF RESEARCH GRANTS

Senator ANDREWS. To get back to the normal round of questioning, I assume that the funding in your fiscal budget keeps you on a par with your share of the NIH goal of these new and competing research grants?

Dr. RALL. That is correct, sir; $12.6 million will fund 114 competing research grants in 1982.

PROGRAM PRIORITIES

Senator ANDREWS. And if you were faced with a major budget cutback, what would your priorities be?

Dr. RALL. I think I would go along by and large with what the other Institute Directors have said, that the research grant program is critical. I wouldn't guarantee its level would be exactly where it is, depending upon the depth of the cuts.

I view our constellation of intramural research programs as the next important area, and I would certainly try to keep a few dollars out for training because we need the future scientists very much indeed.

CHEMICAL WASTE

Senator ANDREWS. In view of the recently passed superfund legislation, can you give us a rough idea of the extent of chemical waste in the environment that is considered to be extremely dangerous?

Dr. RALL. Well, if you hadn't put those last few words in your question, it would be a lot easier to answer.

Senator ANDREWS. The way we read it, we read about it being in extremely dangerous demand. If I went out and took table salt and ingested a couple of pounds of it, I probably would be in dire straits, too, but we aren't going to ban salt.

Dr. RALL. The numbers are reasonably well-known. We produce 320 billion pounds of chemicals, all chemicals, all synthetic and organic chemicals, each year. Our waste product is approximately that same amount—320 billion pounds a year that somehow has to be dumped somewhere.

One point that I tried to make when I finished my opening statement: The desire to get better methods really is critical to all of this because most chemicals are not toxic. Most chemicals do not need to be regulated. Most chemicals you can mostly forget about.

The problem is, we are faced with literally hundreds of chemicals, and the only test we have to decide whether they are toxic enough to regulate cost $500,000 and take 3 or 4 years to run, and that is too expensive, and it takes too long. And there is no way, using those tests, that you can ever look at the thousands of compounds we are exposed to.

So much of our effort is to try to develop more rapid tests using cells and tissue culture and bacteria, even using whole animals for short periods of time, so that we can predict toxicity. Then some appropriate mixture of the private sector and the Federal Government—it should not just be the Federal Government; the private sector has an enormous responsibility here—should use these tests to study compounds to which all of us are likely to be exposed. That will let you separate out those relatively few that need careful attention, which means, to answer your question, some small fraction of the 320 billion pounds is likely to be hazardous, and we don't today know the size of that fraction.

CARCINOGENS

Senator ANDREWS. How many of these substances would be known carcinogens?

Dr. RALL. Somewhere on the order of 3,000 chemicals have been studied for carcinogenicity. No more than about 200 or 300 of them have been shown to be carcinogenic in laboratory animals, and something on the order of 25 or 35 in human beings.

Now a number of interesting things. There is a test called the Ames Test which predicts reasonably well for carcinogenicity. Dr. Ames in California developed this test, and he sent his graduate students out to the drugstores and grocery markets, where they got all sorts of consumer products and tested them for mutagenicity, which we think predicts for carcinogenicity, using the Ames test. He found that only about 5 to 7 percent of those chemicals were positive in the Ames test, suggesting that only about 5 percent of the chemicals we deal with are likely to be carcinogenic.

So it is not an enormous problem where every new chemical is going to be carcinogenic and needs to be regulated. It looks like 5 percent, and we may know most of those because the testing programs of the last few years have emphasized chemicals whose structures look nasty to good chemists, and 50 or 60 percent of those have been found to be carcinogenic.

TOXIC WASTE

Senator ANDREWS. But the results from the research that you are conducting would protect the public in that you could tell the chemical manufacturing plant what compounds they had to break their waste down into so that that waste would then be safe?

Dr. RALL. We would like to go even one step further than that. We would like to develop a methodology, verify it, validate it, and then

basically tell the private sector, "Here's the methodology; it is your job to check your waste and determine which is the highly toxic and must be taken care of in clay lime pits and all that sort of stuff and which is relatively nontoxic and can be put in the landfill."

Senator ANDREWS. But you said a moment ago that you felt that it isn't the responsibility of the public sector, the Government, to do some of this testing, some of this examining.

Dr. RALL. Some of the tests.

Senator ANDREWS. Let me run another hypothetical. When you're talking about Agent Orange—and this isn't a hypothetical; this is actual—the Shell Manufacturing Co. produces herbicides in a plant in the Netherlands. It produced—and in other locations—they produced one herbicide that is particularly effective on wild oats. Wild oats is a weed that raises hob in a very small area of the Central Northern Plains, and it happens to encompass most of the State of North Dakota and a little bit of three or four other States, and it cost us $10 million—no, more than that; $100 million per year in the control of wild oats, or lack of control of wild oats.

And Shell has been manufacturing and selling in Canada a wild oat herbicide that works very effectively. It's the best thing that we've seen. And now we're beginning to get other chemicals that are better, but for the last decade, that was the greatest thing ever seen. But because the market wasn't broad enough in the United States—most of the spring wheat is grown in Canada—the companies couldn't justify doing the research to prove it was safe to be used in the United States. Yet the consumers in the United States were exposed to it because they were eating flour milled from wheat produced in the prairie provinces of Canada. The wheat flows back and forth across the border.

You know, it's ridiculous. Our costs of production were up, and this happens in a number of other smaller crops—sunflowers, for instance, which is a native American plant the Europeans have been raising for 100 years to lower their cholesterol, and it makes a great quality food. We are beginning to raise them now, and we can't use the same herbicides that we use on rice and on others because you've got to do the testing for that separate small crop.

GOVERNMENT INTERFACE WITH PRIVATE INDUSTRY

In your experience with Agent Orange and similar substances in your concern for the safety of the American public, which is after all what we are all concerned about—whether we happen to be farmers or those who work at NIH, our ultimate goal is to make products and foods safe for the American consumer. Where could we have Government interface with private industry to provide licensing for these herbicides and pesticides that otherwise can't be commercially justified and, in effect, could it be done by then levying back against the chemical company a proportion of the fee per gallon or some such thing, if the Government charged—where do we sit on this? The last thing I want is to have my son out there in the field exposed to some herbicide that is not safe, because that is my family being exposed.

At the same time we've got a responsibility for lowering our net unit cost of production. And the knowledge seems to be in the Government

and the corporations seem to be less and less inclined to look at us and do this.

Dr. RALL. I see one development that has come along from a very unexpected source that might be very, very useful. At the World Health Assembly of the World Health Organization about 4 years ago the developing countries asked WHO to set up an international program on chemical safety—IPCS—which would provide for all of the developed countries to pool their information on the safety of the chemicals and to write up documents—what we call criteria documents in the trade—that would describe how toxic a chemical is and to what extent you should control it and so forth.

This process is well underway now. It is not under full steam, but it is being set up very rapidly. It includes Canada and other countries like that. So if that compound, that herbicide, had been registered in Canada we would have all the information, therefore, in one of these international reviews of the chemical and it would be much easier for the Environmental Protection Agency to register that, because the whole dosier would have been put together on the toxicity of the chemical. The Environmental Protection Agency is part of this program.

So, although it was originally designed to help the developing countries understand better what products were imported to them, it may be useful in the exact situation you describe of a pesticide which has only a small market in the United States but by going through IPCS you could more rapidly get it registered in the United States.

Senator ANDREWS. In other words, as a clinician dealing in the end result, the impact on health of individuals of the use of herbicides and pesticides and a host of other chemicals, you would say that you would be satisfied with the safety of a program that allowed for the interchange between principal nations of the Western World, reputable nations of the Western World, so that a product registered in one could share that information for registration without having to reinvent the wheel and redo the whole thing in another country.

Dr. RALL. And that is in large part what IPCS is trying to do.

Senator ANDREWS. But the key thing that you can testify to is the fact that you would be satisfied with the safety of that type of an interchange.

Dr. RALL. I would as a research scientist. But I must point out that I am not a regulator.

Senator ANDREWS. I am totally aware of that. And sometimes regulators want to carve out their own little empires to the extent that they cost us a whale of a lot more, and we aren't really gaining, in fact, we are falling further and further behind.

I have a whole host of other questions, Doctor, that we can provide to you that can be answered for the record.

I would appreciate it if you would provide those answers at the same time you return the corrected hearing transcript.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

HERBICIDE 2, 4-D & DIOXIN

Question: What studies are NIEHS or the National Toxicology Program (NTP) funding on the herbicide 2, 4-D?

Answer: The NTP has completed three mutagenesis studies, one reproductive assessment, and one neurobehavioral investigation on 2, 4-D. All were negative or showed limited effects. A mutagenesis study in Drosophila (fruit flies) is in progress. Simulated Agent Orange (equal parts of 2, 4-D and 2, 4, 5-trichlorophenoxyacetic acid, with the toxic contaminant -- 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin) was given to male mice to determine any adverse influence on mating frequency, average fertility, percent implantations, resorptions, and fetal malformations. No untoward effects were observed for these measured parameters.

Question: Are these studies being done in response to the Environmental Protection Agency's request for further information about the health effects associated with 2, 4-D?

Answer: The studies noted above were planned on the initiative of the NTP and the concurrence of the NTP Executive Committee, which includes the Administrator of EPA. The NTP makes available all results to the Executive Committee and other governmental agencies, and to industry, academia, and the public.

Question: What, if any, studies on dioxin currently are being conducted by your Institute or NTP?

Answer: Additional studies on dioxin include chemical characterization and synthesis, mechanisms of toxic actions, species comparisons, and the establishment of an international registry of persons exposed to phenoxy acid herbicides and the dioxin contaminants.

POLYCHLORINATED BIPHENYLS (PCBs)

Question: We understand NIEHS is interested in the effects of toxic substances on metabolism, reproduction, and the nervous system. The Institute is currently funding a study to detect the long-term effects of PCBs in humans using young children whose mothers' milk was found to contain traces of PCBs. Please inform the subcommittee about the status of the PCB neurobehavioral study.

Answer: At the present time between 800 and 900 children have been enrolled in the study with some having been followed for as long as 2 3/4 years. Clinical data for the period from birth to age 6 months has been cleaned and edited for most enrollees, and analyses for PCBs/DDE have been performed for approximately 800 specimens. A preliminary analysis of this data set is planned for the summer of 1981. In addition, formal agreements to extend the follow-up interval to 5 years are almost completed. It should be noted that this study is not specifically a "neurobehavorial" study, although developmental endpoints are being evaluated.

Question: Is your methodology sufficiently sensitive to obtain good data?

Answer: The analytical chemistry methods being employed in this study are believed to represent the current state of the art.

The morbidity data being collected is as sensitive as possible without the provision of clinical care. As part of the methodology, we see the children, check their records, and examine the children ourselves. The developmental data are obtained from standard developmental scales, but the scope of the study prohibits the generation of more refined data such as evoked potentials. The sample size is as big as can reasonably be handled. Also, the data analysis methods are standard for this type of investigation.

FOOD SAFETY

Question: With the recent congressional and public interest in harmful contaminants and naturally-occurring carcinogens in foods, what research do you support to provide information which will help to improve the safety of the food supply?

Answer: The research program of the National Institute of Environmental Health Sciences supports the Bureau of Foods, Food and Drug Administration, in two broad areas: (1) various aspects of animal and laboratory research may be helpful in determining the harmful and carcinogenic effects of naturally-occurring carcinogens and other contaminants, and (2) risk analysis/assessment research may be helpful in estimating or evaluating these results in terms of their potential effect on man.

Question: To what extent is there cooperation and/or coordination with the Bureau of Foods in the Food and Drug Administration to develop answers to food safety questions that will be useful to both agencies?

Answer: NIEHS and the FDA have a continued interface at many levels: (1) The FDA sends liaison representatives to The National Advisory Environmental Health Sciences Council; (2) collaboration in the National Toxicology Program which involves not only FDA but other regulatory agencies as well as NIOSH and NCI. The program provides a strong interface between regulators and researchers; (3) collaboration on the Annual Report on Carcinogens under Public Law 95-622; and (4) both NIEHS and FDA are members of the Task Force on Environmental Cancer and Heart and Lung Disease, mandated by the Clean Air Act.

Question: Should there be a maximum allowable level for contaminants and carcinogens in foods?

Answer: We understand that current practices indicate an affirmative answer to this question and this practice should be continued. It is our understanding that the basic premise FDA tests in reaching a decision is to maximize the amount of food available on the marketplace while minimizing possible adverse public health implications.

There are a number of difficulties, however, that crop up. One deals with the limit of detection of contaminants. As analytical methods improve and the limit of detection is lowered, new evaluations may have to be made. Another aspect is the intake of the contaminant which depends on the average level in the food and the quantity of that food consumed by the population, including possibly the relatively heavy consumer.

Such determinations have been made by the FDA on contaminants such as mercury, PCB, PBB, and aflatoxins.

TRACE MINERALS

Question: We're advised that evidence suggests that many Americans may experience subtle nutritional deficiencies of certain trace minerals that now exist in the food and water supply. If the environment is "cleaned up," to what extent would the sources of these trace minerals in the diet be removed?

Answer: Environmental "clean up" might affect water hardness if pollutants are removed by procedures which demineralize or deionize water. However, removal of organic compounds from water does not require demineralization procedures. Depletion of minerals in soil due to use of "incomplete" fertilizers has also been suspected of producing food low in mineral content, but it is unclear how various types of environmental "clean up" would contribute to this concern.

Question: What would be the health effects?

Answer: It has been observed that there is an inverse relationship between water hardness and death due to certain cardiovascular diseases and hypertension, renal stones, and sudden infant death syndrome or crib death. These effects are thought to be largely related to a deficiency of magnesium, but deficiencies of chromium, copper, manganese, silicon, vandium, and zinc may also be of some importance.

MUTATIONS

Question: In FY 1981, you described an in vitro (test tube) method devised by the Institute which uses the hemoglobins of red blood cells to discover mutant cells caused by environmental insults. Has the Institute succeeded in developing a parallel system for detection of mutations in mice?

Answer: The ability to detect hemoglobin mutations in the single red blood cells depends on the quality of the antibodies. Unfortunately, the affinity of the antibody, which was purified for this purpose, was not strong enough to use in the mutation experiments. This problem can be solved by using antibodies produced by hybridoma cells. Production of hybridomas has been initiated.

The hemoglobin system detects mutations in somatic cells. However, it is the germinal cells that are important for transmission of mutations to the next generation. A system for detection of point mutations directly in sperm has been developed. It is based on the sperm specific enzyme, lactate dehydrogenase-, or LDH-X. By using the antigenic differences between the rat and mouse forms of the enzyme, LDH-X point mutations can be detected directly in sperm from mice.

Mutations which were induced in germinal stem cells after treatment of mice with procarbazine, mitomycin C, and TEM have been detected using the LDH-X system. All three of these compounds are anticarcinogenic. Procarbazine is presently used to treat cancer patients. Mitomycin C

and TEM were used earlier as drugs for treatment of cancer in humans.

One important feature of the LDH-X system is that mutations can be detected up to one year after treatment of the animal. The system, therefore, may show an accumulation of mutations after low-dose chronic exposure, which is generally the mode of exposure of the human population to environmental pollutants.

Question: What other investigations are being done to discover subtle changes in cell systems before the cells have a chance to mutate?

Answer: Two types of changes occur in cells before mutation expression: primary DNA damage, and DNA sequence changes.

The NIEHS is conducting a modest program to detect DNA damage by chemical tests, focusing on areas unlikely to be sufficiently explored elsewhere. Currently the emphasis is on damage due to induced purine glycosidic bond migration and to cytosine deamination. Both are potentially important sources of gene mutations. A very promising alternative approach would be to develop and apply new methods to introduce specific damages into highly defined recombinant DNA sequences, and then to determine the mutational consequences of such damages. This approach is important because most chemicals produce multiple types of DNA damage, and it is usually far from clear which of these are lethal, which premutational, and which innocuous.

The direct assay of DNA sequence changes following exposure to mutagens should grow out of investigations of the organization and arrangement of genes in higher organisms. It is evident that a significant proportion of DNA sequences do not encode proteins, but it is not yet known what roles the non-coding sequences play or just how much they can be modified before mutant gene expression is produced. Through the use of recombinant DNA techniques for purifying genes and the genetic manipulation of mutant forms of genes, the molecular mechanisms of gene function and regulation are being worked out and the types of changes that produce mutations are being studied. A significant effort is also going into understanding the nature and the function of mobile genetic elements. These are families of DNA sequences that have the ability to change positions in chromosomes and as they do so, create structural changes in genes that may result in mutations. Studies are underway to fully characterize selected families of mobile elements and to understand their roles in mutation. Of particular interest is determining whether the mobility, and thus the mutational potential of such sequences, is more or less sensitive to mutagens than that of the DNA sequences encoding proteins.

Question: If perfected, how rapidly could people be tested for mutations?

Answer: Further development of the hemoglobin system in mice requires production of several different hybridoma antibodies to hemoglobin. This process will take approximately two years. After this it will take another 3-5 years before sufficient amounts of data have accumulated from comparison of mutation data of laboratory animals and humans treated with the same mutagenic compounds such as anticancer drugs.

The application of the LDH-X system to human screening is a couple of

years ahead of the hemoglobin system. The affinity of the antibodies is sufficiently strong to detect mutations in mice, and human sperm contain enough LDH-X for detection of mutations. Five anticancer drugs, all presently used in humans, have been selected for testing in mice. As the results from these tests are analyzed, samples will be obtained from humans treated with the same drugs. The comparison of the human and mouse data will determine the usefulness of this system as an epidemiological system for detection of humans exposed to mutagens. This whole process will probably take between three and five years, depending on available resources.

A long range goal is to develop assay systems that will detect changes at the DNA level. Studies on chromosome organization and gene regulation are designed to form the foundation of such assays by defining mutational targets in molecular terms. Strides toward understanding basic mechanisms of gene function in development have been made very rapidly since recombinant DNA techniques and DNA sequencing began to be coupled with genetic analysis.

Remarkable advances are also being made toward understanding spontaneous mutation events and in understanding the impact of mutations on populations. How quickly this information can be extended and generalized, and assays developed that can be applied to human populations cannot be accurately predicted because, in addition to lacking some fundamental information about genes, their mutant forms, and how they act, only a part of the requisite technology now exists.

ANIMAL TESTING

Question: Many times a chemical found to be carcinogenic in one animal species is not carcinogenic in another animal species. Is NIEHS studying this problem and what have you found?

Answer: A large percentage (perhaps 90 - 95%) of all chemical carcinogens cause tumors in more than one species. For those chemicals found to cause tumors only in one species, this is usually because only a few experiments have been performed. For example, over a period of time DDT was found to cause tumors only in mice. Subsequent experiments in rats revealed induction of tumors in this second species.

Question: What progress has been made in understanding the factors that would account for these variations?

Answer: It is already known that for many chemicals, there are differences in degrees of toxicity and patterns of chemical metabolism between sexes and between species. The NTP is studying chemical disposition for selected compounds in rats and mice to study the absorption, distribution, metabolism, and excretion of these chemicals to give partial answers as to perhaps why species may respond by different degrees to toxic chemicals. Some of these findings may affect the carcinogenic process. Additional studies by the NTP for selected important chemicals are being carried out to identify these differences in relation to potential human hazards. Also, the NTP is taking part in a symposium sponsored by NCI and EPA which will focus on organ and species specificity in chemical carcinogenesis.

INDEPENDENT SCIENTIFIC PANEL

Question: There has been increasing interest in establishing a separate panel of independent scientists to review studies and settle scientific disputes that arise during the regulatory process. What good would such a panel do and could the Board of Scientific Counselors of the National Toxicology Program be used for this purpose?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Mt. St. Helens

Question: What effect are the volcanic eruptions of Mt. St. Helens having on the health of local inhabitants?

Answer: The immediate or short-range health effects resulting from exposure to ashfall and dust levels from Mt. St. Helens are primarily respiratory. Hospitals in Vancouver, Washington and Portland, Oregon report an increase in emergency room visits by patients with respiratory problems following each of the ashfalls. The largest portion of the visits represented visits for asthma, wheezing and shortness of breath, or reactive airway diseases.

Immediately following the May 25th eruption, there was also an increased incidence of emergency room visits for foreign bodies (eyes) and conjunctivitis.

Question: How widespread are the health effects?

Answer: Grantees of NIEHS, especially those associated with the Environmental Health Science Centers, initiated a series of research projects (using animals) almost immediately following the first eruption of Mt. St. Helens, to study the health effects from exposure to the volcanic fallout. These studies include, for example, dust feeding studies, analysis of respirable dust; inflammatory effect of the dust; and studies on reactions of macrophages, lung tissues, blood and blood cells, and membranes to dust following short and long-term exposure. These studies, when completed should, along with follow-up evaluation of exposed humans, provide detailed information on specific health effects and extent of health effects associated with exposure to volcanic dust from Mt. St. Helens.

LOVE CANAL

Question: The situation of Love Canal in New York continues to be of major concern. What role has the Institute played in attempting to establish a link between the chemicals found at the dump site and the health complaints of residents from that area?

Answer: NIEHS has attempted to establish a link between chemicals found in the Love Canal dump site and the health complaints of residents through efforts at several levels. In 1979, NIEHS participated in a series of meetings with the residents of the Love Canal area and health professionals of the New York State Department of Health. The results of these reviews were conveyed by Secretary

Califano to Honorable John Lafalce, Rep. New York, on July 25, 1979. NIEHS participated in a Department-wide review of the potential health effects of toxic chemical dumps and tabulated the available toxicological and health data regarding chemicals identified in the Love Canal waste dump (DHHS Report of the Sub-committee on the Potential Health Effects of Toxic Chemical Dumps of the DHHS Committee to Coordinate Environmental and Related Programs)..This Report was released following testimony by Dr. David Rall, Director, NIEHS, at hearings before the House of Representatives Subcommittee on Oversight and Investigations Committee on Interstate and Foreign Commerce on May 22, 1980.

NIEHS is presently assisting in the planning and financial support of proposed studies of health effects among Love Canal residents to be conducted by the New York State Medical School at Buffalo, New York.

Question: When will it be possible to determine the cause of these health problems?

Answer: It is unlikely that specific chemicals will be identified as the cause of health problems present in Love Canal residents because of the lack of quantitative information regarding exposure of residents to specific chemicals, a lack of measurable parameters or tests that can be employed to identify health effects due to chemicals in human population (e.g., measures of unexpressed genetic effects or subtle neurologic effects) and the enormous psychosocial overlay that now exists in the residents of that area due to the uncertainties regarding the level of health risk to people living in the area.

Question: Do you offer assistance in such situations - or do you wait to be called?

Answer: NIEHS responds to requests for assistance that are made through the Department of Health and Human Services. The focus for such requests at the present time is through an Executive Committee reporting the Assistant Secretary for Health. NIEHS assistance may then be provided in collaboration with the appropriate agency within the Department designated as the lead agency.

TRICHLOROETHYLENE (TCE)

Question: Trichloroethylene--or TCE-- is used as a degreasing agent in several industrial processes. It is considered to be an animal carcinogen. During the past two years, several communities have discovered the presence of TCE in their drinking water supplies and are concerned about the potential health effects. What are these communities doing to deal with their problem?

Answer: Epidemiologic studies of residents in communities in Montgomery and Buck Counties, Pennsylvania, have been conducted by the Centers for Disease Control, Atlanta. CDC has recommended to state authorities that exposure to trichloroethylene (TCE) be stopped and that alternative drinking water supplies be utilized.

Question: What suggestions has the Institute made?

Answer: The National Institute of Environmental Health

Sciences has continued its investigations into the potential toxicological effects of TCE. Previous animal tests by the National Cancer Institute's Carcinogenesis Bioassay Program demonstrated that TCE caused liver tumors in mice but not in rats. Further studies are underway to determine if other strains of rats are sensitive to TCE. In the past year, the National Toxicology Program has completed studies showing that TCE is not teratogenic in rats and rabbits. No specific suggestions have been made to CDC or EPA regarding the toxicity of TCE.

Question: What is the current status of the epidemiological study on TCE being conducted by the Environmental Health Sciences Laboratory at Mount Sinai Hospital?

Answer: Epidemiological studies being conducted by the Environmental Health Sciences Laboratory at Mount Sinai Hospital on retired dry-cleaning workers in the New York City area are still in progress. It will not be possible to provide any results regarding this study until it is completed.

CHLORINE AND CANCER

Question: Chlorine is known as a very effective disinfectant. Yet we read reports indicating a link between drinking chlorinated water and several types of cancer (rectal, colon and bladder). What can you tell us about this matter and how serious is the problem?

Answer: Chlorination of drinking water became a matter of concern when two independent studies found trihalomethanes in all chlorinated drinking waters they analyzed. The most abundant compound was chloroform. An explanation for the formation of these compounds was soon postulated; namely, the reaction of chlorine, added for disinfection, with humic substances present naturally in the water.

In December 1974 Public Law 93-523, The Safe Drinking Water Act, mandated that the EPA conduct studies on drinking water to determine the source, nature, and extent of existence of these trihalomethanes and other compounds and to find means of prevention or control of these properties of the most abundant of these trihalomethanes, namely chloroform. Even the highest concentration encountered in chlorinated drinking water, however, is still very low.

An epidemiological study carried out in 1964 had suggested that a higher incidence of cancers was observed in populations, suggesting that there may be a link between various cancers and river-born carcinogens. Since 1974, several studies have been reported on similar associations between chlorinated surface waters and cancer as contrasted with unchlorinated ground water.

These associations were between chlorination of water and cancer of the rectum, bladder, and colon. Other types of cancer did not show a positive correlation. However, even the positive correlations did not apply to each of the three types of cancer in every study or to all subgroups of populations. Also, little information is available on the concentration of the individual chlorinated compounds over time and, particularly, no information is available on trihalomethanes years ago when their presence would have been responsible for the long process of cancer induction. However, it is important

to explore the problem in the future and to make efforts to quantitate the other chemicals found in chlorinated drinking water. A study on nonvolatile organic chemicals in ground water also has been made.

Chlorination of water is carried out until an excess of chlorine remains. This is essential to allow disinfecting properties for the water in case of contamination by industrial or urban and rural effluents. The nature of these chlorinated products is not well established and becomes more difficult as the products become less volatile. With higher degrees of chlorination, degradability may readily decrease and toxicity often increases leading to a potentially increased health hazard. The problem is worth further exploration and investigation.

Also the presence of bromine in some of the chlorinating products or the oxidation of naturally occurring bromides in the water by chlorine may lead to other types of halogenated products with different toxicities.

Question: How valid are such reports?

Answer: To answer the question: How valid are such reports? I should like to quote the famous British scientist, Dr. Richard Doll who stated: "The characteristic feature of this study is, however, that information is obtained from communities as a whole and not about individuals. Evidence of an association...is, therefore, indirect and though it may be extremely valuable in suggesting a hypothesis for detailed study by other methods, conclusions about etiology cannot be drawn from it."

BIOASSAY PROGRAM

Question: The bioassay program, established by the National Cancer Institute, tests selected compounds for their potential for causing in mice and rats. Several hundred chemicals have been tested in the bioassay program. Out of the total number of chemicals tested, how many are currently being regulated, how many have been banned, and how many are in the process of being regulated?

Answer: To date 230 final technical reports have been published on chemicals tested in the bioassay program. In early 1980 a paper entitled "Toward a Classification Scheme for Degrees of Experimental Evidence for the Carcinogenicity of Chemicals for Animals" was published which evaluates the degree of evidence of carcinogenicity in animals for 192 of the bioassay chemicals and places them in nine categories under a classification scheme developed by the authors. According to this scheme at least sufficient evidence of carcinogenicity in one species existed for 97 of the 192 bioassay chemicals. This response will provide information on that subset of the 97 chemicals for which regulations have been proposed or finalized.

This reply is limited to these chemicals for three reasons:

(1) The National Toxicology Program and its component agencies have reviewed the regulatory status of these chemicals as part of the effort to develop the Annual Report on Carcinogens.

(2) For the remaining 95 chemicals in the above-mentioned paper

the evidence for carcinogenicity ranges from equivocal to nonexistent in two animal species.

(3) The bioassays for most of the remaining chemicals not included in the paper but for which final technical reports have been published were only recently completed. Sufficient time has not elapsed in most cases for the development of regulations.

Fifty-five of the chemicals are currently being regulated or have been proposed for regulation by one or more of the following agencies: Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC) , and Occupational Safety and Health Administration (OSHA). In 1977 CPSC declared Tris (2,3-dibromopropyl) phosphate to be a "banned hazardous substance" for use in children's clothing under the Federal Hazardous Substances Act. Pursuant to receipt of the bioassay results on chloroform, FDA promulgated regulations to remove chloroform from foods, drugs, and cosmetics as an ingredient. Moreover, the registrations for nearly all pesticide uses of chlordane, chlorobenzilate, heptachlor, and aldrin have been cancelled by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act.

Final regulations exist for 28 of the chemicals and proposed regulations have been published for 35 chemicals. A number of these chemicals have proposed regulations pending as well as final regulations in effect under different statutes administered either within the same agency or by more than one agency. The attached table lists the 55 chemicals and the status of regulations by agency.

Question: Please list these chemicals and their status of regulation by agency.

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
1) 3-amino-9-ethylcarbazole hydrochloride (132-32-1)	TSCA, Sect. 8(a) reporting rule requiring process and use data (proposed)			
2) o-anisidine hydrochloride (134-29-0)				Permissible Exposure Limit (PEL) 0.5 mg/m (o-anisdine)
3) chloroform (67-66-3)	CWA Section 304(a) Water quality criteria published in final 11/80 CWA, Sect. 311. Hazardous spill regulation establishing reportable quantity (500 lb., 2270 kg) and imposing reporting requirements promulgated 8/29/79. A proposal to reduce reportable quantity to 100 lb. (454 kg). 7/9/80 FIFRA, Sect. 6. RPAR issued 4/6/76 RCRA, Sect. 3001-3004. Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements.	Pursuant to receipt of NCI bioassay, FDA promulgated regulations to remove chloroform from foods, drugs & cosmetics as an ingredient		PEL: 50 ppm (240 mb/m3) ceiling

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
	Also designates chloroform as a hazardous constituent of waste and subjects wastes known to contain it to the same requirements. Promulgated 5/19/80 SDWA-Regulation regarding removel of chloroform and three other trihalomethanes promulgated 11/20/79. Establishes technology-based maximum contaminant level of 100 ug/l			
4) cupferron (135-20-6)	TSCA, Section 8(a) reporting rule requiring process and use data (proposed)			
5) p-cresidine (120-71-8)	TSCA, Section 8(a) reportrule requiring process and use data (proposed)			
6) 1,3-dibromi-3-chloropropane (96-12-8)	-FIFRA, Section 6-Notice of all uses, and suspension order affecting all uses except one for pineapples in Hawaii published 10/29/79. Final action after RPAR, except for hearings now in progress. -RCRA, Section 3001-3004 Subjects waste product,			PEL-1ppb 8 hr. TWA Airborne concentration No skin or eye contact Additional Regulation: Protective clothing, respirator, hygiene, training and medical surveillance requirements for workers, monitoring require-

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
	off-specification batches, and spill residues in excess of 100 kg to handling and report/recordkeeping requirements. Also, designates DBCP as a hazardous constituent of waste and subjects wastes known to contain it to the same requirements. Promulgated 5/19/80. -TSCA, Section 8(a)-Reporting rule for submission of use and related data (proposed)			ments, housekeeping and waste disposal requirements, sign requirements for regulated areas: labeling requirements for containers. (OSHA)
7) 1,2-dibromoethane (106-93-4) ethylene dibromide	-FIFRA, Section 6 RPAR Issued 12/14/77 -RCRA, Section 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements. Promulgated 5/19/80.			PEL-20 ppm 8 hr TWA; 30ppm ceiling; 50ppm max peak for 5 mins. in an 8 hr time period.
8) 1,2-dichloroethane (107-06-2)	CWA, Sect. 311 Hazardous spill regulation establishing reportable quantity & imposing reporting requirements (final)	FD/CA, compound labelled animal carcinogen; agency initiated revocation of regulations allowing residues in foods where used as extractant (proposed)		PEL: 50ppm (200mg/m3) 8 hr TWA 100ppm ceiling 200ppm max. peak for 5 min. in any 3 hr. period.

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
	CWA, Sect. 304(a) Water quality criteria published in final RCRA, Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling & report/recordkeeping requirements. Promulgated 5/19/80			
9) 1,4 dioxane (123-91-1)	-RCDA, Section 3001-3004 Subjects waste product, off-specification batches. and spill residues in excess of 1000 kg. to handling and report/recordkeeping requirements. Promulgated 5/19/80 -TSCA, Section 8(a) reporting rule requiring process and use data (proposed)			PEL: 100ppm (360 mg/m3) 8 hr. TWA
10) hydrazobenzene (122-66-7)	-CWA, Section 304(a) Water quality criteria published in final (1980) -TSCA Section 8(a)-reporting rule requiring process and use data (proposed)			

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
11) 4,4' -methylene bis (N,N-dimethyl) benzeneamine (101-61-1)	TSCA Section 8(a)-reporting rule requiring process and use data (proposed)			
12) Michler's Ketone (90-94-8)	TSCA Section 8(a)-reporting rule requiring process and use data (proposed)			
13) nitroacenaphthene	TSCA Section 8(a)-reporting rule requiring process and use data (proposed)			
14) nitrilotriacetic acid, trisodium salt (5064-31-3)	TSCA, Section 8(a) reporting rule requiring process and use data (proposed)			
15) reserpine (50-55-5)	RCRA, Section 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and reporting recordkeeping requirements. Promulgated 5/19/80	Regulation requiring zero residue for reserpine and its metabolites in turkey meat. Approval of drug for use in turkeys to lessen aortic rupture withdrawn at request of sponsor (1/80)		
16) selenuim sulfide (7446-34-6)				PEL: 0.2 mg/m3 8 hr TWA (selenuim compounds)

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
17) 4,4'-thiodianiline (139-65-1)	TSCA, Section 8(a) reporting rule requiring process and use data (proposed)			
18) Thiotepa (52-24-4) Tris (aziridinyl) phosphine sulfide	RCRA, Section 3001-3004 designates compound as hazardous constituent of wastes known to contain it. Subjected to handling and report/recordkeeping requirements.			
19) O-toluidine hydrochloride (636-21-5)	RCRA, Section 3001-3004- Subjects waste product, off-specification batches and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements. Promulgated 1/80. Also designates o-toluidine hydrochloride as a hazardous constituent of waste, and subjects wastes known to contain it to the same requirements promulgated 5/19/80.			
20) Tris (2-3-dibromopropyl) phosphate (126-72-7) TRIS	-RCRA, Section 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping require-		FHSA, In 1977, CPSC acted to remove all TRIS treated children's clothing from the market-recall of all articles in channels of distribution and of any	

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
	ments. Also designates Tris as a hazardous constituent of waste and subjects wastes known to contain it to the same requirements. Promulgated 5/19/80. -TSCA, Section 8(a)-Because manufacture of this chemical has been discontinued, no regulatory action under TSCA was deemed necessary. Because this was reported for the Inventory, it could not be subjected to PMN requirements. Accordingly a rule requiring that EPA be notified of intent to begin or resume manufacture or importation was promulgated, 10/24/80.		unwashed garments in hands of consumers ordered. In 1978 CPSC interpreted FHSA to to prohibit export of same products.	
21) 1-amino-2-methyl-anthraquinone (82-28-0)	TSCA, Section 8(a)-reporting rule requiring process and use data (proposed)			
22) 5-nitro-o-anisidine (99-59-2)	TSCA, Section 8(a)-reporting rule....(proposed)			
23) para-nitrosodiphenylamine (156-10-5)	TSCA, Section 8(a)-reporting rule....(proposed)			

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
24) 4-amino 2-nitrophenol (119-34-6)	TSCA, Section 8(a)-reporting rule....(proposed)			
25) aniline hydrochloride (142-04-7)	TSCA Section 8(a)-reporting rule requiring process and use data (proposed)			PEL: 5ppm (19 mg/m3) 8 hr TWA (aniline)
26) azobenzene (103-33-3)	TSCA Section 8(a)-reporting rule....(proposed)			
27) chlordane (57,74-9)	-FIFRA, Sections 3,6 Cancellation of most registrations, 3/28/78. Designation of few remaining for restricted use. -CWA, Section 304(a) Water quality criteria published final 11/28/80. -CWA, Section 311 Hazardous spill regulation establishing reportable quantity (1 lb., 0.454 kg), and imposing reporting requirements promulgated 8/28/79. -RCRA, 3001-3004-Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg (chlordane). to handling and report/record-			PEL: 0.5 mg/m3 8 hr. TWA

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
	keeping requirements. Also designates chlordane as hazardous constituent of waste, and subjects wastes known to contain chemical to the above requirements Promulgated 5/19/80.			
28) chlorobenzilate (510-15-6)	-FIFRA, Section 6 Cancellation of all registration except certain use on citrus crops, 2/13/79. The remaining use registrations are conditional. -RCRA, Sections 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements. Also designates chlorobenzilate as a hazardous constituent of waste and subjects wastes known to contain it to the same requirements. Promulgated 5/19/80.			
29) 5-chloro-o-toluidine (95-79-4)	TSCA Section 8(a)-reporting rule requiring process and use data (proposed)			

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
30) 4-chloro-toluidine hydrochloride (3165-93-3)	TSCA Sect. 8(a) reporting rule (proposed) RCRA Sect. 3001-3004 Subjects waste product, off specification batches and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements.			
31) para,para'DDE (72-55-9)	-CWA, Section 304(a) Water quality criteria (final) -CWA, Section 307(a) Toxic pollutant effluent standards promulated (1/77) -CWA, Section 311 Hazardous spill regulation establishing reportable quantity (1 lb., 0.454 kg) and imposing reporting requirements. Promulgated 8/79 -RCRA-Sections 3001-3004 Subjects waste product, off-specification batches, and spill residues of DDE, DDT and TDE in excess of 1000 kg to handling and report/record-			PEL: 1 mg/m3 8 hr. TWA

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
	keeping requirements. Designates DDE, DDT and TDE as hazardous constituents of waste, and subjects wastes known to contain any or all of them to the same requirements.			
32) Direct Black 38 (1937-37-7)		TSCA Section 8(a)-Reporting rule requiring process and use data (proposed)	Proposed ban on all benzidine based dyes for use to impart color in consumer products (1980) Final rulemaking expected fall, 1981.	
33) Direct Blue 6 (2602-46-2)		TSCA Sect. 8(a) reporting rule proposed)	Proposed ban on all benzidine based dyes for use to impart color in consumer products (1980). Final rulemaking expected, Fall 1981.	
34) Direct Brown 95 (16071-86-6)		TSCA Sect. 8(a) reporting rule (Proposed)	Same as for Direct Black 38 and Direct Blue 6	
35) Heptachlor (76-44-8)		FIFRA, Sections 3, 6 Cancellation most registrations 3/78. Designation of few remaining for restricted use CWA, Section 304(a) Water quality criteria published - final 11/80		PEL: 1.5 mg/m3 8 hr. TWA

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
	CWA, Section 311 Hazardous spill regulation establishing reportable quantity (1 lb., .454 kg), and imposing reporting requirements promulgated 8/79. RCRA Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1 kg to handling and report/recordkeeping requirements. Also designates heptachlor as hazardous constituent of waste, and subjects wastes known to contain heptachlor to above requirements (promulgated 5/80)			
36) Hexachloroethane (67-72-1)	CWA, Sect. 311 Hazardous spill regulation establishing reportable quantity and imposing reporting requirements (proposed) RCRA, Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/record keeping requirements. Promulgated 5/19/80			1 ppm (10 mg/m3) 8 hr TWA

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
37) 6-Nitro benzimidazole (94-52-8)	TSCA Sect. 8(a) reporting rule (proposed)			
38) N-Nitroso-diphenylamine	TSCA Sect. 8(a) reporting rule (proposed) RCRA Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements.			
39) p-quinone dioxime (105-11-3)	TSCA Section 8(a) reporting rule (proposed)			
40) 1,1,2,2-tetrachloroethane (79-34-5)	RCRA, Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements. Promulgated 5/19/80 CWA, Sect. 304 (a) Water quality criteria for chlorinated ethanes published in final, 11/28/80. CWA, Sect 311 Hazardous spill regulation designating reportable quantity (100 lbs) proposed			PEL: 5 ppm (35 mb/m3) 8 hr. TWA

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
41) tetrachloroethylene (127-18-4)	RCRA, Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements. Promulgated 5/19/80 CWA, Sect. 304(a) Water Quality Criteria published in final, 11/28/80. CAA, 111(d) New source performance standards for degreasing, proposed 6/11/80. Affects facilities using tetrachloroethylene and four other solvents. CWA, 311 Hazardous spill regulation designating reportable quantity (1000 lb., 454 kg) proposed 7/9/80			PEL: 100 ppm TWA 200 ppm ceiling 300 ppm max for 5 min. in any 3 hr. period
42) Toxaphene (8001-35-2)	CWA, Sect. 304(a) Water quality criteria published in final, 11/28/80 CWA, Sect. 307(a) Toxic pollutant effluent standard promulgated, 1/12/77 CWA, Sect 311			PEL: 0.5 mg/m3 8 hr. TWA

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY			
	EPA	FDA	CPSC	OSHA
	Hazardous spill regulation establishing reportable quantity (1 lb. 0.454 kg) and imposing reporting requirements promulgated 8/29/79. FIFRA, Sect. 6 RPAR issued 5/27/77. RCRA, Sec. 3001-3004 Subjects waste product, off-specification batches, and spill residue in excess of 1000 kg to handling and report/recordkeeping requirements. Also designates toxaphene as a hazardous constituent of waste and subjects wastes known to contain it to the same requirements. Promulgated 5/19/80. SDWA, 1412 Primary drinking water standard promulgated 12/24/75.			
43) 1,1,2-trichloroethane (79-00-5)	RCRA, Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/record-keeping requirements. Promulgated 5/19/80 Also designates 1,1,2-trichloroethane as a hazardous constituent of waste, and subjects wastes known to contain it to the same requirements.			PEL: 10 ppm (45 mg/m3) 8 hr. TWA

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
	CWA, Sect. 304(a) Water quality criteria published in final, 11/23/80 CWA, Sect. 311 Hazardous spill regulation designating reportable quantity (100 lb.). Proposed 7/9/80.			
44) Trichloroethylene (79-01-6)	RCRA, Sect. 3001-3004 Subjects waste product, off-specification batches, and spill residues in excess of 1000 Kg to handling and report/recordkeeping requirements. Promulgated 5/19/80 CWA, Sect. 304(a) Water quality criteria Published in final 11/28/80 CWA, Sect. 311 Hazardous spill regulation, designating reportable quantity (1000 lb., 454 kg) and imposing reporting requirement promulgated 8/29/79.	Revocation of regulation setting residue levels in trichloroethylene in foods in process. New regulation will prohibit any detectable levels in foods		PEL: 100 ppm ($535\ mg/m^3$) 8 hr. TWA 200 ppm ceiling 300 ppm max. peak for 5 min. in any 2 hr. period- reprosal in planning stage

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
	CAA, 111(d) New source performance standards for solvent metal cleaning (degreasing) proposed 6/11/80.			
45) Trifluralin (1582-09-8)	FFRA RPAR Issued (8/79)			
46) Aldrin (309-00-2)	FIFRA, Sect. 6 Registrations for virtually all uses cancelled (10/74)			PEL: 0.25 mg/m^3 8 hr. TWA
	CWA, Sect. 304(a) Water quality criteria published in final (11/80)			
	CWA, Sect. 307(a) Toxic pollutant effluent standards promulgated (1/77)			
	CWA, Sect. 311 Hazardous spill regulation establishing reportable quantity (1 lb., 0.454 kg), and imposing reporting requirements promulgated (8/79)			
	RCRA, Sect. 3001-3004 Subjects waste product, off-			

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
	specification batches and spill residues in excess of 1 kg to handling and report/recordkeeping requirements. Promulgated 5/19/80. Designated as hazardous waste			
47) 3-amino-4-ethoxyacetanilide (17026-81-2)	TSCA, Sect. 8(a) Reporting rule (proposed)			
48) 2-amino-5-nitrothiazole (121-66-4)	TSCA, Sect. 8(a) Reporting rule (proposed)			
49) 2,4-dinitrotoluene (121-14-2)				PEL: 1.5 mg/m^3 (all dinitrotoluenes)
50) Captan (133-06-2)	CWA, Sect. 311 Hazardous spill regulation establishing reportable quantity (1 lb. 0.454 Kg) and imposing reporting requirements promulgated (8/79) FIFRA, RPAR published (7/80) RSCA, Sect. 8(a) Reporting rule (proposed)			
51) C.I. vat yellow 4 (128-66-5)	TSCA, Sect. 8(a) Reporting rule (proposed)			

STATUS OF REGULATIONS

Chemical (CAS #)	AGENCY EPA	FDA	CPSC	OSHA
52) Dicofol (115-32-2)	CWA, Sect. 311 Hazardous spill regulation establishing reportable quantity and imposing reporting requirements (final)			
53) 3-Nitro-para-aceto-phenetide (1777-84-0)	TSCA, Sect. 8(a) Reporting rule (proposed)			
54) Piperonyl sulfoxide (120-62-7)	RCRA, Sect. 3001-3004 Subjects waste products, off-specification batches and spill residues in exess of 1000 Kg to handling and report/recordkeeping requirements. Promulgated 5/19/80.			
55) Trimethylthiouea	TSCA, Sect. 8(a) Reporting rule (proposed)			

INDEX OF ABBREVIATIONS IN TABLE

1. TSCA - Toxic Substances Control Act
2. CAA - Clean Air Act
3. CWA - Clean Water Act
4. FD&CA - Food, Drug and Cosmetic Act
5. FIFRA - Federal Insecticide, Fungicide and Rodenticide Act
6. FHSA - Federal Hazardous Substances Act
7. PEL - Permissible exposure limit, set by OSHA
8. PMN - Premanufacturing notice
9. p.p.m.- Parts per million
10. RCRA - Resources Conservation and Recovery Act
11. RPAR - Rebuttable presumption against registration, issued under FIFRA
12. SDWA - Safe Drinking Water Act

Question: Please explain why there has been a two-fold increase in out-put of bioassay reports since the program left the National Cancer Institute.

Answer: With respect to the increase in out-put of bioassay reports, the Bioassay Program completed a number of bioassays for which final technical reports were not written prior to its affiliation with the NTP. To remedy this situation and facilitate production of future reports, the program utilized the services of several contractors to prepare technical reports on these chemicals.

As of October, 1978 the majority of the technical reports on previously tested chemicals had been completed. Moreover, a mechanism for the timely production of reports on chemicals finishing bioassay testing had been put in place. Between October, 1978 and the present, the Bioassay Program has processed reports on 122 chemicals. Ninety-seven reports were reviewed by the NCI's Clearinghouse on Environmental Carcinogens, 94 of which have been announced in the Federal Register, and 25 reports have been reviewed by the Technical Report Review Subcommittee of the NTP Board of Scientific Counselors at three meetings between June, 1980 and February, 1981. The bioassays of all of these chemicals were initiated prior to the inception of the NTP, and all of the technical reports published to date were prepared while the program was still under NCI guidance.

Thus, although the output of bioassay reports has risen significantly since the creation of the NTP, it is the result of promulgation of reports prepared for the most part before November, 1978 on chemicals tested at an even earlier date.

The NTP assures that the mechanism for preparation of timely reports is being maintained and improved upon. In addition, the Technical Report Review Subcommittee has instituted changes in the reports to improve their content and expand their scope. Final reports to be published shortly will reflect these changes.

STATUS OF NTP

Question: NTP is funded from a pooling of resources from the existing budgets of several institutes -- yours included. When it was established, it was considered to be an experimental approach for coordinating efforts in research of toxic chemicals. What is the status of the NTP?

Answer: The progress of the National Toxicology Program, now half-way into its third year, was recently reviewed by the Department of Health and Human Services. The study team found the NTP moving progressively forward toward each of its defined goals. For example, progress has been made in broadening the scope of testing activities in developing better test methods, and in selecting chemicals that are of priority as to effects on health. The DHHS study recommended that the NTP's experimental status be removed and that the NTP be established as the permanent mechanism for coordinating toxicological research, with a continuing emphasis on meeting the needs of regulatory agencies. A reorganization has been proposed to integrate the NIEHS and NCI components of the NTP under a single administrative structure under NIEHS. This will enhance the overall coordination and managerial aspects of the NIH components of the NTP which contribute 84% of the total 1982 budget.

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Question: What NTP testing is being performed at the NCTR?

Answer: Currently, NCTR has three chemicals on test for carcinogenicity and four chemicals on test for teratogenicity. Plans are to place approximately eleven additional chemicals on test by end of the fiscal year.

Maintaining New Research Grants

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator - initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, prepared by President Reagan, provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NIEHS share of that amount is $12,373,000 and 112 grants.

Question: How is inflation impacting--or how will it impact--on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 112 new and competing research project grants.

Question: Why is it so important to stabilize new research grants regardless of other budget priorities within NIH?

Answer: Biomedical research support at stable and predictable levels ensures the ready availability of research facilities and personnel throughout the scientific community, providing for the fundamental knowledge leading to identification, understanding and amelioration of problems associated with the health of man. Stabilization assures that funds will be available throughout the life of the grant or program and allows the individual Institutes to more clearly define their program needs and identify a stable source of funding. The necessary science base which this stability provides favorably affects all other aspects of the goal of providing improved health care to the nation.

Question: What happens if, in a particular year, the quality of new research proposals declines: To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: Each year the NIH receives, processes and reviews many more applications which are judged to be scientifically meritorious than can be funded. Only those grants which are assigned high priority scores and are relevant receive funding and many equally meritorious proposals are not provided for. Thus it is unlikely that a sufficient number of high quality grants would not be available in any particular year. Moreover, the practice of maintaining a registry of high quality research proposals up to one year following the review provides a backlog of applications for possible funding.

If indeed research proposals of sufficient quality and relevance were not available for the programs of the Institute, such proposals might

be generated through the NIH Announcement and Request for Applications--RFA--mechanism.

Fundamental differences exist in the role of grants in support of the goals of the Institute versus the role of contracts and intramural programs. Thus it may not be feasible or wise, or indeed possible, to substitute one mechanism for another.

Where To Cut

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts:

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justification recently submitted to the Congress has attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

INDEPENDENT SCIENTIFIC PANEL

Question: There has been increasing interest in establishing a separate panel of independent scientists to review studies and settle scientific disputes that arise during the regulatory process. What good would such a panel do?

Answer: The argument for establishing such a panel is that it would free the regulator and the policymaker from their difficult roles regarding the resolution of scientific differences. While this proposal has a certain attractiveness, in my view all proposals in this area tend to overlook one central point, that is, uncertainty is a basic ingredient of science. The resolution of that uncertainty is an essential role of the scientist. However, that frequently takes longer than regulatory agencies are permitted, and they are compelled to act in the face of uncertainty. The criteria which they

use as the basis for their decision making frequently involves other than purely scientific issues such as numbers of individuals exposed, and quantity of the substance manufactured. These are critical issues for regulatory decision makers and also frequently affect the choice of which chemical should be tested, but they are not issues of science. A so-called science court might clearly identify the scientific uncertainty but could scarcely resolve it. As I said in my testimony last year, the various regulatory agencies should clearly attempt to establish the risk of a substance using commonly agreed upon policies and principles, and they have taken action aimed at accomplishing that purpose. In general, I agree that some central focus would be useful for determining the risk associated with a toxic substance. However, I said last year, "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 chemicals. Thus, there may be practical limits to our ability to centralize responsibility for these functions."

Question: Could the Board of Scientific Counselors of the National Toxicology Program be used for this purpose?

Answer: I do not believe that the use of the NTP Board of Scientific Counselors for this prupose would be appropriate. For one thing, it is charged with responsibility for monitoring the quality of the science and of the testing programs of the NTP, and thus could be viewed as not neutral in an issue of scientific dispute. If the Congress were to decide to put such a mechanism in place I believe that it would have to be separate from either the research or the regulatory agencies.

SUBCOMMITTEE RECESS

Senator ANDREWS. At this time the subcommittee will stand in recess until the hour of 9:30 a.m. tomorrow when we meet again in this room to hear further budget requests from the NIH.

Thank you very much.

[Whereupon, at 4:55 p.m., Wednesday, February 18, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, February 19.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1982

THURSDAY, FEBRUARY 19, 1981

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

The subcommittee met at 9:35 a.m., in room 1114, Everett McKinley Dirksen Senate Office Building, Hon. Thomas F. Eagleton presiding.

Present: Senators Eagleton, Rudman, Specter, and Burdick.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE ON AGING

STATEMENT OF ROBERT N. BUTLER, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. ROBERT L. RINGLER, DEPUTY DIRECTOR
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCOMMITTEE PROCEDURE

Senator EAGLETON. We are going to spend a few minutes up here reconnoitering. In the light of the President's budget speech last night, giving us so little time to get our act together, maybe it will save time in the long run. So bear with us for a few minutes.

[Pause.]

Senator EAGLETON. Good morning, ladies and gentlemen.

The Subcommittee on Health and Human Services will continue its hearings with respect to the National Institutes of Health. Today we will hear from witnesses representing the National Institute on Aging, Dr. Butler. The Division of Research Resources will give testimony as will the John E. Fogarty Center and the National Library of Medicine, and likewise we will hear testimony with respect to the Office of the Director, Buildings and Facilities.

Dr. Fredrickson and gentlemen, we welcome you, and you may proceed.

Who is the first?

Dr. FREDRICKSON. Dr. Butler is here.

Senator EAGLETON. Before we start, let's do some overview questions first with Dr. Fredrickson, in light of the fact that we have some of the more specific figures today than we had yesterday.

Dr. Fredrickson, the administration's program for economic recovery includes a section on the NIH. As you may be aware, it states the funding "will allow continuation of previous year's commitment and permits substantial numbers of new awards each year." However, the statement also says that "The funding increases will not fully cover projected inflation."

Could you explain for us what that language portends specifically for NIH?

Dr. FREDRICKSON. Mr. Chairman, the President's program for economic recovery, released last night, contains the following specific information about his proposals for the budget on NIH in fiscal years 1981 and 1982:

For fiscal year 1981 the administration will request budget authority reductions totaling $126 million below the NIH current base. Mr. Chairman, that current base refers to the 1981 continuing resolution level plus proposed pay increase supplementals that were proposed by President Carter and sent to the Congress in January. Thus the current base would be the 1981 continuing resolution plus approximately $27 million in pay raise supplementals.

To continue. President Reagan will request budget authority reductions for 1981 totaling $126 million below the NIH current base. This will still allow an $89 million increase over the 1980 level.

For 1982, a further increase of $246 million is proposed, from $3.5 billion to nearly $3.8 billion in budget authority.

In addition, the administration will propose some legislative changes in order to carry out its proposed principal area of reduction. This involves primarily a reduction in the institutional payments that are now made by NIH and other research training under the National Research Service Awards Act of 1974.

The proposal would eliminate the current practice of paying more to an institution for a federally supported trainee than is charged in tuition and fees to nonfederally supported students at the same time; that is, the administration would eliminate the current indirect costs for training resident fellowships and the current institutional costs for those training programs.

In 1981, the reduction in the budget accrued by elimination of the payment of institutional allowances would be approximately $41.5 million, and the further reduction in the 8-percent indirect cost now obtained on training grants will result in a further saving of $9.2 million.

For 1981 the budget is intended to permit the funding of approximately 4,800 competing research project grants, compared to 5,000 in the fiscal 1981 Carter budget, and to 4,800 actually awarded in fiscal year 1980, and 5,900 in fiscal year 1979.

The 1982 budget, under these proposals, would result in a saving of approximately $42.4 million in institutional allowances now paid on training grants, and another saving of $9.5 million by elimination of the 8-percent indirect costs on those training grants.

The 1982 budget should permit funding of approximately 4,900 competing research project grants, compared to the figures which I earlier cited.

I think those are the basic elements of what the President proposes to change in the NIH budget for those two fiscal years.

1982 PRESIDENT'S BUDGET

Senator EAGLETON. We will put in the record at this point the sheet of paper labeled National Institutes of Health, 1982 President's Budget." It is an itemization Institute by Institute of the Reagan proposals, both with respect to rescissions for fiscal year 1981 and the budget request for 1982.

[The document follows:]

NATIONAL INSTITUTES OF HEALTH—1982 PRESIDENT'S BUDGET (REAGAN)—SUMMARY BY APPROPRIATION

[Budget authority in thousands of dollars]

	1980 comparable	1981 comparable	1982 request	Change
Cancer	999,191	982,969	1,025,946	42,977
Heart	527,663	539,183	579,602	40,419
Dental	68,428	70,135	74,627	4,492
Arthritis	341,415	363,150	380,594	17,444
Neurology	242,175	249,056	276,156	27,100
Allergy	215,573	230,499	243,755	13,256
General Medical Sciences	312,479	314,936	341,201	26,265
Child Health	209,059	217,201	231,093	13,892
Eye	113,031	116,054	132,324	16,270
Environmental Health	83,896	92,069	110,058	17,989
Aging	70,063	74,516	84,186	9,670
Research Resources	169,228	173,813	191,863	18,050
Fogarty Center	8,987	9,254	9,589	335
Subtotal	3,361,188	3,432,835	3,680,994	248,159
National Library of Medicine	43,979	45,188	47,677	2,489
Office of the Director	20,248	22,374	23,502	1,128
Buildings and facilities	3,250	11,750	10,310	[1] 1,440
Total, NIH	3,428,665	3,512,147	3,762,483	250,336

[1] Excludes $70,000 transferred to the Departmental Management Fund.

REDUCTION IN TRAINING GRANTS

Senator EAGLETON. We have handed you yet another sheet of paper also labeled National Institutes of Health. It may get sort of confused in the record, but nonetheless, in the first column of this sheet that we have just handed you, the first column says fiscal year 1981, that's the actual appropriation for fiscal year 1981, is that correct?

Dr. FREDRICKSON. I believe, Mr. Chairman, that this is the Carter budget, less the amounts proposed for rescission by the President.

Senator EAGLETON. So that's the Carter revised, let's call it that.

The bottom line on NIH on that is $3.593 billion, correct?

Dr. FREDRICKSON. That is correct.

Senator EAGLETON. On the earlier sheet the bottom column is $3.517 billion, a difference of about $76 million. Of what does that difference consist?

Dr. FREDRICKSON. That difference, Mr. Chairman, consists primarily of a reduction resulting from removal of institutional costs for training grants now paid to institutions and indirect cost of 8 percent now paid to those institutions. It also includes a reduction of some 500 trainees from a current level of about 10,500 to 10,000 trainees in that fiscal year.

Senator EAGLETON. Now these cuts, then, in these training grants, these are training grants that help produce, as it were, and sustain medical doctor researchers.

Dr. FREDRICKSON. The training grants support both M.D. and Ph. D. researchers.

Senator EAGLETON. And Ph. D. researchers. And the number of training grants that would have been allotted under the Carter revised budget are what, as contrasted with the Reagan revision?

Dr. FREDRICKSON. I think the main reduction, Mr. Chairman, is in the number of full-time equivalents who would be trained under the existing grants, and they will be reduced by some 500-plus individuals.

Senator EAGLETON. I'm sorry?

Dr. FREDRICKSON. The number of people proposed to be trained in 1981 would be reduced by approximately 500, a few more than that, to a total of 10,000 trainees. That is true for both 1981 and 1982 where it is proposed to maintain a level of 10,000.

INSTITUTIONAL COSTS FOR TRAINING

Senator EAGLETON. Going on now with the Reagan proposal, the proposal to "eliminate the current practice of paying more to an institution for a federally supported trainee than it is charged in tuition and fees to nonfederally supported students at the same institutions."

Would you please explain what you had in mind and what the difference in costs are in this regard.

Dr. FREDRICKSON. The institutional costs that are now awarded to institutions who are training biomedical scientists includes funds that reimburse the institution for the salaries of faculty during the time that they are involved in training. It also provides for support for supplies for the teaching exercises, for equipment that may be necessary in the teaching programs, and for additional costs of lecturers, curriculum development, and the maintenance, then, of a standard at maximum quality training program.

The 8-percent indirect costs apply to all grants, but reduced in the case of training grants by NIH rule for many years to 8 percent, paying the same kind of costs that indirect costs pay for grants—heat, light, the maintenance of buildings, and other such costs for that training program.

You asked, Mr. Chairman, what the reduction in savings would be. I had earlier described those as approximately $41 million to be saved by eliminating the institutional amounts, and $9.2 million to be saved from eliminating the indirect costs in 1981. Very similar figures apply for 1982: $41.6 million and $9.5 million respectively.

LEGISLATIVE REQUIREMENTS

Senator EAGLETON. Reading from the justification sheet that goes with the Reagan proposal, it says as follows: "In addition, the administration will propose that the legislative requirement for the institutional payments and NRSA be eliminated."

What legislation exists on the books in this regard? What does it require legislatively? And I take it would thus require a legislative change in order to eliminate it or modify it.

Dr. FREDRICKSON. It would require a legislative change to eliminate the paying of any institutional costs, Mr. Chairman. The NRSA Act of 1974 does specify costs shall be reimbursed to the institution for training. It does not say by what formula. Therefore, one could reduce the amount of institutional costs, as we view it, without changing the statute. But one could not entirely eliminate the payment of institutional costs.

Senator EAGLETON. I see. And is the Reagan proposal merely to reduce it? Or is it proposed in fact to eliminate it?

Dr. FREDRICKSON. It is proposed to eliminate such costs.

BUDGET REDUCTIONS FOR 1981

Senator EAGLETON. Would you break out for us the $126 million cut in budget authority proposed for fiscal year 1981. How much of it is for training, how much for competing research grants, intramural research contracts, et cetera?

Dr. FREDRICKSON. Mr. Chairman, let me give you these figures decrements from the 1981 continuing resolution, if I may.

Senator EAGLETON. All right.

Dr. FREDRICKSON. We would see a decrement or decrease of $21 million for research project grants and about $11 million in research centers. There would be a further decline of approximately $6 million in the support of other research grants other than the RO–1 and PO–1 project grants. Research training would be reduced by $62 million; research contracts by $14 million; intramural research by $7 million; and the cancer control program by approximately $2 million. That is the aggregate change from the 1981 continuing resolution in President Reagan's proposed budget for 1981.

Senator EAGLETON. Did you say that new research grants for fiscal year 1981, it was 5,000, would be cut to 4,000——

Dr. FREDRICKSON. Approximately 4,800.

Senator EAGLETON. The Carter budget, according to your justifications, contains a 4.6-percent increase for research training to permit continued support of approximately 10,500 trainees in fiscal year 1982. How many trainees will the new budget request support in both 1981 and 1982?

Dr. FREDRICKSON. It will support 10,000 in both years, Mr. Chairman.

Senator EAGLETON. In both. Had that 10,500 figure, had that been a fairly constant figure in the Carter years?

Dr. FREDRICKSON. That figure actually represented a modest decrease in the last 2 years, Mr. Chairman. The full-time equivalent trainees in 1978, for example, totaled 11,123, and in 1979, it was 11,197.

Senator EAGLETON. 1978 was?

Dr. FREDRICKSON. For that year, we had 11,123.

Senator EAGLETON. 1979?

Dr. FREDRICKSON. There were 11,179 in 1979. In 1980, we had approximately 10,664. The estimates for 1981 had been 10,500.

I can submit, Mr. Chairman, a list of these numbers of full-time equivalents from 1969 on, if you would like to have it.

Senator EAGLETON. Why don't you give us that list and we will put it in the record at this point.

[The information follows:]

FULL-TIME EQUIVALENT TRAINEES

1969	16,138	1976	9,654
1970	14,810	1977	10,198
1971	14,288	1978	11,123
1972	14,613	1979	11,197
1973	12,675	1980	10,664
1974	13,547	1981 Carter budget	10,567
1975	12,272		

INFLATION RATE FOR BIOMEDICAL RESEARCH

Senator EAGLETON. So in these recent years there has been just a gradual withering away of 11,100 something, 11,197, 10,664, 10,500, and if this recommendation is implemented, 10,000.

Dr. FREDRICKSON. That is correct, Mr. Chairman. It would be 10,000.

Senator EAGLETON. In the preparation and computation of your budget, Dr. Fredrickson, from yesterday's testimony I take it that you are using an inflator cost of 9.5 percent.

Dr. FREDRICKSON. For 1982, that is correct.

Senator EAGLETON. For 1982, and that was on instructions, I take it, from the Office of Management and Budget.

Dr. FREDRICKSON. Yes; those are the figures that are issued.

Senator EAGLETON. It's not clear to me. Is that—insofar as you know is that a Government-wide figure that the administration is using throughout the entirety of the budget even beyond NIH?

Dr. FREDRICKSON. I am told that it is, Mr. Chairman.

Senator EAGLETON. If in fact the rate of inflation is higher than that, then, of course, you will have to eat the difference.

Dr. FREDRICKSON. That is correct.

SHORTAGE OF CLINICAL INVESTIGATORS

Senator EAGLETON. Dr. Fredrickson, I have an article before me from the New England Journal of Medicine, dated December 6, 1979. It is labeled "Special Article, Clinical Investigator as Endangered Species," written by James B. Wyngarden, M.D. Are you familiar with that article, perchance?

Dr. FREDRICKSON. I am familiar with it and its author, as well as the figures he uses, because they come from NIH, Mr. Chairman.

Senator EAGLETON. Let me read a few excerpts from that article and then ask you to comment upon them.

This paper deals with the physician investigator as an endangered

species, and with the future of clinical research "* * * 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 in the annual programs of our national society, but they are clearly visible to department chairmen and division chiefs who find the recruitment pool of thoroughly trained physician investigators smaller each year. * * * Therefore, the NAS committee sought to preserve 2,800 of the 4,200 postdoctoral clinical trainee positions and submitted recommendations to Congress. * * * For example, in 1977 the NAS committee authorized 2,800 postdoctoral trainees of fellowships in the clinical sciences, but only 2,304 were filled. * * * The number of postdoctoral trainees supported by NIH training grants in 1968 through 1977 appears in figure 1. A precipitous decline in postdoctoral traineeship awards to M.D.'s began in 1975 and continues to present."

And then it has this chart. I know it's hard to see out there. But it tracks back to 1968, and there were over 3,000. Those would be postdoctoral M.D.'s.—and held roughly at around 3,000 through the early 1970's and then goes down at a very rapid rate in the time frame of 1973 through 1977 from that 3,000 level—I'm talking just the M.D.'s now—down to about—oh, I'm guessing—let's say about 1,300. Ph. D.'s had a slight increase, but then started to tip downward.

And we may put out the other excerpts from this article in the record as well.

Would you comment on the thrust of this article, what it portends for medical research in this country.

Dr. FREDRICKSON. The thrust of the article, which is basically correct, is that we are declining or decreasing each year in the number of M.D.'s that we have been training. The total number of trainees supported by NIH has also declined over the years, particularly from the years of maximum growth, which was 1955–65, when perhaps 25 percent of our total resources went to training. It has declined now to about 5 percent of total resources to a kind of new equilibrium level as an attempt to maintain the pool of new investigators who have to keep the vigor and vitality of the system going.

In 1974, whether by coincidence or because of the NRSA Act, we don't know, the number of M.D.'s who began to apply for training grants began to decline somewhat. The percentage of M.D.'s in our training grants program has fallen from 66 percent in 1970 to about 31.5 percent in 1979.

Senator EAGLETON. Sixty-six percent of your trainees were M.D.'s in 1970. At the end of the decade——

Dr. FREDRICKSON. It was about 31 percent. Those were M.D.'s and also a few dentists and veterinarians. I am talking about those with clinical degrees. But there is perceived to be a real problem in attracting patient-qualified physicians or scientists, those with clinical or professional degrees, into research. It is a special concern of all of us, the National Academy of Sciences and the NIH. All of us will have an interest in being sure that the continuation of biomedical research from fundamental information to practical application is sustained.

Mr. Chairman, we have prepared a report for the committee which deals with the question of the supply of clinical investigators, and it contains these figures as well as certain others that I have just described.

Senator EAGLETON. If President Reagan's proposals are implemented, what impact on this trend might the Reagan budget have?

Dr. FREDRICKSON. I think it is fair to say the reduction from 10,500 to 10,000 cannot be in itself considered to have a dramatic effect on this particular trend. The question that we cannot adequately answer for you, Mr. Chairman, is what effect will it have on the institutions who will now have to find other means of bearing the costs of training. I think we cannot honestly tell you that impact.

There are costs that accrue to the training of scientists of any kind, and they may be particularly great in some areas for clinical investigation.

Senator EAGLETON. Well, it would be a fair, I guess, commonsense conclusion that although the cut from the 10,500 to 10,000 standing by itself is not a gigantic cut, significant but not gigantic, let's put it that way, that unless the training institutions make up that gap through their own independent funding sources, the net sum effect will ultimately be that there will fewer M.D. researchers.

Dr. FREDRICKSON. I think that the total amount of public moneys available for training are going to be an important lever in the future in coping with this problem. We may, for example, have to consider something we have never done—to put a quota on M.D.'s, give them preference in research for training slots. We may very well have to raise the stipends again, because they are sufficiently below what people who are just getting residency training for ordinary practices are making. There is a special problem there. It is a problem I think we cannot ignore but must attempt to adjust.

So we have a problem. We have discussed the disincentives in the report that is coming to you, that I described. It is true that we must find a way to maintain a sufficient number of clinically trained people in investigation or we will not reap the harvest from this new biological revolution that we have been describing to the committee in the last few days.

Senator EAGLETON. All right.

Dr. Butler, we now resume with you.

Thank you, Dr. Fredrickson.

PREPARED STATEMENT

Dr. BUTLER. May I begin by introducing the Deputy Director of the National Institute on Aging, Dr. Robert Ringler.

With your permission, Mr. Chairman what I would like to do is submit the opening statement for the record and just give the briefest highlights.

Senator EAGLETON. Very good.

[The statement follows:]

Statement of Robert N. Butler

Today, more and more people are living to old age. Our current population of 25 million persons aged 65 or older is a massive testimony to our society's ability to create conditions for longer life. During the 20th century life expectancy from birth has increased from 47 years of age in 1900 to 73 in 1980. The vast majority of our elderly population enjoy good health and independent living well into old age. However, there is a segment of this population which is less fortunate. Each year approximately 1.3 million people, of which one million are elderly, will spend time in nursing homes. The economic impact of this is astronomical; the current national cost of nursing home care is approximately $21.6 billion.

Restraint in cost increases for the health care of the elderly is an issue of increasing importance both to the American people and their government. Research on aging offers one approach to reducing the degree and duration of physical, social and economic dependency, and will enable individuals to live free, independent and healthy lives for as long as possible. Research supported by the National Institute on Aging has made significant progress toward reducing dependency, and today I would like to share with you the highlights of some of these studies.

Intramural Research

An accomplishment we are quite proud of comes from NIA's Gerontology Research Center (GRC). Dr. Reubin Andres and his associates have studied current criteria for diagnosing diabetes. Their research is based on data on healthy adults studied repeatedly over many years. In these studies, which are a part of the Baltimore Longitudinal Study of Aging (BLSA), performance on a standard glucose tolerance test was found to change with age. A decrease in the ability of older persons to clear glucose from the bloodstream was found to be normal and benign within certain broad limits, indicating that an adjustment for age must be taken into account. If it were not, an unreasonably and unacceptably high percentage of otherwise normal individuals would be classified as diabetic.

Their findings have had a widespread impact on diabetes specialists. The National Commission on Diabetes has recommended new standards based largely on NIA's work. More recently, the National Diabetes Data Group of the NIH issued its recommendations for interpreting the glucose tolerance test and suggested a major alteration in the standards consistent with those proposed by the NIA scientists.

The impact of these changes will be to reduce dramatically the number of false positive diagnoses of diabetes, especially in the elderly, as well as to substantially decrease the health cost for this group of individuals. The latest figures show that approximately $7.7 billion is the total annual cost of diabetes. Results of the BLSA Study show that this figure could be reduced significantly when the new standards are routinely applied. The quality of life would also improve because those who previously would have been diagnosed as diabetic would be spared the anguish and expense of a demanding drug and diet regimen.

The scope of NIA investigations that contribute to changed clinical and research outlooks extends beyond longitudinal studies. Using an innovative technique in which blood values of glucose or insulin can be held constant over an extended period of time, NIA scientists have documented the existence of a gut hormone which

stimulates insulin secretion by the beta cells of the pancreas. These cells respond poorly to the gut hormone in the elderly, and in this defect may be partially responsible for the decline with age the body's capacity to metabolize sugar. This new dimension in understanding the complex mechanism for controlling the blood sugar level promises to lead to new research advances which could be of significance in controlling multiple disorders of glucose metabolism.

NIA Clinical Director Dr. Reubin Andres has also examined data from some 40 studies involving six million people comparing body weights defined by life insurance tables as desirable with mortality rates. His preliminary finding is that 10 to 25 percent in excess of what is presently called desirable body weight may be conducive to lower mortality. He does note, however, that minor degrees of obesity are harmful for individuals with diabetes or hypertension. These findings will continue to be examined. We are considering a technical consensus conference on optimal body weight with a view to developing recommendations for health care professionals and the general public.

Senile Dementia of the Alzheimer's Type

The importance of the study of aging and its relation to disease can hardly be overstated. Some problems facing our older population are so costly that our entire society would benefit if these problems could be eradicated. Of the more than one million older Americans living in nursing homes today, an estimated 50 percent have senile dementia. The national cost of such care is about $6 billion annually. If through research and a better understanding of the problem we can reduce the number of senile dementia patients by 15 percent, we could effect a savings of institutional costs of approximately $1 billion annually.

Federal research on senile dementia of the Alzheimer's type of (SDAT) has increased by more than 200 percent since the creation the National Institute on Aging. NIA's support alone has increased from $274,000 in 1976 to $4,211,000 in 1980. Two major international conferences sponsored by the National Institute on Aging, the National Institute of Neurological and Communicative Disorders and Stroke, and the National Institute of Mental Health did much to stimulate new research on the causes and prevalence of senile dementia as well as the options for research on treatment approaches. Public awareness of senile dementia as a pervasive problem has increased, in part due to the efforts of NIA and NINCDS, in encouraging cooperation among the seven self-help groups that had been formed independently by the families of victims of Alzheimer disease and SDAT.

We have made very encouraging progress during the past five years toward understanding senile dementia. For example, researchers have found a correlation between a decrease in activity of the enzyme choline acetyltransferase (ChAt) in the brain and changes in both memory and brain pathology. This work offers the hope of effectively treating patients with SDAT. Other studies are examining the role trace metals, particularly aluminum, play in the development of SDAT and how they gain access to the brain. Studies of slow-acting transmissible viruses are being pursued to determine if a hidden virus is responsible for the slowly progressive damage to the brain that produces symptoms of SDAT only after a long period of time.

As part of our total Institute effort, Dr. Stanley Rapoport, Chief of NIA's Laboratory of Neuroscience, has been defining normal

metabolic activity and pathology during the aging process. He has found significant changes in metabolism and pathology in animals susceptible to brain disease similar to senile dementia of the Alzheimer's type in man. Brains of very old, healthy animals maintain normal metabolic activity and pathology. Once we have been able to completely characterize normal and abnormal changes of aging, pharmacologic approaches can be developed to treat reversible cognitive defects of aging and dementia.

Geriatric Medicine

A report to you would not be complete without an update on our geriatric medicine program. The Institute has established a Geriatric Medicine Academic Award designed to stimulate faculty and curriculum development in geriatric medicine and research. In June 1980, the NIA held a meeting of its first 18 Geriatric Medicine Academic Awardees. This provided a forum for their discussion of progress in curricular reform and in catalyzing research in aging. Many felt that the granting of the award itself gave credence to geriatric medicine and facilitated the task of building a program in geriatrics at their institutions. It was felt also that the impact has spread to other schools not supported by NIA funds but which are developing small programs in geriatrics.

The twentieth century triumph of extension of life means not only that the number of older people are mounting, but also that most people can now look forward to living out their full life course. Findings are beginning to show how the productive middle years can be extended and the disabilities of old age can be prevented or postponed, and costs of health care and dependency can be restrained.

Biographical Sketch

Robert N. Butler, M.D.

Director, National Institute on Aging

National Institutes of Health

Dr. Robert Neil Butler is currently the Director of the National Institute on Aging, one of the eleven research institutes at the National Institutes of Health in Bethesda, Maryland. Dr. Butler left private and consultative practice in psychiatry to join NIA on May 1, 1976. During his research, academic and service career he has served as a consultant for the U.S. Special Committee on Aging and the National Institute on Mental Health; held faculty positions at the Howard University School of Medicine, the George Washington University School of Medicine, the Washington School of Psychiatry and the Washington Psychoanalytic Institute; and has conducted research as a psychiatrist with the National Institute of Mental Health (1955-1962) and the Washington School of Psychiatry (1962-1976). He is the author of four books and has won the Pulitzer Prize for Why Survive? Being Old in America, (1976).

Dr. Butler received his B.A. from Columbia University in 1949 and his M.D. from Columbia in 1953, served his residency at the University of California and became a diplomate of the American Board of Psychiatry and Neurology in 1961. He is the author of several articles, a veteran of the U.S. Maritime Service, a member of many professional organizations and has made numerous television appearances.

COST RESTRAINT

Dr. BUTLER. As you know, we now have some 25 million individuals over 65 years of age in the United States. This is rather an extraordinary testament to the ability of this society and of science to create conditions for longer life.

The majority of these older persons enjoy good health and remain independent in their community. A substantial number, however, account for a disproportionate consumption of health, service, and other related costs. For example, nursing homes this past year accounted for some $21.6 billion from all sources, private, Federal, and State. If I had one sentence to describe the objective of the National Institute on Aging and of research on aging, it would be to find ways of reducing the degree and the duration of various forms of dependency—economic, physical, and social—and of making it possible for people to live independent and healthy lives as long as possible.

I would like to cite just three instances in which efforts at research have contributed to cost restraint. Dr. Reuben Andres, using participants in the Baltimore longitudinal study of aging, has found that impairment in the body's ability to respond to the challenge of glucose levels, which occurs with age, precludes glucose tolerance alone as a basis for diagnosis of diabetes. This finding, which can only come about as a result of longitudinal studies, has been of great value to the National Diabetes Data Group of NIH, which recently issued its recommendations for interpreting the glucose tolerance test, and suggested a major alteration of standards consistent with those proposed by the NIA scientists. Without this change, we would have many false diagnoses of diabetes at great personal cost and anguish, particularly for older persons who might go to physicians for unnecessary treatment for diabetes. Clearly it also would reduce overall medical costs.

Over the last 4 years, we have also been much interested in the problem of senile dementia of the Alzheimer's type, which we believe accounts for some 50 percent of the individuals who are living in nursing homes. Senile dementia is so incapacitating that its victims cannot remain at home for fear that they might leave the gas on in the stove or wander in the streets. Senile dementia may cost us about $6 billion annually. If we can find through perfection of diagnostic skills, prevention, treatment, and, of course, firm knowledge of the causation of various forms of senility, particularly the Alzheimer's type, we can make a genuine contribution to easing the enormous personal anguish on families and on health costs. Keeping just 15 percent of the people out of nursing homes, for example, could amount to a savings in institutional costs of approximately $1 billion each year.

Because we have taken a lead role in developing a special intiative around senile dementia, with I might add, the very strong support of our sister Institutes, the National Institute of Neurological and Communicative Disorders and Stroke, and the National Institute for Mental Health, we have recently created a progress report on developments over these last years. We also brought together a number of families to develop support groups to help them in dealing with the tragic impact of senile dementia. This led to the development of a major national federation of self-help.

All of this would be pure hopefulness if there weren't in fact some very exciting scientific leads. For example, there is a reduction in the enzyme acetyl transferase, which is responsible for synthesis of acetyl choline in the memory portions of the brain. This suggests the possibility that one day we might be able to provide means for replacement of this enzyme.

We also fortunately have in our new laboratory of neuroscience in Baltimore an outstanding scientist who is running a very basic neurobiology program which focuses on understanding cerebral vascular permeability and pharmacology in the central nervous system. He is already utilizing the new positron emission tomography system to analyze specific functional and localized regional activity in dementia compared to normal patients.

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DEVELOPMENT OF GERIATRIC MEDICINE

And the third instance that I would like to mention is the development of geriatrics itself within the American medical schools and related allied health schools training. The type of medical investigator that was just mentioned is disappearing. There is no way we can really begin to encourage the finest of research or engage their interest unless we have respectability and intellectual depth within the medical school.

We are very proud that over the last several years, after rigorous competition, some 21 schools are now participating. This beginning presence of excellence in the evolving field of geriatrics will hopefully result in better and more research. Again, we have developed a recent progress report in that particular topic.

In conclusion, while the 20th century certainly describes a triumph of extension of life, moving the average life expectancy in just 80 years from 47 to 73, it is obvious that we must also enhance the quality of that life. We must reduce the costly and personally destructive disabilities and illnesses of age by either preventing or postponing them, and finally by effective means of both rapidly diagnosing and treating them.

Thank you.

GERIATRIC MEDICINE ACADEMIC AWARDS

Senator EAGLETON. You mentioned 21 schools, I think you said, in the quest of excellence or something with respect to geriatric medicine. That does not mean 21 schools have endowed chairs in gerontology. I think last year only one school did. Was it Cornell?

Dr. BUTLER. That's correct.

Senator EAGLETON. Has there been any improvement in the past year? Are we up to two?

Dr. BUTLER. As a matter of fact, we are, but this is a measure of the problem before us. It has not been possible to fill that second chair, in part because of the lag between identifying and building the intellectual resources, and accomplishments of a body of future leaders—of models who would be outstanding teachers and research innovators and service delivery of those. We are just at the beginnings.

I believe we have created a ripple effect. Some 64 schools competed for the NIA Geriatric Medical Academic Award. Only 21 achieved it. That's about 33 percent. But those other schools obviously were beginning to think about it, and some of them have indicated they will be reapplying. They have also begun to develop some programs of their own. We think perhaps as many as 40 of the 126 medical schools have some beginnings in geriatrics.

Senator EAGLETON. You said some others would reapply. Reapply for what?

Dr. BUTLER. For the grant; that is, they can try to learn from their earlier rejection how to sharpen and clarify their applications.

Senator EAGLETON. Twenty-one schools did receive grants?

Dr. BUTLER. Twenty-one of the 64, about 33 percent, did win the award after rigorous competitive peer review.

Senator EAGLETON. A recent Rand Corp. study, basing the study on population size and utilization patterns, estimated that there would be a

need for anywhere from 7,000 to 10,000 geriatricians by 1990. At about the same time when this study was released, the AMA released a survey which revealed that only 700 physicians identify themselves as having a primary, secondary, or even tertiary specialty in geriatrics.

Given the magnitude of the estimates of need for geriatricians and given the magnitude of the nursing home care and institutional care problem that you identified in your testimony, the explosion in costs, how would you propose to strengthen the geriatric medicine academic award program?

Dr. BUTLER. Well, it's a very profound problem, as you say. The extent to which we need well-prepared people in geriatrics as geriatricians should not, by the way, be thought to mean additional physicians beyond those presently being trained. Geriatricians can come from among those who are already being trained.

It's a catch-22. It's a cart before the horse in some places. Until we have developed some genuine expertise, some role models, some curricular advances within our 126 medical schools, we can't really begin to have the well-trained individuals we need. We have to move as rapidly as we can.

One of the things which we do on an annual basis is bring together the program awardees—that is, those 21 people this year, for example—to compare audio visual aids, student assistance problems, how they have fared in mainstreaming, teaching of aging within the medical school framework, and techniques of teaching. They have gotten students to participate in research activities. That's one way of utilizing this approach.

Another would be to have further continuing—now I'm not just speaking of the National Institute on Aging; I'm speaking broadly—medical education through residency and expansion of residencies within internal medicine. We are seeing some of this happen on an individual basis in a few schools around the country, but there has not been a national policy or a broad effort to solve what clearly is a major need. There are some 7,000 long-term care institutions in the United States that should have medical directors, for example. There are 7,000 people whom you need right now without ever even thinking about the needs of faculty within 126 medical schools, nursing schools, and retirement communities. Almost weekly we receive calls asking us to recommend outstanding people.

NEED FOR GERIATRIC SPECIALISTS

Senator EAGLETON. If the Rand study is correct in its estimates—and I have no independent reason to dispute it—and if we are so woefully behind in anywhere close to achieving the desired level of geriatric specialists, geriatricians, and what have you, should we be thinking in terms of some specialized paramedic trainee development in this regard? You mentioned how many institutions for long-term care in the country?

Dr. BUTLER. 7,000—which within the present regulations are supposed to have medical directors. There are actually 18,000 nursing homes in the United States, but not all are required to have medical directors.

Senator EAGLETON. So there are 18,000—let's use that figure for starters—long-term care institutions of one type or another in varying qual-

ity, and the day will probably not arrive when we have 18,000 M.D.'s specifically trained in geriatrics to take up assignments as directors of those institutions.

What should we be thinking of, if at all, in terms of training bright, intelligent, dedicated individuals who do not possess an M.D. degree to help fill this gap? Or should we be thinking at all in that area?

TEACHING NURSING HOMES

Dr. BUTLER. I think we should. I'm trying to separate out the appropriate response from the mandate of the NIA in terms of its training and now speak more broadly to the general issue.

I think one very important route that has already had some beginnings is the geriatric nurse practitioner. One of the very special problems in American nursing homes is the fact that although there are over 1 million registered nurses, only something like 60,000 registered nurses work in those 18,000 nursing homes. Work in a nursing home is regarded as working in the pits, quite frankly. It's not a desirable job.

This is one of the reasons I have recently developed the concept of teaching nursing by establishing an affiliation between an outstanding, high-quality nursing home or home for the aged and each of our 126 medical schools, with required rotations of medical students, nursing students, and health and policy people to really begin to peer—for the first time—into this extraordinary institution. Nursing homes only emerged significantly 15 years ago, after the advent of medicare and medicaid in 1965. They have been fast moving. We know very little about what goes on inside them, who gets admitted to them, why they remain there, for how long, why as long as they do. Aren't there better ways to care for the elderly which will keep costs from rising as fast as they are?

Nursing home costs are growing more rapidly than any other type of health dollar. I think you are quite correct; we must look not only at medicine but at nursing, medical social work, speech pathology, and podiatry. Many people can make a contribution to long-term care in general and to geriatrics on an out-patient basis as well.

We need new training settings in which this can occur. I do think a physician has to take clear leadership. It would be too convenient for physicians to get out of the way of it, since they haven't been deeply involved up to now. I think it's absolutely critical that the multiple pathology and unique problems of the aged under the careful clinical investigative study of physicians, but certainly in coordination with the range of other health professions.

Senator EAGLETON. You and I have talked about this idea before, and I'm personally very impressed with it. In this era of belt tightening—we're going to be in this era for some time, I would suppose—how would we, meaning society propose to fund such an operation or operations of teaching those people, filling it with teaching institutions?

Dr. BUTLER. We are in the process of trying to look into that. We were asked by the outgoing Secretary and the Chairman of Health and Human Resources via a task force to consider the feasibility of a teaching nursing home. We plan to do that and learn as much as we can, through contact with HICFA for example, and AOA.

We also feel that once the environment has been established in the relationship of the medical school framework that investigator-initiated research can occur. People can come in with outstanding proposals and utilize the traditional NIH mechanisms. Poststroke patients might be of great interest to the National Institute of Neurological and Communicative Diseases and Stroke, for example.

Certainly long-term care is a huge issue in this country—500,000 additional older persons each year. It's not going to go away. Anything that we can do to develop a trans-NIH interest in long-term care through the traditional utilization of present efforts is possible. We also are thinking of building relations with the nonprofit sector, the American Association of Homes for the Aged, and the profit sector, the National Council of Health Centers, for example. We have had some positive responses to the teaching nursing home concept, so it's possible that private funds will also contribute to the development of such institutions. We won't only be thinking in terms of governmental funds, but of a social partnership involving various sectors.

INTRAMURAL CLINICAL RESEARCH

Senator EAGLETON. Does the National Institute on Aging have a program at the clinical center on the NIH campus?

Dr. BUTLER. Not in full measure. I mentioned in my opening statement highlights that Dr. Stanley Rapoport, who is the Chief of our Laboratory of Neuroscience, is engaged at the clinical center in some beginning studies of senile dementia. He is utilizing a new technique for measuring special analogs of glucose and the positron emission tomography technique. We have hoped that we might be able to develop a significant presence especially devoted to both basic and clinical applications of the neurosciences—for example, understanding cerebrovascular permeability better. Why are older persons more vulnerable to the neurocentral nervous system effects and toxic effects of various medications? What can we further learn about the various forms of dementia?

It seems to us that the science is ripe now for undertaking such studies. Moreover, we have the enormous advantage of all the other Institutes at NIH, which also have a legitimate, appropriate, and necessary contribution to make to our understanding of aging and of the diseases associated with aging. This is particularly with the National Institute of Neurological and Communicative Disorders and Stroke—and also the National Heart, Lung, and Blood Institute in terms of circulatory problems and stroke. We hope that we might one day have a small, effective, catalytic unit—catalytic in the sense that we will be working ecumenically and closely with the other key Institutes in addressing many of the causes of costly disabilities, specifically central nervous system disabilities and age.

Senator EAGLETON. We're glad to have with us Senator Specter of Pennsylvania. I hope you'll feel free, if you wish to ask some questions.

Senator SPECTER. Thank you very much.

Senator EAGLETON. Glad to have you with us.

Why is it that NIA does not have a full-fledged, full-grown, fully participatory role in the clinical center? Is it that there ain't no room at the inn, or you're out of money, or you're too new—the new boy on the block?

Dr. BUTLER. I think the major reason we have not yet obtained space in the clinical center is that we had to come up with a first-rate, well thought out, significant scientific program. I don't think we should simply have space in the clinical center. That would be quite inappropriate. We have to have something significant to contribute.

We also have had a program, as you know, in Baltimore, which has been primarily a general physiology program. It's not based upon the studies of the interaction of aging and disease. We don't have and never will have there quite that capacity and certainly nothing comparable to what would be available at the clinical center. I don't think there has been any appropriate point for the Institute to press the cause of space in the inn, just to have space in the inn. But as we demonstrate what an important contribution we can make, I think the situation becomes somewhat different. Then it becomes a matter of the availability of resources. Whether we will have those remains, I think, to be seen.

QUALITY OF LIFE

Senator EAGLETON. You referred in your prepared statement to the remarkable achievements of medical science insofar as the prolongation of life is concerned and other new techniques and new methods, et cetera, will be discovered and utilized in the future. For example, I'm told the Allergy Institute says the mastery of the immune system may soon be at hand.

With all of this explosion of knowledge and progress, what research has been done by the Institute, or do you contract out on some of the other ramifications of extending life? Have we examined—has anyone examined the cost implications, for instance, to the social security system and the other various retirement systems of extending life expectancy?

Dr. BUTLER. I think you're quite right that prolonging life without looking into the other implications, economic and otherwise, would be a serious lapse. We do support what is referred to as a macroeconomic model. It is based upon the conception of our most recent Nobelist in the United States in economics, Lawrence Klein, University of Pennsylvania. It's an endeavor to do more than simply look at social security actuarial liabilities, which of course is important. We must also look at the labor supply needs, the impact of health variables, the demands or claims made upon the health and services system—all interweaving with the changing age composition of our society—and be able to look 15, 20 more years ahead.

We are supporting such a novel model called the Hudson-Jorgenson model. This is part of our general program of looking at quality of life issues, in looking at social and behavioral implications of the extension of life itself. But of course we're not only interested in extending life, we're interested in extending productive healthy life. One of the key elements in the macroeconomic model and one of the key elements of the Institute itself must be that we be assured that we have people whose

vigor and health makes the quality of life possible. Just to have people live longer without having a robustness is not really the kind of living that I think many people are interested in.

LIFE EXPECTANCY

Senator EAGLETON. Senator Specter?

Senator SPECTER. Having joined this dialog in midstream, I may rephrase some steps that you have already undertaken. But where do you stand in a general way on research to expand life expectancy?

Dr. BUTLER. In order to clarify the point, life expectancy is a projection from birth to length of life using any given year as a base point. Research supported and conducted by the PHS and NIH as a whole has contributed to the extension in average age from 47 in 1900 to 73 today. That is what is meant by life expectancy.

Life span refers to the maximal inherent or natural life span of a particular species. In the case of man, it is thought to be in the range of 100 to 110 years of age. There have been a relatively rare number of people in the United States, roughly 13,000 individuals, who lived to be centenarians.

The concept of extending the genetic clock or the basic unit of life as prescribed by the concept of age span is not at the forefront of medical and biomedical science in the field of aging today. There are those that are deeply interested in it, but there are no major breakthroughs around the corner, although that is obviously often of great interest to some.

PROBLEMS OF AGING

Senator SPECTER. So that the concerns of aging focus more on ways of dealing with problems of aging within the current life expectancy as opposed to seeking ways to expand life expectancy.

Dr. BUTLER. One of the exciting things about science is, of course——

Senator SPECTER. Is that so?

Dr. BUTLER. That's correct.

Senator SPECTER. Excuse me.

Dr. BUTLER. That is absolutely correct. I was going to amplify briefly to say that the National Institute on Aging is interested in the degradation of various bodily functions over time, why we become more vulnerable to certain diseases, for example, senile dementia. Why does 50 percent of all cancer occur after 65 years of age? Why senile emphysema, why bone loss with age?

We are trying to understand these various facets of age, and would like to find ways of retarding some of those processes that do increase the vulnerability to disease with age, like the decline of the immune system that Senator Eagleton mentioned or the hormonal system that makes women vulnerable to osteporosis, a condition which accounts for many hip fractures.

Our main objective is certainly to maintain the vigorous physical integrity of the individual and not to extend life beyond what we think of as its natural inherent length, per se.

Senator SPECTER. Is there some Federal agency which focuses on expanding life expectancy?

Dr. BUTLER. No; not to my knowledge. I don't mean that we do not have researchers who are not devoted to unraveling the genetic control of lifespan, that is, looking at protein synthesis, investigating certain specific theories regarding the length of life, immunoendocrinology, DNA, protein error theories, et cetera. There are a number of scientific studies going on that bear on that general question. Some are supported by the Institute.

The profound objective of aging research has to be to maintain the vigor of life as well as life itself. One doesn't want to simply have people live longer without the productivity and the appropriate vigor that goes with it.

Senator SPECTER. What is the longest that anyone has lived, to your knowledge?

Dr. BUTLER. It's very hard to authenticate. It's believed that in the United States perhaps 111 years is the oldest anyone has ever lived. Someone, in fact, who died relatively recently. Many have made great claims of longevity, but the authentication is difficult. I believe that the Guiness Book of Records accepts 113 as being about the oldest individual in the world, although there are claims as high as 138, 145, maybe longer.

Senator SPECTER. I'm handed a question about the Georgians of Russia, who are alleged to have lived——

Senator EAGLETON. I was just going to ask that same—he stole my question.

Dr. BUTLER. I think there has been a worldwide fascination concerning longevity in three different areas of the world. In the Caucasus, there are individuals who do seem to have a higher ratio of survival. That is to say, if you look demographically at the number of people 80 and above and the number of people 60 and above, the proportion is relatively higher there. This is also true in a portion of the Ukraine and in other parts of the Soviet Union.

I had occasion, as an official member of a delegation, to visit the Soviet Union and see some of these people. They do indeed appear to be vigorous and healthy. But it's very hard to scientifically authenticate their actual age. The Soviet scientists who guided us did not introduce anybody who was over 111 years of age. They did not make any claims that might be thought of as outrageous. They were quite temperate and thoughtful.

The Institute does support the work of a grantee at Scripps Institute of Oceanography who has developed a chemical technique for measuring the passage of time. It involves the racemization of particular amino acids which are contained in certain stable proteins, tooth enamel for example. In an attempt to test this technique, we secured a tooth from a long living person from the Soviet Union and sealed the actual age of that individual in an envelope. Using this technique, the tooth was tested. The test indicated that the tooth was virtually the same age as the known age of the individual. So, it does appear that we have a quite rigorous chronometric technique for testing and authenticating

claims with respect to age, something we didn't have some years ago. This is a very interesting development.

Senator EAGLETON. Let me just ask one followup on that. Although I guess the medical basis is not yet established, what's the best guess, educated guess, as to why there are these long living Georgians in Russia as opposed to Jimmy Carter Georgians?

Dr. BUTLER. My sense is that more of them may live longer, rather than the actual extent of life. That's not a very scientific answer. But I think that a significantly greater number than usual seem to live beyond 100 years. I'm not sure if they really live beyond 110, 111.

FACTORS AFFECTING LONGEVITY

Senator EAGLETON. What's the reason or the best sense that you have that so many of them achieve even the age of 80, 90, or 100?

Dr. BUTLER. If we assume it's valid, studies in the United States supported by the Institute would indicate that these populations have the following features: The elderly are highly integrated into their family life; they are not in any sense put on the shelf; and they are really a very vital part of the community. Second, they are physically quite vigorous. They are horsemen or walkers and very active. Third, their dietary intake is moderate. That doesn't mean that they don't have a drink or that they don't smoke or that they don't eat meat, but they are extremely moderate and very lean people. I could see that from my own personal observation.

Finally—and I don't know how to evaluate this—they seem to be masters of their own lives, and the Soviets—and even before it was the Soviet Union, referred to a concept of psychic quiet. These people really seem to believe the adage of the Biblical statement, "Sufficient unto the days the evil thereof." They do not worry about something until it's really at hand, so that they are very peaceful, quiet people who seem to be very confident, quite in control of their lives, and that may be a very stress reducing and a very important factor. But all of that is phenomenological and descriptive, and certainly not solid science.

Senator EAGLETON. Sorry.

EXERCISE AND AGE

Senator SPECTER. But within your last answer, you touched on the matters that I would like to pursue, and that is the factor of activity as promoting longevity or promoting vigor itself as it relates to what had been a heavy emphasis in this country on reducing retirement age which now seems to be taking a contrary course.

And my question is, How important is a heavy schedule or vigorous pursuits in maintaining longevity and maintaining vigor during the latter stages of life.

Dr. BUTLER. Scientifically we cannot at this time answer that question, "Yes." We know there is a specific increase in longevity as a consequence of physical activity. But assuming that possibility, we are supporting a variety—in fact, a significant number—of studies in exercise physiology. First, we would like to know what can be introduced that would prevent physical declines of various sorts. Second, when various

physical declines occur, could we arrive at the point of writing medical prescriptions for individuals to help overcome whatever declines they have experienced.

The Institute sponsored, in conjunction with the President's Commission on Physical Fitness and Sports, a major conference on exercise physiology. The relationship of exercise to the immune system, to the hormone system, to psychic status, and to bone integrity was examined. How many women, for example, have a fracture of the hip in no small measure because they simply are not in good condition? These women have what some might call a gait disorder, are unstable and fall unnecessarily simply because they haven't retained good physical activity. We mustn't assume that because people are older, they can't be involved in effective exercise programs.

Health promotion and disease prevention, including not only exercise but nutrition, are very important. Animal studies being carried out in our Baltimore laboratories involve animals whose caloric intake is curtailed. A particular group of these animals is placed on a treadmill, which is also physically active. These studies have indicated that the interaction of physical activity plus the caloric restriction is more life prolonging than either one alone—certainly more prolonging than for those mice which were neither nutritionally restricted nor exercise limited.

Senator SPECTER. Is there any scientific data on the absence of that, in your own judgment, as to whether a person would be likely to live longer and be more robust if he did not retire at age 65?

Dr. BUTLER. In my opinion, intellectual, personal, and social fitness are all important. We talk so much about physical fitness. There are data from some studies in which I was privileged to participate at NIH in the 1950's in which people who had more highly organized structure to their lives, had goals, and were involved, lived longer. The sample in the studies to which I refer was too small, but there have been reports from other nations and other scientists suggesting that the more people have an involvement in life, have some purpose, have some activity, be it paid work or voluntary work, the fewer health problems they have and the longer their life will be.

In the future we are going to have to have a measure called health expectancy as well as life expectancy. We have to have a way of measuring physical vigor and the all around status of older people, not just the length of life.

GERONTOLOGY AS A SPECIALTY

Senator SPECTER. Doctor, I notice in your credentials a background in psychiatry. Is it characteristic for a man to head the Institute on Aging to be in the psychiatric field as opposed to physiology?

Dr. BUTLER. The word "psychiatry" doesn't mean that you are not biologically and physiologically oriented. I began my career at NIH in 1955 working in cerebral physiology, and the board certification I received was in psychiatry. But I always operated in my own mind as what I call a gerontologist. In this country, we don't have a recognized specialty of geriatrics or gerontology. If we had one, I would probably be called a geriatrician and psychiatrist.

And to answer whether it's unusual for the Institute of Aging to have a psychiatrist as their director, I'm the first director, so at least at the moment——

Senator SPECTER. So it's the norm. [Laughter.]

Thank you, Mr. Chairman.

Senator EAGLETON. Would most physicians who would offer themselves out as having a gerontological bent—would most of them probably come out of the internal medicine discipline, if they would so hold themselves out to be practitioners of gerontology?

Dr. BUTLER. Yes; I think family practitioners, general practitioners, and internists have been showing an increasing interest in geriatrics. In my own opinion, it's of crucial importance, particularly with the clinical investigator being an endangered species, that we attract outstanding people in internal medicine to be part of the development of geriatrics. Also because of the close relationship of central nervous system disabilities, I think we need people from neurology and psychiatry as well.

Senator EAGLETON. By the way, I lose track of board certifications. Is one in this day and age board certified as an internist, or are there now various subspecialties of internal medicine in which one is specifically certified?

Dr. BUTLER. There are many subspecialties. Allergy, for example, is one.

Senator EAGLETON. That you are certified as an internist-allergist?

Dr. BUTLER. Yes; or cardiologist, for example.

Dr. FREDRICKSON. Or as an internist and then a subspecialty in addition to that.

Senator EAGLETON. Will there be a day where there will be internist-gerontologist?

Dr. BUTLER. My own expectation is that there will be a day when a subspecialty of geriatrics will exist. The reason geriatrics rather than gerontology is based on the precedent of pediatrics as the medical application of knowledge research to the treatment of children. I don't personally favor a full-blown, new primary care specialty of geriatrics. I see no reason why at 65 years of age someone should be turned over to a whole new breed of physicians. We need neurologists, gynecologists, many who simply are mainstreamed and know their own field. But we do need an outstanding leadership of consultants, teachers, and researchers. They would be in a subspecialty, just as you have outstanding cardiologists to whom the internist can turn when he needs special help.

FEDERAL HEALTH PRIORITIES

Senator EAGLETON. I have one final question for you, Doctor, from the document the President released yesterday, "America's New Beginning—A Program for Economic Recovery." It's a page, although it's not in the NIH section—it's in the Health and Human Services Section—I will read it to you.

One of the gentlemen has it. Would you turn to page 6–16. That's the chapter on Health and Human Services. The third paragraph down. Do you have that page?

The sentence begins: "The administration will propose legislation to refocus Federal aid on a limited number of national priority medical

specialties rather than providing large subsidies for all specialties." And then the paragraph goes on and cites some statistics and what have you.

Do you have any notion as to where geriatrics might fare or how it might fare in this proposed legislation to refocus Federal aid?

Dr. BUTLER. We have to look at that question from a national perspective and as a national problem. The number of older persons is growing daily. We have an additional 1,600 net gain of older persons everyday. We cannot be supporting all sorts of specialties, but we have to address the enormous costs of people over 65—62 percent of all Federal health dollars now go to this age group; 30 percent of all health dollars from whatever sources now go to this age group. The Federal dollars are spent either through medicare, medicaid, or veterans' benefits programs.

If you think of priority setting as based on a kind of grid—health-cost needs, population-increased needs, epidemiological burdens, and the impact on families or individuals—obviously at some time there will be a national decision, I'm convinced, to address the need for an adequate supply of well-trained people in medicine, nursing, and the allied fields to deal with more effective, less costly diagnosis, prompt treatment, and of course, the unraveling of knowledge related to the causes of so many of the disabilities and diseases of age.

So I would have to say that I hope at some point our Nation will make that kind of decision as it takes a hard, healthy look at tightening of belts and looks at where some of the needs are going to be extraordinarily dramatic.

Senator EAGLETON. Thank you very much, Dr. Butler. We will move on now—if we have additional questions, Dr. Butler, we will submit them to you, and we'll await your response.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

SENILE DEMENTIAS

Question: To what extent does senility research at NIA encompass techniques of caring for patients at home?

Answer: The NIA's major contribution in this context is an ongoing effort to develop accurate diagnostic techniques for the various dementias. In the not too distant past, elderly people exhibiting confusion, forgetfulness, and other symptoms of senility were, in effect, "written off." The future now looks brighter for some of these people. As high as 20 percent of all cases diagnosed as senility may be reversible disorders which counterfeit symptoms normally associated with senility. Accurate, early diagnosis will allow individuals with reversible disorders to be properly treated, very probably at home through drug and/or dietary regimens. "Senility Reconsidered: Treatment Possibilities for Mental Impairment in the Elderly," published in the July 1980 issue of the Journal of the American Medical Association (JAMA), has received very wide distribution. It describes diagnosis and treatment approaches to this costly condition. Much remains to be learned, of course. At present there is a lack of reliable and valid tests to assess psychological function. Specifically, physicians need a quick, simple, highly sensitive mental status test which can detect brain disorders in the earliest stages. Comprehensive neuropsychological tests are also needed.

At a different level, NIA grantees and intramural scientists are involved in a wide range of research focusing on phenomena associated with senile dementia. Such phenomena include the apparent correlation between certain neurochemical changes and changes in both cognition and brain pathology, abnormal concentrations of aluminum in the brains of Alzheimer's disease victims, and the high risk of senile dementia among relatives of senile dementia patients (4.3 times greater than in the general population). These studies, and others involving possible implication of slow viruses in senile dementia and unusual susceptibility of certain tissue types to senile dementia, may ultimately lead to new ways of treating and ameliorating this condition on all its forms.

Question: Does NIA support the extension of knowledge to help families care for members with senile dementia?

Answer: In FY 1980, the NIA issued two lay-oriented publications on senility. One was the October 1980 issue of the Age Page, entitled "Senility: Myth or Madness?" The second was a pamphlet answering common questions about Alzheimer's disease. Both publications, while stressing the need for physician care, also discussed ways in which families can help members stricken with senile dementia of the Alzheimer's type. Suggestions included maintaining normal routine as much as possible, provision of memory aids, encouragement of physical and social activities, and frequently stimulating the patient with information about the immediate environment. All these activities encourage use of skills and knowledge that still remain and may slow deterioration of the individual affected by senile dementia of the Alzheimer's type.

Question: To what extent do private organizations assist families in caring for aging parents?

Answer: Public awareness of senile dementia as a pervasive problem has increased, in part due to efforts of the National Institute on Aging and the National Institute of Neurological and Communicative Disorders and Stroke, in encouraging cooperation among the seven self-help groups that had been formed independently by the families of Alzheimer's disease patients. At a meeting at the National Institutes of Health in October 1979, the seven groups voted to form a new national voluntary health association, the Alzheimer's Disease and Related Disorders Association. This group plays an important role in providing emotional support to families with a parent, grandparent, or other relative stricken with senile dementia. In addition, they provide respite care so that the one caring for a senile person may have an opportunity to shop or do other errands.

In addition to this group, there are a number of other private self-help health groups which provide information dealing with specific diseases. These include the American Cancer Society, the American Diabetes Society, the American Heart Association, and the Arthritis Foundation. Organizations specifically oriented to the elderly include the Gray Panthers and the Senior Actualization and Growth Exploration (SAGE).

Question: Aren't there instances where depression is mistaken as senility? What are you doing about this problem?

Answer: Depression is only one of a number of disorders which may be misdiagnosed as irreversible senile dementia. Treatable disorders include those induced or aggravated by depression, drug toxicity, and endocrine-metabolic imbalances. As previously mentioned, up to 20 percent of those individuals diagnosed as senile may actually have reversible disorders. While methods for detection of early dementia have improved over the years, there still is no test which can accurately distinguish between treatable disorders and irreversible senile dementia. The NIA is now involved with the National Institute of Mental Health, the National Institute of Neurological and Communicative Disorders and Stroke, and the National Institute of Allergy and Infectious Diseases in an initiative on Alzheimer's disease and the dementias of aging. One of the planned activities is development of sensitive and reliable techniques for identifying treatable patient populations.

CLINICAL RESEARCH

Question: Does this year's budget attempt to expand geriatric research facilities that have been so limited in the past?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Have training grants been increased?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

OBESITY IN THE ELDERLY

Question: Has NIA supported research designed to investigate the increasing body of evidence that mild obesity may increase overall life expectancy for the elderly?

Answer: Yes. Scientists in the intramural program of the NIA at the Gerontology Research Center have emphasized the importance of age changes in body composition over the more than 20 years of the Baltimore Longitudinal Study of Aging. A variety of procedures have been used to quantify the trend toward increasing obesity over the entire adult life span. Some of these procedures are simple and could be used in large population studies; some are complex and are suitable only for smaller experimental studies. Since the volunteers in this study are being followed over their lifetimes, it will be possible to ferret out links between obesity and the development of specific diseases, between obesity and accelerated aging, and between obesity and longevity.

Question: Does this relationship appear to be true?

Answer: The results from the Longitudinal Study do add further evidence to the data forthcoming from studies elsewhere in the world. For example, men in their 60's did best when their weights were some 8 to 16 percent over the middle of the range indicated in the 1959 Desirable Weight Table. For those in their 70's, minimal mortality occured in subjects who were 16 to 24 percent overweight.

Question: What effects can result from the underweight state of many elderly?

Answer: This is a simple question but it does not have a simple answer. First of all, the undernourished elderly person may be suffering from a wide variety of illnesses which interfere with proper nutrition. Illnesses, in general, result in loss of appetite and some interfere with proper digestion and absorption of food. Secondly, social and economic deprivations in the elderly may lead to nutrition problems--both inadequate intake and poor food quality. Thus, specific deficiencies may result in nutritional diseases, such as vitamin deficiency states. In addition, there is evidence that poor general nutrition leads to increased susceptibility to disease (infectious processes are an example) and to decreased ability to cope with an illness which might, in a well-nourished person, be handled without much difficulty. All of this should not be taken to mean that we have a comprehensive understanding of the long-term effects of moderate to severe leanness in otherwise healthy people. We do not. Epidemiologists and nutrition scientists will have to begin to "think about the unthinkable," that is, that it is in fact not healthy to be as lean as possible. Hypotheses still need to be generated and tested in order to gain a better understanding of the impact of fat stores in the body on health and on longevity.

Question: In which chronic diseases might mild obesity be detrimental?

Answer: There are indeed a number of conditions in which obesity plays a detrimental role. Among the most important ones are diabetes mellitus and hypertension. The type of diabetes that

develops during the middle and later adult years and does not require insulin therapy for survival nearly always occurs in obese individuals. The diabetic state ameliorates if weight loss is successfully carried out. The obesity-hypertension link is not as strong. Still, in the hypertensive who is obese, there is evidence of lowering of blood pressure when weight is lost. Individuals with elevation of fat levels in the blood (either cholesterol or triglycerides) can also be expected to show improvement with weight loss. Then, there are certain orthopedic problems which, while not caused by obesity, still will become less symptomatic with weight loss. These include especially degeneration or osteoarthritis of weight-bearing joints, such as the hips and knees.

Thus, a "prescription" for a person's best weight or "desirable" weight is no simple matter. All of these factors--and even the person's family history--have to be taken into account.

NUTRITION FOR THE ELDERLY

Question: Please explain what the Institute is doing in defining nutrient needs of the elderly.

Answer: The National Institute on Aging supports research designed to investigate the nutrient needs of the elderly. For example, total energy requirements in the elderly are known to be reduced as a result of a decreased basal metabolic rate as well as a decreased level of activity. The basal metabolic rate (energy required at rest for the basic functioning of such organs as the heart, lungs, and brain, but excluding energy required for digestion of food) is directly related to the lean body mass--primarily muscle. It has been found in study conducted at the University of California that the basal metabolic rate remains constant with increasing age and between the sexes. Thus the decrease in basal metabolic rate with increasing age is not due to a change in the rate at which the body tissues use energy, but rather is due to loss of muscle mass with increasing age. In addition, it was found that the energy expenditure for such sedentary activities as lying at rest and sitting quietly was the same in old as in young men when normalized to the individual's basal metabolic rate. These findings provide a sound basis for defining the energy needs of the elderly.

The NIA is also involved in studies aimed at determining the nutritional status of elderly populations and relating the status to subsequent health related outcomes. For example, a five year prospective study of approximately 300 healthy elderly individuals (65 years and older) is being conducted to determine the incidence of subclinical malnutrition in this population. NIA is also taking the lead in a 10 year follow-up survey of the adult participants in the HANES (Health and Nutrition Examination Survey) study which was conducted in 1971-1973. Food intake information and blood levels of many nutrients are available for the original participants (approximately 14,000 persons between the ages of 25 and 74). These same individuals (now ages 35-84) will be re-interviewed beginning late this summer. The aims are: 1) to identify any changes in dietary patterns which have occurred in the U.S. population over the last ten years, and 2) to identify which, if any, of the original measurements (eg. nutritional status) are predictors of subsequent events such as morbidity, hospitalization, institutionalization and mortality, and physical and cognitive disability.

Question: How does this area of interest fit into the Institute's overall set of research priorities?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

KNOWLEDGE ABOUT AGING

Question: There is, as your justifications acknowledge, an enormous need for new knowledge about the aging process and the aged. What knowledge are you developing on the elderly's needs, capabilities and status, and ways to maintain or restore their health and well-being?

Answer: In the biomedical and clinical areas, studies of particular importance include research on senile dementia of the Alzheimer's type, nutrition, and pharmacology. Our efforts and advances in senile dementia have already been discussed. Little is now known about specific nutritional requirements of the elderly. We do know that nutritional and caloric requirements change as one ages and that there is a reduced energy requirement. Changes in gastrointestinal function with age can also be expected to alter absorption of many nutrients. The NIA is beginning to support studies in these areas, but the questions are complex and the answers will only come with time. In pharmacology, recent research strongly suggests that the elderly respond differently to drugs than do young adults. There are many possible causes: pharmacokinetics (absorption, transport, distribution, metabolism, and elimination of drugs); changes in responsiveness to drugs; and sensitivity to the effects of other drugs, to nutritional status, and to disease states. Since the causes for differences in drug response may vary with individual drugs or with whole drug classes, we must seek both generalized principles regarding the effects of post-maturity aging on drug response and specific information regarding individual drugs. Research is also being conducted on diabetes in the elderly, obesity, deficiencies of eyesight and hearing, and a large number of other subjects which have immediate impact on the elderly.

There are also social and behavioral considerations. For example, studies are being conducted on conditions which influence the health and well-being of the elderly; cost effective strategies for preventing, easing, or reversing disabilities such as memory loss or sensory deficits; eating behavior; and work motivation. Special efforts are being made to probe linkages between the changing social environment and such disabilities as memory loss, chronic ill health, sensory impairments, and low self esteem. The focus is on research which will lead to maintenance of functioning and productivity.

Question: What impact is the increasing number of elderly in our population having on American society?

Answer: As the elderly become a more visible part of the population as a whole, a major concern will be the increasing level of dependency between retirees and those still working. The number of pensioners will more than double by the year 2035, while the labor force will grow at a much slower pace unless fertility rates increase sharply. If medical breakthroughs allow men's life expectancy to equal women's, the potential number of elderly dependents will be even

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greater. The result is likely to be more concern with medical care and facilities, especially long-term care facilities; shifts in attitudes toward the elderly; and a new societal view of the aging process which includes the notion that accumulation of decrements normally associated with old age is not inevitable. It is also important to mention the so-called "dependency ratio." This is a measure of the ratio of older persons (65 years and older) and younger persons (under 18) over the working generations. Because of the decline in the birth rate, the dependency ratio is not notably increasing.

EXTENSION OF LIFE

Question: An explosion in medical knowledge will obviously result in prolonging life. For example, the Allergy Institute says that mastery of the immune system is at hand. To what extent have you examined the cost implications to Social Security and retirement systems of extending life expectancy?

Answer: The National Institute on Aging has anticipated the need to assess the cost implications to the retirement income structure of extending life expectancy. In order to address this question, we have entered into an Interagency Agreement with the President's Commission on Pension Policy to develop a demographic and macroeconomic model of the U.S. economy and retirement income system. We expect to receive this model in June 1981 and will maintain ongoing research not only on the impact of life expectancy, but other demographic phenomena that could increase the number of elderly in our population.

The financial problems of the Social Security system and other retirement systems arise not so much from the longevity of retirees as from the changing ratio of workers to retirees, a change brought about as much by lowered birth rates as by longevity. Except for extreme high and low ends of the income distribution, the value of contributions made over the 40 to 50 working years is received in benefits in the first 10 to 20 years of retirement. As people live longer after retirement, there will clearly be more expense associated with both Social Security and retirement pensions. I would like to point out, however, that as people live longer, they also tend to be increasingly healthy, vital, and interested in continued participation in the work environment. We have already seen the age of mandatory retirement lifted from 65 to 70. It seems highly possible that as people live longer they will also work longer, and so maintain the proportion between the working and retirement periods of their lives.

Question: What studies do you have about possible adverse effects to the lives of younger people as a result of them having to support greater financial burdens of the elderly?

Answer: Work done by Herman B. Brotman suggests that the gross dependency ratio, that is the ratio of those under 18 and over 65 to the working population, will actually decline in the future. The number of elderly per 100 workers will rise and peak in 2030. Based on current fertility rates, the number of children per 100 workers will decline. When the two trends are combined, it appears that workers of the future will carry a quite reasonable "burden" of old and young dependents.

Several studies relative to financial dependence are currently being conducted by NIA grantees on intergenerational transfers of funds. A study by an economist at the University of Wisconsin is focusing on the relationship between transfers of resources among relatives and transfers of resources from government as they effect economic well-being across generations. At Northwestern University, a grantee is developing an economic model which will relate intergenerational transfers to the distribution of income and wealth within society. Other research projects include studies of work and retirement, life style changes that can maintain health and prevent disease, and social changes and stresses which may contribute to pathogenesis.

Question: To what extent will extending retirement ages adversely affect job opportunities for younger workers?

Answer: The NIA is certainly conscious of the implications of retirement age on younger workers. We have a number of studies underway which examine retirement age policies relative to other factors that may affect continued labor force participation. These include studies of the retirement decision itself, the relation of health to retirement, economic consequences of retirement, and positive incentives for continued participation in the workforce.

COORDINATION OF RESEARCH

Question: What are you doing to develop research projects for the elderly in conjunction with the Administration on Aging and the National Institute on Handicapped Research?

Answer: The Administration of Aging is represented on the NIA Ad Hoc Interagency Committee on Aging, as is the National Institute for Handicapped Research. This committee is composed of representatives from 30 Federal agencies. It meets approximately every three months and provides opportunity for continuous dialogue on each agency's programs. For example, at the committee's last meeting, the Administration on Aging and the Institute for Handicapped Research gave seminar discussions on their respective research programs. Such activities allow coordination of research and encourage cooperation wherever feasible.

Question: How do you avoid duplication and overlap in research grants concerning the elderly among various Federal agencies?

Answer: The agencies which support research concerning the elderly fund quite different kinds of research. The National Institute on Aging, for example, focuses on basic and applied research in the biomedical, clinical, and social-behavioral areas. The Administration on Aging (AoA) has a research and demonstration program directed primarily at improving the delivery of services to the elderly. The previously mentioned Ad Hoc Interagency Committee on Aging also encourages collaboration and helps avoid duplication. The Institute has had numerous meetings with other Federal agencies interested in aging research. The AoA is also present at all National Advisory Council on Aging meetings.

NUTRITIONAL STATUS OF THE ELDERLY

Question: We understand there is a need for more information on the nutritional status of the elderly. What, if any, information do you get from the nutrition programs for the elderly?

Answer: The NIA is supporting a large program of basic nutrition research directed to the special needs of the elderly. Nutrition programs for the elderly, such as the well-known Meals on Wheels or the National Nutrition Program for Older Americans, are primarily service oriented and do not provide a great deal of information on the nutritional status of the elderly. In fact, only limited information is currently available on which to base nutritional recommendations specific to this population. At this time, the NIA is supporting a number of studies directed at discovering basic information about nutritional needs of the elderly and how these needs differ from those of younger individuals. One grantee is developing a new method to study protein synthesis and protein needs of the elderly. Another project is a five-year study of 300 healthy individuals. The study is aimed at determining the incidence of subclinical malnutrition and the effects of this malnutrition on subsequent morbidity and mortality. The NIA is also taking the lead in a 10-year follow-up survey of participants in the 1971-1973 Health and Nutrition Examination Survey. A major aim of the present survey is to identify any of the original measurements which may be predictors of subsequent events such as morbidity, hospitilization, institutionalization and mortality, and physical and cognitive disability.

Question: To what extent do you work with the Administration on Aging on this?

Answer: The Administration on Aging's National Nutrition Program for Older Americans is essentially a meal delivery program. It evaluates its effectiveness. The NIA makes nutritional information, including new knowledge, available to AoA and its area agencies on aging (AAA).

Question: What problems have you encountered?

Answer: Research on the nutritional needs of the elderly is a new territory. There continues to be a great need for research in nutrition in people over 50. Recommended daily allowances are extrapolated from studies of the under 50 age group. There is also a lack of researchers in the field of nutrition and age. Therefore we have identified this area as an important priority and have actively supported the Health and Nutrition Examination Survey of the National Center for Health Statistics. As information becomes available, we have provided it to AoA and to the broad health practicing community.

Question: What is the relationship between dietary habits and aging?

Answer: We currently have very little information on this important area. The little information which is available does suggest that dietary habits can contribute to the development of age-related disorders such as diabetes and hypertension. Additional factors which are also interrelated include genetic factors and other environmental factors, as well as dietary intake factors.

This question is being actively pursued using laboratory animals. It has been known for some time that moderate, long term food restriction will delay the aging process and increase life span in several species of laboratory animals. Research has also made it clear that as people get older the quality of their diet has to improve to counterbalance lowered caloric intake. The National Research Council Recommended Dietary Allowances include reduced energy requirements with increased age and a concommitant reduction in vitamins known to be associated with energy expenditure (i.e., thiamin, riboflavin and niacin). In addition, the recommended iron intake is lower in post-menopausal than in pre-menopausal women. Food intake data obtained from NIA Baltimore Longitudinal Study participants has been analyzed for age-associated trends in food intake. Major findings show decreased intake of total calories, fat, and carbohydrate with increasing age, but a relatively constant level of protein intake. The percent of calories deriving from fat decreased with age, while the percent from carbohydrate increased. In addition, the intake of saturated fatty acids decreased with age.

DIAGNOSTIC TESTS

Question: We understand that senile dementia has many causes, some of which can be reversed at an early stage. How successful are you in getting at the problem at an early stage?

Answer: The accurate diagnosis of dementia is often a challenge for physicians and researchers. To aid in sorting out the reversible disorders, which may constitute as much as 20 percent of all cases in which older people seem confused, disoriented, and forgetful, the NIA sponsored a consensus development meeting on treatment possibilities for mental impairment of the elderly. The results were published in the July 1980 issue of JAMA under the title "Senility Reconsidered: Treatment Possibilities for Mental Impairment in the Elderly." One of the serious inadequacies pointed up during the course of the consensus process was the lack of reliable and valid tests to evaluate psychological functions. Specifically, while there have been a number of technological improvements which help in diagnosis, physicians still need a simple, quick, mental status test which is sensitive enough to detect brain disorders in the earliest stages. Also needed are comprehensive neuropsychological tests.

Question: What kinds of diagnostic tests are now available for senile dementias?

Answer: Currently used diagnostic approaches include the Mental Status Questionnaire, the Mini-Mental State, and the Clinical Dementia Rating. In addition, there have been two potentially useful technological advances. In the early 1970's, computers revolutionized the ability to view the human brain. Today's CT scanner resulted. Thousands of X-ray beams pass through the skull towards sensing devices which transmit electronic signals to a computer. The computer then synthesizes the measurements and converts them to a color coded image of individual "slices" of the brain. This procedure is quick, painless, and noninvasive, and is highly valuable for pinpointing abnormalities in the brain which may mask themselves as senile dementia. Though the CT scanner can not definitely diagnose senile dementia of the Alzheimer's type, it points to such a diagnosis by excluding other conditions.

Another new technique--positron emission tomography (PET)--is fast becoming known among researchers for its unique ability to monitor biochemical activity of the human brain. The PET allows researchers to monitor brain activity when subjects are at rest or normally active, when drugs are introduced into the system, and when disease begins to interfere with normal activity. The PET's present value to biomedical research, particularly research on the dementias, is incalculable. One day it may be used in the medical diagnosis of brain disease as well.

Question: To what extent in NIA involved in the dissemination of information on these tests?

Answer: A recent example of such information dissemination is "Senility Reconsidered: Treatment Possibilities for Mental Impairment," which appeared in JAMA in July 1980.

SENILITY VERSUS DEPRESSION

Question: Sometime back, Dr. Butler, you talked about the importance of distinguishing between senility and depression in dealing with the elderly. Where do you stand on this? Have you done further work on it?

Answer: This certainly is a problem of tremendous concern to the Institute, and we have devoted a major effort toward elucidating the causes of senile dementia and its related disorders. Through this effort we hope to distinguish between reversible and irreversible disorders. Depression is an emotional condition that can temporarily upset the normal activity of extremely sensitive brain cells and mimic symptoms of senile dementia of the Alzheimer's type. When properly diagnosed, depression can be reversed with prompt treatment.

Question: To what extent are you sharing your findings with long-term care institutions, senior citizens groups, etc.?

Answer: Over the past several years, the NIA has held several conferences on senile dementia of the Alzheimer's type. The most recent was a consensus development meeting on treatment possibilities for mental impairment of the elderly. Summaries of such conferences are published in professional journals for the benefit of interested individuals and groups. Special articles on status of current research and new findings which may lead to better understanding, diagnosis, and treatment of the dementias are also published periodically. For example, "Aging: Research Leads and Needs," published in Forum on Medicine in 1978, discussed recent studies of senile dementia of the Alzheimer's type and possible new approaches to treatment of aged persons. More recently, another article, "Senility Reconsidered: Treatment Possibilities for Mental Impairment in the Elderly," was published in JAMA. This article focused on the crucial importance of distinguishing between curable and irreversible brain disease. Finally, the Institute has developed two publications for general consumption: an Age Page entitled "Senility: Myth or Madness" and a pamphlet answering common questions about Alzheimer's disease.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

CLINICAL RESEARCH

Question: Does this year's budget attempt to expand geriatric research facilities that have been so limited in the past?

Answer: The national Institute on Aging has no construction authority, therefore cannot support expansion of geriatic facilities. We do make every effort to use facilities currently available, such as the Bethesda Clinical Center. However, NIA is developing an academic presence for the field of geriatrics at various medical and dental schools throughout the country with the view of improving and expanding research in geriatrics.

Question: Have training grants been increased?

Answer: The NIA supports a small program for training clinical investigators. The number of trainees is expected to remain constant from FY 1981 to FY 1982.

NUTRITION FOR THE ELDERLY

Question: How does this area of interest fit into the Institute's overall set of research priorities?

Answer: The Institute considers research directed toward determining the nutrient needs of the elderly to be an area of highest priority. Examples of studies being funded by NIA in this area have been discussed above. We are currently considering ways to stimulate increased interest in this area within the biomedical research community.

MAINTAINING NEW RESEARCH GRANTS

Question: The Fiscal Year 1982 Budget continues to emphasize the stabilization of new, investigator-initiated research grants at 5,000. How much funding will you need in Fiscal Year 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The NIA share of that amount is $19,721,000 and 146 grants.

Question: How is inflation impacting -- or how will it impact -- on this goal: What inflator are you using?

Answer: An inflation factor of 9.5 percent was taken into account in developing the cost of funding the 4,900 new and competing research project grants.

Question: Why is it so important to stabilize new Research Grants regardless of other budget priorities within NIH?

Answer: It is important to maintain a proper balance among the various research mechanisms. Research project grants are the mainstay of NIA and represent an investigator's independent efforts to plan research to better understand mechanisms of the aging process. This type of research has led to the many advances evident today. Under the stabilization effort, NIA is still able to maintain a modest program in other research. This is important for the development of centers of excellence at medical and dental schools to encourage the improvement and expansion of research in the geriatrics field. This program encompasses our Geriatric Medicine Academic Award and Geriatric Dentistry Academic Award.

Question: What happens if, in a particular year, the quality of new research proposals declines: To what extent would you then want to fund fewer new grants and put greater emphasis on research contracts or intramural research?

Answer: In fiscal year 1981, the National Institute on Aging will fund 18 percent of approved research project grants; in 1982, 21 percent will be funded. Consequently, many high quality research grants will go unfunded. NIA does not expect this trend of high quality research in grant applications to change significantly and therefore would not fund fewer research grants in favor of contracts or intramural research.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981 -- and if you can estimate it -- in FY 1982? What percentage of grants will you fund in both years?

Answer: In FY 1981, the National Institute on Aging will pay to a priority score of 190, awarding 18 percent of its approved grants. In FY 1982, NIA will pay to a priority score of 200, awarding 21 percent of approved grants.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, intramural activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justification recently submitted to the Congress have attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

Division of Research Resources

STATEMENT OF JAMES F. O'DONNELL, ACTING DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
RICHARD L. SHAFER, EXECUTIVE OFFICER
WILLIAM K. RUSS, BUDGET OFFICER
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator Eagleton. The next witness is Dr. Thomas G. Bowery, the Director of the Division of Research Resources. The mission of the division is to create, develop, and maintain research resources needed by the NIH to support biomedical investigators throughout the Nation.

Dr. Fredrickson. Mr. Chairman, this is Dr. James O'Donnell, who is the Acting Director of the Division of Research Resources.

Senator Eagleton. OK, Dr. O'Donnell, we are delighted to have you, and you may proceed.

Dr. O'Donnell. Thank you, Senator Eagleton.

I am pleased to have with me my executive officer, Mr. Shafer, and on his left, my budget officer, Mr. Russ.

I will submit my opening statement for the record, and I would like to just give you a brief overview.

[The statement follows:]

STATEMENT OF JAMES F. O'DONNELL

It is my pleasure to appear before you for the first time to testify on behalf of the Division of Research Resources and our planned activities in fiscal year 1981. As you know, these programs initiate, develop, and sustain research resources in which research can be accomplished with the greatest efficiency. Some of our programs support specialized research resources such as the General Clinical Research Centers and the Regional Primate Research Centers. Our Biomedical Research Support Program provides the foundation for the early initiation of much innovative research. DRR's Biotechnology Research Program is the NIH focus for assistance, support, and direction in the application of state-of-the-art technologies and shared use of sophisticated resources. Finally, DRR's unique Minority Biomedical Support Program is increasing the capacity to conduct biomedical research at predominantly minority institutions or at institutions which have large numbers of minority faculty and students. Through this Program, more citizens of ethnic minority extraction will be prepared to enter the mainstream of the national biomedical research effort.

The Division of Research Resources' Five-Year Program Plan was developed during the past year with the advice and assistance of the National Advisory Research Resources Council and the several program review and advisory committees associated with this Division's programs, and with assistance from the biomedical research community. We examined alternate strategies for reaching our goals, discussed them with the Council and with the principal officials of the National Institutes of Health, and eventually identified the priority issues. The top three of these issues are:

1. Strengthening the program of nationwide shared biotechnology research resource centers;

2. Strengthening the Biomedical Research Support Program; and

3. Retaining the existing base of clinical research resources.

In addition to priorities and objectives established during our long-range planning process, we also considered it important that support be maintained for DRR's research resources and centers for use by Institute-funded investigators, relative to the number of competing research project grants. In fact, it is vital that the Division of Research Resources be able to provide a stable environment for Institute-supported investigators. Biotechnology Research, our top-priority program, will support resources in biomedical computing to help investigators understand and analyze data, molecular structures, and complicated intramolecular relationships. One example, PROPHET, is a system which supports research groups in universities as well as in some government and private-sector laboratories; another, CADUCEUS, contains a broad base of knowledge and rules for diagnosing diseases in internal medicine. In addition

to computers, resources for examining the biological structure and function of biological systems ranging from the submicroscopic scale to complete organisms continue to play an important role in biological/biomedical investigations in all fields of research. The biomedical engineering resources such as those that focus on the use of microelectronics technology to facilitate the production of devices needed to conduct health research form a small but important part of the efforts in the biotechnology area. An example of such is the science supporting the ion selective nature of the field effect transistor, which could lead to the development of the long-sought-after implantable glucose sensor for an artificial pancreas.

Our second priority is the strengthening of the Division of Research Resources' Biomedical Research Support Program (BRSP). BRSP is a vital contributor to the research institutions' abilities to conduct federally supported research and provides the flexible basis on which to draw when fast decisions in support of the research effort must be made and implemented, e.g., when funds are needed immediately to repair a vital piece of research equipment; when funds are needed immediately to support a pilot research project; when funds are needed immediately to help establish a newly hired scientist at the institution. Another significant contribution is the funding for the procurement of new, and replacement of obsolete, research instrumentation. In order to help assure the availability of new equipment, the Division of Research Resources proposes to use a portion of the Division's funds for the Biomedical Research Support Program to meet this need, and to make competitively reviewed supplemental awards to the existing Biomedical Research Support grants. These supplements would be for purchase and installation of instruments which could be justified only on the basis of shared use among two or more research projects. The cost range of these instrument systems would be $75,000 or more. The effort we are proposing here is admittedly a small but significant step in the direction of providing the necessary instrumentation to investigators and their institutions so that they may carry out the biomedical research activities of this country.

Our third priority is the Clinical Research Program which supports General Clinical Research Centers around the country. These Centers will continue to provide 80% of the NIH-supported inpatient research cost and will therefore continue to provide the core for the extramural clinical research effort of the National Institutes of Health. We will continue to encourage research involving outpatients rather than the hospitalized patients wherever possible in order to reduce the costs to the lowest possible level. A second cost-efficient activity within the Clinical Research Program of the Division of Research Resources is the Clinical Associate Physicians (CAP) activity. This effort represents a small but very important component of NIH's attempts to encourage more physicians to actively engage in clinical research.

We plan to continue operation of the seven Regional Primate Research Centers. These Centers, located around the country and constructed in the 1960s, provide unique environments for the conduct of biomedical research using nonhuman primates. We will also continue the training of a few postdoctoral-level investigators in laboratory animal medicine. These individuals will, upon completion of their training, provide professional care to many species of laboratory

Brief Chronology of Employment:

1953 - 1955	Graduate Teaching Assistant, Department of Biochemistry, University of Chicago
1957	Visiting Lecturer, Biochemistry, Summer, University of Colorado
1957 - 1968	Assistant-Associate Professor, Biological Chemistry and Experimental Medicine, University of Cincinnati, College of Medicine
1963 - 1964	Visiting Professor in Chemistry, Xavier University, Cincinnati, Ohio
1968 - 1969	Grants Associate, Division of Research Grants, National Institutes of Health (NIH)
1969	Health Scientist Administrator, Population and Reproduction Grants Branch, Center for Population Research, National Institute of Child Health and Human Development (NICHD), NIH
1969 - 1971	Program Director, Population and Reproduction Grants Branch, Center for Population Research, NICHD, NIH
1971 - 1976	Assistant Director, Division of Research Resources, NIH
1976 - Pres.	Deputy Director, Division of Research Resources, NIH
1979 - Pres.	Member, Senior Executive Service
1981 - Pres.	Acting Director, Division of Research Resources, NIH

Military Service

U.S. Army, November 20, 1950 - November 19, 1952

Societies:

New York Academy of Sciences
Society of Research Administrators

Other NIH Activities:

Executive Secretary, National Advisory Research Resources Council, 1971-Present
Chairman, Awards Board, Division of Research Resources, 1971-Present
Member, Extramural Forum Subcommittee, 1971-1972
Member, Editorial Subcommittee, 1971-1972
Member, Executive Committee for Extramural Affairs (ECEA), 1971-September 1979
Member, Research Subcommittee, ECEA, 1971-1972
Member, Staff Training in Extramural Programs (STEP) Committee, 1971-1974
Member, Belmont Retreat Subcommittee, 1972
Member, Subcommittee on External Training Opportunities, 1972-1973
Director, STEP Module on Committee Management, 1973
Chairman, Research Subcommittee, ECEA, 1973-1977
Member, NIH Extramural Training Advisory Committee (NETAC), 1973-September 1979

Member, Grants Associates Board:
Liaison Member, 1970-1971
Full Member, 1973-1977
Director, STEP Module on Grantee-Contractor Relationships, 1974
Chairman, Panel of ECEA Retreat on Peer Review, February 1974
Chairman, Panel at Grants Associates Board Retreat, July 1974
Chairman, NIH Training Design Team, 1978-Present
Member, NIH Scientific Review Group Orientation Subcommittee, February 1979-November 1980
Member, NIH Research Resources Coordinating Committee (RRCC), July 1979-December 1980
Member, Task Force on Grants Technical Assistants/Grants Clerks/ Committee Management Officers, October 1979-June 1980
Member, Extramural Program Management Committee (EPMC), October 1979-Present
BID International Representative, November 1979-Present
Member, Review Policy Committee, January 1980-June 1980
Member, EPMC Agenda Subcommittee, February 1980-May 1980
Member, NIH Core Grants Work Group, RRCC, July 1980-November 1980
Member, EPMC Agenda Subcommittee, January 1981-Present

NIH Training:

Federalism and Decentralization of the Executive Branch, 3 Days, December 1971
Federal Executive Institute, Organizational Development and Team Building, 5 Days, July 1972
Organizational Development/Team Building, 5 Days, January 1973
Organization Development Seminar, 2 Days, May 1973
Legislative Operations Roundtable for Executives, 5 Days, May 1973
Managing Through Face-to-Face Communication, 5 Days, December 1973 (American Management Association)
Kepner-Tregoe, Government Management Seminar, 8 Days, November 1975
Management Development Program, 3 Days, March 1976
Equal Employment Opportunity and the Federal Employee, 1 Day, May 1976
Federal Executive Institute, Executive Leadership and Management, 15 Days, September 1977
Legal Aspects of Program Administration, Legal Education Institute, 3 Days, January 1979
Federal Executive Institute, Executive Development, 2 Days, April 1979
Program for Senior Managers in Government, Harvard Business School and Kennedy School of Government, 15 Days, August 1979
Performance Appraisal Training-Phase I, NIH, 1 Day, September 1979
Data Processing for Non-DP Executives, Advanced Management Research International, Inc., 3 Days, February 1980
Basic Program Officials Guide to Contracting, DHEW, 4 Days, April 1980
Performance Appraisal and the Communication Process, NIH, 1 Day, July 1980

Awards:

Quality Increase for Performance from September 1973 to September 1975. Awarded October 1975.
NIH Director's Award for Performance from 1977 to 1978. Awarded June 1979.

OVERVIEW OF DRR MISSION

Dr. O'DONNELL. It is my pleasure to have the opportunity for the first time to testify on behalf of the Division of Research Resources and our planned activities. The programs of the Division include the general clinical research centers, biotechnology resources, animal resources, biomedical research support, and minority biomedical support.

These programs initiate, develop, and sustain the resource environment across the Nation in which biomedical research may be accomplished with the greatest efficiency and economy.

The Division's 5-year plan which we developed in the past year with the advice and assistance of the National Advisory Research Resources Council and several review committees associated with our programs and with the assistance of the biomedical research community, lays out our ambitions for the fiscal year 1982 and the years following.

Our priorities, which are identified therein, are strengthening the programs of biotechnology research resources which are nationally shared centers; strengthening the biomedical research support program; and third, retaining the existing base of clinical research resources.

We have also considered the importance of support for the DRR resources and centers, which are available for use by the Institute-funded investigators relative to the number of competing research grants awarded by the NIH.

We must be able to continue to provide this stable environment for the national research community.

Biotechnology research, which is our top priority, will support resources in biomedical computing, resources for examining the structure and function of biological systems ranging from submicroscopic level to that of complete organisms, and to support biomedical engineering resources such as those which focus on the use of microelectronics technology to facilitate the production of devices needed to conduct health research.

The Biomedical research support program is our second priority. It enables the research community to make quick local decisions through the use of these flexible funds for supporting those research needs for which other funds are not available. For example, to repair a vital piece of research equipment, to support a pilot research project, to provide surrogate funds for an investigator, or to help replace broken or obsolescent equipment.

Our third priority is the support of the general clinical research centers across the country. These centers will continue to provide the clinical resources for approximately 80 percent of the NIH extramurally supported in-patient research activity.

Our other research interests include operation of the seven regional primate research centers, which provide unique environments for the conduct of research using nonhuman primates. We also support other laboratory animal science activities, such as animal diagnostic disease laboratories, development of animal models for the study of human disease, the training of postdoctoral investigators in laboratory animal medicine, as well as assisting institutions to comply with the animal welfare regulations.

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The minority biomedical support program continues to have a significant impact on the ability of predominantly ethnic minority institutions to become more actively involved in the conduct of biomedical research, and encourage more young minority students to choose careers in biomedical research fields.

I would be pleased to answer any questions.

MINORITY INSTITUTIONS

Senator EAGLETON. On the minority institutions, are they still for practical purposes, two in number? Is that Howard and Meharry? Is this what is referred to as "minority medical"?

Dr. O'DONNELL. They are the only two major minority institutions that have 4-year medical schools. A third one is Morehouse College of Medicine, a 2-year medical school, which has just begun operating within the last 2 years.

Senator EAGLETON. Tell us, using any one of the two existing institutions, what you may have in mind. Or, with respect to Morehouse, how do you assist those two and soon to be three medical institutions, primarily minority, in the developing of a greater—I guess you would call it in that respect—in-house research capacity in the development of research clinicians?

Dr. O'DONNELL. Those three institutions, Howard, Meharry, and Morehouse, are only 3 of the 80 institutions that we are supporting. They all share in common one focus; the development of biomedical research competence.

When we initiate programs in these institutions, we provide basically for release time for some of the faculty to engage in research. We provide research support for some of the investigators. And chiefly, we provide support for students at the undergraduate or the graduate level so they will have an opportunity to participate with the faculty in biomedical research activities.

So, hopefully, the students will, through this experience, be induced to pursue careers in biomedical research.

In the case of the medical students, in their off hours at these institutions, some might be able to participate with faculty members in biomedical research activities.

Senator EAGLETON. Are there any recent studies of Howard and Meharry graduates—since Morehouse is fairly new in the business—as to what percentages of those graduates go into research medicine? And, is that percentage increasing?

What statistics do we have? And what do the statistics show?

Dr. O'DONNELL. I will have to provide that for the record, sir.

[The information follows:]

MBS GRADUATES OF HOWARD UNIVERSITY AND MEHARRY MEDICAL COLLEGE WHO HAVE GONE INTO RESEARCH MEDICINE

There are no studies available that show exactly what percentage of MBS graduates from Howard and Meharry go into research medicine, however, the figures below do indicate a high probability that a large percentage of MBS graduates from these two institutions will pursue careers in research medicine.

It can generally be assumed that most of those individuals pursuing the Ph. D. degree will eventually end up working in biomedical research, and that a large percentage

of those pursuing M.D. and D.D.S. degrees will also end up in research medicine occupations.

Howard University.—The MBS program has supported 268 students at Howard University since 1972. The student participants included: 122 undergraduates, 109 graduate students, 24 dental students, and 13 medical students. A total of 80 have completed their undergraduate degrees at Howard University. The career choices of those students who have completed all degrees are as follows:

14 have already completed the Ph. D.;
21 have already completed the M.D.;
27 have already completed the D.D.S.:
15 are presently in graduate school pursuing a Ph. D.;
34 are presently in medical school pursuing an M.D.;
1 is in veterinary school;
2 are in dental school; and
87 did not pursue advanced degrees in biomedical sciences and took other jobs as teachers, technicians, and other fields.

The other 67 students are still participating in the MBS program.

Meharry Medical College.—Only graduate students are supported through the MBS program at Meharry. There have been 12 students graduated with a Ph. D. to date. One of them has elected to go for the M.D. degree and the other 11 are in biomedical research careers. There are presently 17 graduate students supported by the MBS program at Meharry and all are pursuing the Ph. D. degree.

MINORITY BIOMEDICAL SUPPORT PROGRAM

Dr. FREDRICKSON. Mr. Chairman, may I inject a word?

Senator EAGLETON. Yes.

Dr. FREDRICKSON. The Division of Research Resources does indeed, with its minority biomedical support program, carry out a very important part.

We have a number of other programs; such as the minority access to research careers program, which is under the supervision of the National Institute of General Medical Sciences. There are other minority programs throughout the NIH. So there is a continuing and vigorous attempt to get into the mainstream, minorities not only from Meharry and Howard, but from a large number of institutions, including, in addition to blacks, women, Hispanics, and native Americans.

I attended a meeting just 2 days ago that one of our Institutes held, which was attended by 50 to 60 minority students from across the country who are enrolled in some of the best schools and have very high grade point averages—over 3.5—who are aiming for medical school or science careers. I think we are making, slowly but surely, real steps in identifying those people and offering opportunity for the gifted.

Those same students will be offered a chance to come into NIH next summer. Last year we had more than 50 who got an opportunity to engage in research directly on the campus.

I just wanted to interject for the record the fact that we make an attempt in many areas, in many programs, to try to fill those needs.

MINORITY ADMISSIONS TO MEDICAL SCHOOLS

Senator EAGLETON. Ancillary to this hearing, do you know what statistics show, Dr. Fredrickson, on the admission of students to all the medical schools in the country, not just Meharry and Howard, but what have we got, 100 medical schools, 110?

Dr. O'DONNELL. 126.

Senator EAGLETON. As to the percentage enrollment of blacks and Hispanics in the schools?

Dr. FREDRICKSON. I believe the percentage of black students has fallen off. It was rising in the last few years, but it is my impression—and we will correct it for the record—that the increase has stopped and there is beginning to be a decline throughout the country.

[The information follows:]

MINORITY MEDICAL STUDENTS

Data for the school year 1979–80 showed that black and Hispanic students represented respectively 5.7 and 4.5 percent of first-year enrollment. Compared with the previous year, this indicates a slight percentage decrease for black students and a moderate percentage increase for Hispanic students. Even though the number of black students did increase by 38 from the previous year, an increase in total student enrollment caused a 0.1-percent decrease in these statistics for black students.

DECLINE IN MINORITY STUDENTS

Senator EAGLETON. Is there any reason that is known for that falloff?

Dr. FREDRICKSON. I cannot say that there is a recognized reason, Senator Eagleton. Financial. I would say.

Senator EAGLETON. Mostly financial.

Dr. O'DONNELL. From our experience in the last 7 years, of the students that we have supported and involved in research, about 50 percent of them are choosing careers in medicine or the professional fields. So we are increasing the numbers that are going into these fields.

GENERAL CLINICAL RESEARCH CENTERS

Senator EAGLETON. Your testimony says you will support 71 general clinical research centers throughout the Nation.

It also says you will discontinue supporting four.

Dr. O'DONNELL. Yes; under the present budget, we will initiate phaseout support for those four.

Senator EAGLETON. When you say phaseouts for those four, are you the sole or main basis of support for those? And phaseout means they will, in fact, close?

Dr. O'DONNELL. They would close their clinical research activity in terms of the environment that we are supporting; yes, sir.

Senator EAGLETON. Do we specifically know which four will be closed?

Dr. O'DONNELL. We have not yet made our final awards.

Senator EAGLETON. In this instance it would be a final nonaward to those four.

Dr. O'DONNELL. It will be a phaseout award this year, to let them terminate their activities in an orderly manner.

PRIVATE FUNDING OF GCRC'S

Senator EAGLETON. If these centers are important to the teaching hospitals and to the university medical centers in which they are located, why can't the funding be taken over by private organizations? The funds just ain't there?

Dr. O'DONNELL. To a small extent there are some private funds that have continued to support a small amount of clinical research activity in some institutions where there has been a phaseout of our support. These will be very limited activities. And, of course, if sponsored by a pharmaceutical house, it will be in keeping with their mission.

Our centers are general, where investigators from all multidisciplinary interests would be able to carry out clinical studies.

Senator EAGLETON. What's the typical budget? I know this is a general question, but what is the typical operating budget of one of these clinical research centers?

Dr. O'DONNELL. Approximately $850,000.

BUDGETARY DATA

Senator SPECTER. Mr. Chairman, this might be an appropriate time for a question as to your ability to fund generally based on what President Reagan has announced. And I have been provided with the figures which show the modifications on research resources.

My question, Dr. O'Donnell, have you had an opportunity to review President Reagan's figures for 1981, 1982 request?

Dr. O'DONNELL. I have not seen the figures this morning. I assume they are comparable to the rescission request by President Carter, and similar to his 1982 level.

Senator SPECTER. I have a chart which shows, starting with 1980 comparable—on research resources as a 1980 comparable, a figure of 169,228.

And then a figure in 1981 under Reagan lists as 173,942.

And then from the fiscal year 1981, category appropriation, it is 174,126.

And then the Carter fiscal year 1982 request was 192,111.

And the Reagan 1982 request is 191,924.

So, starting with the Reagan 1982 request compared to the Carter 1982 request, there appears to be relatively little difference.

Dr. O'DONNELL. That's right.

Senator SPECTER. Less than $200,000.

Does that please you?

Dr. O'DONNELL. It pleases me that there was not any greater difference; yes. [Laughter.]

Senator SPECTER. Dr. Fredrickson, this might be a point to ask you on figures more broadly.

Have you had an opportunity to review the figures which President Reagan has proposed for the Institute?

Dr. FREDRICKSON. Yes; I have, Senator Specter. We actually received them this morning, but we have been familiar with what might be coming.

Senator SPECTER. What is your general reaction?

Dr. FREDRICKSON. Our general reaction is that we are primarily concerned about the thrust of the impact which was directed toward research training. And as the chairman and I discussed earlier, we really do not know how to assess precisely what impact the withdrawal of institutional allowances will have on institutions with regard to biomedical research training. But that is primarily the thrust.

Senator SPECTER. You may have gone over this before. Is there any standard reduction, as you look over this entire list of categories?

Dr. FREDRICKSON. I think in reviewing the impacts for you very briefly, Mr. Specter, in terms of my review yesterday morning, I would have the following comments:

There is a modest reduction in the ability to fund competing research project grants from about 5,000 as in the Carter budget to some 4,800. The primary differences are in training, however, where we are reducing from approximately 10,500 trainees, to 10,000 trainees in each of the fiscal years 1981 and 1982.

More particularly, however, we find in this proposal the elimination of the payment of indirect costs for training and of institutional support. The latter allowances represent about 22 to 24 percent of the training award amounts to the institutions. They cover primarily faculty salaries, equipment, supplies, and other materials to maintain the curriculum for training, and some fees for the students in the individual fellowship programs.

The indirect costs that we discussed yesterday for research grants are limited to 8 percent in training grants, and have been for many years by an administrative decision of NIH. These, too, will be eliminated.

Senator SPECTER. Dr. Fredrickson, if you start with the total figure for NIH on President Reagan's list, would it be your preference to reallocate that figure of $3,763,789 in a different order of priorities among the various subtotals?

Dr. FREDRICKSON. Being forewarned that we might incur such a reduction, we had opportunity for an intensive consultation at NIH. I think this distribution that was required by the cut is one that more or less is satisfactory——

Senator SPECTER. Came out the way you recommended it?

Dr. FREDRICKSON. Yes; it did, sir. We had definitely an opportunity to attempt to adjust.

Senator SPECTER. You testified yesterday that you had submitted, in response to the Secretary's request, proposed cuts in the 2-percent range. Correct?

Dr. FREDRICKSON. That is correct. That was one of a series.

Senator SPECTER. What were the other items in the series of proposed cuts?

Dr. FREDRICKSON. I think at one time we were concerned that we might go down as low as the 1980 level, which would have been a much more severe cut.

Senator SPECTER. What percentage would that be?

Dr. FREDRICKSON. It would have been about an 11-percent cut by the time we got to 1982.

Senator SPECTER. Would you feel comfortable sharing those figures with this subcommittee?

Dr. FREDRICKSON. I will certainly produce those, sir.

Senator SPECTER. I would like to have them included in the record. I am prompted on that submission, but I think it would be useful to the subcommittee to see what reductions you would have made, had it gone full range or 11 percent, which I take it was the maximum you had been asked to submit if the cuts had been that deep.

Dr. FREDRICKSON. We will be glad to provide you with our impact of what would have been the effect on various items in the distribution from 11 percent on back up, if that will help you.

[The information follows:]

OPTIONS FOR BUDGET REDUCTIONS

As part of the Reagan reduction exercise, the following four options for possible budget reductions were submitted to the Department:

National Institutes of Health 2/2/81

BA/Outlay Reductions
(dollars in millions)

Mechanism	1980	1981 Presently Available	1981 Revised	1981 Difference	1981 Outlay Reduction	1982 Presently Available	1982 Revised	1982 Difference	1982 Outlay Reduction
Research Project Grants	$1,593.1	$1,771.6	$1,662.2	$109.4	$47.5	$1,925.5	$1,640.0	$285.5	$182.1
Research Centers	338.3	341.7	341.7	--	--	372.6	346.5	26.1	11.0
Other Research Gts.	204.1	189.9	189.9	--	--	199.2	184.6	14.6	6.1
Training	176.4	183.8	144.8	39.0	3.9	192.4	145.4	47.0	35.6
Contracts	406.8	354.9	354.9	--	--	357.0	328.5	28.5	12.0
Intramural	377.9	423.1	407.1	16.0	16.0	465.9	449.9	16.0	16.0
Disease Control	66.7	56.5	56.5	--	--	57.6	56.6	1.0	.5
NLM	43.9	45.4	45.0	.4	.4	47.7	46.5	1.2	1.2
Other	221.6	226.7	226.7	--	--	230.8	230.8	--	--
TOTAL	$3,428.8	$3,593.6	$3,428.8	$164.8	$67.8	$3,848.7	$3,428.8	$419.9	$264.5

Assumption I: OMB Proposal - Operating at 1980 level in both 1981 and 1982.

1981 - 2% Outlays, 5% Budget Authority
1982 - 7% Outlays, 11% Budget Authority

Note: Research Project Grants - permit the funding of approximately 3,950 competing research project grants in 1981 and approximately 3,400 in 1982. This compares to a level of 5,944 in 1979, 4,785 in 1980 and a projection of 5,000 in both the 1981 and 1982 Carter budgets. The NIH would propose to place a limitation on indirect cost for research grants in order to fund an additional 200 competing grants in 1982.

Research Training - eliminate indirect costs and 50 percent of institutional allowances and reduce number of trainees to 10,000 in 1981 and 9,500 trainees in 1982. This saves $39 million in 1981 and $47 million in 1982.

2/2/81

National Institutes of Health

BA/Outlay Reductions
(dollars in millions)

Mechanism	1980	1981 Presently Available	1981 Revised	1981 Difference	1981 Outlay Reduction	1982 Presently Available	1982 Revised	1982 Difference	1982 Outlay Reduction
Research Project Grants	$1,593.1	$1,771.6	$1,666.9	$104.7	$45.3	$1,925.5	$1,808.2	$117.3	$108.8
Research Centers	338.3	341.7	338.4	3.3	1.5	372.6	372.6	--	1.8
Other Research Gts.	204.1	189.9	188.5	1.4	.7	199.2	199.2	--	.7
Training	176.4	183.8	144.8	39.0	3.9	192.4	152.4	40.0	34.9
Contracts	406.8	354.9	354.9	--	--	357.0	357.0	--	--
Intramural	377.9	423.1	407.1	16.0	16.0	465.9	465.9	--	--
Disease Control	66.7	56.5	56.5	--	--	57.6	57.6	--	--
NLM	43.9	45.4	45.0	.4	.4	47.7	47.7	--	--
Other	221.6	226.7	226.7	--	--	230.8	230.8	--	--
TOTAL	$3,428.8	$3,593.6	$3,428.8	$164.8	$67.8	$3,848.7	$3,691.4	$157.3	146.2

Assumption II:

1981 - 2% Outlays, 5% Budget Authority
1982 - 4% Outlays, 4% Budget Authority

Note: Research Project Grants - permit the funding of approximately 4,000 competing research project grants in 1981 and approximately 4,870 in 1982. This compares to a level of 5,944 in 1979, 4,785 in 1980 and a projection of 5,000 in both the 1981 and 1982 Carter budgets.

Research Training - eliminate indirect cost and 50 percent of institutional allowances and reduces the number of trainees to 10,000 in 1981 and 1982.

2/2/81

National Institutes of Health

BA/Outlay Reductions
(dollars in millions)

Mechanism	1980	1981 Presently Available	1981 Revised	1981 Difference	1981 Outlay Reduction	1982 Presently Available	1982 Revised	1982 Difference	1982 Outlay Reduction
Research Project Grants	$1,593.1	$1,771.6	$1,717.6	$54.0	$23.3	$1,925.5	$1,850.5	$75.0	$62.2
Research Centers	338.3	341.7	339.2	2.5	1.1	372.6	372.6	--	1.4
Other Research Gts.	204.1	189.9	188.5	1.4	.7	199.2	199.2	--	.7
Training	176.4	183.8	173.9	9.9	1.0	192.4	182.5	9.9	8.8
Contracts	406.8	354.9	354.9	--	--	357.0	357.0	--	--
Intramural	377.9	423.1	415.1	8.0	8.0	465.9	465.9	--	--
Disease Control	66.7	56.5	56.5	--	--	57.6	57.6	--	--
NLM	43.9	45.4	45.4	--	--	47.7	47.7	--	--
Other	221.6	226.7	226.7	--	--	230.8	230.8	--	--
TOTAL	$3,428.8	$3,593.6	$3,517.8	$75.8	$34.1	$3,848.7	$3,763.8	$84.9	$73.1

Assumption III:

1981 - 1% Outlays, 2% Budget Authority
1982 - 2% Outlays, 2% Budget Authority

Note: Research Project Grants - permit the funding of approximately 4,500 research project grants in 1981 and 4,860 in 1982. This compares to a level of 5,944 in 1979, 4,785 in 1980 and a projection of 5,000 in both the 1981 and 1982 Carter budgets.

Research Training - reduce the number of trainees to 10,000 in 1981 and 1982

2/2/81

National Institutes of Health

BA/Outlay Reductions
(dollars in millions)

Mechanism	1980	1981 Presently Available	1981 Revised	1981 Difference	1981 Outlay Reduction	1982 Presently Available	1982 Revised	1982 Difference	1982 Outlay Reduction
Research Project Grants	$1,593.1	$1,771.6	$1,738.6	$33.0	$14.2	$1,925.5	$1,909.3	$16.2	$25.6
Research Centers	338.3	341.7	339.2	2.5	1.1	372.6	372.6	--	1.4
Other Research Gts.	204.1	189.9	188.5	1.4	.7	199.2	199.2	--	.7
Training	176.4	183.8	173.9	9.9	1.0	192.4	182.5	9.9	8.8
Contracts	406.8	354.9	354.9	--	--	357.0	357.0	--	--
Intramural	377.9	423.1	423.1	--	--	465.9	465.9	--	--
Disease Control	66.7	56.5	56.5	--	--	57.6	57.6	--	--
NLM	43.9	45.4	45.4	--	--	47.7	47.7	--	--
Other	221.6	226.7	226.7	--	--	230.8	230.8	--	--
TOTAL	$3,428.8	$3,593.6	$3,546.8	$46.8	$17.0	$3,848.7	$3,822.6	$26.1	$36.5

Assumption IV:

1981 - 1/2% Outlays, 1% Budget Authority
1982 - 1% Outlays, 1% Budget Authority

Note: Research Project Grants - permit the funding of approximately 4,680 in 1981 and 5,100 in 1982. This compares to a level of 5,944 in 1979, 4,785 in 1980 and a projection of 5,000 in both the 1981 and 1982 Carter budgets.

Research Training - reduce the number of trainees to 10,000 in 1981 and 1982.

FAIRNESS OF DECREASE

Senator SPECTER. I have not had an opportunity to review the final percentage net.

Have you calculated it?

Dr. FREDRICKSON. In fiscal year 1981 it is approximately a $126 million decrease from a base of about $3.64 billion, a decrease of 3.5 percent, Senator Specter.

Senator SPECTER. About 4-percent cut overall?

Dr. FREDRICKSON. I believe so, sir.

I will correct that arithmetic for the record.

Senator SPECTER. Recognizing that you have only had a very limited exposure to the overall Reagan approach, what is your feeling as to the fairness of the cut at your Institution compared with the overall cuts the President announced last night?

Dr. FREDRICKSON. Indeed, I am extremely unfamiliar with the range of the cuts. I would say that NIH did not expect to excape the austerity mood, and I am grateful that it was not deeper than this. And I am also grateful that we had, through the intervention of Secretary Schweiker, opportunity to make these allocations and to discuss their impact before the decision was made.

Senator SPECTER. One of the things I think Congress can be very concerned about in view of the President's figures, will turn on fairness overall. As to how the cuts affect everybody.

Obviously you don't know nearly as much about the rest of the budget as you do about your own Institution. But I would be interested if you would take a look overall and give response to this subcommittee on your feel for the fairness of the cuts at NIH compared with the overall cuts as you perceive them.

Dr. FREDRICKSON. I will be very glad to respond, Senator Specter, with this caveat if I may, and that is, NIH subtends a sector of activity, of public support of particular activity. Thus, there really is no other comparable agency with which to make a direct comparison.

I think that one has to view these attempts at austerity, these needful adjustments to the economy, in terms of how much one can afford to reduce or eliminate a particular activity. The reductions will slow down the effort that we maintain to the extent that you see in the budget, but that still will leave us with a strong and capable scientific apparatus.

But, I will respond to your request as best I can. I think it is very difficult to compare the budgets of any organizations, and the changes the President may have recommended, because of the different philosophies regarding the opportunities for picking up support in the private sector, where public support is diminished.

[The information follows:]

THE FAIRNESS OF NATIONAL INSTITUTES OF HEALTH BUDGET CUTS

Due to the lack of complete data on the budget reduction proposals, a detailed comparison of the fairness of the reductions in the National Institutes of Health budget compared with overall budget cuts is not possible at this time. However, the fairness of the cuts can best be judged in general terms in light of the administration's budget-cutting criteria, and its view of the proper role of Government spending. Guidelines for spending reductions, as set forth in the administration's "Program for Economic Recovery," indicate that the administration focuses on particular areas of spending, such as

efforts to "revise entitlements to eliminate unintended benefits" and to "reduce subsidies to middle- and upper-income groups." Because its mission of biomedical research lies outside areas targeted by these guidelines, NIH did not absorb reductions as dramatic as those absorbed by agencies whose programs lie within these guidelines. However, insofar as the administration desired to "impose fiscal restraint on other national interest programs," NIH programs shared in the reductions for this category.

Regarding the appropriateness of Government spending, the administration's goal—again, set forth in its program for economic recovery—was to "shift the Federal budget priorities so that Federal resources are spent for purposes that are truly the responsibility of the Federal Government," and to "restrain Federal involvement in areas that are properly left to State and local governments or to the private sector." The risk and expense involved in biomedical research has traditionally prevented the private sector and the States from making a substantial investment in this area. For example, the cost of ongoing longitudinal studies to determine the incidence of heart disease and stroke in men would be prohibitive to private industry. Because of this, and because of the fundamental importance of biomedical advances to the improvement of the Nation's health, biomedical research is recognized as an appropriate purpose of Government spending.

While fair in directing NIH to contribute to the austerity measures necessary to improve the Nation's economy, the administration's proposals are also fai. to the American people in protecting its vital, unique commitment to the support of biomedical research.

BIOMEDICAL RESEARCH SUPPORT PROGRAM

Senator SPECTER. I understand that limitation.

The problem that Congress will face, is that with the necessarily limited dollars we have, we are going to have to make an assessment as to what is overall fair. I, for one, would be interested in your assessment, how this affects your organization. I realize it is not an easy question. You may have, or some who would respond to this question I propose to ask, generally might have some reticence to disagree with the President's assessment.

But, to the extent that you can give us your own judgment, I would be interested to know if it is fair overall as you view it, subject to all the limitations you have described.

Dr. FREDRICKSON. I would be glad to attempt to do that, Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

Senator EAGLETON. The biomedical research support program, I am told, has operated for 19 years, and has received an estimated $800 million in appropriations over that 19-year period.

Yet, we are surprised that your program objectives are so general and amorphous, that is is sometimes difficult, if not impossible to measure the extent to which this money has met such very general, amorphous goals.

Can you comment on that? Is that a fair, if you want to call it, charge, commentary?

Dr. O'DONNELL. To some extent it is, Senator Eagleton.

This program is unique, the National Institutes of Health and any of the science agencies, in that the institutions that are recipients do not have to tell us beforehand what precisely they will be using these funds for. It is a flexible award in which they are able to respond to their own needs, which are generated by a research, enterprising institution.

If an institution has a young investigator who is new to that institution and he or she wants to try some pilot research, instead of submit-

ting a formal proposal to NIH to request funds, the institution can provide him, through the BRS program, with those resources to help him get some modest equipment, to get his laboratory started, and to carry out the pilot studies.

It can help a seasoned investigator who has a unique idea to try out. If he had to wait for a year to be funded after submitting a formal application, the opportunity might pass by.

So that in that respect we can't evaluate the program in terms of what they said they would do beforehand, except to say that they use the money in response to their own determined needs. We feel that enabling them to make those local decisions is a benefit of the program.

Dr. FREDRICKSON. Mr. Chairman, may I add something?

Senator EAGLETON. Yes, sir.

Dr. FREDRICKSON. In extension of those comments, I think yesterday as we were trying to lay out the overview of NIH and its aggregate allocations, I did emphasize this matter of communal resources for which this Division is responsible. You have already alluded to them.

I am very grateful that, in this budget we are looking at this morning, there was basically the possibility of sustaining the capacity to cope with inflation by this Division. Its purchasing power has been eroding slowly for almost two decades. I think that what is does is absolutely good for the maintenance of the whole system.

The Division provides collective resources, as you, yourself, inquired about, for clinical research. It does things that the categorical Institutes cannot do and will not do for the totality of the system.

It is vital, and I am pleased that we were able to at least sustain pretty much the capacity to meet inflation in the 1982 budget for these Institutes. Its role is really more important than I think we are sometimes capable of describing.

Senator EAGLETON. It is absolutely the case.

At NIH, Dr. Fredrickson, you have some glamour institutes; the Cancer Institute, I guess, being the chief one. And that is understandable. The heavy focus of public concern, public attention on cancer. I guess no family has ever been totally immune from it—maybe the neighbors across the street, or a fellow worker, or a friend of the family, et cetera.

I am not denigrating the National Cancer Institute. But, although so much of the attention is focused on certain institutes, we must not lose sight of the fact that we have got a whole system in this country of medical research.

You could double the funding of the Cancer Institute and thereby say we really have declared a full, unabated war on cancer. But, if you let the rest of the system atrophy, you would ultimately lose the war.

So, although Research Resources and General Medical Sciences, do not have a place in the public relations as do other components of NIH, if they wither on the vine, then the whole system including the more publicized Institutes, would be traveling down a dreadful road.

Dr. FREDRICKSON. I agree with your assessment, Mr. Chairman. You are correct.

DYNAMIC SPATIAL RECONSTRUCTOR

Senator EAGLETON. Let me ask about this:

I think every once in a while staff gives you questions that tell you how smart the staff is. I never heard of this, so I think maybe I ought to know something about it.

Tell me about the dynamic spatial reconstructor that has recently been developed in the Mayo Clinic with funds from your Division? Never heard of it. I ought to know a little about it, I guess.

Dr. O'DONNELL. That's a unique three-dimensional X-ray scanner developed as a research tool to measure internal anatomy and physiological function of the heart, lung, and circulatory system. It is an activity which we are funding at the Mayo Clinic. What it is doing is allowing us, for example, to view the human heart in three dimensions, so that the heart, lungs, and the circulatory process can be examined more closely and provide new insights into both normal and disease processes of these organs.

It is really a whole new attempt at visualizing organs, so hopefully it will provide a better diagnostic view.

Senator EAGLETON. How much did you put into this endeavor, in rough figures?

Dr. O'DONNELL. I believe that resource has been funded at about $3.3 million, since it was initiated a few years back.

Senator EAGLETON. It continues to show promise?

Dr. O'DONNELL. Yes, sir.

Senator EAGLETON. We have no further questions, Dr. O'Donnell.

Senator Burdick, do you wish to ask some?

Senator BURDICK. Thank you, no.

Senator EAGLETON. As true of all witnesses, your entire opening statement will appear in the record in full, and we will submit other questions in due time.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

REORGANIZATION OF DRR

Senator Specter: What were the conclusions of the most recent study on possible reorganization of the Division of Research Resources?

Answer: In November 1973, the NIH Office of Management Policy completed an examination of organizational options for the programs of the Division of Research Resources (DRR).

The options included:

- A stronger, more independent DRR
- Merger of DRR and the National Institute of General Medical Sciences
- Alternative locations within NIH for individual DRR program components

The report did not recommend one of the options but instead established a basis for further inquiry.

Subsequently, the Director, NIH asked the DRR to arrange for an evaluation of its programs in relation to emerging needs and opportunities for research resources. This evaluation was carried out during 1975 and 1976 by a group of non-Government scientists and research administrators coordinated by Bolt Beranek and Newman, Inc. The study reaffirmed the importance of the DRR programs and along with recommending a variety of actions to expand and strengthen research resources activities, endorsed the then current organizational structure.

Having the benefit of these two studies, the Director, NIH elected in 1976 to make no organizational changes involving DRR.

Senator Specter: Since another study on possible reorganization of the Division is under active consideration, what are the circumstances that warrant still another effort in that direction?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Senator Specter: In the event of a reorganization, can there be assurance regarding continued support for General Clinical Research Centers, Biotechnology Resources, and Biomedical Research Support Programs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Senator Specter: In view of the Division's demonstrable success in administering these large and complex resource programs, what provision could be made to preserve that expertise?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Senator Specter: If the Division's activities were redistributed to other NIH organizations, is there any assurance that the Minority Biomedical Support Program would be continued?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

PRIMATE BREEDING PROGRAM

Question: The National Primate Plan was established to deal with a shortage of foreignbred nonhuman primates, such as the rhesus monkey from India. What is the status of your effort to breed primates at various centers in the U.S.?

Answer: The role of DRR in the National Primate Plan is to provide supplies of scarce primate animals for the NIH extramural scientific community. In the face of severe shortages of rhesus monkeys, other more available species, such as cynomolgus monkeys, are used as substitute models whenever possible. With the funding available for this effort, rhesus monkey breeding contract programs are currently meeting their initially established goals, with annual production of 1,000 to 1,100 offspring. However, high priority requirements for rhesus monkeys in the polio safety testing programs, as well as necessary replacements of female breeders in the colonies, leaves only about 20% of the actual production available for the NIH extramural community. We estimate that approximately 1,000 rhesus monkeys are needed by NIH extramural scientists in 1981.

Question: How much will this effort cost and how has it been affected by inflation?

Answer: Current DRR-funded rhesus breeding efforts cost approximately $1.2 million per year--slightly over $1,000 per animal produced. Costs for this effort have increased significantly due to inflation. For example, costs of food and other supplies rose approximately 20% in 1980, a rate higher than the national cost-of-living index.

COST EFFICIENCY OF PRIMATE BREEDING IN THE PRIVATE SECTOR

Question: Wouldn't it be cheaper to let private enterprise take care of this problem?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Is this possible?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Could you save money?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

FUNDING OF GENERAL CLINICAL RESEARCH CENTERS BY PRIVATE ORGANIZATIONS

Question: If these Centers are important to the teaching hospitals and University Medical Centers in which they are located, why can't the funding be taken over by such private organizations?

Answer: The General Clinical Research Centers are important for research and are critical to maintenance of a clinical research effort at an institution. The Centers are more important to NIH, and the national clinical research effort than to the institutions which have primary responsibilities for teaching and patient care. There is no reason in principle why private funds couldn't be used; but in practice it is rarely done because of the burden of generating this outlay for a non-revenue producing activity. The General Clinical Research Centers purpose is to economize and to increase effectiveness of NIH categorical research grant expenditures.

Question: To what extent have you looked into this possibility or into a cost-sharing approach?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What can be done to reduce federal costs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

CARTER RESCISSION

Question: The Carter Budget proposed a rescission of $10.5 million in the Division for fiscal year 1981. If this rescission was allowed to stand, what would its impact be on your work?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

IMPACT OF STABILIZATION ON DRR

Question: You say that stabilization of research grants among the other institutes will put "increased demand" on DRR supported resources in 1982. What impact would the proposed rescission have on your ability to meet this "increased demand"?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

DYNAMIC SPATIAL RECONSTRUCTOR

Question: Please tell us about the dynamic spatial reconstructor that has recently been developed at the Mayo Clinic with funds from your Institute.

Answer: The Dynamic Spatial Reconstructor (DSR) is a dynamic 3-dimensional X-ray scanner which is unique. The DSR was developed as a research tool to make measurements impossible to obtain with commercially available instruments. These measurements are of internal anatomy and physiological function of the heart, lung, and circulation. It is the hope of the Mayo investigators that these heretofore unavailable measurements will provide new insights into both normal and disease processes of these organs. The system was first used in the fall of 1979. Since that time, it has continued to undergo necessary engineering developments (e.g., computer interfacing, phantom studies to evaluate performance and experimental animal studies). An integral part of the research proposal involves scanning patients because many disease processes in man are highly specific to man and cannot be studied in animals. With the completion of the above studies and radiation dosage measurements, the Mayo team will be ready to scan the first of a selected number of human subjects.

COST OF DSR

Question: What has been the total cost of this machine thus far?

Answer: The total system cost is about $3.3 million, $3.0 million is from NHLBI and $0.3 million from DRR. The DRR grant at the Mayo Clinic is essentially in support of computer-oriented research, much of which has provided technological underpinnings which led to the development and design of the DSR.

Question: What will the final cost be?

Answer: The DSR is presently operational and the only ongoing cost is that of maintenance. It is, however, not up to its full design level. If experimental data indicate the need to achieve this level, an additional 14 X-ray tubes and TV cameras will be required at a cost of approximately $700,000. Thus, the final cost will be $4 million.

CLINICAL APPLICATIONS OF DSR

Question: When it is ready for clinical application, what impact will the development of this X-ray device have on the rising costs of medicine?

Answer: The DSR is a research tool not intended for patient care or to serve as a prototype for clinical diagnostic systems. It is the intent of the Mayo investigators to limit human subject studies to research protocols not possible with animal subjects. Therefore, the DSR is not expected to impact the cost of clinical medicine.

Question: X-ray technology is moving forward with astonishing speed and complexity. How do these advances relate to one another, and can you realistically expect such devices to pay for themselves in terms of medical as well as societal benefits?

Answer: X-ray technology as a method of medical diagnostic and research imaging has progressed rapidly in recent years. CAT scanners have become an essential tool for patient diagnosis. The computer techniques developed for CAT imaging are now being modified for use with ultrasonic imaging techniques. PETT scanners can be used to monitor metabolic processes and NMR imaging (zeugmatography) detects proton densities. Industry has very active programs for development of NMR imaging systems and feels that this technique has great potential as a research and diagnosis tool. These techniques each measure different parameters and from a research point of view are different but complementary.

The DRR is not involved in support of direct patient care and thus cannot realistically project the costs or benefits of these various imaging techniques to patients or physicians. From a research point of view, each of these technologies will provide independent information on human systems and diseases, hopefully leading to better treatment with minimum radiation risk.

EQUIPMENT

Question: What role does the Division play in the development or procurement of computer hardware and software for either the NIH Institutes or outside requests for such equipment?

Answer: The Biotechnology Research Program of the DRR supports regional and national resources developing complex methods, specialized expertise and state-of-the-art hardware for applications in biomedical research. The Program has had a long history of supporting innovative solutions for biomedical problems. The following task dedicated systems were developed within the Biotechnology Resources Program:

System Acronym	To Serve	Developed By
LINC (Precursor to the Mini-computer revolution)	Neurophysiology Experiments	MIT and Washington U.
Programmed Console	Radiation Therapy Treatment Planning	Washington U. (now commercial)
PROPHET	Medicinal Chemistry and Pharmacology	BRP
MMS-X	X-ray Crystallography	Washington U .
CLINFO	Clinical Investigation	BRP (now commercial)
LMM	Neurophysiology	U. of Washington

We expect to continue the marriage of state-of-the-art computer capabilities to the needs of researchers supported by the NIH. The experts in our Biotechnology Resources are uniquely equipped to arrange this marriage by defining the unmet not yet clearly seen needs and then prepare solutions from ever-changing hardware and software. Our grantees are now examining needs for task dedicated systems which are expert in determining the structure of biologically active compounds, in consulting for glaucoma, rheumatology and internal medicine and in methods of medical decision analysis. Opportunities for commercial diffusion will be greatly enhanced by the cost reductions afforded by the very large scale integrated (VLSI) circuit technology. Two of our experts are working on a new set of design principles that can reduce the design problem to five man months from the fifty man months presently needed to produce a successful VLSI device. This new expertise will greatly increase the program's potential to serve the scientists working on health problems.

Question: What, if anything, does DRR have to do with the PETT (Positron Emission Transverse Tomography) program now under development at the National Institute of Neurological and Communicative Disorders and Stroke?

Answer: The only activity supported by the DRR involving PETT, Positron Emission Transverse Tomography, is at our resource at Washington University in St. Louis. One role of this resource is to continue to explore new research capabilities in collaboration with NINCDS grant for PETT work at this institution. The latest work is to develop and design a PETT time-of-flight capability. This new capability will actually determine where on a line containing the positron emission the point of emission occurs. The ability to do this will allow reconstruction of dynamic images, much higher image resolution of positron processes in regions of interest, decrease radiation doses to patients, and provide shorter scan durations.

DETERIORATION OF EQUIPMENT AND FACILITIES

Question: What success have you had in determining the seriousness of the deterioration of equipment and facilities at colleges and universities?

Answer: This is a very difficult and complex question which has resulted in several major studies in the past several years. These studies and surveys continue to identify equipment that has worn out and not been replaced, newly developed equipment that is not being provided to investigators, and new technology in engineering, physical sciences, and mathematics that need to be adapted and applied to biomedical research. These are the three ways in which deterioration of research equipment has become serious in institutions that conduct biomedical research.

We have no way of determining just how serious the deterioration problem is, but from grant applications, scientific papers, discussions with principal investigators, observations at project site visits, and the many requests we receive from colleges and universities for facilities and equipment support, it is apparent that the problem is substantial, and growing as more and more large shared equipment items continue to wear out or become obsolete due to new technology.

INCREASED COSTS OF MEDICAL EQUIPMENT AND DEVICES

Question: Has the cost of medical equipment and devices increased at a disproportionate rate compared to other elements in your budget?

Answer: Compared to other elements of our budget, equipment costs have not increased disproportionately. In fact, personnel costs are taking a larger part of the budget then used to be true, probably the result of differential growth rates in research personnel costs generally as compared to the DRR budget. The cost of medical equipment for research (capital costs, operating, and maintenance costs) has increased partly because of inflation, but largely because of advances in its complexity and sophistication. This increased cost is more than offset by the dramatic increases in the capability of the equipment. Advances in capability result in reduced costs because of savings in time required to complete a research task, and in greater productivity and quality of results because of increased precision and achievements that otherwise would not be possible.

OBJECTIVES OF THE BRSG PROGRAM

Question: The Biomedical Research Support Grants Program, we are told, has operated for 19 years and received an estimated $800 million in appropriations over that period. Yet we are advised that your program objectives are so general you cannot measure the extent to which they are being met. What is your comment on this?

Answer: We are concerned that recent opinions written on the subject seem to imply that because the Biomedical Research Support Grant (BRSG) Program has broad objectives which do not lend themselves easily to precise measurement, NIH should make adjustments to assure the objectives be changed or redefined to make them measurable and quantifiable. Specific measurable and time bound objectives are not present in the BRSG Program in keeping with the basic intent in order to help institutional programs be adaptable, flexible and able to respond to a wide variety of requirements and demands in the biomedical research community which occur with the passage of time.

Question: Please state the official objectives of the Program.

Answer: The objectives of the Program are to provide funds on a continuing basis to eligible institutions heavily engaged in health-related research to strengthen their programs by allowing flexibility available to the institutions to meet emerging opportunities in research, to explore new and unorthodox ideas, and to use these research funds in ways and purposes which they (the institutions), in their judgement, feel would contribute effectively to the furtherance of their research program.

EVALUATION OF THE BRSG PROGRAM

Question: Have you established a firm date for making an objective assessment of the program? If not, why not?

Answer: As yet, we have not established a firm date for making an objective assessment of the program. However, we intend to continue our efforts to restate the objectives of the Biomedical Research Support Grant Program as more measurable objectives by June 30, 1981. Included in this time frame are meetings of the General Research Support Review Committee and the National Advisory Research Resources Council, both of which will consider this problem and provide staff with advice on restating these objectives. However, advisors and staff may conclude that the objectives for this program are best left alone; that the program's effectiveness would be constrained by more measurable goals. Then, by September 30, 1981, we will have either arrived at a strategy by which to conduct the evaluation against the newly stated objectives, or with the assistance of our advisers and NIH evaluation staff, arrived at the conclusion that existing evaluation methodologies cannot be used to evaluate this program at this time.

Question: How long will it take to complete a program evaluation effort whose results can be used to guide future program funding levels?

Answer: As noted above, we intend to have completed an evaluation of the program and restated the objectives of the Biomedical Research Support Grant Program in as measurable terms as possible by June 30 of this year; however, it is important to note that, during the 19 years of the program's existence, specific measurable and time-bound objectives have not been present. In keeping with the basic intent to help institutional programs to be adaptable, flexible, and able to have the ability of responding to a wide variety of requirements and demands in the biomedical research community which occur with the passage of time, studies by the National Research Council of the National Academy of Sciences in 1965, by two nonfederal consultants in 1969, and by the Research Resources Evaluation Panel in 1976 have all concluded that this program is exceptionally important to research institutions in this country, specifically because of its flexible nature and broad objectives. In summary, there is significant disagreement among knowledgeable staff and advisors about whether the development of specific and measurable program objectives can enhance or might seriously damage the Biomedical Research Support Program.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

REORGANIZATION OF DRR

Senator Specter: Since another study on possible reorganization of the Division is under active consideration, what are the circumstances that warrant still another effort in that direction?

Answer: There is always a need to be sure that Federal programs are managed in the most effective and cost efficient manner possible. In the case of the Division of Research Resources' programs, we have an organization which is the focus for noncategorical programs in support of NIH's extramural research effort. Since most of NIH's extramural programs are categorical in nature, it is appropriate for the NIH Director to

consider again whether such a noncategorical focus is the best way to organize these programs within the NIH.

Senator Specter: In the event of a reorganization, can there be assurance regarding continued support for General Clinical Research Centers, Biotechnology Resources, and Biomedical Research Support Programs?

Answer: I am confident that the primary concern of the Director, NIH, in consideration of any options with respect to reorganization of DRR programs would be that these national research resource programs continue to be available to the biomedical research community in support of the NIH research effort.

Senator Specter: In view of the Division's demonstrable success in administering these large and complex resource programs, what provision could be made to preserve that expertise?

Answer: If another organizational focus is decided upon for the DRR programs, I am certain that the Director would wish to have the staff expertise continue to remain associated with those programs.

Senator Specter: If the Division's activities were redistributed to other NIH organizations, is there any assurance that the Minority Biomedical Support Program would be continued?

Answer: The Minority Biomedical Support Program is NIH's major extramural activity concerned with improving the biomedical research capability of minority institutions and encouraging more minority students and faculty members to be involved in health-related research. The Program will continue to receive high priority.

MAINTAINING NEW AND COMPETING GRANTS

Question: How much funding will you need in fiscal years 1981 and 1982 to maintain your share of the NIH goal of 5,000 new and competing research grants?

Answer: The revised budget request, proposed by President Reagan provides for the funding of approximately 4,900 new and competing research project grants for $571,621,000. The Division of Research Resources does not plan to fund any research project grants in 1981 or 1982. All of DRR's extramural grant support goes into the research centers and the other research mechanisms.

Question: How is inflation impacting--or how will it impact--on this goal? What inflator are you using?

Answer: The Division of Research Resources does not support any research project grants, and thus, has no impact on the goal of stabilization.

Question: To what "Payline" will you fund new and competing grants in fiscal 1981--and if you can estimate it--in FY 1982?

Answer: The Division of Research Resources does not support any research project grants and thus, our funding decisions are not based on research project grant paylines.

Question: What percentage of grants will you fund in both years?

Answer: The Division of Research Resources does not fund any research project grants.

WHERE TO CUT

Question: If faced with a major budget cutback, what are your priorities? Where could cuts be made without impairing essential research?

Answer: In making reductions from the budget submitted to you in January we have attempted to develop a budget which maintains a viable research program for FY 1982 and strikes a balance among research grants, in-house activities and training. While these reductions will not impair essential research, further cuts may alter this balance as well as our research capability.

Question: How much can be saved through more efficient management, less official travel and fewer consultant contracts?

Answer: In 1981 cuts were made in travel, consultant services, procurement contracts and personnel compensation because of the hiring freeze. Further reductions in consultant services were made in 1982. Additional cuts in these areas in FY 1982 could not be absorbed without affecting essential research activities.

Question: Please provide for the record the effects of various levels of funding reduction on your major activities.

Answer: The budget justification recently submitted to the Congress has attempted to depict the effects of reductions made from the budget proposals submitted in January. These justifications clearly show the levels of funding reductions by budget mechanism and major disease category.

COST EFFICIENCY OF PRIMATE BREEDING IN THE PRIVATE SECTOR

Question: Wouldn't it be cheaper to let private enterprise take care of this problem?

Answer: Past experience has shown that, in general, private enterprise has not been willing to bear the rather significant costs associated with the initial establishment of primate breeding colonies without cost-sharing or supplemental funding arrangements from other sources (e.g., federal, pharmaceutical industry). Based on available information, costs of primate breeding in our contracts are comparable to those of private enterprise.

Question: Is this possible? Could you save money?

Answer: Although no monetary savings would be anticipated, we believe it to be a desirable goal for private enterprise to engage in routine primate breeding production for the biomedical community. An exception would be for the highly specialized research needs of the DRR-supported Regional Primate Research Centers, where breeding on location at each Center will continue to be necessary.

FUNDING OF GENERAL CLINICAL RESEARCH CENTERS
BY PRIVATE ORGANIZATIONS

Question: To what extent have you looked into this possibility or into a cost-sharing approach? What can be done to reduce federal costs?

Answer: During the past 10 years several steps have been taken to reduce the costs of operating these Centers. These include recovery of nearly $12 million per year from third party insurance carriers for the care of sick patients on the Center and conversion of inpatient studies to less expensive outpatient studies wherever feasible. Third party insurance carriers have vigorously resisted paying research costs on patients who do not require hospitalization for their disease. In our experience, medical schools and hospitals have been unable to assume the high costs of maintaining a quality clinical research effort once a Center is terminated.

CARTER RESCISSION

Question: The Carter Budget proposed a rescission of $10.5 million in the Division for fiscal year 1981. If this rescission was allowed to stand, what would its impact be on your work?

Answer: The administration is committed to Federal support of biomedical research activities, but as a part of a general effort to achieve economies and reduce lower priority activities, the Carter administration proposed a rescission of $10,561,000. Within overall funding constraints, priority will be given to stabilizing support for research resources necessary to provide support to biomedical research investigators. This proposed rescission will involve the elimination of 13 ongoing renewal grant awards and 7 renewal research and development contracts. 4 of the existing 75 General Clinical Research Centers will be phased out under this rescission, 3 Laboratory Animal Sciences grants will terminate, and 6 of the 80 existing Minority Biomedical Support grants will not be funded. Also, there will be a $1,694,000 reduction in the funds available for the Biomedical Research Support Program formula for distribution to eligible institutions. In addition, 4 proposed new Minority Biomedical Support grants wil not be funded, and 10 new Biotechnology Resource grants that were proposed as part of the Office of Science and Technology Policy initiative will go unfunded.

The Reagan administration has proposed a rescission of $10.7 million for the Division of Research Resources in 1981. In addition to the reductions indicated above for the Carter rescission, the Reagan rescission proposes the elimination of $184,000 for institutional allowances and for indirect cost payments to institutions receiving National Research Service

Awards. The reason for eliminating these payments is that no similar costs are levied upon non-federally supported students.

IMPACT OF STABILIZATION ON DRR

Question: You say that stabilization of Research Grants among the other Institutes will put "increased demand" on DRR supported resources in 1982. What impact would the proposed rescission have on your ability to meet this "increased demand"?

Answer: The proposed Reagan rescission in 1981 will reduce NIH funding levels by $126 million. NIH will be able to support 4,797 new and competing research project grants at the rescission level. Many of the investigators on these awards will need access to specialized research resources to begin their research and will create an increased demand on DRR to provide these resources. The Reagan rescission proposal for DRR of $10,745,000 will have the following impact on our ability to meet this increased demand:

In the Clinical Research Program four centers will receive phaseout budgets. Throughout all the Centers, a total of 131 positions will be abolished, of which 93 are nursing positions. There will be no new CLINFO's established in 1981, 5 new CLINFO's had been proposed in 1981, but none will be funded under the rescission. There will be no increase in x-ray work or laboratory tests. The number of funded research beds will decrease from 604 in 1980 to 593 in 1981. The number of "A" research patient days (those which are normal research patients and from which the Centers receive no third party health insurance reimbursements) will decrease by 19,993 days in 1981 from 1980. The total research patient days (Type "A" & "B") supported in 1981 will be 164,000; a reduction of 11,000 patient days from the 175,000 patient days that could have been funded at the Continuing Resolution level.

In the Biotechnology Research Program $3.9 million of the $5.0 million Office of Science Technology Policy initiative to expand efforts to provide additional regional instrumentation facilities for biomedical and behavioral scientists will not be started. $3.0 million of the OSTP initiative that will not be started will be in the area of Biological Structure and Function. Resources that will not be funded are in the areas of Nuclear Magnetic Resonance, Laser technology, and Synchroton radiation. The other $0.9 million of the OSTP initiative that will not be started is in the area of state-of-the-art computer resources which assist researchers in the analysis and interpretation of laboratory and clinical data.

In the Laboratory Animal Sciences and Primate Research Program DRR will support 3 less laboratory animal sciences resource grants consisting of 1 animal model grant, 1 institutional animal resource improvement project, and 1 diagnostic laboratory. Also, 4 primate breeding contracts and 1 animal model contract will be terminated as a result of these reductions.

In the Biomedical Research Support Program the percentage of BRS formula awards to total NIH Research grants will go down from 2.0% to 1.9%. The average value of a BRSG award will be reduced 3%. The average number of subprojects funded at each institution will be reduced by one, from 17 in 1980 to 16 in 1981.

In the Minority Biomedical Support Program four new awards that had been planned in 1981 will not be funded. Six renewal awards will not be funded at the larger predominantly majority institutions. Approximately 64 approved projects will go unfunded. Approximately 50 minority faculty, 80 undergraduate and 30 graduate students will have their support terminated. The MBS funding problem will be compounded because reimbursable support of the MBS program by NIH categorical institutes will be limited. We expect a 20% reduction in support from other BID's in 1981. This will put further demands on DRR to pick up this other support.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF DR. CLAUDE J. M. LENFANT, ACTING DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. VIDA H. BEAVEN, SPECIAL ASSISTANT TO THE DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH

ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator EAGLETON. Our next witness will be Dr. Claude Lenfant, Acting Director of the John E. Fogarty International Center for Advanced Study in the Health Sciences.

The Fogarty Center provides advanced studies on international aspects of biomedical research, and supports science exchanges in the United States and other countries under various bilateral agreements.

Dr. Lenfant, we welcome you.

Dr. LENFANT. Thank you, Mr. Chairman.

With your permission, we would like to submit the statement for the record, and I would like to make some additional brief comments.

[The statement follows:]

Statement of Dr. Claude J. Lenfant

As the recently designated Director of the John E. Fogarty International Center, I am grateful for this first opportunity to appear before you to report what has been achieved since the Center's last report. You heard last year about an evaluative report prepared in 1979, at the request of Dr. Fredrickson, by staff members from various agencies within the Department. This evaluation recognized the long, creditable contributions of the FIC to international cooperation in the health sciences, a role envisioned in 1968, when the Center was created as a dynamic memorial to Congressman John E. Fogarty. Over the years, the FIC program has evolved in response to advances in health-related research in this country and abroad, and to increasing awareness of problems of world health. Further changes are recommended in the evaluative report and some have already been implemented. Other changes will involve development of new approaches that are dictated by the present international scene or by reexamination of the impact of current programs or procedures. Therefore, of paramount importance is obtaining advice from scientists with expertise in internationl health research as recommended in the evaluative report. Such advice, similar to that available to other NIH units, is essential to the FIC planning effort.

The following sections of this Statement highlight changes made since the last report to you.

International Issues Study-Program

Among recommendations of the evaluative report that receives special attention, is the development of an "International Issues Study-Program" within the FIC. There is clearly a need for the FIC to work with experts knowledgeable about international aspects of health-related research in order to conceptualize FIC programs addressed to problems of world health. In developing such a study-program, the FIC will examine how experts at the NIH and in the scientific community can contribute to identifying and having an impact on biomedical and behavioral research and other academic pursuits here and abroad. The International Issues Study-Program will develop plans to exploit opportunities for cooperation between researchers in this and other countries, especially in developing countries where diseases once considered local are now being found in this and other countries. Thus, as the United States benefits from experiences in other countries, it will bring new knowledge and research approaches to studies of diseases in this country. A planning conference on "Eradication of Infectious Diseases," which was held at the NIH in 1980, is an example of how resources available to the FIC can be effectively mobilized to address international health issues.

Scholars-in-Residence Program

The Fogarty Scholars-in-Residence Program, in existence since 1968, has effectively served to attract outstanding scientists to the NIH, scientists who have not only benefitted from their tenure in this program, but have contributed to activities of the categorical institutes through participation in conferences, grand rounds, lectures and through interaction with NIH scientists and physicians. The 1979 evaluative report on the FIC included recommendations for

procedures that would make this already successful program even more valuable by broadening the range of biomedical, behavioral and social scientists who participated, and by encouraging increased interaction with the NIH community. Some of these recommendations have already been implemented. It is now envisaged that the Scholars-in-Residence Program will have another important role; namely, as a resource for information and advice about international issues to be addressed in the International Issues Study-Program.

Scientific Conferences

As in the past, the FIC manages and contributes to support of international research conferences initiated by its staff or by scholars in the Fogarty Scholars-in-Residence Program. It will also continue to entertain requests for financial support for the international aspects of conferences initiated by NIH bureaus, institutes or divisions. There have, however, been changes in the FIC role in supporting international aspects of conferences initiated extramurally. These changes were recommended in the FIC evaluative report to ensure that all extramural requests for international conferences were subject to customary peer review. All such requests must now be submitted to the Division of Research Grants as conference grant applications. The FIC is also in the process of more explicitly defining the limits of its role in such extramural conferences.

Fellowship Programs

One facet of the FIC fellowship program, the International Research Fellowship Program, enables foreign postdoctoral scientists to pursue a research program in a laboratory in this country. An evaluation of this program completed in January 1980 notes that "in almost all cases, United States and foreign critics continue to view the program as prestigious, mutually beneficial and a strong force for nurturing good will and international scientific collaboration." As reported to you last year, of about 1,800 scientists who have participated in the program since 1958, 90 percent returned to their home country, and a follow-up study indicates that 75 percent continue to be active in biomedical fields that are also of interest and concern to scientists in the United States. The other facet of the FIC fellowship program is the Senior International Fellowship Program, which enables mid-career biomedical scientists at universities and medical schools in this country to engage in study and research at foreign institutions. This is also an arrangement that is of benefit both here and abroad as it encourages international cooperation among biomedical and behavioral researchers with mutual or complementary interests.

To give greater cohesion to the two facets of its fellowship program the FIC recently modified its procedures by bringing them under the purview of a single program manager, and by requiring review of applications by the Division of Research Grants rather than by ad hoc committees appointed by the FIC. Another change, recommended in the FIC evaluative report of 1979, is now being implemented to ensure follow-up data on former fellows by means of a computer-based information system and periodic site visits to host institutions and former fellows.

The International Research Fellowship Program has enabled biomedical scientists and academic institutions in the United States to estabish research collaborations with the biomedical research community abroad. Academic institutions in 38 states have served as hosts to foreign biomedical researchers, and many United States scientists, including 11 Nobel Prize winners, have participated as preceptors for foreign fellows under this Program.

Finally, to further extend the already great impact of this program it is being expanded on a selective basis, within the limits of available resources, by encouraging additional countries to establish nominating committees to select postdoctoral candidates for the International Research Fellowship Program.

International Cooperation and Coordination

Within the NIH, the FIC is the focus for international activities, having an integrating role in bringing together NIH and other Federal agencies in bilateral cooperative agreements between the United States and other countries, including China, Egypt, France, the Federal Republic of Germany, Hungary, India, Israel, Italy, Japan, Poland, Romania, the Soviet Union, Spain and Yugoslavia. The FIC also is the coordinating focus for collaboration between NIH and such international organizations as the World Health Organization, Pan American Health Organization, the European Commission of the European Economic Community and the European Medical Research Councils. The FIC, on the recommendation of the 1979 evaluative report, has strengthened this facet of its program through staff additions with special responsibility for international cooperative activities.

Additional activities envisaged include the development of new cooperative relationships in the health sciences with several African nations, as part of a general interest in relating increasingly to developing countries. A major program involving cooperation of NIH and other PHS agencies with Nigeria is moving from the present planning phase to an operational program. The proposed joint collaborative program with the People's Republic of China may include an exchange program for individual health scientists and research fellowships. In discharging its role, the FIC is fostering closer interaction with the NIH institutes through the international representatives. The FIC is also extending its informational resources, including the development of a data file and publication on Chinese scientists and institutions, a comprehensive survey of biomedical research support available in other developed countries, and special analyses aimed at facilitating international cooperation and facilitating scientific collaboration.

Gorgas Memorial Laboratory

The FIC serves as the administrative channel by which funds appropriated by the Congress are made available to the Gorgas Memorial Institute in Washington for the maintenance and operation of the Gorgas Memorial Laboratory (GML) in Panama. This laboratory, established in 1929, has conducted studies of tropical diseases that have contributed greatly to medical knowledge and in doing so have served the interests of both the United States and Panama. The GML programs have provided information about the transmission and treatment of tropical diseases to which a sizeable segment of the

U.S. Army is exposed. Many of these diseases which are reaching this country to an ever increasing extent as a result of expanding air travel by U.S. citizens and foreign tourists and businessmen. The GML has also provided training programs in tropical diseases for United States scientists and technical staff, programs that have been of great value in increasing our ability to recognize and treat these disorders.

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 1981, 900 scientists from 56 countries are expected to participate 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.

I shall be pleased to reply to any questions of the Committee.

LENFANT, Dr. Claude J.M.
Acting Director, Fogarty International
Center, NIH

October 12, 1928. Paris, France.

Education. B.S., University of Rennes, France, 1948. M.D., University of Paris, France, 1956. Postdoctoral Fellow, University of Buffalo, 1957-1958. Postdoctoral Fellow, Columbia University, 1958.

Professional History. 1954, Research Assistant, Centre Marie Lannelongue, Paris, France. 1955-1956, Research Associate, Centre Marie Lannelongue. 1956-1957, Director, Laboratory of Experimental Surgery, Centre Marie Lannelongue. 1959-1960, Assistant Professor of Physiology, Univ. of Lille, France. 1961-1965, Clinical Instructor of Medicine and Physiology and Biophysics, Univ. of Washington. 1961-1968, Associate Director, Institute of Respiratory Physiology, and Staff Physician, Firland Sanitorium, Seattle. 1968-1971, Associate Professor of Medicine and Physiology and Biophysics, Univ. of Washington. 1969-1971, Consultant, University Hospital, Seattle. 1970-1972, Acting Associate Director, Collaborative R&D Program, National Heart, Lung, and Blood Institute (NHLBI), NIH. 1970-1972, Associate Director for Lung Programs, (NHLBI), NIH. 1971-1972, Professor of Medicine and Physiology and Biophysics, Univ. of Washington. 1972-1974, Acting Chief, Pulmonary Research Branch, NHLBI, NIH. 1972-1980, Director, Division of Lung

Diseases, NHLBI, NIH. Present, Acting Associate Director for International Activities, NIH, and Acting Director, Fogarty International Center, NIH.

Professional Organizations. Association of American Physicians, American Society for Clinical Investigation, American Physiological Society, American Society for Clinical Research, French Physiological International Federation for Medical Electronics, American Society of Zoologists (Division of Comparative Physiology), Society for Experimental Medicine and Biology, Undersea Medical Society, New York Academy of Sciences.

Honors, Awards. Thesis Prize, 1956. Commendation - Tohoku Medical Society, Sendai, Japan, 1973. Superior Service Honor Award, DHEW, 1974. University of California, Los Angeles, Regents' Professor, 1978. Testimonial Dinner, American Thoracic Society, Las Vegas, 1979. Honorary Fellow, American College of Chest Physicians, 1979. Visiting Professor National Yang-Ming Medical College Taipei, Taiwan (named Honorary Professor, 1980).

Publications: 170 Scientific papers

Editorial Responsibilities: 1970-1976, American Journal of Physiology, and Journal of Applied Physiology--Editorial Board. 1971-1978, Respiratory Physiology--Editorial Board. 1973-1979, American Review of Respiratory Disease--Editorial Board. 1973-1975, Undersea Biomedical Research--Editorial Board. 1975-1984, Proceedings of Society for Experimental Biology and Medicine--Editorial Board. 1976-1979, Revue Francaise des Maladies Respiratories--Editorial Board. 1976-1982, Journal of Applied Physiology: Respiration, Environmental and Exercise Physiology--Associate Editor. 1979-1981, American Journal of Medicine--Associate Editor. Lung Biology in Health and Disease--21 Volumes Monograph series published by M. Dekker, Inc., New York--Executive Editor (15 volumes published).

INTRODUCTION OF ASSOCIATES

Dr. LENFANT. I have with me the former Acting Director of the Fogarty International Center, Dr. Beaven.

Senator EAGLETON. Go ahead, Doctor.

Dr. LENFANT. I would like to make some brief comments about the functions of the Fogarty International Center. The Fogarty International Center plays a part in the management and provides a focus for international activities within the National Institutes of Health.

Basically, we have three specific functions.

The first one is to coordinate the international activities of the NIH Institutes and to assist them in pursuing their own international activities.

Second, we serve as an interface between the National Institutes of Health and other governmental agencies and international organizations such as the World Health Organization.

And third, we have programs of our own, which have some very specific purposes.

All of our programs aim at developing, improving, and strengthening communications and exchanges which are related to biomedical research.

I would be pleased to discuss further any details, and to answer any questions that you may have.

RESULTS OF U.S. INVESTMENT IN FOREIGN RESEARCH

Senator EAGLETON. Let me put it this way. Senators and politicians believe we live in a tangible world. We like to see tangible results. No magical cures have been effectuated, we want precise terms.

Is our dollar being properly invested?

I realize in many areas, especially in the health science area, results don't always lend themselves to simple and easy tangible answers. I don't accept that as a given. Nonetheless, can you identify some things in the more tangible area where you believe that the Fogarty Center has been of service, things beyond good will in countries, and amorphous things like that.

Dr. LENFANT. Yes; indeed, there are some specific benefits to the United States from international cooperation. And I might cite some: For instance, coronary angioplasty, which is a technique which has been known for years in this country. It came from Switzerland: a series of drugs concerned with the treatment of coronary disease came from England; in the pulmonary diseases, which is my basic specialty, I would like to say that much of our knowledge today of the natural history of respiratory diseases comes from England; the research results that explain the development of such diseases come from Sweden; Finland has provided us with techniques for the production of interferon from white blood cells, and, in fact, is the largest supplier of interferon to the United States; blood substitutes which are of great research importance today were discovered in Japan; and China has given us much information on reproductive research on male contraception.

DISSEMINATION OF RESEARCH RESULTS

Senator EAGLETON. Let's take those examples you mentioned, China, Sweden, Japan, Great Britain, and two or three perhaps other nations.

What did you—not you as an individual—what did the Fogarty Center do to, as it were, bring that information to the United States and have it widely enough disseminated so that it has a practical medical applicability by the American medical practitioner?

Dr. LENFANT. I think there are two independent processes which need to be clarified here.

The first one is that, clearly, the U.S. scientific community benefits greatly from learning quickly about what is being done in other countries. Research and the resultant knowledge is sometimes a slow and difficult process, and a small piece of information may be needed to complete a project. By hearing what is being done in other laboratories in various parts of the world, U.S. scientists may solve or help in the resolution of a research project in this country.

That research productivity is achieved through a continuous exchange of scientists between our country and the countries which I mentioned. The Fogarty International Center is indeed very much involved with the promotion of these exchanges.

The second thing which is foremost in our minds, is what is the benefit to our country as a whole from that information that is coming from abroad.

The general public benefits from any scientific development, because there is a continuous transfer of scientific information into the mainstream of medical practice in our country. Therefore, any input coming from another country has an effect. Within a relatively short period of time—in some instances a longer period of time than other instances—it is incorporated into our medical practice.

COMPARISON OF DRUG LICENSING

Senator EAGLETON. This is a related question, but I think pertinent to your testimony.

It is alleged that other nations are—this question relates to pharmacology medicine.

It is alleged in the context of the Food and Drug Administration that other nations are more innovative and more advanced in various pharmacologies, and that there are all kinds of pills and methods being utilized in other countries that are not as yet utilized here in the United States because of the overly cautious posture of the Food and Drug Administration.

I know that is not your department, but you deal with medical practitioners and research clinicians around the world, et cetera.

Would you care to comment on that allegation that is frequently ventilated in the press and has been for years?

Dr. LENFANT. Well, I think the situation has no "yes" or "no" answer. There is an order that has to be considered.

I do not believe that other nations are ahead of us when it comes to developments and conceptualization of pharmacological products. However, what they have is the opportunity to test and assess the efficacy of those drugs more rapidly than we can do it, because we have a regulatory process which is by and large more stringent than elsewhere.

But, I think, in looking back at the history of the last 20 to 30 years, I would say that all in all we have had much benefit from some resistance to bringing into this country drugs which had been developed abroad and not fully tested. There are many examples. I might mention one that I have been very familiar with.

Some years ago in Switzerland and Germany an appetite reducing drug was developed. That drug was used by a great number of people. Suddenly we discovered an epidemic of related pulmonary artery hypertension which led to a number of pulmonary disorders that were very difficult to treat, and created many public health problems.

So I would say that all in all the benefits are probably on our side.

Senator EAGLETON. Senator Specter?

PROGRAM JUSTIFICATION

Senator SPECTER. Thank you, Mr. Chairman.

Doctor, I notice that in contrasting the figures from President Carter's budget with those of President Reagan's budget, that the Fogarty Center remained intact as to its figures.

Do you have any explanation as to why there was no cut in your unit?

Dr. LENFANT. Not directly; but, I can infer and draw my own conclusions if I may.

The first one is the value of our programs to further exchanges and communications with our friends abroad——

Senator SPECTER. Because of the important work your unit is doing?

Dr. LENFANT. Yes; that has been recognized.

And also, if you note from that list, we are by and large, the smallest NIH unit and cutting from that budget would not really yield too much.

Senator SPECTER. A million here and a million there.

Dr. FREDRICKSON. Senator Specter, would you permit me to add one comment to that?

Senator SPECTER. I was just about to ask you.

I will let you make a comment first, then I may have a question.

Dr. FREDRICKSON. I think I, too, am responsible for saying that at least no cut occurred in the current dollar level for Fogarty. We probably are in a situation now that we have never been in before. For 20 years we perhaps could have gone to sleep in this country because we were so much bigger and so much more active in biomedical research. This situation is certainly no longer true, and we are constantly reminded we have to be careful not to lose the edge that we now retain in certain new advanced technologies.

We at NIH probably represent a kind of hub of American science, and we are visited by nearly every country who wants to collaborate with us and who knows about NIH. We have reached a point now where we are going to have to husband our bilateral arrangements or exchanges, even our use of travel funds, in order to be sure that we maintain a cognizance of what is going on elsewhere to a higher degree than we ever had before.

Senator SPECTER. So you asked that Fogarty be retained at its preexisting level.

Dr. FREDRICKSON. I did, because I think the function of Fogarty is probably more important than it ever has been.

Senator SPECTER. As I scan these various departments, Fogarty is the only one which remained intact.

Dr. FREDRICKSON. Yes; because it is relatively quite small, and there is very little change we can make in terms of the number of people that it can bring into its activities. I think we would be practicing no economy at all to reduce Fogarty.

RATIONALE FOR TRAINING GRANT REDUCTIONS

Senator SPECTER. In addition to my interest in Fogarty, I am also interested in the process, as to how Mr. Stockman's unit responded to your recommendations. Did you recommend cuts in all the others which then received cuts in contrast to Fogarty where you recommended it remain the same?

Dr. FREDRICKSON. The development of this recommendation was somewhat less direct in terms of each Institute. That is, we were faced with a requirement to reduce the training in certain ways that I have

described. Fogarty has no such training programs, so it would not automatically incur a reduction in that area. Thus it is in distributing the major impacts that we find the distribution change among the various Institutes.

Senator SPECTER. Were you requested to make cuts only in training?

Dr. FREDRICKSON. The primary thrust was to absorb the cuts that we are directed to take first through the reductions in the training aspects of institutional costs.

Senator SPECTER. Who made that direction, if I may ask?

Dr. FREDRICKSON. I think that was OMB.

Senator SPECTER. That they identified for you the type of cuts in training as opposed to leaving it to your discretion as to where you would allocate those cuts?

Dr. FREDRICKSON. In the aggregate of NIH those directions were transmitted to us—that we should take that step first in adapting to whatever level of reduction they finally arrived at; yes.

Senator SPECTER. What was the basis for their saying that, if you know?

Dr. FREDRICKSON. The administration describes its rationale in the fourth paragraph of page 6–12 of the document that we have been examining this morning—the President's economic plan. They would like to eliminate the current practice of paying more to an institution for a federally supported trainee than is charged in tuition and fees to nonfederally supported students at the same institution. I am quoting from the rationale.

Senator SPECTER. Why had that differential existed, if you know, on cost for federally supported trainees contrasted with——

Dr. FREDRICKSON. The basic philosophy of supporting training in the NIH, which is 30 years old now, began in 1938——

Senator SPECTER. My question is, Why did the institution charge more for federally supported grants?

Dr. FREDRICKSON. The National Research and Training Award Act of 1974 continued a tradition that had existed for 30 years, which allowed the institutions to be reimbursed for the cost of educating those students, particularly in these highly scientific——

Senator SPECTER. So that was a computation of full costs as opposed to what others were charged?

Dr. FREDRICKSON. The institutions do not get full cost, Senator Specter. The indirect costs, for which they are reimbursed, are limited to about 8 percent of the total grant. This compares to 28 percent in research grants. They also receive institutional support outside of indirect cost per se for faculty salaries, equipment, and other costs incurred in providing these training programs.

One of the reasons NIH has reimbursed the institutions is that, through this mechanism, we have felt that we could control the quality of the instruction offered; that we could guarantee that a certain curriculum, certain quality of instruction, existed. We were trying to avoid what can happen in the absence of any training, and that is purely an apprentice system where the apprentice ends up learning only what the sorcerer knows, which may not suit him for a career in science.

Senator SPECTER. Was Mr. Stockman's recommendation on the limiting training issue that you have already testified?

Dr. FREDRICKSON. It was; yes.

Senator SPECTER. Thank you very much.

Senator EAGLETON. Senator Burdick.

Senator BURDICK. Nothing.

QUALITY OF FOREIGN MEDICAL RESEARCH

Senator EAGLETON. Let me ask this of Dr. Lenfant or Dr. Fredrickson or both. From a governmental point of view, within the fabric of the Federal Government, who would be in a position to evaluate the quality of medical research or the quality of medical care in the foreign nation?

Dr. LENFANT. I think that for biomedical research the National Institutes of Health would be in a prime position to make this evaluation, because, as I mentioned earlier, each of the Institutes of NIH, or most of them, has a program of research which is international in scope, and therefore our best scientists go to these countries and can evaluate the value and potential benefit of what is being done there. They then come back with diverse evaluations which enter into the process of continued enhancement of new biological developments.

Senator EAGLETON. That's medical research. How about delivered medical care?

Dr. LENFANT. I will ask Dr. Fredrickson perhaps——

Dr. FREDRICKSON. I think in many ways NIH clinical scientists probably can assess that quite well in terms of the range of technical virtuosity in a country. I would say that other Federal groups, perhaps the Health Services Administration and others, are better able to evaluate delivery of medical care in the field where the scientific content is very low or where there is no research activity at all.

Senator EAGLETON. I love that phrase "the range of technical virtuosity."

To your knowledge, Dr. Fredrickson, was anyone at NIH, including yourself or any other person at NIH, consulted as to the quality of medical virtuosity in Mexico at the time the decision was being made by the Carter administration as to whether to admit the Shah for treatment?

Dr. FREDRICKSON. I am fairly certain that no one at NIH was consulted.

Senator EAGLETON. We have other questions, Doctor. Thank you very much. We will submit those to you in writing.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

USEFULNESS OF FOGARTY

Question: The Fogarty International Center provides for, among other matters, exchanges of scientists between this country and foreign nations. Please explain what tangible good--besides good will--comes out of this program.

Answer: Through the interpersonal communication that is possible only if scientists are working together, the exchange of scientists between this and foreign countries accelerates the transfer of new knowledge, technologies and techniques that have an impact on biomedical research and also on the applications of research to health care here and abroad. Where diseases are more prevalent abroad than in this country (or vice versa), collaboration between foreign and United States scientists in epidemiologic studies or clinical trials has increased the availability of comparable data, which is essential to a statistically significant study. In many instances, research initiated in one country has been a stimulus to more extended studies elsewhere. Among recent examples is the development of a catheter with a balloon tip that can be passed through a coronary artery and used to compress the material causing an obstruction. This procedure (called percutaneous transluminal coronary angioplasty), which was pioneered by the Swiss, is now undergoing trials in this country as a possible substitute for coronary bypass for certain types of obstruction.

Question: What sort of work or study do foreign scientists do at Fogarty and what do our people do abroad?

Answer: Foreign scientists who come here under Fogarty programs are able to participate in biomedical research or clinical experiences that are relevant to their background, training and scientific and medical interests. When going abroad, our scientists are usually attracted by special or unique features of a given country or laboratory. For example, in some instances they wish to study diseases that occur only rarely in the United States but to which our countrymen are exposed. In other cases, the scientist is going abroad to learn research techniques developed in a foreign laboratory or to work under a world leader relative to a particular biomedical problem.

Question: If this program is regarded as essential to the biomedical research community, why don't medical schools form a consortium and finance it themselves?

Answer: Fogarty International Center programs that provide for exchange of scientists are responding to the broad aspects of health-related research that are often reflected in government-to-government agreements, and are usually dictated by health issues of world-wide concern. These concerns are usually beyond the scope of a given medical school or even a group of medical schools. Moreover, medical schools at present even lack resources for adequate realization of their own goals. They do, however, provide assistance to international exchange programs through use of their facilities, staff supervision, and other services available to foreign scientists. The Fogarty International Center has a coordinating function that is designed specifically to meet such overriding needs as those arising from health problems that are of world-wide interest.

GORGAS MEMORIAL INSTITUTE

Question: What role does the Gorgas Institute in Panama play in regard to the medical problems of Latin America?

Answer: The Gorgas Memorial laboratory (GML) is particularly concerned with tropical and infectious diseases that are prevalent in its immediate locality as well as in other parts of Latin America. It emphasizes research, training, surveillance and advisory activities relative to infectious and tropical diseases. The GML has a unique capability for conducting studies on the causation and transmission of these diseases in their natural setting, and is within easy reach of both clinical and field conditions for study.

Question: What evidence can you supply that Gorgas has made progress against malaria and other tropical diseases?

Answer: The GML has contributed to the development of animal models for malaria research, thus making it possible to undertake controlled studies in the laboratory. It also conducts studies on new antimalarial drugs, of which several offer considerable promise as alternatives to older drugs to which resistance is developing. The GML has identified animal reservoirs for viruses during periods between epidemics, findings of importance relative to control and prevention of disease.

Question: Could Gorgas be self-sustaining without U.S. assistance? How much does the Institute get from project grants and contracts?

Answer: No research institution can be fully self-sustaining. It must have some base of staff and financial stability, which may come from private sources, endowments, university, commercial or government support. In the absence of U.S. assistance, the GML would have to find some other source for its core support. Support from grants and contracts is also essential, but this is usually for short-term projects and must be built on a long-term institutional base.

In FY 1980, the GMI/GML derived 36.1% ($960,000) of its support from grants and contracts. This is an increase over previous years.

Question: What impact, if any, has there been on the Institute from the Panama Canal Treaty?

Answer: The main laboratory of the GML and most of its activities have always been located in the Republic of Panama and therefore have not been affected by the Panama Canal Treaties. An additional laboratory building and several small field sites located in the former Canal Zone are covered in annexes to the treaties for continued use by the GML. Thus, the treaties have not altered the operation of the GML in any significant way.

National Library of Medicine

STATEMENT OF MARTIN M. CUMMINGS, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

KENT A. SMITH, DEPUTY DIRECTOR

PREPARED STATEMENT

Senator Eagleton. We will now move on to the National Library of Medicine. Dr. Martin Cummings is the Director of the National Library of Medicine. The library services furnishes a resource in support of biomedical research.

Senator Burdick, he's been very patient. I think he had some questions. In the interest of time I am going to yield to him right at the outset with his questions.

Dr. Cummings. I will be very pleased to summarize my full statement, Mr. Chairman and Senator Burdick.

Senator Eagleton. Your prepared statement will be inserted in the record at this point.

[The statement follows:]

STATEMENT OF MARTIN M. CUMMINGS

Civilization advances through the communication of knowledge. The storage, retrieval and processing of information is an essential resource for all social, cultural and economic progress. Writing about the social framework of the present information society Daniel Bell (a professor of Sociology at Harvard University) describes four revolutions -- Speech, Writing, Printing, and Telecommunications -- that have changed the way people live:

> Speech was central to the hunting and gathering bands - the signals that allowed men to act together in common pursuits.
> Writing was the foundation of the first urban settlements in agricultural society - the basis of record keeping and the codified transmission of knowledge and skills.
> Printing was the thread of industrial society - the basis of widespread literacy and the foundation of mass education.
> Telecommunications - the ties of cable, radio, telegraph, telephone, television, and now, newer technologies are the basis of an "information society."

Each of these revolutions was based on new ways of exchanging information - adapting new technologies for this purpose.

Knowledge is the source of progress and power. The library - from the earliest collection of stone tablets to the modern computerized information center - is the reservoir and repository of knowledge, and therefore, is a critical resource for the functioning of society. The modern library also organizes and disseminates information in a socially acceptable way where rich and poor alike may share its benefits.

This has never been more true than in the late twentieth century, as we move into an era where information and knowledge, together with agriculture and manufacturing, are becoming strategic resources of our society. The information industry accounts for half of the U.S. labor force and 46% of the gross national product. Burgeoning high technology makes possible the transition to an information society. This is particularly important in the sciences.

The National Library of Medicine is in the forefront in the transition from the printed word to computer-based communications technology which makes it easier to store, find, and retrieve medical information. The Library serves as the nation's principal resource for information needed in biomedical research, health professional education, and the delivery of health care services in both the private and the public sectors. Users of the NLM include commercial and industrial organizations, hospitals, clinics and nursing homes, and academic institutions for medical, dental, and nursing education and research.

The results of research must be disseminated if they are to be of benefit to society. In fact, research is incomplete until it is documented and published. Research projects culminate in published results almost all of which are acquired, indexed, organized, and distributed by the NLM. The research scientist uses NLM resources to locate scientific and technical information. Access to the information is available either as a direct user of NLM or through its Regional Medical Library Network. Computerized data bases such as MEDLINE and TOXLINE inform the scientist, educator, and practitioner where information exists.

The NLM saves health professionals from tedious thumbing of textbooks and journals by providing systematic, computer assisted scans of the latest available information no matter where it has been published. When a doctor, nurse, dentist or veterinarian wants the latest information on a specific topic, the computerized bibliographic systems of the NLM stand ready to comb the current literature and extract a list of references and abstracts that guide the seeker swiftly to the most relevant articles for his purposes.

Let me give you an example. Recently I ran a test of our system myself, and what I am going to report to you is what I found when I requested a search for information on a currently important topic: the management of coronary artery spasm. This is a condition that produces severe chest pain in individuals with coronary artery disease, even at rest. I asked the MEDLARS system what it could tell me about the latest in treatment and patient management. It took 10 minutes to formulate the search and have the computer examine over 400,000 citations, resulting in an immediate retrieval of 16 references and 13 abstracts on the management of coronary artery spasm. It took about 20 minutes to read them and I was pretty sure that I wanted to read two of the articles in their complete form. So I made another request of the Library asking for photocopies of these two articles. Twenty minutes later I had them. Last year NLM alone provided 1.3 million such computer searches and 250,000 articles or entire books were sent to health professionals through their libraries.

That's what the services of NLM are all about: providing rapid, thorough, convenient and economic ways of selection from the great mass of medical literature, those relevant items that serve the needs of an individual health professional who has a specific question. I point out that not all questions can be answered, only those for which the information has been published and indexed accurately. We are constantly improving these services. A new

and improved information system, called MEDLARS III is currently being developed by NLM staff.

MEDLARS III will include important new services for the biomedical community such as a fully automated online interlibrary loan service which will untimately allow the nation's medical libraries to request journal articles online through our computer. Bibliographic searching will be simplified greatly; the user will be able to enter a single search to be run against multiple files using common English commands rather than artificial computer language.

NLM also provides specialized information services in toxicology and environmental health through online data bases such as TOXLINE and CHEMLINE, specialized search services at the Oak Ridge National Laboratory, and interagency projects such as the Chemical Substances Information Network. These services allow the producers of drugs and chemicals as well as health professionals to have rapid access to information about the effects on humans and the environment of drugs, chemicals and other toxic substances.

In addition to its resources in Bethesda, NLM supports and coordinates a national network of eleven Regional Medical Libraries. They in turn are linked to 103 Resource Libraries, and more than 3,000 local health science libraries. The Network provides services such as lending materials between libraries, searching NLM's online bibliographic data bases, and providing acquisition and cataloging information to other libraries. In addition it provides training and consultation to small institutions and encourages resource sharing among libraries. NLM shares the products of its labor intensive cataloging efforts with libraries in the Network, thus saving these libraries the cost of cataloging. Each of the eleven Regional Medical Libraries coordinates information delivery services within its own region and cooperates with libraries throughout the Network to provide nearly 2 million interlibrary loans annually.

NLM's grant programs under the Medical Library Assistance Act provide support for the establishment, development, and enhancement of health information services for health professionals. Grant assistance is used to maintain and improve the biomedical information network; to support research into new ways of representing, transmitting and utilizing biomedical information; and to train information specialists and computer scientists. A special initiative within this grant program known as Computers in Medicine supports research and training in the computer sciences related to how biomedical knowledge

can be organized so that clinicians faced with decisions about patient care can obtain information in an easy-to-use format.

The NLM dedicated the new Lister Hill Center Building in May 1980. It provides sophisticated resources for the Lister Hill National Center for Biomedical Communications and the National Medical Audiovisual Center (recently moved from Atlanta) as well as for several other NLM and NIH programs. The architectural and engineering plans for the renovation of the present library building have been completed and will improve the protection of the collection and safety of the readers.

The Lister Hill National Center for Biomedical Communications is the research and development arm of the National Library of Medicine. One major objective of the Center is to improve the manner in which books, journals and audiovisual media are stored, retrieved and used. A principal effort of the Center is to develop "knowledge-based systems" which would provide specific, current information useful for patient care and health care delivery.

The National Medical Audiovisual Center's primary mission is to improve the transfer of health science information from research into practice through the use of audiovisuals. NMAC lends audiovisual materials to be used in health professional education and also supports an online data base of audiovisual materials known as AVLINE. The Center conducts workshops to train health science educators in the use of advanced educational technologies, assists in preparing educational materials, provides consultation on audiovisual facilities planning, and conducts research in how to improve the use of audiovisuals in health professional education.

The rapid growth of computer and communications technologies in our society presents challenges and opportunities for new ways for communicating knowledge. In addition to our present use of available technology, we are actively working with industry to investigate many newly emerging technologies, such as:

- o Telefacsimile - which would allow copies of articles from journals or other documents to be sent across the country almost instantly;
- o Electronic mail - enabling scientists to communicate with each other through computer terminals;
- o Video disc technology for improved storage and retrieval of information;
- o Computer-generated printing - to save money and increase the timeliness of the scientific literature;
- o Education through audiovisual devices - improving the training of health science students, scientists and practitioners.

Mr. Chairman, I shall be pleased to answer questions and supply any additional information desired for the record.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service, National Institutes of Health

Biographical Sketch

NAME : Martin Marc Cummings

POSITION : Director, National Library of Medicine

BIRTHPLACE AND DATE : Camden, New Jersey, September 7, 1920

EDUCATION : B.S., Bucknell University, 1941
M.D., Duke University, 1944

HONORARY DEGREES :
Honorary Doctor of Science, Bucknell University, 1969
Honorary Doctor of Science, University of Nebraska, 1971
Honorary Doctor of Science, Emory University, 1971
Honorary Doctor of Humane Letters, Georgetown University, 1971
Honorary Doctor of Medicine, Karolinska Institute, Stockholm, Sweden, 1972
Doctor Honoris Causa, Academy of Medicine, Lodz, Poland, 1977

EXPERIENCE

1964 to Present	:	Director, National Library of Medicine
1963-1964	:	Associate Director for Research Grants, National Institutes of Health
1961-1963	:	Chief, Office of International Research, National Institutes of Health
1959-1961	:	Professor of Microbiology and Chairman, Department of Microbiology, University of Oklahoma School of Medicine
1953-1959	:	Director, Research Services, Veterans Administration Central Office
1953-1959	:	Special Lecturer in Microbiology, George Washington University School of Medicine
1953	:	Associate Professor of Bacteriology, Emory University
1949-1953	:	Chief, Tuberculosis Research Laboratory, Veterans Administration Hospital of Atlanta
1948-1953	:	Instructor through Associate Professor of Medicine, Emory University
1947-1949	:	Director, Tuberculosis Evaluation Laboratory, Communicable Disease Center, U.S. Public Health Service
1945-1947	:	Assistant Resident Medicine, Boston Marine Hospital

1944-1945	:	Intern, Boston Marine Hospital
1942-1944	:	U.S. Army (ASTP)
PROFESSIONAL ASSOCIATIONS	:	American Academy of Microbiology, Inc.
	:	American Association for the Advancement of Science, Board of Directors
	:	American Board of Microbiology.
	:	American Clinical and Climatological Association
	:	American Federation for Clinical Research (Emeritus)
	:	American Osler Society, President
	:	American Society for Clinical Investigation (Emeritus)
	:	Association of Research Libraries
	:	Gorgas Memorial Foundation, Board of Directors
	:	Institute of Medicine, National Academy of Sciences
	:	Medical Library Association
	:	Society of Sigma XI
	:	Washington Society for the History of Medicine
SPECIAL AWARDS & HONORS	:	Veterans Administration Exceptional Service Medal
	:	DHEW Superior Service Award
	:	DHEW Distinguished Service Award
	:	Distinguished Alumnus Award, Duke University, 1969
	:	Honorary Member, Alpha Omega Alpha
	:	Honorary Fellowship, College of Physicians, Philadelphia, 1973
	:	Rockefeller Public Service Award, 1973
	:	Honorary Member, American Medical Writers Association, 1974
	:	Alumnus Membership, Phi Beta Kappa, 1974
	:	Modern Medicine Distinguished Achievement Award, 1976
	:	Distinguished Service Award and Honorary Fellowship, College of Cardiology, 1978
	:	Honorary Member, Academy of Medicine of the Institute of Chile, 1978
	:	Certificate of appreciation for outstanding contributions to medical communication and to the American Medical Writers Association, 1978
	:	John C. Leonard Award, Association for Hospital Medical Education, 1979
	:	Harold Swanberg Distinguished Service Award, American Medical Writers Association, 1979
	:	Fellow, American Association for the Advancement of Science, 1980
	:	105 scientific and historical publications, co-author of textbook in the field of tuberculosis

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OVERVIEW

Dr. CUMMINGS. The Library, as you know, was founded in 1836, and this year we celebrate the 25th anniversary of its conversion from the Army Medical Library to the National Library of Medicine with the passage of the National Library of Medicine Act of 1956.

We have for more than a century been interested in providing a service to all elements of the health community. I believe the Library has been successful in doing this both in rural and urban settings and has shared its resources equally with the commercial as well as the academic and clinical sectors of medicine.

The Library's importance, I think, is measured in a way by the number of articles and books that it receives from the output of medical science. Last year, for example, we indexed more than 250,000 medical articles and cataloged more than 17,000 books.

The findings from this effort are printed, published, and sold nationally and internationally and the sales of our indices and catalogs remain at a high level.

We believe that with the new technologies that have been applied we save all health professionals the tedious task of combing the current literature. It is now relatively easy for an investigator or practitioner to examine the literature and rapidly acquire references or abstracts which then lead him to the literature.

REGIONAL LIBRARIES

We have supported a network of regional and local libraries throughout the country. This network is comprised of some 3,000 local hospital libraries, about 120 resource libraries, principally in the medical schools of the country, and 11 regional libraries.

Through this network we provide about 1 million loans to individuals and institutions who do not have the documents they seek. Importantly, also, through this network last year we provided almost 2 million searches of our data bases by computer networking.

I am informed that this represents more than half of all computer searches in all fields of science and education. The numbers themselves are not important, however, Mr. Chairman. The fact that the user pays to access the system gives us some feeling of the quality of the response. And I think it is very important that I point this out. Nevertheless, we continue to seek better ways of providing information, and in our 1982 plan we do make a proposal to improve the computer-based system that we call MEDLARS through some new and more efficient methodologies.

We have a very modest grant program through which we support training, research, and resource sharing.

In addition, because of the new facility which the Congress supported over the last 8 years, namely, the new Lister Hill National Center for Biomedical Communications, we have for the first time brought together all of the elements of the National Library in one modern and sophisticated facility.

INTRAMURAL PROGRAMS

The intramural research program within this facility is now working to improve the organization of knowledge, its synthesis and compaction, and is developing new methodologies for distributing such information to institutions and individuals throughout the country.

In addition, the National Medical Audiovisual Center previously located in Atlanta, has been transferred to Bethesda, and it now has joined the NLM family. It deals with medical information in nonprint formats, much the same way that we deal with the printed material; namely, it organizes materials, and it provides loans of these materials, and, when they are well received, they are sold to users through the GSA National Audiovisual Center.

This is a brief overview, Mr. Chairman, of some of the activities of the Library. I will close by saying that all of them are designed to improve the transfer of medical information, not only through libraries, but through medical institutions everywhere.

I would be pleased to answer any questions.

RESOURCE GRANT PROGRAM

Senator EAGLETON. Senator Burdick?

Senator BURDICK. Mr. Chairman. Dr. Cummings, I know your resource grant program at the Library of Medicine, particularly the improvement grant which has done so much to improve medical knowledge and information to our local community hospitals. I would like to know what effect this budget cut of approximately $1 million will have on this program, and I'm asking the same question on behalf of our colleague, Senator Hollings.

Dr. CUMMINGS. Well, I should say for the record that the cut you refer to is not a cut imposed by the new budget. This is a reduction in this program from 1981 to 1982 contained in the original budget.

You ask what its effect will be. It will simply reduce the number of institutions to whom we can provide support for resource building and resource sharing.

One of the major efforts within that program, Senator Burdick, was to have small institutions join together in a consortium so that they might share their holdings and through such sharing reduce the costs of library services. It will simply mean that there will be some cutback in the number of such institutions that can be supported.

Senator BURDICK. It would be more helpful to have the $1 million, wouldn't it?

Dr. CUMMINGS. There's no question that more institutions would benefit by having that than the present situation.

Senator BURDICK. Would you give this committee a report on the progress the Library of Medicine has made in the computer and medicine program? Would the cut in the Library budget reduce the effectiveness of the program and even retard the momentum already established by the funds which Congress appropriated for fiscal 1980? This is also asked on behalf of Senator Hollings.

Dr. CUMMINGS. Let me again for the record point out that we do not believe that we have a cut in our budget. The amounts that have been

authorized for the Library are the same as those that were available to us last year. What has, in fact, occurred is a shift in priorities which has taken funds from the extramural program and made them available for the MEDLARS III development that I referred to in my statement to the chairman.

In essence, the extramural program is reduced by about $1 million, and funds for the development of this new information system go up by about the same amount.

My view is that we have been treated fairly, and I do not believe that we would be justified in making a request for restoration of those funds.

Senator BURDICK. And that was also true in regard to the grant program that we talked about?

Dr. CUMMINGS. Yes; as I said earlier, I think when we were advised that there would be a reduction in the funds for the extramural program, with the support of NIH and our Department, we were allowed to take that adjustment as we saw fit. And I think it's important for me to say again that it was our judgment that it was more important to put the money in the development of a new information system than to put it in the extramural program.

Senator BURDICK. Thank you, Doctor.

CATALOGING BACKLOG

Senator EAGLETON. Let me ask you, Doctor, last year I believe you testified the cataloging backlog at the National Library of Medicine equaled 1 full year's acquisitions. What's the backlog status as of now?

Dr. CUMMINGS. Well, the current cataloging backlog is still approximately equal to 1 year's acquisitions. At last accounting, it was about 18,500 items. I should say that fighting the backlog problem, Mr. Chairman, is not a budget problem; it is a staffing and a personnel problem. We are, in an effort to deal with this backlog, taking certain shortcuts in the cataloging by producing limited descriptions of the items so that the public at large knows what we have. But this places a lien on the catalog in the future.

Senator EAGLETON. You say it's not a budget problem but a personnel problem. Do I infer that you have moneys available to hire some backlog catalogers but no one wants the job?

Dr. CUMMINGS. No. The main problem that we have is to find qualified catalogers who know the foreign languages, and in our case the backlog is in languages such as Russian, German, Polish, Scandinavian, and Japanese. But in addition to that, we have been under certain constraints, hiring constraints even before the present freeze. There has been a constraint on hiring for some months.

So I simply want to say that we have the funds. It's a matter of getting the personnel on board. We have nibbled away at the problem, but we have not solved it.

Senator EAGLETON. Do you have translators? Suppose you receive an article this week that someone out in—it's in Swedish, and somebody said, "I believe this is a terrific article." By hearsay, he hears this is a very fine piece of work.

Do you have translators who could rather quickly translate it?

Dr. CUMMINGS. Our staff has competence in about 40 foreign languages, and I happen to know we have competence in Swedish. Ordinarily, we would not fully translate articles as a matter of routine. But if we were requested under the hypothetical situation you posed, that this might be very important, then our staff would put aside its routine duties and do a translation of that article.

Senator EAGLETON. Out there in the general realm of the dissemination of medical knowledge, going beyond the confines of NIH, who is out there to translate and to get into the pipeline interesting, timely pieces that come from abroad? I mean, if you don't do it, who does it, and when do they do it?

Dr. CUMMINGS. There are a number of independent translators who essentially do piece work and hire themselves out for various tasks. There are one or two industrial groups who have staffs with competence in foreign languages, and we have, in fact, trained the staffs of some of these groups to do indexing in a foreign language. There are several such organizations here, in Philadelphia, and elsewhere.

Primarily, when we have a major problem of this sort, we seek the competence of our counterparts overseas, and some of the indexing that's included in our system is done for us in places like Sweden, West Germany, the United Kingdom, and elsewhere.

ONLINE BIBLIOGRAPHIC ACCESS

Senator EAGLETON. It's our understanding about 1,200 of the more than 5,000 health libraries in the country have access to medical literature through online bibliographic data base searches, that last year you were forced to place a moratorium on additional users because of limited computer capacity. Will you have to continue this moratorium during the oncoming year?

Dr. CUMMINGS. I'm very pleased that you recall that difficult time, Mr. Chairman. Let me briefly tell you how that problem was dealt with, because I think that it represents a marvelous example of how NIH works.

It became very clear that we could not acquire a new computer system at the costs that were estimated, between $9 and $15 million. That was beyond our reach, and there were other problems associated with that procurement.

I am pleased to tell you that another part of NIH, the Division of Computer Research and Technology, made available to us a computer system that they were replacing, and we were able to acquire that for the unpaid balance, which in that case was about $700,000. We, in turn, then gave our computers to another part of NIH, the Clinical Center, which had a desperate need to have the kind of capacity that we enjoyed, and had been getting services from a bureau in New Jersey.

So within the family, we were able to shift our hardware and essentially hardly lost a beat. This was all done over a weekend with assistance from the engineers, and I'm very pleased to report that to you. That problem has been solved, and the moratorium has been lifted, and several hundred new institutions, mainly hospitals, have joined the network.

Senator EAGLETON. Dr. Fredrickson, does the President's hiring freeze he announced, I guess the day he was sworn in, apply across the board to NIH?

Dr. FREDRICKSON. It does, Mr. Chairman, although there have been some exemptions or relief proposed by classifying employees into three groups: Those urgently needed for patient care, those related to patient care, and all others. With the Secretary's order yesterday, we have been able to hire several urgently needed people.

Senator EAGLETON. Those are in the patient care?

Dr. FREDRICKSON. They are related directly to patient care—nurses and physicians.

Senator EAGLETON. Besides additional exemptions, it's only been a few weeks, but have you had occasion to seek additional exemptions beyond emergency patient care slots?

Dr. FREDRICKSON. We are in the process of seeking such exemptions now.

Senator EAGLETON. We have some other questions, Dr. Cummings, for you, and we will submit those to you in writing. Thank you very much.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

CATALOGING BACKLOG

Question: The Director of NLM stated last year that the Library had a backlog of at least 15,000 books that had never been cataloged. There were to be no new positions in the NLM budget for FY 1981, and as a result it was estimated that the backlog would grow to over 25,000 volumes. During the past year has there been any improvement in your cataloging backlog?

Answer: The present cataloging backlog is approximately 18,500 items. This represents no significant change in the backlog. Several steps were taken to arrest further growth of the backlog.

The Library was able to contract for the cataloging of about 2,000 books in languages in which the Library lacked the expertise. We also established a program for a "limited cataloging" level for those items judged to be of more limited interest and value. This type of cataloging is being established under new cataloging rules and results in substantially increased productivity by catalogers. Moreover, "weeding" of the backlog resulted in the elimination of a number of items that were either out-of-scope or of too marginal interest to be included in the Library's collection.

Further improvement in reducing the backlog could have occurred had it been possible to fill existing vacancies. At all times there have been 2-3 cataloger vacancies. These have been difficult to fill because of the inability to locate qualified individuals with language expertise such as Japanese, Russian, German, and Swedish.

Question: What is your present estimate of staff positions needed to deal with the backlog?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

INFORMATION RESOURCE BASE

Question: I have a chart here which shows that average health science library budgets increased by 34-35% between 1975 and 1978. For that same period of time, NLM's budget rose 30%. While the 5% difference between average medical school libraries and NLM may appear small, given that the former are in terms of thousands of dollars, and the latter in terms of millions of dollars, doesn't this really suggest an enormous decline in the national information resource base?

Answer: Yes, there has been a decline in the relative rate of growth of the NLM's budget as compared with the rate of growth of the medical school libraries it serves. National health information transfer is based upon an interlocking arrangement among the nation's health-related libraries and the NLM, thereby providing the nation's principal information resource in support of biomedical research, health care delivery, and health professional education. The rate of inflation has seriously impacted all library budgets in three critical areas: the acquisition of books and journals, indexing and

A COMPARISON OF LIBRARY BUDGETS AND COSTS
Revised 1975-79 Comparison

Revised NLM

U.S. Medical School Libraries	1975	1979	Percentage Change
Average Annual Total Expenditures (in thousands)	$ 473	$ 778	+64.4%
Average Book and Journal Expenditures (in thousands)	$ 146	$ 252	+72.6%
Average Number of Journal Subscriptions	2,186	1,950	-12.1%
Average Cost per journal	$42.38	$63.31	+ 49%
Total National Support for Research and Development (in millions)	$4,587	$7,691	+67.7%
NIH Research & Development (in millions)	$1,846	$3,162	+71.3%
National Library of Medicine Budget (in millions)	$28.8	$44.0	+52.8%

cataloging them for the use of health professionals, and the sharing of information through a national network.

The attached table shows that the costs of books and journals have been rising faster than library budgets and that journal holdings are declining. As the nation's primary biomedical information resource, NLM must continue to acquire books and journals which must be cataloged and indexed before they can be useful to the health professional. Indexing and cataloging are highly intellectual labor-intensive tasks which require a growing number of skilled NLM personnel and result in a substantial net savings to the nation's medical libraries.

The products of NLM's indexing and cataloging activities are available through a national Regional Medical Library Network which is authorized by the Medical Library Assistance Act (MLAA). As the budgets of libraries in the network are constricted, the demand for the NLM to provide services grows. Continued support of the network by NLM is critical to the future of the nation's medical libraries. NLM endeavors to strengthen this network by stimulating the development of resource-sharing consortia of local libraries through the grant programs of the MLAA.

A review of more recent data indicates that these trends in reduced library budgets and increased costs are continuing without abatement. The importance of NLM's services to the nation cannot be underestimated.

STAFFING REQUIREMENTS

Question: The budget for 1982 does not recommend any new positions for the Library. How do you propose to cope with what is obviously a severe manpower need?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

ASSISTANCE TO HEALTH LIBRARIES

Question: Under the Medical Library Assistance Program, the budget proposed a decrease of 32 awards, for a total of 107 grants and contracts. Given the tremendous explosion in book and journal costs, how many of the 5,000 health libraries in the country need assistance under this program just to develop minimal collections?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

EFFECTS OF INFLATION

Question: Past budget increases for the Library have been very small. Acquisition of foreign materials cost over 40 percent more than it did a year ago. The inflation factor for most large

research libraries runs approximately 20 percent a year. Will you give us a specific breakdown of where your budget will be hit hardest by the current inflationary economy we are experiencing?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: If you had to cut back, where could you do it?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

COMPUTER SYSTEM

Question: Last year there was mention that NLM was in its sixth year of upgrading its computer system and in the process had run into problems because technology had outstripped the confines of the original procurement costs. There was testimony that the answer to the whole problem might require starting the competitive bidding process all over again. Where do you stand at this point in your efforts to upgrade the NLM computer capacity?

Answer: We cancelled our competitive procurement for an upgraded computer system when a Government-owned computer, an IBM 370/168 MP system became available to us as surplus property. This system which no longer met the requirements of the NIH's Division of Computer Research and Technology has replaced our IBM 370/158 MP system and will quite adequately meet our needs for the next three to four years for it increases our capacity nearly threefold.

Question: How much will it cost this year and in total?

Answer: Based upon the projected cost of the new equipment which was not acquired and the commercial value of the equipment which we did obtain, the savings to the Government is approximately $9,000,000. Further savings have accrued to the Government through the transfer of the IBM 370/158 MP system which is now being utilized by the NIH Clinical Center.

LISTER HILL CENTER

Question: The Lister Hill Center's mission is to explore the uses of advanced computer and communications technology as they relate to the health field. What is the current status of the Center?

Answer: During the twelve years of its existence, the Lister Hill Center has continually evolved its programmatic focus in response to information needs of the biomedical community, and to take advantage of the latest in computer and communications technology tools developed by industry. The Lister Hill Center today is applying state-of-the-art devices, systems, networks, and information management techniques to the solution of information transfer problems in the health field, in several key areas. The following programs illustrate the extent of these applications areas.

Since 1977, the Lister Hill Center has been developoing an automated minicomputer-based Integrated Library System to help meet the needs of libraries of all sizes, and to facilitate their interaction with each other and with the National Library of Medicine. Parts of this system are operational, and are available through sale by the National Technical Information Service.

In 1976, the Lister Hill Center initiated the Knowledge Base Program, designed to provide up-to-date authoritative answers to health professionals' questions. Three experimental knowledge bases are in various stages of development and demonstration. Each is being derived from the literature as a consensus of expert views on the state of knowledge. Related to the Knowledge Base Program is a new information science support activity which will explore advanced computer techniques for organizing, storing, manipulating, and retrieving textual information.

More recently, the Lister Hill Center began investigating methods to electronically scan, store, retrieve and distribute a portion of the printed material acquired for the National Library of Medicine collection. A related program is investigating the use of optical devices for storing and retrieving library-related visual materials presently in 35-mm slides and other media.

Other programs are exploring the use of modern tools such as microprocessors and video discs for more effective and efficient storage, retrieval, transmission, and display of data, text, and audiovisual information.

Question: Is it fully operational?

Answer: The Lister Hill Center moved into its new facilities next to the National Library of Medicine in April of 1980. New laboratories have been partially operational while awaiting installation of advanced computer and communications systems. These systems will enable important research and development in information science, document storage and retrieval, and video processing to be initiated.

Question: How large is the staff?

Answer: At present, the total staff of the Lister Hill Center number 65, of which 47 are professionals. The latter category includes 10 special experts, visiting scientists, and individuals appointed under the Intergovernmental Personnel Act, needed to provide special expertise for a limited time in support of specific programs.

ASSISTANCE TO MEDICAL LIBRARIES

Question: The authorization for the Regional Medical Libraries program expires on September 30th of this fiscal year. Is funding for this activity high on NLM's priorities, and what accomplishments have come out of this program?

Answer: Support for Regional Medical Libraries is high on NLM's priority of programs authorized by the Medical Library Assistance Act. This national network of participating medical school and

hospital libraries provides rapid and efficient access to information to support health care delivery, education and research.

The impact of the Regional Medical Library (RML) Program on the users of health science information is measurable and dramatic. The program has been successful in bringing the tremendous volume of medical information closer to the health professional by improving local library collections, by facilitating and expanding online access to information, and by supplementing local services with the resources of major medical schools and the NLM. Libraries participating in the network provide nearly two million interlibrary loans of books and journal articles to health professionals. Approximately 85 percent of these are provided within four days of receipt of the request. A growing number of loans are being provided by hospital libraries, whose staff have received RML training on fundamental operation and administration of library services. Tools are now available in each region which identify journals held at major libraries so that requests for information can be routed most efficiently and can be filled close to the site of the requestor. The RML Program has increased local participation and decreased NLM's backstop role while filling more than 95 percent of all requests.

More than 500 hospitals and every medical school in the United States now have direct access to NLM's online network. There are more than 1,300 MEDLARS centers, with at least one in every state. Development of online centers is coordinated by the RML's which also assist in training new search analysts and updating their capabilities. Nearly two million computer searches are being performed annually for health professionals.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

CATALOGING BACKLOG

Question: The Director of NLM stated last year that the Library had a backlog of at least 15,000 books that had never been cataloged. There were to be no new positions in the NLM budget for FY 1981, and as a result it was estimated that the backlog would grow to over 25,000 volumes. During the past year has there been any improvement in your cataloging backlog?

Answer: The present cataloging backlog is approximately 18,500 items. This represents no significant change in the backlog. Several steps were taken to arrest further growth of the backlog.

The Library was able to contract for the cataloging of about 2,000 books in languages in which the Library lacked the expertise. We also established a program for a "limited cataloging" level for those items judged to be of more limited interest and value. This type of cataloging is being established under new cataloging rules and results in substantially increased productivity by catalogers. Moreover, "weeding" of the backlog resulted in the elimination of a number of items that were either out-of-scope or of too marginal interest to be included in the Library's collection.

Further improvement in reducing the backlog could have occurred had it been possible to fill existing vacancies. At all times there have been 2-3 cataloger vacancies. These have been difficult to fill because of the inability to locate qualified

individuals with language expertise such as Japanese, Russian, German, and Swedish.

Question: What is your present estimate of staff positions needed to deal with the backlog?

Answer: Because there has been a chronic level of about 3 cataloger vacancies, it would require at least six cataloging positions to provide enough catalogers with the requisite training, experience and language expertise to be able to reduce the backlog to a minimal level. The rate at which the backlog could be reduced would be affected by the ability to supplement the in-house limited cataloging by contract, by improved productivity resulting from automating some of these operations under MEDLARS III, and by increased cooperation with other national libraries to share descriptive cataloging and language expertise.

Question: The budget for 1982 does not recommend any new positions for the Library. How do you propose to cope with what is obviously a severe manpower need?

Answer: Federal hiring freezes and the difficulty of locating eligible people with needed cataloging and language expertise have hampered NLM's efforts to hire catalogers. For example, if NLM cannot hire six additional catalogers, staff devoted to other activities will have to be reassigned to cataloging. After a 4 to 6 months training period, these people will be able to assist significantly in the cataloging effort. However, important production activities in other areas will be affected adversely if existing staff is reallocated in this way.

ASSISTANCE TO HEALTH LIBRARIES

Question: Under the Medical Library Assistance Program, the budget proposed a decrease of 32 awards, for a total of 107 grants and contracts. Given the tremendous explosion in book and journal costs, how many of the 5,000 health libraries in the country need assistance under this program just to develop minimal collections?

Answer: Of the estimated 5,000 health libraries in the United States, about 2,000 are in need of assistance to develop an adequate information resource. A 1979 survey of health science libraries identified only 2,775 institutions which had libraries meeting the authors' minimum criteria of 25 serial or journal titles, 500 monographs or books and some staff.

The proposed FY 1982 Medical Library Assistance Act budget will result in a reduction of support to libraries by almost 10 percent from the 1981 funding level with particularly adverse impact on the creation of community library resource sharing consortia that are proving to be cost effective. Based on progress to date in meeting the need (200 institutions each year), the proposed budget reduction will lengthen the time required to provide the needed assistance from ten years to sixteen years.

The impact of inflation on the Medical Library Assistance Act budget each year (reducing real dollars by about two percent annually), coupled with the rapidly increasing costs of books and journals, makes the task all the more difficult. Journal costs have trebled in ten years, and book costs have doubled.

EFFECTS OF INFLATION

Question: Past budget increases for the Library have been very small. Acquisition of foreign materials cost over 40 percent more than it did a year ago. The inflation factor for most large research libraries runs approximately 20 percent a year. Will you give us a specific breakdown of where your budget will be hit hardest by the current inflationary economy we are experiencing?

Answer: Budget increases for acquisitions of library materials have exceeded those for total Library expenditures. During the period 1975 to 1980 the expenditures for literature rose from $723,000 to $1,650,000, an increase of 128 percent. This exceeds the national inflation rates for the same period. The recent increase in the strength of the dollar, particularly against the German mark and the Swiss france, should reduce the inflationary pressures in some foreign literature acquisitions substantially.

Question: If you had to cut back, where could you do it?

Answer: If budget cuts are necessary we would protect direct services to our nation's health professional community and sacrifice some elements of our extramural and intramural research and development programs.

National Institutes of Health

STATEMENT OF CALVIN B. BALDWIN, ASSOCIATE DIRECTOR FOR ADMINISTRATION

ACCOMPANIED BY:
DONALD S. FREDRICKSON, DIRECTOR
COLLEEN F. BARROS, BUDGET OFFICER
EDWIN D. BECKER, ASSOCIATE DIRECTOR FOR RESEARCH SERVICES
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator Eagleton. Our final witness is the Office of Director, Buildings and Facilities, Mr. Calvin Baldwin, Associate Director for Administration who will advise us of the activities of the Office of Director.

Mr. Baldwin. Thank you, Mr. Chairman.

Let me introduce two witnesses who have not been introduced to the committee before.

On my far left, Mrs. Colleen Barros, who is our Budget Officer; and on my left, Dr. Edwin Becker, who is the Associate Director for Research Services.

I have submitted my statement for the record, and if I may, I will give you a brief summary.

[The statement follows:]

STATEMENT OF CALVIN B. BALDWIN

I am pleased to have the opportunity to discuss with the Committee the Office of the Director of the National Institutes of Health and the Buildings and Facilities fund of the NIH.

Office of the Director

The appropriation to the Office of the Director provides for the central direction and administration of the National Institutes of Health, including some very essential support services. Since most components of the National Institutes of Health are located within the Bethesda, Maryland area, it is efficient and economical to provide management support and program services on a consolidated basis.

Specifically, this appropriation includes support for the Director, his immediate staff, and the offices responsible for equal employment opportunity, program planning and evaluation, medical applications of research, public and scientific communication, protection from research risks, and various management support activities, including budget, accounting, personnel, management analysis and review, and contracts and grants administration.

The appropriation for the Office of the Director is divided into two budget activities -- Program Management and Direct Operations.

Program Management: The Program Management activity funds the Immediate Office of the Director, including the principal associates of the Director and staff officers who provide policy advice and assistance to the Director in the administration and coordination of the intramural and extramural research programs of the Bureaus, Institutes and Divisions. The offices supported by the Program Management portion of the appropriation provide leadership in the implementation of Congressionally mandated programs, such as the dissemination of research information, Freedom of Information and Privacy Act requirements, as well as Executive Branch priorities in civil rights compliance and equal employment opportunity programs. Moreover, these offices undertake various initiatives which the Director deems necessary in carrying out the agency's prescribed mission. One such office is the Office for Medical Applications of Research which is responsible for establishing and conducting a process for public appraisal of preventive or treatment measures which are new or whose merit has been questioned. The process, called "consensus development", is an effective means for disseminating information on the clinical application of the results of biomedical research.

Direct Operations: The direct operations activity of this appropriation provides for the administration and operation of NIH accounting functions and certain personnel activities. The accounting functions supported include financial analysis and reporting, auditing and processing of vouchers, payment of invoices, and the settlement of claims. Personnel services include counseling, training, and a wide range of personnel services for over 11,000 employees.

The Office of the Director is operating at a level of $21,678,000 under the FY1981 Continuing Resolution.

Buildings and Facilities

The second appropriation for which I am testifying is the Buildings and Facilities appropriation which provides funds for the design, construction, and repair and improvement of buildings and supporting facilities for the National Institutes of Health.

Clinical Center Modernization: The Clinical Center, a 27-year old building, houses all the patient care and clinical research programs of the National Institutes of Health at Bethesda and some of the basic research programs. The modernization of this building began in 1979 and is required in order to bring it into compliance with modern fire and safety codes and to improve functional and environmental components. The program, involving more than 50 projects, is scheduled over 9 years so that clinical and basic research can remain operational during the entire modernization period.

Repairs and Improvements - Plant: This program is responsible for the 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. There is a recurring need to provide for the repair and upgrading of the physical plants.

Repairs and Improvements - Program: These repairs and improvements provide for the alterations directly related to program needs. 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

Biographical Sketch

NAME : Calvin B. Baldwin, Jr.

BIRTHPLACE AND DATE: Radford, Virginia; December 22, 1925

PRESENT POSITION AND TITLE : Associate Director for Administration, NIH

EDUCATION

June 1943	:	Bethesda-Chevy Chase High School, Bethesda, Md.
June 1949	:	University of North Carolina, Chapel Hill, N.C.--A.B.
1949-1951	:	University of North Carolina, Chapel Hill, N.C.
1952-1953	:	American University, Washington, D.C.
1960-1961	:	Harvard University, Cambridge, Mass.--M.P.A.

EXPERIENCE

1980-Present	:	Associate Director for Administration, NIH
1970-1980	:	Executive Officer, National Cancer Institute, NIH
1963-1970	:	Executive Officer, National Institute of Child Health and Human Development, NIH
1962-1963	:	Assistant Chief, Grants Management Branch, Division of Research Grants, NIH
1961-1962	:	Executive Officer, Division of General Medical Sciences, NIH
1958-1961	:	Administrative Officer, Division of General Medical Sciences, NIH
1957-1958	:	Administrative Officer, Division of Research Services, NIH
1955-1957	:	Budget Examiner, Office of the Director, National Institutes of Health
1953-1955	:	Organization and Methods Examiner, National Institutes of Health, PHS, DHEW, Bethesda, Md.
9/52-2/53	:	Civil Service Intern, Federal Security Agency, PHS
1951-1953	:	Methods Examiner, Federal Security Agency, Public Health Service, Washington, D.C.
1949-1950	:	Research Assistant, Institute of Research in Social Science, Chapel Hill, N.C.

MILITARY SERVICE

1944-1946	:	Corporal, United States Army

HONORS AND OTHER SPECIAL RECOGNITION

: Phi Beta Kappa
: W.A. Jump Meritorious Award, 1960
: DHEW Superior Service Award, 1973

OVERVIEW

Mr. BALDWIN. My testimony will complete your hearings on NIH and will cover two appropriations which are in support of the NIH program.

First is the appropriation for the Office of the Director, which includes the Director and his immediate staff, who assist him in the administration and coordination of intramural and extramural programs of NIH.

This appropriation also provides for management support activities, such as budget, accounting, personnel, and contract administration.

The second appropriation for which I am testifying is buildings and facilities. This appropriation provides funds for the design, construction, repair, and improvement of the NIH physical plant.

For example, we are in the process of modernizing our Clinical Center, which is 27 years old, and which houses all of the patient care and clinical research programs of the NIH at Bethesda, as well as some basic research programs.

Also, funds are provided in this appropriation for the major repairs and improvements of the physical plants at Bethesda, our Poolesville, Md. animal farm, the Gerontology Research Center in Baltimore, and the facilities of the National Institute of Environmental Health Sciences at North Carolina.

RENTAL BUILDINGS

Senator EAGLETON. What relationships, if any, does your function and duties have with GSA?

Mr. BALDWIN. We have rental buildings in various parts of suburban Montgomery County and we rent these buildings through GSA. Otherwise, we control our own buildings, sir.

Senator EAGLETON. I don't know how to ask this question, but—well, I will ask in terms of personnel.

What percentage of NIH personnel is off campus in rental properties in the greater Wasington area vis-a-vis on campus in Bethesda?

Mr. BALDWIN. I would estimate that, of our 11,000 employees, between 3,000 and 4,000 are off campus, and about 2,500 are in rental buildings.

To conclude my summary statement, I would say that some of the Bethesda campus buildings, such as a number of the laboratories, are 40 years old and require major repairs and improvements. That is what part of the budget goes for. Thank you very much, Mr. Chairman.

GROWTH POTENTIAL

Senator EAGLETON. How much growth room have you got out there on the campus, Dr. Fredrickson or Mr. Baldwin?

Dr. FREDRICKSON. I would say that the National Capital Parks and Planning ceiling on the campus is something on the order of 15,000 employees. We are considerably below that, but that is a rather abstract ceiling. We could accommodate perhaps one or two major laboratory buildings, but we do not have enough room, for example, to bring on campus the population from Westwood and other rental buildings, where we have a very large concentration of our extramural employees, about 2,300 people.

Senator EAGLETON. Is it a continuing prestige problem?

Dr. FREDRICKSON. It is a prestige problem, and a logistics problem, too. It is an inefficient system. If we had a consolidated office facility where we could consolidate the people from other buildings, I think we could overcome both serious logistics problems and prestige issues that do arise occasionally.

CAPITAL IMPROVEMENTS

Senator EAGLETON. Mr. Baldwin, in terms of your budget for fiscal year 1982, what are—give me the top three capital improvement items by your reckoning or by your opinion.

Mr. BALDWIN. May I ask Dr. Becker to respond to that.

Senator EAGLETON. Surely.

Dr. BECKER. The major item is the renovation and improvement of the Clinical Center. As Mr. Baldwin pointed out, this is over 25 years old and badly in need of renovation and improvement. There is a multiyear program which was begun last year with the support of Congress to provide approximately $7 million each year for a number of years in order to bring this up to what is regarded as the current standards for a research hospital.

Senator EAGLETON. How many years—at $7 million a year, how many years?

Dr. BECKER. It will be about 8 or 9 years before that project is completed. We cannot do it more rapidly even if the money were available, because——

Senator EAGLETON. Because of the disruptive nature?

Dr. BECKER. Correct.

The other items are in our repair and improvement projects, and these are generally small items, small projects, which can't be predicted very far in advance. So we can't come in for appropriation for a specific item. It may be only $100,000 or so. These things come up with relatively short leadtime—repairs, equipment, maintaining the roads and so on. Those are the items that are in the budget request for fiscal year 1982.

Senator EAGLETON. You have no major—beyond those $7 million a year you have no major capital improvements?

Dr. BECKER. There is a program which was begun last year to renovate a number of the older buildings. We have six laboratory buildings at NIH which are nearly 40 years old. Congress appropriated $1.5 million for fiscal year 1981 in order to plan for the expansion and renovation of one building, which we can relatively easily empty. And the object is then to improve that and move people from the next building and so on.

There is no money requested in the fiscal year 1982 budget for that project, but it is intended as a multiyear project.

Senator EAGLETON. Thank you very much, Mr. Baldwin. Dr. Fredrickson, thank you.

As usual, you and your associates have been excellent witnesses and we appreciate your appearance before us.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

INCREASE REQUESTED

Question: The Carter budget requests an increase of $958,000 for the operations of the Office of the Director. What is the reason for this increase?

Answer: Approximately forty percent of the increase is requested to support personnel services expenses, such as within-grade pay increases and annualization of the October 1980 pay raise. Another thirty-three percent is requested to meet anticipated costs under the Service and Supply Fund and to cover the Office of the Director's portion of the overall payment for centrally furnished services. The remaining amount is needed to offset increases for services under the Federal Telecommunications System and increases associated with the cost of travel, training and contractual services. An amount of $40,000 is included for equipment which the Department is purchasing to establish and operate a new centralized personnel tracking system (SYCOR).

Question: Why was it necessary for the Office for Protection from Research Risks to move into what appears to be a computerized operation for keeping track of human research subjects? How much will this cost when completed?

Answer: The Office for Protection from Research Risks (OPRR) is not establishing ". . . a computerized operation for keeping track of human research subjects." In fact, OPRR maintains no records, computerized or not, of identities of individuals who are subjects of research. OPRR does, however, maintain records on institutions conducting HHS-funded research involving human subjects. These records provide information enabling OPRR to determine that these institutions have submitted written assurances to the Department that HHS funds will be used only in accord with HHS policy for protecting the rights and welfare of human research subjects and that the institutions have established procedures that are in compliance with that policy.

The records, which contain institutional assurances and the names and titles of institutional officials responsible for the implementation of human subject protections, are now being converted to a computerized format. The new format is designed to allow cross-referencing with other NIH records--primarily the Information for Management Planning Analysis and Coordination (IMPAC) system for records maintained by the Division of Research Grants (DRG). The conversion will assist OPRR to carry out its oversight responsibility by facilitating access to the records containing information on whether institutions are (or are not) providing required human subject safeguards. Further, the computerization, along with the cross-referencing capability, will avoid the need for obtaining duplicate information already maintained by DRG.

The conversion to computer-compatible record keeping is now approximately halfway to completion. The total computer costs of the conversion are not expected to exceed $10,000, and thereafter yearly costs should also not exceed that amount. The conversion will allow access to the same information far more quickly than before. Furthermore, maintenance and operation of these records will require only two persons rather than the three previously required.

Question: If you were asked to reduce your spending level, what areas could you recommend for cuts?

Answer: The recommendation would depend on the size of the reduction under consideration. Expenses incurred by the Office of the Director are for personnel and the operating costs needed to support personnel in the performance of their duties. It is possible that a modest reduction in the level of spending could be accomplished through cutbacks to operating monies, such as travel, training, equipment rental, etc., without necessitating a simultaneous reduction in personnel. However, a reduction of more significant proportions would entail cutbacks to both personnel and support costs.

CLINICAL INVESTIGATORS

Question: late last year the Committee urged the Director to establish an NIH-wide program on clinical investigation training to redress the shortage of clinical investigators. What have you done in response to the Committee's request?

Answer: An NIH report on this subject has been prepared for the Committee. The report, "Assuring the Supply of Clinical Investigators," summarizes the activities of the NIH Coordination Committee on Manpower, with respect to the examination of all programs for research manpower development and the establishment of modifications and innovations to assure an adequate supply of clinical investigators.

Question: How bad is the shortage of clinical investigators?

Answer: The NIH observed the decline in absolute numbers of postdoctoral fellows holding clinical degrees until 1976. In 1970, of 7,246 postdoctoral fellows, 4,659 held clinical degrees; in 1975, the number of postdoctoral fellows had decreased to 5,680 with 2,698 holding doctoral degrees. In 1976, there were 1,950 clinical postdoctoral fellows in training, a pool that has remained relatively constant in number since that time. Therefore, although the percentage of individuals in clinical postdoctoral training continues to show a modest decline, the absolute numbers of clinical postdoctoral fellows has remained relatively constant since 1976 at an average of 1,900 per year. In addition, the NIH Advanced Development Programs continue to attract physicians into research careers.

BROADENING ADVISORY GROUPS

Question: Late last year the Committee renewed its request to NIH to provide more slots for nurses and other health professionals on various advisory boards, peer review groups and study sections. What have you done in response to the Committee's request?

Answer: The steps the NIH has taken to broaden membership on various advisory boards, peer review groups and study sections are outlined in a report of February 1981, to the Senate Committee on Appropriations. That report, "NIH Advisory Boards, Peer Review Groups, and Study Sections" reads, on page 3, as follows:

SOURCES OF MEMBERSHIP

Decisions regarding the types of expertise needed to fulfill the review and advisory functions of each committee are made by the Director of the NIH component using the committee in consultation with the Committee's executive secretary. Appropriate nominees are then identified by NIH staff through such means as contacts with former committee members and scientific colleagues; professional societies, foundations, and associations (for example, the Arthritis Foundation, the Council of Primary Health Care Practitioners, the American Society of Respiratory Therapists, the American Black Nurses Association, and the American Association of Hospital Pharmacists); and the recently established NIH Consultant File. The computerized Consultant File is a compilation of names of people who responded to announcements published by the NIH in the NIH Guide to Grants and Contracts, the Federal Register, and widely read scientific journals. The announcements requested names of individuals who wished to be considered for membership on NIH committees and for other peer review activities. The Consultant File, to be expanded and updated periodically, may be searched by field of expertise, name, geographic area, or female or minority status. It currently contains some 8,000 names. Curricula vitae and bibliographies are also available.

ALLIED HEALTH PROFESSIONALS

Allied health professionals play an important role in the NIH review and advisory process. We believe that this field is well represented: 24% of the membership on NIH advisory councils and boards, and about 12.5% of the total 2007 current members on all NIH public advisory committees. As vacancies occur and as needs for advice evolve, the NIH will continue to call upon allied health experts to meet the obligations of committees at both the initial review and the council levels. These individuals round out the perspectives of the wide range of experts needed to carefully assess the merit of research grant applications and contract proposals and to provide advice on program and policy issues.

BUILDINGS AND FACILITIES

Question: You are requesting $6.7 million for renovations to the Clinical Center at NIH. How much of this amount pertains to meeting life safety code requirements and how much falls into the general area of cosmetic improvement?

Answer: About 75% of the FY 1982 Clinical Center Modernization program involves life safety work and the remainder is work to correct functional obsolescence. In the process of altering and/or replacing work now in place to achieve the above objectives, some cosmetic improvements will result.

Question: What accounts for the $1.7 million decrease from the Fiscal 1981 Level?

Answer: A portion of the decrease is attributable to the smaller amount requested this year for Clinical Center modernization ($0.27 million below that in FY 1981). The principal decrease results from

the fact that this year no funds are requested for the nine-year project to renovate six of the older laboratory buildings. Last year $1.5 million was appropriated for the initial phase--moving occupants from Building 8 and design of renovations for that building.

Question: Why are you requesting an extra $330,000 in Fiscal 1982 for Repairs and Improvements?

Answer: The increase of $330,000 in Fiscal 1982 for Repairs and Improvements reflects a ten percent increase over the 1981 level. Funding in the amount of $3,250,000 has been appropriated for this account for the past four years (FY 1978 through FY 1981). In this four-year period, the Engineering News Record Construction Cost index has increased 31 percent.

SUBCOMMITTEE RECESS

Senator EAGLETON. The subcommittee will stand in recess until 2 p.m. today when we will meet again in this room and hear budget requests for the Alcohol, Drug Abuse, and Mental Health Administration.

[Whereupon, at 12:20 p.m., Thursday, February 19, the subcommittee was recessed, to reconvene at 2 p.m. this same day.]

(AFTERNOON SESSION, 2:05 P.M., THURSDAY, FEBRUARY 19, 1981)

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF ROBERT L. TRACHTENBERG, ACTING ADMINISTRATOR

ACCOMPANIED BY:

JOHN R. DE LUCA, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
WILLIAM POLLIN, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE
HERBERT PARDES, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH
KENT L. AUGUSTSON, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT
ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

SUBCOMMITTEE PROCEDURE

Senator RUDMAN [presiding]. Good afternoon. We are going to hear this afternoon from Robert Trachtenberg, who is the Acting Administrator for the Alcohol, Drug Abuse, and Mental Health Administration and, I also believe, Aaron Liberman, Associate Superintendent of St. Elizabeths.

I want to welcome you all here. You all look remarkably well. Nobody looks too shellshocked after last night.

I would like to invite you or anyone in the hearing room who wishes to remove their jacket and be more comfortable to feel free to do so. I expect I might well do that before too long myself, so if anyone here cares to, feel free to.

I wonder, if you might, Mr. Trachtenberg, introduce the members of your panel to us this afternoon?

PREPARED STATEMENT

Your prepared statement will be inserted in the record at this point.

[The statement follows:]

STATEMENT OF ROBERT L. TRACHTENBERG

It is a pleasure for me to have the opportunity to appear before this Subcommittee, pending appointment of a new agency Administrator, to discuss the programs of the Alcohol, Drug Abuse, and Mental Health Administration. The Directors of the three Institutes which comprise our agency are with me to participate in answering the Committee's questions.

Mr. Chairman, let me state at the outset, that we are very optimistic regarding the significant progress we have made in efforts to understand and treat alcoholism, drug abuse, and mental illness. These problems today place an immense human and dollar burden on the people of our country. To cite only a few statistics on the extent of these problems:

- Some 10 million adult Americans are estimated to suffer from alcoholism. More than 3 million young people also experience alcohol problems. In one survey of 10th-12th graders, 31 percent reported being drunk at least 6 times a year. Unfortunately, only 15 percent of those who need help with alcohol problems are receiving adequate care.
- We believe there are up to 450,000 heroin users in the U.S. Other drug abuse problems also continue: Some 23 million of our citizens are marijuana users, and approximately 15 million report having tried cocaine.
- Mental disorders will affect 15 percent of the U.S. population --or 34 million persons--during the course of a year. While we are making advances, there are still more patients in hospitals receiving treatment for mental problems than for any other illness.

As the Committee can realize, in financial terms such problems collectively exert a tremendous drain on the Nation's economy annually. The cost to society of alcohol, drug abuse, and mental health (ADM) disorders has been documented by many major studies and was estimated at over $120 billion in 1977. Alcohol abuse accounted for about $53 billion; drug abuse, about $15 billion; and mental illness, about $53 billion. These are conservative estimates of measurable economic costs only. About $85 billion of the total cost is due to lost productivity resulting from premature mortality, excess morbidity, and reduced job efficiency.

Industry spokesmen agree that ADM disorders cost American industry billions of dollars each year. General Motors, for example, announced recently that absenteeism costs that company alone more than one billion dollars per year, of which ADM costs are a major portion, adding hundreds of dollars to the cost of producing each automobile. ADM problems are also a major problem in the military. A recent Department of Defense study found that 21 percent of personnel studied reported significantly impaired work performance from drug use; almost half of that 21 percent reported serious work impairment of 40 or more days in a single year.

Notwithstanding the size and scope of the problems, our progress to date encourages us to believe that ADAMHA programs can continue to help reduce the cost in human suffering as well as the economic consequences associated with these disorders. The contributions that ADAMHA funded research has made to our understanding of the causes, treatment, and prevention of ADM disorders have been and promise to continue to be substantial. ADAMHA funds about 80 percent of all the ADM research in the Nation, including problems in such key areas as schizophrenia, depression, alcoholism and drug abuse. This research has led to major biomedical and behavioral treatment interventions. For example, scientists at the National Institute on

Alcohol Abuse and Alcoholism recently developed a new method which appears capable of identifying alcoholism early in its development on the basis of statistical comparisons of blood samples. Grantees of the National Institute on Drug Abuse have continued their pioneering investigations of endorphins, which are naturally occuring opiate-like chemicals in the brain. This research may make possible someday the development of a Salk-like vaccine for the treatment and prevention of drug abuse. Other investigators working with support from the National Institute on Drug Abuse have developed, and are now field testing, a kit for measuring marijuana metabolites in urine. This may make it possible to detect whether a person is driving under the influence of this drug.

Dramatic advances also have been made in "mapping" brain functions. By using a new technique developed by the National Institute of Mental Health, scientists have been able to trace metabolism of deoxyglucose inside the brain. This is a giant step forward in that it appears to have enormous potential for assessing the effects of various treatment agents. This would lay the groundwork for reducing the number of people affected by major mental illnessess such as depression and schizophrenia.

Newly developed treatment techniques have allowed a reduction in the size of the population institutionalized because of such disorders in the United States from close to 600,000 in 1955 to approximately 150,000 in 1981. American corporations have utilized knowledge from ADM research in their development of occupational alcoholism programs. In the past ten years, the number of major American corporations with such programs has risen from a little more than 20 percent of the Fortune 500 corporations to well over 50 percent in 1979.

Our ability to provide effective treatment for alcohol, drug abuse, and mental health problems, depends heavily upon a steady flow of new knowledge, their causes, and the best possible therapeutic approaches. In terms of both economics and ultimate results, we believe that a strong research program is the best investment that can be made in promoting our primary goals.

In other areas, our treatment programs are now providing services to over 4 million persons throughout the nation. We have established valuable management linkages with the States first through our State-wide service grants in drug abuse, and, more recently, with the alcoholism services development program, which is developing as the conduit for our alcoholism treatment funds.

In mental health, we have been in the process of implementing the newly enacted Mental Health Systems Act, which promotes increased ties with State and local agencies as well as improves our general responsiveness to the mental health service needs of the nation. This new services program emphasizes provision of community mental health services which are truly comprehensive, organized to achieve maximum flexibility and accountability, and fully coordinated with local health and related social support services. Priority target populations are the chronically mentally ill, the elderly, severely mentally disturbed children and adolescents, and other underserved segments of our population. The goal of better mental health care for these groups is achieved through several targeted funding mechanisms, and through continued support for general mental health treatment programs in communities. Pilot programs addressing needs of the chronically mentally ill have been very successful, and the fact that a number of States have invested many times the federal contribution reinforces our belief that real benefits can be gained from this program.

My last area of emphasis is the alcoholism service initiative launched in 1980. The initiative, based on recommendations of a

special task force conducted by the Department, has focused on six areas of special need: women, youth, domestic violence, the fetal alcohol syndrome, occupational alcoholism programs and the Department's Employee Assistance Program. Considering the pervasive problem of alcohol abuse in our society and the past relative lack of federal resources devoted to this problem, we believe that a targeted effort such as this is the best way to address it. All indices of disease incidence and cost versus resources expended addressing it indicate that alcoholism is the most neglected disease in our society.

Finally, Mr. Chairman, I would like to turn to our role in developing and promulgating regulations, an area that I understand is of special interest to the Committee. ADAMHA is not a regulatory agency, per se. Most regulations developed by the agency are required to clarify and implement our grant and contract programs, as required by authorizing legislation or the Adminstrative Procedure Act. Our responsiblilities in this area are to develop the implementing regulations consistent with Administration policy and the intent of Congress, request and analyze public input, and publish the final regulations in the Federal Register and the Code of Federal Regulations.

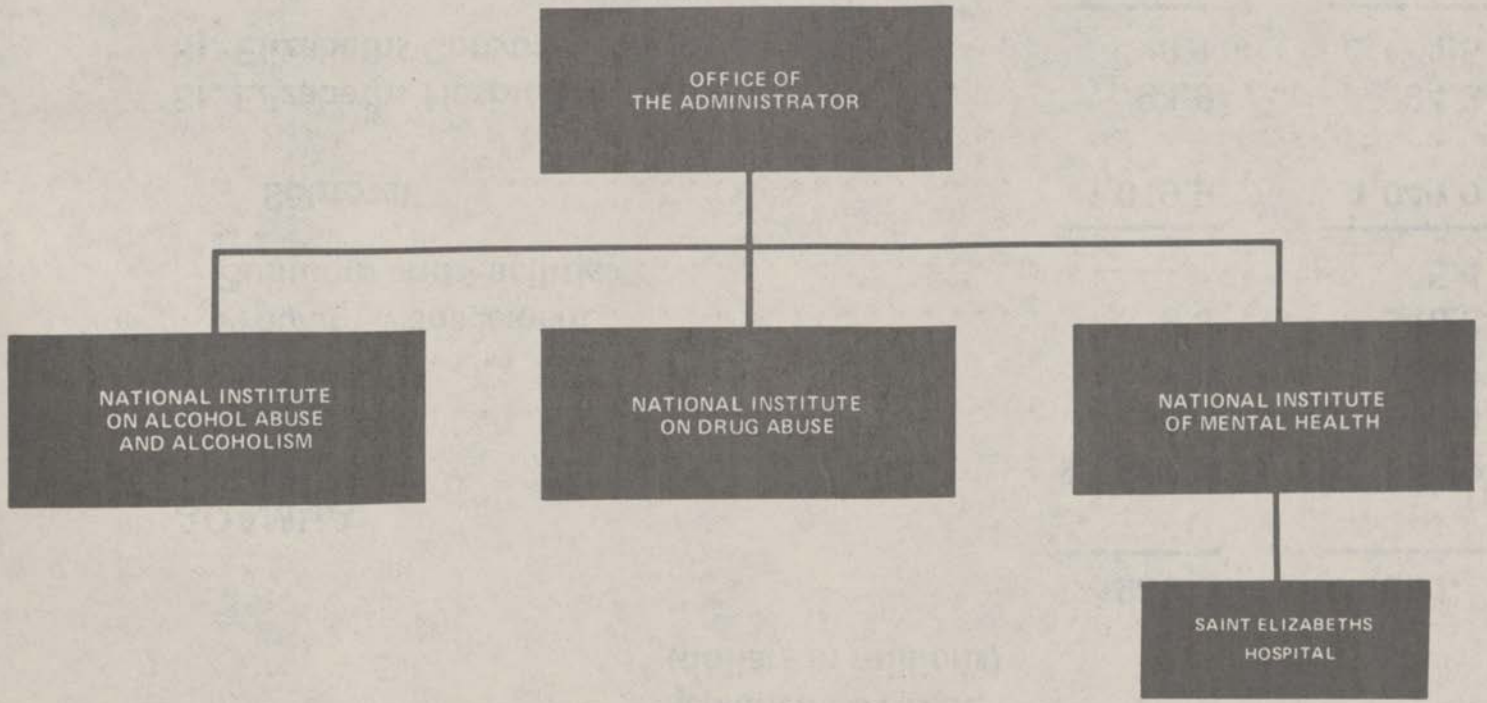
As a rule, ADAMHA regulations do not impact upon the general public. They have the most direct application for agency grantees and contractors, and comments on proposed regulations are received primarily from current or prospective funding recipients. Enforcement of grant guidelines and regulations is part of the ongoing program management carried out by project and grants management officers on a day-to-day basis. The character of this enforcement is to assure that grantees are expending Federal funds in conformance with the purpose for which they were appropriated.

Only one set of our regulations impacts upon programs other than those directly supported by the agency. Patient confidentiality regulations restrict disclosure and use of alcohol, and drug abuse patient records maintained in connection with treatment programs which receive Federal funds directly or indirectly. With respect to both these as well as other ADAMHA regulations, the additional cost they impose upon the private sector is minimal.

ADAMHA will spend approximately $344,000 in 1981 to develop program regulations. These figures represent the cost of devoting 9.4 workyears of effort to assuring that regulations are in place for all programs, especially those newly authorized by the Mental Health Systems Act. ADAMHA's responsibility for promulgating regulations is limited to providing printing and publication costs, estimated to be $115,000 in 1981.

We would be pleased to answer any of the questions the Committee may have.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION



ADAMHA BUDGET
(dollars in millions)

	1980	1981
ADAMHA:		
NIMH	$ 564.3	$ 606.2
NIDA	272.8	265.4
NIAAA	173.0	161.2
Program Management	9.8	10.8
Buildings and Facilities	---	5.4
Subtotal	1,019.9	1,049.0
St. Elizabeths Hospital	91.9	94.3
St. Elizabeths Construction & Renovation	8.1	1.5
TOTAL	$1,119.9	$1,144.8

ADAMHA BUDGETED POSITIONS

	1980	1981
NIMH:		
Intramural Research	432	432
Program Support	689	689
Subtotal	1,121	1,121
NIDA:		
Intramural Research	81	81
Program Support	303	303
Subtotal	384	384
NIAAA:		
Intramural Research	36	36
Program Support	155	155
Subtotal	191	191
Program Management	224	224
Subtotal	1,920	1,920
St. Elizabeths Hospital	4,252	4,113
TOTAL	6,172	6,033

Saint Elizabeths Hospital
Treatment Programs

NUMBER OF PATIENTS TREATED OR OUTPLACED (1981):

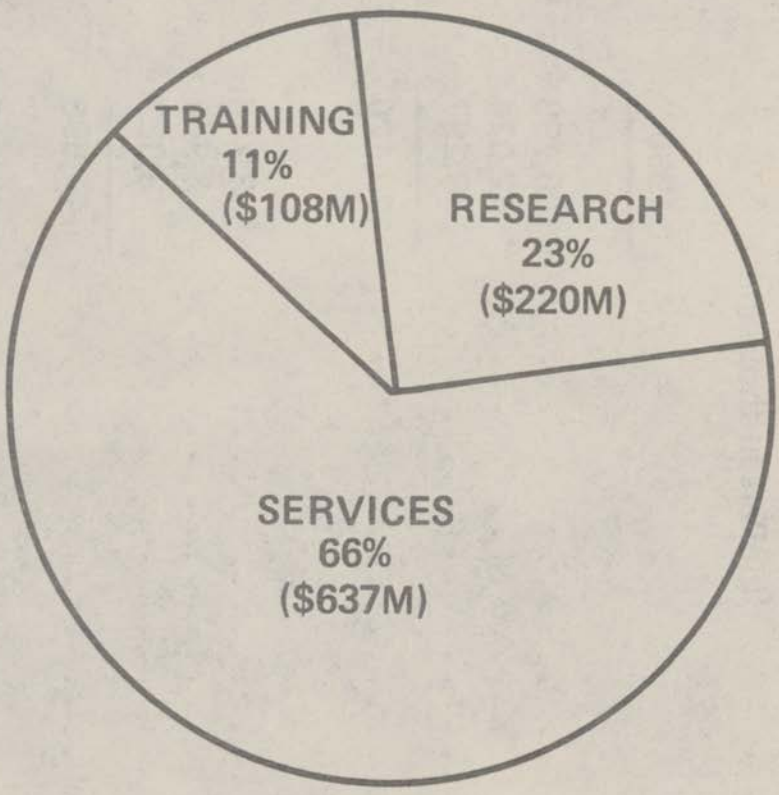
INPATIENT (Average Daily Patient Load)	OUTPATIENT (Average Daily Patient Load)	DAY CARE	OUTPLACED
2,050	3,200	275	250

796

INPATIENT DISTRIBUTION:

D.C. RESIDENTS	1,734	(85%)
FEDERAL BENEFICIARIES:		
D.C. NONRESIDENTS	185	
U.S. NATIONALS/PRISONERS	16	
OTHER	115	
TOTAL	2,050	

ADAMHA Program Distribution of Obligations

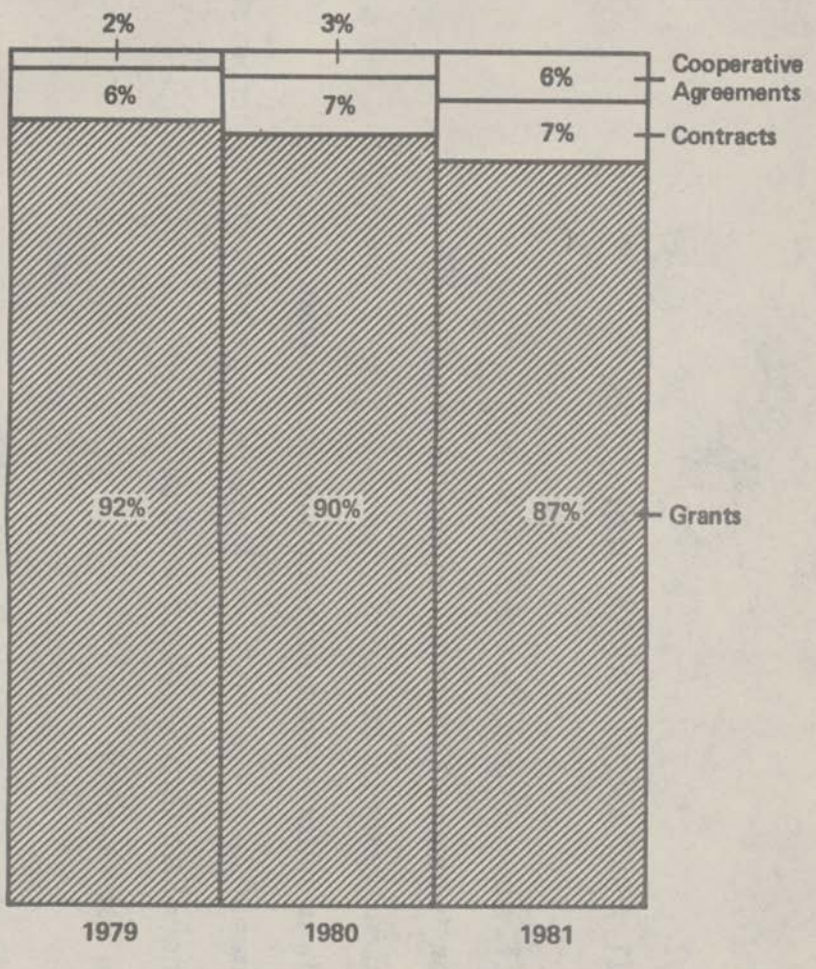


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ADAMHA Research Programs
(dollars in thousands)

	1980	1981
Extramural:		
NIMH	$109,799	$113,287
NIDA	42,024	41,737
NIAAA	18,297	18,234
Subtotal	170,120	173,258
Intramural:		
NIMH	33,716	37,771
NIDA	3,948	4,263
NIAAA	3,932	3,415
Subtotal	41,596	45,449
TOTAL	$211,716	$218,707

ADAMHA Extramural Research Funding Mechanisms



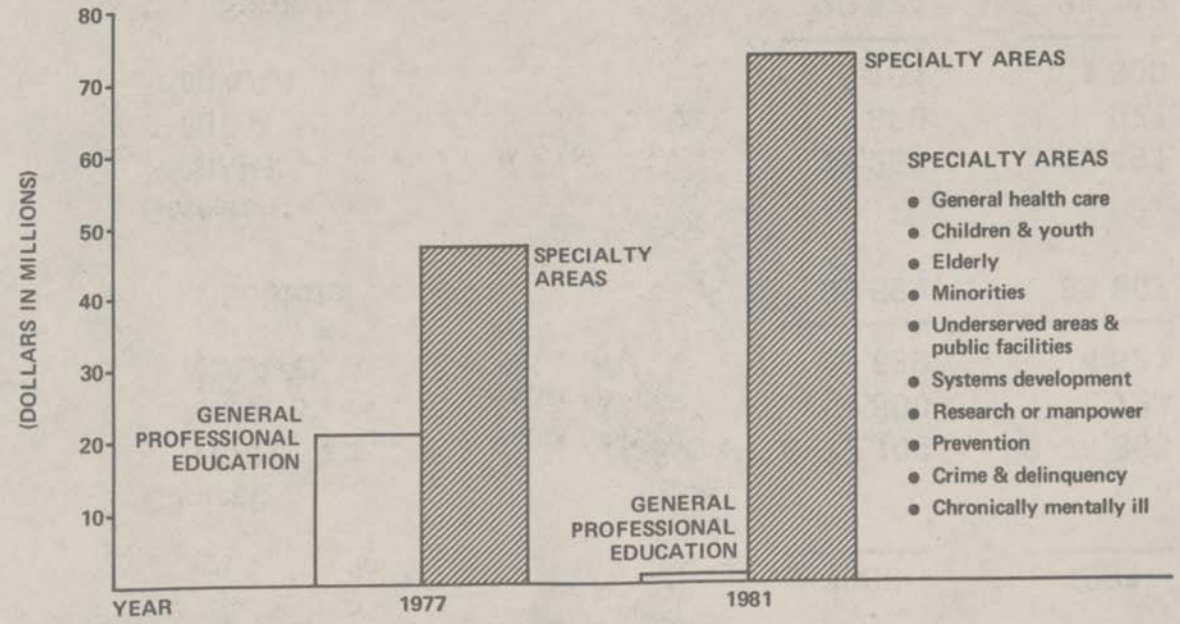
RECENT RESEARCH BREAKTHROUGHS

- Development of P.E.T. scanner; first "psychiatric x-ray"
- A new medication for "treatment resistant" manic-depression
- Replacement of damaged brain tissue
- Discovery of endorphins, naturally occurring opiate-like substances
- Development of buprenorphine — a less toxic, longer acting treatment for heroin abuse
- Early diagnosis of alcoholism through blood samples
- Alcoholism and brain deterioration

ADAMHA TRAINING PROGRAMS
(dollars in thousands)

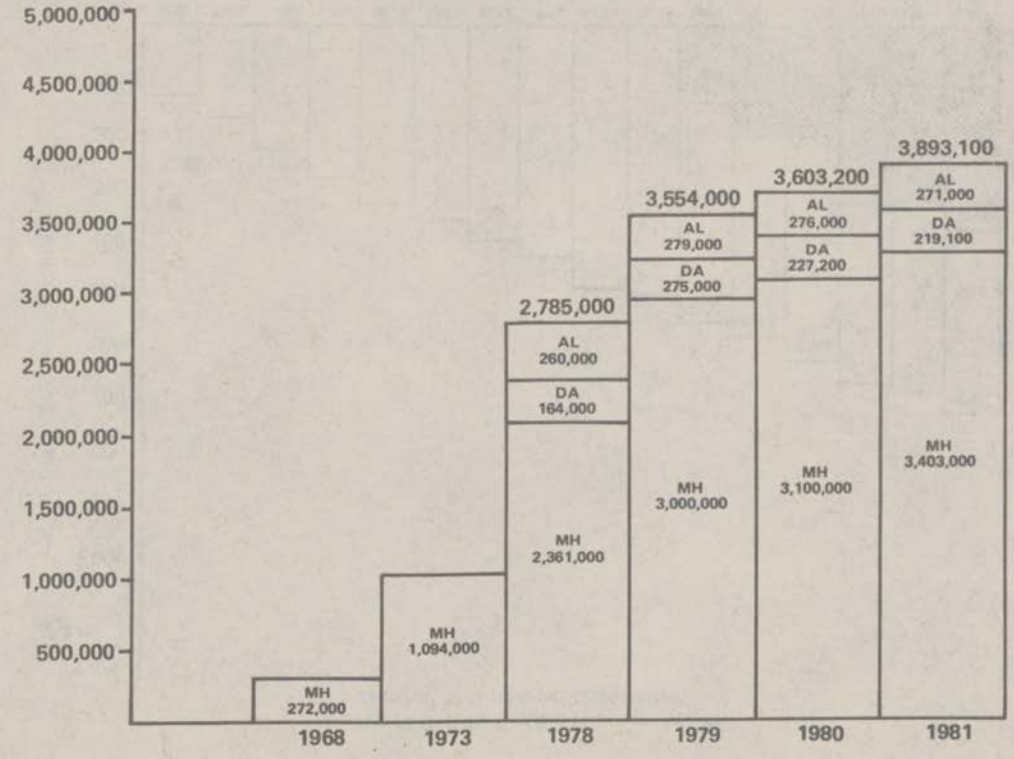
	1980	1981
Clinical:		
NIMH	$ 72,103	$ 74,363
NIDA	7,800	6,723
NIAAA	5,689	4,521
Subtotal	85,592	85,607
Research:		
NIMH	18,253	19,491
NIDA	880	921
NIAAA	1,191	1,300
Subtotal	20,324	21,712
TOTAL	$105,916	$107,319

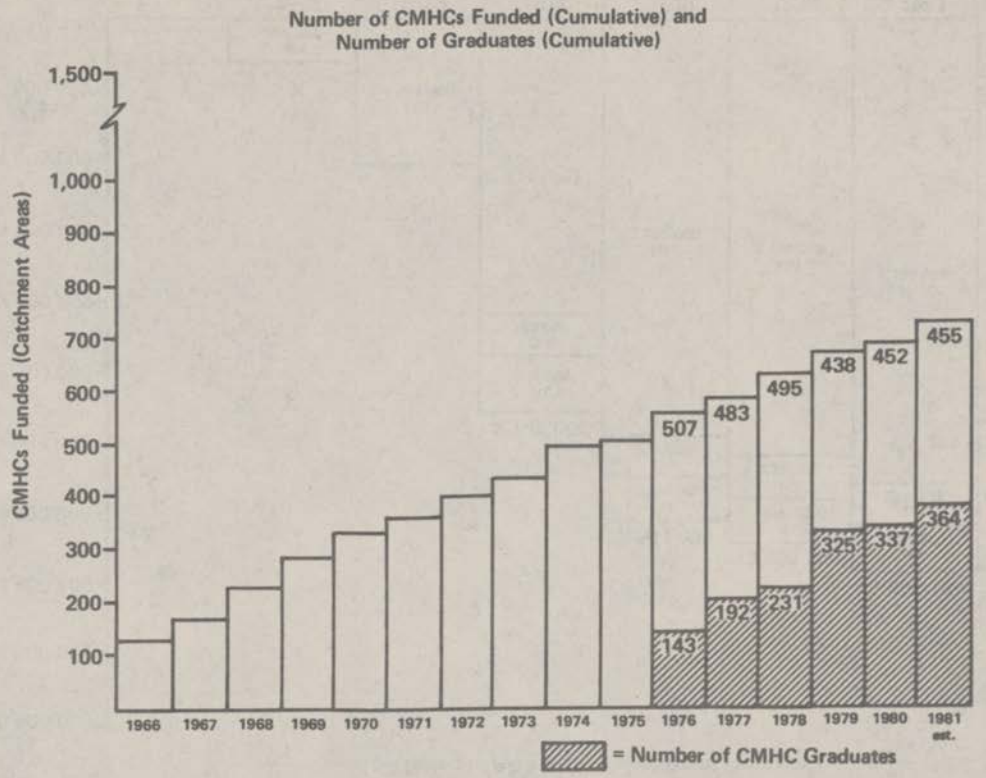
Estimated Distribution of NIMH Clinical
Training Funds by Priority Area
FY 1977 and FY 1981



FY 1977 TOTAL: $67,582,000
FY 1981 TOTAL: $74,363,000

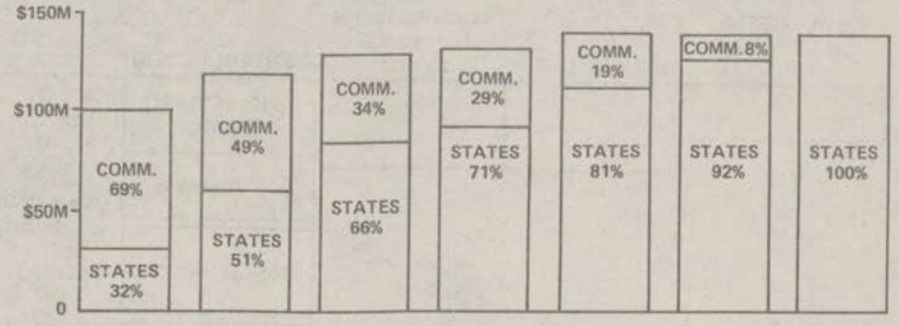
Patients Treated in ADAMHA Project Grant Programs



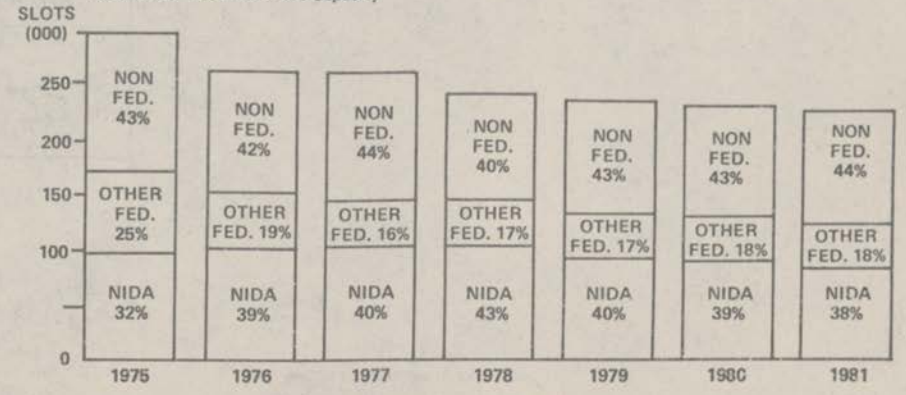

Number of CMHCs Funded (Cumulative) and
Number of Graduates (Cumulative)
CMHCs Funded (Catchment Areas)
1,500
1,000
900
800
700
600
500
400
300
200
100
1966
1967
1968
1969
1970
1971
1972
1973
1974
1975
1976
1977
1978
1979
1980
1981
est.
507
483
495
438
452
455
143
192
231
325
337
364
= Number of CMHC Graduates

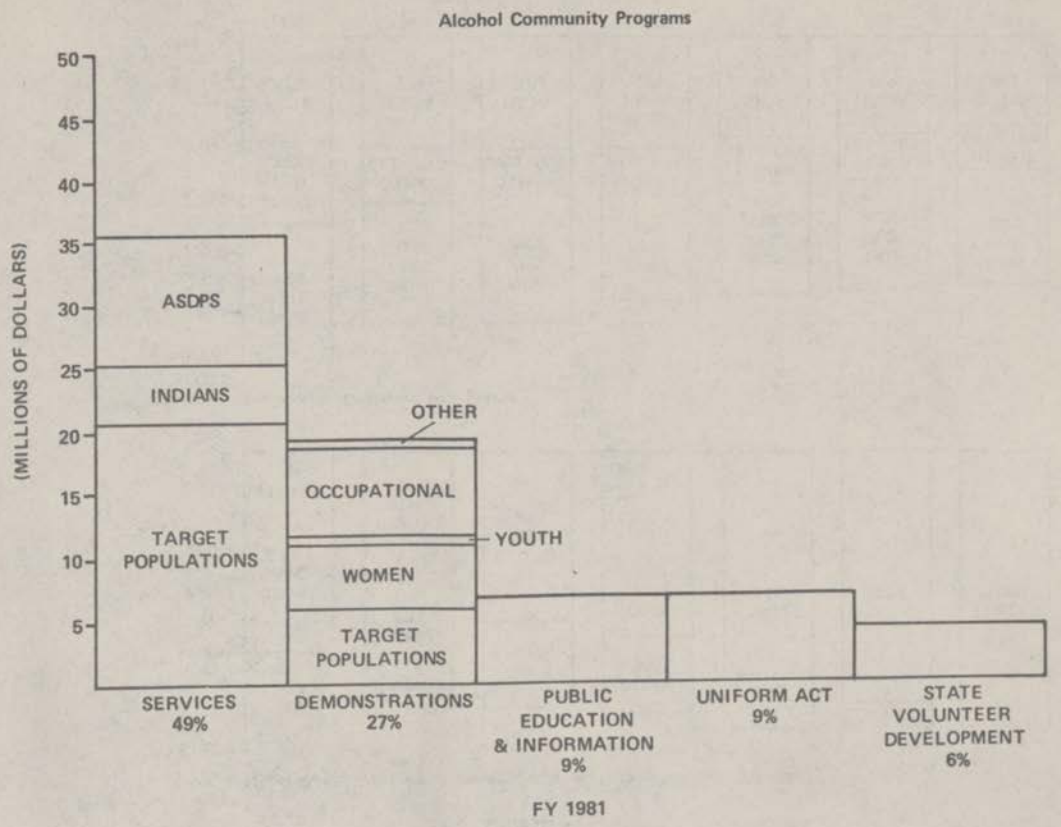
Drug Abuse Treatment Network

NIDA Direct Treatment Funding: States vs. Communities



Nationwide Treatment Slot Capacity




Alcohol Community Programs
(MILLIONS OF DOLLARS)
50
45
40
35
30
25
20
15
10
5
ASDPS
INDIANS
TARGET POPULATIONS
OTHER
OCCUPATIONAL
YOUTH
WOMEN
TARGET POPULATIONS
SERVICES 49%
DEMONSTRATIONS 27%
PUBLIC EDUCATION & INFORMATION 9%
UNIFORM ACT 9%
STATE VOLUNTEER DEVELOPMENT 6%
FY 1981

BIOGRAPHICAL SKETCH

ROBERT LAWRENCE TRACHTENBERG

2704 Bellmawr Court
Wheaton, Maryland 20906
301-460-3434

Business Phone: 301-443-4795

Date of Birth: February 17, 1937
Place of Birth: Brooklyn, New York

Married - 4 children

Fairleigh Dickinson University - 1957 - B.A.
New York Law School - LLB - 1959 (Law Review)
Admitted to practice in New York and D.C.

5/1/79 to Present - Deputy Administrator, Alcohol, Drug Abuse and Mental Health Administration, Public Health Service, HHS. As Deputy Administrator, shares with the Administrator the responsibility for planning, managing, and providing the overall direction necessary for effective accomplishment of ADAMHA programs and activities. Particular focus on development of management accountability systems and the setting of priorities for expenditure of $1.2 billion annual budget.

1/75 - 5/79 - Associate Commissioner for Hearings and Appeals and Chairman of the Appeals Council for the Social Security Administration. Directed a 4,500 person organization. Was responsible for providing program and management direction over a decentralized hearings program and centralized appellate system. Employed over 650 administrative law judges. OHA is one of the largest systems of administrative justice in the Federal Government.

9/73 - 1/75 - Deputy Assistant Secretary for Grants and Procurement Management in the Office of the Secretary, Department of Health, Education, and Welfare. Developed, promulgated and enforced all procurement and grant regulations and policy for DHEW, including cost policy and minority business. Also monitored and evaluated performance of the more than 200 grant and procurement offices within the Department.

8/67 - 9/73 - Office of Economic Opportunity, Deputy General Counsel. Served in a variety of positions in the General Counsel's office, culminating with Deputy General Counsel. Specialized in procurement and grant law with all facets of legal and business management, including supervision of OEO's investigative operations.

7/60 - 8/67 - Department of the Army. Served in various positions in the Department of the Army, including 4-1/2 years in the Judge Advocate General's Corps and the rest as a civilian trial attorney. Specialized in government procurement law and business and administrative law matters.

AWARDS:

Recognition Award, William A. Jump Foundation	1974
Secretary's Citation, HEW	1975
Commissioner's Citation, Social Security Administration	1976
Secretary's Citation, HEW	1977
Commissioner's Citation, Social Security Adminstration	1978
Member, Administrative Conference of the United States	1975-1979
Senior Executive of Meritorious Rank Awarded by President	1980

INTRODUCTION OF ASSOCIATES

Mr. TRACHTENBERG. I'd be pleased, Mr. Chairman. To my far right is Mr. Tony Itteilag, who is the Department's Budget Officer and whom you probably have seen a number of times already here today.

Senator RUDMAN. Yes; I'm getting to know Mr. Itteilag.

Mr. TRACHTENBERG. To my immediate right is Dr. Herbert Pardes, who is the Director of the National Institute of Mental Health. To my immediate left is the ADAMHA Financial Officer, Kent Augustson, and to his left is the Director of the National Institute on Alcohol Abuse and Alcoholism, Mr. John De Luca. To his left is the Director of the National Institute on Drug Abuse, Dr. William Pollin.

Senator RUDMAN. I believe you have a statement, and I would ask you to proceed with that statement.

Mr. TRACHTENBERG. Thank you, Mr. Chairman.

I was going to start out this discussion by telling you that I'm one of the few general managers who is privileged enough to travel with two psychiatrists and one expert on alcoholism. As I already introduced them to you, they are here.

With your permission, I would like to proceed with our overview presentation. It's important to say at the outset that the successful attainment of the mission of the Alcohol, Drug Abuse, and Mental Health Administration will have not only an enormous benefit for the public health of the Nation but could also be of major economic benefit as well.

BURDEN OF ILLNESS

The ADAMHA mission is to prevent, control, and treat the illnesses of alcoholism, drug abuse, and mental illness. The economic burdens of these illnesses are staggering. The most recent study that we have indicates the cost to society to be about $120 billion annually. These costs relate to lost productivity, decreased job efficiency connected with increased mortality, morbidity, and, of course, health-related costs. The breakout is somewhat over $50 billion in alcoholism, a similar amount for mental illness, and if you just look at the direct costs for drug abuse, about $15 billion.

Mr. Chairman, in the drug abuse area if you add the amount of funds that are actually diverted from the economy which go into the illicit purchase of illicit drugs, the estimate from the Drug Enforcement

Agency is that we're talking about perhaps another $60 billion. And of course these figures do not include the noneconomic costs, the costs that relate to the destruction of human dignity, the dissolution of families, and the abuse of children and spouses alike.

Before I proceed with the actual chart presentation to give you this overview, Mr. Chairman, I think it's important for me to remember and indeed for the committee to remember that when we talk about programs, when we talk about numbers and how we carry out our programs, we sometimes neglect to stress that the purpose of our existence is to serve people who are stricken with illnesses of enormous consequence and to seek methods to prevent others from experiencing these devastating illnesses.

With this in mind, then, and with your indulgence, I would like to begin the chart presentation.

ADAMHA ORGANIZATION

The first chart is simply an organization chart of the agency. The supervisory activity is in the Office of the Administrator. We are organized in a way to carry out the major program accounts of ADAMHA—research, training, and community programs.

We have another division called prevention, which is not a program account because it is not a line item in the budget. In my view, the combination of these functions—research, training, services, and prevention—in one agency provides something very unique in the Public Health Service and permits us greater flexibilty in exercising leadership in the ADM system of the Nation.

By law, the Office of the Administrator supervises the three Institutes so that we are in a position to assure that appropriate and equitable support is given to each of the Institutes and that there is the proper amount of coordination among the Institutes in the development and implementation of ADM programs.

But when all is said and done, the main reason for the existence of ADAMHA is to support the Institutes' capacities to get the job done. It is in these Institutes that our in-house scientists work in the various laboratories that we have, and it is through these Institutes that financial assistance is provided to expand knowledge on the cause, treatment, and prevention of ADM illnesses, to make available new treatment services, to help the States and local governments with technical assistance, to support and maintain nationwide health delivery systems, to help train and educate degreed and non-degreed professional workers, and to develop effective prevention measures.

In establishing the Institutes in law, the Congress made them quasi-independent entities which operate independent programs and are the leaders in establishing policy in their respective fields. Except for support functions provided by the Office of the Administrator, they are self-contained entities, having full responsibility for setting policy, awarding grants and contracts, and administering and evaluating programs.

ADAMHA BUDGET

Turning to chart 2 now, it depicts the three appropriation accounts of the agency. The main account covers the ADM activities of the three Institutes and is a single appropriation to ADAMHA. We also have an appropriation account for St. Elizabeths Hospital, and we have a construction account for construction and improvement at the hospital.

At this point, Mr. Chairman, I should add that if it's satisfactory to you and the committee, after our presentation about the ADAMHA program, we have Dr. Pardes and the new Superintendent of St. Elizabeths Hospital here to present the budget insofar as St. Elizabeths is concerned.

Senator RUDMAN. That will be fine.

Mr. TRACHTENBERG. As you note from the chart, we are at a budget of about $1 billion now. It actually shows 1980, but it's been at that level since around 1979. Of this amount, the NIMH represents about 60 percent of the program effort, drug abuse about 25 percent of the effort, and alcohol programs about 15 percent. The program management number is somewhere around 1 percent of the total budget.

POSITIONS

Turning now to chart 3, you will observe in this chart, Mr. Chairman, that of the 6,000 budgeted positions for ADAMHA, more than 4,000 of these are assigned to St. Elizabeths Hospital. Of the remaining 1,900 budgeted positions, about 30 percent support our own scientists who are working in federally owned and federally leased laboratories at NIH, at the Baltimore City Hospital, and in other locations.

We can move now to chart 4.

ST. ELIZABETHS HOSPITAL

Because of the fact that St. Elizabeths Hospital is the only direct patient care facility that we run, I would like to take just a very brief moment to touch on St. Elizabeths and give a sense of the activity to the committee.

With me today, as I mentioned earlier, is Dr. William Dobbs, the newly appointed Superintendent of St. Elizabeths. As you may recall from the first chart, the organization chart, NIMH is the governing body of St. Elizabeths Hospital. Patients at the hospital are either District of Columbia residents or Federal beneficiaries.

As you will note from the chart, 85 percent of the total in-patient population is made up of District of Columbia residents. Well over 5,000 patients are treated in the various care settings provided by the hospital on an average daily basis.

Under the hospital supervision is also a forensic facility and the Area D Community Mental Health Center, which serve around 175,000 District of Columbia residents. Under the leadership of Dr. Dobbs and Dr. Pardes, the Joint Commission on Accreditation of Hospitals has accredited the hospital, which is in our view quite an achievement. We have received accreditation for a second year in a row, this coming after several years when the hospital did not have a JCAH accreditation. This was a major undertaking involving all facets of the hospital staff. One

very big element of it is to improve through our third account, the construction account, these very old and very historic buildings that are on the campus.

PROGRAM DISTRIBUTION

Turning now to chart 5, I just want to briefly give you a sense of how our three-legged stool, so to speak, is divided between services, research, and training. As you will note, 66 percent of our activity involves services. Close to 23 percent involves research, and 11 percent involves training.

With your permission now, Mr. Chairman, what I would like to do is go into each of these three areas and give you a sense of what we are doing and why we feel so excited about what is going on now and what the prospects for the future are.

Senator RUDMAN. I think that's very important, to do that in detail, because I'm going to have a number of questions in light of developments of the last several days that are probably going to digress somewhat from what the normal questions might have been during this hearing. So please proceed.

RESEARCH OVERVIEW

Mr. TRACHTENBERG. Highlighting research first, since it is indeed our highest priority, you will note by the lower section of the chart that about 25 percent of our total research budget is spent in furthering our knowledge in our intramural laboratories. Of course, the largest investment is in the NIMH, whose facility is part of the NIH campus. Here, some of the Nation's and probably the world's leading scientists add productively to the body of knowledge in this relatively young field of mental disorders.

The NIDA intramural facility is called the Addiction Research Center. It is split up at this point between a preclinical laboratory function that is still located in their previous home in Lexington, Ky., and their new facility which is on the campus of the Baltimore City Hospital. Hopefully, we will be able to integrate these two programs, and they will be able to continue providing important information on drug abuse liability testing.

The NIAAA is in the midst of establishing a 10-bed patient facility on the NIH campus as part of their Clinical Center. We think this is a very important activity, and it's a high priority for ADAMHA to have this come about.

Looking to the upper part of the chart, three-quarters of our money is spent basically through extramural research projects that either come through mechanisms such as principal investigator-initiated project grants, research contracts, cooperative agreements, small grants, or a variety of other mechanisms.

If we can turn to the next chart, it might give you a better sense of how those mechanisms are actually divided up between our various extramural research funding activities.

EXTRAMURAL RESEARCH

As you will note, the bulk of our extramural funds are expended in project grants. They have gone from 92 down to 87 percent of the total research effort, but that's largely because of the introduction of cooperative agreements which is another form of financial assistance, where there is a greater involvement of the Federal employees along with the scientific individuals in the academic or private institutions.

We are very proud of the integrity of the process by which research applications are reviewed and how decisions are made about funding. This process is very much similar to the NIH process. It is a dual review process, and if I can just discuss it very briefly, the applications are first reviewed with intensity for excellence by a study group of peer scientists or relevant experts in the field. These people generally come from the private sector.

The applications are reviewed against published criteria and a numerical score is assigned. The lower the numerical score, the higher the quality and excellence of the particular application.

Those applications which are recommended for approval are then presented to one of the three national advisory councils which are established in law to serve each of the three ADAMHA Institutes. After these applications are voted upon by the National Advisory Council, decisions are made on funding. Within available funds, applications are funded primarily on the basis of priority scores within funding applications submitted in each program area.

Each of the study groups which I mentioned earlier is chartered under the Federal Advisory Committee Act. At the present time, we have 28 of these chartered groups.

The subject areas of our extramural research are divided—and these are 1980 figures—between biomedical, which represents about 48 percent of our total effort; clinical research, which is about 29 percent of the effort; social policy research, which relates to about 15 percent; and epidemiological research at about 8 percent.

So after getting a sense of the mechanisms and how we go about making our awards, I guess the next question is, what has this Federal investment achieved and what can we look to in the future?

RESEARCH ACCOMPLISHMENTS

Mr. Chairman, not being a scientist and not wishing to go beyond any limitations of my own expertise, I want to give you a sense, as a lay person, indeed perhaps as a taxpayer, of some things that we think are very exciting in the research field. I also want to give you a sense of what some of the accomplishments are and what perhaps are some of the things that we look to in the future.

This list could have been much, much longer. It was limited partly by time and partly by my own limited ability to understand the in-depth scientific issues that are involved here.

I have here capable people who can expand on any one of these things in detail if you wish.

I actually was thinking, in the interest of time, to just take a couple of minutes to give you a representation of research in each of the three Institutes, to give you some sense of what is being accomplished.

Probably an opening remark should be that brain research is exploding. It has to be one of the most exciting areas in the entire scientific field, and I take pride in telling you and the committee, Mr. Chairman, that ADAMHA is at the leading edge of the breakthroughs in this science area.

PETT SCANNER

The first activity relates to the development of a PETT scanner, which is a positron emission transaxial tomography scanner. It's called the first psychiatric X-ray.

Let me try to explain. The PETT scanner has been around for about 10 years in various primitive forms. NIMH intramural scientists developed a way to measure the metabolism in the brain, however, by hooking it up with the PETT scanner. The result was that not only could you see the anatomy of the brain, but you could see actual brain activity.

Now that to me is an incredible accomplishment. It helps understand how normal brains function and it will help pinpoint neuropsychiatric deficiencies that relate to chemical imbalances in the brain.

Something that seems equally incredible to me is that this past summer NIMH scientists were using the scanner to study a schizophrenic patient and the auditory cortex of the patient's brain lit up on the screen. This may have been the first physiological evidence of a schizophrenic hearing voices.

Again, I think an amazing step. But the scanner itself could not have been used in the way it was but for the NIMH scientist who developed this particular ability to measure glucose levels within the brain.

ENDORPHINS

Giving equal time, I will touch on a NIDA activity. It's the fourth one down on the list, the discovery of endorphins. Endorphins are naturally occurring opiate-like substances that are in the brain. The discovery has enormous potential.

NIDA scientists have discovered about 12 different endorphins through the research that we have been supporting.

They have influences in the modulation of pain, and may have connections with compulsive disorders like gambling and overeating, something very dear to my own heart.

They could affect schizophrenia and the treatment of schizophrenia, and could be involved in learning disorders and memory. Indeed, it is even possible that someday a Salk type vaccine could be developed that would block the effect of illicit opiate drugs.

Again, I think this area has an enormous potential.

In any of these areas Dr. Pollin and Dr. Pardes could put it in English if it would be more helpful to you. But I tried to give you a sense of my own perspective of what these things mean.

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EARLY IDENTIFICATION OF ALCOHOLISM

Another area, in the field of alcoholism, is the early diagnosis of alcoholism through blood samples. As you know, it is difficult to diagnose alcoholism or alcohol problems. The important thing, though, is the earlier you find a patient with an alcohol problem, the more responsive they are to treatment. NIAAA scientists have been able to develop a statistical method of evaluating blood samples to be able to pick up problem drinkers and to pick out people that are hidden alcoholics.

The potential of this technique is, not only in treatment, but it is also possible that it may be used in determining a pregnant woman's drinking habits and thus used as a tool to prevent the fetal alcohol syndrome.

Indeed, this diagnostic method may be a way to avoid surgical procedures for examining the liver to determine whether or not a liver condition is alcohol or nonalcohol-related.

So, again, the potential in this area is enormous. But it is important that the committee note—and as a lay person the scientists constantly remind me—that it is not only the successes that count. It's just as important to learn what doesn't work.

With your permission, Mr. Chairman, I would like to move to the next chart, unless you would like to go through any of these other items.

Senator RUDMAN. I would only like to say to you that that's very interesting. I am particularly fascinated by your PETT scanner, because great paranoia might exist if it was used as a prerequisite to run for public office. [Laughter.]

CLINICAL PROGRAMS

Mr. TRACHTENBERG. Our next chart shows that the second leg of the stool to which I referred before represents our clinical and research training programs.

As you will note, the heaviest investment in both clinical and research training comes from NIMH. The NIMH focus is somewhat different than that of the NIAAA and the NIDA programs.

I would like to talk about the NIMH area first.

Their direction is to train people in the four core disciplines of psychiatry, psychology, social work, and psychiatric nursing.

The General Medical Education National Advisory Committee recently issued a report that indicated a shortfall in the number of psychiatrists coming out of the medical schools.

They estimate that there will be a shortage of about 8,000 general psychiatrists and 4,900 child psychiatrists by 1990. Our own data tend to reinforce this kind of information.

For instance, the number of first-year psychiatric residents has gone down from 1,500 in 1975 to barely 1,000 in 1979. The percentages of psychiatric residents as compared to all residents has gone from 12 percent in 1976 to 7 percent in 1979. So our own data reinforces this GMENAC report.

RESEARCH TRAINING

While I still have this chart up and before I go to the next chart, I want to also mention our research training.

Again, NIMH has the heaviest investment in research training. At the 1980 level, it was approximately $18 million and it's closer to $20 million in 1981. It is our view that a dynamic enterprise can only grow and challenge new frontiers of knowledge if there are adquately trained researchers qualified and capable of meeting the challenge.

So to put it very, very bluntly, if you are going to have a research program you have to have a research training effort to keep the pool of researchers there so that the kind of exciting, creative applications can still come into the system. We are very, very heavily invested there.

I should also note that in my view much of the professional research and clinical manpower needs of NIAAA and NIDA are drawn from the manpower pools that NIMH is responsible for developing.

TRAINING REDIRECTION

So I have touched on research training and touched on clinical training in terms of the shortages of psychiatrists. Let me move to the redirection chart.

Mr. Chairman, you will notice a change in this chart between 1977 and 1981. In 1977, NIMH was heavily invested or more heavily invested in what we call general professional education in the four core disciplines. The direction in terms of speciality areas—and the specialty areas are areas of underserved and unserved populations and underserved areas and public institutions and things of this nature—began shifting because we were realizing that the numbers are there except for psychiatry in terms of a manpower base. But what was missing was getting these people into the areas where they were most required.

So we have made an important funding shift toward the specialty areas over the past couple of years, and indeed if you would have looked at 1976 or 1975, the general professional education funding level would have been much higher.

Our ability to enforce or enhance the placement of the stipended clinical trainees that we fund as a result of the clinical training dollars has been improved by virtue of a provision of the Mental Health Systems Act which now provides a payback for our stipended clinical trainees. So now, similar to the National Research Service Award Act, they will have to pay back 1 year for every year of supported training. And it will be in one of those specialty areas.

In NIDA and NIAAA the focus is primarily on the training of nondegreed professionals and specialized training for existing degreed professionals in order to assure that an adequate supply of skilled personnel is available to meet the particular needs of their service systems.

There is a lot more. We could talk further about clinical training in the other two Institutes, but I think in the interest of time we should move to the next chart.

SERVICE PROGRAMS

The third leg of the stool is services. And you will note that this chart shows the number of patients treated in ADAMHA project grant programs.

We are close approaching 4 million persons treated. To put these numbers in some sense of perspective, Mr. Chairman, I should note that 34 million people suffer from mental disorders. There are 10 million adult problem drinkers, about 3 million young people have problems with the use of alcohol, and there are currently an estimated 30 million drug abusers. The 30 million consist of people who used an illegal drug within the last month for nonmedicinal purposes. Of course, even more individuals have used or experimented with illicit drugs at some time in their lives.

But the raw data are only part of the story. Thanks to research advances in pharmacology, we have been able to treat people in less restrictive environments. Mental institutions, which in 1963 housed some 500,000 people, now have about 148,000 people, based upon 1978 data.

In economic terms, we have learned that more people with alcohol- and drug-related problems can be treated as outpatients and costly inpatient care can be held to a minimum.

Senator RUDMAN. Mr. Trachtenberg, let me interrupt for just one moment. About how much longer is your opening statement going to be? I don't want to hurry you, but I have a reason for asking.

Mr. TRACHTENBERG. I can be finished in about 5 to 7 minutes, Mr. Chairman.

Senator RUDMAN. Senator Specter has some questions he would like to ask, and Senator Specter has a number of other things to attend to this afternoon. I wonder if I could have him finish, or would you like to ask those questions now.

Senator SPECTER. Would it be unduly burdensome, Mr. Trachtenberg, if we interrupted for a few questions at this stage?

Mr. TRACHTENBERG. I am at your leave, sir.

Senator SPECTER. If that is acceptable to the Chair, I appreciate leave to ask you just a few questions.

Senator RUDMAN. Please proceed.

Senator SPECTER. I do have other commitments.

BUDGET CUTS

Do you know yet what the impact of the cuts announced last night by President Reagan will have on your unit?

Mr. TRACHTENBERG. No; I do not have any specific numbers. And it is very difficult at this point, being so soon after the President's speech last night, to really give a good sense of what the impact will be.

Senator SPECTER. We had available this morning some of the NIH statistics, but I take it those are not yet available for your review?

Mr. AUGUSTSON. Just on research training.

Mr. TRACHTENBERG. On research training, we are aware of eliminating the overhead level for institutional support, which affects indirect costs and institutional allowances. I know about that.

AGENCY INVOLVEMENT IN CUTS

Senator SPECTER. Were you consulted in advance of last night about your ideas on where cuts could come in your budget if there had to be cuts at various levels?

Mr. TRACHTENBERG. We went through a number of exercises in which we provided information both to the Department, and I assume from the Department, to OMB, and some of them were "what-if" exercises such as what if you cut 1 percent, what if you cut 2 percent of outlays, what was the result of those kinds of activities. And then a number of other requests were made for information that related to size of the programs and things of that nature. But in terms of being specifically asked my views, I would never expect that to have happened, and it didn't.

Senator SPECTER. What inquiries were made, then, as to what cuts you would have recommended if there had been a cut, say, of 2 percent across the board.

Mr. TRACHTENBERG. We did it basically as across-the-board cut in the various areas. We did not pinpoint.

Senator SPECTER. Without exercising your own discretion as to where you would have wanted the cuts?

Mr. TRACHTENBERG. There was a massaging process. I can't recall the specifics of it.

Senator SPECTER. Massaging process.

Mr. TRACHTENBERG. Looking at which areas we could afford to take some of the cuts in more than others. The reason I am vague is because I don't remember what those areas are, to be very frank. It happened a couple of weeks ago, and it was just one of a number of things that we were involved with at that time.

Senator SPECTER. Did you make an estimate as to what you felt would be the maximum cuts sustainable and still carry out the function of your unit?

Mr. TRACHTENBERG. No, not in those contexts; no.

Senator SPECTER. When you receive the cuts as recommended by Mr. Stockman's unit I would be interested to know your evaluation of the impact of that on your unit. This year's chronology is somewhat difficult because we are having the subcommittee hearings really with blinders on, not being able to ask you really what the current administration has in mind, but I for one would be interested in knowing what your response is on those cuts.

VIOLENT CRIME REDUCTION

What impact does your unit have on reducing violent crime?

Mr. TRACHTENBERG. I think we could look at that from each of the Institutes respectively, but let me just give a sense of an overview and then we can go from there.

In the drug abuse area, which obviously is the important area with respect to crime, obviously if we can reduce the opportunities that people have to abuse drugs or we can somehow effectively treat the large number of people who are drug abusers, that will have important impact in terms of reducing crime.

We have been involved with the White House liaison group on drug matters, on issues of drug abuse, but ours is basically a public health function, and it has to be recognized as such. If we treat effectively, if we find cures, that will certainly have an impact on violent crime.

Senator SPECTER. Is it your judgment that your work does have an impact on violent crime?

Mr. TRACHTENBERG. In our review, the data I have looked at in terms of our applying data systems indicate we have been treating people with a fair amount of success. Now that doesn't stop the increase in the numbers of people who have heroin available to them and are heroin abusers. It had gone down quite a bit in the last couple of years, and we have been noticing trends going up. But for a while there, it was less a public health problem. We are seeing indications of it growing again in the last few months.

Senator SPECTER. Would your expectation be that a reduction of your funding as it would be applied in the drug abuse field would result in an increase in drug related crimes?

Mr. TRACHTENBERG. I am not clear at this point, Senator, whether or not we are talking about a reduction in funding of drug abuse. It would be according to what that reduction is. We fund now at about 86,000 treatment slots. A treatment slot is the capacity to continuously treat one person over a year's time; several people are thus treated during the year under one treatment slot. We have a very high utilization rate of the total number of those slots.

DRUG-RELATED CRIME RATE

Senator SPECTER. Do you have any statistics available of the rate of criminal incidents among those whom you treat in the drug abuse field?

Mr. TRACHTENBERG. I see Dr. Pollin anxiously pointing up a desire to answer that question. I am going to turn the response to him, if I may.

Dr. POLLIN. There have been two major studies this past year. Those studies pointed out that the incidence of crime in heroin addicts is the order of approximately 60,000 to 70,000 crimes per year per 200 heroin addicts. Second, they showed that less that 5 percent of these crimes, of self-reported crimes, appear on arrest records.

Senator SPECTER. 60,000 every 200 addicts?

Dr. POLLIN. This was a figure arrived at by two separate studies, one in Florida, one in Baltimore——

Senator SPECTER. That's 300 per addict?

Dr. POLLIN. With respect to your first question, the relationship between treatment and crime—it should be pointed out that a majority of these crimes were not violent crimes, they were property crimes. The figure that is of greatest interest to us is that in an 11-year comparative study of addiction, the rate of criminal activity was six times greater in individuals actively addicted, as compared to those periods during that same 11-year span, when they were in remission.

This issue, which has been a somewhat contentious one in the past, now seems quite solidly resolved in terms of demonstrating a very significant relationship between active addiction to heroin and a high level of criminal activitiy, which comes down dramatically during addiction-free periods.

Senator SPECTER. And what relation does the incidence of alcohol have—does that come under your purview with respect to criminal contact?

Dr. POLLIN. I think Mr. De Luca can speak best on that.

Mr. DE LUCA. The Senator is switching purviews. As the Director of the National Institute on Alcohol Abuse, I have a very deep concern about the association of violent crime to excessive consumption of alcohol. To be specific, we have determined that there is an association, a strong association, between excessive consumption, the state of intoxication, and violent crime.

We are deeply concerned about violence in the family and the effect alcohol has at high consumption levels, of triggering violence in certain individuals. We are conducting substantial research to determine whether or not there is an actual triggering mechanism. Our statistics indicate that there is a strong association between the state of intoxication and violent crime.

Senator SPECTER. Mr. Trachtenberg, I didn't want to interrupt you for too long a period of time. I did have another commitment. What I would very much appreciate, would be that after you receive the figures as to the recommendations by Mr. Stockman's unit, if you could provide this subcommittee with information as to what impact that is going to have on your drug abuse treatments, your alcohol treatments, and what your judgment would be as to the impact on incidence of crime, violent and otherwise, I would very much appreciate that, so we can assess what those budget cuts are going to mean on the criminal law enforcement field.

Mr. TRACHTENBERG. We will do so.

[The information follows:]

BUDGET IMPACT ON CRIME REDUCTION

Results of studies conducted in the area of predictors of violent behavior report an important correlation between alcohol, drug abuse, and mental health problems and crime. The National Institute on Alcohol Abuse and Alcoholism reports that most studies show that 40 to 60 percent of homicide victims and an even higher percentage of homicide offenders had been drinking when the murder was committed. One of the best recent studies of alcohol and violent death reports the following percentages of victims in New York City during a 1-year period (1974–75) who were also intoxicated: 16 percent of all suicides, 27 percent of all homicides, 38 percent of all fatal highway crashes, 41 percent of all fires. The most extensive American study on the subject of rape and alcohol indicates that where alcohol was involved at all, both victim and offender had been drinking. A conservative estimate indicates that at least one-third of all suicides—27,063—in 1975 may have been alcohol-related. While studies are not extensive, family violence, including child-abuse and wife-beating, seems to frequently involve a history of drinking problems and alcohol abuse.

A recent study of drug addicts in Baltimore determined that they steal about $669 per week and that treatment significantly lowers their criminal activity. Similarly, a long-established mental health role relates to the treatment and rehabilitation of criminal offenders. More recently, a new role has emerged with respect to the prevention of future acts of violent behavior.

In fiscal year 1982, the basic health care block grant will provide the States with 75 percent of the service funds received in the fiscal year 1981 current services budget under the various categorical grants included in it. In all three areas of treatment services, drug abuse, alcohol, and mental health, the immediate effect this reduction will have on the delivery of services and on the incidence of crime is difficult to predict, and

will undoubtedly vary among the States since resources will be allocated according to their own priorities. The States may choose to allocate large portions of their block grants to the provision of drug abuse treatment in order to prevent crime; for every $1 spent on treatment, we estimate that we prevent 20 dollars' worth of crime. In determining what impact the specific cuts will have on alcohol-related violent crimes, presumably the areas most vulnerable to budget cuts will be projects such as the testing of innovative new prevention programs, particularly in the drinking driver and family violence areas. Again, these decisions will be the States' to make on an individual basis.

ADAMHA also conducts research programs into the nature and prevention of criminal behavior, particularly through programs supported by the NIMH Center for Studies of Crime and Delinquency. In their effort to reach responsible judgments pertaining to an individual's future dangerousness, the criminal and civil justice systems often seek the assistance of mental health professionals.

In the process, there has been criticism of the field when inaccurate diagnoses have resulted in the release of persons who repeat their previous patterns of violent behavior. The problem has been that there are few, if any, reliable instruments for the clinical prediction of violent behavior.

Recently, the National Institute of Mental Health research programs have attempted to study the problem of predictability, particularly as it relates to homicide. Ten percent of all deaths among adolescents and young adults are the result of homicide, and it is the leading cause of death for nonwhite males aged 25 to 44. Research is still in an early stage, as much of it entails the tracking of subjects through a portion of their adult lives, to test various theories of predictability. Much of this research entails assessments of social as well as biological factors which may contribute to, or act as predictors of future violent behavior. Under the revised budget, these efforts must necessarily be reduced in scope since much of the program is considered social research, which is to be phased down in 1982.

COMMUNITY MENTAL HEALTH CENTERS

Senator SPECTER. Thank you, Mr. Chairman.

Senator RUDMAN. Senator Specter, thank you. If you would like to go back to your statement at the point where you left it, Mr. Trachtenberg, and you can finish that. Then I expect what we are going to do—I have some questions I would like to ask your panel that are somewhat different than the ones we had originally planned to ask. Then I expect we will go on to the next segment of your presentation.

You may proceed.

Mr. TRACHTENBERG. Thank you, Mr. Chairman. I would like to move to the next chart, please.

The first service program that I will discuss is the community mental health centers program, a responsibility of the National Institute of Mental Health. You will observe, Mr. Chairman, that there has been a steady increase in the number of community mental health centers that we have been funding. Indeed, at the fiscal year 1981 point, we will be at about 50 percent of our national goal to place a community mental health center in each of the 1,500 catchment areas located throughout the country.

Federal financial support to the community mental health centers is based on the declining Federal share for an 8-year period. The community mental health center, through third-party payments and other non-Federal revenues is expected to become self-sustaining at the end of that 8-year period. Very few programs fail and the State financial support of the programs has been impressive.

As you will note on the chart, the number of graduate CMHC's is fast approaching the number that we fund. Despite the gains in the ac-

complishments of the community mental health center program, Congress has recognized in the enactment recently of the Mental Health Systems Act, that in many areas populations like the chronically mentally ill, the elderly, severely disturbed children and minorities, are either underserved or unserved in many areas of the country. They have recognized that there needs to be a greater linkage between the general health sector of our country and the speciality ADM sector.

You might be aware, Mr. Chairman, of the fact that more than one-half of the people suffering from mental disorders at any one time, one-half of the 15 percent I noted before, one-half of the 34 million, is seen by somebody in the general health sector. So it's very important that the right kind of linkage is developed between the speciality sector of ADM and the general health sector. Likewise, the Systems Act has noted that the States need to develop a capacity to deal with these multiple and diverse mental health programs.

The Mental Health Systems Act is designed to assure that the States set their own priorities in a manner which assures that these problems in the system are appropriately corrected.

DRUG ABUSE SERVICES

Turning to the NIDA treatment system, you will note that in fiscal year 1981, looking to the top part of the chart, Mr. Chairman, that all their treatment funds are spent through the States, through the grant mechanism, and the States then have subcontract arrangements with the various treatment projects located throughout their States. NIDA represents about 40 percent of the total treatment capacity that exists in the Nation today, and you will note that from the bottom chart that breaks it out into treatment slots.

The present service system was an outgrowth of the Special Action Office on Drug Abuse Prevention, which due to a virtual epidemic in heroin abuse in and around 1972, began a major effort to fill a nationwide gap in heroin treatment services. In 5 short years this gap was closed and has remained at the 40 percent level that I just mentioned earlier.

I should note at this point, that NIDA has responsibility for treating in addition to narcotics, individuals who have drug abuse and drug-dependence problems, as well. The statewide services that NIDA has developed with the States is, in my view, a model for effective Federal-State relations, and in my view, further, is working rather well. NIDA currently funds about 60 percent of the 86,000 treatment slots that are available nationally. The 86,000 slots that I mentioned to Senator Specter represents a capacity at any one point in time to treat enrolled clients. However, on an annual basis, we're talking about serving 230,000 clients treated through the NIDA State treatment system. The State establishes its needs through a State-planned submission, and is then responsible for the management of the individual subprojects. NIDA in turn provides States with technical assistance and holds the State accountable for technical assistance and for the full utilization of the treatment slots which it provides.

ALCOHOL TREATMENT SYSTEM

If there are no questions on the NIDA treatment system, we can move to the last one, the alcohol treatment system.

As you will note, Senator, the bulk of the alcohol community services funds, about 49 percent are expended in serving those individuals who are not being adequately served in the private sector, because they are not presently being covered by some third-party insurance coverage. Thus, the vast majority of these people would probably not receive alcohol treatment services but for this Federal effort.

Moving now to the second bar of the Alcohol Institute's national leadership role. It expends about 27 percent of its alcohol community program dollars in funding demonstrations to determine new and more effective ways of reaching special populations.

For instance, you will note there, that we have employee assistance programs under the part of the bar that is referred to as "occupational." As a result of the Alcohol Institute's leadership in this area, there has been a substantial increase in the number of such programs in industry over the past 10 years. Ten years ago, among the Fortune 500 companies, about 20 percent had employee assistance programs for alcoholism. Our figures indicate that now over 58 percent of these companies have such programs.

There are other areas of special population where demonstrations are necessary because our normal treatment processes are not getting to women and youth. Therefore, we have developed special treatment techniques which utilize improved technologies for reaching these specialized groups.

Ultimately, when we find which treatment services work best for such special groups it's part of our mandate to disseminate this information to the field for further implementation.

Moving down the chart, I'll touch briefly on the Uniform Act. Under the Uniform Act we provide financial incentives to States who have, among other things, decriminalized public intoxication through their State legislatures and brought the public inebriate, the alcohol problem, which is a public health problem, out of the criminal justice system and into the health delivery system.

Lastly, we have a State volunteer development program, by which we can hopefully get individuals at the State and community level to combat alcoholism by volunteering to work in our various alcohol system treatment programs.

With that, I appreciate your indulgence, Mr. Chairman. That concludes my overview, and I and the Institute directors are available for any questions.

Senator RUDMAN. Thank you very much.

That's an excellent statement, and I think it has given us a very good overview of what you do.

Mr. TRACHTENBERG. Thank you, Mr. Chairman.

Senator RUDMAN. I think the problem this committee faces today is a very real one. It seems to me that one of the most useful things that we might do here this afternoon, this being probably one of the few opportunities before major legislative reforms are proposed, that you will have an opportunity to testify here, is to examine these burdens.

PROPOSED PROGRAM CHANGES

I would like to take, frankly, a broad look at the philosophical changes that are being proposed by the President and by OMB and to get at them in a very specific way. I expect that the real battleground in this committee and this Congress will be that philosophy, which is a radical departure from the way in which we have administered Federal funding in a wide variety of areas to our States. I come from a very small State and, thus, probably am more familiar with the detailed impact of a number of these Federal programs than someone might be in a large State. So I have a full understanding of what the President meant last night, and what he is directing himself to.

The time has come, perhaps, to stop talking in generalities and philosophies and get down to some specifics, and I propose to do that with your panel here this afternoon.

I would like to read to you from the document that was circulated yesterday to Members of the Congress and others, just one excerpt from the booklet entitled "America's New Beginning: A Program for Economic Recovery." There is a section of that report, which is entitled "Returning Management of Health and Service Programs to the State." Let me quote it for you. It says:

> As a part of the effort to return decisionmaking authority where appropriate, the States and localities, the administration will propose to consolidate the present collection of about 40 Federal categorical grants for health and social services, into one or more block grants to States.

Let me read to you some of the things that are being considered for packaging in that way: child abuse, runaway youth, developmental disabilities, low-income energy assistance, community health centers, black lung clinics, migrant health, high blood pressure, home health services, SIDS, genetic services, hemophilia, family planning, emergency medical services, program management, mental health services, alcohol abuse services, drug abuse services, health incentive grants, health education, venereal diseases, fluoridation, immunization, rat control, lead paint, adolescent health, and a number of others.

PROPOSED STATE RESPONSIBILITIES

Now, what really we are coming down to—and I'd like you to put your chart 3, the pie chart, back up there, if you would—but it seems to me that what we are really coming down to is whether or not this Congress is going to say that the decisionmaking for the allocation of these resources should now go back to the States.

That's really where we are at.

Now, your pie chart shows roughly 66 percent services, about $637 million in this particular program.

And in reviewing the President's proposal that I expect will be in the legislative package, I expect that that area will probably be very much under consideration for block granting to the States.

And what they are really saying, of course, is that the State of New Hampshire and its legislature—which, I might point out, is the third largest English-speaking deliberative body in the world, with a legislature of 400 in the House and a town form of government, in which

everybody gets involved, is much more qualified to determine how these Federal dollars are being allocated among these programs than many bureaucrats, or Congressmen, or Senators.

As a matter of fact, the people of my State have the strange idea that only a small part of the wisdom of America resides in the District of Columbia.

And so, what I would like to address with you, very seriously, here today, is a scenario where all of these funds are lumped into block grants, and the States will make their decisions—California one way, Pennsylvania another way, New Hampshire another way, New Mexico another way, ad infinitum.

STATE SERVICE EXPERIENCE

I would like to go through your panel, today, with your experiences with the States in each of these areas, and tell us how you think this will affect the total mission, if you will, of what this legislation was all about in the first place—whether you think it can be done, or cannot be done—whether the program will be as effective, or less effective, and what your problems are with it.

And I would like to, now, throw that general question open for any comment from each of you, starting with Mr. Itteilag, I believe.

Mr. ITTEILAG. Senator, the only comment I want to make, at the start of the discussion, is that the President's proposal stipulates that only service programs will be turned over to the States.

And I think that's where the discussion can be held most intelligently.

Senator RUDMAN. I believe that's what I was directing myself to.

Dr. PARDES. Senator Rudman, I think the question you put is really one of the central questions of the entire group. Let me just comment on how we would perceive it, within the Mental Health Institute.

As you probably are aware, the Congress passed a Mental Health Systems Act, which suggested a substantial move in the direction of State and local determination of mental health programs.

Probably, if one looked at a spectrum of Federal direction vis-a-vis local direction, the Systems Act represents a kind of intermediary step. It called for the State to be a much more active systems manager, and to rank and determine the kinds of programs it felt would be most appropriate within its area.

It does not go as far as a block grant goes. However, it was in that general direction.

I think one could have a legitimate discussion as to how far one should be going in that direction, at this particular time. But certainly, the Systems Act is consistent with the general thrust of the President's recommendations.

PRIORITY AREAS FOR CONSIDERATION

Mr. TRACHTENBERG. I just want to put something in a bit of perspective, and perhaps play a little bit of the devil's advocate, in terms of these proposals.

You and I know that it's very difficult to crystal ball gaze, and no one, if he could avoid it, should engage in unnecessary conjecture.

One of the things that I don't know, in terms of being high up in the decisionmaking process, is as to what extent this will be truly a block grant, and to what extent there will be some identification of high priority areas. I think that might be an interesting thing to follow through, and see.

Another point that I think needs to be made is that, in my own experience, I grew up in terms of my job experience as one of the war on poverty warriors. I was General Counsel of the Office of Economic Opportunity in the 1960's.

I think that the Federal-State role, and indeed the State role, has changed a lot over the last 20 years. And I think, in many respects, organizations like OEO contributed to that change.

Many of the social programs that developed over the past 20 years, I think, developed because the Congress sensed a need, and that that need wasn't getting filled appropriately by the States.

I think 20 years later, there has been capacity building, there has been a strengthening of the understanding of the States in terms of what their people need. And I think there is a sense of priority, in terms, particularly, of underserved and unserved populations, that didn't exist when organizations like OEO were established 20 years ago. Or almost 20 years ago.

And I think this is an important perspective, in terms of the sophistication in this particular capacity of the States.

You could also argue, for instance, just as Dr. Pardes mentioned in the Mental Health Systems Act, that maybe we haven't been doing a very good job, up until now, because the Systems Act recognizes that there are underserved and unserved populations, despite the large numbers of dollars that the Federal Government, along with the States, has been putting into community mental health centers.

Senator RUDMAN. I think, in my own State, I might point out, there's a strong feeling right along, amongst people that are decisionmakers, that there's been too much rigidity in a lot of Federal programs; and flexibility, which comes with local people and local knowledge, has been sadly lacking.

Mr. TRACHTENBERG. I believe the chronic and mentally ill, the people I mentioned before—that that new focus needs to be there.

The other side of the coin is, at least as we perceive our programs, the Systems Act, as Dr. Pardes said, is indeed moving toward a different kind of relationship. It's not big Federal Government telling the little States what they need.

But the other side of that—and we are looking at this right now—is an incredible number of regulations and details that are going to have to be put in, in order to establish various funding priorities, and various other priorities in the program.

And without those, there's going to be all kinds of litigation, law suits, and everything else, if we don't do it. So there is that element.

As I mentioned before, in NIDA—NIDA in many respects is a model of Federal-State relations. In many respects, NIDA is as close to being a grant to the State as you can manage. And yet, there is that Federal overview and the national leadership of a Federal organization, pushing the States into those areas where they are most in need.

The big question is: Will the money—whether it's an ADM program or any other thing you talked about—will the money get to the people who most need that money?

And I don't know.

RESPONSIBILITY FOR FUNDING PRIORITIES

Senator RUDMAN. You see, the real question is probably coming down to the fact that, with a finite number of Federal dollars for all of these programs that can be put into the States, the question then is who prioritizes where that money goes?

That's really what this is all about.

Frankly, I don't know the answer, and I intend to ask these questions in as many of these hearings as I can, between now and the time that it's necessary to vote on them. Because it is a radical departure.

I forget who it was—there was a French philosopher, back at the turn of the century, who said: "There are many complex problems in the world, for which there are simple solutions, and most of them are wrong."

And I think we have to be extraordinarily careful that, whatever we do, we don't disturb those who have true needs; and yet, we should try to return, I believe, more power to the local governments.

Whether or not these block grants will come through the Congress in a general form or with some specificity and some allocation—so there has to be a continuation of certain types of programs—but yet, at the local level—I just don't know.

But I'm sure of one thing: There's going to be a radical departure this year and the next year, as to how we administer these moneys. That's why I'm asking these questions.

I'd like to move down the panel, if I could.

Dr. PARDES. Senator, if I could just comment on one point you made, regarding the mental health services.

Your comment about a recognition of a need to break rigidity, create more flexibility, was something that was agreed to by all people who are composing the Systems Act. So, a second major feature is flexibility, in order to address that very concern.

Senator RUDMAN. Thank you.

STATE ALCOHOLISM RESPONSIBILITIES

Mr. DE LUCA. Mr. Chairman, we're talking philosophically. And I would suggest that one of the principles that we would have to discuss is: Why are these programs at the Federal level, to begin with? What rationale might have been in place 10 years ago, when Congress made the decision to pass the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act and, in fact, established the National Institute on Alcohol Abuse and Alcoholism?

I think that it is essential, as this very important discussion takes place, to understand what unique contributions the Institute has made to the problems of alcoholism and alcohol abuse nationally which, before congressional attention, tended to be ignored.

There is a concern in the area of the public health aspects of the problem of alcoholism. Because of the uniqueness of this disease and the tendency for individuals to deny their illness, people do not come forward and demand services. Thus, without national attention this very subtle, complex, and personally devastating problem would be without a public health focal point.

I think that the unique aspect of this public health problem is going to have to be well understood as we attempt to rethink the delivery of Federal services.

On the other hand, we have developed during the past 10 years, a very constructive working relationship with the States.

Before coming to Washington, I was the New York State Commissioner for Alcoholism Services. I feel very comfortable and positive about the State's capability to make proper and clear decisions which at times are easier, simpler, and more responsive to the needs of communities and towns within those States.

The national Institute has, I think, in many ways, moved to enhance the State/Federal relationship.

It's interesting to note that, of the $681,000 the Institute awards to New Hampshire, all is given directly to the State of New Hampshire. Thus, the State government really controls where the Federal dollar is spent.

Senator RUDMAN. I'm well aware of that, of course.

The question, then, becomes: Whether or not the State might rather have some of that money for other systems?

DRUG ABUSE PRIORITIES

Dr. POLLIN. Mr. Chairman, we, the pointy-headed bureaucrats, are aware—perhaps more than others—of the burdens that the systems that we try to run often impose.

And we are strongly committed to the importance of the basic principles which underlie the formulation and presentation of the block grant proposal.

We are particularly aware of the need for, and the possibilities for, economy.

We are, at times, painfully aware of the need to attempt to simplify procedures, to avoid multiple deadlines, conflicting instructions and duplication of forms. We are aware of the waste not only in terms of dollars, but in terms of human resources, that has developed because of the complex structures that have inadvertently and, often in a somewhat unplanned way, emerged because of our multiple good intentions.

The other side of that coin is the one that has been made by the other members of this panel: The fact that, empirically, we know that there are often major national problems that, for a variety of local or current reasons, have not received the attention and the support that is necessary.

And, in certain cases—as is true particularly of drug abuse—these problems have a quality that is somewhat akin to that of infectious diseases. There is a very real contagious element that characterizes the spread and the change in drug abuse patterns.

It becomes very important in the national, as well as the local, interest to attempt to insure that these matters receive the minimal necessary attention.

It seems to me, Mr. Chairman, that the key issue that we have to attempt to bring to the fore, and a very difficult one, is the issue of balance.

How do we balance the very legitimate impulse and need to economize, to simplify, to return decisionmaking and prioritymaking power to the locality and, at the same time, ensure necessary levels of accountability and of prioritization?

That does require, in some instances, a national as well as a local point of view.

Senator RUDMAN. When you find the answer to that, you drop me a note. [Laughter.]

Dr. POLLIN. I think it's an answer we can't arrive at philosophically. I think it depends upon the specifics of procedures.

Senator RUDMAN. I believe that we will have to have a number of discussions of this type, with a number of people who have high responsibility and knowledge in the area, to assure that whatever we do, those areas that are absolutely critical for mandate—if you will—are in fact preserved.

I think that is really how I feel. And I expect that that list might be shorter than some people realize.

We are on a rather tight schedule today. There are a few questions which the staff has prepared and which I have looked at. And I think that we should go over these, if we have time.

If you could economize time in your answers, I would certainly appreciate it.

COORDINATION OF ADAMHA SERVICES

Could you tell us to what extent there is coordination between the local alcohol, drug abuse, mental health centers, you know, within a given locality, a geographic area, to the extent that a certain amount of things could be done, if you will, that would economize and be helpful to each other since they are all generally funded on the same basic program?

Mr. TRACHTENBERG. Well, probably the most candid answer is there probably could be more coordination. I have thought sometimes about the possibility of an economy of dollars by having the same three programs in the same areas, physically located in the same areas. There are a number of problems in terms of the people with the various disorders, even though there's a great commonality between alcohol, drug, and mental health problems. People like to come for alcohol problems to an alcohol clinic. Drugs, I think feel the same way, and mental health the same way. There is an element of coordination in the Mental Health Systems Act in that alcohol and drug abuse services are included. So in that respect there is a continuation or an effort at coordination.

I read that in a limited way, some of the studies that say when patients come to the more specific treatment modalities—alcohol treatment program, for someone with an alcohol problem or to a drug abuse treatment program for a drug abuse problem—the outcomes are better.

There are a lot of areas there that probably could be coordinated better, but on the other hand, there's probably a good deal of reasons why, if we do it, we need to do it very carefully and cautiously.

DEINSTITUTIONALIZATION

Senator RUDMAN. The next item just really deals with the whole question of the institutionalization. What are you doing in terms of budget allocation? What percentage of your money that you spend is aimed at getting people out of these institutions into more normal settings?

Mr. TRACHTENBERG. Let me have Dr. Pardes answer that.

Senator RUDMAN. You can have anyone you like answer.

Dr. PARDES. The Systems Act programs for the chronically mentally ill are aimed at fostering the capacity of those people to both come out of the hospital and also make it on the outside—so there is a specific NIMH authorization for chronically mentally ill patients. The Institute had also operated a community support program which has been picked up by a number of the States. These States, liking the model, have added their own dollars into it.

HEROIN INCREASE

Senator RUDMAN. My next question has to do with drug abuse. You may not know the answer to this; there may be a better source. But do you have any information at all on the level of heroin that is presently entering the country? That's very closely related to what you have done in terms of prevention and treatment.

Dr. POLLIN. We know that there has been a significant increase in the amount of heroin coming into the country over the past several years due to substantially increased supplies in Southwest Asia, and we have seen a significant increase in the number of heroin addicts in the Northeast Corridor.

Senator RUDMAN. Do you work with DEA in any way? Is there any connection between these agencies in terms of their enforcement areas and so forth?

Dr. POLLIN. There's very close interaction. I can spell out the details.

Senator RUDMAN. That's all right. I just wanted to know if there was. I assumed there was, but I just wanted to ask the question.

OVERMEDICATION

One other question on the drug abuse area. There has been a lot written and said about overmedication, particularly among older people. How do you view that as a problem?

Dr. POLLIN. We think that's a very real problem, and we've had a number of specific initiatives addressing it. We think it is a problem that is inevitably bound to grow, given the changing demographics of the population and the increasing number of drugs developed by industry.

Dr. PARDES. Senator, if I can just comment, I think one of the important issues with regard to overmedication is proper education of the practitioners who dispense those medications. In fact, when one looks at the source of the largest number of overmedications, it is often in the

general health sector. That's one of the reasons we make a major effort to try to educate our general health practitioners about proper mental health treatments.

Mr. TRACHTENBERG. I would like to mention, the Surgeon General, about a year ago, put out a special information bulletin to physicians throughout the country about a concern on overmedication and the interaction of drugs and alcohol. We worked closely with FDA in developing that.

EFFECT OF LOWERED DRINKING AGE

Senator RUDMAN. All right. Last question I have for this panel, and I'm not sure whether you have an answer statistically, but have you done any work at all in trying to analyze what the effects has been of lowering the drinking age in certain States? I know the National Highway Traffic Safety Administration has statistics, and I'm familiar with those, but I'm much more interested in the statistics that you might generate on that.

Mr. DE LUCA. We have been funding, Mr. Chairman, several studies to gain that data. We have our best information from the studies in the Midwest where the drinking age was lowered to 18. There are indications in the information that we collected to date that when the drinking age is lowered to 18, there is an increase in the actual fatalities related to drunk driving situations.

Now what we don't know is that as you increase the age level—as you increase the age level back up to 19, 20, or 21, whether or not then you accomplish prevention. One study in Michigan suggests that you do experience a lowering of alcohol-related crashes and fatalities when you restore the age limit to 21. When most of the legal drinking age of the country about 15 years ago was at 21 there were very few States at 18. Then we went through a period where the drinking age was lowered to 18, the majority of States was 18. Now States are beginning to move their drinking age back up again.

The studies we are doing are to see whether or not there is benefit from raising the drinking age, whether or not you can correct the situation, and we have indications that previous history of lowering the age did increase the number——

Senator RUDMAN. Increase?

Mr. DE LUCA. Did increase the number of fatalities at that point in time?

Mr. TRACHTENBERG. I was going to add, if you'd like more detailed information for the record, we'd be pleased to submit it.

Senator RUDMAN. I think that would be helpful.

[The information follows:]

AGE LIMITS FOR DRINKING

The issue of age limits for drinking has become an increasing concern in the past decade at the State levels, especially as changes in these limits are believed to be connected to increases in alcohol-related highway accidents for youth. In the 1970's as many as 30 States lowered the age for drinking, mostly in response to a general trend in lowering the age of majority for voting. Typically the age limits were reduced from age 21 to 18 or 19. During 1973 to 1978 a considerable body of research that examined the impact of these liberalizations of age restrictions on highway casualties was conducted.[1]

There are conflicting interpretations of the evidence. Some researchers argue that much of these increased reports of alcohol-involvement are mainly an artifact of changed highway patrol enforcement and reporting procedures. On balance, however, most researchers agree that lowering the age limits is associated with an increase in fatal crashes and serious morbidity. Based in part on these studies conducted during the seventies, several States have moved to raise the age limits for drinking to higher or previous levels. While research on the impact of these more recent changes is underway, at least one study in Michigan concludes that highway crash data indicate that restoring the age limit to 21 in that State resulted in an 18- to 31-percent reduction in alcohol-related highway crashes for the 18–20 age group during the 12-month period after the change.[2] Another study is currently being conducted in Massachusetts of this same question by Boston University.

Ongoing research is designed to explore issues such as how precisely law enforcement officers perceive and enforce age limit laws, and the role of the State alcohol beverage control authorities in enforcement. More data are also needed about the actual implementation of these laws, and their long-term impacts, particularly of raising the law once limits have been lowered. Research concerning the response of the alcoholic beverage industry at producer and retail levels to changes in age limits is also necessary.

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[1] Douglass, Richard. "The Legal Drinking Age and Traffic Casualties." Alcohol Health and Research World 4 (Winter 1979–80), pp. 18–25. For another view see Richard Zylman, "Fatal Crashes Among Michigan Youth Following Reduction of Legal Drinking Age." Quarterly Journal of Studies on Alcohol 35 (1974), pp. 283–286.

[2] Wagenaar, Alexander. "The Minimum Legal Drinking Age: A Time Series Impact Evaluation." Ph. D., Dissertation, University of Michigan, 1980.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

Evaluation of Drug Treatment Programs

Question: Where do we stand on evaluation of drug treatment programs?

Answer: NIDA's evaluation activities over the past decade have centered around both the process and the outcome of drug treatment programs. In the area of process evaluation, NIDA has conducted or supported ongoing assessments of compliance with facility and operational requirements, assessments of quality of care provided, and studies of the efficiency of program operations. In the area of outcome evaluation, NIDA has conducted or supported numerous studies on the effectiveness of treatment.

Some of the earliest treatment effectiveness studies were based on NIDA's Drug Abuse Reporting Program (DARP), which collected data on approximately 44,000 clients admitted to treatment at 52 agencies throughout the U.S. and Puerto Rico between 1969 and 1973. Research based on these data have yielded much important information regarding the life patterns of drug abusers. For example, DARP-based studies have shown that drug abuse is a chronic disorder requiring multiple treatment interventions over a period of years, that the intervals between return to treatment typically increase with time, and that heroin users have higher death rates, and meet more violent deaths, than non-opioid users.

Followup studies of three separate DARP cohorts have been completed and published by NIDA. The major finding of these studies has been that drug treatment is effective in reducing drug use and criminality and in promoting productive lifestyles.

In addition to the DARP-based studies, NIDA has sponsored numerous demonstration projects designed to study different treatment approaches and the related client response. Some examples of these projects are listed below:

1. Factors Related to Recovery and Relapse on Followup, Eagleville, Pennsylvania

2. Addict Aftercare Needs and Service, Walnut Creek, California

3. Therapeutic Communities: Self-Evaluation of Fifteen Programs, Chicago, Illinois

4. Drug Treatment Followup Studies, New York, New York, and Washington, D.C.

A major new treatment effectiveness study being conducted by NIDA is the Treatment Outcome Prospective Study (TOPS), designed to be the most comprehensive study of drug treatment ever undertaken. It is a nationwide longitudinal study involving 14,000 clients at 38 federally funded centers in eight cities for the period 1979 through 1981. A followup is planned for each yearly cohort.

A distinct from the above efforts to evaluate the outcome of treatment programs, a multi-tiered monitoring system to evaluate the process of care rendered in drug treatment programs has been

established over the past decade by NIDA, State drug agencies, and local treatment programs. The role of each of these tiers in assuring that drug abuse treatment and rehabilitation clinics are operated in an "efficient, economical, and effective manner" is described briefly below.

Local Treatment Programs - Self evaluation by the local treatment programs is promoted through several NIDA manuals, namely Manual for Drug Abuse Treatment Program Self Evaluation and Clinical Record System for Drug Abuse Treatment Programs.

NIDA provides technical assistance to local programs in improving clinical needs assessment and performance measurement capabilities. Local program personnel have access to training programs such as NIDA's National Training System course, "Introduction to Program Evaluation." In addition, a number of programs voluntarily contract with the Joint Commission on the Accreditation of Hospitals (JCAH) to evaluate their compliance on a periodic basis with national accreditation standards for drug abuse treatment programs.

State Agencies - State governments are responsible for assessing the economy, efficiency, and effectiveness of local treatment programs under State jurisdiction. The current process must include, but is not limited to, quarterly documented site visits to each program, and annual site visits to each clinic. For clinics, the assessment must cover the following areas:

1. Staffing;

2. Treatment Slot Utilization;

3. Case Management;

4. Treatment Process, including adequacy of client records for (a) case management, (b) CODAP reporting, (c) billing, and (d) determining the effectiveness of the treatment services provided. At least a 10 percent random sample of the client records at each clinic must be reviewed annually;

5. Treatment Facility; and

6. Methadone Security (if applicable).

In order to assist States in these activities, NIDA has published a Statewide Services Contract Program Review Manual which details techniques for the monitoring and evaluation of drug abuse treatment programs. A series of seminars was held nationwide to explain this manual to all of the States. In addition, individual assistance in implementing the manual has been given by a NIDA contractor to 15 States. The manual is currently being implemented in more than half of the States.

NIDA - NIDA Project Officers monitor the quality of the States' monitoring and evaluation programs. Guidance for these monitoring activities is contained in the NIDA Division of Community Assistance (DCA) Policy and Procedures Manual. In December 1980, responsibility for monitoring compliance with FDA Methadone Regulations was shifted from FDA to NIDA. In addition to the monitoring done by its own Project Officers, NIDA utilizes

a contractor to undertake more comprehensive program management reviews (PMRs) of all management systems at State drug abuse agencies and operating programs. These reviews include the organizational, fiscal, subcontract management, and client recordkeeping/reporting systems within NIDA-funded programs.

Question: After more than a dozen years of operations, do we have some idea of whether all these drug abuse programs are working?

Answer: Following more than a decade of intensive evaluation research, NIDA is pleased to be able to report that the methods of treatment commonly used beginning in the 1970s are associated with improved patient outcomes. While it is difficult to arrive at a consensus on the desired goals of treatment, three generally accepted outcome criteria have emerged: reduction in use of drugs; reduction in crime; and an increase in productive activity, such as holding a job, attending school, and homemaking.

Data are emerging also that show the comparative value of the various means of treatment for differing types of patients. These findings clearly demonstrate the worth of publicly funded programs. At the same time, they provide guidelines for selecting and improving the forms of treatment best suited to the needs of drug abusers.

Outcome studies such as those referred to in the previous response are designed to assess patient behavior, before, during, and after treatment, rather than to answer directly the question of whether drug abuse programs are working. In order to prove that any treatment program is responsible for an individual's eventual drug abstinence, it would be necessary to design a prospective study which would restrict treatment from a controlled portion of the study population, a course of action which is not ethically feasible.

The major findings from the outcome studies of the last decade are summarized below.

- o Methadone maintenance, therapeutic community, and outpatient drug free treatment produce significant reductions in drug use and criminality and significant improvement in productive activity such as employment.

- o While detoxification as a "treatment" for drug abuse is relatively ineffective in terms of lasting effect, it provides an introduction to longer term treatment modalities and provides a short-term control that permits a drug abuser with a heavy addictive habit to survive until he is ready to seek alternative and more definitive treatment. For example, of the 38,567 patients who left federally-funded detoxification treatment during 1979, the reason for discharge for 16 percent was given as "transferred/referred" to long term treatment.

- o There is a linear relationship between the length of drug abuse treatment episode and the favorability of treatment outcomes.

- o Clients who complete treatment do significantly better than those who leave treatment under other circumstances.

- Non-opiod drug abuse clients and opiod addicts appear to do equally well in therapeutic community and outpatient drug free treatment.

- While not a direct measure of treatment effectiveness, it has been found that addicts who overcome their dependence on heroin and other opiates commit 84 percent fewer crimes than dependent addicts.

- Recent trends in heroin indicators give us further reason to infer that the nationwide network of over 3,500 drug treatment programs is impacting positively on drug abuse. From 1976 to 1979, heroin-related emergency room mentions decreased by 66 percent; from 1976 to 1978, heroin/morphine medical examiner mentions fell 77 percent. Furthermore, the recent large influx in Southwest Asian heroin into this country has by and large been limited to the Northeast quadrant of the United States, whereas past experience has shown that heroin increases in one area have spread throughout the nation.

That some drug abusers experience relapse after treatment and may have successive treatment episodes does not rebutt the generally consistent findings that many clients in drug abuse treatment programs do well during and after treatment. Drug abuse, as is the case with other chronic disorders, is a difficult and complex problem which requires a commitment of resources on a continuing basis. Nor should the fact that clients may be in treatment for long periods necessarily be viewed as a negative phenomenon. The important consideration is that substantial numbers of people are recovering, and remain abstinent after treatment, and that a great many other individuals manage to curtail their continued drug use, such that their employment potential is enhanced and dysfunctional aspects of their lifestyles are brought under control.

Question: How does your new evaluation project, the "Treatment Outcome Prospective Study" differ from previous studies, in order to provide answers needed to assess the effectiveness of drug treatment efforts?

Answer: The Drug Abuse Reporting Program (DARP) was established over 10 years ago at Texas Christian University. It has been one of NIDA's major efforts in long-term evaluation of federally supported community treatment programs. DARP has assessed the impact of drug abuse treatment based on a longitudinal followup of large national samples of clients who were addmitted to treatment during 1969-1973 and followed up for approximately five years. This series of studies utilized a data base of treatment admission records and client status reports at intervals during treatment. Followup interviews provided indepth reporting on treatment outcomes and client functioning over the post-treatment period.

The DARP studies have basically been conducted on a retrospective model which views the client after treatment has been completed. They have expanded our knowledge of the natural history of drug abuse in such areas as post-treatment drug use patterns, social productivity, and criminal behavior.

However, there are several major limitations associated with the DARP project. Designed originally as a Federal management information system, the DARP followup studies grew out of the availability of this data base. Consequently, little is really known about the client experience during the actual treatment phase, the type or frequency of service, etc. Further, we have reason to believe that the reliability of the early clinic data may be suspect since the programs at that time had no research training or experience. On the other hand, the TCU Institute of Behavioral Research applied rigorous research methodologies in the cohort followup and analysis phase.

The development of the Treatment Outcome Prospective Study (TOPS) is a clear sequel to the Drug Abuse Reporting Program. It is designed to fill in the current gaps in our knowledge of the backgrounds and behaviors of clients entering drug treatment programs and the impact of treatment on client outcomes. TOPS is a longitudinal, descriptive, and correlational survey. Naturally occurring dynamics of the treatment process, such as early termination and dropout, provide an opportunity to employ a non-equivalent comparison group which can facilitate the attribution of overt client behavioral changes to the treatment process.

TOPS is designed to track a multi-year census of 14,000 clients upon admission to 38 treatment centers in eight cities during the 1979-1981 period. The programs employ trained researchers to interview clients at the time of initial contact, periodically while in treatment, and at 90 days, one year, and two years after termination from treatment. The data that are collected are used to:

1. Describe in detail the backgrounds and characteristics of drug abusers contacting the treatment programs;

2. Examine variations in client behavior before, during, and after treatment;

3. Examine variations in behavior among groups of clients with selected background characteristics and experiences; and

4. Identify those demographic (and other background) characteristics, treatment services, or other experiences which appear to be most important in explaining differences and changes in major types of outcome behavior including drug and alcohol use, criminality, and economic (productive) behavior during and subsequent to treatment.

Within the design and the systematic monitoring of individual client behavior over significant periods of time, the TOPS is expected to develop knowledge about the dynamics of drug treatment by identifying the factors which may help to determine why and for whom treatment does or does not work. This will enable treatment programs to modify their efforts and thereby provide more meaningful, efficient, and effective treatment.

A major distinction in TOPS as compared with the earlier DARP studies is in the area of client characteristics. The DARP study population were primarily heavy opioid users, many of whom had experienced treatment episodes at the Lexington or Fort Worth

Public Health Service Hospitals. In contrast, the nature of drug abuse problems, the current broad network of treatment services, and the types of clients seeking treatment have all changed considerably since DARP. Contemporary clients manifest a wider range of drugs of abuse. Changes have also occurred in policy areas which impact eligibility for treatment. For example, Federal Methadone Regulations have modified admission criteria from an earlier two-year documented history of opiate dependence to one year.

The TOPS study will serve both policy and research purposes. A primary policy objective is to establish sets of behavioral expectations for individuals who have had treatment experiences. Since an important aspect of the TOPS design and approach is the identification and analysis of the association of client behaviors with client characteristics, community environments, and the treatment process, it will be possible to conduct studies and evaluations of individual programs, groups of programs, and the national treatment effort in terms of reasonable improvement expectations across selected behavioral measures.

In terms of research, the objective of TOPS is to provide information that will generate clear testable hypotheses about treatment effects. It will be a focal point in NIDA's ongoing efforts to evaluate and understand the dynamics of drug treatment. For example, TOPS data will permit asking such questions as, "Do drug abuse clients who receive vocational training or job placement services fare better in post-treatment crime measures, drug consumption, and productivity?" Thus TOPS will serve both to generate new, more directed research and to substantiate the findings of previous research on a broader scale.

ADDICTION RESEARCH CENTER

Question: Should the Addiction Research Center be moved from its present location in Lexington, Kentucky, to Baltimore?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Does its location, so far from other NIDA programs limit its effectiveness?

Answer: The isolation of the ARC in its former facilities in Lexington, Kentucky, was one of the major reasons NIDA sought to relocate the ARC when the U.S. Bureau of Prisons decided to terminate the participation of Federal prisoners in research programs.

One of the major benefits resulting from the relocation of the Addiction Research Center to Baltimore has been its proximity to other major research organizations in the Baltimore metropolitan area. A number of collaborative arrangements have been implemented which take advantage of this proximity, and others are in the planning stages.

Among those which have been implemented:

- Appointment of ARC scientists to the faculties of the Schools of Medicine of Johns Hopkins University and the University of Maryland.

- Collaboration of ARC staff fellows with an internationally recognized neuroscience program at the University of Maryland and with researchers at the Johns Hopkins Pulmonary Laboratory.

- Agreement with Johns Hopkins to provide advice and technical assistance to the ARC on the development and design of the animal care and animal laboratory facilities being prepared to house these functions when they are relocated from Lexington, Kentucky.

- Arrangement with the Chesapeake Physicians Professional Association to provide research subject recruitment, intake, evaluation, counseling, medical treatment, discharge, and followup services.

- Collaboration with the Behavioral Pharmacology Research Unit, located at the Baltimore City Hospital, on research in the area of the behavioral aspects of compulsive cigarette smoking.

DRUG ABUSE PREVENTION

Question: How broadly do you interpret your mandate to promote drug abuse prevention efforts?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What is there about the drug efforts that distinguishes them from other activities designed to get young people on the right track in life?

Answer: The adolescent drug abuse prevention programs of the National Institute on Drug Abuse (NIDA) are distinguished from other youth-oriented prevention strategies in that they focus on altering drug behaviors. These programs evaluate prevention strategies to determine the most effective activities and identify innovative drug abuse prevention approaches that should be developed.

Many of NIDA youth-oriented prevention programs are unique in that they focus on renewal and revitalization of the role of the family in the prevention of drug-taking behavior among its adolescent members. The programs provide resources and support services to family self-help groups on the State and grass roots level to allow the family members themselves to become the influential force in drug abuse prevention.

Because there are social and behavioral aspects of youth drug-taking behavior which are unique, there is now and will continue to be a need for programs to provide drug-specific information. Consequently, NIDA prevention efforts are not limited to education and information alone, but include programs to reduce, eliminate, and/or delay drug use and use-related dysfunctional behavior through alternatives for youth. Such programs of alternative behaviors help youth develop increased

levels of confidence and self reliance, and provide constructive ways for them to meet the real or imagined need served by drug-taking behavior.

EFFECT OF DRUG ABUSE PROGRAMS

Question: What evidence is there that the programs of the National Institute on Drug Abuse have had a measurable effect in reducing the incidence of drug abuse?

Answer: While it is difficult to document causal relationships between drug abuse patterns and NIDA's treatment and prevention efforts, we are encouraged to see changes in the drug abuse patterns that suggest NIDA's programs are successful. For example, from 1976 - 1979, heroin-related deaths dropped nearly 80 percent; heroin-related emergency room visits fell 69 percent during the same period; and the percentage of patients admitted to federally funded treatment who stated heroin as their primary drug of abuse dropped from 65 percent in 1976 to 40 percent in 1979. Diazepam (Valium) related emergency room visits declined by approximately 18 percent from 1978 to 1980. High school students' use of the hallucinogenic drug PCP has dropped markedly from 7.0 percent in 1979 to 4.4 percent in 1980. For the second consecutive year there has been a decline in the daily use of marijuana by high school students. In 1978, 10.7 percent used the drug daily, whereas, the percentage dropped to 10.3 percent in 1979 and 9.1 percent in 1980. Between 1975 and 1978, there was an almost two-fold increase in daily or near-daily marijuana use (defined as use on 20 or more occasions in the past 30 days), from 6 percent to 11 percent. However, since 1978, the daily use has dropped to 9 percent. The university investigators who provide these data credit the substantial media attention given to new scientific evidence on marijuana's effects with much of the increased student concern with health consequences. (Half of all seniors now believe there is a great risk of harm associated with being a regular marijuana user, up from 35 percent in 1978). Some peer disapproval of regular marijuana use always has existed among high school seniors, the investigators note, but disapproval has increased appreciably over the last two or three years (75 percent in 1980 say they personally disapprove of regular use, up from 66 percent in 1977).

DRUG ABUSE PREVENTION

The budget shows that in 1981, NIDA is allocating 90 percent of its grant money to treatment programs and 10 percent to prevention. In 1982, only 7 percent of grant funds will be spent on prevention programs.

Question: Why is support for prevention declining?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: Would it not make a lot more sense for the Federal Government to use most of its limited resources on prevention programs while relying on State and local governments to pick up most of the cost of the treatment programs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

GAO REPORT ON DRUG PROGRAM DEFICIENCIES

In a report released in April 1980, the General Accounting Office maintained that at many drug abuse treatment centers, ineligible people are being treated and that also treatment slots go unused. Additionally, according to GAO, providers are not treating as many people as reported.

Question: What is the National Institute on Drug Abuse doing to better enforce admission criteria?

Answer: In an effort to better enforce admission criteria, NIDA is developing treatment standards for statewide services grants which will more strongly emphasize the Institute's policy for discouraging treatment of the casual drug user. In developing these standards, the former Federal funding criteria, which includes an admission policy section, is being comprehensively reviewed and revised. In addition, the Institute is working with the Criminal Justice System through technical assistance efforts and interagency planning groups in communicating the need to discourage the use of traditional drug abuse treatment for casual drug users. The Institute has also recommended to the States that programs should place increased emphasis on matching services to specific client needs, and should develop linkages with other service agencies so that only those clients with the greatest clinical need are being treated.

Question: What are you doing to both determine reasons for differences in utilization rates, and to use information gained to increase the use of the treatment capacity?

Answer: NIDA has instituted a survey to identify treatment units with 30 or more slots who have reported their utilization for the months of May through September 1980. Those units with an average utilization of 90 percent or less and those with an average utilization over 100 percent are under review for identification of any unusual circumstances that would preclude that treatment unit from the survey. The next step will be to collect all existing information from our computerized systems on those units and perform an analysis in order to determine the existence of significant characteristics between the two groups. The results of the survey should provide NIDA with information that may be applied to those units with varying utilization rates in maintaining a higher level of utilization.

It should be noted, however, that in the most recent past, NIDA has taken a very aggressive approach in reducing the level of funding to States when their individual treatment units do not meet NIDA's 90 percent utilization requirement, even though the State may be at or above the 90 percent level. The enforcement of this requirement reduces the number of units below 90 percent utilization to a much smaller percentage.

Question: What are you doing to enforce proper reporting by providers of drug abuse treatment services?

Answer: NIDA Project Officers are able to identify, on a monthly basis, those programs that fail to report to CODAP or are consistently late in reporting. This information is conveyed to our grantees with requests for corrective action, and they are warned that failure to report will result in NIDA withholding funds from the State.

Secondly, the grantees have the responsibility to validate the reporting of their treatment units and to provide corrective assistance when problems are identified. NIDA provides a monthly report to the States indicating the level of utilization of each service provider in the grant. Irregularities in reporting can be easily identified allowing the State to initiate inquiries and corrective action, if appropriate.

Finally, when Project Officers conduct site visits to the grantee, they randomly sample the grantee's monitoring effort, and our contractor also reports on the accuracy of the treatment units reporting to the State.

DRUG ABUSE MONITORING

Question: Tell us about your drug abuse monitoring activities.

Answer: NIDA's Division of Community Assistance Project Officers are assigned to certain States and are responsible for monitoring each of the States' use of NIDA treatment funds. The specific monitoring activities basically revolve around compliance with the statewide services grant and the State plan requirements. Ideally, Project Officers should conduct onsite monitoring visits to each of their States on a quarterly basis. However, due to travel limitations, they must measure compliance with requirements, in part, through review of form submissions and other requested documentation.

The Division has issued a Project Officer's Review Guide to assist the Project Officers in monitoring the single State agencies (SSAs). The guide identifies topics that have to be reviewed periodically and provides for consistency in asking monitoring questions. Currently in process is the development of a Project Officer Monitoring Manual which will incorporate the informal guide and provide specific direction for Project Officers in their monitoring of individual treatment programs as well as the SSAs.

NIDA's Grants Management Branch staff also conduct monitoring site visits to the States. They review and evaluate the States' financial, contract, personnel, property, and information management systems.

Question: How many site visits were made to grant holders during 1979?

Answer: During 1979, there were 313 program management site visits made to grantees/contractors. This figure cannot be

averaged out to determine how often each State was visited because, due to the complexity of some States, it was necessary to visit cetain ones more often than others.

There were 49 financial management site visits made to grantees and/or contractors during 1979.

Question: How up-to-date is your accounting firm (Touche Ross) in its schedule of audits?

Answer: Touche Ross and Company does not perform audits of single State agencies or NIDA-funded treatment programs. The firm conducts State assessments (SAs) of the State agencies and program management reviews (PMRs) of specific treatment programs in accordance with a NIDA schedule prepared in consultation with the firm and the State Project Officers. At this time, the contractor is on schedule for each of its reviews.

Question: How often do you withhold payment or continuation approval because of a project's failure to meet standards or because of other delinquencies?

Answer: NIDA does not withhold payment to grantees, i.e., SSAs when individual treatment programs under their administration fail to meet treatment standards or engage in fraudulent activities. Instead, we withdraw or reduce the amount of funds available under the statewide grant that may be used to support the specific treatment program in question. This creates an unexpended balance in the grantee's award, which is applied against the next year's award.

Question: With the single State agencies assuming much of the monitoring function for the National Institute on Drug Abuse, how do you determine how well they are doing it? In other words, how do you monitor the monitors?

Answer: The Division of Community Assistance (DCA) and the Grants Management Branch (GMB) monitor the single State agencies (SSAs) in several ways. DCA Project Officers do onsite monitoring of the SSAs which also involves sampling a few treatment programs to ensure that NIDA funds are being properly utilized. On these visits, Project Officers use a monitoring guide to provide uniformity in approach. The Division also employs the services of a contractor, Touche Ross, to perform program management reviews and State assessments which are later acted upon by the Project Officers. In addition, the SSAs must submit to DCA monthly utilization information and periodic performance evaluations.

GMB monitors the States' financial, contract, personnel, property, and information management systems through site visits and review of form submissions.

The products of DCA, GMB, and the contractor's monitoring efforts are reviewed by Institute staff throughout the year to determine the level of State compliance with Federal standards.

DRUG ABUSE-SHIFT TO STATE AND COMMUNITY PROGRAMS

Question: Do you plan to continue drug abuse prevention and treatment programs indefinitely, or do you foresee the day when the States and communities will eventually assume this burden?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Have you ever cut off funding for a drug abuse project?

Answer: When we were direct grantors and not working through the States, NIDA had the responsibility to monitor and give assistance, when needed, to correct or improve the capability of programs to provide the required services. However, when it became evident that a program was unable to meet the Federal requirements, action has been taken to reduce the level of support or withdraw Federal support entirely. We have withdrawn funding from a number of programs due to their lack of compliance to the Federal funding criteria, poor fiscal management, and inappropriate services as well as instances of fraudulent activities. More recently with the statewide grants, NIDA has assisted SSAs in withdrawing their financial support of programs funded through the SWSG that have not met the grant or State contract requirements.

Question: If so, did the project die, or did alternative support materialize?

Answer: Once NIDA support has been removed from a program, reporting requirements no longer exist; therefore, we cannot document the continued presence of the treatment facility. However, NIDA makes arrangements with the State to assure that quality care for the clients is not interrupted and that they are placed in other funded facilities.

MARIJUANA

Question: Based upon all your research, are you able to draw any reliable conclusions about the effects of smoking marijuana over a long period of time on physical and mental health?

Answer: Some reliable conclusions arising from marijuana research include:

1. Many kinds of psychological functioning and performance are seriously impaired while the marijuana user is intoxicated. These include: learning ability, problem solving, recall, verbal expression, and complex psychomotor performance such as that involved in driving and flying. Such research findings make clear that marijuana use in conjunction with school attendance and the operation of a motor vehicle or other demanding psychomotor tasks is undesirable.

2. Epidemiological research into the incidence and prevalence of marijuana use has shown patterns of first use at increasingly younger ages and patterns of more frequent use. However, the latest reliable figures indicate a decline in the number of

users. Such uniformly collected data provides a sensitive indicator of changes in the marijuana use picture.

3. Psychosocial research has enabled us to define groups at high risk of becoming seriously involved with marijuana, particularly those who begin their involvement in the use of alcohol and tobacco early and show early evidence of delinquent behavior and alienation.

4. Marijuana research has also established physical evidence of withdrawal symptoms when very heavy use of marijuana is discontinued and evidence that use can be disruptive in much the same way that alcohol use is.

5. Converging lines of animal and human research indicate a potentially serious risk to pulmonary health related to marijuana use.

6. A possible effect on reproduction and on the body's immune response, together with other preliminary findings, have significantly eroded the belief that marijuana is a "harmless" drug.

Question: What is your position on the use of marijuana for treatment of glaucoma and to counter the effects of chemotherapy for cancer patients?

Answer: We believe the institutes with expertise in the disease being studied are in the best position to provide comments on the treatment of that disease. NIDA's expertise is with the complex operation of the drug itself and how this pertains to a number of social concerns.

Such research will, of course, receive NIDA's full cooperation both with respect to supply of the drug and technical consultation on the drug's effects. In the past, NIDA has supported a number of preclinical studies on the therapeutic effects of cannabis-derived products.

Question: To what extent do you coordinate with the National Eye Institute on your research into glaucoma?

Answer: NIDA has been working in close cooperation with NEI for the past five years. NIDA sponsored preclinical research of the efficacy of THC eye drops in rabbits and has developed and manufactured various THC dosage forms for study by NEI-supported investigators. In March 1981, NIDA and NEI will jointly sponsor a conference to review the research findings developed to date.

HEROIN

In your prepared statement you referred to increased need for heroin treatment slots from a major influx of heroin from Southwest Asia.

Question: Is there a significant increase in the amount of pure heroin entering the U.S. in the past couple of years?

Answer: Estimates of the supply of heroin entering the United States from principle foreign sources have been made by the

National Narcotic Intelligence Consumers Committee and are contained in the Supply of Drugs to the U.S. Illicit Market from Foreign and Domestic Sources in 1979. The estimates show an approximate doubling of metric tons of heroin originating from Southwest Asia from 0.6 - 0.8 metric tons in 1978 to 1.2 - 1.5 metric tons in 1979. However, the estimated overall tonnage entering the U.S. from all foreign sources shows a decline, principally due to lesser amounts entering the U.S. originating in Mexico.

Question: Have you been able to identify the primary sources?

Answer: The National Narcotics Intelligence Consumers Committee has identified the primary sources of heroin entering the United States as being Mexico, Southeast Asia, and Southwest Asia. While the total estimated metric tonnage of heroin originating in Mexico and Southeast Asia has shown a decline between 1976 and 1979, heroin originating in Southwest Asia shows a dramatic increase from a negligible amount in 1976 to between 1.2 and 1.5 estimated metric tons in 1979.

Question: To what extent are you working with the Drug Enforcement Administration and the U.S. Customs Service to investigate and seize shipments of heroin?

Answer: Since the National Institute on Drug Abuse is not a law enforcement agency, it is not involved in the investigation and seizure of shipments of heroin entering the United States. However, National Institute on Drug Abuse staff maintain a close working relationship with staff of the Drug Enforcement Administration in monitoring heroin indicator trends in the United States.

Question: Is the proposed budget sufficient to respond to the increase in heroin addiction?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: How many new addicts were there in each of the last two years?

Answer: While the illicit nature of heroin use makes precise counts of the numbers of users difficult to obtain, analysis of heroin indicator data show a substantial increase in activity in the Northeastern part of the United States and sporadic increases in other major U.S. cities such as Detroit, San Francisco, and Phoenix. Analysis of treatment admission data shows an overall decline in new admissions to treatment for primary heroin use between the mid and late 1970s, as well as a generally low level of newly initiated heroin use. At present, demographic analysis of heroin trend data shows that the substantially increasing heroin activity in the major areas of the Northeast involve former users returning to heroin use as a result of increased availability. While current data do not suggest large increases in teenage heroin use, which characterized the heroin epidemics of the late 1960s and early 1970s, continued increases in supply and

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the establishment of distribution networks could affect drug demand changes in both a younger age group and in areas outside of the Northeast.

Question: What specific narcotics education programs aimed at vulnerable populations are under way or in the planning stages?

Answer: NIDA prevention program efforts are not directed at specific drugs but rather toward four population groups known to be at high risk of drug abuse: youth, women, the elderly, and minority group members and can be categorized as related to knowledge development, technology transfer, service delivery, and resource mobilization. All program initiatives developed within these categories are designed to directly or indirectly prevent drug-taking behavior among the target populations.

An example of a specific narcotics education program is "The Door - A Center of Alternatives." Located on the east side of New York City, "The Door" offers broad comprehensive alternative education and career development services for inner-city adolescents, between the ages of 12 and 20, who are at high risk of becoming drug involved, of remaining under educated, and of becoming part of the hard core unemployed. The specific aim of "The Door" drug abuse prevention program, through its various services and workshops, is the development of competence and self esteem in adolescents by assisting young people to overcome learning deficiencies by promoting skills development and by helping in the development of better coping mechanisms.

Through prevention service grants to the States, NIDA provides support to local communities for the development of youth alternative projects, called Channel One projects. These alternative projects are intended to give young people exposure to a variety of rewarding and meaningful activities that offer positive alternatives to drug-taking behavior. Examples include community services such as working with the elderly, restoration, conservation, and perservation of the environment. There are currently 90 Channel One projects located in over 30 States. Many of these projects are located in the inner cities and are aimed at high risk youths who are just beginning to experiment with heroin and other narcotics.

Other NIDA prevention activities and services aimed specifically at high risk populations include those performed by the Center for Multicultural Awareness (CMA). The Center provides technical assistance, materials development, and share information and resources on ethnic minority program development. CMA works with States to develop culturally relevant prevention programs and booklets for the major ethnic groups. Over the past few years, CMA has provided technical assistance to over 35 States and territories; conducted 10 multicultural workshops for over 200 participants; developed a resource library containing over 1,200 entries; and developed 21 documents on a variety of subjects including a six-booklet series of "Multicultural Drug Abuse Prevention," four booklets on "Families and Drug Abuse Prevention," and several cultural-specific bibliographies.

NIDA also recognizes the high risk potential and vulnerability of low-income youth to drug abuse, and has developed a manual for program planners and developers working with low-income communities. The manual is intended to serve as a resource for program planners, service providers, community leaders, and others who are in a position to influence policy and support the development of drug abuse prevention programs. It describes some of the better planning procedures and prevention strategies that are currently being used in low-income communities across the country.

OVER MEDICATION

Question: How serious is the problem of overmedication, particularly of older people?

Answer: The problem of overmedication is serious, particularly for older persons because the elderly consume more prescription and over-the-counter drugs than any other group. Nearly 20 percent of the patients entering the geriatric services of general hospitals have disorders directly attributable to the effects of prescription drugs. Since many of the elderly are on fixed incomes, they frequently turn to over-the-counter preparations and home remedies to avoid the cost of seeing a physician. Those of 65 and over comprise 10 percent of the population; they consume 25 percent of the medication. Over 80 percent of the nation's elderly suffer from at least one chronic condition as opposed to 40 percent of the remainder of the population. The potential for drug abuse by the elderly is present both in institutional and non-institutional settings. A General Accounting Office (GAO) report shows that on the average, an elderly person takes four to seven types of medication daily, but that figure may double for nursing homes. Serious problems result from overuse of over-the-counter drugs and prescription drugs especially when used in combination with prescription drugs or alcohol. As the largest consumer of legal drugs, the elderly are at risk of dependency problems involving a wide variety of substance.

Question: What is being done to alleviate the problem of overmedication?

Answer: NIDA is committed to the prevention of overmedication particularly among the elderly who are most at risk. This drug problem is more often one of misuse rather than the deliberate abuse of legally available prescription drugs. Education and information provided to both the elderly and the health care professional help to prevent drug misuse. NIDA has supported the development of "The Elder Ed Project: A Model Education Program, Prevention, and Medication Misuse for the Elderly." This project provides a booklet for individuals "Using Your Medicines Wisely: A Guide for the Elderly," as well as a film and discussion materials for groups in the community. These materials are aimed at better use of medicines by the elderly through education.

For health professionals working with the elderly, NIDA has developed and disseminated two training documents. One, entitled "Drug Misuse and Abuse Among the Elderly," was developed for

medical staff, social workers, and volunteers; the other, entitled "Improving the Use of Drugs by Elderly Patients," is aimed at pharmacists and pharmacy students.

Little definitive information exists regarding use and misuse of drugs by the elderly. In an effort to define the relevant issues and problems as well as to suggest appropriate governmental responses, NIDA has initiated research studies and demonstration projects. This effort has produced a number of publications such as "The Aging Process and Psychoactive Drug Use," "A Study of Legal Drug Use by Older Americans," "A Survey of Drug Taking Behavior of the Elderly," and "Drug Abuse and the Elderly: Perspective and Issues."

Although a variety of programs have been developed for the elderly, more effective ways are needed to reach and educate the elderly regarding drug taking behavior. Health providers must also be part of this educational strategy, perhaps on a combined community basis with input from a variety of professions, agencies, and services. NIDA is planning a national program to determine the most effective ways of reaching and educating the elderly about the use and misuse of drugs.

EVALUATIONS

Question: What percentage of the Institute's research allocations have in fact been expended or are planned for targeting on evaluation efforts? Specifically, the committee would like to learn of the extent to which service delivery programs are effective, or could become more so.

Answer: Our FY 81 evaluation ceiling is currently $3 million. Of this amount we estimate that about $1 million will be spent from our research allocations. This is about 0.4% of our total 1981 research budget under the continuing resolution.

Community Mental Health Centers (CMHCs) have been a very effective means of delivery of high quality services nationwide and yet being cost effective at the same time. Inpatient care and long term hospitalization have been shown to be both the most restrictive modality and the highest cost per patient. At CMHCs, the percent distribution of inpatient care episodes have decreased while outpatient care episodes have increased. In 1969, there were 205 operating CMHCs, which showed 18% of the total episodes were for inpatient care. 1978 statistics show that of 600 operational centers, inpatient care episodes were only 12% of the total episodes. Moreover, long term hospitalization at State and county hospitals have significantly decreased while CMHC services and other outpatient services have increased.

Trends show that CMHCs are continuing to improve on reaching unserved and underserved groups. 1972 statistics show that only 15.5% of non-white races were served by CMHCs while in 1978 this has increased to 20%.

An array of flexible grant mechanisms would assist in providing even more effective delivery system.

Following more than a decade of intensive evaluation research, NIDA is pleased to be able to report that the methods of treatment services commonly used beginning in the 1970s are associated with improved patient outcomes. While it is difficult to arrive at a consensus on the desired goals of treatment, three generally accepted outcome criteria have emerged; reduction in use of drugs; reduction in crime; and an increase in productive activity, such as holding a job, attending school, and homemaking.

Recent trends in heroin indicators give us further reason to infer that the nationwide network of over 3,500 drug treatment programs is impacting positively on drug abuse. From 1976 to 1979, heroin-related emergency room mentions decreased by 66 percent; from 1976 to 1978, heroin/morphine medical examiner mentions fell 77 percent. Furthermore, the recent large influx in Southwest Asian heroin into this country has been limited to the Northeast quadrant of the United States, whereas past experience has shown that heroin increases in one area have spread throughout the nation.

Services provided by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) grantees have resulted in positive client changes in terms of abstention rates, reduced consumption, increased employment and better earnings. Hospitalization rates and alcohol-related arrests have been shown to drop substantially from intake into treatment to a followup of the clients six months or more later. As an example of the magnitude of these changes, one recent report showed that 55 percent of the treated clients had abstained from drinking since treatment, hospitalization had decreased by 14 percent, and serious symptoms such as blackouts and tremors had decreased by 75 percent. The number of days free from alcohol had increased for treated clients and family stability was substantially improved. Employment had risen by 13 percent and mean income for the group had risen by $54 per month.

As one means of making the services program even more effective and providing a more integrated system of health care at the State level, the Institute initiated the State Alcoholism Services Demonstration Program in 1980. Under this program funds are channeled through the State Alcoholism Authority (SAA) for support of projects formerly funded directly by NIAAA and the SAA has full responsibility for monitoring the projects. Early results suggest that this decentralization can be done without interfering with the quality of care. This mechanism of direct funding to the States also allows for special attention to be paid to the needs of special populations.

REORGANIZATION

Question: What savings would occur by combining alcohol and drug abuse programs into one Institute?

Answer: By consolidating these two programs there should be some savings in management overhead, both administrative and programmatic.

Question: What disadvantages would you foresee with such a consolidation?

Answer: The national focus on each of these public health problems has been heightened with the visibility of separate Institutes. As a result, these fields have made significant advancements in the

past few years. Under consolidation, there would be a loss of this separate identity which might curtail the current momentum. It may also be perceived by the service populations as a decrease in the Federal commitment to each program.

Question: What about advantages?

Answer: Since both Institutes are concerned with substance abuse, consolidation could have a clear programmatic rationale. By reducing overhead and focusing administrative control, it should result in improved management and more consistent policy implementation. For the field, it could lessen reporting requirements and regulations by combining such efforts as State plans, data gathering activities, and, to a limited degee, some program operations.

Question: Another reorganization plan could include moving the research arm of all three Institutes--Alcohol, Drug Abuse and Mental Health--into NIH; the services to the Health Services Administration; and training to the Health Resources Administration. What, if any, validity do you see with that proposal?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

QUALITY OF RESEARCH

Question: What assurances can you give that the quality of ADAMHA research is comparable to that of NIH?

Answer: ADAMHA is very proud of the quality and accomplishments of its research programs. Quality of scientific investigations and findings are best judged by experts in particular disciplines and areas of research. Accordingly, ADAMHA, like NIH and other research organizations, uses advisory and consultation mechanisms designed to yeild such judgements. These include a dual review process for proposed extramural projects, expert panel reviews of intramural programs, and ongoing and periodic reviews of research areas, programs, and policies. Such mechanisms afford expert advice on the best opportunities for scientific advancement. However, it is also important to note that the quality of research results are judged primarily through an expert review process used by scientific journals in deciding what to publish, and that outstanding scientific contributions are recognized through awards and other professional honors.

The key process for ensuring the quality of our extramural programs is the dual review process, which ADAMHA, like NIH, has used for over three decades. The dual review process has been the subject of numerous Congressional committee, Presidential Commission, and other reviews, which have consistently validated the reliability of the process for assessing scientific merit. The statutory requirements for initial peer review and secondary review by the Council are further evidence of the confidence in this process.

Under the dual review process, every application is first reviewed in depth by a group of experts (most of them from non-Federal institutions) who are peers of the scientists applying for support. This review involves a thorough assessment of the significance of the proposed project to the state of knowledge in the field, the appropriateness and feasibility of the proposed methods, the qualifications and

expertise of the proposed staff, the availability of resources needed to carry out the research, and the reasonableness of the proposed budget in relation to the research. On the basis of this scientific merit evaluation of a proposed project, reviewers recommend approval or disapproval of an application. For those recommended for approval, a numerical score is assigned. The fact that only about 50% of research proposals submitted to ADAMHA are recommended for approval is evidence of the rigor of this review process.

The second stage of the dual process is presentation of applications for final recommendation to a National Advisory Council for each Institute. The Council's review provides an important oversight and check on the appropriateness of the initial peer review, as well as an opportunity for policy considerations to be weighed with scientific assessments. Decisions on which applications to fund are made by Institute staff within each program area primarly on the basis of numerical scores through the dual review process.

Since the peer review system is so crucial for determining the best scientific opportunities, the integrity and quality of the process itself are crucial. Accordingly, the management of the peer review process is separate from the management of programs in order to ensure maximum objectivity. Further, like NIH, ADAMHA considers the scientific competence of an investigators as the primary criterion for selection of review group members. In this regard, factors such as the quality of scientific training, the record of publications in relevant biomedical or behavioral science journals, and awards and other honors received for scientific contributions are major considerations. In orienting reviewers, we stress the importance of reviews based solely on scientific merit. This focus on merit is assured by the combined efforts of review group members, chairpersons, executive secretaries, supervisory staff in review units, and Council oversight.

ADAMHA's intramural programs provide facilities and working climates which foster the conduct of long-term interdisciplinary research by highly talented scientists. A form of peer review is used to regularly assess the productivity and excellence of work done in intramural laboratories. The prototype for such reviews is a Board of Scientific Counselors, a mechanism developed by NIH, which periodically conducts indepth reviews of research done in each laboratory and makes recommendations to the Director of an Institute on intramural program directions and allocation of resources. NIMH has used this mechanism effectively over a number of years. The other two ADAMHA Institutes are in the process of setting up similar mechanisms, and have in the meantime used ad hoc consultations with prominent scientists to assess the quality of and recommend directions for their intramural programs.

Another category of activities essential to ensuring the quality of research programs is ongoing and periodic assessments of research areas, programs and policies. As in our sister agency NIH, ADAMHA Institutes use diverse approaches tailored to the nature, size and organization of research programs. In all cases, however, expert review of the state of the art in particular fields provides a crucial underpinning for review of funding priorities, allocation of funds among program areas, and weighing of scientific opportunity with public health needs. Several expamples of mechanisms for addressing these important issues are: (1) NIMH and NIDA systems for engaging outside consultants in reviews of selected research areas each year, in order to generate recommendations for future directions; and (2) a recent NIAAA-initiated review by the Institute of Medicine/

National Academy of Sciences to assess areas of greatest opportunity in alcohol research for the next five years.

The extent and significance of accomplishments by ADAMHA-sponsored scientists, as reflected in the various reviews discussed above, scientific publications, and awards for scientific achievement, is extensive. Several examples of recent breakthroughs illustrate the productivity and quality of the national alcohol, drug abuse, and mental health research programs administered by the ADAMHA Institutes.

One is the revolutionary research on endorphins, which are opiate-like substances naturally occuring in the brain. Over a dozen such substances have been identified by NIDA researchers. This research has dramatically increased our knowledge about the functioning of the brain and holds promise for eventually developing more effective treatments for narcotic addiction and possibly psychiatric disorders.

Another highly promising development is the use of the PETT (positron emission transaxial tomography) scanner to detect and see activity of different parts of the brain. The recent developement by an NIMH intramural scientists of a method of measuring metabolism in the brain has opened up exciting opportunities for use of the PETT scanner in understanding brain function and pinpointing dysfunction.

In, the alcohol research field, discovery and description of the "fetal alcoholism syndrome" (FAS) by an NIAAA supported investigator has heightened public awareness of the effects of alcohol on unborn children and stimulated critical research on the basic mechanisms of the problem so necessary to prevent and treat FAS.

Other research findings hold prospects for direct application to improving treatment. For example, initial clincal trials on a drug named carbamazepine, demonstrate its effectiveness in large numbers of manic depressive patients who are not responsive to the usual treatment with lithium. Also, studies on a drug called buprenorphine seem to indicate that it is a promising new treatment for narcotic addicts. Another important development comes from initial findings that statistical analysis of blood samples normally taken for routine pysical examinations can be used to identify early problem drinkers.

The accomplishments of ADAMHA supported scientists are reflected in the numerous honors, awards, and other forms of recognition they have received. In a recent attempt to catalogue some of these honors, over 200 awards and other honors were identified as having been received by ADAMHA intramural and extramural research scientist over a ten-year period. Several distinguished examples include Dr. Julius Axelrod's receipt of the Nobel Prize in Physiology and Medicine in 1970, Dr. Rose Yalow's receipt of the same award in 1977, and Dr. Solomon Snyder's receipt in 1978 of the Mary E. Lasker Award for Basic Biomedical Research.

In conclusion, the vitality of our research programs, and ultimately our ability to understand, treat, and prevent alcoholism, drug abuse, and mental illness, depend heavily on the quality of the research we conduct and support. We are confident of the excellence of our research programs, and look forward to continued advancments in science and practical applications that will be forthcoming from these activities.

AUTHORIZED PROGRAMS

Question: Are there any funds included in the Fiscal 1982 budget for programs not yet authorized?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: If so, what are they and do you anticipate any problems with their enactment?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

ALCOHOL, DRUG, AND MENTAL HEALTH CENTERS COORDINATION

Question: To what extent is there coordination between the various alcohol, drug abuse, and mental health treatment centers within a given locality?

Answer: Legislation for these programs requires program coordination of these programs within the community. Under the Mental Health Centers Act, CMHCs are to develop affiliations with alcohol and drug treatment programs within the catchment (service) area. Furthermore, if the existing drug and alcohol services are considered inadequate to meet the needs within the catchment area, the CMHC is expected to develop these services as part of its programs.

Question: What, if any, efforts are being considered to consolidate these programs at the local level?

Answer: Actual consolidations at the program level have not been considered a productive treatment approach for patient-related reasons. However, in many instances, alcohol and drug programs are organized under a single "substance abuse" State or local administrative agency, with alcohol and drug services provided in individual programs at the same site. A recent survey of alcohol and drug treatment units found that at least 1200 out of several thousand facilities surveyed were mental health facilities which contained an alcohol and/or a drug abuse program unit within them.

Question: What problems would you anticipate with such consolidation?

Answer: Consolidations of such services are likely to reduce the number of clients seeking or using the services. Alcoholics are usually older than drug abusers and neither likes to be identified with the other. In this same vein, neither drug addicts nor alcoholics consider themselves as having "mental problems" and consequently find it hard to accept services in a facility providing mental health services.

Mental health professionals have earned baccalaureate or higher degrees and are responsible for providing direct treatment services in the mental health field. While professionals direct many alcohol

and drug treatment services (e.g. in-patient detox), indigenous treatment specialists composed of former drug addicted persons or former alcoholic persons often provide direct services in this field. Credentialling can become a source of conflict when the three programs are consolidated.

Finally, attention to each of these three public health problems was heightened with the visibility of separate programs. Under consolidation, such attention would likely decrease and the problems associated with these problems increase.

Question: Do you have estimates as to how much could be saved?

Answer: Administrative costs at the top level might be reduced somewhat, but if services are to be provided at the existing level, no further savings would be realized beyond fiscal management and evaluation and data units. Treatment staff would remain largely the same. On the other hand, as indicated before fewer clients might avail themselves of the services and this could permit a sharp reduction in staff. Offsetting these savings are the difficult to measure direct and indirect costs of human suffering of the individuals, their families, and their communities when alcoholism, drug abuse, and mental illness remain untreated.

NEW INITIATIVES

Question: What new initiatives or demonstration projects are planned for next year?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

SCHOOL DRUG AND ALCOHOL ABUSE

Question: How much did the Federal Government spend in Fiscal 1980, and how much will be spent in fiscal year 1981 in school drug and alcohol abuse programs?

Answer: The National Institute on Drug Abuse (NIDA) spent over $2 million in FY 1980 and estimates spending over $1 million in FY 1981 to develop, demonstrate, and evaluate effective school drug abuse prevention strategies.

The National Institute on Alcohol Abuse and Alcoholism spent $1,084,000 in fiscal year 1980 and will spend $584,000 in fiscal year 1981 for education in the schools.

Question: How are these programs coordinated with Bureau of Health Education (CDC)?

Answer: The NIDA Prevention Branch encourages coordination of drug abuse prevention programs with the Bureau of Health Education (now the Center for Health Promotion and Education) of the Center for Disease Control. BHE officials participated in planning NIDA's annual State Prevention Coordinators Skills Development Workshop. As a result of this interaction, a system of information exchange between BHE's Risk Reduction Coordinators and NIDA's State Prevention Coordinators was initiated. This system facilitates communication and eliminates duplication of efforts among Federal, State, and community substance abuse prevention

programs. In addition, a variety of exchanges have been initiated through Pyramid, Center for Multicultural Awareness, and National Prevention Evaluation Resource Network projects.

In 1978 the Congress enacted Public Law 95-626 to provide $10 million in funds for the development of a risk reduction program designed to deter smoking and the use of alcoholic beverages among children and adolescents. This program is being administered by the Center for Disease Control, Bureau of Health Education (BHE) in coordination and with cooperation from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Office on Smoking and Health.

NIAAA has provided BHE with information and materials regarding exemplary alcohol education programs. Many of the alcohol/smoking reduction proposals received by BHE were based on previous NIAAA-funded models. NIAAA provided assistance in reviewing these grant proposals, and continues to provide technical assistance and resources to the staff of BHE responsible for monitoring these projects. Information regarding evaluation protocols for alcohol education programs as well as common data set items is shared between BHE and NIAAA.

Question: Describe promotion and prevention activities.

Answer: During the last five years, the Institute has played a key role in developing a coherent national policy in school drug abuse prevention. It has developed testable prevention models and has funded evaluation research projects to measure their effectiveness. Technical assistance has been provided through nationwide resource projects which put local community and school groups in touch with the expertise they need to initiate innovative prevention programs and to evaluate their operations. School prevention materials relevant to various racial/ethnic populations have been developed. Special efforts have been focused on the States to increase their capability to plan, develop, implement, and monitor prevention activities for schools.

Conceptually, NIDA's drug abuse school prevention activities are organized around four major program modalities. Information programs involve the development of printed and non-printed informational materials such as pamphlets, posters, brochures, films, and television and radio spots that present a drug abuse prevention message or provide factual information about drug abuse. Affective educational strategies include courses in communication skills, techniques for problem solving, and decision-making skills. Many of these programs are designed for application in a school setting although the modality is not limited to school-based efforts. Alternatives programs include work-oriented, recreational, and other activities that meet individual developmental needs and channel productive energy into school and community-sanctioned projects such as the restoration of historical landmarks or the retrofitting of homes to better conserve energy. School credits are given for these programs. Intervention activities are primarily directed at individuals who are substantially involved in drug abuse. Specific intervention approaches include counseling, hot lines, cross-age tutoring, and positive peer group pressure.

Education and information dissemination targeted to children and youth have been a high priority within the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Two examples of our programs dealing with Native Americans may be illustrative. One program stesses the utilization of peer leaders in an alcohol education and peer counseling program at a Native American boarding school. The program evaluation indicated short term positive results and has resulted in the development of a manual to assist other native American schools in implementing similar programs. NIAAA is pursuing the possibility of disseminating information about this model program through the Bureau of Indian Affairs.

Secondly, NIAAA is sponsoring an alcohol education prevention program being tested on two Indian reservations in California. The project is developing culturally-relevant prevention education materials for Indian youth. The alcohol-related attitudinal and behavioral impact of the program on participants is being evaluated.

Question: What percent are they of the overall budget for alcohol and drug abuse?

Answer: Expenditures directed specifically at school drug abuse programs amounted to almost 1 percent of NIDA's total FY 1980 budget and approximately 16 percent of NIDA's prevention budget. It should be noted, however, that while not specifically directed at school programs, most of NIDA's prevention expenditures are directed specifically toward youth.

In fiscal year 1980, the National Institute on Alcohol Abuse and Alcoholism spent .006 percent and will spend less than .004 percent in fiscal year 1981 for promotion and prevention activities in the schools.

PRIVATE SECTOR EFFORTS ON DRUG AND ALCOHOL PROBLEMS

Question: What efforts have you undertaken to encourage private companies to deal with mental health, drug and alcohol problems of their employees?

Answer: During 1980 the Institute opened a campaign to alleviate the stigma of mental illness. The initial target of the campaign is to address the difficulty surrounding employment opportunities and prospects for former mental patients. Activities were aimed at stimulating employment by increasing public awareness of the problem and attempting to stimulate a positive response. Available research information is being packaged for distribution to TV writers, producers and directors, to sensitize them to the effects of stereotyping the mentally ill.

The 20,000 person membership of the National Restaurant Association has offered its cooperation in a research study on employment of the mentally restored. The Washington Business Group on Health will be sending us its study of 250 of the Fortune 500 corporations which identifies hiring policies and practices as related to the mentally restored. The Lerner-Institute for Labor and Mental Health, a clinical/services training program, is training trade union personnel in a variety

of mental health skills so they can function as first-line prevention agents in the workplace.

NIDA's prevention efforts in the workplace focus on prevention and early intervention and provide visibility on the workplace as a prevention setting in a number of ways:

1. The State Drug Abuse Prevention Grant Program provides the opportunity for State governments to award contracts for prevention services in the workplace to local agencies. Emphasis is given to services provided in occupational settings.

2. The Prevention Resource Sharing and Technical Assistance System (PYRAMID) solicits, collects, categorizes, and disseminates information specific to prevention of drug abuse in the workplace. This program offers information materials and onsite assistance to State and local governments and other private or public organizations that request training in developing drug abuse prevention programs or directly to private companies interested in initiating a program.

3. The Channel One program involves business and industry assistance to local communities to develop prevention programs. Although this is not a prevention program in the workplace per se, it indirectly provides the opportunity for companies to become aware of and involved in drug abuse prevention efforts. It is expected that such exposure will lead to more direct prevention efforts in the workplace.

4. NIDA is actively participating in the ADAMHA Prevention Conference in the Workplace which will provide recommendations on future directions and strategies.

5. NIDA has also developed materials for private companies' use as they develop their own programs to prevent drug abuse in the workplace. Several of these initiatives include a prevention focus while others may be considered within the more traditional employee assistance program (EAP).

   a. Drug Use in Industry (1979) - This study focused on the nature and extent of current drug use in the industrial setting; the impact of such drug use on industry, including the impact on job performance; the extent, nature, and success of drug education and treatment programs in the industrial setting; and the policies and practices of companies with regard to job applicants and employees using drugs;

   b. Developing an Occupational Drug Abuse Program (1978) is available for companies that are considering or intend to implement an occupational drug abuse program. This publication includes state-of-the-art implementation procedures and available resources. Through use of the Dunn and Bradstreet mailing list, this publication has been widely circulated to business and industry;

   c. NIDA has also co-funded with NIAAA (1977) an evaluation project conducted by the United Labor Legislative

Committee of Texas (ULLC). This project promoted employee assistance programs in companies which did not have them; and

d. NIDA supported the development of a business and industry prevention program in the area of stress reduction and improved management techniques. The course was developed under a NIDA grant by the Charlotte Drug Education Center, Charlotte, North Carolina.

6. NIDA has also provided support for:

a. Monographs and papers on various aspects of occupational programming. One monograph, Drug Abuse Prevention in the Workplace which is now being developed, describes the evolution of occupational programs and provides a rationale for and describes prevention strategies in the workplace; and

b. A Blue Cross demonstration project aimed at developing third-party payment mechanisms for drug and alcohol abusing employees.

A leadership capability in occupational alcoholism programming has been established by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in all 50 States, the District of Columbia and Puerto Rico to provide technical assistance and consultation to both public and private workforces within their jurisdictions. The Institute has also trained a national network of personnel to assure a uniform state-of-the-art in program development applied to each State and territory. Although this network has built a solid and established foundation, the movement has not achieved sufficient credibility and stature to continue on its own momentum. As a recent survey of State formula funds showed only a small percentage of State funds were expended on occupational programs.

The occupational programs have assisted organizations and occupations, from the largest to the smallest, from the blue-collar worker to the board rooms of corporate industry. It is a concept supported by both organized labor and corporate management who willingly support an effort that saves both lives and profits. The leadership position exercised by NIAAA has demonstrated a cost effective, high productivity approach that has attracted the professions, ranging from doctors and lawyers to unique and critically sensitive occupations, such as police and airline pilots. In a great many instances these occupational programs have been so effective that when initiated, they have served as a stepping stone to penetrate an entire industry.

Question: To what extent have private companies developed their own Mental Health, Alcohol and Drug Abuse Prevention Programs over the last few years?

Answer: In general, private companies have not developed their own mental health prevention programs. However, some private companies have developed the following activities which have a preventive component: (a) employee assistance programs

which offer assessment of the employee's presenting problem and some counseling, (b) retirement counseling, (c) stress management, and (d) placement of laid-off employees. However, overall, preventive mental health efforts have had little impact on the workplace and little opportunity to demonstrate their effectiveness.

When the National Institute on Alcohol Abuse and Alcoholism (NIAAA) was established in 1971, fewer than 300 occupational programs could be identified. The quality and uniformity of programs were unknown, but believed to be diverse and of varying quality. The 1971 thrust by NIAAA channeled through the States helped to develop, and, later replicate occupational alcoholism programming. As a result of this national leadership, more occupational programs exist. They are also better managed and more effective. These efforts are supported by both business and labor leaders. The occupational concept has continued to grow in acceptance until today over 5,000 programs exist in the U. S., both in the public and private work sectors. However, new concepts and strategies are needed to reach the millions of people who work in settings that employ from several to 100 employees where the majority of persons work.

There has been a considerable increase in the number of programs in the workplace designed to address drug and alcohol problems. However, it is difficult to precisely assess the extent to which these programs are specific to drug abuse and whether they are primary prevention/early intervention oriented or treatment and rehabilitation. Estimates of the numbers of programs that have emerged over the last few years vary. One figure indicates that the number of occupational programs focusing on substance abuse increased from 500 to 5,000 from 1973 to 1981. Another figure indicates that from 1971 to 1977 the number went from 300 to 1,500, with the caveat that it is unclear what portion represents specific drug abuse prevention efforts.

Most of the programs in work settings have been historically focused on alcohol identification and referral. With the increase in reported drug use starting in the late 1960s, a greater focus is being included on drug abuse and drug abuse-related problems as a part of these programs.

Each grantee will administer a uniform benefit structure for Medicare and Medicaid eligible providers that will include reimbursement for unlimited episodes for detoxification services; up to 30 days per calendar year for inpatient alcoholism treatment, including halfway house care; up to 45 visits per calendar year for outpatient services; and individual and group counseling as well as a specific array of alcohol-related services including nursing care and physical therapy. A contract proposal is being developed to provide an evaluation of the demonstration.

Question: What cost estimates are available on the implications of expanding alcoholism services under Medicare and Medicaid?

Answer: Studies have indicated that there is a cost-offset to providing alcoholism treatment services, i.e., alcoholism treatment services provided reduce general health care costs. The demonstra-

tion with the Health Care Financing Administration is expected to specifically document such savings. A study of 12 alcoholism programs conducted by the Alcohol, Drug Abuse and Mental Health Administration showed that the magnitude of reductions in medical care utilization, sick days or sickness and accident benefits paid was quite substantial, i.e., reductions ranging from 26 percent to 69 percent with a median of 40 percent. A State employees alcoholism demonstration project developed to provide services to California State employees showed that for every dollar expended for treatment of these employees during the period of 1974-78, there was an estimated savings of 42 cents in non-alcoholism health care costs.

TEENAGE DRINKERS

Question: What programs are being geared specifically toward teenage drinkers?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: In last year's testimony, you indicated the intent to conduct a multi-media campaign for disseminating information on alcohol abuse. You stated this was one of the most important and effective ways to reach young people.

What is the status of that campaign?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

EFFECT OF ALCOHOL ABUSE PROGRAMS

Question: What evidence is there that the programs of the National Institute on Alcohol Abuse and Alcoholism have had a measurable effect in reducing the incidence of alcohol abuse and alcoholism?

Answer: The reversal in the mortality rate from liver cirrhosis, long used as an indirect measure of the level of alcohol misuse among population groups, represents an important development which has occurred within the past decade. Death rates from this cause had been steadily increasing since the end of Prohibition until 1973 when the rate peaked. Since then, cirrhosis mortality rates have been declining each year.

While the cause for this decline is not clearly understood and is probably multifactorial in nature, the programs of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) have helped to increase awareness of the adverse effects of alcohol on the liver and have influenced the health care system to provide earlier and intensified intervention to help reduce this major cause of death. In 1977 cirrhosis of the liver still remained the eighth leading cause of death for all ages, and the fourth leading cause of death among persons age 45-64 years.

While more specific measureable data on the effect of our limited resources on a problem of this magnitude is not available, it should be noted that , as well as increasing public awareness,

the NIAAA is targeting services to over a quarter million people previously unreached by the general health care sector. In addition, the evaluation of these prevention demonstration programs has begun to show promising results in reducing alcohol-related problems among youth. Analysis of the outcome of particular program strategies has shown success in increasing knowledge about alcohol, modifying attitudes and values, and increasing decisionmaking and coping skills. Assessment of the impact on drinking behavior is also showing positive results. For example, those students most exposed to one school-based program over three years showed a marked decrease in incidence of drunkenness and problem drinking when compared with students in a control community and with students in previous years at the same grade level.

PREVENTION OF ALCOHOLISM

Question: In 1980, NIAAA used 9.7% of its community programs funds for prevention programs. In 1982, the percentage of funds allocated to prevention programs is virtually the same--10%.

Why isn't there a much greater emphasis given to prevention programs?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

EVALUATION OF ALCOHOLISM PROJECT GRANTS

Question: What portion of alcoholism project grants and contracts support prevention projects?

Answer: In FY 1980 obligations for project grants and contracts totalled $78.7 million. Of this amount, $7.6 million, or 9.7 percent, were for prevention projects.

Question: What portion goes to treatment and rehabilitation activities?

Answer: In FY 1980, obligations for treatment and rehabilitation activities totalled $51.5 million, or 65 percent of total project grants and contracts.

Question: How often is a project evaluated?

Answer: Service projects are evaluated on an average of every 18 months to assure that they are providing adequate patient care. This is done through staff visits and through a management information system. All programs also are part of an ongoing evaluation project which assesses treatment effectiveness.

Prevention programs on the other hand are funded by the Institute as demonstrations with evaluation built into the research design. The evaluation is conducted as required during the life of the project dependent upon the approved research methodology.

Question: What criteria do you use to evaluate a program's effectiveness?

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Answer: The effectiveness of our prevention efforts are measured in terms of: consumers demands for prevention materials, the ability to increase knowledge regarding the potential for developing problems with alcohol, teachers increased competency to convey information regarding alcohol, teachers increased ability to identify and offer assistance to students with alcohol problems, the reduction in accidents which are alcohol related and the successful training of clinical personnel in the identification of women at risk of having a Fetal Alcohol Syndrome (FAS) baby.

In the service area, a program is evaluated in terms of whether it is meeting its original goals and objectives, whether it is in compliance with State or local licensure requirements and, above all, whether it is providing adequate patient care as measured by increased sobriety, increased employment, increased income and improved health status.

Question: Once a project is evaluated, how is the information used?

Answer: Information is used as a management tool to determine which programs are most in need of technical assistance, which programs seem to be doing extraordinarily well in terms of treatment outcome and, in combination with technical site visits, which programs are worthy of further support.

Evaluations have also been used to determine whether a formal replication of the program is warranted. The Institute has one such formal replication of three prevention curricula under way. This activity is about to move into its dissemination phase where program individuals will be trained in the component parts of the curriculum models.

Meaningful information is disseminated as rapidly as possible through scientific journals and other informational exchanges such as the National Clearinghouse for Alcohol Information. Based on this information, Federal, State and local governments, as well as program officials can decide whether to utilize specific program models or techniques.

INTERCULTURAL ALCOHOLISM PROJECT

Question: What is the status of the U.S./Japan Joint Alcoholism Research Project?

Answer: As arranged during the October, 1980 meetings in Japan, Dr. Hiromasa Ishii of Keio University Medical School visited the National Institute on Alcohol Abuse and Alcoholism (NIAAA) Intramural laboratories and met with NIAAA Extramural and Intramural Research staff on November 5. Definitive plans were made and agreed to for collaboration in the exchange of biomedical data and liver samples.

Dr. Kazutoyo Inanaga of Kurume University Medical School in Kyushu and President of the Alcohol Medical Association of Japan came to Washington on November 9 and discussed possible pilot studies with the Director and key NIAAA staff.

Followup in the biomedical area involves three major activities:

- Agreement to provide liver material on an "as available" basis from Japanese sudden death victims to Dr. T. K. Li at the Indiana University Medical School for use in investigating the biochemical heterogeneity of the isozymes of alcohol dehydrogenase under an existing research grant from NIAAA. Dr. Ishii is currently in the process of obtaining final approval from the Keio University Department of Medicine to provide the liver samples.

- Discussions which were held at the University of Hawaii have resulted in liver samples from seventeen Japanese individuals being provided to Dr. Li by the Pathology Department.

- NIAAA intramural scientists are working out detailed arrangements with Dr. Ishii to field test the blood chemistry screening instrument under development by them in Japanese populations having a high incidence of liver cell carcinoma.

Followup activities in the epidemiological research area are evolving more slowly pending the availability of funds and scientist resources in Japan. While there is general agreement to cooperate in undertaking comparable cross-cultural community-based studies of drinking patterns and associated problems in both countries, the planning and implementation process is both complex and costly in terms of required resources -- even for the establishment of pilot projects.

As a next step, plans are being made for Dr. Ogata of the Hokkaido Mental Health Center to visit the United States from April 13 to April 30 for discussions on establishing collaborative cross-cultural community studies. He will also visit some of the NIAAA-funded Alcohol Research Centers. Prior to his visit, NIAAA staff will prepare a proposed action plan for organizing and initiating community studies which will be reviewed with Dr. Ogata.

Question: What projects will be undertaken in this joint venture?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

WARNING LABELS ON ALCOHOLIC BEVERAGES

Question: What is the HHS position regarding the advisability of health warning labels on alcoholic beverages?

Answer: The Health and Human Services position regarding warning labels on alcoholic beverages was expressed in a report to Congress and the President last November. This report was prepared jointly with the Treasury Department in response to a requirement in P.L. 96-180. The report states that it would be premature to recommend health warning labels for alcoholic beverages at this time. Although both Departments believe that alcohol-related health hazards are an extremely significant public health problem, it is not clear at this time that the risks associated with alcoholic beverages can be effectively communicated through labeling. In addition, both Departments are concerned that we not over-use one of the government's most important forms of health alert -- a general health

hazard warning label -- if it is possible to communicate the information adequately through other means.

Question: How effective do you believe health warning labels will be in preventing fetal alcohol syndrome?

Answer: The Joint Health and Human Services/Treasury report to Congress noted that a warning label directed toward alcohol consumption during pregnancy may fit some of the conditions under which such labels tend to be effective -- the threat to health is unequivocal, will be manifested relatively quickly, and requires only a short-term behavior change.

In addition, women of childbearing age are thought to be particularly susceptible to messages concerning the health of their unborn child. A warning label could alert the family and friends of pregnant women, as well as the women themselves, helping to develop a support system for the short-term behavior change required.

Despite these considerations, the Departments did not recommend warning labels directed toward risks of alcohol consumption during pregnancy. The decision not to recommend warning labels was based on several factors, including:

- o A pregnant woman or a woman in childbearing years confront multiple hazards to the safe completion of pregnancy. In our judgment, such information can be more successfully conveyed through a public information campaign covering all significant risks to pregnancy rather than through a labeling effort directed toward the single risk of alcohol consumption, with corollary efforts singling out smoking and caffein.

- o A number of experts consulted warned that singling out a specific health issue such as fetal alcohol syndrome for a warning label may cause consumers to discount the importance of other significant alcohol related health hazards.

However, we are eager to communicate to women of child-bearing age and to their families, friends, and physicians two basic points:

- o Alcohol consumption during pregnancy can harm a developing infant, with effects such as spontaneous abortion, severe physical and mental defects, and low birth weight, among others.

- o The safest course of action for women who are pregnant, or considering pregnancy, is not to drink alcoholic beverages at all.

ALCOHOLISM COMMISSION

Question: What is the status of the National Commission on Alcoholism and Other Alcohol-Related Problems?

Answer: The National Commission was established by P.L. 96-180. Members were sworn in at the Commission's first meeting on December 8, 1980. A second meeting is scheduled for late April. The Department intends to work with the relevant appropriations subcommittees of both chambers of Congress to assure that

operating funds are available for the Commission and looks forward to resolution of this matter.

Question: Have any meetings yet been held?

Answer: At the request of former Secretary Patricia Roberts Harris, the Commission met on December 8, 1980. It was at this session that the members of the Commission were sworn in.

Question: Does HHS intend to request funds for the Commission in its revised FY '82 budget?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

ALCOHOLISM INSURANCE

Question: What is the status of the Alcoholism Insurance Initiative started this year?

Answer: The development of increased health insurance coverage for alcoholism treatment has been a high priority of the Institute for a number of years. As early as 1974 and 1975 the National Institute on Alcohol Abuse and Alcoholism (NIAAA) provided assistance to grantees in developing accounting and management procedures which would assist them in securing reimbursement from health insurers. Simultaneously, the Institute funded the development of alcoholism treatment standards by the Joint Commission on Accreditation of Hospitals (JCAH), so that some uniform national standards would be available.

Since the JCAH standards have become oriented to large institutional providers of services, the Institute has funded a contract for the development of standards for Federal treatment programs which are predominately free-standing inpatient and outpatient centers and halfway houses. These standards will provide a basis for insurors to know that acceptable services are furnished in programs which meet the standards.

In 1976 through 1978, the Blue Cross Association under contract with NIAAA surveyed member plans and developed a model benefit package for health insurance coverage of alcoholism treatment programs. This package and supporting materials have been distributed to member plans nationwide.

The current Alcoholism Insurance Initiative consists of seven components. The first was a National Alcoholism Health Insurance Conference convened last fall at which 20 leaders from the private and non-profit health insurance sectors met to discuss barriers and methods of expanding coverage. Second, as an outgrowth of this conference a National Marketing Symposium is being planned to develop and disseminate techniques for expanding the availability of alcoholism coverage.

Third, the Blue Cross/Blue Shield Association was awarded a contract to market test alcoholism benefits in three geographic sites to see how best to sell benefit packages.

Fourth, the Health Care Financing Administration (HCFA) is reviewing and plans to award 5 grants to demonstrate alcoholism

coverage under Medicare and Medicaid by about 75 previously unreimbursed providers such as low cost outpatient treatment programs. The demonstration will run four years and will be accompanied by an evaluation effort. The NIAAA is working cooperatively with HCFA on this project.

Fifth, contract proposals have been requested to study the impact of expanding health insurance coverage for alcoholism services. This effort will document the cost benefits and offsets of other health costs in four already operating benefit packages such as those in States which have mandated coverage.

The sixth and seventh initiatives are efforts to develop National Health Insurance models and to study the experience of States which have mandated or considered mandating coverage and to develop a model State law for such purposes.

Question: What percentage of funding for treatment projects is derived from third-party reimbursement over the past several years?

Answer: Overall, third-party reimbursement constitutes the largest contributor to funding the Nation's alcohol treatment system. Of the total 4,703 alcoholism treatment units surveyed in April 1979 approximately 32.1 percent of all funds ($255 million of a total of $795 million) was contributed by third-party funding. Private insurance carriers were the largest contributor among third-party funding, providing $143 million or 56 percent of all third-party funding.

The Institute's funded projects have increased their third-party funding from 15.4 percent in 1976 to 21.0 percent in 1979. At the same time, there has been a steady increase in the percentage of private insurance as part of third-party funding receipts from 2.4 percent in 1976 to 2.9 percent in 1979. However, because of the wide range of clientele and the National Institute on Alcohol Abuse and Alcoholism programs, coverage for alcoholism treatment ranges from 10 to 45 percent, depending on the type of program.

Question: Can you give us an idea of the percentage of employee's health policies which now include coverage for alcoholism treatment?

Answer: There has been a highly significant growth in the availability of health insurance coverage for alcoholism treatment. The National Institute on Alcohol Abuse and Alcoholism has worked extensively with the commercial carrier industry in a voluntary partnership to encourage this expansion. A survey by the Health Insurance Association of America of leading insurance companies published in 1978 showed that more than 80 percent provided some type of coverage for alcoholism. Their percentage of policies specifying exclusions or limitations on alcoholism coverage dropped from 16.5 percent in 1972 to 13 percent in 1975. A 1979 survey of executives of a sample of Fortune 500 companies showed that 74 percent of the executives reported their companies provided health insurance coverage for inpatient treatment and 51 percent for outpatient care. The survey noted that ". . . executive awareness of such coverage has improved markedly within the past three years."

Question: What progress has been made on the demonstration program, in conjunction with the Health Care Financing Administra-

tion, showing the feasibility of expanding alcoholism services under Medicare and Medicaid?

Answer: In August, 1980, the Health Care Financing Administration (HCFA) issued a special solicitation announcing the demonstration grant program and technical assistance was provided to applicants by both HCFA and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Applications were reviewed on March 5 and 6. It is anticipated that five grants will be awarded by early June. The five umbrella grantees will coordinate and administer networks of free-standing inpatient and outpatient alcoholism treatment centers and halfway houses. Each grantee will administer networks of up to 18 treatment facilities previously ineligible for Medicare and Medicaid coverage.

ALCOHOL RESEARCH

Question: What portion of alcohol research funding is planned for each of the following areas:

(1) teenage alcoholism;
(2) impact of alcoholism on families;
(3) fetal alcoholism syndrome;
(4) effectiveness of occupational alcoholism programs;
(5) alcoholism and the elderly; and
(6) alcoholism and domestic violence?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

ALCOHOL EDUCATION

Question: What portion of the Alcohol Institute budget is being used for Public Information?

In FY 1981 it is estimated that the National Institute on Alcohol Abuse and Alcoholism will use $1.9 million or 1.2 percent of the total budget for public education programs. These include the implementation and evaluation of a mass media public education program through the State and local governments, preparation and printing of publications, responses to public inquiries, and other public education activities.

Question: How is the Alcohol Institute working with the schools?

Answer: Since the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) Division of Prevention was created in 1972, a significant portion of its effort has been devoted to stimulating the development of alcohol education programs in schools, from elementary grades through college. Highlights of these efforts include:

° Funded 19 school-based grants from 1974-81. These demonstration projects have tested innovative prevention strategies, including curriculum development, teacher training and peer training. The most outstanding of these efforts were chosen for replication.

° Initiated a replication project to test model strategies for suitability and effectiveness in 8 different sites across the country. The model programs were chosen as exemplary because

of their program design, their attention to evaluation issues, their ability to document significant program events and their potential for generalization. The models include the best of NIAAA's school-based projects:

- Cambridge and Somerville Program on Alcohol and Rehabilitation (CASPAR) Alcohol Education Program of Somerville, Massachusetts (socio-cultural model) -- CASPAR is a school/community project offering: a field-tested school curriculum for grades 3-12; basic and advanced alcohol education courses for teachers; school- and community-based alcohol education workshops for youth; training workshops for selected high school students who become peer leaders in alcohol education; and community education and organization efforts to raise community awareness.

- King County (Education Service District (ESD) #121), Washington (health education model) -- This model includes: a field-tested school curriculum for grades K-12 which can stand alone or be integrated into existing curricula; a teachers' instructional manual and accompanying kits of teachers aids for each grade level; a training guide for implementing teacher training workshops; and a design for using trained teachers to educate other teachers in their schools.

- University of Massachusetts, Amherst (systems-wide model) -- This project offers a systems-wide approach which affects multiple levels of the university community. Activities include: training of peer educators to lead workshops and develop programs for special target audiences; academic courses; and inservice training for staffs of the residence halls, campus pubs, and health and safety departments; media campaigns, exhibits, and speakers.

° Developed strategies and programs targeted at college and university populations. Assisted in motivating colleges and universities to create and implement self-sustaining prevention projects on campus. At least 81 percent of the schools involved in the pilot program started prevention projects and the program concept was expanded to over 500 universities nationwide. The University of Massachusetts education/community development model, an outgrowth of this effort, is being tested as part of the replicaltion project described above.

° Developed jointly with the Department of Education two film series and print materials for use in junior and senior high schools. Films have been viewed by close to 2 million students in classrooms across the country.

° Developed an idea book of alcohol abuse prevention for teenagers, with the assistance of the National Association of Secondary School Principals (NASSP), which officially endorsed the publication. When the idea book was first announced to high school principals across the country through NASSP, more than 40 percent requested copies within a few months.

° Developed a selected list of alcohol-specific curricula. The 11 selected curricula cover alcohol education for grades K through 12, as well as units on driver education and fetal alcohol effects. Annotations, ordering information and a list of alcohol resources for teachers are included.

PATIENT LOAD

The budget shows that in 1982, the service programs for medical health will treat 4.05 million patients. Of this number, only 450,000 or 11% are listed as being in underserved categories-- the chronically mentally ill; severely mentally disturbed children and adolescents, the elderly and other priorities populations.

Question: Is 11% a reasonable figure for meeting the needs of the underserved?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Do you expect this percentage to increase in future years and if so what is the ultimate target and when will it be achieved?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How many of the 3.6 million patients being served by mental health centers are in underserved categories?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

SOURCES OF INCOME

Question: What are all the sources of income for the Community Mental Health Centers for 1979, 1980 and the estimates for 1981?

Answer: Based on the most recent data, the following table gives sources and estimate of percentage of income for community mental health centers for 1979 and 1980:

Sources of CMHC INCOME	Percentage of Total
Government:	
Federal CMHC Grants	19.1
Other Federal	5.7
State	28.6
Local	7.9
Receipts for services:	
Patient fees	4.8
Insurance Payments	8.8
Medicare	3.3
Medicaid	10.9
Other	7.9
Fund raising and other	3.0

Overall there has been a slow but steady consistent decline in the percent of Federal grant support over the years and a similar increase in receipts for services. The estimates for 1981 would remain essentially the same.

ELIGIBILITY FOR TREATMENT

Question: What are the rules determining who is eligible for treatment at a community mental health center?

Answer: The Community Mental Health Centers Act (CMHC) required that a center provide services principally to individual residing in a defined geographic area, and, within the CMHC's limits of capacity, that the services be available regardless of the individual's ability to pay. In practice, CMHCs have developed sliding fee schedules. P.L. 96-398, the Mental Health Systems Act, continues this philosophy of providing mental health services.

STATE MENTAL HEALTH MANPOWER DEVELOPMENT PROGRAM

Question: The budget for the National Institute of Mental Health includes $7 million in grants to the states to assist them in "planning, problem identification, and systems development" with respect to the training of mental health personnel.

Why is it a federal responsibility to pay for state planning and why can't the states finance this kind of planning with their own money?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What percentage of FY 1981 service training funds will be used to support grants with an emphasis on minority recruitment?

Answer: Approximately 21 percent of FY 1981 service training funds, or $15.6 million, is dedicated to the support of grants with minority recruitment.

Question: Specifically, do you have plans to address shortages through changes in distribution of personnel in addition to increases in training programs?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: To what extent is there a true shortage of psychiatrists in all regions of the country, or is it a question of maldistribution?

Answer: Although the degree of shortage varies from region to region, there is an overall shortage of psychiatrists, and not merely a problem of maldistribution. The Graduate Medical Education National Advisory Committee (GMENAC) estimated that the country will need an additional 8,000 general psychiatrists and 4,900 child psychiatrists over the projected supply by 1990 in order to provide adequate mental health care to the population. The Committee recommended an immediate increase of 20% in the number of residents in these specialties.

COMMUNITY MENTAL HEALTH CENTERS

Question: Do you have preliminary results from the ABT Associates survey of clients served in mental health centers?

Answer: No. However, data on client/patient characteristics and services utilization for the first panel of 16 community mental health centers (CMHCs) will be available by late spring of this year, and completion of the first phase of this project, including submission of the complete final report, is scheduled for July 31, 1981. These data are the results of the first phase of a major ongoing project to provide previously unavailable information on the specific relationships among client/patient characteristics, services utilization, organizational characteristics, costs, and impacts on clients/patients. By collecting information on a client-specific basis from a representative sample of CMHCs, this project allows much more detailed and sophisticated analyses of the above issues than have the previous aggregated project-wide data collection systems. During the first phase of this project, 16 CMHCs have been inducted into a program of specialized uniform data reporting and are now actively reporting into the system. During the second phase, which is currently being supported through a second contract, an additional 32 CMHCs soon will be inducted into the system, providing client-specific data from a representative cohort of 48 CMHCs when complete.

Question: Have the costs exceeded the initial award of $438,000?

Answer: Yes. The first phase of this project, which was initiated in September 1979, at a cost of $437,970 and scheduled for completion in March 1981, was intended as a feasibility study to determine whether or not the larger project involving all 48 CMHCs was possible to carry out in a valid and meaningful

way. During 1980, a modest increase in cost and a 4-month extension in time were granted to the contractor to allow adequate completion of 3 tasks in the contract for which insufficient funds had been provided in the original negotiations. These 3 tasks included preliminary work on services to the chronically mentally ill, measurement of client/patient functioning, and the relationships of organizational characteristics with patterns of services utilization. As a result, the total cost of the contract was raised to $484,285, and the scheduled date for completion of the contract was moved back to July 31, 1981. In addition, because the first phase of this project has demonstrated the feasibility of the larger project, a second contract to induct the remaining 32 CMHCs of the cohort and collect and analyze the data from all 48 CMHCs has been initiated. That second contract was funded in September 1980, at a cost of $745,987 and is scheduled for completion in June 1982.

Question: For each of the last three fiscal years, how much has been spent for mental health research and training grants for minorities?

Answer: Support for minority research and training grants is set forth in the following table:

	1978	1979	1980
Research....	$9,300,000	$10,594,000	$11,551,000
Training....	9,022,000	10,400,000	14,978,000

Question: Would you support the transfer of HHS Alcohol and Drug Abuse education programs to the Department of Education's Office of Comprehensive School health?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

PROPOSED ELIMINATION OF ALCOHOL STATE GRANTS

Question: What specific services would be affected by the Carter Administration proposal to eliminate the Alcohol State Formula Grant program?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: In what ways are States being encouraged to assume a greater responsibility for alcoholism treatment?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has long been a supporter of a strong State role in the delivery of alcoholism treatment services. Historically, 62 percent of the Formula Grants have gone for service delivery. In addition, the Institute funds a Uniform Act Grant program which provides Federal funds directly to States which have enacted legislation to decriminalize public intoxication.

To enhance these efforts and develop a better system of care, the Institute has recently implemented an Alcoholism Services Development Program (ASDP) whereby formerly NIAAA funded community-based treatment programs are incorporated into a State administered program. To date five States: Connecticut, New York, South Carolina, Michigan and New Jersey have implemented such programs and plans call for a rapid expansion of this program to other States. By giving States more flexibility and responsibility for program administration, the needs of local communities can be better addressed and programs formerly federally administered become part of the State system of care. At the same time this partnership leaves the Institute in a position of assuring adequate care to special groups, such as the poor, women, minorities, and the handicapped.

Question: As the States and private sector assume more of the responsibility for alcoholism programs, what role does the Alcohol Institute see for itself in the future?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

DRINKING AGE

Question: What have you concluded regarding the effects of changes in the drinking age on:

-- Alcohol-related traffic fatalities
-- Incidence of teenage alcoholism

Answer: There is convincing evidence that a lowered drinking age results in increased traffic fatalities. There are no data on the impact of changes in the minimum drinking age on teenage alcoholism.

Question: How did you arrive at these conclusions?

Answer: Several well-designed studies indicate that the lowering of the legal drinking age leads to an increase in alcohol-related collisions among young drivers. Perhaps the most illustrative example comes from various studies conducted by Richard Douglass, Ph.D., of the University of Michigan's Highway Safety Institute. Michigan provides a good opportunity to study this issue as the State lowered its drinking age from 21 to 18, then reversed itself by first raising it back to 19 and then back to 21.

The Douglass studies conducted over an eleven year period in which the minimum drinking age was lowered and then raised again produced the following findings: lowering the drinking age increases traffic accidents among young people. Raising the drinking age decreases alcohol-related traffic accidents among young people. Since Michigan's drinking age was raised to 21 in 1978, there has been a 17 percent reduction in the number of alcohol-related traffic accidents among young people. The restoration of a minimum drinking age of 21 has clearly saved lives, reduced serious injuries and reduced as well the emotional, financial and social costs associated with such tragedies in the State of Michigan.

Increased rates of motor vehicle accidents among young people as a result of lowering the drinking age have also been documented by other studies (Willaims et al, 1974; Schmidt and Kirnaczewski, 1974).

There are no data on the impact of legal change on the incidence of teenage alcoholism. The studies to date, however, suggest that removal of certain legal restrictions, particularly where they were previously enforced, leads to an increased level of alcohol consumption. Recent data on senior high school students yield a consistent correlation between the drinking behavior of these students and the minimum drinking age laws of various States -- a higher proportion of students in 21 year old States report abstinence or lower alcohol beverage consumption than students in 18 year States (Maisto & Rachal, 1980). The increase in consumption has been attributed to two groups of teenagers -- teenagers who are heavy drinkers and abstainers who have become drinkers. This latter group accounts for a less significant percentage of the increase in alcohol consumption.

MENTAL HEALTH PRIORITIES

Question: What are your priorities for the coming year in mental health?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Where do you place the greatest priority and least priority?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

PAYBACK REGULATIONS

Question: The Mental Health Systems Act gives NIMH the authority to require a service payback from all students in the four major disciplines of psychiatry, psychology, social work and psychiatric nursing who accept NIMH stipends during their training.

Of the 3,700 clinical trainees receiving NIMH training support, how many will receive direct stipends?

Answer: All NIMH clinical training stipends are awarded through institutional grants. None are awarded to students directly.

Question: What is the estimated average stipend per recipient?

Answer: Pre-doctoral stipends are for $5,040 per year. Postdoctoral stipends range from $13,380 to $17,040 per year, depending on the years of experience of the trainee. In addition, support is usually given for tuition and other fees.

Question: When will payback regulations be issued in final form?

Answer: The draft Notice of Proposed Rulemaking has been written and is currently being reviewed by the Office of the

General Counsel and others within the Department. We anticipate that the process will be completed as soon as possible. We hope to publish it in the Federal Register, and begin to implement payback provision on this basis.

Question: What will be the expected payback requirement?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

ACHIEVEMENTS IN MENTAL HEALTH RESEARCH

Question: What do you regard as the three most significant findings in mental health research financed by NIMH over the last three years?

Answer: The collective body of findings resulting from our most recent research investments in the major mental illnesses has provided us with significant new information, both for improved diagnosis and treatment of mental illness, and for determining future directions in research. If our findings were to be grouped into three major areas, they can be summarized as follows:

1. Traditionally, schizophrenia and depression were thought to be two homogeneous disease categories. We have now determined that each is, in reality, a collection of many subtypes which require individualized diagnostic and treatment procedures. For example, there is evidence that: the depressive phase of bipolar, manic-depressive disorder differs from the depressive phase of unipolar depressions; these depressions can be differentiated diagnostically; and they should not be treated as the same disorder. In schizophrenia, research has indicated that monoamine oxidase, which was once implicated for schizophrenic illness generally, is more specifically identified with the hallucinatory aspect of schizophrenic illness. This indicates that patients with auditory hallucinations are not of a homogeneous class with all other schizophrenic types; that they may be differentiated by the monoamine oxidase factor and thus respond differentially to treatment. The numerous research projects contributing to these finding have greatly increased the rate of success in treating schizophrenia and depression, and progress is still being made in this area. One day, when research with the emerging new technology of position emission tomography reaches fruition, the differentiation of subtypes of illnesses will be performed by non-invasive brain scans where scientists will be able to <u>see</u> which area of the brain is malfunctioning and therefore identify the specific disorder requiring treatment. This technique is already being used for identification of the brain site of epileptic seizures.

2. For several years, there has been appreciation for the fact that major mental illnesses have been controlled with medications and as a result, relapse and rehospitalization rates have been markedly reduced. However, it has also become apparent that treatments beyond psychoactive medication are required for optimal treatment of the major mental illnesses. The Institute has been addressing this problem during recent years, with major success in the identification of factors which

can both cause and correct recurrent mental illness. We have been particularly successful in the identification of combined treatment approaches which work well with former schizophrenic patients. In the area of depression, the Institute has conducted extensive studies of the antidepressant drugs. Although these medications are highly successful in the treatment of depression, research has shown that individuals will respond differently to various medications with resulting variations in the success of treatment. We have, for example, identified a procedure with the capability of predicting effectiveness of the widely used tricyclic antidepressant, imipramine, for individual patients: it has been found that patients with low urinary excretion of the neurotransmitter metabolite MHPG (3-methoxy-4-hydroxy-phenylglycol) will respond most favorably to imipramine; while those patients with high urinary excretions of this metabolite will fail to respond to this specific drug. As a result, we anticipate further improvement in our ability to administer appropriate treatments with longer term results.

3. The role of heredity in the incidence of major mental illness has been established by NIMH research, however, misunderstanding and over-simplification of this concept has proven costly in terms of failure to recognize other factors which may contribute to the incidence of the problem. As a result of NIMH supported research, we have made major progress in discovering the degree to which genetic factors must interlock with other elements to produce mental illness. Let us take schizophrenia as an example. Although heredity has been recognized as a significant factor in this disorder, we now know that developmental factors at various age levels are critical markers of vulnerability, resistance, breakdown, and recovery. This finding is of enormous usefulness in maximizing the value of preventive treatments with those individuals who are most at risk of developing this disorder.

Question: Explain how these findings have stengthened or are expected to strengthen the prevention and treatment of mental illness.

Answer: These findings represent progress toward two significant goals: making possible a higher degree of accuracy in providing the appropriate treatment for each specific disorder; and providing greater predictability for those who are most at risk of developing mental illness.

The achievements related to the first goal have strengthened the treatment of mental illness in the sense that we have moved closer to curing various disorders, as opposed to simply managing these problems with medication. We also foresee related benefits in terms of lower cost per incident of illness, a higher level of economic productivity among the mentally restored, and longer term benefits for the mental health of the children and others closely associated with the primary victims.

The identification of relationships between genetic and other factors contributing to mental illness has had particular value for the prevention of mental health problems. Before the development of this body of research, it would have not been economically feasible to provide preventive therapies for all individuals having a hereditary history of mental illness. It

is now becoming increasingly possible to narrow the risk factors to relatively small, highly specific groups of individuals - thereby making prevention programs economic reality.

PREVENTION RESEARCH

The Department of Health and Human Services has increased the priority given to health prevention measures. However, ADAMHA seems to be de-emphasizing prevention in mental health research. For example, total new research grants increase from $48 million in 1980 to $61.4 million in 1982 - an increase of 28%. At the same time, the new prevention research grants decline from $3.5 million to $2.4 million, a decrease of 31%.

Question: Why is prevention research being given a lower priority in the 1982 budget?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

GENERAL MENTAL HEALTH/TRAINING

Question: What are your priorities in mental health training programs in the coming year?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What are the prospects for alleviating the problem of mental health personnel shortages that is described in the findings of the Mental Health Systems Act?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be proveded to the Subcommittee.

Question: Are there any research findings or accomplishments from the past year that will be of particular assistance in treating mental health patients in the near future?

Answer: In addition to the previously described research findings relating to schizophrenia, depression, and the relationship of genetic factors to the incidence of mental illness, there are some additional findings which offer considerable promise.

Loss of memory and cognitive function is regarded as one of the most dreaded aspects of the aging process. NIMH is currently supporting studies investigating the nature of memory function in normal advancing age and in states of psychopathology. As a result we know now that serious memory disturbance in older persons is always related to some form of disease or toxic reaction, and not to normal aging. Thus, we are presently studying the effects of new behavioral and pharmacological treatments for memory impairment in persons with Senile

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Dementia. A good number of these studies are based on evidence that the cholinergic system in the brain is directly implicated in memory deficits, and that a deficiency in the availability of acetylcholine (Ach), a neurotransmitter in the brain, is related to the presence of senile dementia of the Alzheimers type. It is hypothesized that by administering dietary choline (or its precursor, lecithin), brain concentrations of Ach will be elevated and memory impairment reversed.

In the treatment of severe mood disorders (i.e., depression and mania), the effectiveness of lithium in controlling the manic phase of the mood swings has improved the treatment of these patients profoundly. Now studies are underway which evaluate the effectiveness of combining an antidepressant drug with lithium in an effort to control both phases of this profoundly life-disruptive mood disorder. Further, by using newly developed techniques to measure blood levels of these drug, adjustment of dosage can be done in a way to accomplish maximum efficacy and minimum chance of side effects or toxicity.

Question: Is anything being done to upgrade the training and ability of general health practitioners to deal with mental health patients as so many persons with emotional problems take them to their family doctors rather than to mental health personnel?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

MENTAL HEALTH RESEARCH

Question: What percent of NIMH research is in the area of neurosciences? Is there overlap with the neurological institute at NIH?

What percent is in the Area of behavioral sciences?

Answer: The distinction between these two fields of science has become blurred as scientific disciplines become increasingly interdependent, both methodologically and theoretically. Many investigators in the neurosciences include some aspect of behavior in their research, while behavioral science studies often involve some biological component. Expenditures in 1980 by the predominant organizational units responsible for each area were: neuroscience, $16.3 million or 11.9%; behavioral science, $13.3 million or 9.3%.

While NINCDS and NIMH do share some common areas of concern, the two Institutes' programs are focused on different disease and problem clusters. Through a variety of mechanisms, overlap is kept to a minimum. These mechanisms include written grant referral guidelines that describe and delineate which areas of science each institute has the major role of support for, the central assignment of applications by Division of Research Grants, which insure that the projects appropriate to each institute are assigned to it for support, and coordination of the staff level.

Question: What is being done to assure that a balanced approach to research is maintained?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

STATE MENTAL HEALTH ROLE

Question: The Carter Fiscal 82 Budget Justification speaks about encouraging an increased State role in the administration and management of treatment programs and declining Federal support reflecting increases in State, local and third party contributions. In what specific ways will the 1982 budget for mental health services encourage an increased State role in the administration and management of treatment programs?

What actions will be taken to assure increased State, local and third party contributions to mental health care, as Federal support decreases?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

COMMUNITY MENTAL HEALTH CENTERS - EMPHASIS ON CHRONIC DISORDERS

Question: Should Community Mental Health Centers treat those who are considered "troubled" as well as those with severe or chronic mental disorders?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What percentage of those treated are considered chronic?

Answer: Because of differences in definitions, estimates of those treated in CMHCs that represent the chronically mentally ill have ranged from 5% to 30%, with general concensus that 20% of those treated are chronically mentally ill. Over half of those treated in CMHCs are diagnosed as among the very seriously mentally ill. NIMH is currently supporting under contract a study that will provide more definitive information on this issue.

MENTAL ILLNESS PRIORITIES

Question: The Committee would appreciate learning what are the top five priorities of the NIMH, and for each of these, what percentage of the Institute's research and training budget is expected to be allocated for them.

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

RAPE PREVENTION

Question: The Carter Fiscal 1982 Budget contains no specific funds for rape services and reduces funds for rape prevention research.

Why are these programs being reduced?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Are sufficient funds available within other National Institute of Mental Health programs to lessen the need for a specific earmark for this purpose?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

DEPRESSION

Question: Your budget justification mentions success in treating manic depressive patients with lithium carbonate. Can you briefly describe the use of lithium carbonate in this manner?

Answer: An estimated 10-12 million individuals in the United States suffer from recurring episodes of mania or major depression. These episodes usually occur at unpredictable intervals and become more frequent as the individual ages. Research shows that lithium is effective in treating most manic episodes and some depressive episodes. However, its major value is its effectiveness in preventing the occurrence of future manic and depressive episodes. When fully effective, lithium will prevent all future attacks, even in patients who have had numerous prior episodes. Even when lithium does not prevent a manic or depressive episode, it may dampen or lessen its severity so that the individual can continue to lead a productive life. It must be recognized that lithium is not a cure for recurrent manic or depressive illness. It is similar to insulin for diabetes or antihypertensive medication for high blood pressure in that it must be taken continuously to be effective. If medication is stopped, the probability of having another manic or depressive attack may be just as great as before taking lithium, no matter how long the medication has been used. As is the case with many drugs used to treat medical disorders, the mechanism of action of lithium is not clear. Also, we don't know why some patients respond to lithium while others do not. Current research sponsored by the NIMH is attempting to answer these and other critical questions pertaining to lithium treatment.

Question: To what extent is the general public being made aware of this new treatment?

Answer: The NIMH receives numerous inquiries from the public regarding lithium therapy. In response to this interest in the drug, NIMH staff has prepared a pamphlet of Lithium Therapy in Psychiatry for public distribution. This pamphlet discusses the psychiatric uses of lithium, its benefits, and the precautions that should be followed to avoid toxic effects. The pamphlet also provides a list of sources of published information for various aspects of lithium treatment. In addition, there have been numerous newspaper articles, reports in news magazines, radio programs, and discussions on TV talk shows devoted to lithium therapy. The public is becoming increasingly familiar

with this extremely useful drug. Indicative of the impact of lithium on mental health care in the United States, a published study estimating the costs of care for patients with manic-depressive illness before and after the introduction of lithium concludes that the use of this drug has saved $2.88 billion in ten years and has resulted in a $1.28 billion gain in work productivity, or a conservative total of over $4 billion.

Question: To what extent are physicians aware?

Answer: In recent years, there have been more reports on the use of lithium in the scientific and professional literature than for any other psychiatric drug. These reports stem from research sponsored by the NIMH and from studies conducted at various treatment centers in the United States and Europe. The reports, coupled with review articles in medical newsletters and promotional material from pharmaceutical companies, have alerted not only psychiatrists but also primary care physicians to potential benefits of lithium for patients with manic-depressive or recurrent depressive illness.

COMMUNITY MENTAL HEALTH CENTERS - NON-FEDERAL SUPPORT

Question: What steps are being taken to assure that Community Mental Health Centers make it on their own after an initial commitment of Federal support?

Answer: Since maximum Federal Community Mental Health Center (CMHC) funding support is provided on a decreasing formula, it is essential that centers locate alternate sources of funding. Regional offices consult with CMHCs on an ad hoc basis and provide on-site monitoring approximately once a year, with one of the primary goals being an overview of the center's status in moving towards financial independence. Two percent technical assistance funds provided in our legislation allow efforts to help CMHCs expand and broaden their financial awareness and fiscal management through courses, on site technical assistance and development of financial resource material. The NIMH's Staff College provides courses on expanding financial resources to CMHC Executive Directors, amongst other financial and accounting courses. Of the 208 Centers which have totally terminated Federal funding to our knowledge only 2 have ceased to function. A few have been forced to cut back on a few services, particularly in more expensive areas such as outreach. However, should a center experience difficulty, they may apply for a financial distress grant.

Question: To what degree do you help Community Mental Health Centers locate alternative sources of support to replace Federal grants?

Answer: Consultation is provided by Department of Health and Human Services regional office personnel on an ad hoc basis and yearly on-site monitoring to centers on this matter. The National Institute of Mental Health, through its two percent technical assistance program and Staff College, has sponsored workshops, conferences and direct on-site technical assistance to help centers identify other sources of revenue such as State and local taxes, as well as fee for services, direct patient billing, Medicare, Medicaid and voluntary fund raising with such groups as Community Chest. Corporate and business managerial strategies have been studied and incorporated by center executive staff.

Question: How much are States spending on mental health hospitals and centers?

Answer: Based on the most recent data, it is estimated that the states spent approximately $401.8 million on Centers in 1980. Using the same data base, State expenditures for mental hospitals totalled $4,827 billion in 1980. Because of the varied financial and accounting systems used by the States, this represents a very rough estimate.

STATE AND LOCAL FUNDING OF COMMUNITY MENTAL HEALTH CENTERS (CMHC)

Question: How many Community Mental Health Centers are there currently receiving Federal support?

Answer: Since the passage of the Community Mental Health Center (CMHC) Act in 1963, 789 centers had been funded as of the end of FY 1980. During the first 17 years of the program, ending September 30, 1980, 478 centers received construction grants, 489 centers had received staffing grants, and a total of 210 initial operations grants had been awarded. Of those centers which received basic support for staffing or initial operations, 337 have terminated basic funding assistance and 208 centers are receiving no Federal CMHC funds.

Question: On the average, what percent of their total operating costs is provided through Federal dollars?

Answer: With Medicare and Medicaid the total percentage would be 39 percent. Excluding reimbursements from Medicare/Medicaid the percentage of operating costs is approximately twenty-five percent.

Question: What is being done to encourage State and local governments to assume a greater share of the support for operating Community Mental Health Centers?

Answer: State and local funds in support of Community Mental Health Centers (CMHCs) amount to approximately 37% and total Federal grant support about 25% of the total Center's budget. The balance of support is generated through fees, third party and Medicare/Medicaid payments and other fund-raising efforts. Centers have traditionally sought funding through municipal, county and State government mechanisms and special taxing strategies. The Mental Health Systems Act (MHSA) calls specifically for the State Mental Health Authority, in developing the Mental Health Services Program, to describe actions to be taken for continuing services that were provided through Federal financial assistance that is no longer available.

In addition, MHSA provides time limits on the period of Federal support, as well as a declining percentage of grantee costs which are eligible for Federal funding. As a result, State and local governments are obliged to develop plans for outside funding at the outset of their grant period.

Question: What kinds of distress assistance is available to Community Mental Health Centers which, after completing their periods of Federal financial support, cannot make it financially on their own.

Answer: Through the remainder of fiscal year 1981, Community Mental Health Centers (CMHCs) completing the basic eight years of program support may apply for a Financial Distress Grant. While authorization for this grant expires with fiscal year 1981, P.L. 96-398, the new Mental Health Systems Act allows centers which require it to apply for limited assistance in support of non-revenue-producing services. This would include such functions as consultation and eduction, provision of follow-up services to patients and the employment of case managers. These grants are limited to 5 years.

Question: What do you do to help such centers find alternative funding sources?

Answer: Through consultation provided by Department of Health and Human Services Regional Office assistance is offered to States and to centers on this matter. Additionally, the National Institute of Mental Health has sponsored national, regional and State workshops and training activities designed to offer help on identifying other sources of funding, and on more effective management.

MENTAL HEALTH/UNDERSERVED POPULATIONS

Question: Among the priority groups now considered underserved, as outlined in the Mental Health Systems Act, what percent do you estimate as being underserved because services are not physically accessible to them, such as in rural areas?

Answer: We estimate that a minimum of 50 percent of the underserved are being underserved because services are not physically accessible to them.

Question: What percent are underserved because the system is not able to take care of their needs, such as the elderly and chronically mentally ill?

Answer: States receiving Community Support Program (CSP) contracts or grants from NIMH have conducted various types of needs assessments focused on the chronically mentally ill adult population who would be capable of living in the community with adequate rehabilitation and support services. Methodologies were not comparable, so reliable national statistics on unmet need are not available. However, a review of State findings indicates that between 60% and 90% of the population had some service needs which were not being met. The greatest unmet need was for residential services. Other services in short supply were psychosocial rehabilitation, vocational rehabilitation, mental health services, case management and advocacy and basic health care.

One problem is that chronically mentally ill people are not able to take initiative in locating services that are available to them. Those most in need of assistance are most likely to drop out of treatment and rehabilitation programs. Outreach and case management services are necessary to link clients with appropriate programs. Many States and communities are having difficulty financing such outreach activities.

In considering needs of the elderly it is useful to keep in mind that of the 23 million Americans over the age of 65, up to 25 percent have been estimated to have significant mental health problems. Yet only 4 percent of patients seen in public outpatient mental health clinics and 2 percent of those seen in private psychiatric care are elderly. Elderly persons are often labeled as "senile" yet as many as 20 to 30 percent of those so labeled have specific conditions that can be diagnosed, treated and often reversed.

MENTAL HEALTH RESEARCH

Question: What will be the priorities for mental health research in the coming year, and how will they differ from the current year?

Answer: This matter is currently under review by Secretary Schweiler. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Are there new research priorities which reflect provisions in the new Mental Health Systems Act?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Can you cite some specific research findings or accomplishments from the past year or two that will be of particular assistance in mental health treatment programs in the near future?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

TRAINEE SUPPORT

Question: The Committee is concerned that NIMH has not been providing accurate statistics on its commitment to insuring that underserved areas will receive adequate mental health care. The Committee has learned that from FY '76 to FY '80 a total of $116,478,000 was spent on psychiatry training while only 19% of these funds (or $22,635,000) ever actually went for trainee support, the rest going for institutional support. Information received indicates that the majority of the trainee support (4,634 "slots" out of 6,213 over the five year period) were for two or three month summer positions for medical students, which would not entail any obligations. Thus, NIMH apparently only has 105 "obligated" psychiatrists in training per year at a cost of nearly $221,868 per psychiatrist.

The Committee would appreciate learning if these figures are correct, and if so, what steps will be taken to insure that a more realistic effort will be made in FY '82 to address the needs of our Nation's underserved areas.

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

MENTAL HEALTH MANPOWER

Question: Are young scientists being drawn into mental health research careers?

Answer: Young scientists tend not to be drawn into research careers. This is particularly true of MD's. There are several reasons for this:

A. A greater orientation of psychiatrists towards service delivery;
B. A lack of role models and research tradition in many departments of psychiatry;
C. Limited research opportunities during medical school and residency;
D. Difficulties in conducting clinical research; and
E. Low stipend levels and salary differentials.

Nevertheless, we have been able to double the number of M.D.s supported by NIMH institutional research training grants over the last few years.

Question: How will the new service payback requirement in the Mental Health Systems Act alleviate the problem of insufficient manpower in the mental health field?

Answer: The training programs supported by NIMH will help produce greater numbers of mental health professionals and paraprofessionals specifically trained to work with underserved populations and in public facilities. The new service payback requirement will assure that these individuals will, after training, work in those areas and with those populations where they are most needed. Together they should produce a better supply and distribution of mental health personnel. However, the overall shortages identified by GMENAC study will still exist.

Question: What guarantees do you have to insure that individuals who benefit from Federal mental health training stipends actually go to work in underserved areas or State institutions?

Answer: The new service payback section of the Mental Health Systems Act amends the clinical training authority of ADAMHA to require that all students in psychology, psychiatry, nursing or social work who receive ADAMHA support must, after training, work in areas or entities designated by the Secretary as having a shortage of qualified personnel. These will include State hospitals, community mental health centers, psychiatric manpower shortage areas, and other facilities which care for underserved population groups. Any individual not fulfilling

the packback obligation must repay the government funds equal to three times the amount of support received, plus interest.

Question: What percentage of funds for mental health manpower programs will be directed to each of the four core mental health professional disciplines: psychiatry, psychology, social work and psychiatric nursing?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: Which mental health professional discipline is experiencing the greatest shortage of trained personnel?

Answer: The greatest shortage which has been identified is in psychiatry. The Graduate Medical Education National Advisory Committee (GMENAC) estimated that in 1990 there will be a shortage of 8,000 general psychiatrists and 4,900 child psychiatrists, in spite of an overall surplus of physicians. There is also a shortage of psychiatric nurses, as also indicated by GMENAC.

SHORTAGE OF PSYCHIATRISTS

Question: The Graduate Medical Education National Advisory Committee (GMENAC) reported that despite a projected overall surplus of physicians in 1990, the present shortage of psychiatrists and child psychiatrists is expected to be even more accute. An increase of 20 percent in the number of residents in these specialties was recommended. What are the reasons for the shortage of physicians pursuing the mental health careers?

Answer: We are unsure of the exact reasons why psychiatry is not chosen more often as a career but several have been widely suggested. Among them are the fact that psychiatry is the lowest paying of all the medical specialties, that much emphasis has lately been put on recruitment into the primary care specialties, and that the medical student's exposure to psychiatry may have been one that did not integrate psychiatry into medicine, so that psychiatrists were not considered to be "real doctors." The decrease in the number of foreign medical graduates entering the country for training has also had a pronounced effect on the number of psychiatric residents.

Question: What plans are being formulated to encourage more graduating physicians to choose this specialty?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: What activities are being planned that will focus specifically on the recruitment of minority manpower in the mental health field?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

INTERAGENCY COOPERATION

Question: Last year's hearings made mention of the collaboration between the Departments of Housing and Urban Development and Health and Human Services in developing programs for deinstitutionalized patients in the communities.

Specifically what types of collaborative efforts have been underway between ADAMHA and HUD in the area of mental health?

Answer: In FY 1980, the HUD/HHS Demonstration Program awarded an additional $25 million in construction funds, and $5 million in rent subsidies to develop housing with related services for 3,000 chronically mentally ill persons.

These awards bring the total program, FY 1987 through FY 1980, to $65 million for construction, $13 million in rent subsidies, and an expected $30 million in Medicaid funds for support services. This significant interagency initiative combines resources from HUD for construction and rent subsidies, HHS for coordination and planning, HCFA for support services in the housing projects, and NIMH for evaluation and technical assistance on quality of services, and all applications are reviewed by each of the Federal agencies.

NIMH continues jointly funding a broad national evaluation of this program to demonstrate the cost-benefit impact of these service arrangements. This study is the first of its kind to examine the effectiveness of housing and related support services in reducing rehospitalization and fostering community integration of the chronically mentally ill.

Technical assistance in a broad range of HUD-related financing strategies for mental health services i.e., Community Development Block Grants, Section 8 rental subsidies, public housing programs, etc. has been provided to State and local mental health authorities and agencies.

A three-way national technical assistance workshop was held in Washington, D.C., July 29 - August 1. Participants included local sponsors in the HUD/HHS Demonstration Program for Deinstitutionalization of the Chronically Mentally Ill, State and regional office mental health, and Medicaid representatives, and consumers. The two Departments committed themselves to the implementation of projects already funded as well as to a collaborative effort to develop longer-term programs to meet the housing and community support needs of chronically mentally ill persons. A manual on housing/mental health was prepared for the workshop, and it will be made broadly available to the field.

Question: How successful have they been?

Answer: The HUD/HHS Demonstration Program has been successful in allocating funds for nearly 200 local agencies to develop approximately 1,900 units of housing for roughly 3,000 chronically mentally ill persons. The funded projects have been very slow in developing, however, because the HUD Funding Programs used in the Demonstration were originally designed for other purposes and have not yet been adapted to the kinds of housing needed by this group, or that needed by the disabled in general such as small-scale scattered-site housing.

The HUD/HHS Demonstration has also stimulated a high level of collaboration between State Mental Health Authorities, HUD Area and regional offices and State Medicaid Agencies, as well as State Housing Fnancing Agencies.

Question: Do the budgets of HHS and HUD include funds for continuation of these programs?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

MENTAL HEALTH PREVENTION

Part of the impetus for the Mental Health Systems Act was the conclusion that "present knowledge of methods to prevent mental illness through discovery and elimination of its causes and through early detection and treatment is too limited."

Question: How much has been spent on mental health prevention research over the last five years?

Answer: Virtually all mental health research has as its ultimate objective the prevention of mental illness or the promotion of mental health. For planning, budgeting, and program analysis purposes, mental health prevention research activities have been classified into two categories. Activities called a cluster of projects, which are part of a planned initiative to develop or apply prevention strategies, or obtain findings directly transferable into a prevention program are one category. Funds for this type of prevention research first became available in fiscal year 1980 with an appropriation of $4 million. In FY 1981 $3.4 million has been budgeted for such purposes.

The other category includes single project activities designated as prevention related and of prevention potential. Such activities are supported as part of the ongoing research programs and not as part of a targeted initiative. Over the last five years, $20 million has been spent in this manner.

Question: How much more do we know about prevention as a result?

Answer: Mental health prevention research conducted over the past five years and presently in progress has provided both basic and applied findings directly relevant to interventions on behalf of populations at risk for mental illness and emotional dysfunction. Major advances in prevention have resulted from the increase in scientific knowledge, for example, by identifying high-risk populations and developing services for them by utilizing natural, social, and neighborhood support systems. Identification of family stress factors has led to anticipatory guidance or early education to obviate dysfunction. The promotion of acquiring interpersonal cognitive skills can aid greatly in stress management.

Question: What types of studies have been conducted?

Answer: Some of the studies which have been conducted include the effects of marital disruption on children, the impact of severely disturbed parents on children and mental health interventions with infants and parents at particular risk for mental illness. Others incude promoting mental health among the elderly and facilitating life transitions. Identification of high risk factors in depression has been an important study.

Question: What new treatment methods have resulted?

Answer: prevention research has increased knowledge of the use and benefits of such techniques as mental health consultation, education and information, crisis intervention, and anticipatory guidance or early education. The development of social supports and networks and social systems modification are also important adjuncts.

Question: How much do you plan to spend on mental health prevention research in fiscal year 1981?

Answer: In FY 1981, approximately $3.4 million will be spent on targeted mental health prevention research aimed at developing a prevention program, initiative or strategy, or activities whose results would be directly transferable to a prevention program.

In addition, other operating components of NIMH will spend approximately $ 2 million for prevention related and prevention potential research which can be translated into prevention strategies at some later date. These research projects are supported as part of the regular research programs and not as part of a tartgeted initiative.

Question: What specific projects will be funded?

Answer: Research studies being considered for funding in 1981 are:

- Effects of Divorce on Children - Preventive approaches
- Sequelae of Marital Disruption on Children
- Evaluation of Families and Divorce Workshop
- Preventing Psychopathology in Children of Divorce
- Short and Long-term Effects of Broken Homes on Children
- National Longitudinal Study of Marital Disruption
- Gain Program: Group Activities for Individual Needs
- Primary Prevention with Children of Severely Disturbed Mothers
- Impact of Affectively Ill Parents on their Children
- Parental Mental Illness and Outcome in At-Risk Children
- Program Impact on Children of Mentally Ill Mothers
- Prevention of maladjustment in Children of Disturbed
- Impact of Severely Disturbed Parents on Children
- Caring for Elders and Mental Health of Family Members
- A Longitudinal Study of Schooling and Delinquency
- Black Family Mental Health and Teen-Age Pregnancy
- Can we Predict the Mental Health of Young Black Males
- Social Support and Mental Health in the Black Community
- Social Support, Strains, Well-being of Divorced Women
- Patterns of Differential Responsiveness to Stress
- The Three-Mile Island Accident: Psychiatric Sequelae
- Children and Families Vulnerable to Mental Disorders
- Cognitive, Speech, and Vulnerability to Schizophrenia

- Studies of Persons at Risk for Depressive Disorders
- Mental Health Considerations in Pediatric Care
- High-risk Factors in Depression

Other Prevention research contemplated as part of ongoing research:

- Effects of Spousal Illness and Death in Older Families
- Mental Illness and Divorce
- Stress and Personality Interactions in Health and Illness
- Relationships in Reducing the Negative Physical and Psychological Impact of Job Loss
- Social Origins of Stress
- Adaptation and Stress Among Vietnamese Refugees
- The Economy as Stressor of Metropolitan Populations
- Family Coping Following Job Loss
- Private and Social Response to Job Loss: A Metro Study
- Stress Inoculation and Adherence to Health Decisions
- Stressful Life Events Rating Problems in Epidemiology
- Studies of Schizophrenic-prone Young Adults
- Identifying Preschool Children at Risk
- Service Needs of Children at Risk of Schizophrenia
- Behavioral Study of Children of Schizophrenic Parents
- Children and Families Vulnerable to Mental Disorders
- Epidemiological Analysis of Type A/B Behavior
- Schizophrenia Offspring from Birth to Adulthood
- Jobs, Job Search, Social Support and Depression
- Patterns of Differential Responsiveness to Stress
- Short- and Long-Term Effects of Broken Homes on Children

PHASE OUT OF SUPPORT FOR MENTAL HEALTH CENTERS

Question: The basic authorizing legislation contemplates federal financial support for community mental health centers for a maximum of eight years.

What are the projected requirements for federal aid to the community mental health centers over the next five years?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

Question: When do you expect the need for federal funding to be phased out?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

IMPACT OF SOCIAL POLICIES ON MENTAL HEALTH

Question: The 1982 budget narrative states that research will be undertaken on "social policies and their effects on the mental health functioning of special populations."

What are some examples of social policies that will be the subject of this type of research?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How will the results be used to improve mental health?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How much money is included for this type of research in 1982.

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

NEW MENTAL HEALTH LEGISLATION

Question: How do you plan to implement the various provisions in the new legislation relating to mental health promotion and mental illness prevention?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How will these new legislative mandates be coordinated with other HHS general health promotion and disease prevention activities?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: When do you expect that regulations for implementation will be ready for initial publication in the Federal Register?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How are you going to carry out provisions in the newly authorized Mental Health Systems Act in light of budgetary constraints?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

Question: How much in your budget reflects new provisions in the Mental Health Systems Act?

Answer: The budget amount for this program is currently under discussion within the Reagan Administration. After the revised budget is forwarded to the Congress, we will provide an appropriate answer to this question.

DEINSTITUTIONALIZATION

Question: What portion of the mental health budget is aimed at getting individuals out of institutional settings?

Answer: Support for deinstitutionalization cuts across all segments of our budget. For example, recent research findings will help reduce the relapse rate among previously hospitalized mental patients. During 1980, we spent seven percent of our clinical training budget ($5,401,000) on programs to train individuals to deal with deinstitutionalized, chronically mentally ill patients. Our entire services program is oriented toward keeping individuals out of institutionalized settings, who might without mental health services need to be institutionalized. Funds which were directed for this effort amounted to $294,801,000 in 1980. The combined training and services effort in this area constituted 55 percent of the entire NIMH budget in 1980. The percentage is probably higher, but it is difficult to assess the specific dollar investment in the research area.

Question: What precautions are being taken to insure that individuals are not just being thrown out into the street, but are provided essential supportive services?

Answer: Last year, NIMH provided Community Support Program (CSP) grants or contracts to 17 States, averaging approximately $350,000 per State. The States in turn used these projects to define the problems concerning discharged mental patients within their State, to clarify State level responsibility for solving the problems, to organize local community services in a more effective way, and to improve their State policies and plans impacting on the chronically mentally ill.

Some of these States established local demonstration areas where they tested different approaches to organizing services for discharged mental patients, in an effort to help these people readjust to society. The local demonstrations also are finding ways to assist and support families, neighbors, employers, landlords and others affected by the presence of mentally disabled persons in their midst. The local demonstrations are testing various approaches to organizing and more effectively using currently available resources. An evaluation strategy is underway to determine the effectiveness of different approaches under different circumstances.

Current legislation requires that CMHCs work with public mental hospitals to provide follow-up care for patients discharged to the community. In States with CSP projects, the staff of the State mental health agency is working with hospitals and CMHCs to improve linkages, assure that effective follow-up and related support services are provided, and to increase community involvement in developing opportunities and services for discharged patients.

In addition, hospitals receiving reimbursement under Medicare are required to meet certain conditions of participation in the program. One of these conditions relates to medical records, and specifies that hospitals must develop individual treatment plans and discharge plans. NIMH is collaborating with

the Health Care Financing Administration in monitoring these requirements and in providing technical assistance to hospitals.

Question: What alternative community services are Federal, State and Local dollars supporting for individuals who leave the institutions?

Answer: Community Support Program (CSP) projects are helping clarify responsibility for meeting the needs of discharged mental patients. Also the projects are helping organize currently available services more effectively. Projects are experimenting with better ways to use available dollars, facilities and personnel.

Initial results from evaluative studies are promising that the CSP efforts are beginning to produce significant results in addressing a complex problem. For example:

An analysis of CSP reports shows that CSP States have increasingly earmarked State mental health budgets for community services for the chronically mentally ill. The 17 States currently participating in the program plan to spend approximately $18 dollars for community support programs for every $1 from NIMH/CSP.

A field test of a client instrument at 18 local CSP demonstration sites serving 4,284 clients indicated that:

Despite their illnesses, poverty and disability, they are making an adjustment to the community. Only 28% were rated as having poor adjustment or severe maladjustment at work, school or training programs.

Community support programs appear to be reducing the need for rehospitalization. In the current study, clients enrolled in the local programs spent an average of 50 percent less time in hospital the first year in the program than the prior year. Evaluation studies done by the States in specific local areas have found even greater reductions in hospitalization.

Question: Roughly, what percentage of Federal, State, and Local Dollars are going for support of these services?

Answer: Due to the variety of services needed in the community, it is hard to discriminate the funding sources for the support services. Currently the Community Support Program is funding a study in Colorado to examine the various costs of a total service and the funding sources. A recent report to the Secretary of Health and Human Services entitled "Toward a National Plan for the Chronically Mentally Ill," has provided some funding estimates of services for the chronically mentally ill population. However, these estimates include institutional care as well as community services. The funding by program and funding source are listed in the table attached.

Most of the funding for Title XVIII is provided for inpatient care. If the Federal total is adjusted by deleting Title XVIII reimbursements for inpatient care, the Federal total is $3,373 million. If the State and local expenditures are adjusted by deleting funds for State-operated inpatient

institutions (which is approximately 65% of their funding for this population), the State and local total is $2,545 million. With these two adjustments the Federal share is 57% of the total, compared to 45% of the total share when the adjustments for institutional care are not made.

Senator Chiles: When Congress passed the Mental Health Systems Act last year, we targeted the community mental health program to certain "priority population groups" who have been shown to be severely underserved in the current system. These groups include the elderly, the chronically mentally ill, severely disturbed children and adolescents.

I understand you are in the process of developing the regulations to implement the new law. What steps are you taking to insure the intent of Congress that States and CMHCs focus on these groups who have been underserved is carried out?

Answer: This matter is currently under review by Secretary Schweiker. Once the new Administration's policy has been established, it will be provided to the Subcommittee.

[CLERK'S NOTE.—The following is the administration's response to those questions in the record that were under review by the Secretary at the time the Department submitted earlier responses.]

ADAMHA REORGANIZATION

Question: Another reorganization plan could include moving the research arm of all three Institutes---alcohol, drug abuse, and mental health---into NIH; the services to the Health Services Administration; and training to the Health Resources Administration. What, if any, validity do you see with that proposal?

The current organization of ADAMHA is appropriate to their present mission. It serves as the focal point to coordinate health efforts in the most debilitating, debasing, and underserved diseases of our society. You should be aware, however, that there are two major proposals before Congress that will strongly influence my consideration in this regard. First is the proposal to include all of ADAMHA services in the basic health services block grant to the States; the second involves the phasing out of the ADAMHA clinical training program by the end of fiscal year 1982. Should these proposals pass the Congress, it could lead to a review of the structure of the Agency so as to insure the most appropriate arrangement for the functions of the Institutes.

AUTHORIZED PROGRAMS

Question: Are there any funds included in the fiscal year 1982 budget for programs not yet authorized? If so, what are they and do you anticipate any problems with their enactment?

Answer: In the 1982 budget, funds which are proposed for research training in the alcohol, drug abuse, and mental health areas require reauthorization under the Public Health Service Act, Section 472. National Research Service Awards are made to individuals in research training at non-Federal public or non-profit private institutions, or directly to such institutions which in turn support

student trainees. A reauthorization proposal has been submitted to the Congress and we anticipate no problems with its enactment.

For the services programs, the Drug Abuse Prevention, Treatment, and Rehabilitation Act and the Alcohol Act will also expire at the end of the fiscal year 1981. These programs are planned for consolidation into a basic health care block grant and will be administered by the Office of the Assistant Secretary for Health (OASH) in 1982. Reauthorization of the current programs is not being requested; rather, a separate block grant authority will be proposed. Since reauthorization will not be sought for the Alcohol Act, the 1982 budget proposes authorization for all alcohol research activities under the Public Health Service Act, Section 301. This is consistent with the authority currently used for both mental health and drug abuse research.

Question: Should the Addiction Research Center be moved from its present location in Lexington, Kentucky, to Baltimore?

Answer: The Addiction Research Center is presently in the process of being moved from Lexington, Kentucky, to the campus of the Baltimore City Hospital (BCH) in Baltimore. In February 1980, the clinical research laboratory became operational in Baltimore. It occupies 10,000 square feet of space leased from BCH. The Office of the Administrator has also been moved to Baltimore. Funds appropriated by Congress in FY 1981 will be used to renovate Building C on the BCH campus to house the remaining portions of the ARC program. Once those renovations are complete, in FY 1983, the remainder of the ARC program will be moved to Baltimore.

The need to relocate the ARC arose when the U. S. Bureau of Prisons withdrew its permission for Federal prisoners to participate in clinical research studies. Efforts to reestablish a clinical research unit in Lexington using non-prisoner volunteer research subjects were unsuccessful because of the paucity of narcotic addicts in the Lexington area, local community resistance to having such research subjects brought in from other geographical areas, and the loss of hospital support facilities previously available to the ARC from the Federal Correctional Institute. The new site in Baltimore was chosen because of its proximity to major Federal agencies concerned with drug abuse, access to significant populations of narcotic addicts, the nearness of first rank research and medical facilities such as Johns Hopkins Hospital and University, the availability of a wide range of support services required for clinical research, and, finally, the availability of building space to accommodate the needs of the ARC.

Question: How broadly do you interpret your mandate to promote drug abuse prevention efforts?

Answer: We believe NIDA should take an active role in the promotion of drug abuse prevention efforts by supporting an extensive program of knowledge development and dissemination in prevention and acting as a resource for State and community efforts.

In FY 1982 we will, for example, continue our activities directed at the preparation and dissemination of a wide range of prevention materials for professional and lay audiences. These materials cover all aspects of drug use and abuse and are intended to discourage both the illegal and unwise use of licit and illicit

drugs. Because the development of these materials requires an awareness of both the latest information on the adverse effects of numerous substances on health and social function, the identification of new and potentially serious patterns of drug misuse before they assume national importance, and an awareness of the wide range of prevention techniques appropriate to different target groups, it is an activity that can most effectively and most efficiently be conducted at the national level. Examples of recent NIDA efforts in support of these activities include the development and dissemination of Elder Ed materials, which provide the elderly with information on the proper use of common medications, and the National Media Campaign, which will develop and disseminate media-oriented drug abuse prevention programs.

NIDA will also continue to play a role in the support of State prevention efforts by acting as a resource for information on new and more effective prevention techniques and by providing assistance in the delivery and evaluation of prevention programs.

Question: Would it not make a lot more sense for the Federal Government to use most of its limited resources on prevention programs while relying on State and local governments to pick up most of the treatment programs?

Answer: This approach to the Federal-State partnership is consistent with the FY 1982 revised budget request. Although NIDA's support of community-based treatment services is only about 30 percent of the total, it is still too large in terms of actual dollars to expect the States to absorb in a short period of time. Such a shift in financing would result in a major reduction in services provided. Under the block grant approach, which allows the States the flexibility to administer programs in accordance with their priorities, there will be a 25 percent reduction below the 1981 level in the Federal support for community services. Depending upon how States choose to allocate this money, there may or may not be a reduction in prevention services. NIDA will continue its national level prevention programs to develop and disseminate information and materials and serve as a resource for State and community efforts.

Question: Why is support for prevention declining?

Answer: In FY 1981, NIDA will spend $16,025,000 on prevention. This is 10 percent of our community programs (project grants and contracts) budget, and $3,181,000 more than was spent in FY 1980. In FY 1982, financial support for prevention activities will be included within the basic health care block grant. Depending on how the States use this money, there may be no overall reduction in prevention funding levels. NIDA's prevention activities will be directed at prevention research, the dissemination of prevention information and materials, and acting as a resource for State and local efforts in the delivery and evaluation of prevention programs.

Question: Do you plan to continue drug abuse prevention and treatment programs indefinitely or do you foresee the day when the States and communities will eventually assume the burden?

Answer: Beginning in FY 1982, the States and communities will begin to play a substantially larger role in the provision of drug

abuse treatment and prevention services as Federal support for these activities, formerly provided through categorical grants, is provided through basic health care block grants. While a Federal role will continue in the gross distribution of these funds, the States and localities will decide what types of programs to maintain, increase, or eliminate. In the future, it may be possible to further reduce Federal support for these activities given the progress of the States in developing their resources under the health care block grants. It will, however, continue to be desirable for the Federal Government to maintain a role in prevention research and in the development and dissemination of prevention materials and information because only at the national level can new research findings be most effectively and efficiently collected and translated into useful prevention programs.

Question: Is the proposed budget sufficient to respond to the increase in heroin addiction?

Answer: The most recent evidence of increased heroin abuse indicates that the problem is, at the present time, largely localized in major cities in States along the Northeastern corridor. In FY 1982 the basic health care block grant will provide 75 percent of the total funds available for community program activities in the FY 1981 current services budget. The individual States will have the latitude to apportion whatever part of their available block grant funds for drug abuse treatment they deem appropriate. Since heroin abusers are less than 50 percent of the clients admitted to treatment nationally and since each State will have roughly 75 percent of last year's resources, it is likely that most States could still address any increase in heroin abuse should they wish to divert funds from other drug abuse treatment services. The utilization rate for all drug abuse treatment programs in those States most seriously affected by the increased availability of Southwest Asian heroin varied from 94 percent to 104 percent.

PREVENTION OF ALCOHOLISM

Question: In 1980, NIAAA used 9.7% of its community programs funds for prevention programs. In 1982, the percentage of funds allocated to prevention programs is virtually the same---10%.

Why isn't there a much greater emphasis given to prevention programs?

Answer: The revised FY 1982 budget submitted by the Reagan Administration reflects a proposal to include these funds as part of a consolidated basic health care block grant to be located within the Office of the Assistant Secretary for Health. The appropriation requested is approximately 75 percent of the fiscal year 1981 current services. The decision of which programs should continue will reside with each State.

ALCOHOL RESEARCH

Question: What portion of alcohol research funding is planned for each of the following areas:

1) teenage alcoholism;

2) impact of alcoholism on families;

3) fetal alcoholism syndrome;

4) effectiveness of occupational alcoholism programs;

5) alcoholism and the elderly; and

6) alcoholism and domestic violence?

Answer: The $24.8 million requested for alcohol research in 1982 includes the following: $1.4 for studies relating to teenage alcoholism; $.7 million for research on alcoholism and the family; $1.3 million for fetal alcohol syndrome research; $.4 million for research aimed at the development of more effective occupational programs; $.2 million for research into alcoholism and alcohol-related problems of the elderly; and $.3 million for studies of alcoholism and domestic violence.

INTERCULTURAL ALCOHOLISM PROJECT

Question: What projects will be undertaken in this joint venture?

Answer: Projects proposed in the biomedical area involve the exchange of data, the provision of liver material from Japan, and field testing the National Institute on Alcohol Abuse and Alcoholism (NIAAA)-developed blood chemistry screening instrument in Japan. All of these activities will occur within existing laboratories. No requirement for NIAAA funds is anticipated at present.

In the epidemiological area, a community-based cross cultural study of drinking patterns and the prevalence of alcohol-related problems has been proposed. Comparable studies would be designed and carried out on a cooperative basis in Japan with Japanese funding and in the U.S. with NIAAA funding. At the current time, no definite agreement has been reached with Japan on the specific design, work plan, and schedule for initiating the proposed project. However, $90,000 of FY 1981 research funds have been provisionally budgeted for Phase I of this project; planning estimates for FY 1982 and FY 1983 are $95,000 and $160,000, respectively for subsequent phases of the project.

ALCOHOLISM COMMISSION

Question: Does HHS intend to request funds for the Commission in its revised FY '82 budget?

Answer: The Department's FY 1982 budget does not specifically request funds for the Commission since the funding level and mechanisms were unclear at that time. A reprogramming request for 1981 has been forwarded to Congress in support of the Commission.

TEENAGE DRINKERS

Question: What programs are being geared specifically toward teenage drinkers?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA), through its demonstration grant program, has supported a variety of projects to test prevention strategies targeted toward

youth. These projects incorporate innovative approaches to alcohol abuse prevention and include careful evaluation of program process and impact. The strategies utilized in these programs include alcohol education curricula and teacher training, peer counseling, community education, and skills development. Prevention strategies targeted toward school dropouts and runaway youth and children from alcoholic families have also been developed. National youth organizations have been assisted in developing alcohol education programs to reach their membership.

Specific examples of these programs are as follows:

Minimizing Alcohol Problems By a Focus on Youth; Pittsburgh, Pennsylvania: Through education and intervention programs, the project aims to minimize alcohol abuse and facilitate healthy attitudes about alcohol in three adolescent target groups, functional and actual dropouts, and young people who desire individual instruction about alcohol and its effects. Specific techniques of intervention include: individual and peer instruction; peer modeling; tutoring; vocational counseling and placement; and use of existing community resources as required.

Prevention of Alcohol Problems in Pre-Delinquent Youth; Denver, Colorado: The central objective of this project is to evaluate the effectiveness of an established volunteer program, as well as the effectiveness of efforts aimed at preventing alcohol abuse among pre-adolescents and teenagers. This program recruits, trains, and matches adult volunteers one-to-one with youth referred by the police or schools and provides program staff with intensive training around issues related to adolescent alcohol problems.

Cambridge and Somerville Program on Alcohol and Rehabilitation (CASPAR) Alcohol Education Program, Somerville, Massachusetts: CASPAR is a school/community project offering: a field-tested school curriculum for grades 3-12; basic and advanced alcohol education courses for teachers; school and community-based alcohol education workshops for youth; training workshops for selected high school students who become peer leaders in alcohol education; and community education and organization efforts to raise community awareness.

Education Service District (ESD) 121 Alcohol Education Curriculum Project, Seattle, Washington: This model includes: a field-tested school curriculum for grades K-12 which can stand alone or be integrated into existing curricula; a teacher's instructional manual and accompanying kits of teaching aids for each grade level; a training guide for implementing teacher training workshops; and a design for using trained teachers to educate other teachers in their schools.

A University Demonstration, University of Massachusetts: This project offers a systems-wide approach which affects multiple levels of the university community. Activities include: training of peer educators to lead workshops and develop programs for special target audiences; academic courses; inservice training for staffs of the residence halls, campus pubs, and health and safety departments; and media campaigns, exhibits, and speakers.

Westchester County Student Assistance Program, Westchester, New York: This program is implementing and evaluating a school-based prevention and early intervention program for adolescent children of alcoholic parents and for youth with nonsevere alcohol and drug

related problems. The program is an adaptation of the employee assistance approach for use with high school students.

The Institute is also supporting two programs which are targeted to girls and women (ages 10-44) to educate them about Fetal Alcohol Syndrome and the risks of drinking during pregnancy.

Finally, the Institute is conducting a major public education campaign directed at women and youth. The campaign includes messages on the Fetal Alcohol Syndrome, alcohol problems among women and alcohol problems among youth, including the risks of drinking and driving.

ALCOHOLISM PUBLIC EDUCATION CAMPAIGN

Question: In last year's testimony, you indicated the intent to conduct a multi-media campaign for disseminating information on alcohol abuse. You stated this was one the most important and effective ways to reach young people.

What is the status of that campaign?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is conducting a major public education campaign intended to focus national attention and resources on the problems of alcohol abuse and alcoholism. The campaign is designed to address NIAAA's long-term goals of increasing public awareness of alcohol problems, modifying attitudes regarding alcohol use, and reducing alcohol-related problems.

The NIAAA Public Education Campaign is directed at two principal target audiences: women and youth. The campaign includes messages on the fetal alcohol syndrome, alcohol problems among women, and alcohol problems among youth, including drinking/driving.

Campaign materials include television public service announcements, radio public service announcements, and print materials. State Alcoholism Authorities and national, State and local organizations serving women and youth will participate in the development of all campaign materials. Supplemental information will be provided to target audiences through the mass media with personal involvement in campaign-related project activities at the local level. NIAAA believes that this strategy will increase the positive impact of the campaign and its effectiveness in addressing the alcohol-related problems of women and youth.

Presently, we are in the middle of the materials development phase. We have completed a literature review; conducted focus groups to obtain input from the target audience; held concept development meetings to get input from the field; and prepared a campaign strategy report which outlines the campaign concepts and message strategy. We are now in the process of testing scripts, storyboards, and posters with each primary target audience.

ALCOHOL EDUCATION

Question: Would you support the transfer of HHS Alcohol Abuse Education Programs to the Department of Education's Office of Comprehensive School Health?

Answer: The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) would not support the transfer of Health and Human services Alcohol Abuse Education Programs to the Office of Comprehensive School Health in the Department of Education because the prevention of alcohol abuse problems through education is a fairly new concept and, as such, needs to be carefully developed and evaluated. This is best achieved under the supervision of a scientifically-oriented governmental agency such as NIAAA rather than an educationally-oriented one such as the Department of Education.

Alcohol abuse prevention activities are different from educational activities in that they are concerned with finding new methods of preventing problems of alcohol abuse rather than developing new educational approaches to address these issues. Although this can include development of some education methods, it is not limited to this activity. The broad prevention perspective necessary to aid in the development of new alcohol abuse prevention programs would be limited if the educational programs were transferred to an agency whose primary mission is education.

NIAAA has worked closely with specialists in education, alcoholism and community health in order to develop models of alcohol-specific prevention programs. These programs take place in a variety of settings including schools, community alcoholism programs and universities and utilize a variety of methods. This methodological and environmental flexibility could be lost if these programs were no longer under the sponsorship of NIAAA.

These programs are being replicated in eight sites nationwide. The system for disseminating these model programs is in place. It would be expensive and less efficient to transfer this system to another agency.

PROPOSED ELIMINATION OF ALCOHOL STATE GRANTS

Question: What specific services would be affected by the Administration proposal to eliminate the alcohol State formula grant program?

Answer: The revised budget proposed by the Reagan Administration includes a rescission of alcohol formula grant funds in 1981 but incorporation of the program into a block grant to the States in 1982 at approximately 75 percent of the current services level.

The impact on formula grant activities in terms of specific services currently supported should be minimal because of the two year availability of these funds and the fact that very little of the monies are expended in their first year of availability. That is, our investigation of expenditure records shows that awards made to the States in 1980 are - as of the end of February - only 10 percent to 15 percent disbursed to programs. Consequently we believe that a one year rescission is a responsible and effective cost saving measure.

The role of the States in planning and implementing alcoholism programs has been strengthened over the past few years. The formula grant funds have become a smaller percentage of total funds expended within the States as State and local participation has increased. For these reasons it is anticipated that the provision of alcoholism services will be continued by the States during 1981.

Consolidation of the program into a block grant to the States in 1982 will provide flexibility to the States in allocating funds based on the need for alcoholism prevention and treatment programs. Although no matching funds will be required it is expected that State funds will be allocated as needed for continuation of services and that increasing third-party payments will contribute to the availability of services within the States.

Question: As the States and private sector assume more of the responsibility for alcoholism programs, what role does the Alcohol Institute see for itself in the future?

Answer: The Administration's proposal for health services block grants is rooted in the conviction that States rather than the Federal government should determine which health services to provide and how to provide them. Federal funds currently awarded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) for prevention of alcohol abuse and alcoholism are proposed for inclusion in the block grant. If the proposal is approved, decisions about expenditures of health services funds for prevention of alcohol-related problems will rest with the States. There is widespread parental and community concern and active debate in many State legislatures -- about alcohol-related problems among young people. We anticipate that State decisions on the use of health services funds will reflect such concerns.

The Administration also anticipates an active Federal role in alcohol research. Indeed, the long-range goal of NIAAA's research program is the development of new knowledge in order to reduce the incidence and prevalence of alcohol abuse and alcoholism and reduce the deaths and human and economic costs associated with alcohol use, abuse, and alcoholism.

For example, research is proceeding to develop diagnostic techniques to aid in the early identification of alcohol-related problems and efforts will be increased to identify genetic and other factors which cause some individuals to develop alcohol problems while others drink and experience no problems. Support will also be provided for continued research on the effects of alcohol consumption during pregnancy. Given the seriousness of these effects on developing infants and the recognition that they are fully preventable, there is urgent need for improved understanding.

The Administration's strategy for reducing alcohol misuse - including misuse among young people - also includes dissemination of information on alcohol-related problems to individuals, organizations, State and local governments, and the scientific community.

MENTAL HEALTH PRIORITIES

Question: What are your priorities for the coming year in mental health?

Answer: The Institute is focusing on critical problems in the area of mental health. These include active support of its new centers in neuroscience, schizophrenia, affective disorders, and child and adolescent disorders. In addition, we are expanding our work in epidemiology with enlargement of our epidemiological catchment area program. The Institute is also focusing increased attention on the issue of treatment assessment both of a somatic and behavioral nature. Finally, increased

attention to careful investigation in prevention of mental illness and identification of high risk populations for the development of disorders will be vigorously encouraged. As a complement to these research efforts the Institute will continue its vigorous attempts to encourage clinical investigators to enter the field of research and mental health.

Question: Where do you place the greatest priority and least priority?

Answer: The ranking of priorities is difficult, as the success of each is interrelated with the others. Research into the causes of mental illness would have to come first. A thirty-year investment in mental health research has produced a body of knowledge and improvements of treatment which could not have been attained through non-Federal support. More specifically this accumulated knowledge has led to several current studies which promise landmark advances in our knowledge of brain function.

Our greatest priority lies in the area of major clinical problems in the field of mental health such as schizophrenia, affective disorders, etc. Also, of high priority is work on the basic sciences which relate to the etiology and treatment of major psychiatric disorders. Within the programs for which funds are requested in 1982 we will be emphasizing support of the training of clinical investigators, epidemiologists, and people who work in the area of treatment investigation. The lowest priority will be given to social research which has low order of relevance to the major mental health and mental illness problems of the Institute.

STATE MENTAL HEALTH ROLE

Question: The Carter Fiscal 82 Budget Justification speaks about encouraging an increased State role in the administration and management of treatment programs and declining Federal support reflecting increases in State, local and third party contributions. In what specific ways will the 1982 budget for mental health services encourage an increased State role in the administration and management of treatment programs?

What actions will be taken to assure increased State, local and third party contributions to mental health care as Federal support decreases?

Answer: The revised 1982 budget represents a major step in the direction of greater State, local and private involvement. The services program is one of those proposed for consolidation into a basic health care block grant. The appropriation requested in 1982 is 75 percent of the current-year level for these programs. Accordingly, States will have an opportunity to administer these funds in accordance with their own priorities. It will be the responsibility of the States to seek other sources of funding.

COMMUNITY MENTAL HEALTH CENTERS - EMPHASIS ON CHRONIC DISORDERS

Question: Should community mental health centers treat those who are considered "troubled" as well as those with severe or chronic mental disorders?

Answer: The goal of the CMHC program has been to ensure that comprehensive mental health services are available and accessible to all individuals residing in the catchment area who may need them. In fact, over one-half of the individuals seen in community mental health centers are severely disturbed, with the remainder presenting less serious mental health problems. Many who are classified as "troubled" are, in fact, in the early stages of what could eventually become a more serious problem. For this reason, it makes sense to deal promptly with any degree of mental health problem.

MENTAL ILLNESS PRIORITIES

Question: The Committee would appreciate learning what are the top five priorities of the NIMH, and for each of these, what percentage of the Institute's research and training budget is expected to be allocated for them.

Answer: Our top priorities include these areas:

- o Advancement of knowledge of the biological, psychological, and epidemiological aspects of mental illness. Our 1982 research program of $102.8 million, or 62 percent of the total revised NIMH request, is devoted to this priority.

- o Enhancement of the success and cost effectiveness of current and emerging treatment methods, through programs of treatment assessment and services research. We expect to spend $12.6 million, or 5 percent of the budget.

- o Development of improved methods for the prevention of mental illness and promotion of mental health. Approximately $3.8 million, or 2 percent of the budget will be devoted to this priority in 1982.

- o Support of research training programs which will ensure a continuing supply of new researchers in the biological, psychological and epidemiological aspects of mental illness. Approximately $27.7 million or 11% of the budget will be utilized in this manner.

- o Completion of an orderly phase-out of clinical training activities in 1982. Clinical training continuation costs total $47.3 million, or 20 percent of our 1982 budget.

RAPE PREVENTION

Question: The Carter Fiscal Year 1982 budget contains no specific funds for rape services and reduces funds for rape prevention research.

Why are these programs being reduced?

Answer: Under the revised budget request, rape services, as well as all other mental health service programs are proposed for inclusion as part of a general health care block grant to the States. This particular item has also been excluded from the Carter budget; however, that decision was based upon the need to fund as many other Systems Act authorities as possible within the limitations of available resources.

Under the Carter budget, rape research was limited to $1.5 million in 1982 because this amount also represented the statutory maximum authorized for the program under Section 601(d) of the Mental Health Systems Act. Under the Reagan budget, this amount has been further reduced to $1,189,000, in accordance with administration proposals to phase down social research in 1981 and 1982.

TRAINING PAYBACK UNDER SYSTEMS ACT

Question: What will be the expected payback requirement?

Answer: The draft regulations now state that trainees will be required to pay back with a month's service for each month of ADAMHA support. This service can be performed, as the law states, in a public mental hospital, in any entity receiving a grant under the Mental Health Systems Act, or in a designated health manpower shortage area. In addition, trainees may work in other public or private non-profit facilities when the majority of patients or clients seen come from underserved population groups specified in the findings of the Act or which are the focus of ADAMHA funded programs. Students will be required to find their own jobs and be paid by the facilities in which they are employed. ADAMHA will not fund the placement or subsidize the salaries of individuals fulfilling their payback obligations.

PREVENTION RESEARCH

Question: The Department of Health and Human Services has increased the priority given to health prevention measures. However, ADAMHA seems to be de-emphasizing prevention in mental health research. For example, total new research grants increase from $48 million in 1980 to $61.4 million in 1982 - an increase of 28%. At the same time, the new prevention research grants decline from $3.5 million to $2.4 million, a decrease of 31%.

Why is prevention research being given a lower priority in the 1982 budget?

Answer: Research into the prevention of mental illness continues to be one of the Institute's highest priorities. The revised research budget declines by six percent from 1980 to 1982. At the same time, the revised 1982 budget includes a total of $3.8 million for prevention, which represents a seven percent increase over the 1980 level. There is a reduction in the level of funds available for new and competing awards; however, this is the result of a larger share of the prevention budget being required to meet continuation costs in 1982.

PATIENT LOAD

Question: The budget shows that in 1982 the service programs for mental health will treat 4.05 million patients. Of this number, only 450,000 or 11% are listed as being in underserved categories -- the chronically mentally ill; severely mentally disturbed children and adolescents, the elderly and other priorities populations.

Is 11% a reasonable figure for meeting the needs of the underserved?

Answer: The revised 1982 budget includes a proposal to consolidate mental health service programs into a basic health care block grant. By making these funds directly available to the States, it will be possible for each State to direct its resources to areas of greatest need. It should also be noted that the earlier estimate of 450,000 persons in underserved categories related only to those to be served by programs which were just beginning under the new authorities created by the Systems Act. They should be considered additive to those served within the 3.6 million total treated by the previously existing CMHC program. The latter total included 1.9 million or more, in the underserved categories. This would bring the proportion of underserved patients treated to nearly 60 percent.

Question: Do you expect this percentage to increase in future years and if so what is the ultimate target and when will it be acheived?

Answer: With the proposed conversion of this program to a block grant, we are not able to predict the degree to which the States will choose to increase the availability of services to underserved areas of the population. We would expect that since most States have expressed concern for the underserved, that they would continue these activities.

Question: How many of the 3.6 million patients being served by mental health centers are in underserved categories?

Answer: The number is about 1.9 million.

STATE MENTAL HEALTH MANPOWER DEVELOPMENT PROGRAM

Question: The budget for the National Institute of Mental Health includes $7 million in grants to the States to assist them in "planning, problem identification, and systems development" with respect to the training of mental health personnel.

Why is it a Federal responsibility to pay for State planning and why can't the States finance this kind of planning with their own money?

Answer: The revised 1982 budget includes a proposal to discontinue new awards for all training programs in 1981 and 1982, and to phase training out completely by the end of 1982. Accordingly, the States will be financing their own manpower development activities in the future.

Question: Specifically, do you have plans to address shortages through changes in distribution of personnel in addition to increases in training programs?

Answer: Over the past three years, we have made a concerted effort to correct maldistributions of mental health personnel. We have made significant progress in this direction, essentially eliminating all grants for general professional education in favor of grants targeting resources to train personnel to work with underserved populations. While the revised budget calls for elimination of clinical training grants and contracts by the end of 1982, we hope to be able to continue to influence the application of this approach in mental health training institutions.

GENERAL MENTAL HEALTH/TRAINING

Question: Are there any research findings or accomplishments from the past year that will be of particular assistance in treating mental health patients in the near future?

Answer: In addition to the previously described research findings relating to schizophrenia, depression, and the relationship of genetic factors to the incidence of mental illness, there are some additional findings which offer considerable promise.

Loss of memory and cognitive function is regarded as one of the most dreaded aspects of the aging process. NIMH is currently supporting studies investigating the nature of memory function in normal advancing age and in states of psychopathology. As a result we know now that serious memory disturbance in older persons is always related to some form of disease or toxic reaction, and not to normal aging. Thus, we are presently studying the effects of new behavioral and pharmacological treatments for memory impairment in persons with Senile Dementia. A good number of these studies are based on evidence that the cholinergic system in the brain is directly implicated in memory deficits, and that a deficiency in the availability of acetylcholine (Ach), a neurotransmitter in the brain, is related to the presence of senile dementia of the Alzheimers type. It is hypothesized that by administering dietary choline (or its precursor, lecithin), brain concentrations of Ach will be elevated and memory impairment reversed.

In the treatment of severe mood disorders (i.e., depression and mania), the effectiveness of lithium in controlling the manic phase of the mood swings has improved the treatment of these patients profoundly. Now studies are underway which evaluate the effectiveness of combining an antidepressant drug with lithium in an effort to control both phases of this profoundly life-disruptive mood disorder. Further, by using newly developed techniques to measure blood levels of this drug, adjustment of dosage can be done in a way to accomplish maximum efficacy and minimum chance of side effects or toxicity.

Question: What are your priorities in mental health training programs in the coming year?

Answer: In the area of research training, we will focus on development of an adequate supply of researchers in the areas of neurosciences, behavioral sciences, psychopharmacology, clinical investigations, and evaluation of treatments and services for the mentally ill. Clinical training will be phased down in 1981 and 1982, in anticipation of the elimination of this program in 1983.

Question: What are the prospects for alleviating the problem of mental health personnel shortages that is described in the Mental Health Systems Act?

Answer: As just indicated, the 1982 budget includes proposals to phase out clinical training activities. The shortage of mental health personnel is a problem of national concern; however, it is presently overshadowed by the greater need to achieve national economic recovery.

Question: Is anything being done to upgrade the training and ability of general health practitioners to deal with mental health patients as so many persons with emotional problems take them to their family doctors rather than to mental health personnel?

Answer: NIMH has been concerned that general health practitioners receive better mental health training so that they are able to diagnose and treat the emotional problems of their patients. We have supported the training in mental health and psychiatry of all medical students, and of many primary care residents. The psychiatry consultation/liaison programs fosters the close collaboration of general health care providers and psychiatrists, and teaches physicians about mental health problems. Overall, $9.4 million, or 13% of the 1980 NIMH clinical training budget supported programs which helped health practitioners give better care to mental health patients or to patients whose physical problems are worsened by emotional problems.

MENTAL HEALTH RESEARCH

Question: What is being done to assure that a balanced approach to research is maintained?

Answer: The NIMH actively maintains various formal as well as informal mechanisms and activities to consider the appropriate distribution of its research portfolio. These are, in the main, comparable to the activities and mechanisms traditionally found within federal scientific research agencies. Specifically, the Institute receives the counsel and guidance of its National Advisory Mental Health Council (NAMHC): in addition to considerations of the full Council, a special Research Committee of the NAMHC was formed in 1979 and meets four times a year to provide a specialized and continuous advisory function to the Institute's research management staff. Upon the advice of the Research Committee, the NIMH began in 1980 an additional external advisory function by periodically convening leading scientists in areas of study which cross organizational entities to form clusters of research concerns (e.g., research on services issues, on childhood disorders). Internally, at the Institute level, the directors of all intramural and extramural research units meet as the Institute's Research Advisory Group for the purpose of formulating consensus around cross-cutting research issues such as priority areas, future directions, innovations, and distribution of the portfolio.

Not apparent in these mechanisms and activities is the process by which fields of investigation within mental health define their own equilibrium by virtue of their growth, rate of development, and interaction with each other. Thus, the maintenance of balance between different approaches or aspects of the mental health research field can never be entirely externally imposed, and is always guided from within by the opportunities and demands of a given field at a given time.

Question: Are sufficient funds available within other National Institute of Mental Health programs to lessen the need for a specific earmark for this purpose?

Answer: With the exceptions of those aspects of rape prevention which may be considered as social research - and

therefore the subject of phase-out in 1981 and 1982 - other NIMH research programs deal with mental health issues which impact directly or indirectly upon the problem of rape. A major source of such study would be found among those research projects dealing with violent behavior, and with crime and delinquency.

MENTAL HEALTH RESEARCH

Question: What will be the priorities for mental health research in the coming year, and how will they differ from current year?

Answer: In 1982, the Institute will be phasing out social research, while maintaining the basic and applied research in the neurosciences, behavioral sciences, psychopharmacology, clinical investigations, and evaluation of treatments and services for the mentally ill. This will represent a redirection in our research portfolio, which had previously included a significant segment of social research.

Question: Are there new research priorities which reflect provisions in the new Mental Health Systems Act.

Answer: The Administration will seek legislative changes to convert the present service grant authorities of the Mental Health Systems Act to more generalized support under a health block grant. For this reason, the research priorities for 1982 are not designed to follow MHSA provisions. Accordingly, our research priorities for 1982 emphasize the more basic studies which will have universal application to all segments of the population.

Question: Can you cite some specific research findings or accomplishments from the past year or two that will be of particular assistance in mental health treatment programs in the near future?

Answer: The collective body of findings resulting from our most recent research investments in the major mental illnesses has provided us with significant new information, both for improved diagnosis and treatment of mental illness, and for determining future directions in research.

Researchers have demonstrated in animals a procedure involving transplantation of brain tissue which has significantly improved a movement disorder. Using rats in which a circling pattern of running has been induced, they have transplanted a small piece of fetal brain tissue (from the substantia nigra) into the rat's ventricle. The tissue survived, grew into the surrounding brain tissue and in the next two months effected a 50 percent improvement in the movement disorder. The potential implications of this finding for study and treatment in Parkinsonism and other disorders is enormous.

Positron emission tomography is an emerging research technology which, in essence, reproduces "pictures" (computerized images) not only of brain structures, but of the brain's chemical behavior. This technology will one day allow researchers to "see" what normal chemical functioning of the brain looks like, and to "see" what processes and areas of the

brain are malfunctioning in specific psychiatric and neurological disorders.

Carbamazepine has been evaluated as a treatment for patients who are not responsive to lithium or other drug treatments for manic-depressive illness. Initial clinical trials have been completed, with extremely promising results, as indicated by repeated improvement during carbamazepine treatment, relapse upon placebo substitution, and renewal of clinical improvement when the active drug is substituted. Carbamazepine has been very effective in more than half of the manic patients in the study, and slightly less than half of the depressed patients. In addition to its effectiveness during the acute stages of affective illness, data indicate that carbamazepine may have significant preventive effects against recurrence of manic and depressive episodes.

TRAINEE SUPPORT

Question: The Committee is concerned that NIMH has not been providing accurate statistics on its commitment to insuring that underserved areas will receive adequate mental health care. The Committee has learned that from FY '76 to FY '80 a total of $116,478,000 was spent on psychiatry training while only 19% of these funds (or $22,635,000) ever actually went for trainee support, the rest going for institutional support. Information received indicates that the majority of the trainee support (4,634 "slots" out of 6,213 over the five year period) were for two or three month summer positions for medical students, which would not entail any obligations. Thus, NIMH apparently only has 105 "obligated" psychiatrists in training per year at a cost of nearly $221,868 per psychiatrist.

The Committee would appreciate learning if these figures are correct, and if so, what steps will be taken to insure that a more realistic effort will be made in FY '82 to address the needs of our Nation's underserved areas.

Answer: Total expenditures for the five year period are consistent with our own estimates for psychiatry training. The annual average is $22.7 million. Of that amount, approximately $11.3 million has been spent for the provision of psychiatric training to an average of 65,000 medical students annually and for consultation/liaison training which impacts approximately 20,000 primary care residents. Of the remaining $11.4 million, approximately $2.6 million relates to psychiatry stipends and $8.8 million to teaching costs. The faculty supported with these teaching costs not only train an average of 115 stipended psychiatric residents annually, but also an additional 4,000 non-stipended residents in those programs. The teaching provided also affects the training of approximately 10,000 residents annually in other health disciplines.

The provision of psychiatric training for medical students and residents in other disciplines has enormous importance for the improvement of care for underserved segments of the population. Approximately 54 percent of all persons with mental disorders rely exclusively on the general medical sector for care. This is particularly true for the underserved segments of the population who, for a variety of reasons, have not had

adequate access to specialized psychiatric help. It is therefore important that practitioners in non-psychiatric specialties be adequately trained in screening, referral, and short-term mental health services.

To summarize, the overall totals cited are correct; however, the unit cost estimates for training psychiatric residents are grossly overstated because of a large number of non-stipended trainees supported by our budget. In addition, the investment of funds in the provision of training for non-psychiatric specialties has been undertaken expressly for the purpose of upgrading the quality of care for those who do not have access to, or avail themselves of, specialized psychiatric services.

MENTAL HEALTH MANPOWER

Question: What percentage of funds for mental health manpower programs will be directed to each of the four core mental health professional disciplines: psychiatry, psychology, social work and psychiatric nursing?

Answer: As part of a plan for better targeting of the allocation of Federal funds, the Administration is proposing to end general subsidies for the training of several categories of health professionals. Mental health clinical training programs are included among these categories.

To implement this policy, 1981 rescission requests and 1982 budget amendments have been submitted to Congress. Until Congress acts upon these proposals, no new or competing clinical training grants will be awarded. Such awards would be resumed only if the current set of budget proposals is disapproved by Congress.

Continuation commitments for projects funded prior to submission of the revised budget would be fully supported through the end of fiscal year 1982. Clinical training support would be phased out completely at that time.

SHORTAGE OF PSYCHIATRISTS

Question: What plans are being formulated to encourage more graduating physicians to choose this specialty?

Answer: As indicated, the Administration is proposing to phase out clinical training activities in 1981 and 1982.

Question: What activities are being planned that will focus specifically on the recruitment of minority manpower in the mental health field?

Answer: Clinical training activities will be phased out during 1981 and 1982.

INTERAGENCY COOPERATION

Question: Do the budgets of HHS and HUD include funds for continuation of these programs?

Answer: The funding sources for the HUD/HHS Demonstration Program included Section 202, mortgage loan authority and Section 8 rent subsidies from HUD for housing development, as well as Medicaid funds available through Section 1115 waivers from HHS for support services. While, in individual cases, State Mental Health Authorities and local service agencies may be able to tap these HUD and HHS resources, no funds have been specifically set aside in either Departments' budgets for continuation of these programs.

PHASE OUT OF SUPPORT FOR MENTAL HEALTH CENTERS

Question: The basic authorizing legislation contemplates federal financial support for community mental health centers for a maximum of eight years.

What are the projected requirements for federal aid to the community mental health centers over the next five years?

Answer: The Administration will propose legislation to merge the present categorical support of community mental health centers into a general health care block grant to States. If the legislation and related budget proposals are approved, the transition would occur in 1982. At that point, future funding levels for community mental health centers will be determined by the States.

Question: When do you expect the need for federal funding to be phased out?

Answer: As indicated, federal funding would continue for the foreseeable future in the form of a block grant. Decisions relative to the continued funding of community mental health centers would be made by the States.

IMPACT OF SOCIAL POLICIES ON MENTAL HEALTH

Question: The 1982 budget narrative states that research will be undertaken on "social policies and their effects on the mental health functioning of special populations."

What are some examples of social policies that will be the subject of this type of research?

Answer: Under the revised budget request, the support of social research will be phased out. Although 1981 and 1982 continuation support will be provided for social research projects funded prior to submission of the revised budget, no new awards will be made in this area.

Question: How will the results be used to improve mental health?

Answer: As indicated earlier, new social research will no longer be funded. It should be noted, however, that findings from previously supported social policy research have proven of value in the identification of mental health problems that are unique to specific segments of the population, such as minorities, children and adolescents, the elderly, residents of rural areas and those living at the poverty level.

Question: How much money is included for this type of research in 1982?

Answer: Because no new funds are proposed for social research in 1981 and 1982, there is $9 million remaining in the form of continuations from projects funded in 1980 and earlier.

NEW MENTAL HEALTH LEGISLATION

Question: How do you plan to implement the various provisions in the new legislation relating to mental health promotion and mental illness prevention?

Answer: Because the Administration is proposing to transfer all mental health service funds to a general health care block grant in 1982, and also to seek necessary related changes in authorizing legislation, there are no plans to implement the prevention provisions of the present Mental Health Systems Act.

Question: How will these new legislative mandates be coordinated with other HHS general health promotion and disease prevention activities?

Answer: As indicated, funds requested for prevention activities under the previous budget request will be included in the proposed general health care block grant. For this reason, the locus of coordination will be within the individual States.

Question: When do you expect that regulations for implementation will be ready for initial publication in the Federal Register?

Answer: The development of implementing regulations will now depend upon the outcome of Congressional action on the block grant proposal contained in the revised budget request. If the block grant proposal is approved, it will not be necessary to issue regulations.

Question: How are you going to carry out provisions in the newly authorized Mental Health Systems Act in light of budgetary constraints?

Answer: The proposed block grant is expected to meet the service needs of the States, and at a funding level which is somewhat less than would have been required under the Systems Act.

Question: How much in your budget reflects new provisions in the Mental Health Systems Act?

Answer: All funds previously dedicated to the implementation of the Systems Act have been deleted from the revised budget. The mental health share of the proposed block grant reflects an investment which is equal to 75 percent of the 1981 current services level.

DEINSTITUTIONALIZATION

Question: What portion of the mental health budget is aimed at getting individuals out of institutional settings?

Answer: Support for deinstitutionalization cuts across all segments of our budget. For example, recent research findings will help reduce the relapse rate among previously hospitalized mental patients. During 1980, we spent seven percent of our clinical training budget ($5,401,000) on programs to train individuals to deal with deinstitutionalized, chronically mentally ill patients. Our entire services program is oriented toward keeping individuals out of institutionalized settings, who might without mental health services need to be institutionalized. Funds which were directed for this effort amounted to $294,801,000 in 1980. The combined training and services effort in this area constituted 55 percent of the entire NIMH budget in 1980. The percentage is probably higher, but it is difficult to assess the specific dollar investment in the research area.

Question: Describe deinstitutionalization programs planned for Fiscal Year 1982.

Answer: Much of the deinstitutionalization effort will be discontinued in 1982, as the major share of the Institute's effort in that area has been derived from its clinical training and service programs. As previously indicated, clinical training programs are being phased down in 1981 and 1982, and will be phased out completely in 1983. Service programs are proposed for conversion to a general health care block grant in 1982. It is hoped that the States will continue the efforts which were initially stimulated with Federal funds provided under the Community Support Program.

Senator Chiles: When Congress passed the Mental Health Systems Act last year, we targeted the community mental health program to certain "priority population groups" who have been shown to be severely underserved in the current system. These groups include the elderly, the chronically mentally ill, severely disturbed children and adolescents.

I understand you are in the process of developing the regulations to implement the new law. What steps are you taking to insure the intent of Congress that States and CMHC's focus on these groups who have been underserved is carried out?

Answer: Under the present block grant proposal, the States will use the funds made available to address those areas which, in their individual judgement, reflect the most pressing priority needs.

NEW INITIATIVES

Question: What new initiatives or demonstration projects are planned for next year?

Answer: Recent research by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has demonstrated the importance of genetics in understanding the susceptibility of individuals to the development of alcoholism and to the development of medical problems that

can result from alcohol use. While studies to date have indicated a genetic influence in the development of alcoholism, particularly among males, further work is now needed to more specifically identify and assess the relative contributions of particular genetic and environmental influences. New studies will include research to clarify the different roles that genetic or psychological factors might have for men and for women, and would utilize studies of twin and adoptees as well as explore family and personality factors that may act to predispose or precipitate the development of alcohol problems.

Research funds will also support investigations to further explore the recent findings that the key enzymes responsible for the metabolism of alcohol (i.e. its use and elimination from the body) can exist in different individuals. New forms of the enzyme have been found to occur selectively in different racial/ethnic groups, e.g., one form in Blacks, another enzyme form in Japanese populations. Since the harmful effects of alcohol consumption seem to be directly related to the process by which it is metabolized, this research will contribute greatly to a better understanding of the basis for alcoholism and the (possibly inheritable) differential vulnerability of individuals to the damaging effects of alcohol.

Research will also be undertaken to better understand the actions of alcohol on the body and the mechanisms by which it exerts its effects. Studies include such questions as the natural history of alcoholism and the differences for various subpopulation groups (e.g., women, youth); the processes of dependence, tolerance, and withdrawal; the impact of alcohol on the fetus; and the mechanisms by which alcohol may adversely impact on metabolism, immunologic responses, endocrine functions, neuropsychiatric processes, and nutrition, and acts as a significant contributing factor for a variety of major medical illnesses.

Recent findings have also indicated some potentially very productive lines of inquiry in seeking a better understanding of the impact of alcohol on the brain and its effect on intellectual processes. For example, recent findings on the effects of alcohol on the brains of laboratory rats challenge the traditional view that the brain damage and the resulting impairments in learning and memory that have been observed in chronic alcoholics are the result of malnutrition, and suggest that alcohol per se may be responsible for these effects. These findings and others have provided a very useful base of information that can now be expanded with new studies in such areas as the effects of alcohol on memory and learning, for both social and heavy drinking, the effects of abstinence and of continued drinking on cognitive functioning, the reversibility of these effects, and the implications of this information for the development of appropriate treatment approaches and goals for individual alcoholic patients.

Although it is generally accepted that treatment for alcoholism can and does work, the relevant factors in determining the choice of patients for particular therapeutic approaches have not been isolated and assessed. In view of the need for more definitive knowledge in the area of treatment, research will be supported to explore such questions as the different types and diagnostic categories of alcoholism and alcohol problems, so that patients with particular types of problems and clinical needs can be appropriately matched with particular types of treatment approaches; the assessment of specific treatment modalities and procedures (such as detoxification, emergency medical procedures, or psychopharmacological approaches); and the applicability of specific treatment techniques or procedures to the special needs of particular population groups. Work will also be undertaken to develop improved techniques to treat the medical complications of alcohol use. For example, NIAAA-supported work has demonstrated that alcohol itself, even in the presence of an extremely nut-

ritious diet, can cause cirrhosis, which is a frequently fatal disease that requires lengthy and recurring hospitalizations. This work has importance both for alerting physicians to the critical role of alcohol, regardless of nutrition, in the development of cirrhosis, and as a basis for the development of an effective treatment for this disorder, which was the seventh leading cause of death in 1975 but for which there is now no effective therapy.

Plans are now being implemented for the establishment of a clinical research program in the NIH Clinical Center and the adjoining Ambulatory Care Research Facility (ACRF). This effort, which complies with Congressional directives on this issue, is the result of several years' discussions and is considered extremely important by the Institute. Space and utilization plans for this program have been developed, and renovations are scheduled to begin in FY 1981 and to be completed in March 1982. Funds for this purpose were transferred to NIH in FY 1979 and FY 1980 and are included in the appropriation for FY 1981. The NIAAA clinical research space will consist of the 3B North wing of the Clinical Center for a clinical ward, and 2500 square feet of space in laboratory and animal areas on the 3rd floor of the ACRF for use as support laboratory facilities. Architectural plans developed with NIH and its contractor provide for the clinical ward to include space for 10 beds as well as space for examining rooms, physiological and electrographic testing, therapy and counseling, nursing station and minimal office space for on-duty clinical staff. Designs for the laboratory and animal facilities include 12 modules to be used for cell cultures, phosphorous, iodine, carbon isotope studies, and clinical biochemistry, as well as space for animal facilities. Because of the wide range of physiological functions and health problems that are affected by alcohol consumption, and the need for improved techniques for the early identification and treatment of individuals with alcoholism or other alcohol-derived health problems, studies conducted in the clinical research program will be oriented toward the development and testing of improved diagnostic and therapeutic techniques. In preparation for this program, collaborative efforts have been carried out with NIH Institutes which will provide the preliminary base for the clinical research program and will be expanded with the availability of NIAAA clinical bed space for studies of the importance to the Institute. The development of a strong clinical research base on the NIH campus, therefore, will broaden the alcohol research capacity by allowing the Institute to take advantage of the vast array of scientific talent and facilities at the NIH while still providing distinct advantages to the treatment and prevention programs of the Alcohol field.

The National Institute on Drug Abuse reports that there is an intensive effort on the part of drug companies to develop new benzodiazepines (e.g.,"tranquilizers") which are longer acting, more like sedatives, or ahorter acting. The market of the 1980's will be flooded with new compounds of this class yet very little is known about their possibility for abuse or long-term effects. In FY 1982, NIDA will begin a program to analyze these drugs to determine their abuse liability, drug interactions, behavioral effects, and health hazards.

One of the latest "street drugs" is alpha-methyl-fentanyl, often mislabled "China White." This drug, suspected in a number of deaths in California, is not yet "scheduled," and is, therefore, still legally available. It is both cheap and easy to synthesize from readily available precursors. In FY 1982, NIDA intends to conduct the appropriate animal studies to enable us to render assistance to DEA and make recommendations relative to scheduling decisions. We will also study the metabolism of this and related compounds in humans, assuming that it can be done safely. This should enable the development

of a test whereby emergency room personnel can identify the drug on admission of persons in dire need of treatment.

Newly published research findings indicate close connections between neurohormones in the hypothalmus and reinforcement and memory. In FY 1982, NIDA will conduct the basic studies of these substances to determine their possible role in producing psychological "highs" and the development of tolerance to drugs which can be thought of as a type of memory.

NIDA will explore the use of technology, particularly the PETT (position emission transaxial tomography) scanning technique for study of regional activity in the brain and distribution of drugs in subjects who have not abused the drug and in individuals who are tolerant to the drug or in withdrawal.

The latest "fashion" in drug use is to smoke the drug. It was know that heroin and cocaine could be used in this manner but now even valium is being smoked. Street wisdom declares that this gives the individual a more intense effect, a "higher high." There is a need for study of this new phenomenon, smoke analysis and investigation of the pharmakinetics of such drug abuse.

Review of physician prescription practice statistics indicates a dramatic rise in the use of tranquilizers other than valium. Of particular interest is atavan which is rapidly replacing valium as the tranquilizer/hypnotic of choice. NIDA will attempt to study the patterns of sedative-hypnotics and tranquilizers and the nature and extent of such use.

Increasing concern has been expressed with regard to mounting drug abuse in occupational settings. While employee assistance programs abound, there is virtually no study examining the efficacy of different strategies for recruiting individuals into those programs. More significantly, there is no data with regard to the efficacy of employee assistance or substance abuse programs as they affect drug abusers specifically. Efforts are needed to clarify numbers of persons in need of employee assistance as a consequence of substance abuse, the types of workplaces most likely to show such problems, and, most significantly, the effect of different employee assistance/substance abuse programs and models on worker performance and industrial productivity.

There now exists a body of data pointing to the general effectiveness of selected drug abuse treatment forms, e.g., methadone maintenance, outpatient drug-free treatment, and therapeutic community treatment. Each of these forms contain within them a number of individual treatment and rehabilitation services. There is a continuing need to understand the ways in which treatment programming can be made more effective through the emphasizing of certain initiatives and de-emphasizing of others. In short, there is need to separate treatment programs into their component parts, e.g., counseling, family therapy, vocational rehabilitation, etc., in order to explore the real efficacy of each and thereby increase the cost effectiveness of drug abuse treatment overall.

As a part of that activity, it will be necessary to explore the relationship between treatment outcome and drug abuse client characteristics at intake with a particular emphasis on client diagnosis. In so far as diagnosis suggests the extent and nature of client adjustment problems, it gives promise of aiding significantly in the determination of treatment components approriate to client need. Thus, the relationship of treatment components to refinement of service delivery strategies.

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The major portion of The National Institute of Mental Health's initiatives will relate to its research program.

- An initiative in childhood depression will be directed toward increasing knowledge of the origin, prevalence, and diagnostic criteria relating to childhood mental illness.

- Special attention will be given to the development of treatments for senile dementia, which will reduce the number and severity of side effects, while maintaining or improving the rate of success.

- Research projects will be supported for the purpose of developing successful medications for schizophronic patients who are currently considered to be treatment resistent to available drugs. Special attention will be given to schizophrenics who display relatively mild pathological symptoms, but who experience severe maladjustment problems.

- NIMH research will seek further understanding of genetic factors and specific subtypes of depression for which there is a chance of helitability. We know that depression is too general a term upon which to base treatment. Depressive illness actually represents a wide array of highly specific disorders, each of which responds to a unique type of therapy or preventive measures. Our goal in 1982 will be to make further progress in sorting out their various disorders.

- A major research priority will continue to be the diagnosis and treatment, and the ultimate reduction of risk for tardive dyskimesia, which is the major side effect of anti-psychotic medications. This disorder produces bizarre and involuntary body motions, making its victims conspicuous, and thereby frustrating efforts to become part of mainstream community life. It occurs in 20 percent of persons receiving long-term medications with neuroleptic drugs.

NATIONAL INSTITUTE OF MENTAL HEALTH

STATEMENT OF DR. HERBERT PARDES, DIRECTOR

ACCOMPANIED BY:

DR. WILLIAM F. DOBBS, SUPERINTENDENT, ST. ELIZABETHS HOSPITAL
DR. AARON LIBERMAN, ASSOCIATE SUPERINTENDENT FOR ADMINISTRATION, ST. ELIZABETHS HOSPITAL
JAMES E. PITTMAN, EXECUTIVE OFFICER
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ANTHONY ITTEILAG, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator RUDMAN. We're going to move on to St. Elizabeths testimony. I'm going to declare a 5-minute recess here while we stretch and gather ourselves together.

[A brief recess was taken.]

Senator RUDMAN. Back on the record. Let's reconvene the hearing. Dr. Pardes, I will let you proceed on the St. Elizabeths portion of this hearing.

Dr. PARDES. Thank you, Senator. In addition to the people you have already met, let me introduce Mr. James Pittman on my right, the Executive Officer.

Senator RUDMAN. Your name again, sir?

Mr. PITTMAN. James Pittman.

Dr. PARDES. On my left, Dr. William Dobbs, the new Superintendent of St. Elizabeths Hospital. On his left Dr. Aaron Liberman, who is the Executive Administrator of St. Elizabeths Hospital, and on his left, the NIMH Budget Officer, Mr. Ed Goody.

In the interest of time, I would be happy to just condense my opening statement.

Senator RUDMAN. I would like you to do that, if you would. Then we will have it incorporated into the record. Why don't you proceed on that basis.

[The statement follows:]

STATEMENT OF DR. HERBERT PARDES

It is a pleasure to have the opportunity to appear before you to discuss the programs of 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 Hospital staff, I am pleased to say that substantial progress has been made in several areas.

APPOINTMENT OF NEW SUPERINTENDENT

Earlier this year, I was pleased to announce the appointment of Dr. William Dobbs as Superintendent of Saint Elizabeths Hosptial. Dr. Dobbs, who served as Acting Superintendent from December 1979 to his appointment as Superintendent is a graduate of Emory University Medical School and is board certified in psychiatry and neurology. During a twenty-nine year career in the Washington area and Saint Elizabeths Hospital, Dr. Dobbs has served as a director of several clinical divisions as well as director of training. The Hospital is indeed fortunate to be led by this man of distinguished professional achievement and personal character.

MAINTENANCE OF ACCREDITATION

Saint Elizabeths Hospital was surveyed by the Joint Commission on Accreditation of Hospitals in June 1979. Subsequently, the Adult Psychiatric Programs, the Alcoholism Program and Child and Adolescent Program were granted one year accreditation. The Area D Community Mental Health Center was granted a two year accreditation in 1978.

The Hospital was re-surveyed during August 1980 and was again granted a one year certification. At the same time, the Joint Commission took the unusual step of sending a commendation letter to the Superintendent citing the considerable progress made by the Hospital in achieving accreditation since 1975.

During the month of January, the Area D Community Mental Health Center was re-surveyed. Although the Center will not be notified formally of the Joint Commission's decision for several months, comments made by the surveyors at the summation conference were favorable and supportive.

Thus, the Hospital has succeeded in maintaining its accredited status through this second series of surveys. It is our feeling that the Hospital is achieving a level of excellence which will assure the continuing availability of high quality services to its patients.

OUTPLACEMENT OF PATIENTS

Another area of accomplishment relates to the final submission of a joint plan by the District of Columbia Government and HHS for implementation of the Dixon Plan. The Dixon Plan is the outgrowth of a lawsuit, which has resulted in the submission of a formal planning effort with the District of Columbia, to deinstitutionalize several hundred Saint Elizabeths Hospital patients in the least restrictive environment possible. The management and

staff of the Hospital have worked to forge a reasonable and realistic working agreement with the District of Columbia.

Saint Elizabeths staff and staff from the District's Department of Human Services are now working together on the Appendix to the Final Implementation Plan. In addition, the first 33 patients are being prepared for placement at the J.B. Johnson nursing facility which was turned over to the District of Columbia last October, and which will be opening soon.

CONSTRUCTION

Over a period of several years Congress appropriated $67.6 million for physical plant improvements, to restore and maintain the accreditation of Saint Elizabeths Hospital. During the past year, it has been necessary to adjust the program to stay abreast of requirements as they develop in the execution of our construction plans. However, the construction program continues to move ahead and remains within the Hospital's budget allocation.

MANAGEMENT IMPROVEMENTS

With respect to the management of the Hospital, we have noted some significant improvements during the last 12 months.

- Overtime has been reduced.
- The cost of administrative services during the first quarter of this fiscal year has been reduced as a percentage of total expenditures. Thus, we are providing more resources for patient care.
- During the last year, the hospital reorganized its administrative component. This reorganization enhanced the ability of top management to operate the Hospital efficiently. A significant feature of this reorganization was the establishment of an Office of Special Audits, which investigates problems relating to the possible waste or misuse of resources.
- During 1979, the Hospital initiated a contract with Georgetown University Hospital to provide its patients with secondary and tertiary medical and surgical care.

All of this, I believe, is contributing to a 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 reasonable balance between the quality of administration and the availability of patient services. If either suffers, the other is adversely affected.

REGULATIONS

Finally, Mr. Chairman, I would like to comment upon the matter of developing and promulgating regulations, as this is an issue of interest to the Committee. Saint Elizabeths Hospital does not issue regulations which impact upon the general public. The Hospital itself is governed by a body of patient admission statutes, and these statutes are implemented internally by various administrative procedures.

We will be pleased to answer questions the Committee may have.

ACCREDITATION

Senator RUDMAN. Why don't you summarize it, Doctor, however you would like to do it.

Dr. PARDES. The last several years at St. Elizabeths Hospital I think represent a very positive story. About 3 years ago, the hospital had been facing a situation of disaccreditation and was hampered, as Mr. Trachtenberg indicated earlier, by a number of old buildings for clinical patient care. We also had the problem of some turnover in leadership. Recently, as I mentioned, Dr. Dobbs has been identified as the new Superintendent of the hospital, so the hospital has continuing leadership.

The hospital has had several reaccreditation surveys. Those surveys have all turned out successfully. The most recent results that we have are of the survey of the hospital generally in August 1980, at which time we were granted a 1-year certification. At the same time the joint commission took the unusual step of sending a commendation letter to the Superintendent citing the considerable progress made by the hospital in achieving accreditation since the mid-1970's.

During the month of January, our area mental health center was also resurveyed. While the center will not be notified formally of the joint commission's decision for several months, comments made by the surveyors at the summation conference were extremely favorable and supportive.

OUTPLACEMENT

In the area of our outplacement efforts, the hospital continues to work very closely with the District on the implementation of the Dixon plan. The Dixon plan is the outgrowth of a lawsuit. It is focused on deinstitutionalizing several hundred of the St. Elizabeths Hospital patients, putting them in the least restrictive environment possible. The management staff of the hospital have worked to forge an agreement with the District of Columbia, and we have a good working relationship in accomplishing the demands of that plan.

As a relatively recent development, I would call to your attention that we have secured the opening of the J. B. Johnson facility, a District of Columbia facility, to which we are in the process of sending some 150 patients from St. Elizabeths which would substantially reduce the inpatient census.

OTHER PROGRESS

In the area of construction, we continue on our construction plan within the budget allocated by the Congress, and we are putting our priorities on taking care of the clinical areas, the areas where patients are served.

We also have to respond to the various accreditation committee's recommendations as they come in from year to year, and I'm happy to report to you that we are doing that successfully within the allocated budget.

Finally, in the area of management, we have been able to reduce the cost of administrative services. We have also reorganized some of our administrative structure and instituted an office of special audits in order to be able to monitor very closely any possible waste or misuse of resources.

During 1979, we also contracted with Georgetown Hospital to provide our patients with secondary and tertiary medical and surgical care. This relationship is working very well and is resulting in savings in the overall costs of care for this population.

In essence, I think that is a story of relative positive accomplishments, and we'd be happy to answer any questions, if you'd like, Senator, on St. Elizabeths.

PUBLIC CORPORATION

Senator RUDMAN. Dr. Pardes, how far along is the plan to form a public corporation?

Dr. PARDES. That plan is now up before the new department heads for their own consideration. If you would like, Mr. Pittman, who has been working on that, might be able to elaborate.

Senator RUDMAN. I would just like to know the approximate timetable as to when we might hear about that in more detail.

Mr. PITTMAN. Mr. Chairman, as Dr. Pardes has indicated, that matter is before the Department. We expect, within 6 to 8 weeks, to get a determination as to whether or not the provisions and recommendations that we have worked with the District of Columbia on are acceptable or whether or not we would have to modify them to any degree. But I expect in 1 to 2 months that determination will be made.

Senator RUDMAN. I assume there would be close liaison with the staff of this committee so we might understand what the timetable was and what was going on in light of the timetable you have just stated.

Mr. PITTMAN. Yes, sir.

PATIENT CARE COSTS

Senator RUDMAN. I wonder if you could tell us what your annual patient cost is compared to other institutions, similar institutions? What is yours in dollars? What is your annual cost per patient of operating that facility?

Dr. PARDES. I would say when one compares it on a per diem or annually, you will find that our costs are about ninth when compared to the costs of other metropolitan areas in the United States. There's a variability in the costs of patient care, as I'm sure you're aware, from area to area of the country.

Senator RUDMAN. Just what were the approximate numbers on a daily or annual basis, taking out of course your clinical research component? What would the other costs be?

Dr. DOBBS. Our per diem costs in 1980 were $122 per day, for example.

Senator RUDMAN. That's what your costs are?

Dr. DOBBS. Yes; however, that cost includes the whole range of hospital activities. We spend probably in the upper half of most hospitals, as I understand it, depending on how you evaluate.

Many State hospital figures are somewhat lower in the administrative area, because a lot of their administrative overhead is provided by a State office that's not connected with the hospital. Ours is entirely accounted for in the budget before you.

Senator RUDMAN. I would expect the costs here in the District to be relatively high anyway. In general, costs otherwise are.

Dr. DOBBS. Our costs are much lower than private care in the District area. It's about one-third what private care on the average costs.

RESEARCH

Senator RUDMAN. Now according to your budget, you mentioned $2.2 million to be spent on clinical research in 1981. Can you tell us what your research projects are that are underway in that budget?

Dr. DOBBS. It's divided into two general areas. One project that has been ongoing for many years, a very useful relationship with NIMH that we call the William A. White unit, in which we jointly support research into some of the areas of brain disorders in mental patients. That unit has an in-patient component that we support with staffing. NIMH supports the professional laboratory. It's a cooperative endeavor.

Senator RUDMAN. Can you point to specific improvements you believe in treatment that evolved over the years from that specific research that you carried on?

Dr. PARDES. Let me just comment. One of the major developments that Mr. Trachtenberg showed earlier, which was the successful transplant of brain tissue from one animal to another, was conducted in that laboratory. There is the possibility that this technique could assist in the treatment of Parkinsonism. That's a dramatic breakthrough.

I could cite other examples. That happens to be one of the most productive laboratories in the country.

Senator RUDMAN. That was done within this clinical research project?

Dr. PARDES. Right.

Senator RUDMAN. I want to thank you all very much. Any questions that haven't been asked, I expect that when you return the corrections, they will be answered. I enjoyed the opportunity to spend the afternoon with you. I think we may all have learned something; at least I have.

[The following questions were not asked at the hearing but were submitted for response for the record:]

Questions Submitted by the Subcommittee

SAINT ELIZABETHS HOSPITAL

Question: How far along is the plan to create a public corporation to manage St. Elizabeths Hospital?

Answer: During the preceding year a Departmental Task Force and District representatives have developed a set of recommendations to establish a public mental health corporation to administer St. Elizabeths Hospital and certain District mental health services. The Department's efforts are in response to a charge in the Fiscal Year 1981 budget to transfer St. Elizabeths to a public corporation in 1982.

The District's Mayor has approved these recommendations and they are pending review by the Secretary. Department representatives are drafting legislation and subject to the Secretary's guidance appropriate consultations will continue between Departmental officials and interested Congressional committees, affected employees, union officials and related professional groups and individuals.

Question: Do you have a timetable for completion of a plan?

Answer: A revised timetable and plan will be completed following the Secretary's decision and guidance on the recommended provisions for an independent mental health corporation.

COST PER PATIENT

Question: What is the average annual per patient expenditure at St. Elizabeths?

Answer: The average annual expenditure for inpatients was $45,523 in 1980.

Question: Can you indicate how this compares with average per patient expenditures at State mental health hospitals in near-by States?

Answer: The State data we have may be somewhat understated, in view of the fact that many State hospital systems obtain portions of their administrative and logistic support from centralized and separately budgeted sources. By contrast, the budget for St. Elizabeths represents the full cost of all services provided.

With that qualification in mind, the Institute has developed some estimated 1980 information, based on 1977 actual data, escalated for inflation. Pennsylvania spent $33,600 per patient annually; Virginia spent $17,780; Maryland spent $24,200; Delaware spent $38,600. In terms of cost per patient, Saint Elizabeths ranks between the eighth and ninth highest State, with its annual cost of $45,523.

According to budget documents, in 1981, an estimated $2.2 million will be spent on clinical research programs at St. Elizabeths.

Question: What specific research projects are underway?

Answer: First, it should be noted that the research budget is divided into two general areas. Approximately three-fourths of that amount supports clinical and related staff who provide basic services for the NIMH Division of Special Mental Health Research, which is located in the hospital's William A. White building. Saint Elizabeths provides the basic clinical services for patients who participate in this program, and the NIMH Intramural Research budget pays for the laboratories and the research staff. The arrangement is similar to the one under which the National Institutes of Health provides logistic and basic patient services for our research facilities on the NIH campus.

The remaining 25 percent of the budget represents the cost of the hospital's own research facilities.

The most significant single research project underway in the SEH-NIMH joint program is the brain tissue transplant study, referred to earlier. Researchers have demonstrated an ability to transplant brain tissue between laboratory animals which have various movement disorders, with dramatic results in terms of alleviating symptoms. This finding has major implications for the treatment of Parkinson's disease, as well as various drug side effects.

The hospital's own research component conducts studies oriented toward increasing the effectiveness of patient treatment programs at the hospital.

Question: What information has been obtained from this research program that has improved the quality of treatment at St. Elizabeths?

Answer: Control of violent behavior has long been a subject of concern in large psychiatric hospitals. This has been particularly true for Saint Elizabeths, where approximately 19 percent of the inpatient population consists of individuals admitted under various forms of criminal proceedings. A recent research project analyzed sixty incidents of violent behavior among patients, and categorized the factors which appeared to contribute to the problem. As a result of this study, hospital research staff were able to show ways in which ward rules, staffing patterns, policies concerning personal possessions, and groupings of patients could be altered in a manner which minimized the risk of violent incidents.

Nursing assistants comprise the major share of patient treatment staff. Because this employee group represents the most constant and significant presence in the lives of hospitalized patients, the ability to accurately predict the effectiveness of each nursing assistant is an important contributing factor to successful treatment. Hospital research staff have studied the performance of groups of nursing assistants during their initial training, and compared strengths and weaknesses during the training experience with later performance on the job. As a result of these studies, it has been possible to accurately predict the effectiveness of individual employees in treatment settings. From a management

perspective, it has also been possible to make reasonably accurate predictions of employee turnover.

Another hospital-sponsored research project had the goal of determining whether it was feasible to place patients in cooperative outside living arrangements without staff supervision. The study was successful, and resulted in development of a four to six month pre-placement program, which enabled patients to function successfully when subsequently placed in such outside cooperative living arrangements. This is resulting in substantial savings in terms of staff, and the findings were incorporated into the design of the Dixon implementation plan.

SUBCOMMITTEE RECESS

Senator RUDMAN. This subcommittee will stand in recess until 10 a.m. tomorrow in this room when we hear testimony from the Health Resources Administration.

Thank you all very much.

Dr. PARDES. Thank you, Senator.

[Whereupon, at 3:35 p.m., Thursday, February 19, the subcommittee was recessed, to reconvene at 10 a.m., Friday, February 20.]

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