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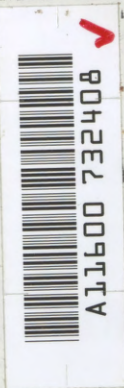
HEALTH SCIENCE PROMOTION ACT OF 1979

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON

HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON

LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

NINETY-SIXTH CONGRESS

FIRST SESSION

ON

S. 988

ENTITLED THE "HEALTH SCIENCE PROMOTION ACT
OF 1979"

APRIL 26 AND MAY 2, 1979



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HEALTH SCIENCE PROMOTION ACT OF 1979

THURSDAY, APRIL 26, 1979

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The committee met, pursuant to notice, at 10:15 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Schweiker, Williams, and Javits.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. We will come to order.

Today the Subcommittee on Health and Scientific Research convenes for its first day of hearings on the Health Science Promotion Act of 1979, which I introduced on Monday, together with Senators Schweiker, Williams, and Javits. As the title clearly indicates, this legislation has the primary purpose of promoting the effectiveness and productivity of this country's substantial investment in research related to health and the delivery of health care.

Over the last 2 years, the Subcommittee on Health and Scientific Research has held 10 days of hearings as part of a continuing program of oversight of our Federal investment in the health sciences. During that same period, I have personally visited not only the National Institutes of Health, but also Houston, Denver, San Francisco, Los Angeles, and Salt Lake City. This has been a fascinating experience for myself and the other members of the subcommittee. It was an exercise that, in my opinion, was long overdue. When we began our intensive program of oversight, it had been a full 10 years since comparable hearings were held by a committee of this Congress.

What we have learned is that the health sciences in this country have made and continue to make valuable progress in providing the tools necessary to improve the health of Americans. We have found that, as a result of the work of health science researchers, our country's physicians and hospitals have accomplished therapeutic triumphs which would have been impossible, perhaps inconceivable, 25 years ago. We have been convinced anew that our country's investment in the health sciences is the bedrock upon which our health care system rests, and that a strong, stable, and continuing commitment to the health sciences must remain a fundamental tenet of national health policy.

It is because we value our investment in the health sciences that we must be continually alert to ways in which the Federal Government can improve its role in supporting health-related research.

While I believe most of our health science institutions are fundamentally sound, our oversight activities have documented a number of difficulties. These need to be addressed so that, as we enter the 1980's, we can be confident that we have a streamlined, productive, and efficient Federal program for the support of health-related research.

First and foremost, we must improve the planning of our health science programs so as to increase the continuity, stability, and predictability of Federal support for health research. In recent years, we have seen a series of confusing swings in research priorities and research funding at the Federal level. These upheavals are unfair to scientists who have dedicated themselves in good faith to the directions mandated by the Federal Government only to have the directions change because the mind of the Federal Government changes. It is our hope that the mechanism proposed in the Health Sciences Promotion Act—the creation of a President's Council for the Health Sciences—will enable us to increase the stability and continuity of Federal health programing.

Second, the subcommittee has noted the need for some modifications in the structure and organization of the National Institutes of Health in order to improve the functioning of that organization. Title II of the Health Sciences Improvement Act addresses these issues, in addition to reauthorizing certain expiring programs.

Finally, title III of the Health Science Promotion Act aims at dealing with a problem which, in my opinion, seriously threatens the productivity of our research enterprise. This is the proliferation of reporting and paperwork burdens which our health science investigators now face when they receive Federal dollars. The legislation directs the National Institutes of Health to undertake certain experiments for the purpose of reducing paperwork requirements without compromising the essential principle that the public get value for money in the expenditure of Federal dollars.

Supporting the health sciences with Federal expenditures is a complex, subtle, and difficult task. It involves intricate relationships among Federal and private institutions, and among multiple public agencies and statutes. Clearly, public policy proposals affecting our health science programs need careful scrutiny and full and vigorous discussion before they are adopted. We begin that process of debate and exchange today.

[The introductory statement of Senator Kennedy and text of S. 988 follows:]

[From the Congressional Record--Senate, April 23, 1979]

By Mr. KENNEDY (for himself, Mr. SCHWEIKER, and Mr. WILLIAMS):

S. 989. A bill entitled the "Health Science Promotion Act of 1979": to the Committee on Governmental Affairs.

HEALTH SCIENCE PROMOTION ACT OF 1979

● Mr. KENNEDY. Mr. President, I am today introducing, on behalf of myself and Senators SCHWEIKER and WILLIAMS, the Health Sciences and Promotion Act of 1979. As the title clearly indicates, this legislation has the primary purpose of promoting the effectiveness and productivity of this country's substantial investment in research related to health and the delivery of health care. I would like to take this opportunity to explain in general terms the genesis of this legislation, its purposes and its provisions.

Over the last 2 years, Mr. President, the Subcommittee on Health and Scientific Research has held 10 days of hearings as part of a continuing program of oversight of our Federal investment in the health sciences. During that same period, I have personally visited not only the National Institutes of Health, but also health research centers across this country—in Boston, Miami, Houston, Denver, San Francisco, Los Angeles, and Salt Lake City. This has been a fascinating experience for myself and the other members of the subcommittee. It was an exercise that, in my opinion, was long overdue. When we began our intensive program of oversight, it had been a full 10 years since comparable hearings were held by a committee of this Congress.

What we have learned, Mr. President, is that the health sciences in this country have made and continue to make valuable progress in providing the tools necessary to improve the health of Americans. We have found that, as a result of the work of health science researchers, our country's physicians and hospitals have accomplished therapeutic triumphs which would have been impossible, perhaps inconceivable, 25 years ago. We have been convinced anew that our country's investment in the health sciences is the bedrock upon which our health care system rests, and that a strong, stable, and continuing commitment to the health sciences must remain a fundamental tenet of national health policy.

It has become fashionable in some quarters, Mr. President, to question the contribution of research to the health of our people. It is argued, for example, that the connection between research expenditures and improved health outcomes is difficult to document. In addition, some critics contend that what progress we have made in improving the health of our citizens has derived from improvements in our country's standard of living and from the adoption of more healthy behavior on the part of many of our citizens. These latter developments, it is said, owe little to health science research.

Mr. President, the investigations of our

subcommittee do not support this skepticism about the value of health science research. We have accumulated countless examples of research products which have made direct, incontrovertible contributions to our struggle to deal with the country's major killers and cripples. Take, for example, open heart surgery, or kidney dialysis and transplantation. Or take our new pneumonia vaccine, the advent of coronary care units and cardiac pacemakers. Take the tremendous inroads we have made in curing childhood cancers. Take our many new antibiotics, the development of anticoagulation for dealing with pulmonary embolus, or our new treatments for Parkinson's disease. And I could go on.

What is more, Mr. President, while I do not for a moment question the importance of living standards or lifestyle changes in improving our people's health, I would ask one simple question. How, Mr. President, have our people come to know what behavior changes could contribute to their health? How did we detect and confirm the relationship between cigarette smoking and cancer, between cholesterol and heart disease, between exercise and atherosclerosis? And how did we confirm, retrospectively, the role which improved living standards have played in improving our Nation's health? How, in other words, have we come to know what we now understand about what diseases are preventable, and how to prevent them? Through health science research, of course. And if we are to continue to improve our ability to prevent disease and promote good health, then our investment in the relevant health sciences must continue and expand.

Mr. President, I think the evidence clearly shows that our investment in the health sciences has paid ample dividends, but my response to skeptics includes one additional point. I think the burden is on those who question our society's investment in the health sciences to show the American people another avenue through which aspirations for better health can be realized. Our commitment to research admittedly rests somewhat on the faith that science is the route to progress in health. But do the critics of health science research propose an alternative? Do they know of some method for conquering illness other than the systematic application of talent and intelligence to understanding how disease comes about and how to overcome it?

Mr. President, take away the American people's commitment to the health sciences, and we take away our hope that our lives can be better in the future than they are today.

I do not mean to suggest that there is not room for improvement in the way our country has conducted its programs of health-related research. While I believe our health science programs and institutions are fundamentally sound, our oversight of the Federal investment in health science research has documented a number of problems which need to be addressed if our country is to continue to take full advantage of its considerable investment in health research. The aim of the Health Sciences Promotion Act of 1979 is to address those difficulties so

that, as we enter the 1980's, we can be confident that we have a streamlined, productive and efficient Federal program for the conduct and support of research in the health sciences.

Before I elaborate more fully on the provisions of the Health Sciences Promotion Act, Mr. President, let me make one additional point. This bill is not the full or final answer to all that ails our Federal health research institutions. Supporting the health sciences with Federal expenditures is a complex, subtle, and difficult task. It involves intricate interrelationships with our universities and medical schools, with our hospitals and medical manufacturers, with other Federal statutes supporting manpower training and health care delivery programs. Clearly, public policy proposals aimed at reforming our health science programs need careful scrutiny and full and vigorous discussion before they are adopted. In putting forth the Health Sciences Promotion Act of 1979, I hope to initiate the kind of wide-ranging debate which can produce wise and constructive legislation.

The bill we introduce today is a first step toward consolidating the gains we have made over the first 30 years in crafting health science policy. I hope those who share our commitment to improving the health of Americans will come forward with suggestions for revising and improving these initial proposals.

The Health Sciences Promotion Act of 1979 has three titles. Each addresses a problem or cluster of related problems in the governance of our Federal health science institutions.

First, title I addresses the need to improve the planning of our investment in the health sciences so as to increase the continuity, stability, and predictability of Federal support for health-related research.

Second, title II proposes certain administrative and organizational modifications in the structure of the National Institutes of Health in order to promote the continued development of that institution as the Nation's major instrument of support for the biomedical sciences. This title also contains reauthorizations for certain programs which will expire in 1980, including the National Cancer Act and the National Heart, Lung and Blood Act, which received only 2-year extensions during the last session of Congress.

Third, title III of the act proposes certain experimental initiatives aimed at reducing the burden of paperwork affecting researchers supported by our largest health science institution, the National Institutes of Health.

Mr. President, I will discuss very briefly each of these titles and their major provisions.

I think, Mr. President, that the problems addressed by title I of the act—the need for improved planning in the allocation of health science dollars—is one of the major lessons of our oversight effort, and is clearly apparent to anyone who traces recent developments in Federal support of the health sciences. In recent years, we have seen a series of confusing swings in research priorities and research funding at the Federal level.

These upheavals are unfair to scientists, who have dedicated themselves in good faith to the directions mandated by the Federal Government only to have the directions change because the mind of the Federal Government changes.

I would point out that Congress bears a measure of responsibility for this situation. During the past decade alone, we have enacted the National Heart, Lung and Blood Act, the National Cancer Act, the National Diabetes Research and Education Act, and the National Arthritis Act.

We also launched specific research programs for sudden infant death syndrome, hemophilia, sickle cell anemia, and other genetic diseases.

It is no wonder that, so far as health legislation is concerned, Congress is now called the "Disease of the Month" club.

It is fair to say that each of the programs I have mentioned has made valuable contributions to science and human health. I am proud to have been involved in creating many of them.

But I think we must recognize the biomedical research community needs clearer signals from the Congress and the administration if we are to get maximum benefit from our health science expenditures. Shifting priorities and unpredictable budgets generate needless inefficiency and undermine the faith of our young scientists in the reliability of the Federal Government as a partner in the research enterprise. Laboratories get set up in response to short term Federal priorities, only to find that support is suddenly unavailable. Young investigators plan their training around a given direction in health science policy only to find that the talents they nurtured are no longer valued by the Federal Government.

While our health science budgets were growing in the 1950's and 1960's, the disease-by-disease approach to funding health science research worked well enough, for budgets never got smaller. The only issue was where the health science investment would increase next. But especially in times of tight Federal spending, it is essential to provide some predictability and continuity to our support of health-related research.

The administration has begun to address this problem through the creation of a 5-year plan for health science research supported by the Department of Health, Education, and Welfare. In a recent review of that exercise, the Institute of Medicine of the National Academy of Sciences endorsed the principle of long-range planning in the health sciences, but suggested the need for a continuous planning process with more permanence than the ad hoc procedure which the administration is currently following.

To quote the Institute of Medicine report:

We believe that health research planning, when well-performed, will prove to be a valuable mechanism for developing sound and productive national health research policy. Well conceived and executed planning is the nation's best assurance that there will be optimal allocation of resources for health research, and that precious resources will be utilized efficiently.

The report continues:

We... urge that this planning effort lead to the development of a permanent planning mechanism as an important instrument for the determination of a national health science policy. Such a mechanism will be needed at a minimum for the regular review and revision of this current plan in an orderly, efficient way. More generally, a permanent capability for long-term planning will provide a view of research support that extends beyond yearly budget cycles or current political pressures...

It is to achieve this goal of a permanent, institutionalized planning process—a process open to the public eye, with full and free input from all interested parties, lay and scientific alike—that we have proposed the creation of a President's Council on the Health Sciences. This body would bring together a distinguished group of scientists and laymen for the purpose of setting priorities in the health sciences and outlining a proposed 5-year budget.

If, as is currently the case, the executive branch is supportive of planning in health research, this new body would provide the advantage of continuing, independent advice, and review in the development of the administration's plan. If the administration should lose interest at some future time in the planning process, then the Council would provide Congress the advantage of a continuing source of expert advice concerning the optimal allocation of health science dollars.

We are aware of the novelty of planning for the health research enterprise, and with that in mind, we have limited the mandate of the Council to planning for the health science activities of the Department of Health, Education, and Welfare. That is more than enough to bite off for a first exercise with this novel concept.

We have also made it clear that the proposed priorities and allocations of the Council will be binding on neither the administration nor the Congress. The aim is simply to make certain that, when the time comes for decisions concerning budgeting and priority-setting, the Congress and the administration have the benefit of the best possible scientific advice, tempered by the concern and wisdom of interested laypersons.

It is our hope that the 5-year plans set forth by the Council will help the administration and the Congress to achieve more consistency and predictability in the allocation of health science dollars. It is also our hope that, in its systematic review of the health sciences, the Council will alert the Federal Government to areas of relative underfunding and overfunding and to areas of science that need nurturing to improve the state of the art.

I also would note that this new body will replace the Surgeon General's Advisory Health Council, a group which has existed in law for some time, but has ceased effective function. Thus the number of authorized, statutory advisory groups relating to the Department of Health, Education, and Welfare will remain unchanged.

Let me now move on, Mr. President,

to a brief review of the purposes and provisions of title II of the Health Sciences Promotion Act.

This title contains provisions aimed at consolidating the administrative structure at the National Institutes of Health and improving that agency's ability to function efficiently and effectively. Title II also makes certain technical changes in title IV of the Public Health Service Act aimed at making more uniform the statutes of the various NIH institutes.

Mr. President, because this portion of the bill is long, complex, and technical, I will restrict my comments to a few of the title's more important provisions.

To begin with, Mr. President, title II of the Health Sciences Promotion Act creates the National Institutes of Health in law for the first time and provides a distinct mission statement for that organization.

Second, the title contains certain provisions aimed at strengthening the office of the Director of NIH. It has long seemed peculiar to me, Mr. President, that the Director of our Nation's foremost health science research institution has never had any statutory authority, and has never possessed the statutory tools or mandate to coordinate the activities of the 11 NIH institutes and divisions.

We recognize that the independence of the various subdivisions of the NIH is important to maintaining the creativity and pluralism of the science enterprise. At the same time, however, we feel that a few modest measures aimed at strengthening the Director's role could yield important dividends by giving the NIH more structure and coherence, and enabling it to respond more quickly and effectively to unanticipated problems and new health science needs.

A third provision of title II, Mr. President, would require that, in any given year, the NIH spend no less than 45 percent of its entire funds on so-called investigator-initiated research. This is the portion of the research budget which supports the innate creativity of American scientists by encouraging them to come forward with their own, unsolicited proposals for attacking unsolved research problems. Investigator-initiated research also constitutes the great bulk of the basic research done by the institutes. Our main in setting a floor under this portion of our research investment is to make clear that, whatever the immediate demands of politics or policy, the Congress is committed to supporting basic research in the health sciences and recognizes that the work of the individual scientists is the creative force which is the key to progress in our fight against disease.

A fourth provision of title II of the Health Sciences Promotion Act of 1979 concerns the peer review system. Mr. President, the use of peer review in selecting grant proposals for funding is an essential and important feature of our health science institutions. I have no intention of endorsing any proposal which would undermine the current peer review system. Nevertheless, precisely because I value that process so highly, I think it is essential that we remain con-

tinually alert to opportunities to improve it. For that reason, the act would require the Director of the NIH to undertake certain experiments with the peer review system for the purpose of perfecting its functioning.

One specific proposal would require that the Director include nonbiomedical scientists on selected peer review groups. This is consistent with recommendations of a panel which recently completed a comprehensive review of the NIH's peer review system. We are also directing that, on an experimental basis, lay members be included in my peer review committees. Our hope is that this latter initiative will shed some light on the continuing controversy concerning whether such lay input would be useful at the level of initial grant review.

In relation to peer review, I would like to make one additional point. It is a matter of intense concern to me and many of my colleagues that the number and size of initial review groups at the NIH has remained almost unchanged over the last several years despite an effective doubling in the workload of those groups. This erosion of the capacity of our peer review system must not be permitted to continue. We have provided the NIH Director with authority to appoint advisory councils, and we have done so with precisely this problem in mind. It is our specific intent that he use this authority to help bolster the peer review system by appointing new groups as the need arises.

A fifth aspect of title II is an attempt to simplify and make more uniform existing statutes authorizing the various Institutes of the NIH, and to create in law those that have no statutory base. The goal here is to simplify title IV of the Public Health Service Act, which has become a jumble of related but inconsistent authorities creating some of the existing Institutes but ignoring several of the important ones. We are not attempting here to make any major changes in the way the Institutes operate. Rather, the proposed provisions would simply express the basic similarities of the various research agencies housed at the NIH, while permitting each to retain its unique features.

In the course of this technical revision, title II also proposes reauthorizations for the years 1981 to 1983 for the National Heart, Lung and Blood Institute, the National Cancer Institute, and several other disease-related programs in the areas of diabetes and arthritis. The proposed reauthorizations for the National Cancer Institute during fiscal years 1981 to 1983 are \$1.019 billion, \$1.172 billion, and \$1.348 billion for the research programs of the Institute, and \$113 million, \$124 million, and \$137 million for the retitled prevention, education, and control program. The proposed reauthorization for the National Heart, Lung and Blood Institute for fiscal years 1981 to 1983 are \$592 million, \$680 million, and \$782 million for the research programs of the Institutes, and \$50 million, \$55 million, and \$60 million for the NHLBI's prevention, education, and control program.

As part of our reauthorization of the

National Cancer Institute, we have eliminated the budget bypass authority provided that agency. This amendment is proposed for the purposes of discussion, and we welcome comments on its potential effects on the national cancer program. Clearly, the President's Council for the Health Sciences will have to take into account the budget proposals of the NCI in setting its plans and priorities for a 5-year period. Therefore, maintaining the bypass authority may make more difficult the work of the Council. However, we recognize that an alternative arrangement would be to have the budget of the NCI forwarded both to the Council and to the President. This may have certain advantages during the period during which the Council is developing its capacity to plan and set budget policy. We look forward to hearing the research community's assessment of this and other alternative proposals.

Mr. President, there are a number of other important proposals contained in title II of the Health Sciences Promotion Act, but I will comment on just one more. We have included a provision which would require the Congress to renew periodically the authority of each Institute at the National Institutes of Health. While we have not specified authorizations in dollars, we have included what amounts to a sunset provision for the various Institutes. The rationale for this is simple. It is consistent with the general trend toward requiring Federal institutions to justify themselves to the Congress and the American people on a periodic and regular basis. I find it inconceivable that the Congress would ever fail to renew the mandates of these essential health care facilities. However, I think the requirement for periodic congressional and administrative oversight is healthy and necessary, and is in keeping with the general mood of the country at this time.

Before concluding, Mr. President, I would like to mention very briefly the contents of title III of the Health Sciences Promotion Act. The provisions of the title aim at addressing a situation which, in my opinion, seriously threatens the productivity of our research enterprise. I refer to the proliferation of reporting and paperwork burdens which our health science investigators now face when they receive Federal dollars.

Mr. President, the subcommittee has heard a chorus of complaints in recent days concerning the inefficiencies caused by reporting requirements which are now imposed by Federal agencies. No one disputes that the taxpayer should be assured that his dollar is being appropriately utilized by the beneficiaries of Federal largesse. But at the same time, we must consider whether requirements aimed at assuring the accountability of expenditures are defeating the very purpose of those expenditures. We are told by some investigators that they now spend 25 percent of their time filling out forms and performing the various administrative chores necessary to keep their labs in operation. We hear of investigators spending 5 to 10 percent of their grant funds paying for the preparations necessary to justify their work to

site visit teams from Federal research agencies. We see the sadness, anger, and bitterness of many honest, well-intentioned health researchers who feel that an atmosphere of distrust and hostility has developed between Federal agencies and researchers as a result of the tightening web of accountability requirements.

I think it is time that we give serious thought to finding ways to reduce the paperwork burdens on our researchers while maintaining adequate accountability. Title III directs the NIH to undertake experiments in this area with specific emphasis on developing better ways to monitor the outputs of research rather than the process through which the research is undertaken. The main point is this: The public is undoubtedly more concerned with knowing that it is getting value for money in supporting research than with knowing that each penny is spent according to some precise, ad hoc plan. Research, after all, is an inherently unpredictable exercise. Flexibility is essential in taking advantage of unanticipated developments. Researchers should ultimately be judged on whether or not they produce an adequate research product. That is the bottom line. Whether it is possible to develop a realistic monitoring system with that orientation remains to be seen. But it certainly seems worth trying on an experimental basis.

Mr. President, this is a brief overview of the provisions of the Health Sciences Promotion Act of 1979. As I said earlier, this is a complex and important piece of legislation, and we welcome comments and suggestions on ways it can be improved. We will be holding hearings on the bill on April 26 and 27, and look forward to responses at that time from the administration and the affected health science community.

For now let me just say that, as we look toward the 1980's, it is essential that we move forward with confidence that our health science institutions are prepared to handle the challenges and opportunities that they face during that decade. It is our hope that the legislation we introduce today will further that goal.

Mr. President, I ask unanimous consent that a summary of the Health Sciences Promotion Act, and the bill be printed in the Record.

There being no objection, the bill and summary were ordered to be printed in the Record, as follows:

* * * * *

96TH CONGRESS
1ST SESSION

S. 988

Entitled the "Health Science Promotion Act of 1979".

IN THE SENATE OF THE UNITED STATES

APRIL 23 (legislative day, APRIL 9), 1979

Mr. KENNEDY (for himself, Mr. SCHWEIKER, Mr. WILLIAMS, and Mr. JAVITS) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

Entitled the "Health Science Promotion Act of 1979".

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That (a) this Act may be cited as the "Health Science Pro-
4 motion Act of 1979".

5 (b) Whenever in this Act an amendment or repeal is
6 expressed in terms of an amendment to, or repeal of, a sec-
7 tion or other provision, the reference shall be considered to
8 be made to a section or other provision of the Public Health
9 Service Act.

1 TITLE I—PRESIDENT'S COUNCIL ON THE
2 HEALTH SCIENCES

3 PRESIDENT'S COUNCIL FOR THE HEALTH SCIENCES

4 SEC. 101. (a) Title IV is amended by adding at the end
5 thereof the following new sections:

6 "ESTABLISHMENT OF PRESIDENT'S COUNCIL FOR THE
7 HEALTH SCIENCES

8 "SEC. 491. (a)(1) There is established the President's
9 Council for the Health Sciences (hereinafter in this section
10 and sections 492, 493, 494, 495, and 496 referred to as the
11 'Council') which shall be composed of fifteen members ap-
12 pointed by the President. The members of the Council shall
13 be appointed as follows:

14 "(A) Three of the members shall be appointed
15 from among individuals who are distinguished in the
16 biomedical sciences.

17 "(B) Three of the members shall be appointed
18 from among individuals who are distinguished in the
19 behavioral sciences.

20 "(C) Three of the members shall be appointed
21 from among individuals who are distinguished in the
22 social sciences.

23 "(D) Six of the members shall be individuals ap-
24 pointed from the general public who by virtue of their

1 training, experience, and background are especially
2 qualified to serve on the Council.

3 “(2) No individual who is a full-time officer or employee
4 of the United States may be appointed as a member of the
5 Council. The Secretary of Health, Education, and Welfare,
6 the Secretary of Defense, the Secretary of Energy, the Sec-
7 retary of Agriculture, the Director of the Office of Science
8 and Technology Policy, the Administrator of Veterans’ Af-
9 fairs, the Director of the National Science Foundation, the
10 Assistant Secretary for Health of the Department of Health,
11 Education, and Welfare, the Director of the Alcohol, Drug
12 Abuse, and Mental Health Administration, the Director of
13 the National Institutes of Health, and the Administrator of
14 the Health Care Financing Administration (or their desig-
15 nees) shall serve as nonvoting ex officio members of the
16 Council.

17 “(3) No individual may be appointed to serve as a
18 member of the Council if the individual has served for two
19 complete terms.

20 “(4) A vacancy in the Council shall be filled in the
21 manner in which the original appointment was made.

22 “(b)(1) Except as provided in paragraphs (2) and (3),
23 members shall be appointed for terms of four years.

24 “(2) Of the members first appointed—

1 “(A) four shall be appointed for terms of three
2 years, and

3 “(B) three shall be appointed for terms of two
4 years,

5 as designated by the President at the time of appointment.

6 “(3) Any member appointed to fill a vacancy occurring
7 before the expiration of the term for which his predecessor
8 was appointed shall be appointed within ninety days of the
9 date the vacancy first occurred, and the appointment shall be
10 only for the remainder of such term. A member may serve
11 after the expiration of his term until his successor has taken
12 office.

13 “(c) The Chairman of the Council shall be appointed by
14 the President, by and with the advice and consent of the
15 Senate, from among the members of the Council appointed
16 pursuant to paragraph (D) of subsection (a).

17 “(d)(1) Eight members of the Council shall constitute a
18 quorum except that fewer members, as determined by the
19 Chairman, may conduct hearings.

20 “(2) The Council shall meet at the call of the Chairman
21 or at the call of a majority of the members.

22 “(e)(1) Each member of the Council shall be entitled to
23 receive the daily equivalent of the annual rate of basic pay in
24 effect for grade GS-18 of the General Schedule (including

1 traveltime) for each day they are engaged in the actual per-
2 formance of duties vested in the Council.

3 “(2) While away from their homes or regular places of
4 business in the performance of services for the Council, mem-
5 bers of the Council shall be allowed travel expenses, includ-
6 ing per diem in lieu of subsistence, in the same manner as
7 persons employed intermittently in the Government service
8 under section 5703 of title 5 of the United States Code.

9 “DUTIES OF THE COUNCIL

10 “SEC. 492. (a) The Council shall, after consultation
11 with the Secretary and the Assistant Secretary of Health,
12 prepare a National Health Sciences Plan (hereinafter referred
13 to in this section as the ‘Plan’), to be simultaneously trans-
14 mitted to the President, the Secretary, and the Congress, no
15 later than November 30 of each year.

16 “(b)(1) The Plan shall set forth a recommended budget
17 for health sciences research within the Department of
18 Health, Education, and Welfare for the coming fiscal year,
19 and priorities for spending for such research for the subse-
20 quent four fiscal years. In formulating such budget and
21 spending priorities, the Council shall—

22 “(A) take into consideration at least the following:

23 “(i) the mortality and morbidity rates of the
24 diseases and other health problems on which such
25 research may be conducted;

1 “(ii) the areas of research that show promise
2 of making valuable contributions to human knowl-
3 edge with respect to the cause, prevention, or
4 methods of diagnosis and treatment of diseases
5 and other health problems;

6 “(iii) the past and proposed levels of spend-
7 ing for health sciences research by Federal agen-
8 cies other than the Department of Health, Educa-
9 tion, and Welfare; and

10 “(iv) the level of public concern for particular
11 diseases and other health problems; and

12 “(B) specify recommended spending levels for—

13 “(i) research directly relevant to the primary
14 and secondary prevention of disease and disability;

15 “(ii) research directly relevant to the treat-
16 ment and cure of disease and disability;

17 “(iii) research directly relevant to the reha-
18 bilitation of victims of disease and disability; and

19 “(iv) research within the Department of
20 Health, Education, and Welfare in support of reg-
21 ulatory agencies both within the Department of
22 Health, Education, and Welfare, and within other
23 Federal agencies;

24 “(2) In addition to the requirements of paragraph (1),
25 the Plan shall specify which areas of health sciences research

1 have been relatively underfunded or underdeveloped and
2 identify measures to promote research in such areas. In at
3 least the first three years in which the Plan is formulated,
4 epidemiology, the behavioral sciences related to health, and
5 the environmental health sciences shall be deemed relatively
6 underfunded or underdeveloped.

7 "RESPONSE TO PLAN

8 "SEC. 493. At the time that the President's budget is
9 submitted to the Congress for the coming fiscal year, the
10 Secretary shall simultaneously transmit to the Council and
11 the Congress a response to the Plan, including an explana-
12 tion of the differences, if any, between the Plan and the
13 President's budget, and disagreements, if any, with the
14 spending priorities as set forth in the Plan for subsequent
15 fiscal years.

16 "ADMINISTRATIVE PROVISIONS

17 "SEC. 494. (a) The Council may, for the purpose of car-
18 rying out its duties, hold such hearings, sit and act at such
19 times and places, take such testimony, and receive such evi-
20 dence, as the Council may deem advisable.

21 "(b)(1) The Council may appoint and fix the pay of such
22 staff personnel as it deems desirable. Such personnel shall be
23 appointed subject to the provisions of title 5, United States
24 Code, governing appointments in the competitive service, and
25 shall be paid in accordance with the provisions of chapter 51

1 and subchapter III of chapter 53 of such title relating to
2 classification and General Schedule pay rates.

3 “(2) The Council may procure temporary and intermit-
4 tent services to the same extent as is authorized by section
5 3109(b) of title 5 of the United States Code, but at rates for
6 individuals not to exceed the daily equivalent of the annual
7 rate of basic pay in effect for grade GS-18 of the General
8 Schedule.

9 “(3) Upon request of the Council, the head of any Fed-
10 eral agency is authorized to detail, on a reimbursable basis,
11 any of the personnel of such agency to the Council to assist it
12 in carrying out its duties under this title.

13 “(4) Any Federal employee subject to the civil service
14 laws, rules, and regulations may be detailed to the Council,
15 and such detail shall be without interruption or loss of civil
16 service status or privilege.

17 “(c) The Council, to assist it in performing its duties and
18 functions, may enter into contracts with appropriate public or
19 nonprofit private entities. The authority of the Council to
20 enter into such contracts is effective for any fiscal year only
21 to such extent or in such amounts as are provided in advance
22 in appropriations Acts.

23 “(d)(1) The Council may secure directly from any Fed-
24 eral agency information necessary to enable it to carry out its
25 duties. Upon request of the Chairman of the Council, the

1 head of such agency shall furnish such information to the
2 Council.

3 “(2)(A) The Council shall promptly arrange for such se-
4 curity clearances for its members and staff as are necessary
5 to obtain access to classified information needed to carry out
6 its duties.

7 “(B) Any classified information obtained under subpara-
8 graph (A) may be excluded from public reports.

9 “(3) The Council shall not disclose any information re-
10 ported to or otherwise obtained by the Council which is
11 exempt from disclosure under subsection (a) of section 522 of
12 title 5, United States Code, by reason of paragraphs (4) and
13 (6) of subsection (b) of such section.

14 “(e) The Council is authorized to enter into agreements
15 with the General Services Administration for procurement of
16 necessary financial and administrative services, for which
17 payment shall be made by reimbursement from funds of the
18 Council in such amounts as may be agreed upon by the
19 Chairman and the Administrator of General Services.

20 “(f) The Council may at any time publish and dissemi-
21 nate to the public reports respecting its activities.

22 “(g) For purposes of this section, the term “agency”
23 means an executive agency (within the meaning of section
24 105 of title 5, United States Code) or unit thereof.

1 "AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF
2 COUNCIL

3 "SEC. 495. (a) There are authorized to be appropriated
4 to carry out this part, \$1,000,000 for the fiscal year ending
5 September 30, 1981, \$1,000,000 for the fiscal year ending
6 September 30, 1982, \$1,000,000 for the fiscal year ending
7 September 30, 1983, \$1,000,000 for the fiscal year ending
8 September 30, 1984, and \$1,000,000 for the fiscal year
9 ending September 30, 1985.

10 "(b) The Council shall terminate on December 31,
11 1985.

12 "RESEARCH EVALUATION

13 "SEC. 496. (a) The Secretary shall undertake or support
14 (through grant or contract) activities approved by the Coun-
15 cil, designed to—

16 "(1) improve the methodology of evaluating the
17 results of health sciences research;

18 "(2) improve the methodology of allocating re-
19 sources for health sciences research;

20 "(3) improve the methodology of measuring the
21 burden of disease;

22 "(4) evaluate public attitude toward disease; and

23 "(5) evaluate the research undertaken or support-
24 ed by the Department of Health, Education, and
25 Welfare.

1 “(b) To support the activities described in subsection (a),
2 the Secretary may expend annually, no more than one-half of
3 the funds made available under section 513 for evaluation of
4 programs authorized by title IV.”.

5 ADVISORY COUNCILS

6 SEC. 102. (a) Section 217(a) is amended to read as fol-
7 lows: “The National Advisory Mental Health Council and
8 the National Advisory Council on Alcohol Abuse and Alco-
9 holism shall each consist of the Surgeon General, who shall
10 be chairman, the chief medical officer of the Veterans’ Ad-
11 ministration or his representative and a medical officer desig-
12 nated by the Secretary of Defense, who shall be ex officio
13 members, and twelve members appointed without regard to
14 the civil service laws by the Surgeon General with the ap-
15 proval of the Secretary of Health, Education, and Welfare.
16 The twelve appointed members of each such council shall be
17 leaders in the fields of fundamental sciences, medical sci-
18 ences, or public affairs, and six of such twelve shall be select-
19 ed from among the leading medical or scientific authorities
20 who, in the case of the National Advisory Mental Health
21 Council and the National Advisory Council on Alcohol Abuse
22 and Alcoholism, are outstanding in the study, diagnosis, or
23 treatment of psychiatric disorders and alcohol abuse and alco-
24 holism, respectively. Each appointed member of each such
25 council shall hold office for a term of four years, except that

1 any member appointed to fill a vacancy occurring prior to the
 2 expiration of the terms for which his predecessor was ap-
 3 pointed shall be appointed for the remainder of such term.”.

4 (b) Strike out subsection (b) of section 217.

5 (c) Subsections (c), (d), (e), and (g) are redesignated as
 6 (b), (c), (d), and (e), respectively.

7 TITLE II—NATIONAL INSTITUTES OF HEALTH

8 NATIONAL INSTITUTES OF HEALTH

9 SEC. 201. (a) The heading of title IV is amended to
 10 read as follows:

11 “TITLE IV—NATIONAL INSTITUTES OF
 12 HEALTH”.

13 (b) The heading of part A of title IV is amended to read
 14 as follows:

15 “PART A—ESTABLISHMENT OF NATIONAL INSTITUTES
 16 OF HEALTH”.

17 (c) Section 400 is amended to read as follows:

18 “SEC. 400. (a) There is established in the Public Health
 19 Service the National Institutes of Health (hereinafter referred
 20 to in this title as the ‘Institutes’).

21 “(b) In carrying out the purposes of sections 301 and
 22 307 of this title, the Secretary, acting through the Institutes,
 23 shall endeavor to improve the health of the people of the
 24 United States through the support of research and develop-
 25 ment and training in the health sciences concerning—

1 “(1) the processes underlying human health, dis-
2 ability, disorder, and disease,

3 “(2) the normal and pathological functioning of
4 the body and its organ systems,

5 “(3) the interaction between the human organism
6 and the environment,

7 “(4) improved methods of detecting, diagnosing,
8 and treating disease, and

9 “(5) improved methods for the prevention of dis-
10 ease and the maintenance of good health, to which the
11 highest priority shall be given.

12 “(c) In order to meet the goals of subsection (b), the
13 Secretary, acting through the Institutes, shall—

14 “(1) encourage, conduct, and support efforts to
15 expand the base of scientific knowledge through re-
16 search in the health sciences;

17 “(2) encourage, conduct, and support the develop-
18 ment and maintenance of research resources;

19 “(3) identify research advances which have signifi-
20 cant potential for clinical and technological application;

21 “(4) encourage, conduct, and support research and
22 demonstrations concerning new and existing health
23 care technologies, in a manner consistent with the poli-
24 cies and procedures of the National Center for Health
25 Care Technology;

1 “(5) facilitate the transfer of new health care
2 technologies into practice in a manner consistent with
3 the policies and procedures of the National Center for
4 Health Care Technology, and in collaboration with
5 other Government agencies, educational institutions,
6 and professional and voluntary organizations;

7 “(6) foster the dissemination and exchange of sci-
8 entific and technical information in medicine, health,
9 and related fields;

10 “(7) participate with governmental agencies, edu-
11 cational institutions, private and voluntary organiza-
12 tions, other countries, and international organizations
13 in cooperative endeavors in biomedical research, train-
14 ing, resource development, and communications;

15 “(8) develop and disseminate policy recommenda-
16 tions related to the support of health sciences research
17 and development; and

18 “(9) cooperate with and assist other Federal agen-
19 cies charged with protecting the public health in con-
20 ducting research, demonstrations, and evaluations.

21 “DIRECTOR

22 “SEC. 400A. (a) The Director of the National Institutes
23 of Health shall be appointed by the President by and with the
24 advice and consent of the Senate.

1 “(b) The Director of the Institutes in carrying out his
2 functions is authorized—

3 “(1) to obtain (in accordance with section 3109 of
4 title 5, United States Code, but without regard to the
5 limitation in such section on the number of days or the
6 period of such service), the services of not more than
7 three hundred experts or consultants who have
8 scientific or professional qualifications;

9 “(2) to acquire, construct, improve, repair, oper-
10 ate, and maintain centers, laboratories, research, and
11 other necessary facilities and equipment, and related
12 accommodations as may be necessary, and such other
13 real or personal property (including patents) as the Di-
14 rector deems necessary; to acquire, without regard to
15 the Act of March 3, 1877 (40 U.S.C. 34), by lease or
16 otherwise through the Administrator of General Serv-
17 ices, buildings or parts of buildings in the District of
18 Columbia or communities located adjacent to the Dis-
19 trict of Columbia for the use of the Institute for a
20 period not to exceed ten years;

21 “(3) to appoint one or more advisory committees
22 composed of such private citizens and officials of Fed-
23 eral, State, and local governments as he deems desir-
24 able to advise him with respect to his functions;

1 “(4) to utilize, with their consent, the services,
2 equipment, personnel, information, and facilities of
3 other Federal, State, or local public agencies, with or
4 without reimbursement therefor;

5 “(5) to accept voluntary and uncompensated serv-
6 ices;

7 “(6) to accept unconditional gifts, or donations of
8 services, money, or property, real, personal, or mixed,
9 tangible or intangible;

10 “(7) to enter into such contracts, leases, coopera-
11 tive agreements, or other transactions, without regard
12 to sections 3648 and 3709 of the Revised Statutes of
13 the United States (31 U.S.C. 529, 41 U.S.C. 5), as
14 may be necessary in the conduct of his functions, with
15 any public agency, or with any person, firm, associ-
16 ation, corporation, or educational institution; and

17 “(8) to insure that all channels for the dissemina-
18 tion and exchange of scientific knowledge and informa-
19 tion are maintained between the Institute and the
20 other scientific, medical, and biomedical disciplines and
21 organizations nationally and internationally.

22 “(c) The Director may expend annually no more than
23 one-half of the funds made available under section 513 for
24 evaluation of programs authorized by title IV to award
25 grants and enter into contracts for—

1 “(1) research in areas of the health sciences de-
2 termined to be relatively underfunded or underdevel-
3 oped by the President’s Council for the Health Sci-
4 ences;

5 “(2) research which is distinguished by its innova-
6 tive or unconventional character; and

7 “(3) multidisciplinary research concerning more
8 than two diseases.

9 “(d) The Director shall assure that, in any given year,
10 not less than 45 per centum of all funds expended by the
11 Institutes shall be used to support research by individual in-
12 vestigators who are not full-time employees of the Institutes
13 and whose applications for such grants were unsolicited.

14 “(e) All grants and contracts funded under this section
15 shall be subject to peer review as provided in section 485.

16 “(f) The Director shall establish an appeals process for
17 individuals and institutions whose applications for grants
18 under this title have been denied.

19 “(g) The Director shall establish a program of demon-
20 strations and experimentations with alternative methods for
21 conducting peer review of applications for research grants.
22 Such program shall provide for, as a minimum—

23 “(1) the inclusion in selected peer review groups
24 of social scientists and other individuals whose exper-
25 tise is not in the biomedical sciences, and

1 “(2) the inclusion of lay persons on at least five
2 peer review study groups.

3 “DEFINITIONS

4 “SEC. 400B. For purposes of this title, the term—

5 “(1) ‘primary prevention’ means the prevention of
6 the development of a disease in healthy individuals,
7 and

8 “(2) ‘secondary prevention’ means the early de-
9 tection, referral for diagnosis and treatment of disease
10 in asymptomatic individuals.”.

11 REDESIGNATION

12 SEC. 202. (a) Title IV is amended by redesignating
13 parts B, C, D, E, F, G, and H as parts C, D, E, F, G, H,
14 and I, respectively.

15 (b) Title IV is amended—

16 (1) by redesignating part I as part M,

17 (2) by redesignating sections 472, 473, 474, 475,
18 476, 477, 478 and 479 as sections 482, 483, 484,
19 485, 486, 487, 488, and 489, respectively, and

20 (3) by striking section 471.

21 NATIONAL CANCER INSTITUTE

22 SEC. 203. (a) Title IV is amended by adding the follow-
23 ing heading before “SEC. 401.”:

24 “PART B—NATIONAL CANCER INSTITUTE”.

25 (b) Section 401 is amended—

1 (1) by redesignating subsections (a) and (b) as sub-
2 sections (b) and (c);

3 (2) by adding the following after "SEC. 401.":

4 "(a) There is established in the National Institutes of
5 Health the National Cancer Institute (hereinafter in this part
6 referred to as the 'Institute').";

7 (3) by striking "(b)" in subsection (b) (as redesign-
8 ated by paragraph (1)) and substituting "(c)"; and

9 (4) by striking "(a)" in subsection (c) (as redesign-
10 ated by paragraph (1)) and substituting "(b)".

11 (c) The heading to section 403 is amended to read as
12 follows:

13 "CANCER PREVENTION, EDUCATION, AND CONTROL
14 PROGRAMS".

15 (d) Section 403 is amended—

16 (1) by amending paragraph (2) to read as follows:

17 "(2) the demonstration of, evaluation of, and test-
18 ing of, and the education of health professionals in—

19 "(A) effective methods for the primary pre-
20 vention of cancer;

21 "(B) effective methods for the secondary pre-
22 vention of cancer, including the early detection of
23 cancer and the identification of individuals with a
24 high risk of developing cancer; and

1 “(C) improved methods of patient referral to
2 appropriate centers for early diagnosis and treat-
3 ment of cancer; and”; and

4 (2) by striking “the early detection” in paragraph
5 (3) and substituting “the prevention, especially the pri-
6 mary and secondary prevention, and the treatment of
7 cancer”.

8 (e) Section 404(a) is amended—

9 (1) by striking paragraph (8);

10 (2) by adding “and” at the end of paragraph (7);

11 and

12 (3) by renumbering paragraph (9) as paragraph
13 (8).

14 (f) Subsection (b) of section 405 is amended by striking
15 “\$35,000” each place it appears and substituting
16 “\$50,000”.

17 (g) Section 407(a) is amended—

18 (1) by striking “President” in paragraph (1)(B)
19 and substituting “Secretary”;

20 (2) by amending paragraph (2)(A) to read as fol-
21 lows:

22 “(2)(A) Appointed members shall be appointed for four-
23 year terms.”;

24 (3) by adding at the end of paragraph (2)(B) the
25 following: “The Secretary shall, within ninety days of

1 an expired term, or a vacancy occurring for any other
2 reason, appoint a successor to fill such vacancy.”;

3 (4) by striking “President” in paragraph (3) and
4 substituting “Secretary”;

5 (5) by striking paragraph (7) and renumbering
6 paragraphs (8) and (9) as (7) and (8), respectively; and

7 (6) by inserting “and shall conduct a formal orien-
8 tation program and training sessions for new members
9 of the Board in order to provide such new members
10 with the necessary information and training for effec-
11 tive participation on the Board” before the period at
12 the end of paragraph (8) (as renumbered by this Act).

13 (h) Paragraph (1) of section 408(a) is amended by
14 adding at the end thereof the following: “At least one of the
15 members of the Panel shall be a member of the National
16 Cancer Advisory Board.”.

17 (i) Section 410(a) is amended—

18 (1) by striking “and” after “1979;” and

19 (2) by adding before the period at the end thereof
20 the following: “; \$1,019,700,000 for the fiscal year
21 ending September 30, 1981; \$1,172,655,000 for the
22 fiscal year ending September 30, 1982; and
23 \$1,348,555,800 for the fiscal year ending September
24 30, 1983”.

25 (j) Section 410(b) is amended—

1 (1) by striking "and" after "1979;" and

2 (2) by adding before the period at the end thereof
3 the following: "; \$113,300,000 for the fiscal year
4 ending September 30, 1981; \$124,630,000 for the
5 fiscal year ending September 30, 1982; and
6 \$137,093,000 for the fiscal year ending September 30,
7 1983".

8 NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

9 SEC. 204. (a) Section 411 is amended by—

10 (1) striking "hereby"; and

11 (2) striking "Public Health Service" and substi-
12 tuting "National Institutes of Health".

13 (b) Paragraph (1) of section 412 is amended by striking
14 "researches" and substituting "research".

15 (c) Section 413(d) is amended by inserting before the
16 period ", including appropriate emphasis on these lifestyle
17 factors as they affect the present and future health of chil-
18 dren".

19 (d) Section 414(b) is amended—

20 (1) by striking "and" after "1979," and

21 (2) by inserting before the period the following: "
22 \$50,000,000 for the fiscal year ending September 30,
23 1981, \$55,000,000 for the fiscal year ending Septem-
24 ber 30, 1982, and \$60,000,000 for the fiscal year
25 ending September 30, 1983".

1 (e) Section 417(a) is amended—

2 (1) by striking “two” after “diseases of the heart,
3 blood vessels, lungs, and blood;” and substituting
4 “one”, and

5 (2) by striking “five” after “lung or blood dis-
6 eases; and” and substituting “six”.

7 (f) Section 417(b) is amended—

8 (1) by adding at the end of paragraph (1) the fol-
9 lowing: “The Secretary shall, within ninety days of an
10 expired term or a vacancy occurring for any other
11 reason, appoint a successor to fill such vacancy.”;

12 (2) by striking paragraph (3); and

13 (3) by redesignating paragraph (4) as paragraph
14 (3).

15 (g) Section 417(c) is amended to read as follows:

16 “(c) The Secretary shall designate one of the appointed
17 members to serve as Chairman for a term of two years.”.

18 (h) Section 417(d) is amended—

19 (1) by striking “and” after “Secretary of the
20 Council,” and

21 (2) by inserting before the period the following: “,
22 and

23 “(3) conduct a formal orientation program and
24 training sessions for new members of the Council in
25 order to provide such new members with the necessary

1 information and training for effective participation on
2 the Council”.

3 (i) Section 418(b) is amended—

4 (1) by striking “(1)”, and

5 (2) by striking paragraph (2).

6 (j) Section 419A(c) is amended by striking “\$35,000”
7 each place it appears and substituting “\$50,000”.

8 (k) Section 419B is amended—

9 (1) by striking “and” after “1979,” and

10 (2) by inserting before the period the following:
11 “\$592,000,000 for the fiscal year ending September
12 30, 1981, \$680,800,000 for the fiscal year ending Sep-
13 tember 30, 1982, and \$782,000,000 for the fiscal year
14 ending September 30, 1983”.

15 NATIONAL INSTITUTE OF DENTAL RESEARCH

16 SEC. 205. (a) Section 421 is amended by—

17 (1) striking “hereby”; and

18 (2) striking “Public Health Service” and substi-
19 tuting “National Institutes of Health”.

20 (b)(1) Sections 422 and 424 are amended by striking
21 “Surgeon General” each place it appears and substituting
22 “Secretary”.

23 (2) Section 423(a) is amended to read as follows—

1 "In carrying out the provisions of section 422, all ap-
2 propriate provisions of section 301 shall be applicable to the
3 authority of the Secretary."

4 (3) Section 423(b) is amended by striking out "Surgeon
5 General" and substituting "Director of the Institute".

6 (c) Section 422 is amended—

7 (1) by striking "National Advisory Dental Re-
8 search Council" (hereinafter in this part referred to as
9 the "Council") and substituting "National Dental Re-
10 search Advisory Council", and

11 (2) by striking "researches" each place it appears
12 and substituting "research".

13 (d) Section 423 is amended by adding at the end thereof
14 the following new subsections:

15 "(c)(1) The Director of the Institute shall, as soon as
16 practicable after the end of each fiscal year, prepare a report
17 in consultation with the Dental Research Advisory Council,
18 and submit such report to the Secretary, for simultaneous
19 transmittal not later than November 30 of each year to the
20 President and to the Congress. Such report shall account the
21 activities, progress, and accomplishments of the Institute
22 during the preceding fiscal year, and shall include a listing
23 of—

24 "(A) all health care technologies (as defined in
25 section 309(h)) under development through activities

1 supported or undertaken by the Institute which, in the
2 view of the Director and the Council, are ready for in-
3 corporation into medical practice, and

4 “(B) all activities supported or undertaken by the
5 Institute relevant to the prevention of disease, and a
6 statement of the proportion of the funds appropriated
7 for the Institute which support research concerning—

8 “(i) primary prevention of dental disease,

9 “(ii) secondary prevention of dental disease,

10 and

11 “(iii) treatment and cure of dental disease.

12 “(2) The Director of the Institute shall also provide a
13 plan to the President’s Council on the Health Sciences for
14 the proposed activities of the Institute for the next five years.

15 “(d) Under procedures approved by the Director of the
16 National Institutes of Health, the Director of the Institute
17 may approve grants under this Act for research and training
18 in dental diseases after appropriate review for scientific
19 merit. If the direct costs of a grant for such research and
20 training will exceed \$50,000, the Director may approve such
21 grant only after appropriate review for scientific merit and
22 recommendation for approval by the Dental Research Advi-
23 sory Council.”.

24 (e) Part D of title IV, as redesignated in this Act, is
25 amended by adding after section 423 the following:

1 "NATIONAL DENTAL RESEARCH ADVISORY COUNCIL

2 "SEC. 423A. (a) There is established in the Institute a
3 National Dental Research Advisory Council (hereinafter in
4 this part referred to as the 'Council') to be composed of
5 twenty members as follows:

6 "(1) The Secretary and the Director of the Na-
7 tional Institutes of Health (or their designees) shall be
8 ex officio members of the Council.

9 "(2) Eighteen members appointed by the Secre-
10 tary.

11 Twelve of the appointed members shall be selected from
12 among the leading medical or scientific authorities who are
13 skilled in the sciences relating to dental diseases, and six of
14 the appointed members shall be selected from the general
15 public.

16 "(b)(1) Each appointed member of the Council shall be
17 appointed for a term of four years, except that—

18 "(A) any member appointed to fill a vacancy oc-
19 ccurring prior to the expiration of the term for which
20 his predecessor was appointed shall be appointed for
21 the remainder of such term; and

22 "(B) of the members first appointed after the ef-
23 fective date of this section, five shall be appointed for a
24 term of four years, five shall be appointed for a term of
25 three years, five shall be appointed for a term of two

1 years, and three shall be appointed for a term of one
2 year, as designated by the Secretary at the time of
3 appointment.

4 Appointed members may serve after the expiration of their
5 terms until their successors have taken office. The Secretary
6 shall, within ninety days of an expired term, or a vacancy
7 occurring for any other reason, appoint a successor to fill
8 such vacancy.

9 “(2) A vacancy in the Council shall not affect its activi-
10 ties, and twelve members of the Council shall constitute a
11 quorum.

12 “(3) Members of the Council who are not officers or
13 employees of the United States shall receive, for each day
14 they are engaged in the performance of the functions of the
15 Council, compensation at rates not to exceed the daily equiv-
16 alent of the annual rate in effect for grade GS-18 of the
17 General Schedule, including traveltime. All members, while
18 serving away from their homes or regular places of business,
19 may be allowed travel expenses, including per diem in lieu of
20 subsistence, in the same manner as such expenses are au-
21 thorized by section 5703 of title 5, United States Code, for
22 persons in the Government service employed intermittently.

23 “(c) The Secretary shall designate one of the appointed
24 members to serve as Chairman for a term of two years.

25 “(d) The Director of the Institute shall—

1 “(1) designate a member of the staff of the Insti-
2 tute to act as Executive Secretary of the Council,

3 “(2) make available to the Council such staff as-
4 sistance, information, and other assistance as it may
5 require to carry out its functions, and

6 “(3) conduct a formal orientation program and
7 training sessions for new members of the Council in
8 order to provide such new members with the necessary
9 information and training for effective participation on
10 the Council.

11 “(e) The Council shall meet at the call of the Chairman,
12 but not less often than four times a year.

13 “EXPIRATION OF INSTITUTE AND COUNCIL

14 “SEC. 425. The Institute and the Council shall cease to
15 exist on September 30, 1983.”.

16 NATIONAL INSTITUTE ON ARTHRITIS, METABOLISM, AND
17 DIGESTIVE DISEASES

18 SEC. 206. (a) Strike sections 431, 432, and 433.

19 (b) Section 434 is amended to read as follows:

20 “SEC. 434. There is established in the National Insti-
21 tutes of Health a National Institute of Arthritis, Metabolism,
22 and Digestive Diseases (hereinafter in this part referred to as
23 the ‘Institute’).”.

24 (c) Part E of title IV, as redesignated by this Act, is
25 amended by inserting the following after section 434:

1 "ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

2 RESEARCH AND TRAINING

3 "SEC. 434A. In carrying out the purposes of section
4 301 with respect to arthritis, metabolism, and digestive dis-
5 eases, the Secretary, through the Institute and its associate
6 directors for Arthritis and Related Musculoskeletal Diseases;
7 Diabetes; and Digestive Diseases, and in cooperation with
8 the National Arthritis, Metabolism, and Digestive Diseases
9 Advisory Council (hereinafter referred to in this part as the
10 'Council') shall—

11 "(a) conduct, assist, and foster research, investi-
12 gations, experiments, and studies relating to arthritis,
13 digestive diseases, diabetes mellitus and related endo-
14 crine and metabolic diseases;

15 "(b) promote the coordination of research conduct-
16 ed by the Institute, and similar research conducted by
17 other agencies, organizations, and individuals; and

18 "(c) secure for the Institute consultation services
19 and advice of persons from the United States or abroad
20 who are experts in arthritis, digestive diseases, diabe-
21 tes mellitus and related endocrine and metabolic dis-
22 eases.

"ADMINISTRATION"

"SEC. 434B. (a) In carrying out the provisions of this part, all appropriate provisions of section 301 shall be applicable to the authority of the Secretary.

"(b) The Director of the Institute shall recommend to the Secretary acceptance of conditional gifts, pursuant to section 501, for study, investigation, or research into the cause, prevention or methods of diagnosis or treatment of arthritis, digestive diseases, diabetes mellitus and related endocrine and metabolic diseases, or for the acquisition of grounds or equipment, or for the construction, or maintenance of premises, buildings, or equipment of the Institute. Donations of \$50,000 or more to carry out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

"(c)(1) The Director of the Institute shall, as soon as practicable after the end of each fiscal year, prepare a report in consultation with the Council, and submit such report to the Secretary, for simultaneous transmittal not later than November 30 of each year to the President and to the Congress. Such report shall account the activities, progress, and accomplishments of the Institute during the preceding fiscal year, and shall include a listing of—

"(A) all health care technologies (as defined in section 309(h)) under development through activities

1 supported or undertaken by the Institute which, in the
2 view of the Director and the Council, are ready for in-
3 corporation into medical practice, and

4 “(B) all activities supported or undertaken by the
5 Institute relevant to the prevention of disease, and a
6 statement of the proportion of funds appropriated for
7 the Institute which support research concerning—

8 “(i) primary prevention of disease,

9 “(ii) secondary prevention of disease, and

10 “(iii) treatment and cure of disease.

11 “(2) The Director of the Institute shall provide a plan to
12 the President’s Council on the Health Sciences for the activi-
13 ties of the Institute for the next five years.

14 “(d) Under procedures approved by the Director of the
15 National Institutes of Health, the Director of the Institute
16 may approve grants under this Act for research and training
17 in arthritis, digestive diseases, diabetes mellitus, and related
18 endocrine and metabolic diseases after appropriate review for
19 scientific merit. If the direct costs of a grant for such re-
20 search and training will exceed \$50,000, the Director may
21 approve such grant only after appropriate review for scientifi-
22 c merit and recommendation for approval by the Council.”.

23 “(e) The Director of the Institute, acting through the
24 Associate Director for Digestive Diseases, shall (1) carry out,
25 at the facilities of the Institute, a program of research in the

1 diagnosis, prevention, and treatment of digestive diseases;
2 and (2) carry out programs of support for research and train-
3 ing (other than research training for which National Research
4 Service Awards may be made under section 482) in the diag-
5 nosis, prevention, and treatment of digestive diseases, includ-
6 ing support for training in medical schools, graduate clinical
7 training, epidemiology studies, clinical trials, and interdis-
8 plinary research programs.

9 “(f) The Director of the National Institute of Arthritis,
10 Metabolism, and Digestive Diseases, working through the
11 Associate Director for Diabetes (if that position is estab-
12 lished), shall (1) carry out programs of support for research
13 and training in the diagnosis, prevention, and treatment of
14 diabetes mellitus and related endocrine and metabolic dis-
15 eases, and (2) establish programs of evaluation, planning, and
16 dissemination of knowledge related to research and training
17 in diabetes mellitus and related endocrine and metabolic
18 diseases.

19 “(g) There is established within the Institute the posi-
20 tion of Associate Director for Arthritis and Related Muscu-
21 loskeletal Disease (hereinafter in this part referred to as the
22 ‘Associate Director’), who shall report directly to the Direc-
23 tor of such Institute and who, under the supervision of the
24 Director of such Institute, shall be responsible for programs
25 regarding arthritis within such Institute.

15 "NATIONAL ARTHRITIS, METABOLISM, AND DIGESTIVE
16 DISEASES ADVISORY COUNCIL

20 “(1) The Secretary and the Director of the Na-
21 tional Institutes of Health (or their designees) shall be
22 ex officio members of the Council.

23 “(2) Eighteen members appointed by the Secre-
24 tary.

1 Twelve of the appointed members shall be selected from
2 among the leading medical or scientific authorities who are
3 skilled in the sciences relating to arthritis, metabolism, and
4 digestive diseases, and six of the appointed members shall be
5 selected from the general public.

6 “(b)(1) Each appointed member of the Council shall be
7 appointed for a term of four years, except that—

8 “(A) any member appointed to fill a vacancy oc-
9 ccurring prior to the expiration of the term for which
10 his predecessor was appointed shall be appointed for
11 the remainder of such term; and

12 “(B) of the members first appointed after the ef-
13 fective date of this section, five shall be appointed for a
14 term of four years, five shall be appointed for a term of
15 three years, five shall be appointed for a term of two
16 years, and three shall be appointed for a term of one
17 year, as designated by the Secretary at the time of
18 appointment.

19 Appointed members may serve after the expiration of their
20 terms until their successors have taken office. The Secretary
21 shall, within ninety days of an expired term or a vacancy
22 occurring for any other reason, appoint a successor to fill
23 such vacancy.

1 “(2) A vacancy in the Council shall not affect its activi-
2 ties, and twelve members of the Council shall constitute a
3 quorum.

4 “(3) Members of the Council who are not officers or
5 employees of the United States shall receive, for each day
6 they are engaged in the performance of the functions of the
7 Council, compensation at rates not to exceed the daily equiv-
8 alent of the annual rate in effect for grade GS-18 of the
9 General Schedule, including traveltime. All members, while
10 serving away from their homes or regular places of business,
11 may be allowed travel expenses, including per diem in lieu of
12 subsistence, in the same manner as such expenses are au-
13 thorized by section 5703 of title 5, United States Code, for
14 persons in the Government service employed intermittently.

15 “(c) The Secretary shall designate one of the appointed
16 members to serve as Chairman for a term of two years.

17 “(d) The Director of the Institute shall—

18 “(1) designate a member of the staff of the Insti-
19 tute to act as Executive Secretary of the Council,

20 “(2) make available to the Council such staff as-
21 sistance, information, and other assistance as it may
22 require to carry out its functions, and

23 “(3) conduct a formal orientation program and
24 training sessions for new members of the Council in
25 order to provide such new members with the necessary

1 information and training for effective participation on
2 the Council.

3 “(e) The Council shall meet at the call of the Chairman,
4 but not less often than four times a year.

5 “FUNCTIONS OF THE COUNCIL

6 “SEC. 434D. (a) The Council is authorized to—

7 “(1) review research projects and programs sub-
8 mitted to, or initiated by, such Council, relating to the
9 study of the cause, prevention, and methods of diagno-
10 sis and treatment of arthritis, digestive diseases, diabe-
11 tes mellitus and related endocrine and metabolic dis-
12 eases, and certify its approval to the Secretary of any
13 such projects which it believes show promise of making
14 valuable contributions to human knowledge with re-
15 spect to such areas of study;

16 “(2) collect information as to studies which are
17 being conducted in the United States or any other
18 country with regard to the cause, prevention, or meth-
19 ods of diagnosis and treatment of arthritis, digestive
20 diseases, diabetes mellitus and related endocrine and
21 metabolic diseases, by correspondence or by personal
22 investigation of such studies, and with the approval of
23 the Secretary, make available such information through
24 appropriate publications for the benefit of health agen-
25 cies and organizations (public or private), physicians,

1 dentists, or any other scientists, and for the general
2 public;

3 “(3) review applications for grants-in-aid for re-
4 search projects relating to arthritis, digestive diseases,
5 diabetes mellitus and related endocrine and metabolic
6 diseases, and certify to the Secretary, its approval of
7 such projects that show promise of making valuable
8 contributions to human knowledge with respect to such
9 areas of research;

10 “(4) recommend to the Secretary acceptance of
11 conditional gifts, pursuant to section 501, to carry out
12 the purposes of this part;

13 “(5) make recommendations to the Secretary with
14 respect to carrying out the provisions of this part; and

15 “(6)(A) review applications from any public or
16 other nonprofit institution for grants-in-aid for training,
17 instruction, and traineeships relating to the diagnosis,
18 prevention, and treatment of arthritis, digestive dis-
19 eases, diabetes mellitus and related endocrine and
20 metabolic diseases, and

21 “(B) certify to the Secretary the Council’s ap-
22 proval of such applications for grants-in-aid as it deter-
23 mines will best carry out the purposes of this part.

24 “(b) There is established within the Council a committee
25 to advise the Director of the Institute respecting the activi-

1 ties of the Institute concerning digestive diseases. The com-
2 mittee shall be composed of those members of the Council
3 who are outstanding in the diagnosis, prevention, and treat-
4 ment of digestive diseases. The committee shall review appli-
5 cations made to the Director for grants for research projects
6 relating to the diagnosis, prevention, and treatment of diges-
7 tive diseases and shall recommend approval to the Director
8 of those applications and contracts that the committee deter-
9 mines will best carry out the purposes of this part.

10 "EXPIRATION OF INSTITUTE AND COUNCIL

11 "SEC. 434E. The Institute and the Council shall cease
12 to exist on September 30, 1983."

13 (d)(1) Section 435(c) is amended—

14 (A) by striking "and" after "1979,"; and

15 (B) by inserting before the period the following:

16 "and for each of the next three fiscal years".

17 (2) Section 436A(k) is amended—

18 (A) by striking "and" after "1979,"; and

19 (B) by inserting before the period the following:

20 "and for each of the next three fiscal years".

21 (3) Section 436A(l) is amended by striking "1980" and
22 substituting "1983".

23 (4) Paragraph (2) of section 438(d) is amended—

24 (A) by striking "and" after "1979,"; and

1 (B) by inserting before the period the following:

2 "and for each of the next three fiscal years".

3 (5) Paragraph (3) of section 438(d) is amended—

4 (A) by striking "and" after "1979,"; and

5 (B) by inserting before the period the following:

6 "and for each of the next three fiscal years".

7 (6) Section 439(g) is amended—

8 (A) by striking "and" after "1979,"; and

9 (B) by inserting before the period the following:

10 "and for each of the next three fiscal years".

11 (7) Section 440(k) is amended—

12 (A) by striking "and" after "1979,"; and

13 (B) by inserting before the period the following:

14 "and for each of the next three fiscal years".

15 NATIONAL INSTITUTES OF CHILD HEALTH AND HUMAN

16 DEVELOPMENT AND GENERAL MEDICAL SCIENCES

17 SEC. 207. (a) Part F (as redesignated by this Act) is

18 amended to read as follows:

1 "PART F—NATIONAL INSTITUTE OF CHILD HEALTH AND
 2 HUMAN DEVELOPMENT/NATIONAL INSTITUTE FOR
 3 THE GENERAL MEDICAL SCIENCES

4 "Subpart I—National Institute of Child Health and Human
 5 Development

6 "ESTABLISHMENT OF NATIONAL INSTITUTE OF CHILD
 7 HEALTH AND HUMAN DEVELOPMENT

8 "SEC. 441. There is established in the National Insti-
 9 tutes of Health the National Institute of Child Health and
 10 Human Development (hereinafter in this subpart referred to
 11 as the 'Institute').

12 "RESEARCH ON CHILD HEALTH AND HUMAN
 13 DEVELOPMENT

14 "SEC. 442. In carrying out the purposes of section 301,
 15 with respect to child health and human development, the
 16 Secretary, through the Institute and in cooperation with the
 17 Child Health and Human Development Advisory Council
 18 (hereinafter in this subpart referred to as the 'Council'),
 19 shall—

20 "(a) conduct, assist, and foster research, investi-
 21 gations, experiments, and studies relating to maternal
 22 health, child health, and human development, including
 23 the special health problems and requirements of moth-
 24 ers and children, and in the basic sciences relating to

1 the process of human growth and development, includ-
2 ing prenatal development;

3 “(b) promote the coordination of research conduct-
4 ed by the Institute, and similar research conducted by
5 other agencies, organizations, and individuals; and

6 “(c) secure for the Institute consultation services
7 and advice of persons from the United States or abroad
8 who are experts in child health and human develop-
9 ment.

10 “ADMINISTRATION

11 “SEC. 443. (a) In carrying out the provisions of this
12 part, all appropriate provisions of section 301 shall be appli-
13 cable to the authority of the Secretary.

14 “(b) The Director of the Institute shall recommend to
15 the Secretary acceptance of conditional gifts, pursuant to sec-
16 tion 501, for study, investigation, or research into child
17 health and human development, or for the acquisition of
18 grounds or equipment, or for the construction or maintenance
19 of premises, buildings, or equipment of the Institute. Dona-
20 tions of \$50,000 or more to carry out the purposes of this
21 part may be acknowledged by the establishment within the
22 Institute of suitable memorials to the donors.

23 “(c)(1) The Director of the Institute shall, as soon as
24 practicable after the end of each fiscal year, prepare a report
25 in consultation with the Council, and submit such report to

1 the Secretary, for simultaneous transmittal not later than
2 November 30 of each year to the President and to the Con-
3 gress. Such report shall account the activities, progress, and
4 accomplishments of the Institute during the preceding fiscal
5 year, and shall include a listing of—

6 “(A) all health care technologies (as defined in
7 section 309(h)) under development through activities
8 supported or undertaken by the Institute which, in the
9 view of the Director and the Council, are ready for in-
10 corporation into medical practice, and

11 “(B) all activities supported by the Institute rele-
12 vant to the prevention of disease, and a statement of
13 the proportion of the funds appropriated for the Insti-
14 tute which support research concerning—

15 “(i) primary prevention of diseases and disor-
16 ders affecting mothers and children,

17 “(ii) secondary prevention of diseases and
18 disorders affecting mothers and children, and

19 “(iii) treatment and cure of diseases and dis-
20 orders affecting mothers and children.

21 “(2) The Director of the Institute shall provide a plan to
22 the President's Council on the Health Sciences for the pro-
23 posed activities of the Institute for the next five years.

24 “(d) Under procedures approved by the Director of the
25 National Institutes of Health, the Director of the Institute

1 may approve grants under this Act for research in child
2 health and human development after appropriate review for
3 scientific merit. If the direct costs of a grant for such re-
4 search will exceed \$50,000, the Director may approve such
5 grant only after appropriate review for scientific merit and
6 recommendation for approval by the Council.

7 "NATIONAL CHILD HEALTH AND HUMAN DEVELOPMENT
8 ADVISORY COUNCIL

9 "SEC. 444. (a) There is established in the Institute a
10 National Child Health and Human Development Advisory
11 Council to be composed of twenty members as follows:

12 "(1) The Secretary and the Director of the Na-
13 tional Institutes of Health (or their designees) shall be
14 ex officio members of the Council.

15 "(2) Eighteen members appointed by the Secre-
16 tary.

17 Twelve of the appointed members shall be selected from
18 among the leading medical or scientific authorities who are
19 skilled in the sciences relating to maternal health, child
20 health, and human development, and six of the appointed
21 members shall be selected from the general public.

22 "(b)(1) Each appointed member of the Council shall be
23 appointed for a term of four years, except that—

24 "(A) any member appointed to fill a vacancy oc-
25 ccurring prior to the expiration of the term for which

1 his predecessor was appointed shall be appointed for
2 the remainder of such term; and

3 “(B) of the members first appointed after the ef-
4 fective date of this section, five shall be appointed for a
5 term of four years, five shall be appointed for a term of
6 three years, five shall be appointed for a term of two
7 years, and three shall be appointed for a term of one
8 year, as designated by the Secretary at the time of
9 appointment.

10 Appointed members may serve after the expiration of their
11 terms until their successors have taken office. The Secretary
12 shall, within ninety days of an expired term, or a vacancy
13 occurring for any other reason, appoint a successor to fill
14 such vacancy.

15 “(2) A vacancy in the Council shall not affect its activi-
16 ties, and twelve members of the Council shall constitute a
17 quorum.

18 “(3) Members of the Council who are not officers or
19 employees of the United States shall receive, for each day
20 they are engaged in the performance of the functions of the
21 Council, compensation at rates not to exceed the daily equiv-
22 alent of the annual rate in effect for grade GS-18 of the
23 General Schedule, including traveltime. All members, while
24 serving away from their homes or regular places of business,
25 may be allowed travel expenses, including per diem in lieu of

1 subsistence, in the same manner as such expenses are au-
2 thorized by section 5703 of title 5, United States Code, for
3 persons in the Government service employed intermittently.

4 “(c) The Secretary shall designate one of the appointed
5 members to serve as Chairman for a term of two years.

6 “(d) The Director of the Institute shall—

7 “(1) designate a member of the staff of the Insti-
8 tute to act as Executive Secretary of the Council,

9 “(2) make available to the Council such staff as-
10 sistance, information, and other assistance as it may
11 require to carry out its functions, and

12 “(3) conduct a formal orientation program and
13 training sessions for new members of the Council in
14 order to provide such new members with the necessary
15 information and training for effective participation on
16 the Council.

17 “(e) The Council shall meet at the call of the Chairman,
18 but not less often than four times a year.

19 “FUNCTIONS OF THE COUNCIL

20 “SEC. 445. The Council is authorized to—

21 “(1) review research projects and programs sub-
22 mitted to, or initiated by it relating to the study of ma-
23 ternal health, child health, and human development,
24 and certify its approval to the Secretary of any such
25 projects which it believes show promise of making val-

1 uable contributions to human knowledge with respect
2 to such areas of study;

3 “(2) collect information as to studies which are
4 being conducted in the United States or any other
5 country with regard to maternal health, child health,
6 and human development, by correspondence or by per-
7 sonal investigation of such studies, and, with the ap-
8 proval of the Secretary, make available such informa-
9 tion through appropriate publications for the benefits of
10 health agencies and organizations (public or private),
11 physicians, dentists, or any other scientists, and for the
12 general public;

13 “(3) review applications for grants-in-aid for re-
14 search projects relating to maternal health, child
15 health, and human development, and certify to the
16 Secretary, its approval of such projects that show
17 promise of making valuable contributions to human
18 knowledge with respect to such areas of research;

19 “(4) recommend to the Secretary acceptance of
20 conditional gifts, pursuant to section 501, to carry out
21 the purposes of this part;

22 “(5) make recommendations to the Secretary with
23 respect to carrying out the provisions of this part; and

1 “(6) certify to the Secretary the Council’s approv-
 2 al of such applications for grants-in-aid as it deter-
 3 mines will best carry out the purposes of this part.

4 “SUDDEN INFANT DEATH SYNDROME

5 “SEC. 446. The Secretary shall carry out through the
 6 National Institute of Child Health and Human Development
 7 the purpose of section 301 with respect to the conduct and
 8 support of research which specifically relates to sudden infant
 9 death syndrome.

10 “EXPIRATION OF INSTITUTE AND COUNCIL

11 “SEC. 446A. The Institute and the Council shall cease
 12 to exist on September 30, 1983.

13 “SUBPART II—NATIONAL INSTITUTE OF GENERAL

14 MEDICAL SCIENCES

15 “NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

16 “SEC. 447. There is established in the National Insti-
 17 tutes of Health a National Institute of General Medical Sci-
 18 ences (hereinafter in this subpart referred to as the
 19 ‘Institute’).

20 “RESEARCH IN THE GENERAL MEDICAL SCIENCES

21 “SEC. 448. In carrying out the purposes of section 301
 22 with respect to general medical sciences the Secretary,
 23 through the Institute, and in cooperation with the General
 24 Medical Sciences Advisory Council (hereinafter in this sub-
 25 part referred to as the ‘Council’), shall—

1 “(a) conduct, assist, and foster research, investi-
2 gations, experiments, and studies relating to the gener-
3 al or basic medical sciences and related natural or be-
4 havioral sciences, which have significance for two or
5 more other institutes within the National Institutes of
6 Health, or are outside the general area of responsibility
7 of any other institute within the National Institutes of
8 Health;

9 “(b) promote the coordination of research conduct-
10 ed by the Institute and similar research conducted by
11 other agencies, organizations, and individuals; and

12 “(c) secure for the Institute consultation services
13 and advice of persons from the United States or abroad
14 who are experts in the general medical sciences.

15 “ADMINISTRATION

16 “SEC. 449. (a) In carrying out the provisions of this
17 part, all appropriate provisions of section 301 shall be appli-
18 cable to the authority of the Secretary.

19 “(b) The Director of the Institute shall recommend to
20 the Secretary acceptance of conditional gifts, pursuant to sec-
21 tion 501, for study, investigation, or research into the general
22 medical sciences, or for the acquisition of grounds or equip-
23 ment, or for the construction or maintenance of premises,
24 buildings, or equipment of the Institute. Donations of
25 \$50,000 or more to carry out the purposes of this part may

1 be acknowledged by the establishment within the Institute of
2 suitable memorials to the donors.

3 “(c)(1) The Director of the Institute shall, as soon as
4 practicable after the end of each fiscal year, prepare a report
5 in consultation with the Council, and submit to the Secre-
6 tary, for simultaneous transmittal not later than November
7 30 of each year to the President and to the Congress. Such
8 report shall account the activities, progress, and accomplish-
9 ments of the Institute during the preceding fiscal year, and
10 shall include a listing of—

11 “(A) all health care technologies (as defined in
12 section 309(h)) under development through activities
13 supported or undertaken by the Institute which, in the
14 view of the Director and the Council, are ready for in-
15 corporation into medical practice, and

16 “(B) all activities supported or undertaken by the
17 Institute relevant to the prevention of disease, and an
18 assessment of the relative portion of the funds of the
19 Institute which are committed, respectively, to re-
20 search concerning—

21 “(i) primary prevention of disease,

22 “(ii) secondary prevention of disease, and

23 “(iii) treatment and cure of disease.

12 "NATIONAL GENERAL MEDICAL SCIENCES ADVISORY
13 COUNCIL

22 Twelve of the appointed members shall be selected from
23 among the leading medical or scientific authorities who are
24 skilled in the general medical sciences, and six of the appoint-
25 ed members shall be selected from the general public.

1 “(b)(1) Each appointed member of the Council shall be
2 appointed for a term of four years, except that—

3 “(A) any member appointed to fill a vacancy oc-
4 ccurring prior to the expiration of the term for which
5 his predecessor was appointed shall be appointed for
6 the remainder of such term; and

7 “(B) of the members first appointed after the ef-
8 fective date of this section, five shall be appointed for a
9 term of four years, five shall be appointed for a term of
10 three years, five shall be appointed for a term of two
11 years, and three shall be appointed for a term of one
12 year, as designated by the Secretary at the time of
13 appointment.

14 Appointed members may serve after the expiration of their
15 terms until their successors have taken office. The Secretary
16 shall, within ninety days of an expired term, or a vacancy
17 occurring for any other reason, appoint a successor to fill
18 such vacancy.

19 “(2) A vacancy in the Council shall not affect its activi-
20 ties, and twelve members of the Council shall constitute a
21 quorum.

22 “(3) Members of the Council who are not officers or
23 employees of the United States shall receive, for each day
24 they are engaged in the performance of the functions of the
25 Council, compensation at rates not to exceed the daily equiv-

1 alent of the annual rate in effect for grade GS-18 of the
2 General Schedule, including traveltime, and all members,
3 while serving away from their homes or regular places of
4 business, may be allowed travel expenses, including per diem
5 in lieu of subsistence, in the same manner as such expenses
6 are authorized by section 5703 of title 5, United States Code,
7 for persons in the Government service employed
8 intermittently.

9 “(c) The Secretary shall designate one of the appointed
10 members to serve as Chairman for a term of two years.

11 “(d) The Director of the Institute shall—

12 “(1) designate a member of the staff of the Insti-
13 tute to act as Executive Secretary of the Council,

14 “(2) make available to the Council such staff as-
15 sistance, information, and other assistance as it may
16 require to carry out its functions, and

17 “(3) conduct a formal orientation program and
18 training sessions for new members of the Council in
19 order to provide such new members with the necessary
20 information and training for effective participation on
21 the Council.

22 “(e) The Council shall meet at the call of the Chairman,
23 but not less often than four times a year.

24 “FUNCTIONS OF THE COUNCIL

25 “SEC. 449B. The Council is authorized to—

1 “(1) review research projects and programs sub-
2 mitted to, or initiated by, such Council relating to the
3 study of the general medical sciences, and certify its
4 approval to the Secretary of any such projects that it
5 believes show promise of making valuable contributions
6 to human knowledge with respect to such areas of
7 study;

8 “(2) collect information as to studies which are
9 being conducted in the United States or any other
10 country with regard to the general medical sciences, by
11 correspondence or by personal investigation of such
12 studies, and, with the approval of the Secretary, make
13 available such information through appropriate publica-
14 tions for the benefit of health agencies and organiza-
15 tions (public or private), physicians, dentists, or any
16 other scientists, and for the general public;

17 “(3) review applications for grants-in-aid for re-
18 search projects relating to the general medical sci-
19 ences, and certify to the Secretary, its approval of such
20 projects which show promise of making valuable con-
21 tributions to human knowledge with respect to the
22 general medical sciences;

23 “(4) recommend to the Secretary acceptance of
24 conditional gifts pursuant to section 501, to carry out
25 the purposes of this part;

1 “(5) make recommendations to the Secretary with
2 respect to carrying out the provisions of this part; and

3 “(6) certify to the Secretary its approval of such
4 applications for grants-in-aid as it determines will best
5 carry out the purposes of this part.

6 “EXPIRATION OF INSTITUTE AND COUNCIL

7 “SEC. 449C. The Institute and the Council shall cease
8 to exist on September 30, 1983.

9 “PRESERVATION OF EXISTING AUTHORITY

10 “SEC. 449D. Nothing in this part shall be construed as
11 affecting the authority of the Secretary under section 2 of the
12 Act of April 9, 1912 (42 U.S.C. 192), or title V of the Social
13 Security Act (42 U.S.C., ch. 7, subch. V), or as affecting the
14 authority of the Surgeon General to utilize institutes estab-
15 lished under other provisions of this Act for research or train-
16 ing activities relating to maternal health, child health, and
17 human development or to the general medical sciences and
18 related sciences.”.

19 NATIONAL EYE INSTITUTE

20 SEC. 208. Part G of title IV, as redesignated by this
21 Act, is amended to read as follows:

1 "PART G—NATIONAL EYE INSTITUTE

2 "ESTABLISHMENT OF NATIONAL EYE INSTITUTE

3 "SEC. 451. There is established in the National Insti-
4 tutes of Health the National Eye Institute (hereinafter in this
5 part referred to as the 'Institute').

6 "EYE RESEARCH

7 "SEC. 452. In carrying out the purposes of section 301,
8 with respect to blinding eye diseases and visual disorders, the
9 Secretary, through the Institute and in cooperation with the
10 National Eye Advisory Council (hereinafter in this part re-
11 ferred to as the 'Council'), shall—

12 "(a) conduct, assist, and foster research, investi-
13 gations, experiments, and studies relating to blinding
14 eye diseases and visual disorders, including the special
15 health problems and requirements of the blind, and in
16 the basic and clinical sciences relating to the mecha-
17 nism of the visual function and preservation of sight;

18 "(b) promote the coordination of research con-
19 ducted by the Institute, and similar research conducted
20 by other agencies, organizations, and individuals; and

21 "(c) secure for the Institute consultation services
22 and advice of persons from the United States or abroad
23 who are experts in blinding eye diseases and visual
24 disorders.

1 "ADMINISTRATION

2 "SEC. 453. (a) In carrying out the provisions of this
3 part, all appropriate provisions of section 301 shall be appli-
4 cable to the authority of the Secretary.

5 "(b) The Director of the Institute shall recommend to
6 the Secretary acceptance of conditional gifts, pursuant to sec-
7 tion 501, for study, investigation, or research into blinding
8 eye diseases and visual disorders, or for the acquisition of
9 grounds or equipment, or for the construction or maintenance
10 of premises, buildings, or equipment of the Institute. Dona-
11 tions of \$50,000 or more to carry out the purposes of this
12 part may be acknowledged by the establishment within the
13 Institute of suitable memorials to the donors.

14 "(c)(1) The Director of the Institute shall, as soon as
15 practicable after the end of each fiscal year, prepare a report
16 in consultation with the Council, and submit to the Secre-
17 tary, for simultaneous transmittal not later than November
18 30 of each year to the President and to the Congress. Such
19 report shall account the activities, progress, and accomplish-
20 ments of the Institute during the preceding fiscal year, and
21 shall include a listing of—

22 "(A) all health care technologies (as defined in
23 section 309(h)) under development through activities
24 supported or undertaken by the Institute which, in the

1 view of the Director and the Council, are ready for in-
2 corporation into medical practice, and

3 “(B) all activities supported or undertaken by the
4 Institute relevant to the prevention of disease, and an
5 assessment of the relative portion of the funds of the
6 Institute which are committed, respectively, to re-
7 search concerning—

8 “(i) primary prevention of eye disease,

9 “(ii) secondary prevention of eye disease, and

10 “(iii) treatment and cure of eye disease.

11 “(2) The Director of the Institute shall provide a plan to
12 the President’s Council on the Health Sciences for the pro-
13 posed activities of the Institute for the next five years.

14 “(d) Under procedures approved by the Director of the
15 National Institutes of Health, the Director of the Institute
16 may approve grants under this Act for research in blinding
17 eye diseases and visual disorders after appropriate review for
18 scientific merit. If the direct costs of a grant for research will
19 exceed \$50,000, the Director may approve such grant only
20 after appropriate review for scientific merit and recommenda-
21 tion for approval by the Council.

22 “NATIONAL EYE ADVISORY COUNCIL

23 “SEC. 454. (a) There is established in the Institute a
24 National Eye Advisory Council (hereinafter referred to as the
25 ‘Council’) to be composed of twenty members as follows:

1 “(1) The Secretary and the Director of the Na-
2 tional Institutes of Health (or their designees) shall be
3 ex officio members of the Council.

4 “(2) Eighteen members appointed by the Secre-
5 tary.

6 Twelve of the appointed members shall be selected from
7 among the leading medical or scientific authorities who are
8 skilled in the sciences relating to blinding eye diseases and
9 visual disorders, including the special health problems and
10 requirements of the blind, and in the basic and clinical sci-
11 ences relating to the mechanism of the visual function and
12 preservation of sight, and six of the appointed members shall
13 be selected from the general public.

14 “(b)(1) Each appointed member of the Council shall be
15 appointed for a term of four years, except that—

16 “(A) any member appointed to fill a vacancy oc-
17 curring prior to the expiration of the term for which
18 his predecessor was appointed shall be appointed for
19 the remainder of such term; and

20 “(B) of the members first appointed after the ef-
21 fective date of this section, five shall be appointed for a
22 term of four years, five shall be appointed for a term of
23 three years, five shall be appointed for a term of two
24 years, and three shall be appointed for a term of one

1 year, as designated by the Secretary at the time of
2 appointment.

3 Appointed members may serve after the expiration of their
4 terms until their successors have taken office. The Secretary
5 shall, within ninety days of an expired term, or a vacancy
6 occurring for any other reason, appoint a successor to fill
7 such vacancy.

8 “(2) A vacancy in the Council shall not affect its activi-
9 ties, and twelve members of the Council shall constitute a
10 quorum.

11 “(3) Members of the Council who are not officers or
12 employees of the United States shall receive, for each day
13 they are engaged in the performance of the functions of the
14 Council, compensation at rates not to exceed the daily equiv-
15 alent of the annual rate in effect for grade GS-18 of the
16 General Schedule, including traveltime. All members, while
17 serving away from their homes or regular places of business,
18 may be allowed travel expenses, including per diem in lieu of
19 subsistence, in the same manner as such expenses are au-
20 thorized by section 5703 of title 5, United States Code, for
21 persons in the Government service employed intermittently.

22 “(c) The Secretary shall designate one of the appointed
23 members to serve as Chairman for a term of two years.

24 “(d) The Director of the Institute shall—

1 “(1) designate a member of the staff of the Insti-
2 tute to act as Executive Secretary of the Council,

3 “(2) make available to the Council such staff as-
4 sistance, information, and other assistance as it may
5 require to carry out its functions, and

6 “(3) conduct a formal orientation program and
7 training sessions for new members of the Council in
8 order to provide such new members with the necessary
9 information and training for effective participation on
10 the Council.

11 “(e) The Council shall meet at the call of the Chairman,
12 but not less often than four times a year.

13 “FUNCTIONS OF THE COUNCIL

14 “SEC. 454A. The Council is authorized to—

15 “(1) review research projects and programs sub-
16 mitted to, or initiated by, such Council, relating to the
17 study of blinding eye diseases and visual disorders, and
18 certify its approval to the Secretary of any such proj-
19 ects which it believes show promise of making valuable
20 contributions to human knowledge with respect to such
21 areas of study;

22 “(2) collect information as to studies which are
23 being conducted in the United States or any other
24 country with regard to the blinding eye diseases and
25 visual disorders, by correspondence or by personal in-

1 vestigation of such studies, and, with the approval of
2 the Secretary, make available such information through
3 appropriate publications for the benefits of health agen-
4 cies and organizations (public or private), physicians,
5 dentists, or any other scientists, and for the general
6 public;

7 “(3) review applications for grants-in-aid for re-
8 search projects relating to blinding eye diseases and
9 visual disorders, and certify to the Secretary, its ap-
10 proval of such projects that show promise of making
11 valuable contributions to human knowledge with re-
12 spect to such areas of research;

13 “(4) recommend to the Secretary acceptance of
14 conditional gifts, pursuant to section 501, to carry out
15 the purposes of this part;

16 “(5) make recommendations to the Secretary with
17 respect to carrying out the provisions of this part; and

18 “(6) certify to the Secretary the Council’s approv-
19 al of such applications for grants-in-aid as it deter-
20 mines will best carry out the purposes of this part.

21 “EXPIRATION OF INSTITUTE AND COUNCIL

22 “SEC. 454B. The Institute and the Council shall cease
23 to exist on September 30, 1983.”.

1 NATIONAL INSTITUTE ON AGING

2 SEC. 209. Part I of title IV, as redesignated by this
3 Act, is amended to read as follows:

4 "PART I—NATIONAL INSTITUTE ON AGING

5 "ESTABLISHMENT OF NATIONAL INSTITUTE ON AGING

6 "SEC. 461. There is established in the National Insti-
7 tutes of Health the National Institute on Aging (hereinafter
8 in this part referred to as the 'Institute').

9 "RESEARCH ON AGING

10 "SEC. 462. In carrying out the purposes of section 301,
11 with respect to aging, the Secretary, through the Institute
12 and in cooperation with the National Aging Advisory Council
13 (hereinafter in this part referred to as the 'Council'), shall—

14 "(a) conduct, assist, and foster research, investi-
15 gations, experiments, and studies relating to the aging
16 process, and the diseases and other special problems
17 and needs of the aged;

18 "(b) promote the coordination of research con-
19 ducted by the Institute, and similar research conducted
20 by other agencies, organizations, and individuals; and

21 "(c) secure for the Institute consultation services
22 and advice of persons from the United States or abroad
23 who are experts in aging and research on aging.

1 "ADMINISTRATION

2 "SEC. 463. (a) In carrying out the provisions of this
3 part, all appropriate provisions of section 301 shall be appli-
4 cable to the authority of the Secretary.

5 "(b) The Director of the Institute shall recommend to
6 the Secretary acceptance of conditional gifts, pursuant to sec-
7 tion 501, for study, investigation, or research into aging, or
8 for the acquisition of grounds or equipment, or for the con-
9 struction or maintenance of premises, buildings, or equipment
10 of the Institute. Donations of \$50,000 or more to carry out
11 the purposes of this part may be acknowledged by the estab-
12 lishment within the Institute of suitable memorials to the
13 donors.

14 "(c)(1) The Director of the Institute shall, as soon as
15 practicable after the end of each fiscal year, prepare a report
16 in consultation with the Council, and submit such report to
17 the Secretary, for simultaneous transmittal not later than
18 November 30 of each year to the President and to Congress.
19 Such report shall account the activities, accomplishments,
20 and progress of the Institute during the preceding fiscal year,
21 and shall include a listing of—

22 "(A) all health care technologies (as defined in
23 section 309(h)) under development through activities
24 supported or undertaken by the Institute which, in the

1 view of the Director and the Council, are ready for in-
2 corporation into medical practice, and

3 “(B) all activities supported or undertaken by the
4 Institute relevant to the prevention of disease, and a
5 statement of the proportion of the funds appropriated
6 for the Institute which support research concerning—

7 “(i) primary prevention of diseases and other
8 health problems associated with aging,

9 “(ii) secondary prevention of diseases and
10 other health problems associated with aging, and

11 “(iii) treatment and cure of diseases and
12 other health problems associated with aging.

13 “(2) The Director of the Institute shall provide a plan to
14 the President’s Council on the Health Sciences for the pro-
15 posed activities of the Institute for the next five years.

16 “(d) Under procedures approved by the Director of the
17 National Institutes of Health, the Director of the Institute
18 may approve grants under this Act for research on aging,
19 after appropriate review for scientific merit. If the direct
20 costs of a grant for such research will exceed \$50,000, the
21 Director may approve such grant only after appropriate
22 review for scientific merit and recommendation for approval
23 by the Council.

1 "NATIONAL AGING ADVISORY COUNCIL

2 "SEC. 464. (a) There is established in the Institute a
3 National Aging Advisory Council to be composed of twenty
4 members as follows:

5 "(1) The Secretary and the Director of the Na-
6 tional Institutes of Health (or their designees) shall be
7 ex officio members of the Council.

8 "(2) Eighteen members appointed by the Secre-
9 tary.

10 Twelve of the appointed members shall be selected from
11 among the leading medical or scientific authorities who are
12 skilled in the sciences relating to the aging process and the
13 diseases and other special problems and the needs of the
14 aged, and six of the appointed members shall be selected
15 from the general public.

16 "(b)(1) Each appointed member of the Council shall be
17 appointed for a term of four years, except that—

18 "(A) any member appointed to fill a vacancy oc-
19 ccurring prior to the expiration of the term for which
20 his predecessor was appointed shall be appointed for
21 the remainder of such term; and

22 "(B) of the members first appointed after the ef-
23 fective date of this section, five shall be appointed for a
24 term of four years, five shall be appointed for a term of
25 three years, five shall be appointed for a term of two

1 years, and three shall be appointed for a term of one
2 year, as designated by the Secretary at the time of ap-
3 pointment.

4 Appointed members may serve after the expiration of their
5 terms until their successors have taken office. The Secretary
6 shall, within ninety days of an expired term, or a vacancy
7 occurring for any other reason, appoint a successor to fill
8 such vacancy.

9 “(2) A vacancy in the Council shall not affect its activi-
10 ties, and twelve members of the Council shall constitute a
11 quorum.

12 “(3) Members of the Council who are not officers or
13 employees of the United States shall receive, for each day
14 they are engaged in the performance of the functions of the
15 Council, compensation at rates not to exceed the daily equiv-
16 alent of the annual rate in effect for grade GS-18 of the
17 General Schedule, including traveltime. All members, while
18 serving away from their homes or regular places of business,
19 may be allowed travel expenses, including per diem in lieu of
20 subsistence, in the same manner as such expenses are au-
21 thorized by section 5703 of title 5, United States Code, for
22 persons in the Government service employed intermittently.

23 “(c) The Secretary shall designate one of the appointed
24 members to serve as Chairman for a term of two years.

25 “(d) The Director of the Institute shall—

1 “(1) designate a member of the staff of the Insti-
2 tute to act as Executive Secretary of the Council,

3 “(2) make available to the Council such staff as-
4 sistance, information, and other assistance as it may
5 require to carry out its functions, and

6 “(3) conduct a formal orientation program and
7 training sessions for new members of the Council in
8 order to provide such new members with the necessary
9 information and training for effective participation on
10 the Council.

11 “(e) The Council shall meet at the call of the Chairman,
12 but not less often than four times a year.

13 “FUNCTIONS OF THE COUNCIL

14 “SEC. 465. The Council is authorized to—

15 “(1) review research projects and programs sub-
16 mitted to, or initiated by, such Council, relating to the
17 study of aging, and certify its approval to the Secre-
18 tary of any such projects which it believes show prom-
19 ise of making valuable contributions to human knowl-
20 edge with respect to such areas of study;

21 “(2) collect information as to studies which are
22 being conducted in the United States or any other
23 country with regard to aging, by correspondence or by
24 personal investigation of such studies, and, with the
25 approval of the Secretary, make available such infor-

1 mation through appropriate publications for the benefits
2 of health agencies and organizations (public or private),
3 physicians, dentists, or any other scientists, and for the
4 general public;

5 “(3) review applications for grants-in-aid for re-
6 search projects relating to aging, and certify to the
7 Secretary, its approval of such projects that show
8 promise of making valuable contributions to human
9 knowledge with respect to such areas of research;

10 “(4) recommend to the Secretary acceptance of
11 conditional gifts, pursuant to section 501, to carry out
12 the purposes of this part;

13 “(5) make recommendations to the Secretary with
14 respect to carrying out the provisions of this part; and

15 “(6) certify to the Secretary the Council’s approv-
16 al of such applications for grants-in-aid as it deter-
17 mines will best carry out the purposes of this part.

18 “EXPIRATION OF INSTITUTE AND COUNCIL

19 “SEC. 466. The Institute and the Council shall cease to
20 exist on September 30, 1983.”.

1 NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DIS-
2 EASES/NATIONAL INSTITUTE OF ENVIRONMENTAL
3 HEALTH SCIENCES/NATIONAL INSTITUTE OF NEURO-
4 LOGICAL, COMMUNICATIVE DISORDERS, AND STROKE
5 SEC. 210. Title IV is amended by adding the following
6 new parts immediately after part I (as redesignated by this
7 Act):

8 "PART J—NATIONAL INSTITUTE OF ALLERGY AND
9 INFECTIOUS DISEASES

10 "ESTABLISHMENT OF INSTITUTE

11 "SEC. 471. There is established in the National Insti-
12 tutes of Health a National Institute of Allergy and Infectious
13 Diseases (hereinafter referred to in this part as the 'Insti-
14 tute').

15 "ALLERGY AND INFECTIOUS DISEASES RESEARCH

16 "SEC. 472. In carrying out the purposes of section 301
17 with respect to allergy and infectious diseases, the Secretary,
18 through the Institute, and in cooperation with the National
19 Allergy and Infectious Diseases Advisory Council (herein-
20 after referred to in this part as the 'Council') shall—

21 "(a) conduct, assist, and foster research, investi-
22 gations, experiments, and studies relating to allergy
23 and infectious diseases;

1 “(b) promote the coordination of research conduct-
2 ed by the Institute, and similar research conducted by
3 other agencies, organizations, and individuals; and

4 “(c) secure for the Institute consultation services
5 and advice of persons from the United States or abroad
6 who are experts in allergy and infectious diseases.

7 “ADMINISTRATION

8 “SEC. 473. (a) In carrying out the provisions of this
9 part, appropriate provisions of section 301 shall be applicable
10 to the authority of the Secretary.

11 “(b) The Director of the Institute shall recommend to
12 the Secretary acceptance of conditional gifts, pursuant to sec-
13 tion 501, for study, investigation, or research into allergy and
14 infectious diseases, or for the acquisition of grounds or equip-
15 ment, or for the construction or maintenance of premises,
16 buildings, or equipment of the Institute. Donations of
17 \$50,000 or more to carry out the purposes of this part may
18 be acknowledged by the establishment within the Institute of
19 suitable memorials to the donors.

20 “(c)(1) The Director of the Institute shall, as soon as
21 practicable after the end of each fiscal year, prepare a report
22 in consultation with the Council, and submit such report to
23 the Secretary, for simultaneous transmittal not later than
24 November 30 of each year to the President and to the Con-
25 gress. Such report shall account the activities, progress, and

1 accomplishments of the Institute during the preceding fiscal
2 year, and shall include a listing of—

3 “(A) all health care technologies (as defined in
4 section 309(h)) under development through activities
5 supported or undertaken by the Institute which, in the
6 view of the Director and the Council, are ready for in-
7 corporation into medical practice, and

8 “(B) all activities supported or undertaken by the
9 Institute relevant to the prevention of disease, and a
10 statement of the proportion of the funds appropriated
11 for the Institute which support research concerning—

12 “(i) primary prevention of allergy and infec-
13 tious diseases,

14 “(ii) secondary prevention of allergy and in-
15 fectious diseases, and

16 “(iii) treatment and cure of allergy and infec-
17 tious diseases.

18 “(2) The Director of the Institute shall also provide a
19 plan to the President's Council on the Health Sciences for
20 the proposed activities of the Institute for the next five years.

21 “(d) Under procedures approved by the Director of the
22 National Institutes of Health, the Director of the Institute
23 may approve grants under this Act for research in dental
24 diseases after appropriate review for scientific merit. If the
25 direct costs of a grant for such research will exceed \$50,000,

1 the Director may approve such grant only after appropriate
2 review for scientific merit and recommendation for approval
3 by the Advisory Council.

4 "NATIONAL ALLERGY AND INFECTIOUS DISEASES
5 ADVISORY COUNCIL

6 "SEC. 474. (a) There is established in the Institute a
7 National Allergy and Infectious Diseases Advisory Council
8 to be composed of twenty members as follows:

9 "(1) The Secretary and the Director of the Na-
10 tional Institutes of Health (or their designees) shall be
11 ex officio members of the Council.

12 "(2) Eighteen members appointed by the Secre-
13 tary.

14 Twelve of the appointed members shall be selected from
15 among the leading medical or scientific authorities who are
16 skilled in the sciences relating to allergy and infectious dis-
17 eases, and six of the appointed members shall be selected
18 from the general public.

19 "(b)(1) Each appointed member of the Council shall be
20 appointed for a term of four years, except that—

21 "(A) any member appointed to fill a vacancy oc-
22 ccurring prior to the expiration of the term for which
23 his predecessor was appointed shall be appointed for
24 the remainder of such term; and

1 “(B) of the members first appointed after the ef-
2 fective date of this section, five shall be appointed for a
3 term of four years, five shall be appointed for a term of
4 three years, five shall be appointed for a term of two
5 years, and three shall be appointed for a term of one
6 year, as designated by the Secretary at the time of ap-
7 pointment.

8 Appointed members may serve after the expiration of their
9 terms until their successors have taken office. The Secretary
10 shall, within ninety days of an expired term or a vacancy
11 occurring for any other reason, appoint a successor to fill
12 such vacancy.

13 “(2) A vacancy in the Council shall not affect its activi-
14 ties, and twelve members of the Council shall constitute a
15 quorum.

16 “(3) Members of the Council who are not officers or
17 employees of the United States shall receive, for each day
18 they are engaged in the performance of the functions of the
19 Council, compensation at rates not to exceed the daily equiv-
20 alent of the annual rate in effect for grade GS-18 of the
21 General Schedule, including traveltime. All members, while
22 serving away from their homes or regular places of business,
23 may be allowed travel expenses, including per diem in lieu of
24 subsistence, in the same manner as such expenses are au-

1 thorized by section 5703 of title 5, United States Code, for
2 persons in the Government service employed intermittently.

3 “(c) The Secretary shall designate one of the appointed
4 members to serve as Chairman for a term of two years.

5 “(d) The Director of the Institute shall—

6 “(1) designate a member of the staff of the Insti-
7 tute to act as Executive Secretary of the Council,

8 “(2) make available to the Council such staff as-
9 sistance, information, and other assistance as it may
10 require to carry out its functions, and

11 “(3) conduct a formal orientation program and
12 training sessions for new members of the Council in
13 order to provide such new members with the necessary
14 information and training for effective participation on
15 the Council.

16 “(e) The Council shall meet at the call of the Chairman,
17 but not less often than four times a year.

18 “FUNCTIONS OF THE COUNCIL

19 “SEC. 475. The Council is authorized to—

20 “(1) review research projects and programs sub-
21 mitted to, or initiated by, such Council relating to the
22 study of allergy and infectious diseases, and certify its
23 approval to the Secretary of any such projects which it
24 believes show promise of making valuable contributions

1 to human knowledge with respect to such areas of
2 study;

3 “(2) collect information as to studies which are
4 being conducted in the United States or any other
5 country with regard to allergy and infectious diseases,
6 by correspondence or by personal investigation of such
7 studies, and, with the approval of the Secretary, make
8 available such information through appropriate publica-
9 tions for the benefit of health agencies and organiza-
10 tions (public or private), physicians, dentists, or any
11 other scientists, and for the general public;

12 “(3) review applications for grants-in-aid for re-
13 search projects relating to allergy and infectious dis-
14 eases, and certify to the Secretary its approval of such
15 projects that show promise of making valuable contri-
16 butions to human knowledge with respect to the cause,
17 prevention, or methods of diagnosis or treatment of al-
18 lergy and infectious diseases;

19 “(4) recommend to the Secretary acceptance of
20 conditional gifts pursuant to section 501, for carrying
21 out the purposes of this part;

22 “(5) make recommendations to the Secretary with
23 respect to carrying out the provisions of this part; and

1 “(6) certify to the Secretary the Council’s approv-
2 al of such applications for grants-in-aid as it deter-
3 mines will best carry out the purposes of this part.

4 “EXPIRATION OF INSTITUTE AND COUNCIL

5 “SEC. 475A. The Institute and the Council shall cease
6 to exist on September 30, 1983.

7 “PART K—NATIONAL INSTITUTE OF ENVIRONMENTAL
8 HEALTH SCIENCES

9 “ESTABLISHMENT OF INSTITUTE

10 “SEC. 476. There is established in the National Insti-
11 tutes of Health a National Institute of Environmental Health
12 Sciences (hereinafter referred to in this part as the
13 ‘Institute’).

14 “ENVIRONMENTAL HEALTH SCIENCES RESEARCH

15 “SEC. 477. In carrying out the purposes of section 301,
16 with respect to environmental health sciences, the Secretary,
17 through the Institute and in cooperation with the National
18 Environmental Health Sciences Advisory Council (herein-
19 after in this part referred to as the ‘Council’) shall—

20 “(a) conduct, assist, and foster research, investi-
21 gations, experiments, and studies relating to the envi-
22 ronmental health sciences;

23 “(b) promote the coordination of research conduct-
24 ed by the Institute, and similar research conducted by
25 other agencies, organizations, and individuals; and

1 “(c) secure for the Institute consultation services
2 and advice of persons from the United States or abroad
3 who are experts in the environmental health sciences.

4 “ADMINISTRATION

5 “SEC. 478. (a) In carrying out the provisions of this
6 part, all appropriate provisions of section 301 shall be appli-
7 cable to the authority of the Secretary.

8 “(b) The Director of the Institute shall recommend to
9 the Secretary acceptance of conditional gifts, pursuant to sec-
10 tion 501, for study, investigation, or research into the envi-
11 ronmental health sciences, or for the acquisition of grounds or
12 equipment, or for the construction or maintenance of prem-
13 ises, buildings, or equipment of the Institute. Donations of
14 \$50,000 or more to carry out the purposes of this part may
15 be acknowledged by the establishment within the Institute of
16 suitable memorials to the donors.

17 “(c)(1) The Director of the Institute shall, as soon as
18 practicable after the end of each fiscal year, prepare a report
19 in consultation with the Council, and submit such report to
20 the Secretary, for simultaneous transmittal not later than
21 November 30 of each year to the President and to the Con-
22 gress. Such report shall account the activities, progress, and
23 accomplishments of the Institute during the preceding fiscal
24 year, and shall include a listing of—

1 “(A) all health care technologies (as defined in
2 section 309(h)) under development through activities
3 supported or undertaken by the Institute which, in the
4 view of the Director and the Council, are ready for in-
5 corporation into medical practice, and

6 “(B) all activities supported or undertaken by the
7 Institute relevant to the prevention of disease, and a
8 statement of the proportion of the funds appropriated
9 for the Institute which support research concerning—

10 “(i) primary prevention of diseases linked to
11 environmental factors,

12 “(ii) secondary prevention of diseases linked
13 to environmental factors, and

14 “(iii) treatment and cure of diseases linked to
15 environmental factors.

16 “(2) The Director of the Institute shall also provide a
17 plan to the President's Council on the Health Sciences for
18 the proposed activities of the Institute for the next five years.

19 “(d) Under procedures approved by the Director of the
20 National Institutes of Health, the Director of the Institute
21 may approve grants under this Act for research in environ-
22 mental health sciences after appropriate review for scientific
23 merit. If the direct costs of a grant for such research will
24 exceed \$50,000, the Director may approve such grant only

1 after appropriate review for scientific merit and recommenda-
2 tion for approval by the Council.

3 "NATIONAL ENVIRONMENTAL HEALTH SCIENCES

4 ADVISORY COUNCIL

5 "SEC. 479. (a) There is established in the Institute a
6 National Environmental Health Sciences Advisory Council
7 (hereinafter referred to as the 'Council') to be composed of
8 twenty members as follows:

9 "(1) The Secretary and the Director of the Na-
10 tional Institutes of Health (or their designees) shall be
11 ex officio members of the Council.

12 "(2) Eighteen members appointed by the Secre-
13 tary.

14 Twelve of the appointed members shall be selected from
15 among the leading medical or scientific authorities who are
16 skilled in the environmental health sciences, and six of the
17 appointed members shall be selected from the general public.

18 "(b)(1) Each appointed member of the Council shall be
19 appointed for a term of four years, except that—

20 "(A) any member appointed to fill a vacancy oc-
21 curring prior to the expiration of the term for which
22 his predecessor was appointed shall be appointed for
23 the remainder of such term; and

24 "(B) of the members first appointed after the ef-
25 fective date of this section, five shall be appointed for a

1 term of four years, five shall be appointed for a term of
2 three years, five shall be appointed for a term of two
3 years, and three shall be appointed for a term of one
4 year, as designated by the Secretary at the time of ap-
5 pointment.

6 Appointed members may serve after the expiration of their
7 terms until their successors have taken office. The Secretary
8 shall, within ninety days of an expired term or a vacancy
9 occurring for any other reason, appoint a successor to fill
10 such vacancy.

11 “(2) A vacancy in the Council shall not affect its activi-
12 ties, and twelve members of the Council shall constitute a
13 quorum.

14 “(3) Members of the Council who are not officers or
15 employees of the United States shall receive, for each day
16 they are engaged in the performance of the functions of the
17 Council, compensation at rates not to exceed the daily equiv-
18 alent of the annual rate in effect for grade GS-18 of the
19 General Schedule, including traveltime. All members, while
20 serving away from their homes or regular places of business,
21 may be allowed travel expenses, including per diem in lieu of
22 subsistence, in the same manner as such expenses are au-
23 thorized by section 5703 of title 5, United States Code, for
24 persons in the Government service employed intermittently.

1 “(c) The Secretary shall designate one of the appointed
2 members to serve as Chairman for a term of two years.

3 “(d) The Director of the Institute shall—

4 “(1) designate a member of the staff of the Insti-
5 tute to act as Executive Secretary of the Council,

6 “(2) make available to the Council such staff as-
7 sistance, information, and other assistance as it may
8 require to carry out its functions, and

9 “(3) conduct a formal orientation program and
10 training sessions for new members of the Council in
11 order to provide such new members with the necessary
12 information and training for effective participation on
13 the Council.

14 “(e) The Council shall meet at the call of the Chairman,
15 but not less often than four times a year.

16 “FUNCTIONS OF THE COUNCIL

17 “SEC. 479A. The Council is authorized to—

18 “(1) review research projects and programs sub-
19 mitted to, or initiated by, such Council, relating to the
20 study of environmental health sciences, and certify its
21 approval to the Secretary of any such projects which it
22 believes show promise of making valuable contributions
23 to human knowledge with respect to such areas of
24 study;

1 “(2) collect information as to studies which are
2 being conducted in the United States or any other
3 country with regard to the environmental health sci-
4 ences, by correspondence or by personal investigation
5 of such studies, and with the approval of the Secretary,
6 make available such information through appropriate
7 publications for the benefit of health agencies and orga-
8 nizations (public or private), physicians, dentists, or
9 any other scientists, and for the general public;

10 “(3) review applications for grants-in-aid for re-
11 search projects relating to the environmental health
12 sciences, and certify to the Secretary, its approval of
13 such projects that show promise of making valuable
14 contributions to human knowledge with respect to such
15 areas of research;

16 “(4) recommend to the Secretary acceptance of
17 conditional gifts, pursuant to section 501, to carry out
18 the purposes of this part;

19 “(5) make recommendations to the Secretary with
20 respect to carrying out the provisions of this part; and

21 “(6) certify to the Secretary the Council’s approv-
22 al of such applications for grants-in-aid as it deter-
23 mines will best carry out the purposes of this part.

1 “EXPIRATION OF INSTITUTE AND COUNCIL

2 “SEC. 479B. The Institute and the Council shall cease
3 to exist on September 30, 1983.

4 “PART L—NATIONAL INSTITUTE OF NEUROLOGICAL,
5 COMMUNICATIVE DISORDERS AND STROKE

6 “ESTABLISHMENT OF NATIONAL INSTITUTE OF NEURO-
7 LOGICAL, COMMUNICATIVE DISORDERS, AND STROKE

8 “SEC. 481. There is established in the National Insti-
9 tutes of Health the National Institute of Neurological, Com-
10 municative Disorders, and Stroke (hereinafter in this part re-
11 ferred to as the ‘Institute’).

12 “RESEARCH ON NEUROLOGICAL, COMMUNICATIVE
13 DISORDERS, AND STROKE

14 “SEC. 481A. In carrying out the purposes of section
15 301, with respect to neurological communicative disorders
16 and stroke, the Secretary, through the Institute and in coop-
17 eration with the Neurological, Communicative Disorders, and
18 Stroke Advisory Council (hereinafter in this part referred to
19 as the ‘Council’), shall—

20 “(a) conduct, assist, and foster research, investi-
21 gations, experiments, and studies relating to neurologi-
22 cal, communicative disorders, and stroke, including the
23 special health problems and requirements of victims of
24 neurological, communicative disorders, and stroke, and

1 relating to the basic and clinical sciences regarding
2 neurological, communicative disorders, and stroke;

3 “(b) promote the coordination of research conduct-
4 ed by the Institute, and similar research conducted by
5 other agencies, organizations, and individuals; and

6 “(c) secure for the Institute consultation services
7 and advice of persons from the United States or abroad
8 who are experts in neurological, communicative disor-
9 ders, and stroke.

10 “ADMINISTRATION

11 “SEC. 481B. (a) In carrying out the provisions of this
12 part, all appropriate provisions of section 301 shall be appli-
13 cable to the authority of the Secretary.

14 “(b) The Director of the Institute shall recommend to
15 the Secretary acceptance of conditional gifts, pursuant to sec-
16 tion 501, for study, investigation, or research into neurologi-
17 cal, communicative disorders, and stroke, or for the acquisi-
18 tion of grounds or equipment, or for the construction or main-
19 tenance of premises, buildings, or equipment of the Institute.
20 Donations of \$50,000 or more to carry out the purposes of
21 this part may be acknowledged by the establishment within
22 the Institute of suitable memorials to the donors.

23 “(c)(1) The Directors of the Institute shall, as soon as
24 practicable after the end of each fiscal year, prepare a report
25 in consultation with the Council, and submit such report to

1 the Secretary, for simultaneous transmittal not later than
2 November 30 of each year to the President and to the Con-
3 gress. Such report shall account the activities, progress, and
4 accomplishments of the Institute during the preceding fiscal
5 year, and shall include a listing of—

6 “(A) all health care technologies (as defined in
7 section 309(h)) under development through activities
8 supported or undertaken by the Institute which, in the
9 view of the Director and the Council, are ready for in-
10 corporation into medical practice, and

11 “(B) all activities of the Institute supported or un-
12 dertaken by the Institute relevant to the prevention of
13 disease, and a statement of the proportion of the funds
14 appropriated for the Institute which support research
15 concerning—

16 “(i) primary prevention of neurological, com-
17 municative disorders, and stroke,

18 “(ii) secondary prevention of neurological,
19 communicative disorders, and stroke, and

20 “(iii) treatment and cure of neurological, and
21 communicative disorders, and stroke.

22 The Director of the Institute shall also provide a plan to the
23 President's Council on the Health Sciences for the proposed
24 activities of the Institute for the next five years.

1 “(d) Under procedures approved by the Director of the
2 National Institutes of Health, the Director of the Institute
3 may approve grants under this Act for research on neurologi-
4 cal, communicative disorders, and stroke after appropriate
5 review for scientific merit. If the direct costs of a grant for
6 such research will exceed \$50,000, the Director may ap-
7 prove such grant only after appropriate review for scientific
8 merit and recommendation for approval by the Council.

9 “NATIONAL NEUROLOGICAL, COMMUNICATIVE DISORDERS,
10 AND STROKE ADVISORY COUNCIL

11 “SEC. 481C. (a) There is established in the Institute a
12 National Child Health and Human Development Advisory
13 Council to be composed of twenty members as follows:

14 “(1) The Secretary and the Director of the Na-
15 tional Institutes of Health (or their designees) shall be
16 ex officio members of the Council.

17 “(2) Eighteen members appointed by the
18 Secretary.

19 Twelve of the appointed members shall be selected from
20 among the leading medical or scientific authorities who are
21 skilled in the sciences relating to neurological, communica-
22 tive disorders, and stroke, including the special health prob-
23 lems and requirements of victims of neurological, communica-
24 tive disorders, and stroke, and the basic and clinical sciences
25 relating to the neurological, communicative disorders, and

1 stroke, and six of the appointed members shall be selected
2 from the general public.

3 “(b)(1) Each appointed member of the Council shall be
4 appointed for a term of four years, except that—

5 “(A) any member appointed to fill a vacancy oc-
6 ccurring prior to the expiration of the term for which
7 his predecessor was appointed shall be appointed for
8 the remainder of such term; and

9 “(B) of the members first appointed after the ef-
10 fective date of this section, five shall be appointed for a
11 term of four years, five shall be appointed for a term of
12 three years, five shall be appointed for a term of two
13 years, and three shall be appointed for a term of one
14 year, as designated by the Secretary at the time of
15 appointment.

16 Appointed members may serve after the expiration of their
17 terms until their successors have taken office. The Secretary
18 shall, within ninety days of an expired term, or a vacancy
19 occurring for any other reason, appoint a successor to fill
20 such vacancy.

21 “(2) A vacancy in the Council shall not affect its activi-
22 ties, and twelve members of the Council shall constitute a
23 quorum.

24 “(3) Members of the Council who are not officers or
25 employees of the United States shall receive, for each day

1 they are engaged in the performance of the functions of the
2 Council, compensation at rates not to exceed the daily equiv-
3 alent of the annual rate in effect for grade GS-18 of the
4 General Schedule, including traveltime. All members, while
5 serving away from their homes or regular places of business,
6 may be allowed travel expenses, including per diem in lieu of
7 subsistence, in the same manner as such expenses are au-
8 thorized by section 5703 of title 5, United States Code, for
9 persons in the Government service employed intermittently.

10 “(c) The Secretary shall designate one of the appointed
11 members to serve as Chairman for a term of two years.

12 “(d) The Director of the Institute shall—

13 “(1) designate a member of the staff of the Insti-
14 tute to act as Executive Secretary of the Council,

15 “(2) make available to the Council such staff as-
16 sistance, information, and other assistance as it may
17 require to carry out its functions, and

18 “(3) conduct a formal orientation program and
19 training sessions for new members of the Council in
20 order to provide such new members with the necessary
21 information and training for effective participation on
22 the Council.

23 “(e) The Council shall meet at the call of the Chairman,
24 but not less often than four times a year.

1 "FUNCTIONS OF THE COUNCIL

2 "SEC. 481D. The Council is authorized to—

3 "(1) review research projects and programs sub-
4 mitted to, or initiated by, such Council, relating to the
5 study of neurological, communicative disorders, and
6 stroke and certify its approval to the Secretary of any
7 such projects which it believes show promise of making
8 valuable contributions to human knowledge with re-
9 spect to such areas of study;

10 "(2) collect information as to studies which are
11 being conducted in the United States or any other
12 country with regard to neurological, communicative
13 disorders, and stroke, by correspondence or by personal
14 investigation of such studies, and, with the approval of
15 the Secretary, make available such information through
16 appropriate publications for the benefits of health agen-
17 cies and organizations (public or private), physicians,
18 dentists, or any other scientists, and for the general
19 public;

20 "(3) review applications for grants-in-aid for re-
21 search projects relating to neurological, communicative
22 disorders, and stroke, and certify to the Secretary, its
23 approval of such projects that show promise of making
24 valuable contributions to human knowledge with re-
25 spect to such areas of research;

1 “(4) recommend to the Secretary acceptance of
2 conditional gifts, pursuant to section 501, to carry out
3 the purposes of this part;

4 “(5) make recommendations to the Secretary with
5 respect to carrying out the provisions of this part; and

6 “(6) certify to the Secretary the Council’s approv-
7 al of such applications for grants-in-aid as it deter-
8 mines will best carry out the purposes of this part.

9 “EXPIRATION OF INSTITUTE AND COUNCIL

10 “SEC. 481E. The Institute and the Council shall cease
11 to exist on September 30, 1983.”.

12 TITLE III—PAPERWORK

13 REDUCTION OF PAPERWORK

14 SEC. 301. (a) In order to increase the productivity of
15 research undertaken and supported by the Department of
16 Health, Education, and Welfare, while at the same time
17 maintaining adequate accountability for the funds expended
18 for such research, the Director of the Institutes shall conduct
19 experimental programs to reduce paperwork associated with
20 the application for, and administration of, research grants.
21 Such experimental program may include—

22 (1) the elimination or modification of effort report-
23 ing by investigators for selected grants and the utiliza-
24 tion of alternative indicators of work performance,
25 including—

1 (A) periodic peer review to determine the
2 extent to which research projects have achieved
3 their intended purpose;

4 (B) audit of individual grants, on a random
5 basis, to assure that grant funds were expended
6 appropriately;

7 (2) the delegation, to nonprofit and public entities
8 engaged in health sciences research of authority to
9 approve—

10 (A) the carrying over of not more than 15
11 per centum of the grant award for a given year to
12 the next year of the grant;

13 (B) the transfer of not more than 10 per
14 centum of grant funds from one grant to another
15 grant, but only if—

16 (i) the principal investigators on both
17 grants are the same;

18 (ii) the purposes of the grants are close-
19 ly related; and

20 (iii) the transfer does not alter the pur-
21 pose of any individual grant or impair suc-
22 cessful completion of research work under-
23 taken through any grant; and

1 (3) the development of alternative methods to doc-
2 ument compliance with any requirements for cost shar-
3 ing;

4 (4) the elimination of any obligation of recipients
5 of grant funds to account for nonexpended equipment
6 when the original cost of the equipment was less than
7 \$1,000; and

8 (5) the elimination of all reporting requirements,
9 other than a final report, for individual investigators for
10 grants the applications for which were unsolicited.

11 (b) The aggregate total of all the awards for grants
12 under subsection (a)(5) shall in any year be no more than
13 one-half of 1 per centum of all funds expended by the Insti-
14 tutes. In order to assure adequate accountability for the funds
15 expended to support such grants, the requirements of subpar-
16 agraphs (A) and (B) of subsection (a)(1) shall apply to such
17 grants.

Senator KENNEDY. Senator Schweiker?

Senator SCHWEIKER. Thank you, Mr. Chairman.

I am pleased to join Senator Kennedy this morning for hearings on legislative and oversight aspects of biomedical research. Our health research enterprise has made great discoveries and contributed to important advances in our Nation's health and well-being, but enormous challenges remain to be conquered. Senator Kennedy and I introduced S. 988, the Health Science Promotion Act of 1979, on April 23 in the hope that this legislation will provide assistance to the health sciences as they face these challenges.

The desirability of developing a national policy for health research and of formulating a long-range, comprehensive plan for the health sciences has been endorsed by spokesmen for both the public and private sectors. The Institute of Medicine has recently endorsed health research planning in these terms. I quote:

We believe that health research planning, when well performed, will prove to be a valuable mechanism for developing sound and productive national health research policy. Well-conceived and executed planning is the nation's best assurance that there will be optimal allocation of resources for health research, and that precious resources will be utilized efficiently.

Title I of the Health Science Promotion Act will provide a permanent mechanism for the development of health science policy and planning. The Planning Council created in this bill will be responsive to congressional needs for scientific advice and guidance. Senator Kennedy and I will welcome suggestions from the Government and the scientific community that might further improve this planning process.

Title II of S. 988 includes authorities for the Director of the National Institutes of Health that will permit improvements in the peer review system; a flexible funding mechanism for neglected research areas as well as innovative research projects; and a guarantee of significant support levels for investigator-initiated research projects.

The third title of the bill offers the initial steps toward deregulating biomedical research and reducing the oppressive paperwork burden currently imposed on investigators and institutions. We believe that the experimental approaches in this title will enable HEW to maintain accountability while reducing the regulatory burden and the adversarial relationship between Government and academia that has replaced the atmosphere of trust present in past years.

Finally, in terms of oversight, we will focus today on the intramural and extramural programs of the National Institutes of Health. For the past 25 years these Institutes have provided a standard of excellence for the world's biomedical research community. It seems appropriate at this time for our committee to take stock of their accomplishments, evaluate the adequacy of their facilities and support, and judge whether the process and the product can be improved.

Thank you, Mr. Chairman.

Senator JAVITS. Mr. Chairman.

Senator KENNEDY. Senator Javits is going to submit his statement in the record. Senator Javits, we have some of the leading outstanding researchers from Europe here today.

Senator Javits has been, of course, a familiar figure to all of our friends from abroad.

STATEMENT OF JACOB K. JAVITS, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator JAVITS. Mr. Chairman, along with you and other members of this committee, I have been one of the constant proponents of a healthy biomedical research enterprise. Together, with the great help of Chairman Williams and our former Chairman Lister Hill, we have helped to build the National Institutes of Health into the finest center of its kind in the world.

As we begin the hearing process on the Health Sciences Promotion Act, I want to reaffirm my unwavering commitment to effective and comprehensive health sciences research.

Several years ago, we established the President's Biomedical Research Panel to review and assess the conduct, support, policies, and management of biomedical and behavioral research. After careful deliberation, the Panel issued a comprehensive report. The bill which we introduced this week raises many of the same issues the Panel addressed.

This bill provides for stronger leadership of NIH by increasing the authority of the Director and by defining the NIH in law. Of critical importance, the proposal would establish an overall planning mechanism for the research enterprise.

I believe that we can achieve our objective of strengthening health sciences research only with the help and guidance of those universities, researchers, and others who are our partners in this endeavor and will give strict attention to their needs.

Senator KENNEDY. We would like to acknowledge the presence here of the delegation from the European Medical Research Council which is meeting in Washington over the period of the next couple days. They represent the top research people in Europe in the health sciences. They are here to exchange views on research planning and research administration. We applaud their efforts and the efforts of the NIH and the Department of HEW in exchanging information. I think all of us understand that we can learn a great deal from this type of shared experience. Many of the issues that we will be dealing with at the hearings today will be discussed over the next couple days.

Members of our staff will be attending and participating in some of the meetings. We just wanted to extend a very warm word of welcome to our friends from abroad, and we welcome you to this hearing.

We will start our first panel off with some old friends in this committee: Dr. Julius Richmond, Assistant Secretary; Dr. Don Fredrickson, Director in NIH; Dr. Gerald Klerman, Director, Alcohol and Drug Abuse and Mental Health Administration; and Dr. George Pimentel, Deputy Director, National Science Foundation.

We hope to hear your views on this issue.

STATEMENTS OF JULIUS B. RICHMOND, M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; DONALD B. FREDRICKSON, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH; GERALD L. KLIERMAN, M.D., DIRECTOR, ALCOHOL AND DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION; GEORGE C. PIMENTEL, Ph. D., DEPUTY DIRECTOR, NATIONAL SCIENCE FOUNDATION, A PANEL

Dr. RICHMOND. Thank you very much, Mr. Chairman and members of the committee.

On behalf of my colleagues and on my own behalf, I want to express our pleasure at the opportunity to discuss with you today S. 988, the Health Science Promotion Act of 1979, which proposes various changes in the organization and functions of the National Institutes of Health as well as a new approach to planning health-related research conducted by the Department of Health, Education, and Welfare.

It is always a privilege to have an opportunity to engage in dialog with members of this committee who have contributed so much to the development of health sciences over the years in this country and in many ways throughout the world. Today I am sure will be no exception. I would just like to add, also, Mr. Chairman, our words of welcome to our European colleagues who are here to help us develop our programs more effectively. We look forward to the exchanges which we will be having with them.

Some of the provisions in the proposed legislation would require significant changes in HEW policies for the planning and conduct of biomedical and behavioral research. In some instances, these provisions address problems the Department has been struggling with for some time. To the degree that this bill and these hearings provide a framework for thorough consideration of these longstanding issues, a very useful purpose is served. However, because of the serious concerns raised by many of its provisions, the Department cannot support the proposed legislation as it stands.

Among the new proposals, the most significant, in our opinion, is title I, which would establish the President's Council for the Health Sciences. This 15-member presidentially appointed body would prepare a National Health Sciences Plan, to be submitted each year to the Secretary, the President, and the Congress.

In this plan, the legislation directs the Council to recommend a detailed HEW budget for biomedical and behavioral research for the coming fiscal year, and priorities for the allocation of research funds for the next 4 fiscal years.

I know you are aware, Mr. Chairman, that Secretary Califano and the HEW health agencies have been working for the best part of a year to develop a sound set of principles to guide health research planning in HEW.

Senator KENNEDY. Tell us what is the schedule. When will that be finished?

Dr. RICHMOND. That process is proceeding now beyond the point of the development of the guidelines, Mr. Chairman. We now have the critique of the Institute of Medicine and its committee which was formed for the specific purpose of reviewing the principles, and we think that we will develop our long-range proposals stemming

from the priorities which are being recommended by, sometime between August and October of this year.

Senator KENNEDY. Will it be in any shape in having an impact in terms of the budget for next year? Probably not.

Dr. RICHMOND. I think there is some potential that it might. Some of the broad budgetary guidelines for 1981 will be drawn prior to it, but it will not be too late for it to have some impact.

Now we are moving rapidly into the next phases of the process. Here principles are translated into goals, and goals are built into an actual budget strategy. Thus, we agree that a new approach to Federal planning for health research is needed. But the mechanism we chose differs. Let me sum up for you what the Department has been doing:

In the Secretary's planning initiatives, a major objective has been to involve interested members of the public—as well as those conducting research—at all stages in the planning process. This has slowed somewhat the pace of plan development, but we consider the gain in understanding and the increased agreement on the goals of health-related research to be essential, fully justifying long-term investments on this scale. First, recommendations on research support principles were solicited nationally, with hundreds of organizations, institutions, agencies, and individuals invited to respond. Much HEW staff work was devoted to interpreting and synthesizing this material. The resulting draft of research principles was then reviewed at a 2-day national conference held at the NIH last October.

It was a very lively session, Mr. Chairman, as I know some of your staff members undoubtedly reported to you.

Five panels selected by the Secretary from nominees of all of the HEW health agencies heard testimony from many public witnesses, and especially from the biomedical research community concerning concepts and policy considerations underlying the conduct of health research. Each of the panels issued a report. The conference staff then analyzed these final reports and prepared a revised set of draft principles based upon the panels' recommendations. All of these documents were published in a conference report which I would like to submit for the record, Mr. Chairman.

Subsequently, the Institute of Medicine of the National Academy of Sciences reviewed the revised statement of health research principles and published a critique earlier this year. One of the recommendations of the Institute of Medicine was that there be established a permanent health research planning mechanism.

This brings us back to the proposed legislation before us today for I believe, Mr. Chairman, that the President's Council on the Health Sciences is more or less consistent with the IOM recommendation. However, the Department has strong reservations about the proposal, which I would now like to discuss with the committee.

It appears that a freestanding public advisory body would be created which would have relatively little expertise in the day-to-day functioning of the conduct and management of the health sciences. While the view from outside research agencies and their associated communities may be valuable, this would not suffice for enlightened management of so complex a governmental operation. Even the most general kinds of agency planning require consider-

able knowledge and familiarity, not only with the nature and scope of the research areas being supported, but of the dynamics of congressional processes, including appropriations, and fixed and flexible elements in agency budgets. Yet the bill specifies very detailed planning mandates for this council.

Senator KENNEDY. You already have existing at the present time advisory councils. How are they functioning and working? How effective are they?

Dr. RICHMOND. Mr. Chairman, I think the councils which are advisory to the various Institutes, and which do provide some review and some planning, do help in the planning process for the Directors for the various Institutes. That advice and counsel feeds to the Office of the Director. I might mention the Director does have a public advisory committee which is helpful to him in the planning process and certainly in the review of plans prior to their submission to the Secretary and ultimately to the appropriate congressional committees.

I think we have an opportunity, Mr. Chairman, at the present time, to gather opinions from a wide range of sources and particularly many of the councils that have developed some particular competence and interest in relationship to the Institutes which they advise.

Senator KENNEDY. I think it works quite a bit differently in the National Science Foundation.

Dr. Pimentel, the Board itself assumes some major responsibility in policymaking in areas of science policy. Perhaps it would be appropriate at this time to give us a description of how the Board works over at National Science Foundation.

Dr. PIMENTEL. The National Science Board consists of 24 members, presidentially appointed, each for 6-year terms. The appointments are made 8 at a time on 2-year intervals and this Board is the policymaking instrument for the National Science Foundation. It members meet eight or nine times a year for a 2- or 3-day meeting. The preparatory work is done by standing committees, such as the Planning and Policy Committee, the Budget Committee, and the Programs Committee.

The Planning and Policy Committee is charged with attempting to maintain a long-range planning point of view and to address the appropriateness of NSF programs and procedures.

The Budget Committee conducts 5-year outlooks on budgetary matters, but more specifically reviews the upcoming fiscal year's budget in the light of detailed plans proposed by the Assistant Directors from NSF's seven Directorates.

The Programs Committee looks at a selection of award actions and the introduction of new programs. The award actions generally involve the larger commitments—amounts greater than \$500,000 for 12 months \$2 million over the duration of the immediate program. Any new program, however, as it is instituted, is examined in detail by the Programs Committee. Its a recommendation is forwarded to the entire Board, and the entire Board makes a final decision.

Senator KENNEDY. I am just trying to get clear in my own mind how the Science Foundation Board operates as a policymaking institute in the areas of science policy. It appears to function and

work very successfully for the National Science Foundation and why it works in areas of science policy of the National Science Foundation and why it might not be applicable in terms of the NIH?

Dr. PIMENTEL. Senator Kennedy, you reminded me of another detail of NSF operations. There also is, under the leadership of the Director of the National Science Foundation, an executive committee of the Board. It includes the Chairman of the Board and representatives of two Committees that I mentioned; they meet 10 or 11 times a year, always in conjunction with the regular National Science Board meeting.

Senator KENNEDY. Could you respond to that, Dr. Richmond.

Dr. RICHMOND. Yes, Mr. Chairman, I would be delighted to. I think all institutions are products of history and tradition, and the NIH has evolved over time in a way that is really quite different from the NSF. In my view, it is fortunate that in the two areas of science, we have somewhat different models developing, but I think each is equally effective. You will recall that NSF arose at a specific point in time. It did not evolve as the NIH did over a long period. We think that pluralism, which is currently built into the planning and policymaking process within NIH, has been a very valuable one historically. We think it has served us well. It also takes into account something which the NSF does not have and that is an intramural program, a very strong intramural program. In an effort to arrive at a balance between the intramural and extramural, the role of the advisory council for each of the Institutes has become very important in the evolution of our planning process and the development of our research policy.

As the Institutes feed up to the Office of the Director, with his public advisory committee, we can tap into public opinion, and we tap into the scientific community within the Federal establishment, as well as across the country and throughout the world.

I think the most significant dimension of this is the dialog that goes on between the NIH, its staff, and its Director, and the appropriate committees of Congress. It seems to me, Mr. Chairman, that in the interplay between the Office of Director of the NIH and the congressional committees, we have evolved what has been a very strong scientific biomedical scientific establishment.

Senator KENNEDY. What we are looking to is not just NIH, but all science policy within HEW. We are mindful, as your own statement points out, that, quoting you, "Thus we agree that Federal planning for health research is needed."

We are trying to examine whether the model that has been developed within the National Science Foundation is a formulation which at least deserves consideration for the development of science planning as far as an advisory role in terms of HEW.

Why do we not move on then.

Dr. Richmond.

Dr. RICHMOND. Just to round out some of our comments, it seemed to us that it would be difficult for a council that would meet periodically to generate the knowledge and the experience to plan the kind of detailed research agenda for the Department of Health, Education, and Welfare, including a comprehensive research budget for each of the agencies. A more appropriate role for

such a public advisory body would be to recommend overall policy for research programs and to suggest a strategy for matching research needs with available resources and opportunities over a period of several years.

This, Mr. Chairman, is what we have been trying to do through the process which the Secretary has set up and which I described for you. What I am suggesting, Mr. Chairman, is that it may be more desirable to retain a higher order of flexibility to have the Secretary evoke periodically this kind of process, rather than at this time to lock this into a firm institutional arrangement. Certainly we are in the process of gaining experience.

The National Institutes of Health, in its relatively brief history, has experienced some growing pains, has been criticized at times for not responding to congressional dollars in the same way that the space program produced technological wonders, and has taught us many lessons, through experience, in the planning and management of health-related research. Nevertheless, few would dispute that the record the NIH has established over the years has been unparalleled. NIH has indeed produced many of the notable advances in medical and biomedical research in recent years, and is now recognized as the leading institution of its kind in the world.

If we look at programs in outer space, I think it is fair to say our programs in inner space have been no less significant, and no less spectacular. Certainly these have led to the revolution in biology that we have lived through.

I would like to take a moment to mention just a few of the current successes achieved by NIH or NIH-supported scientists. Recent advances in the understanding of the interaction of hormones with receptor sites on cell surfaces, the product of many years of basic research, now hold promise for the treatment of endocrine diseases such as diabetes. Studies on the differences in gene expression between normal cells and those altered by a tumor-producing virus suggest that an understanding of the mechanism underlying cancer may soon be within our grasp. And advances in the use of recombinant DNA techniques have revolutionized the study of gene expression and its control. These procedures are now also being applied to the production of scarce biological materials. It should be noted that the discoveries which led to the development of recombinant DNA methods grew out of investigations on why one strain of bacteria was susceptible to infection by a bacterial virus while a nearly identical strain was resistant.

The health research principles exercise is helping to bring into focus in a definable way, the basis for which the NIH and other HEW research agencies have been planning research in the past. Thus, what is already a successful enterprise promises to work even better. But the body of knowledge and experience upon which we have had to draw in order to bring us to where we are today is vast. It is unlikely, therefore, that an independent body which is assembled only occasionally for the purpose of research planning, regardless of how its membership were to be constituted, could ever acquire the knowledge and experience or be able to devote the necessary time to effectively plan in detail a research agenda so broad and diverse as that encompassed by HEW. For these reasons,

Mr. Chairman, we must oppose the creation of the President's Council for the Health Sciences.

An additional feature of S. 988 which the Department finds rather disturbing is the provision to terminate all of the Institutes—with the exception of NCI and NHLBI—at the end of fiscal year 1983. To quote the language of the draft, each Institute and advisory council shall "cease to exist" at the end of that period. I should like to point out that such a provision is fundamentally different from a periodic reauthorization of appropriations such as that which exists for the National Cancer Institute and the National Heart, Lung, and Blood Institute. If the intention of this provision is to force congressional oversight, it would appear that this proposal is going about it in an inappropriate way. While congressional oversight is both important and necessary, to demand it at a time when Congress may be very busy or preoccupied with other matters may result in it being far less thorough than it ought to be. Would it not be better that Congress perform its oversight functions at times when it can go about it in a thorough and thoughtful manner? Holding this hearing now in the absence of a statutory deadline is an excellent example of how oversight should be conducted.

Mr. Chairman, you stated in the April 23 Congressional Record that you "find it inconceivable that the Congress would ever fail to renew the mandates" of these Institutes. However, in 1978, because of the tremendous volume of legislation before the 95th Congress in its final days, the bill reauthorizing the National Cancer Institute and the National Heart, Lung, and Blood Institute was not passed until in the closing minutes of the 95th Congress, too late to be taken into account in the appropriations bill. The health planning bill, along with scores of others, never came to a vote. However, because of the research authority granted to the Department of Health, Education, and Welfare under section 301 of the Public Health Service Act, both the Cancer and Heart, Lung, and Blood programs could be included in the regular appropriations act. And other programs can be sustained through continuing budget resolutions, even if the reauthorization bills fail to be voted upon. However, in view of the way in which the "sunset" provisions are drafted, it is doubtful that the Institutes could continue to operate, should Congress fail to act, and that is the bill's intent as I understand it. In view of the failure of the 95th Congress to consider many pieces of legislation, I cannot share your confidence that the mandates of the institutes would be guaranteed continuation.

The research institutes of the National Institutes of Health are much more than programs on paper. They are buildings, they are people, and they are ongoing research programs. It is something quite different from other Federal programs of payment for services or welfare. It is an enterprise unto itself. While the operation of Harvard University may be far from perfect, one would not consider writing a law that Harvard University would cease to exist as of a certain time. Other more appropriate mechanisms exist for correcting problems within any ongoing institution or program. The same is true of the Institutes of the National Institutes of Health. Therefore, Mr. Chairman, we would consider it an unfortunate mistake to write into public law that such a precious

asset and resource as the National Institutes of Health be given its right to exist in such precarious terms. And is it not inconsistent with the notion of a permanent mechanism to plan research over a 5-year period even to allow the possibility that a major part of the activity toward which the planning is directed faced a somewhat uncertain future?

The NIH has been a highly successful venture in the past, in large part because of the attention and support given it by Congress. This relationship has flourished without statutory "sunset" provisions, as I hope it will continue to do in the future.

There are a number of other provisions about which I would like to comment briefly. While it is commendable to wish to support basic science and particularly the NIH extramural program by requiring that no less than 45 percent of the NIH funds be used for investigator-initiated unsolicited research proposals, we believe that stipulating a fixed percentage, in this case 45 percent, might under some circumstances pose an unreasonable constraint upon the Director of the National Institutes of Health. And, as you know, the appropriations process in Congress is highly unpredictable. Clearly, in a lean year, possibly such as fiscal year 1980, we will do our best to preserve, above all else, our support of individual and program project research grants. Nevertheless, there may be circumstances where going below a fixed number might be necessary. In fiscal year 1979, approximately 44 percent of NIH's budget went to grants in this category. In addition, as science becomes more and more successful and we know more and more about fundamental biological processes, the structure of research fund allocation may well change, with an increasingly larger fraction of research funds going into applied research and development. That this principle bears true is illustrated by the different fraction of total resources devoted to science base and to application in the various Institutes of the National Institutes of Health. While I may seem to be arguing against what I consider the most important function of the NIH, I only wish to point out that, because the future is intrinsically unpredictable, it is unwise to write into law something that cannot be changed easily.

Senator KENNEDY. You used now the figure 44 percent in terms of research. What has been the record of the NIH over a period of years? Is that represented, does that represent a pretty fair ballpark figure?

Dr. RICHMOND. I think I might, if you permit, ask Dr. Fredrickson, who has been involved in this much longer, to comment on that.

Dr. FREDRICKSON. Mr. Chairman, if we take the project grant first as the base for this question, I believe that the percentage is now higher than it has been in perhaps the preceding past 7 years. There has been a trend during the last 10 years toward more contract research. Clearly that trend has begun to be reversed and at present this particular aspect remains the most protected of our single resource allocations. It is somewhat higher, I guess, in total percentage.

Senator KENNEDY. You certainly would not let it go below certain levels. Has there not been a range over a period of time?

Dr. FREDRICKSON. It has been relatively constant. Certainly in absolute terms, the differences are greater among the Institutes than for NIH aggregate over the years. At any 1 year that is so. [Information supplied for the record follows:]

NIH-ADA-DFM-BF7B
June 15, 1979 7

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
NATIONAL INSTITUTES OF HEALTH

Research Grants - Research Projects, FY 1972-1979
(Obligations in thousands)

Appropriation	1972 Actual		1973 Actual		1974 Actual ^{1/}		1975 Actual ^{2/}		1976 Actual ^{3/}		1977 Actual		1978 Actual		1979 Estimate	
	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total
Cancer.....	\$83,241	22%	\$104,886	24%	\$140,811	24%	\$174,025	25%	\$215,464	28%	\$227,596	28%	\$253,961	29%	\$276,774	30%
Heart.....	100,912	43	107,218	42	142,348	44	131,676	40	165,167	45	190,059	48	209,192	47	245,303	48
Dental.....	14,165	33	14,997	37	17,251	34	17,560	35	18,866	37	21,032	38	24,061	39	26,244	40
Arthritis.....	93,413	61	91,482	64	111,622	63	114,240	66	125,720	72	136,509	62	159,184	61	185,201	61
Neurology.....	51,549	44	47,702	44	68,230	48	66,084	46	69,789	50	68,578	44	78,898	45	102,089	48
Allergy.....	54,646	50	55,266	54	63,346	52	63,326	53	69,431	55	74,829	53	85,675	53	109,821	57
General Medical....	73,806	43	75,537	49	87,172	46	100,610	53	112,333	60	127,302	62	148,534	64	193,564	70
Child Health.....	52,148	45	50,937	46	72,883	51	77,235	54	69,591	51	74,639	51	87,246	53	106,402	53
Eye.....	18,654	51	18,748	55	26,453	59	26,776	61	32,379	65	37,770	59	56,678	67	72,268	69
Environmental.....	8,962	34	8,839	34	12,098	38	12,935	36	14,998	41	18,295	33	22,832	36	28,371	36
Aging.....									9,824	51	16,810	56	20,792	56	32,264	57
Total..	551,496	37	575,612	39	742,214	38	784,467	38	903,562	41	993,419	41	1,147,053	42	1,378,301	45

^{1/} Includes 1973 appropriation restoration. ^{2/} Includes 1974/75 funds. ^{3/} Excludes Transition Quarter.

NOTE: Revised for comparability to the new research grant structure.

Senator KENNEDY. Isn't this an issue which the basic research community cares very deeply about, that is having the assurances that over any period of time that there is going to be a certain minimum standard which is going to be available for investigator-initiated research?

Dr. FREDRICKSON. I think this is of the highest importance to that community, and I think also to all of us, to all the citizens in America, and indeed the world. I think that should be a basic principle, that the support through HEW, as well as other agencies, of fundamental research on biological processes and behavior should have very high priority. It must be maintained in a stable way. I think that principle can be defended without getting into statutes in such specific terms.

Dr. RICHMOND. Mr. Chairman, on this point I would just reinforce what Dr. Fredrickson has said. We are very cognizant of the need to protect our basic research efforts, and certainly I think we have all been pleased that the President and his science adviser and your subcommittee have indicated their concern about protecting that. I feel, Mr. Chairman, that we do have an appropriate review process. We have been through a process of consciousness raising, if you want to call it that, particularly through the research principles effort. We hope to protect that allocation.

Senator KENNEDY. I suppose the question comes when you have a different Director of the NIH, or HEW, or others in responsibility. I think this is something that we have to give thought to.

Senator CRANSTON. I want to say, despite my great interest in this hearing, I have a commitment that drags me elsewhere. I did want to ask some questions that I will submit in writing to you and I appreciate very much your answers. I am very concerned, increasingly concerned, about the difficulties that it seems to me newly emerging researchers, researchers that may have innovative, creative breakthrough type perceptions and thoughts to pursue, are not getting adequate opportunity through the present system. It seems to me that perhaps there should be more generalists involved in the study group and in the peer review system, more people with multidisciplinary concerns and approaches and background. I have some specific questions that I will submit to you.

It is a matter that I am going to be pursuing with great interest, and I appreciate the opportunity hearing from you briefly today and I will be studying carefully what you have to say.

[The questions referred to by Senator Cranston and answers supplied by HEW follow:]

QUESTIONS SUBMITTED BY SENATOR CRANSTON WITH ANSWERS FROM
THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Q. 1. S. 988 directs the Director of N.I.H. to establish a grant appeals process.

A. What is your view on requiring a written description of the appeals process to be provided to each applicant along with the grant application forms?

Answer: The current informal appeals system is implemented through the submission of a revised application which is prepared by the investigator-appellant. By the time the revision is prepared, the investigator has received the copy of the summary statement which is the substantive critique of the action being appealed. Experience has shown that the submission of a revised application is an efficient and effective way to appeal all or part of the substantive determinations of peer reviewers. Every effort is made to facilitate the reconsideration of such revised requests.

The current informal system also provides for appeals consideration where there is a perceived (by the applicant), or actual, incorrect, inappropriate, or inadequate initial review group assignment for scientific merit review.

Details of the current informal appeals system are described in the Guide to Grants and Contracts, Vol. 7, No. 10, August 4, 1978 (attached). It is also routinely described at national scientific meetings or at other public meetings of scientific groups. The description of the current informal appeals system could easily be included in the application packet.

B. Last year Dr. Fredrickson rejected a proposal by the grants peer review study team (G.P.R.S.T.) to set up an ombudsman system for appeals.

What other methods would you suggest for the structure of the appeals process required by S. 988?

Answer: Dr. Fredrickson has not rejected the ombudsman and formal appeals system recommended by GPRST. Implementation of a formal system is pending examination of the fiscal, administrative, and legal issues inherent in setting up such a system. Of particular concern is the additional cost for staff and space which will be required to activate it.

The Director and his staff, therefore, are collecting data on the effectiveness of the current informal appeals system prior to embarking on the more complicated formal appeals system recommended by GPRST. During this study period, the Associate Director for Extramural Research and Training (ADERT) acts in the capacity of ombudsman as needed.

Q. 2. S. 988 provides for "the inclusion of non-biomedical scientists on selected Peer Review groups" but does not deal with the structure of study sections.

What is your view on broadening input on certain study sections by including generalist scientists (scientists with broad interests and experience) as members?

Answer: The NIH peer review system is a two-tiered (dual) review system. The initial review for scientific merit is performed by non-Federal consultants (Study Sections) whose scientific expertise is in the area of research covered by the grant application, with a second level of policy and broad programmatic review by the National Advisory Councils. Generalist scientists, as needed or as considered appropriate, often are appointed as members of National Advisory Councils where their broad perspective, along with that of lay people, is most important and appropriately applied. To include generalist scientists on the study sections would blur the important distinction between the two tiers of the peer review process and potentially do harm by reducing the positions available for critically needed specialists in a wide variety of scientific disciplines.

Q. 3. The bill provides for a discretionary fund to be used by the Director to fund innovative, unconventional, and other unusual research proposals. Last year the Grants Study Team recommended that the study sections set up a mechanism whereby innovative proposals, whether recommended for approval or not, would be flagged for special consideration by the advisory councils. This was rejected on the ground that this would create a separate class of proposals and might work to the disadvantage of the applicant. When the Senate Appropriations Committee, in its report on the fiscal year 1979 Labor-H.E.W. appropriations, directed N.I.H. to report on ways in which the study group and peer review council can be stimulated to place greater emphasis on supporting newly emerging researchers and investigator-initiated innovated approaches to resolving fundamental research questions, the same response was given. In his reply to the task force recommendation and to the Appropriations Committee, Dr. Fredrickson stated that study sections should be encouraged to identify, evaluate, and call attention to innovative aspects of proposals in their summary statements.

A. To what extent is this being done: that is, how many or what percentage of summary statements flag innovative aspects and what percentage of these grants receive funding when compared to those without such comments?

Answer: Each Executive Secretary is expected to, and does, alert the initial review group at each round of meetings to a number of issues requiring special attention. High on the awareness list is the obligation to identify proposals with innovative aspects. The summary statement (pink sheet) calls attention, where it is relevant, to the innovative issue. The staff of the awarding

units have the responsibility (with the advice of their National Advisory Councils) to determine whether the particular application(s) is of sufficient significance to be recommended for funding. (See attached excerpts from pink sheets referring to "unique," "innovative," "high risk," etc., elements of the application.) We have not routinely gathered statistics of the type requested. To assemble these specific statistics would require a manual search of thousands of files and is impractical within the time and staff available.

B. How would you propose to identify innovative proposals for possible funding from the discretionary fund to be set up under S. 988?

Answer: Were a discretionary fund to be set aside for supporting innovative applications, managing the fund would be the responsibility of the Director, NIH. Applications proposed for consideration for the discretionary fund would be referred by each Institute, after each round of Council meetings (three times yearly) or, alternatively, once yearly. As one option, the Director, NIH, would seek advice from the Director's Advisory Committee, which in turn could seek additional assistance as necessary from specialists in the research area of the innovative project. Alternatively, the Director, NIH, could set up a special Advisory Committee made up of present or former members of the Institutes' Advisory Councils. The Committee could function on a regular or an ad hoc basis to advise him on the use of the discretionary fund. In either case, the designation of innovative projects would continue to be made initially by an initial review group and concurred in by an Advisory Council. Because nominations of potential members for initial review groups have been invited from the scientific community, there is now a greater likelihood than heretofore that initial review groups will include individuals who may be receptive to innovative research projects.

C. The bill requires that grants funded from this discretionary fund be subject to "appropriate Peer Review." How could the peer review process be changed from the current process, which is characterized by many scientists as "conservative," to assure a better chance of funding for these high-risk or innovative proposals?

D. Are there additional steps which might be taken to stimulate and fund innovative research?

Answer: (C & D) Applications identified as innovative which were recommended for disapproval or given a low priority for payment could be site visited routinely as part of the initial review for scientific merit. The site visitors would be required to include specialists suggested by the applicant and specialists suggested by NIH staff.

All scientists are anxious to see worthy innovative and/or high-risk research supported. One reason for rejection of an "innovative" proposal is the failure of the investigator to document his or her application clearly, precisely, and explicitly. The lack of specificity may be intentional in that the applicant frequently feels that the reviewers will not "understand" his research because it is in the forefront of the discipline and the reviewers are not his peers. Consequently the proposal may be sketchily or incompletely stated. Precisely because a proposal is unique, it is incumbent upon the applicant to prepare a meticulously documented application with an explicit statement as to the significance of the proposed research.

When an innovative proposal is presented by a young, relatively inexperienced investigator, the funds requested are modest, and the period of support is of reasonably short duration, then the reviewers are often willing to "gamble" on the reasonable expectation of success. However, when the innovative researcher is experienced and fails to provide adequate documentation, it sometimes becomes virtually impossible for the reviewers to find a basis for support. In keeping with the letter and spirit of the Public Health Service Act, the award of an NIH research grant must be for a prospectively described project.

Another reason for rejection is the reluctance of scientific consultants to gamble on a costly, long-term venture where the expectation of success is tenuous. In the current environment of increasing competition for funds, the reviewers are aware that any time a proposal fails, the money will have been used at the expense of worthy projects which were not funded. Therefore, in times of fiscal stringency, high-risk innovative research is more likely to be rejected in favor of traditional or more conservative research.

Q. 4. One criticism of the current system is that multidisciplinary research proposals have a hard time getting funded.

A. What ways are there to encourage funding of interdisciplinary proposals?

Answer: That multidisciplinary projects have difficulty in being funded is an unsubstantiated criticism. Program projects, research center proposals, and other multidisciplinary or interdisciplinary grant applications are encouraged. Carefully conducted initial reviews take into account an Institute's program mission and goals. A project site visit is frequently made a part of the review. The range of funding for approved multidisciplinary grant applications, which varies from Institute to Institute, is from 30-45% of extramural funds. It is our experience that

well-conceived, meritorious multidisciplinary grant applications have an excellent chance of being funded. The approval rate for these applications bears out their success during the course of the present study section and council review procedures.

B. Wouldn't changing the composition of councils and study sections to include scientists with broad interests and experience help to achieve funding of interdisciplinary proposals?

Answer: As stated above, scientists with broad interests and experience serving on Advisory Councils are already providing the necessary insights to assure adequate funding of approved inter- or multidisciplinary proposals.

Q. 5. What steps could be taken to assure that the 5-year plan proposed by S. 988 is flexible enough to allow inclusion of scientific breakthroughs as they occur?

Answer: So long as the five-year plan makes adequate provision for the support of investigator initiated research, there is little reason to fear that scientific breakthroughs will be missed or unduly delayed. Fostering such initiative has been a hallmark of NIH programs and no doubt would be an important feature of any five-year plan with which the NIH was involved.

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INFORMAL PRE-AWARD APPEALS PROCESS**NOTICE**

Recommendations 62-69 of the NIH Grants Peer Review Study Team are concerned with the establishment of a formalized grants appeals system. The Director's decision regarding this set of recommendations was that they be further studied in the light of legal, fiscal, personnel, and other implications associated with adopting the recommendations. He further directed that in the interim, immediate consideration be given to making the function and operation of the present informal appeals system widely known. The following statement is being publicized in accordance with the Director's decision.

Study Section members make judgments on grant applications based on their interpretation of what is presented in the written application and at a site visit. Reviewers and applicants do not always view proposed studies in the same light, and occasional differences of opinion are to be expected. If the principal investigator believes that there are deficiencies, errors, or misunderstandings in the review group's assessment of the application, he or she may submit a revised application for re-review. The introductory section of the revised grant application should contain: (1) documented rebuttal of the Study Section's criticism, i.e., new information or correction(s) or other changes to reply to the deficiencies pointed out in the Summary Statement and (2) an indication of the modifications in the application that reflect the areas of criticism with which the principal investigator agrees. Additional specific procedural information is listed on page 10 of the Information and Instruction for Application for Research Grant brochure enclosed in each research grant application kit.

Experience has shown that the submission of a revised application is an efficient and effective way to appeal all or part of the substantive determinations of peer reviewers. The National Institutes of Health will do everything possible to facilitate the reconsideration of such revised requests.

FROM

GUIDE TO GRANTS AND CONTRACTS, VOL. 7, No. 10, AUG. 4, 1978

GM 26500, Membrane Potential and Neurospora Adenylate Cyclase (CMBD)
Gene Scarborough, University of North Carolina

"... has a unique tool to test this exciting possibility and to investigate the molecular nature of a novel type of enzyme regulation."
(priority score, 145)

GM 18872-05, Stereochemistry in Valine and Leucine Metabolism (P-T)
Donald Aberhart, Catholic University

"It certainly would be a gamble, but, if we wish to support a research program which couples considerable insight and meticulous technique with high risk, then this does seem to be a most worthwhile endeavor."
(priority score, 141)

GM 25136-01, Product Ratios and Microsomal Multiplicity (P-T)
William Trager, University of Washington

"The proposed mathematical treatment of data obtained from microsomes that contain multiple monooxygenases with overlapping substrate specificities may not be sufficient for critical resolution, but should be tried."
(priority score, 210)

GM 23550-01, Genotypic Selection: Syntax and Structure of Sequences (GEN)
George Piecznik, Rutgers University

Concerning a proposal to test theories on the selective value of various DNA structures, the study section called it very original and important. "The question being asked is of fundamental importance to biology and no one else seems to be working on it in this very original and insightful, though slightly unorthodox, way."
(priority score, 138)

GM 22909-04, Protein-Nucleic Acid Cross-Linking Reagents (GEN)
Peter Dervan, California Institute of Technology

His "approach is innovative and worth trying." He is an assistant professor, Ph.D. 1972.
(priority score, 137)

GM 25886-01, Properties of Nuclease-Resisting Mouse Chromatin (GEN)
Kenneth Marx, Dartmouth

"In spite of serious reservations because of the unpredictable outcome of these studies, approval is recommended. The study section felt that "at times one must be willing to take a chance, and this seems to be one of those times."
(priority score, 225)

GM 12427-16, The Organization of Animal Cell Nuclei (GEN)
Joseph Gall, Yale

"The proposal presents an appropriate balance between clearly feasible experiments and other less certain, but highly promising, experiments..."
(priority score, 103)

Senator KENNEDY. Thank you.

Why do we not proceed?

Dr. RICHMOND. There are two references, Mr. Chairman, made in S. 988 to the funds set aside for evaluations under section 513 of the Public Health Service Act. The bill would allow up to one-half of the funds allocated under this section to be used for research evaluation. However, the proposed legislation states that the Council shall approve all such expenditures. It is the Department's position that it is inappropriate for the President's Advisory Council, should it be passed into a law, to have the authority to override decisions of the Secretary or the agency directors. If such a Council were ever to be created, it should remain purely advisory.

The other provision concerning section 513 funds would allow up to one-half of such funds to be used for other research rather than evaluation. In fact, part of the research supported under this section is to be "innovative or unconventional in character." That is the very issue to which Senator Cranston just addressed himself. At present, the National Institutes of Health makes every attempt to support such research, in keeping with its commitment to the support of fundamental science as discussed earlier. Efforts are also made to support research in areas which may have been neglected in the past, or which are multidisciplinary in nature. Therefore, we believe this provision is unnecessary.

Senator KENNEDY. One of the matters that we are very much interested in is the issue of evaluation. We have been interested in that for some period of time. It is my understanding that, first of all, NIH has been required to use its own resources for its evaluation in the program. And second, that the General Accounting Office, in reviewing the NIH's evaluation felt that because the NIH is using its own resources and contacts with the various groups questioned whether it is getting the true kind of independent evaluation which would be essential for its program. I can understand why NIH is interested in evaluation. It is not going to be able to get the additional resources from an independent kind of source. It is a commendable attitude that it still wants evaluation being done, even if they use their own resources.

But this is something I think would be somewhat troublesome. I would be interested in hearing comments on that issue. GAO has looked at this and at least raised this issue with the Congress, and I would be interested in what your response would be.

Dr. RICHMOND. I think I might ask Dr. Fredrickson to make some comments.

Dr. FREDRICKSON. The fraction of the set-aside funds that we use at NIH, which is by no means the whole, is directed toward scientifically planned examination of many aspects of our program. I personally supervise and go over the plans annually and listen to the reports, so I think that we are using those moneys effectively. Sometimes the moneys go actually to fund evaluation by other outside bodies which are entirely independent, such as the Academy or the Institute of Medicine. I think it is possible for us to spend our own money and yet get a hard look from an independent and objective observer. I think that that is not impossible.

Senator KENNEDY. What do you have for organization of staff within the NIH for evaluation?

Dr. FREDRICKSON. We have an office for Program Planning and Evaluation in the Director's office. It has a small staff whose whole job is to guard carefully the quality of the hypotheses and the moneys spent for evaluation. They run the annual program. They help me evaluate it with each Institute in turn, and at this very time I am in the middle of my cycle of evaluating each Institute, what it hopes to use these moneys for, what it has discovered, what we think collectively of the quality of ideas. We have an active, continuing analysis.

Senator SCHWEIKER. How large is that staff?

Dr. FREDRICKSON. I think we have a staff of about three people in the Director's office. Of course they work with the planning offices of each of the Institutes.

Senator SCHWEIKER. How many would be totally involved?

Dr. FREDRICKSON. I would guess perhaps 15 people or more will be actively involved with some portion of their time during the year in watching and supervising these contracts for evaluation.

Senator SCHWEIKER. They are also responsible for planning?

Dr. FREDRICKSON. Yes. We also bring in other members of NIH staff on an ad hoc basis to review proposals of the Institute, so we can have a free play of critique and make sure these are as useful as possible.

Senator KENNEDY. You say they are charged with planning responsibilities and they make decisions on how they are going to allocate resources. How, in their position as evaluators, as to whether that is a wise allocation of resources, can they be completely without some bias?

Dr. FREDRICKSON. NIH is a rather free community; it is not afraid of self-criticism.

Senator KENNEDY. That is the first organization I have heard of.

Dr. FREDRICKSON. We certainly have to defend its proposals and expenditures collectively against the whole community.

Senator KENNEDY. I would be interested in the amounts of evaluation that are done by outside boards. Maybe we could get additional information on that.

Dr. Fredrickson I would be glad to submit for the record a detailed account of that over the last several years.

[Information supplied for the record follows:]

EVALUATION PROJECTS STATUS INFORMATION

As of June 1979, NIH has 41 evaluation projects ongoing that are supported from Evaluation Set-Aside Funds (PHS Act Sec. 513). An additional 15 projects have been completed during the past eighteen months. From this set of 56 projects, 12 (or 21%) have been identified as being done by "outside boards" in the sense of meeting the following criteria for "independence" and relevance:

1. The work was performed by either an ad hoc panel of experts, (often with contractor support) where the charge to the panel provided for an independent assessment and required a report to high level program management, or was performed by an organization known for its independence and arms length relationship with the NIH, such as the National Academy of Sciences, and
2. The study is a program evaluation, a state of the research assessment, or provided evaluative information to be used in management decision making.

Excluded from that list are projects conducted by various consulting firms, and by principal investigators at academic institutions where the work performed was of a more directed nature and often done by a principal investigator and a small team. Also excluded are evaluation projects whose purpose was to develop evaluation methodology, conduct surveys, literature review, etc., but not to directly evaluate NIH programs, support mechanisms, or major components. The projects identified as meeting the above criteria are as follows:

<u>Project No.</u>			<u>FY 78 & 79 Set-Aside \$ in Thousands</u>	<u>Project Status</u>
<u>Project Title</u>	<u>Performer/Contractor</u>			
NIH 75-1				
Personnel Needs & Training for Biomedical & Behavioral Research Personnel	National Academy of Sciences		\$1,850	Ongoing
NIH/NCI 79-303				
Analysis of Federally Sponsored Research in Low Level Ionizing Radiation	National Academy of Sciences		800	About to start

<u>Project No.</u>			<u>FY 78 & 79 Set-Aside \$ in Thousands</u>	<u>Project Status</u>
<u>Project Title</u>	<u>Performer/Contractor</u>			
NIAMDD 74-1				
Evaluation of Research Needs in Nephrology and Urology	Ad hoc Evaluation Panel Chaired by Carl W. Gottschalk Univ. of North Carolina	--		Complete
NIAMDD 77-1				
Evaluation of Research Needs in Endocrinology and Metabolic Diseases	Ad hoc Evaluation Panel Chaired by Sidney Ingbar Beth Israel Hospital Boston, MA	177		Ongoing
NIAMDD 77-3				
Evaluation of Needs and Priorities of Dermatologic Research	Ad hoc Evaluation Panel Chaired by George Odland Univ. of Washington Seattle, WA	126		Ongoing
NIAMDD 78-2				
Evaluation of the Hematology Program of NIAMDD in Rela- tion to Identification of Research Needs	Ad hoc Evaluation Panel Chaired by Ernest Jaffee Albert Einstein College of Medicine Yeshiva Univ., NY	75		Ongoing
NIDR 76-1				
Evaluation of the NIDR National Caries Program	Ad hoc Evaluation Panel and support from CDP Associates, Inc. Rockville, MD	--		Ongoing
NICHD 77-1				
Evaluation of NICHD Mental Retardation and Population Research Centers	Ad hoc Evaluation Panel and support from Orkand Corporation Silver Spring, MD	120		Complete
NINCDS 78-3				
Review and Assessment of NINCDS Research Strategies	Ad hoc Evaluation Panel and support from CDP Associates, Inc. Rockville, MD	225		Ongoing

Project No.		FY 78 & 79	
Project Title	Performer/Contractor	Set-Aside	Project Status
		\$ in Thousands	
DRR 77-1			
Evaluation of Primate Research Centers	Ad hoc Evaluation Panel and support from JRB Associates McLean, VA	--	Complete
DRR 77-5			
Survey of Laboratory Animal Facilities and Resources Supporting Biomedical Research	Institute of Laboratory Animal Resources National Academy of Sciences	--	Ongoing
NLM 77-1			
Evaluation of Laboratory Animal Data Banks	Institute of Laboratory Animal Resources National Academy of Sciences	--	Complete
Total FY 78 & 79		\$3,373	

An indication of the relative cost of these projects is provided by noting that the \$3.4M spent on these projects from set-aside funds in FY 78 and FY 79 (combined) represents approximately 40% of the total NIH set-aside expenditures for FY 78 and FY 79 estimated at \$8.2M. The Congressionally mandated study on Personnel Needs and Training for Biomedical Research being done by the National Academy of Sciences (NIH 75-1) is the single largest draw on evaluation set-aside funds.

Dr. RICHMOND. I would just add to this, Mr. Chairman, that, as the Institute of Medicine has grown in its stature and its capacity to perform studies, we find ourselves increasingly drawing not only on their standing committees, but on ad hoc task forces as we identify problems for study, and we think that is a process which is useful. We have convened other ad hoc groups from time to time.

I think we are not insensitive to the need to go outside for objective reviews from time to time.

The intent of title III, to take steps to reduce the burden of paperwork connected with research grants, is commendable. However, the Department has adequate authority to solve these problems administratively, without the enactment of new legislation. For example, NIH has designed a greatly simplified research grant application form, now awaiting approval by OMB.

Senator KENNEDY. Has that been its primary recommendation? Have there been other recommendations as well?

Dr. RICHMOND. I am not sure I understand the question.

Senator KENNEDY. You have designed a research grant application form. Have they made other recommendations to facilitate the process?

Dr. FREDRICKSON. I think this is the first thrust, Mr. Chairman, of a recent attempt to examine this very question of increasing burden.

The second is to look at the question of longer range funding, which I think is intimately wrapped up with the question of how predictable is the support for research? We find, in consulting study sections with which we are constantly involved, these questions keep changing form. For example, study sections are very reluctant, in a period of this type of austerity, to recommend longer periods of support. But I think this is something we still must direct ourselves to.

With regard to a third aspect, we are examining the question of whether we need to use old funds in a given calendar grant year that might provide for carryover. We think we have the authority to do this without statutory change. We have not done it in the past for administrative reasons, but we are examining that question as well.

Senator KENNEDY. As I understand, Dr. Pimentel, the National Science Foundation has been experimenting in this area as well.

Dr. PIMENTEL. Yes, sir, that is correct.

Senator KENNEDY. Could you very briefly comment on what they are doing and what your initial response and reaction have been?

Dr. PIMENTEL. We have attempted to respond to the feeling that paperwork and accountability requirements are beginning to obstruct the research activities we are trying to support. We have tried to be responsive while maintaining an appropriate accountability. At the beginning of 1978, we simplified the grant closeout procedure, eliminating some individual and final fiscal reports.

We also have combined certain requirements—summary of completed projects and the final technical report which were somewhat redundant—into a single form.

We have encouraged longer term grants as a means of reducing the number of times a scientist must submit his proposals for peer

review and decision. We are moving toward more 3-year, continuing grants.

Last fall, we asked the scientific community to limit formal proposals to 15 single-spaced, typed pages, exclusive of the bibliography. Our purpose is to reduce the demands that have been tending to mount to demonstrate knowledge of all of the conceivably relevant literature, thereby producing excessive documentation of intent. We want to leave enough opportunity for clearer statements of the proposed research.

Our most recent experiment is called the master grant approach to project support; this is an experiment being conducted with the AAU. Its first objectives are to reduce paperwork and to increase the effectiveness of research projects, for example, by increasing the amount of sharing of equipment, particularly of expensive instruments, and other resources. We feel it also may provide greater authority for local decisionmaking on day-to-day activities and may improve accountability for the expenditure of funds. We accomplish the latter by clearly defining the grantee's responsibility in these various activities and by providing well-stated standards for local decisionmaking delegations. The master grant brings under a single contractual agreement all of the research projects proposed within a particular fiscal year from a single disciplinary department. At present, our experiments with master grants are in chemistry departments at perhaps six or eight universities.

Within these grant instruments there are specified conditions under which certain local decisionmaking delegations can be made. Recordkeeping can be on the basis of the aggregate of the activities, according to the local option, as long as the total activity is well accounted. We are particularly interested in sharing of resources, and we have final decision on any significant change of scope or personnel involved.

These experiments are just beginning; a couple more will be negotiated soon. Within 2 or 3 years, we hope the master grant will successfully address the problem of reducing paperwork and still maintaining accountability. If so, we will expand it to other disciplines.

Senator SCHWEIKER. Let me ask one question. How does the appeals procedure work in the National Science Foundation?

Dr. PIMENTEL. We have two levels of appeal. Initially, an investigator can address to the program officer a request to hear an explanation of declination and to see the verbatim, anonymous peer reviews of his proposal.

If the investigator is dissatisfied, he may then request a reconsideration in writing from the cognitive Assistant Director.

There are certain stipulations. The request must be filed within 180 days after the declination, and NSF must respond in 30 days. That is the first level of appeal.

At the second level, if the investigator is still dissatisfied, the submitting institution may request a second reconsideration, which is directed to me as Deputy Director of the National Science Foundation. Once again NSF must respond within 30 days.

At the first and second levels of reconsideration—the first by the Assistant Director, the second by the Deputy Director—the NSF official addressed may make a reconsideration personally, or more

often, another individual is designated within the Foundation who has appropriate expertise but was in no way involved in any earlier examination of the proposal.

We examine the administrative judgment of the scientific merit of the proposal. We ask for additional peer review, if there is any reason to believe the decision was made on inadequate or unfair peer reviews. Finally, we monitor the number of appeals in each of our Directorates on a quarterly basis. These quarterly reports come to me. I hear of every request for a reconsideration and its disposition.

Senator SCHWEIKER. Dr. Richmond, please go ahead and finish your testimony.

Dr. RICHMOND. We are mindful of some of the experiments that NSF is attempting. Dr. Fredrickson is in constant touch with Dr. Pimentel to try to follow this, and we hope to learn from their experiences with these new approaches.

I would just add again that one of the problems in changing the system is that by and large there is a high degree of satisfaction on the part of the scientific community with a process that they think has served them well, but nonetheless, we keep raising with them the issue of further simplification.

Finally, I would like to comment on the provisions respecting peer review. The proposed legislation requires the Director, NIH, to establish a grant appeals process for individuals and institutions denied funds following application for a grant under title IV.

Mr. Chairman, we are acutely aware that from time to time individual cases arise when the system is not very efficient in resolving differences of opinion between applicants and reviewers. We are working to correct this situation and at the same time to prevent the overall system, which provides for the review of over 15,000 NIH grant applications annually, from being needlessly overburdened.

The NIH has given a great deal of attention to ways in which the peer review system can generally be improved. Several changes are now being instituted. I would like to bring to your attention two which are directly related to the issue of appeals. The first builds on the existing procedure and involves changes which will make the preparation and review of revised applications simpler and more efficient. Unsuccessful applicant investigators have always been encouraged to revise their original requests in the light of the peer reviewers' findings. This procedure provides an opportunity to express agreement or disagreement with each criticism and to modify or reaffirm the corresponding sections of the original application. Our new procedure will greatly facilitate this approach.

Second, we are developing a new procedure for those instances in which the applicant may wish to rebut, point by point, the findings of the reviewers. Specific guidelines for NIH staff on handling these rebuttals are being prepared to enable us to resolve these differences on a uniform, direct, and timely basis.

We believe that instituting a continuing series of refinements such as these is a flexible and constructive approach to the question of appeals. These kinds of changes are experimental and we would like the opportunity to try them out before formally establishing an appeals mechanism. We simply do not yet know the

perfect procedure. Moreover, such an appeals process should apply equally to all agencies in the Department of Health, Education, and Welfare conducting research through the investigator-initiated grants mechanism, not simply to NIH.

To summarize, Mr. Chairman, we believe that the proposed legislation has been of great value in raising for discussion many important issues which concern us, both regarding the planning and the conduct of health-related research. However, the Department currently has the statutory authority it needs to address these problems. The health research principles initiative is but one example of the many ways in which we are continually taking steps to improve the effectiveness of our health research agencies and their responsibilities in meeting public needs. It is important that we retain the greatest flexibility in our authorities in order to best meet these responsibilities. Even the statutory creation of the NIH could limit this flexibility.

The HEW health research enterprise has enjoyed a long and fruitful relationship with Congress, one which we wish to continue to nourish and strengthen. But we believe that our mutual desires to continually improve the Nation's health will not be best served by the passage of S. 988.

Thank you very much, Mr Chairman, for the opportunity to appear before you this morning, and my colleagues and I will be glad to entertain additional questions.

[The prepared statement of Dr. Richmond follows:]



FOR RELEASE UPON DELIVERY

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT BY

JULIUS B. RICHMOND, M.D.

ASSISTANT SECRETARY FOR HEALTH

AND

SURGEON GENERAL

BEFORE

THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

April 26, 1979

Mr. Chairman and Members of the Committee:

I am glad to be able to discuss with you today Senate bill S. 988, the "Health Science Promotion Act of 1979," which proposes various changes in the organization and functions of the National Institutes of Health as well as a new approach to planning health-related research conducted by the Department of Health, Education, and Welfare.

Some of the provisions in the proposed legislation would require significant changes in HEW policies for the planning and conduct of biomedical and behavioral research. In some instances, these provisions address problems the Department has been struggling with for some time. To the degree that this bill and these hearings provide a framework for thorough consideration of these long-standing issues, a very useful purpose is served. However, because of the serious concerns raised by many of its provisions, the Department cannot support the proposed legislation.

Among the new proposals, the most significant, in our opinion, is Title I, which would establish the President's Council for the Health Sciences. This 15-member Presidentially-appointed body would prepare a National Health Sciences Plan, to be submitted each year to the Secretary, the President, and the Congress.

In this plan, the legislation directs the Council to recommend a detailed HEW budget for biomedical and behavioral research for the coming fiscal year, and priorities for the allocation of research funds for the next four fiscal years.

I know you are aware, Mr. Chairman, that Secretary Califano and the HEW health agencies have been working for the best part of a year to develop a sound set of principles to guide health research planning in HEW. Now we are moving rapidly into next phases of the process. Here principles are translated into goals, and goals are built into an actual budget strategy. Thus, we agree that a new approach to Federal planning for health research is needed. But the mechanism we chose differs. Let me sum up for you what the Department has been doing:

In the Secretary's planning initiatives, a major objective has been to involve interested members of the public--as well as those conducting research--at all stages in the planning process. This has slowed somewhat the pace of plan development, but we consider the gain in understanding and the increased agreement on the goals of health-related research to be essential, fully justifying long-term investments on this scale. First, recommendations on research support principles were solicited nationally, with hundreds of organizations, institutions, agencies, and individuals invited to respond. Much HEW staff work was devoted to interpreting and synthesizing this material. The resulting draft of research principles was then reviewed at a two-day national conference held at the NIH last October.

Five panels selected by the Secretary from nominees of all of the HEW health agencies heard testimony from many public witnesses, and especially from the biomedical research community concerning concepts

and policy considerations underlying the conduct of health research. Each of the panels issued a report. The conference staff then analyzed these final reports and prepared a revised set of draft principles based upon the panels' recommendations. All of these documents were published in a conference report which I would like to submit for the record, Mr. Chairman.

Subsequently, the Institute of Medicine of the National Academy of Sciences reviewed the Revised Statement of Health Research Principles and published a critique earlier this year. One of the recommendations of the Institute of Medicine was that there be established a permanent health research planning mechanism.

This brings us back to the proposed legislation before us today for I believe, Mr. Chairman, that the President's Council on the Health Sciences is more or less consistent with the IOM recommendation. However, the Department has strong reservations about the proposal, which I would now like to discuss with the Committee.

It appears that a free-standing public advisory body would be created which would have relatively little expertise in the day-to-day functioning of the conduct and management of the health sciences. While the view from outside research agencies and their associated communities may be valuable, this would not suffice for enlightened management of so complex a governmental operation. Even the most general kinds of agency planning require considerable knowledge and familiarity, not only with the nature and scope of the research areas being supported, but of the dynamics of Congressional processes, including appropriations, and fixed and flexible elements in agency budgets. Yet the bill specifies very detailed planning mandates for this council.

It is difficult to imagine that a council that would meet, at the most, one or two days a month could ever amass the knowledge and experience to plan a detailed research agenda for DHEW, including a comprehensive research budget for each DHEW health agency. A more appropriate role for such a public advisory body would be to recommend overall policy for research programs, and to suggest a strategy for matching research needs with available resources and opportunities over a period of several years.

Other provisions of Title I of the proposed legislation also cause concern. The council is directed to identify those areas of health science activity which in its opinion have been relatively underfunded or are relatively underdeveloped in relation to their potential. However, because the results of research are not always easily foreseeable, that would almost seem to be an extraordinarily difficult task. It would be much easier to plan research if the potential of developing a particular area of science were known in advance. But, in fact, most of the time it is not. Therefore, it would seem entirely inappropriate to write into law a directive that is indeed counter to the nature of science itself.

Another provision of the bill specifies that the council should incorporate in its plan, recommendations for funding research "directly relevant" to the prevention of disease, the treatment and cure of disease, and the rehabilitation of victims of disease. While some research may be properly directed toward specific human diseases, the relevance of much fundamental research, at the time of its inception,

is not immediately apparent. One must not underestimate the importance of serendipity in science. Many major research advances have come from totally unexpected areas of investigation. Some of the most important contributions to medicine and public health have come from imaginative and innovative ideas which, at the time they were proposed, showed no immediate promise for any practical application. Indeed, Mr. Chairman, whatever mechanism we ultimately agree upon for the planning of health research must take into account the uncertain nature of the acquisition of knowledge. While the heart of the enterprise we call "science" may at times be fickle, we must ensure that it will always maintain a strong and steady beat.

The National Institutes of Health, in its relatively brief history, has experienced some growing pains, has been criticized at times for not responding to Congressional dollars in the same way that the space program produced technological wonders, and has taught us many lessons, through experience, in the planning and management of health-related research. Nevertheless, few would dispute that the record the NIH has established over the years has been unparalleled. NIH has indeed produced many of the most notable advances in medical and biomedical research in recent years, and is now recognized as the leading institution of its kind in the world.

I would like to take a moment to mention just a few of the current successes achieved by NIH or NIH-supported scientists. Recent advances in the understanding of the interaction of hormones with receptor sites on cell surfaces--the product of many years of basic research--now hold

promise for the treatment of endocrine diseases such as diabetes. Studies on the differences in gene expression between normal cells and those altered by a tumor-producing virus suggest that an understanding of the mechanism underlying cancer may soon be within our grasp. And advances in the use of recombinant DNA techniques have revolutionized the study of gene expression and its control. These procedures are now also being applied to the production of scarce biological materials. It should be noted that the discoveries which led to the development of recombinant DNA methods grew out of investigations on why one strain of bacteria was susceptible to infection by a bacterial virus while a nearly identical strain was resistant.

The health research principles exercise is helping to bring into focus in a definable way, the basis for which the NIH and other HEW research agencies have been planning research in the past. Thus, what is already a successful enterprise promises to work even better. But the body of knowledge and experience upon which we have had to draw in order to bring us to where we are today is vast. It is unlikely, therefore, that an independent body which is assembled only occasionally for the purpose of research planning, regardless of how its membership were to be constituted, could ever acquire the knowledge and experience or be able to devote the necessary time to effectively plan in detail a research agenda so broad and diverse as that encompassed by HEW. For these reasons, Mr. Chairman, we must oppose the creation of the President's Council for the Health Sciences.

An additional feature of S. 988 which the Department finds rather disturbing is the provision to terminate all of the Institutes (with the exception of NCI and NHLBI) at the end of fiscal year 1983. To quote the language of the draft, each Institute and advisory council shall "cease to exist" at the end of that period. I should like to point out that such a provision is fundamentally different from a periodic reauthorization of appropriations such as that which exists for the National Cancer Institute and the National Heart, Lung, and Blood Institute. If the intention of this provision is to force Congressional oversight, it would appear that this proposal is going about it in an inappropriate way. While Congressional oversight is both important and necessary, to demand it at a time when Congress may be very busy or preoccupied with other matters may result in it being far less thorough than it ought to be. Would it not be better that Congress perform its oversight functions at times when it can go about it in a thorough and thoughtful manner? Holding this hearing now in the absence of a statutory deadline is an excellent example of how oversight should be conducted.

Mr. Chairman, you stated in the April 23 Congressional Record that you "find it inconceivable that the Congress would ever fail to renew the mandates" of these institutes. However, in 1978, because of the tremendous volume of legislation before the 95th Congress in its final days, the bill reauthorizing the National Cancer Institute and the National Heart, Lung, and Blood Institute was not passed until in the closing minutes of the 95th Congress, too late to be taken into account in the appropriations bill. The health planning bill, along with scores of others, never came to a vote. However, because of the research

authority granted to the Department of Health, Education, and Welfare under Section 301 of the Public Health Service Act, both the Cancer and Heart, Lung, and Blood programs could be included in the regular Appropriations Act. And other programs can be sustained through continuing budget resolutions, even if the reauthorization bills fail to be voted upon. However, in view of the way in which the "sunset" provisions are drafted, it is doubtful that the institutes could continue to operate, should Congress fail to act, and that is the bill's intent as I understand it. In view of the failure of the 95th Congress to consider many pieces of legislation, I cannot share your confidence that the mandates of the institutes would be guaranteed continuation.

The research institutes of the National Institutes of Health are much more than programs on paper. They are buildings, they are people, and they are ongoing research programs. It is something quite different from other Federal programs of payment for services or welfare. It is an enterprise unto itself. While the operation of Harvard University may be far from perfect, one would not consider writing a law that Harvard University would cease to exist as of a certain time. Other more appropriate mechanisms exist for correcting problems within any ongoing institution or program. The same is true of the institutes of the National Institutes of Health. Therefore, Mr. Chairman, we would consider it an unfortunate mistake to write into public law that such a precious asset and resource as the National Institutes of Health be given its right to exist in such precarious terms. And is it not inconsistent with the notion of a permanent mechanism to plan research

over a five-year period even to allow the possibility that a major part of the activity towards which the planning is directed faced a somewhat uncertain future?

The NIH has been a highly successful venture in the past, in large part because of the attention and support given it by Congress. This relationship has flourished without statutory "sunset" provisions, as I hope it will continue to do in the future.

There are a number of other provisions about which I would like to comment briefly. While it is commendable to wish to support basic science and particularly the NIH extramural program by requiring that no less than 45% of the NIH funds be used for investigator-initiated unsolicited research proposals, we believe that stipulating a fixed percentage--in this case 45%--might under some circumstances pose an unreasonable constraint upon the Director of the National Institutes of Health. And, as you know, the appropriations process in Congress is highly unpredictable. Clearly, in a lean year, possibly such as fiscal year 1980, we will do our best to preserve, above all else, our support of individual and program project research grants. Nevertheless, there may be circumstances where going below a fixed number might be necessary. In fiscal year 1979, approximately 44% of NIH's budget went to grants in this category. In addition, as science becomes more and more successful and we know more and more about fundamental biological processes, the structure of research fund allocation may well change, with an increasingly larger fraction of research funds going into applied research and development. That this principle bears true is illustrated by the

different fraction of total resources devoted to science base and to application in the various institutes of the National Institutes of Health. While I may seem to be arguing against what I consider the most important function of the NIH, I only wish to point out that, because the future is intrinsically unpredictable, it is unwise to write into law something that cannot be changed easily. Fixed percentages for this or that program have, because of changing needs, never been particularly successful in the past. Therefore, Mr. Chairman, the Department opposes this provision.

Two references are made in S. 988 to the funds set aside for evaluations under Section 513 of the Public Health Service Act. The bill would allow up to one-half of the funds allocated under this section to be used for research evaluation. However, the proposed legislation states that the council shall approve all such expenditures. It is the Department's position that it is inappropriate for the President's Advisory Council, should it be passed into a law, to have the authority to override decisions of the Secretary or the agency directors. If such a council were ever to be created, it should remain purely advisory.

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which may have been neglected in the past, or which are multidisciplinary in nature. Therefore, we believe this provision is unnecessary.

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Finally, I would like to comment on the provisions respecting peer review. The proposed legislation requires the Director, NIH, to establish a grant appeals process for individuals and institutions denied funds following application for a grant under Title IV.

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The NIH has given a great deal of attention to ways in which the peer review system can generally be improved. Several changes are now being instituted. I would like to bring to your attention two which are directly related to the issue of appeals. The first builds on the existing procedure and involves changes which will make the preparation and review of revised applications simpler and more efficient. Unsuccessful applicant investigators have always been encouraged to revise their original requests in the light of the peer reviewers' findings.

This procedure provides an opportunity to express agreement or disagreement with each criticism and to modify or reaffirm the corresponding sections of the original application. Our new procedure will greatly facilitate this approach.

Second, we are developing a new procedure for those instances in which the applicant may wish to rebut, point by point, the findings of the reviewers. Specific guidelines for NIH staff on handling these rebuttals are being prepared to enable us to resolve these differences on a uniform, direct, and timely basis.

We believe that instituting a continuing series of refinements such as these is a flexible and constructive approach to the question of appeals. These kinds of changes are experimental and we would like the opportunity to try them out before formally establishing an appeals mechanism. We simply do not yet know "the perfect procedure." Moreover, such an appeals process should apply equally to all agencies in the Department of Health, Education, and Welfare conducting research through the investigator-initiated grants mechanism, not simply to NIH.

To summarize, Mr. Chairman, we believe that the proposed legislation has been of great value in raising for discussion many important issues which concern us both regarding the planning and the conduct of health related research. However, the Department currently has the statutory authority it needs to address these problems. The health research principles initiative is but one example of the many ways in which we are continually taking steps to improve the effectiveness of our health research agencies and their responsibilities in meeting public needs. It is important that

we retain the greatest flexibility in our authorities in order to best meet these responsibilities. Even the statutory creation of the NIH could limit this flexibility.

The HEW health research enterprise has enjoyed a long and fruitful relationship with Congress, one which we wish to continue to nourish and strengthen. But we believe that our mutual desires to continually improve the nation's health will not be best served by the passage of S. 988.

Thank you very much, Mr. Chairman, for the opportunity to appear before you this morning.

Senator KENNEDY. Thank you very much, Dr. Richmond. We appreciate your comments.

I think what we are faced with, listening to your testimony and also your responses, is that we have HEW committed toward planning interdisciplinary considerations within the Department. Those recommendations are going to come up later on this year and have some impact on budgetary considerations. We are very much aware of the outstanding leadership of Dr. Fredrickson and yourself and others in the Department in looking down the road on the development of health science research.

We are also mindful at least on this committee of other periods in our history where we have not had those in leadership positions that have been as sensitive to these particular issues. We are trying to get this discussion going with this legislation.

We have OMB on the one hand making recommendations to the Congress for certain budgetary considerations for NIH, because historically the Congress boosts those up, and therefore in the administration's budget they can say they put those recommendations much lower, because they can always depend on Congress and constituencies that have a particular interest group to raise the figures. We find other areas which are extremely important in terms of health science research, perhaps having gotten the dramatic types of support, and we have seen over a period of time that perhaps the interest or support for those is not as forthcoming as it should be from a scientific point of view, from a research point of view. We see these fluctuations and changes coming annually in the congressional kinds of priorities. There is very little pressure on the Congress to bring itself into a position of accountability. We need a panel that has viewed these various research priorities to make the recommendations. HEW is not bound. There is no requirement of binding, but there are some recommendations in making these judgments based upon both the opportunities as well as the responsibilities of this panel and council. As you point out in your own observation, there have to be some alterations, there has to be some change. NIH has important responsibilities in the areas of scientific research using a somewhat different type of approach

panel. We are immensely proud, obviously, of the achievements and accomplishments of the NIH, as we are of the NSF, but we are very mindful that there is a different mood and attitude in the Congress.

In the past it was really whatever the research community wanted was what the NIH and what HEW was going to get.

Those days are past. You could see it in terms of budget resolutions that were being debated and discussed last evening into the early hours of the morning, and the budget appropriation requests, the ceilings that have been placed. It concerns me very deeply about how we are going to establish some kind of structure which will be, as we have in this legislation, advisory; that will encourage the response of HEW, response to these types of recommendations, a measuring device by which the Congress as well can evaluate both what OMB is requesting, what HEW is requesting, and what its own performance is.

We do not have that measurement now or that measuring device. We might not have the right formula in terms of the process or procedure which could provide that. We are wide open to suggestions and recommendations about how you fashion or shape that particular instrument. I am not sure, based upon your testimony, that we are going to be very much different when we follow the recommendations of HEW a year from today or 2 years from today and 5 years from today. The things that concern me are whether we are really coming to grips with the fashioning and shaping of health science research and policy in the most effective way.

Dr. RICHMOND. Mr. Chairman, we are very mindful of the kinds of issues you have raised and we are also mindful of the fact that there have been times when administrations have not been as supportive of the research enterprise as many of us would have liked. We think it has been very fortunate but also very effective that the appropriate congressional committees, through either oversight or the authorization and appropriation processes, have been very effective in maintaining the momentum of our research establishment. We would hope, with a Secretary who has set in motion a 5-year planning process, that you can appreciate that we are concerned about stability of support. We would like to be able to make those projections.

Having said that, Mr. Chairman, and again I would emphasize the importance of congressional activity in oversight and in authorizations and appropriations, I think that it is important to emphasize that the present pluralistic approach seems to work reasonably well, with input from our intramural professionals, the Directors of our Institutes, their advisory bodies, the Director and his public advisory committee, and the Office of the Secretary. I would also add that the Assistant Secretary's office serves as a coordinating mechanism with other health-related research in the Public Health Service, and all of these seem to have worked reasonably well in arriving at an effective enterprise for biomedical research.

I would just add one other comment, Mr. Chairman, and that is that at a time when people throughout the country are increasingly concerned about the complexity of government, the burden of the many processes that have been put into place, and many of the

regulatory burdens, we feel that another layer between the Department and the Congress in our planning process might pose more difficulties than it would resolve. I guess what I am saying is, Mr. Chairman, we think that the dialog between your subcommittee, for example, and the Department is a very lively, helpful, and effective one and from our vantage point we do not see the significant advantages that would be gained by interposing something that we do not now have.

Senator KENNEDY. We in Congress have basically been very much involved in the disease of the month syndrome, and we have been superimposing that in terms of the research community. I think there is very little that you can fashion and shape within HEW, your own kinds of priorities. You send them over to OMB, and they send you back a marker and that becomes administrative policy. We do not have an independent group or quasi-independent council to get the advice on the budgets, on the priorities that are free from the taint of politics in the broadest sense. A body that is close to the administering department, but also can be responsive to the needs of Congress. I do not know how you come out yourselves on the questions about the relative allocation of resources, and mental health researchers versus occupational health researchers, versus research in smoking. If we are to maintain both the confidence and the acceptability and the enthusiasm of the research community, we are going to need a better way of dealing with these issues than we have in the past.

Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

Dr. Fredrickson, I wonder if you could just briefly summarize for me, so that we have a frame of reference as to how the overall planning mechanism works now; in terms of the Institute, your role, HEW's role.

Dr. FREDRICKSON. Yes; I would be very glad to do that, Senator Schweiker. It might be of assistance to you if I may use one chart.

Senator SCHWEIKER. You are allowed one chart. Go ahead.

Dr. FREDRICKSON. The terms I will use will appear there and perhaps be a useful reinforcement.

Basically the planning process at NIH is a continuous one. It is one which begins at the level of the Institutes themselves, interacting with their own public advisory groups, with their staff and the communities which they support in various disease and noncategorical areas. They derive for themselves a plan, in many instances at least a 5-year plan, some examples of which we can provide for you. Each of these plans contains a projection——

Senator SCHWEIKER. Does each Institute provide a 5-year plan?

Dr. FREDRICKSON. Not every Institute yet.

Senator SCHWEIKER. The NINCDS and the National Eye Institute have long range plans; how many other Institutes do this?

Dr. FREDRICKSON. I would say slightly more than half. At least that many are having an annual planning process that is part of a projection based on interaction with their council.

Senator KENNEDY. I do not think they had that before, Dr. Fredrickson.

Dr. FREDRICKSON. I do not think there were as many, Mr. Chairman.

Senator SCHWEIKER. I think the diabetes plan that we initiated was one of the first ones, as a matter of fact, and I am delighted to see the idea going on.

Are the others planning?

Dr. FREDRICKSON. Yes; they are. Each year another Institute begins this kind of exercise. The most recent to come out with one was the Neurological Institute.

Senator SCHWEIKER. Very impressive.

Dr. FREDRICKSON. The wisdom of the Congress dividing NIH into these Institutes makes for better oversight and concentration of expertise in a particular area. These annual activities that go on within these constituencies then are brought to a central focus in an annual exercise that is conducted by my own office. Each year I meet with each of the Institutes for a long period of time. We go over their plans and their budget, an activity which includes an examination of their whole resource allocation broken down into a new matrix which we have begun to experiment with so we can better understand where we are spending our money. That includes their ambitions, what they would like to do if they had more money, the priorities that they would put against those enhancement values. All of this is summarized in a lengthy report which is available as a matter of record, not only to me and to the Institute but to all the Institutes, so that collectively they begin to understand precisely what the other Institutes are attempting to do. This includes all the Institutes research divisions and the National Library of Medicine, but it also includes from five to seven trans-NIH issues—one of which is diabetes—where we meet with a special committee representing all Institutes having activities in these areas to develop overall trans-NIH plans and projections in the same way.

When we finish this exercise, which takes about 6 weeks, we emerge with a profile or projection of where the Institutes are against the mark provided by the Department. I also have a much clearer idea of not only their specific programs but what they would like to do, and how they propose to go about it.

This is an experiment, but also administration. There have been an incredible number of different ways to try to relieve the burden, to make research more responsive to the needs of the scientist, and to the public. We are constantly seeking descriptions of these, trying to bring them down into manageable packages, so we can understand and project to Congress and the administration where we are spending our money, where we would like to spend it in next year's budget and perhaps 5 years from now.

I think in response to part of what the chairman was saying, that one of the objectives of the whole planning process at NIH now being translated into all the health research agencies in HEW as we have been in the last few months is to provide a description of the research activities in this country so we can more effectively explain to Members of Congress what we really are trying to do, and how we make our allocations against the constituency requests and inquiries that they have. I think that one of our objectives must be to make it clearer and easier to follow a set of principles in specific terms as we present the budget and discuss authorizations with you.

If I could just show you very briefly, Mr. Chairman, and Senator Schweiker, you see before you there a simple projection of an allocation map of all NIH in the aggregate. On your left you will see three bars which are called the science base—science base being all the allocations for research that may be either laboratory or clinical, but which has as its purpose the discovery of fundamental processes, new mechanisms, without being specifically targeted to practical intervention in the health world.

On the right side you will see three bars, the first of which is application, very typically targeted toward intervention, diagnostics, or treatment. It includes development of vaccines and a number of other contract activities.

The smaller bar in the middle is what we call technology transfer. Those are activities in demonstration, education, and promotion—activities that correspond to our sister Institutes that have much larger missions in the areas of care, prevention and so forth.

Finally, the last bar is training. An equally important aspect of the support for research in this country certainly is provision for renewal of the rapidly metabolized investigators within the system, and we think part of that must be supported by Federal means, as you as an authorizing committee have long agreed.

Going back to the science base, it is divided into three bars. The largest bar on your right is the project grants. Investigator-initiated research project and program project grants.

The next bar—again in aggregate for NIH—represents other kinds of research resources. These include center grants, core grants, the biomedical research support grants which go to institutions on a formula basis to allow them more flexibility during the year. There are the general clinical research centers, combined instrumentation on a regional national basis, and a whole variety of mechanisms to make research more effective or to collectivize it and make it more accountable.

Finally, there are included in the science base activities in the Government's own laboratories in the NIH, the intramural program.

Each of our Institutes can follow the same breakdown, and have different profiles, depending on the area we are talking about. Some areas are much more mature, some beginning. So for all of NIH you see this projection. We can provide it for each of them. It gives us some means of tracking things that are of great interest to the Congress and ourselves.

[The charts referred to follow:]

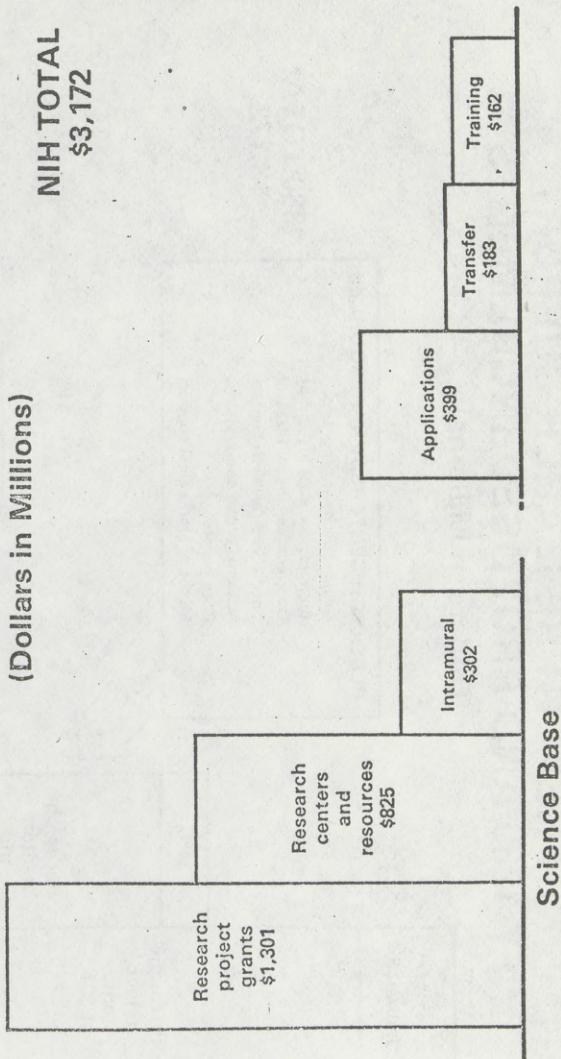
**SCIENCE BASE, APPLICATIONS, TRANSFER,
TRAINING (SATT)**

AS APPLIED TO

**NIH HEALTH RESEARCH SUPPORT
FY 1980 PRESIDENT'S BUDGET**

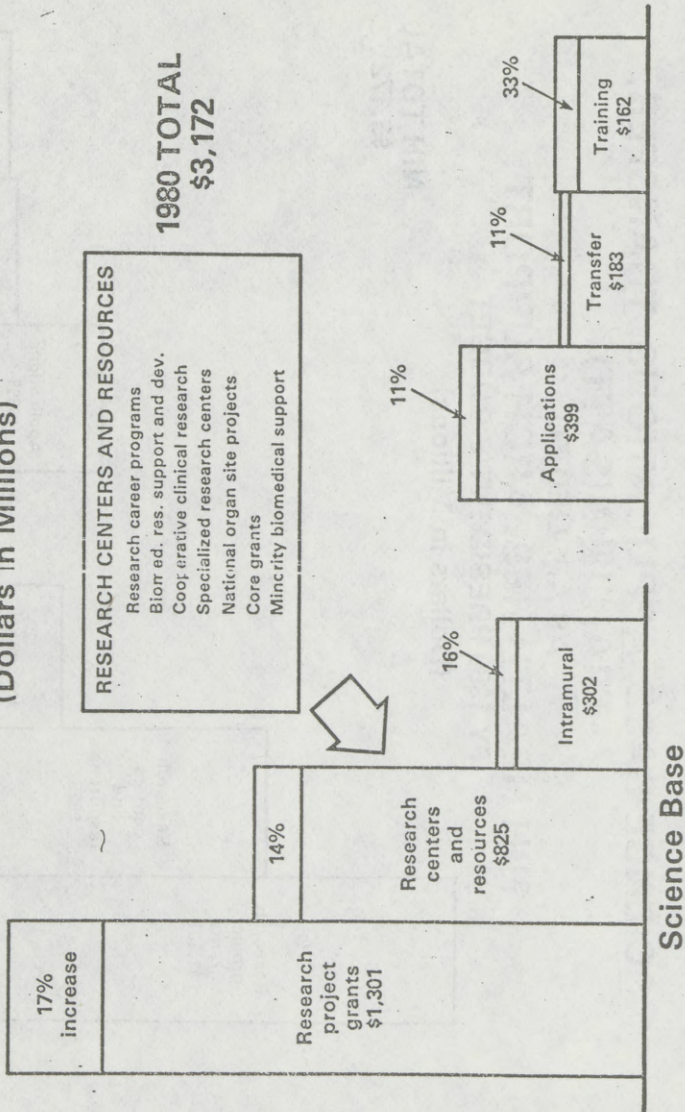
(Dollars in Millions)

**NIH TOTAL
\$3,172**



NIH HEALTH RESEARCH SUPPORT FY 1980 AND PROPOSED INCREMENTS

(Dollars in Millions)



Senator SCHWEIKER. Once you put together a plan, it must at some point interact with OMB. Once they have made a judgment as to whether they agree with your plan and budget, what is your recourse if you feel you have been shortchanged? In other words, what is the next mechanism if you feel OMB has not given you a fair shake?

Dr. FREDRICKSON. We have three opportunities.

The first is to go to the Surgeon General, the head of the Public Health Service, and discuss with him our perception of allocations within the Public Health Service budget. We have an appeals mechanism, and we justify that against the plan we are presented. Often we have one hearing with OMB during the budget cycle where we may do the same.

Third, we have access to the Secretary. We have a direct opportunity to indicate in our arguments why we would like to see things go the other way.

Senator SCHWEIKER. If the Secretary does not agree with the OMB decision, what is the final recourse?

Dr. FREDRICKSON. I have heard that the Secretary is known to disagree.

Senator SCHWEIKER. Who adjudicates that?

Dr. FREDRICKSON. I think he may on occasion take this to the Executive Office, the Cabinet, or the President himself.

Senator SCHWEIKER. The real issue is whether a President's health science council would improve that process. I suppose that is the real thrust of my questions here. Do you see any advantage in having a Presidential body, such as envisaged in this bill, to intercede on behalf of the biomedical research community when there is an obvious difference between the commitments that OMB makes and the desires of the research community? Would this be an advantage or not, as you see it?

Dr. FREDRICKSON. I think that the objective is most important, just as is the objective of this hearing. Some continuity, and agreement of principles is important between Congress and the administration.

My question about such a body is, would it be persuasive enough? Given a month or a year to understand the complex business of all the health agencies engaged in research, I am not persuaded it could do this. It could not do it as effectively as could an organization within the Department itself, acting along certain lines that have been agreed upon with Congress and the administration on a long-range basis, not nearly as well as that group could do it if it were attempting to make these adjustments and projections.

Senator SCHWEIKER. Do you have such a group in mind? I am not clear from Dr. Richmond's answer that we are anywhere near to such a group or where we stand on the critique of the situation.

Dr. FREDRICKSON. I think we are a lot further along than we ever have been. This is the first time in my memory that all the HEW health agencies—all that have research programs or need research information for their missions—have sat down and begun to examine the principles, as is being done in this exercise the Secretary put in motion last April. I think we are going to come to an agreement. We are going to be talking about things in research

that were never coordinated before. We are struggling, trying to find ways now to put this in packages, so that we can give you, the American people, everyone, a complete display of where is all the health research in this country, not only in HEW and the National Science Foundation's contribution, but in the private sector.

I have a series of charts to do that. I will not bore you with them now. But it can be done. Particularly we are trying to experiment with this very basis of projection I showed you today across the whole of the Department.

Senator SCHWEIKER. When might we see a model that the committee can look at?

Dr. FREDRICKSON. I should think we can do that within a fairly short time, Senator Schweiker. We are trying to get an agreement, beating out agreements among our agencies, each of which has a different orientation. They have got their turf and problems, and we have to understand the needs and requirements and capabilities of all these agencies, and see if we can talk with a common language. It is difficult to talk about microbiology on the one hand and some aspect of health services research on the other. It must be done.

Senator SCHWEIKER. What does short time mean?

Dr. FREDRICKSON. Our whole objective with the Secretary's planning process is that we must within, the next couple of months, have finished with recommendations, and certainly I believe it must be the Secretary's intention to share these with Congress. If you in Congress do not agree with them, I think we are wasting our time. Principles within 1 month. Then during the next 2 or 3 months we have to be converting these into the kind of analysis I have just shown you for NIH, analysis to allow us to know not only where we are, but what we want to try for in terms of enhancements, tradeoffs, and budget setting within all these health agencies for 1981. That is where we are moving now, and then by October or by September we will have that as a basis of the arguments for the 1981 budget. The next step is projecting that back for 4 or 5 years in an attempt to get some multiyear strategic dimension that is also very important. We have to get common terms. We have to come to grips with the need for a basis for analysis and choice making. We have to provide the choices to Congress and to the administration too, in terms that everybody agrees we understand, that allow us to make those real decisions that are crucial for the public to make. I think, Senator Schweiker, those are choices that you cannot, as a member of Congress, retreat from. Nor can it be provided for you by a public committee which meets a couple of months a year. They can be helpful. They can go along in parallel to the process, but I think that basically we have got to come to you on a set of terms that we all understand and agree should be the basis for our projection and argument.

Senator KENNEDY. If the Senator would yield, the fact is, as you point out, this is the first time in history that this group has ever gotten together.

Dr. FREDRICKSON. You are right, Mr. Chairman.

Senator KENNEDY. So with all of our problems with our Council meeting just periodically, it may very well have a better track record than what has been done in the past. But as I understand

what you are suggesting, it is that you are going to outline a process and procedure within HEW to achieve that.

Maybe you would just tell us briefly where you are going to be in 2 years from now or 3 years from now in this process. How are we going to be assured that we will have a Secretary of HEW and a Director of NIH that are going to be as interested and committed as you are. How do we know we are not going to backslide?

Dr. FREDRICKSON. Surely it will be difficult to provide the ideal mechanisms by statute or philosophy, Mr. Chairman, but I think if we could agree in a very thorough public scrubbing on a set of principles, then we might be able to write the objectives for the way we go about making decisions on health research for a decade or so, even though many of us as principals will have disappeared. We are trying to seek agreement on these principles among a very broad community and it certainly must include the Congress as we go along.

Senator SCHWEIKER. Do you want to comment, Dr. Richmond?

Dr. RICHMOND. Just to reinforce what Dr. Fredrickson has said, we are gaining experience with this process. It is new. I think as we go through it, whether we would want to recycle that process periodically and recommend to the Secretary that that be done, or whether we would propose some other form of institutionalization, I think it is too early to say. We think it has been a very exciting process, one which we are learning a great deal about, and as a consequence of our learning we hope that we will be able to provide a good deal of information to those of you in Congress who have the responsibility for viewing these issues, so that we think in another couple of years we will be in a better position to make some recommendations.

Senator SCHWEIKER. Did you say a couple of years?

Dr. RICHMOND. As we come to the end of this process.

Senator SCHWEIKER. I hope we are talking about a little shorter time frame than that, Dr. Richmond.

Dr. RICHMOND. We will be reviewing the process, and whether we will recommend—

Senator SCHWEIKER. That encourages this committee to move ahead, I might say, if we are really going to talk about a couple years. I am certainly willing and it is perfectly appropriate to give you folks adequate time to respond. I hope you can do it in less than a couple years.

Dr. RICHMOND. Senator Schweiker, the chairman asked where we would be in a couple of years. What I was suggesting is that by that time we would have some recommendations in place, and the process we are going through would be completed this time.

Senator SCHWEIKER. I thought I heard 1 or 2 months from Dr. Fredrickson, in terms of something we could get our teeth into and analyze to assess differences of opinion and the merits of your proposal, which may have some good points. I hope we do not get too far away from that time frame.

Dr. RICHMOND. We have some other health research in our Department, particularly in our Alcohol, Drug Abuse, Mental Health administration. With regard to your question concerning what the planning process is really like, I do not know whether you would

like to hear from Dr. Klerman, who is Administrator of that agency.

Senator SCHWEIKER. The average length of tenure of a Deputy or Assistant Secretary is 22 months around here. I hope we would do this in less time than the average tenure of the Deputy Secretary. That is one of the problems we have in government. I think you folks have some good and constructive ideas, but I think it is important to bring them into fruition in a time frame we can relate to meaningfully.

That is all.

Senator KENNEDY. Thank you very much.

Dr. RICHMOND. Thank you.

Senator KENNEDY. Our next panel consists of six Directors from NIH. We will hear from Dr. Arthur Upton, Dr. Jay Moskowitz, Dr. Donald Whedon, Dr. Ruth Kirschstein, Dr. Carl Kupfer, Dr. Herbert Pardes.

I know none of you have a prepared statement, but perhaps each of you would give a couple minutes response or comment briefly. I think you have a sense about what our concern is in the development of science research priorities within NIH and what mechanisms can be established that would help us, in the Congress, to help the American people, also help HEW, help the Institute, for which you have an important responsibility in directing and leading. I think you probably caught the flavor of the hearing.

Perhaps each of you would like to make a brief, just a couple-minute comment on it.

Dr. Upton, you are sitting right in front of us here. We will start off with you.

STATEMENTS OF ARTHUR C. UPTON, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE; JAY MOSKOWITZ, Ph. D., DIRECTOR, PROGRAM PLANNING AND EVALUATION, NATIONAL HEART, LUNG AND BLOOD INSTITUTE; G. DONALD WHEDON, M.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES; RUTH KIRSCHSTEIN, M.D., DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; CARL KUPFER, M.D., DIRECTOR, NATIONAL EYE INSTITUTE; HERBERT PARDES, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH, A PANEL

Dr. UPTON. Thank you, Mr. Chairman.

I am indeed grateful for the opportunity to meet with the committee again today. This committee has, over the years, shown unusual understanding of the nature of the cancer problem, through support for efforts to confront that problem and solve it.

I think the purposes surrounding this hearing today are clear to all of us. We are living in a time of increasingly tight resources. There is the need to look ahead wisely and to use judiciously the resources that may become available to us. I have no other remarks at this time. I am grateful for the opportunity to discuss these timely and important issues.

Senator KENNEDY. Dr. Moskowitz.

Dr. MOSKOWITZ. Thank you again for inviting us. We have found at the National Heart, Lung, and Blood Institute, since enactment of the 1972 Act, that planning has become a very integral part of

our activities. We have what we consider a "grass roots" planning system. That is, we deal with the outside community from the initiation of any of our Institute-supported activities. We deal with volunteer health organizations and professional societies. We have a multiple check system in which we use advisory committees, and advisory councils—with the lay public represented—in which our initiatives go through a very stringent program and resource balance in projections. We have found that with this we have had great success in meeting our projected goals in heart, lung, and blood disease over the last 10 years. We have in fact, found a decline in heart disease at almost 2 percent a year and an almost 3 percent per year decline in stroke deaths over the same period. We feel very fortunate that in addition to the development of such a planning process as a mechanism we can give credit to both the involvement of the outside community as well as the foresight that this committee had in giving us this act in 1972 in helping to reduce this dread disease.

Senator KENNEDY. Dr. Whedon.

Dr. WHEDON. Mr. Chairman, I would like to make a few comments in response to your invitation. I think we do sense the feeling on the part of this committee that there should be some device which might more meaningfully bring out possible differences in research plans or degree of support for plans among the various Institutes, the management of NIH, and the OMB.

Before a determination is made as to whether the proposed system is most appropriate, I would like to see more time taken to review it. I would echo what Dr. Moskowitz has said about the rather considerable set of advisory groups that each of us has. I think I would perhaps suggest that this committee and others in Congress might encourage us to make more intensive use of our National Advisory Councils for providing advice and recommendations with regard to projects than we do at the present time.

Now, as I understand the National Cancer Institute's procedure, they do that rather specifically. But I think that in the other Institutes, we have been rather slow to make as much use of the expertise that we and the Department have available in our National Advisory Councils.

Senator KENNEDY. There is the problem in the Cancer Institute of getting vacancies filled. We have requirements in legislation to insure that particular function.

Dr. Whedon. We noted that point in the proposed bill and certainly we are receptive to that idea. We have all had difficulty in making appointments to these groups. With regard to the National Advisory Councils of each of the Institutes, I would point out that, within a body whose responsibility is to advise a particular Institute, one is able, within that scope of responsibility, to assemble experts who can provide really sound advice. Alternatively, I think we have some doubt as to whether a body that has to advise not only the whole of NIH, but also the whole of HEW, can have substantial depth of expertise, particularly if this advisory body includes only three or four biomedically oriented individuals.

Another point I would like to mention is the developing concern for cooperation among Institutes with regard to particular disease and research problems that involve several different Institutes.

Diabetes, for example, is a very clear example of a disease which involves many systems of the human body and is of concern to the research efforts of several of the Institutes. Under Dr. Fredrickson's leadership and urging, we have developed a quite effective trans-NIH process in this respect, through means of a trans-NIH Diabetes Mellitus Coordinating Committee. The active leader of this committee is one of the Associate Directors of my Institute, the Associate Director for Diabetes, Endocrinology, and Metabolic Diseases. A very heavy responsibility has been placed on him for diabetes research. He cannot direct what other Institutes will do, but he can stimulate and promote maximum coordination and cooperation among the Institutes supporting and conducting research on this very important disease.

I think the final comment I would like to make is with regard to the section in the bill that requires that the Institutes—except for the Cancer Institute and Heart, Lung, and Blood Institute—to cease to exist in 1983. We do not understand the purpose of that provision. If there is a desire for periodic close examination of NIH in an oversight manner, we wonder why the process would be different for these other Institutes than it is at the present time for the Heart, Lung, and Blood and Cancer Institutes, wherein there is a periodic renewal of the authorizations for appropriations. There is no stipulation at the present time that those two Institutes cease to exist.

Senator KENNEDY. Would you rather have authorizations?

Dr. WHEDON. Actually, our preference would be to continue to have the existing authorizations under section 301, which provides very broad, open, and continuing authorizations, and which we think has been very effective and very workable.

Senator KENNEDY. Thank you very much.

Dr. Kirschstein.

Dr. KIRSCHSTEIN. Mr. Chairman, I would thank you for the opportunity to address some of these issues and re-echo much of what Dr. Whedon said and reemphasize particularly not only the planning and advisory roles that the Council plays but, in addition, related to what Senator Schweiker said before, I think the National Advisory Councils play an enormously important part in the evaluation of our programs. We present the Council members with an overall picture of our activities each year, and they engage in very active discussions regarding areas that they feel we perhaps are not emphasizing enough, and areas that they think we are not handling in particularly appropriate ways. I think, overall, the National Advisory Councils have been extremely important in helping us in both planning and evaluation. Otherwise I would agree with what my colleagues have said before.

Senator KENNEDY. Dr. Kupfer.

Dr. KUPFER. Thank you, Mr. Chairman.

It is a pleasure to appear before this committee to discuss the development of a rational approach to allocate limited resources for the support of biomedical research.

The National Eye Institute came into being in 1970 just about the time that the very rapid growth of the biomedical research establishment that had occurred during the late 1950's and 1960's was slowing down. It was not the most opportune time to try to

establish a new, full-scale, nationwide research program. We soon found that at any given time in our annual budget cycle, we faced great uncertainty over what level we could reasonably expect for the coming year. We were therefore reluctant to make too many commitments and could not guarantee stable support to even the most productive of our grantees. Increasingly, there were fears that the expectations inherent in the creation of a new National Eye Institute would not be met. At the same time, there were increasing demands for accountability as to how we were using our resources, and it became very apparent that what we needed was some plan to help us utilize rationally the resources that were being made available to us.

In 1973 we discussed with the National Advisory Eye Council the desirability of its undertaking a national plan. Such a plan was published in 1975, and a second one was published in 1978. I think both have provided not only the Congress and the executive branch, but the scientific community itself and the public with a general guide to the direction vision research in the United States is going to go in the next 5 years.

We are very much committed to this type of activity, and I think it is most appropriate that this committee is looking into the further aspects of program planning. Thank you, sir.

Senator KENNEDY. Dr. Pardes.

Dr. PARDES. Thank you, Mr. Chairman. It is a pleasure to be here.

I would just comment as my colleagues have on our deep appreciation of yours, Senator Schweiker's and this committee's concern for research throughout the country.

I do recognize and appreciate your concern for an appropriate balance within the research portfolio of the Federal Government. I would comment for the National Institute of Mental Health that we feel appreciative of the fact that the President saw fit to set up a Commission on Mental Health which has recognized the fact that research support for mental health in the early seventies perhaps, and until the last year or so, has not grown in a sufficient way to take advantage of the opportunities for research in mental health. However, that Presidential Commission on Mental Health made recommendations which have been largely endorsed by the Assistant Secretary of Health and the Secretary of HEW, and we hope that the Congress will see fit to endorse those recommendations regarding support for mental health.

I would just like to make one other comment, and I would just add the qualifier that I am relatively new to the Washington scene, but somewhat concerned about the creation of yet additional tiers of review. My view would be that there is a very great deal of review about all kinds of things in the Government, and the question of how to make that review most efficient and effective is, I must acknowledge, a very challenging one.

Senator KENNEDY. As I understand, the different Institutes have different ways of doing things. This means that perhaps there is no right way or wrong way to run the various research institutions. But there must be lessons we learn from the ways in which different Institutes are handling different issues. That is lessons which

ought to be shared or learned by others. How does this flow in interchange really take place and how effective is it?

Dr. KUPFER. Well, first of all, Mr. Chairman, I would like to stress the fact that we have really in a sense been experimenting with program planning. I think this is a very new kind of activity and we are trying to evaluate it to find out how well the experiment is doing.

I think there are two aspects that might be appropriate to discuss. The first is there are some very general principles dealing with planning that really are not more than general management principles that I think all of us, all the Institutes are utilizing. We appreciate the need, for example, to measure the extent of the problem. We want to know what the public health impact of a particular disease is. We want to know what we have accomplished in this area, and what we are doing now in this particular area. That is an important type of analysis.

Then we would want to look at what are the research opportunities that present themselves. We can identify needs, but unless there is an opportunity to do something about those needs, we are going to be held up for an indeterminate period of time. And then, on the basis of what the problem is and in consideration of the needs and the opportunities, one can begin to develop priorities and set those priorities in terms of the resources that become available.

Now I think these are general principles that probably are used in planning throughout the business world and to a greater or lesser extent can be applied generally to the management of biomedical research. I think all of us in all the Institutes can subscribe to that.

Now other than that, I think the Eye Institute has had some unique opportunities in the sense that we were new when we started formal planning, and we had a relatively small portfolio of grants to begin with. Also we had a research community that had not really been organized for a very long period of time and there were great expectations of what the new Eye Institute would mean. Therefore, I think it was appropriate for us to try this planning experiment, but I think even under the most favorable circumstances, research planning will always be met at first with a certain amount of fear and trepidation on the part of the researcher.

Fortunately, we did have a positive impact on the vision research community and their enthusiasm for planning gradually increased. The 1975 planning report had some strengths and some weaknesses. I think we tried to correct those weaknesses in the second report. But I think we still are very early in understanding what the impact of research planning is, what are the pitfalls, how can we get around them. I think that we have learned that it is best to have a plan which is detailed enough to signal to the research community in what directions we want to go, and to guide the Advisory Council in making program relevance decisions. But on the other hand, we need a document which can be flexible, because obviously with time, certain objectives that have been identified are going to be met, and new opportunities are going to be arising, and we must be in a position to move in different directions when conditions warrant.

I think, therefore, that we are looking at a situation which is clearly experimental. Planning is potentially of great benefit in letting the Congress, the OMB, and the rest of the executive branch, the scientific community, and the public at large know where we are going, and how we are utilizing scarce resources. I think we are learning as we proceed.

Senator KENNEDY. Dr. Upton, how well has the President's cancer panel worked to your estimate?

Dr. UPTON. Mr. Chairman, since my arrival at the Institute, not quite 2 years ago, the President's panel has met at almost monthly intervals, and the meetings have been extremely helpful to me. I think we have been fortunate to have outstanding leaders on the panel who have made systematic surveillance of our program. Their advice on many aspects of the national cancer program has been extremely helpful to me.

Senator KENNEDY. What about your separate budget authority? Do you use it? Does it make much sense to you?

Dr. UPTON. As you know, Mr. Chairman, we are required by law to submit a budget directly to OMB. I, as well as members of the National Cancer Advisory Board and the President's Cancer Panel believe this is a very important instrument which allows us to signal directly to the President and indirectly to Congress, the needs of the program as they are envisaged by our advisers.

Senator KENNEDY. How has it worked? What has been the difference in terms of the requests that were made directly through OMB versus those which would come on up through NIH?

Dr. UPTON. Although NCI submits a budget to OMB at a level recommended by our advisers, it has been my experience that in practice, the departmental request, the request that goes from NIH to the Department, is the administration's request. In that sense I am not sure I can specify in concrete terms how useful this has been in my experience.

Senator KENNEDY. Dr. Kirschstein, you were chairperson at NIH in terms of the peer review process. What is your view of recommendations contained in the report that NIH set up an appeals process?

Dr. KIRSCHSTEIN. The grants peer review study team, which I chaired, did recommend that NIH set up a grants review appeals system. We recognized that the Director of NIH, in not accepting that recommendation, had many problems with it, not the least of which was the fact that currently the workload for the review of research grant applications is rather overwhelming, and this might increase the workload, so that it might perhaps break the back of the system.

There is, of course, in existence today and always has been, an informal appeals system which permits a resubmission of an application after an individual has received the critique of the previously submitted grant application.

Now I think we have actually improved that informal appeals system and made it more clear that we welcome the use of such a system, because one of the recommendations of the grants peer review study team was that the summary statements with the critiques that the study sections prepare should be sent routinely to the applicants. Thus now they have, at firsthand, exactly what a

study section has said about the research and can use that as a basis for resubmission. I think perhaps, in retrospect, that the Director of NIH was quite wise to let that recommendation go into effect and see how the informal system would work then. An applicant is now able to revise his or her application based on the critique. If this informal system does not work, then, we possibly should consider a more formal appeals system in the future.

Senator KENNEDY. What are your special needs in the National Institute of General Medical Sciences, what are the special problems?

Dr. KIRSCHSTEIN. The National Institute of General Medical Sciences (NIGMS), as opposed to the other Institutes that you see represented here, is a noncategorical Institute. The research we support is designed to elucidate the normal and abnormal biological processes that are really fundamental to the understanding of all disease states, and not just to any one of the targeted diseases that the other Institutes handle. Our research actually undergirds the activities of all the other Institutes. Such, fundamental research may become focused on one particular disease entity or be more than one disease entity.

An elucidation of a particular biological or cellular phenomenon may have implications for heart disease, for cancer, or for arthritis. This is what we hope will happen. As the research becomes focused, it is then transferred to the other Institutes for support. The needs of NIGMS are for an ability to fund basic undifferentiated, fundamental research in a stable manner. This can have a long-range impact on all diseases.

Senator KENNEDY. I would ask Dr. Pardes how does the peer review process function at NIMH?

Dr. PARDES. Well, in NIMH and ADAMHA generally, it is in the process of modifying its peer review system. This modification involves the separating out of the review segment of our activity the program development segment, and the separation with the creation of a review office would be done at the Institute level. So, therefore, I would say that this change would probably bring us into somewhat closer similarity or alinement with the review processes conducted at the NIMH.

Senator KENNEDY. How much of an overlap would there be?

Dr. PARDES. Overlap?

Senator KENNEDY. Yes, do you think there would be an overlap at NIH?

Dr. PARDES. What I was referring to is a similarity in process, not necessarily a similarity in substance. I think no matter how you cut the pie in terms of the handling of research, there is always a tendency for some overlap between various components. However, we have been working rather actively to develop a number of coordinating mechanisms with various Institutes within the NIH and ADAMHA as an overall development organization has entered into a formal understanding with the NIH in coordinating various activities of research.

Senator KENNEDY. I think it is probably worthwhile to get on the record a brief comment from each of you about what has happened to your budgets in the period of the last 5 years. We will start off with Dr. Pardes.

Dr. PARDES. If I could take it from approximately 1969 to 1975, the budget of the NIMH in terms of buying power reduced about 34 percent. I think you will find that one of the most striking reductions in the various Institutes' budget support. It is only beginning with the recent activity of the Presidential Commission that we have started to experience some budgetary improvement. Even with the two increases, the 1979 and the projected 1980 increase, the mental health research budget will increase only about 82 percent of the buying capacity that we had in 1969.

Dr. KUPFER. Mr. Chairman, in fiscal year 1974 the budget of the National Eye Institute was approximately \$41 million. Five years later, in fiscal year 1979, it is approximately \$104 million. We have seen a substantial increase in the funding of this relatively new program, and I think this points up the advantage of having some sort of program plan to provide a rational basis for the optimal utilization of these additional resources.

Dr. UPON. Mr. Chairman, the budget for the National Cancer Institute in 1974 stood at some \$581 million and as projected for 1980 it is \$937 million. That represents a substantial increase in current dollars.

I think, however, if one analyzes the purchasing power of the budget, the figures point to a different trend in terms of 1970 dollars. Our budget in 1974 was worth \$474 million, and the projection for 1980 is \$390 million. We actually went through a peak in purchasing power in 1975, at which time the budget was worth \$523 million in 1970 dollars, and since that time projecting to 1980 there will have been a 20-percent decrease in purchasing power. I think this reflects one of the disturbing issues of the times. It would appear that as society we have to run faster and faster to stay in the same place.

Another example I should like to give relates to the purchasing power of the research project grant awards that we are able to make to our scientific community. Although the average total award, research project grant award at the National Cancer Institute has increased about fourfold since 1970, the purchasing power of the direct costs award—the dollars that the investigator has to work with—has shrunk over the same period of time. Even though there are larger awards, the amount an investigator has to work with buys less today than it did several years ago.

Dr. MOSKOWITZ. Mr. Chairman, as you are aware, in 1969 the Heart, Lung, and Blood Institute was the National Heart Institute. At that time the budget was 16 percent of the NIH budget. Since then, in 1972 we became the Heart and Lung Institute, and now in 1979 we are the National Heart, Lung, and Blood Institute. In 1979 we are also 16 percent of the NIH budget. However, there have been a number of changes in the Institute. For example, the lung disease program in 1972 was funded at \$22.6 million. Last year, 1978, it was \$63 million, which is about a 180-percent increase for funding of lung disease research. With the lung program, and other new mandates for blood diseases, the Institute has many new areas of research to pursue but still only receives 16 percent of the NIH budget.

We have the same problems as do the other Institutes here. Our constant dollars funding power is the same as it was in 1974. So

even though we have gone to a budget projection presently of \$575 million, our purchasing power is that of our budget in 1975 which was \$304 million.

Dr. WHEDON. Speaking for the National Institute of Metabolism and Digestive Diseases, if I may expand the time frame slightly and start at 1967, which was the end of the period of some 10 years of rather rapid growth of all of the Institutes, from 1967 to 1976, a period of 9 years, our budget increased slightly on an absolute basis. But in terms of constant dollars, allowing for the effect of inflation, we had a 24-percent decrease over that 9-year period. Then, from 1976 to the present, 1979, we had an increase in constant dollars of about 24 percent. So in this year, we are back where we were in 1967 in terms of purchasing power. I would also point out that the considerable increase we have had during the past 3 years was largely due to the great national interest in intensifying research on diabetes and related research problems. As a matter of fact, the diabetes program is about four times this year what it was in 1976. The other programs have benefited somewhat by this emphasis on diabetes, but in nowhere near the same degree. The push on diabetes, you may be quite aware, came about largely through the creation by the Congress of the National Diabetes Commission, the issuance of the Commission's report and national plan, and the Congressional Appropriations Committees' very clear response to the recommendations of the Commission.

Since then, we have had two additional national Commissions, one for arthritis and the most recent for the digestive diseases. In these times of fiscal constraints, however, there has not been substantial congressional response to the recommendations of these Commissions, and it is not at all likely that we shall have the funding with which to respond to their recommendations.

Thus, the overall situation is that we are back to where we were in 1967 and, although we have had some recent substantial increases, they have not, in our view, been sufficient to deal effectively with all the recommendations made to us by the National Commissions or with the substantial needs and research requirements in our other broad areas of responsibility for many, many diseases.

Dr. KIRSCHSTEIN. I also take the framework of 1968 and would say that, although in 1975, the budget of the National Institute of General Medical Sciences was \$187 million, this was only equivalent to 80 percent of constant 1968 dollars. By 1980, the proposed budget is now \$280 million, and that is only equivalent to 79 percent of what could be done in constant 1968 dollars.

So the National Institute of General Medical Sciences, which is really the undergirding Institute for the support of basic research, is behind where it was in 1968.

Senator KENNEDY. The budgetary figures in and of themselves should not be treated as a final indicator, but what you see is significant kind of fluctuations in budgets, in different periods of time. I suppose to read back through the history, one would ask whether those fluctuations come as a result of where they come from, what the reasons are for them, and whether that is the wisest mechanism and means for which those budget allocations ought to be made. This is something that we have to think about.

I want to thank all of you very much. I am sure I will have additional kinds of questions. We are very grateful for your comments.

[Information supplied for inclusion in the record follows:]

THE INSTITUTE OF MEDICINE'S
REVIEW OF
HEW'S RESEARCH PLANNING
PRINCIPLES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service
National Institutes of Health



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20204

April 16, 1979

MEMORANDUM TO: Participants in the Development of
Department of Health, Education, and Welfare
Health Research Principles

SUBJECT: Public Record on Secretary Califano's Initiative
and Institute of Medicine Review

Enclosed is the public record of Secretary Califano's initiative to develop principles to guide the planning of health research in the Department of Health, Education, and Welfare. This record covers the period April - November, 1978 beginning with the Secretary's address to the Annual Meeting of the American Federation for Clinical Research and ending with the Conference Report of the National Conference on Health Research Principles held at the National Institutes of Health on October 3 and 4, 1978. Also enclosed is the Review of DHEW Research Planning Principles conducted by a special committee of the Institute of Medicine, National Academy of Sciences.

Based upon the Institute of Medicine Review and comments received from Conference participants, the draft health research principles are now being finalized. In addition, the second phase of this initiative - the development of goals and a plan for DHEW health research - is now underway, and we will keep you advised of progress.

Additional copies of the enclosed material can be obtained from Kurt Habel, Chief, Program Planning Branch, Building 1, Room 205, National Institutes of Health, Bethesda, Maryland 20205.

Donald S. Fredrickson, M.D.
Director

Enclosures

DHEW's RESEARCH
PLANNING PRINCIPLES:
A REVIEW

Institute of Medicine
Division of Health Sciences Policy

Supported by National Institutes of Health
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National Academy of Sciences
Washington, D.C.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service
National Institutes of Health

NIH Publication No. 79-1955
March 1979

NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competencies and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 Congressional charter responsibility to be an advisor to the Federal Government, and its own initiative in identifying issues of medical care, research, and education.

2101 Constitution Avenue, N.W., Washington, D.C. 20418

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ACKNOWLEDGEMENTS

This Report was developed by a special Institute of Medicine Committee—special not only because of its extraordinary competence and breadth, but also because of its dedication and hard work under difficult time constraints. The Committee's chairman, Dr. Irving London, and the panel chairmen, Drs. Paul Berg, Keith Brodie, Paul Stolley, Henry Riecken and Joshua Lederberg, deserve particular recognition for their leadership in developing the Report, and for their good cheer and great wisdom at each stage of the study.

Dr. Donald Nutter and Gloria Ruby contributed to the drafting of the Report and to assuring that it include the perspectives of all Committee members.

Dr. Joseph Perpich, project officer for the study from the National Institutes of Health, facilitated the work of the Committee both substantively and administratively. His constructive advice and cooperation in helping the Committee to fulfill its mandate and to meet its deadlines are gratefully acknowledged.

To Pat Cornwell, I would like to express deep appreciation for her patience and hard work in the preparation and typing of the Report.

Sarah Spaght Brown
Division Director and
Study Director

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PREFACE

Background

In late April of 1978, Secretary Califano delivered a major address before the Annual Meeting of the American Federation for Clinical Research, in which he announced his intent to have the Department of Health, Education and Welfare (DHEW) develop by the Fall of 1979 a "comprehensive five-year research plan" for the health-related agencies in the Department.

The plan is to cover the budget period of FY 1982-87, and is to:

- define the health research needs in each of DHEW's health-related agencies, and set overall priorities among these needs;
- define the responsibilities of these agencies for sponsoring or conducting the needed research; and
- provide budget estimates for DHEW activities in health research for the five-year period encompassed by the plan.

In the early summer of 1978, the National Institutes of Health (NIH) was charged with the responsibility for organizing the development of the plan. Other agencies are involved in the planning activity because they participate in supporting, planning, or performing some aspects of health research.

These agencies are the:

Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)

Center for Disease Control (CDC)

Food and Drug Administration (FDA)

Health Care Financing Administration (HCFA)

Health Resources Administration (HRA)

Health Services Administration (HSA)

Office of the Assistant Secretary for Planning and Evaluation,
Office of the Secretary (OASPE)

Office of Health Research, Statistics, and Technology, which
includes the National Center for Health Services Research (NCHSR),
the National Center for Health Statistics (NCHS) and the National
Center for Health Care Technology (NCHCT)

The plan is being developed through a two-step process. The first activity is the formulating of broad principles that will underlie the research plan; the second is the drafting of the plan itself. The goal is to issue a plan in the Fall of 1979 to guide the health research activities of DHEW over a five-year period, beginning with the 1982 budget cycle.

The first step of developing "research planning principles" itself has had several stages. Initially, each of the DHEW agencies and offices engaged in health research developed its own list of proposed principles in consultation with its respective committees and constituents. These principles were compiled and integrated by NIH, and then reviewed by the submitting agencies and offices. Next, comments on the principles were invited from approximately 1,000 professional societies and health organizations and from other federal departments and agencies. The principles were then revised in light of this external review.

The next stage was to present the suggested principles to a national conference held on October 3-4, 1978, in Bethesda, Maryland. This conference was convened by DHEW, through NIH, to obtain additional consideration of the draft principles. The conference was attended by representatives of the scientific community, public organizations, government leaders, and other interested individuals. At the opening session of the conference, Secretary Califano emphasized the need for research priorities and strategies at a time of limited resources for health research.

The rest of the two-day conference was devoted to panel workshops in five areas: fundamental research, clinical applications and health services research, health promotion and regulation, research capability, and unifying concepts. For each of these areas, a panel of about 20 experts heard statements on the principles from individuals and groups that had requested an opportunity to testify. Each panel discussed and amended the DHEW draft and then developed a report commenting on both the conference and the principles. These reports were presented orally at the closing session of the conference, and then submitted in writing to NIH in November.

During the first week of December 1978, NIH released for comment a revised draft of the DHEW health research planning principles. This most recent version is in Part III of this Report. These revised principles represent the combined suggestions of non-government health organizations and professional societies, other federal departments and agencies, participants who provided testimony at the national conference in October, the panel reports of the October conference, and the suggestions of the DHEW agencies and staff offices supporting or performing health research.

The Institute of Medicine Report

This Report is an independent review and analysis of the December 1978 version of principles, and was developed by a Committee of the Institute of Medicine at the request of DHEW. The Committee assembled for this study attended the October conference described above, and reviewed successive drafts of the principles issued over the last several months. After DHEW receives and reviews this Report and other public commentary, a final version of the principles will be released in the Spring of 1979.

This Report not only discusses the individual principles, but also addresses itself to some broader issues in health science policy, and to the nature and process of this current planning activity.

The Report is in four sections following the Summary:

- Part I discusses the contributions of health science research, and the need for an increased commitment to such research, particularly in light of the current burden of illness and the growth in understanding of the factors that contribute to disease.
- Part II discusses the current planning activity, and some of its potential benefits and liabilities, and also comments on the process being used to develop the plan.
- Part III contains the DHEW draft principles and the Committee's commentary on their themes, strengths, and limitations.
- Part IV includes a list of some major issues in health science policy that the Institute of Medicine Committee finds to be inadequately addressed or absent altogether in the principles, and also notes some research requirements for productive health science planning.

SUMMARY

This Committee strongly endorses the introduction of long-range planning for health research as initiated by the Secretary of DHEW. We believe that health research planning, when well performed, will prove to be a valuable mechanism for developing sound and productive national health research policy. Well conceived and executed planning is the nation's best assurance that there will be optimal allocation of resources for health research, and that precious resources will be utilized efficiently.

The plan and the policies growing from it should take into account the past productivity and future promise of the health sciences; our growing understanding of the many factors that affect health; the essential need for research across the full range of the health sciences to permit further advances in the diagnosis, treatment, and prevention of disease; the heavy burdens imposed on society by illness; and the strong support of the public for health sciences research. The plan should also reflect the challenge and opportunity afforded the U.S. health sciences community to continue providing leadership in the development of knowledge needed to prevent disease and promote health not only in this nation, but in many other nations as well.

We support fully the major message of both the research principles presented to this Committee for review and the October 1978 Conference at NIH during which the principles were discussed: namely, a vigorous reaffirmation of federal support for the health sciences, and a clear call not only for an increased commitment to existing programs of high quality, but also for expansion to important new and neglected areas. In neither the principles nor the conference was the notion advocated of limiting or reducing federal support of health research. Further, we support without reservation another message of the principles and of the conference: that fundamental science is the cornerstone of health research, and that support for new and neglected areas must not erode existing support for fundamental research.

An additional perspective which we endorse is a broadened concept of the health sciences. Rather than equating health research with biomedical research only, the principles recognize the importance of such areas as epidemiology and biostatistics, environmental sciences, health services research, and the behavioral and social sciences as they relate to health and prevention of disease. In addition, we wish to emphasize the importance and promise of the physical and chemical sciences and engineering for advancing our understanding of biological and medical processes and for achieving successful and practical solutions to difficult problems in fundamental biology and in clinical medicine.

We believe that current resources devoted to health research are seriously inadequate in relation both to our society's need for the results of health research and to the highly promising opportunities emerging in the health sciences. In 1977, for example, only about 3.4 percent of total national health expenditures was devoted to health research--a figure which, we are convinced, is insufficient and should be increased, particularly since health care should be soundly based in science. An effective plan for DHEW's support of the health sciences requires that health research be adequately appreciated and valued in the competition for resources, and that the need to build as well as to preserve the capability for this vital work be recognized. We are deeply concerned that excessive emphasis on the limitation of resources for health research may lead to a plan of inferior quality and limited utility.

In taking this view, the Committee recognizes that its position may be dismissed as just another example of special interest pleading. We believe nevertheless that health research merits increased support because of its demonstrated contributions to improving health care, its long-term promise for diminishing the crushing personal and economic burdens of illness, and its enhancement of the quality and duration of life--all of which are of high social priority. We also endorse fully the responsibility of the health sciences community to assure that funds are spent efficiently and prudently, through careful research administration and mechanisms that operate to insure that only scientific projects and investigators which meet very high standards are supported.

We are in substantial agreement with the main thrust of the principles, which are presented and discussed in detail in Part III of this Report. Major themes in the principles which we found particularly significant include:

- the essential contribution of fundamental research to the prevention, diagnosis, and treatment of disease;
- the need for long-term, predictable support for the health sciences;
- the vital role of clinical investigation as a bridge between fundamental research and medical practice, and the need to strengthen this field;
- the need for research on personal and group behavior as significant factors determining the success or failure of programs directed toward health promotion and disease prevention;

- the important role of health services research in studying the structure, processes and effects of the health care system;
- the importance of developing improved, efficient mechanisms for technology transfer and information dissemination to facilitate the applications of research;
- the need for analysis and evaluation of the costs, risks, and benefits of new and existing health care interventions, without impeding desirable clinical innovations;
- the need for interdisciplinary and multidisciplinary programs in the health sciences to address the nation's health problems, many of which are highly complex and require the interaction of many scientific disciplines for their resolution;
- the importance of investigator-initiated proposals as a principal mechanism for research grant funding;
- the critical role of excellence as the ultimate criterion by which research should be supported, and the high value of the peer review system in helping to assure such excellence;
- the essential role of training programs to supply qualified research scientists on a continuing basis to all the health sciences;
- the pressing need to attend to the stability, maintenance, and essential physical renewal of the institutions within which much of health research occurs;
- the need to exercise care when changing research priorities in order to avoid wasteful disruptions and dislocations in scientific programs and institutions;
- the recognition that the policy and health care agencies, and especially the regulatory agencies within DHEW have research needs that are not adequately appreciated and must be attended;
- the recognition that the public needs to be better informed about the concepts and practices of regulation in the health area (such as the regulation of foods, drugs and devices), and the data on which regulatory decisions are based, so that public debate on the relevant issues will be conducted with more knowledge and wisdom;

- the importance of having the scientific community inform the public about the accomplishments derived from public support of the health sciences.

Several important issues are inadequately resolved or are not considered in the principles at all. Some of these include:

- the development of an appropriate balance between the requirements of predictability for research support of well established productive investigators, and the need to provide opportunities for promising but untested young investigators;
- the promotion of productive interaction between public and private health research activities;
- the relationship of health research programs and needs in agencies such as the Veterans Administration, the National Science Foundation, and the Departments of Defense and Energy to health research programs and priorities in DHEW;
- organizational aspects of NIH, including both its intramural and extramural programs, and the strengths and limitations of the categorical institute structure;
- the locus of responsibility within DHEW for fundamental research in areas other than the biomedical sciences; and
- mechanisms by which the research needs of the regulatory agencies in particular are to be met.

Since the principles are very general and occasionally ambiguous, and are not assigned any relative value or priority, they appear to offer little guidance for detailed budgeting, setting priorities, or sorting out the health research missions of DHEW agencies. The value and utility of this planning activity will become clearer when the actual plan, drafted on these broad principles, is eventually developed and available for review.

As regards the process being used to develop the plan, we are impressed by the desire of DHEW, and NIH in particular, to incorporate public review and discussion as this process proceeds. We believe, however, that optimal mechanisms have yet to be established to provide for constructive interaction in this process among the public, policymakers, and the health sciences community. This situation is not surprising, given the lack of precedent for enlisting public participation in such a planning process.

The deadline of Fall 1979 for the completion of the plan is unrealistic, particularly in view of the time that has already been consumed in the relatively non-controversial task of stating broad principles. To develop a first rate plan that attends to the many complex issues in health sciences research, and to do so in a manner that continues to provide for adequate review and commentary by the interested parties at each stage of the plan's development, requires more than the several months remaining until the Fall deadline. Even in the best of circumstances, in which a planning process is well defined and the information needed is readily at hand, the time available might be too short. Since the translation of these broad principles into a detailed plan and budget may shape health sciences policy for many years to come, we urge that this process be afforded sufficient time to help assure the development of a comprehensive plan of high quality.

We also urge that this planning effort lead to the development of a permanent planning mechanism as an important instrument for the determination of national health science policy. Such a mechanism will be needed at a minimum for the regular review and revision of this current plan in an orderly, efficient way. More generally, a permanent capability for long-term planning will provide a view of research support that extends beyond yearly budget cycles or current political pressures, and will establish a clear locus for the needed consideration over time of such issues as the appropriate balance of fundamental and applied research, the relationship of the federal government and non-governmental research institutions, the role of research in regulatory agencies, mechanisms for coordinating health research throughout DHEW, approaches to establishing priorities within applied research, and the many other policy problems noted throughout this Report. The character and composition of this planning function need very careful thought, particularly with regard to the relationship of the planning mechanism not only to the health-related agencies of DHEW, but also to other federal agencies engaged in health research, and to the Congress, the Office of Management and Budget, and the Office of Science and Technology Policy.

PART I

THE RESEARCH ENTERPRISE FOR HEALTH

In commenting on DHEW's plans to develop a five-year strategy for its support of health research, the Committee has considered the past accomplishments and future promise of the health sciences enterprise. We have drawn on the record of congressional inquiries into publicly supported health research, documents such as The Report of the President's Biomedical Research Panel, specific assessments of the state of selected areas of health research, and other studies of the nation's commitment to the health sciences. The picture that emerges from these multiple sources is one of progress, hope, and firm public support for a vigorous national program of research directed towards improving health. Such support is focused on a set of important and enduring goals.

These are to:

- advance the fundamental knowledge base of the health sciences;
- translate fundamental knowledge into improved diagnostic, treatment and preventive interventions, and thereby help to alleviate suffering, improve the quality of life, and enhance survival;
- provide the basis for regulatory actions designed to promote safety and health; and
- provide the basis for informed decision making on health policy matters, including the organization, delivery and financing of health care.

Accomplishments of Health Research

Research and development in the health sciences have resulted in important contributions to the health of the public. Some of the advances that illustrate these contributions include:

- the development of antibiotics and other drugs for the control or cure of many bacterial and parasitic diseases;
- the development of immunizations for a variety of viral and other infectious diseases;
- improvements in surgery and anesthesiology which have afforded effective surgical treatment for a wide range of disorders such as congenital anomalies, many forms of neoplastic growth, valvular heart disease, and skeletal disorders;

- the ability to eliminate many gross nutritional deficiency diseases;
- deepened understanding of reproductive biology, leading to the development of contraceptives and treatments for infertility, both of which hold out the promise of voluntary reproduction;
- the development of effective noninvasive diagnostic procedures such as ultrasound imaging and radionuclide techniques;
- the construction of a wide variety of prostheses including joints, heart valves, and pacemakers;
- the development of effective pharmacologic agents to manage such serious disorders as cardiac arrhythmias, angina pectoris, congestive heart failure, hypertension, Parkinson's disease, psychoses and several neoplastic diseases;
- major advances in prenatal diagnosis and neonatal therapy to ease the burden of certain congenital disorders; and
- the treatment of end-stage kidney disease through dialysis and transplantation.

Factors Related to Health and Disease

A parallel advance has been a broadening and deepening in our understanding of the many factors related to health and disease. In recent years, the roles of personal habits and environmental factors in health have become more fully appreciated. Individual behavior--smoking is perhaps the clearest example--is now recognized more widely than ever as an important determinant of health. There is also growing appreciation of the impact on health of changes in the physical and chemical characteristics of the human environment. Particularly in recent decades, we have been exposed to a range of new substances that were unknown to our ancestors, especially pollutants in the air, ground, and water. Even the nature of stress in our society, and our personal relationships at work and at home have changed. The effects of these many factors and changes are profound, some are probably as yet unrecognized, and most of the long-term consequences are poorly understood. Finally, the organization of health care services--their cost, accessibility, continuity and efficiency--also has a major influence on health status. Health care services mean little if they are not applied appropriately to individuals

and populations.

Challenges for Health Research

Important and difficult problems remain, despite these numerous advances in our understanding of basic life processes and the many factors influencing health and disease. Causes of death and disability have changed in recent years, producing a new profile of the burden of illness that is enormously challenging to our ability to achieve effective disease prevention and treatment. The success of public health workers and biomedical scientists in combatting infectious diseases has shifted our orientation to accidents and chronic illnesses as the major limitations on life and health. Accidents now rank as the number one cause of death among all persons in the age range of 1 to 38 years. Cardiovascular disease and cancer are leading causes of death in older people. Mental disorders including the schizophrenias, depressions, and senile dementia and the problems associated with alcohol and other drug abuse are widely prevalent and exceedingly costly to society. Diabetes, chronic kidney diseases, and arthritis have become major sources of costly and often painful disability. Dental diseases remain a heavy health burden.

Problems relating to the organization and financing of health care also are of growing concern, and have been intensified by the recent large increases in health care costs. The rate of increase in these expenditures, especially in hospitals, is growing much more rapidly than the general rate of inflation. Yet effective means have not been found to contain these costs, while still protecting the health of the public and providing needed care. There is reason for concern that some population groups—particularly the totally disabled, those with low incomes, and the socially deprived—do not have adequate access to health care because of financial, and geographical barriers. Others may find the cost of adequate care a threat to financial security. It is also apparent that certain age groups, such as the elderly and the adolescent, often obtain inadequate and inappropriate health care.

Another serious problem involves the technology of medicine—the operations, diagnostic procedures, and equipment that are at the heart of much of medical practice. Despite professional standards that emphasize quality of care, the rapid pace of invention and development in recent decades has outrun the evaluation of new medical practices. Research is needed not only on the effectiveness and safety of these many interventions, but also on the actual methods for measuring the costs, risks, and benefits of medical procedures.

There is also concern that the extent of public understanding of vital health matters is inadequate, as suggested, for example, by the nation's relatively low rate of polio immunization, the continued prevalence of smoking, and nutrition and exercise habits that are unhealthy. It is also clear that present health education strategies are not adequate to bring about needed changes in the health-related behavior of our citizens.

The Range of the Health Sciences

An effective response to these widely varied challenges to life and health requires a vigorous program of research across the full range of the health sciences. A partial list of these intertwined and complementary disciplines follows. It is important to emphasize that many of these sciences include both fundamental and applied components:

- the biomedical sciences, which inquire into the basic nature of life and hold out the ultimate promise of disease prevention and improved care through deeper understanding of life processes;
- the clinical sciences, which bridge fundamental research and medical practice, and provide the links between health problems and the investigation of those problems at the most basic level;
- the population-based sciences such as epidemiology and biostatistics, which examine the distribution, determinants, and effects of disease, and the effectiveness of preventive methods and therapies;
- the behavioral and social sciences, which study the interaction of cognition, emotion, and bodily response; individual motivation, voluntary control, and modification of behavior; learning and decision making; and organizational structures and processes;
- biophysics, bioengineering and clinically-oriented medical engineering and medical physics, which provide conceptual and analytic strengths that advance our understanding of fundamental biological and medical processes, and make it possible to achieve successful and practical solutions to difficult problems in clinical medicine;
- hybrid sciences, such as the nutritional and environmental sciences, which draw on basic and applied disciplines in a multidisciplinary approach to their respective problems;

- health services research, which studies the health care system--its structure, processes and effects--and looks at such practical problems as the organization, quality, accessibility, delivery, and cost of personal health services;
- technology transfer, which is concerned with the study of the sources of innovation; the roles of the private and public sectors in the generation and application of new health technology; the economic, political, and regulatory influences that promote or impede the development of prototype technology, which is an intermediate stage between applied research and large-scale production; and the development of sound methods for the evaluation of existing technology and for predicting and evaluating the impact of new technology.

Each component of these health sciences has special contributions to make to the social goal of improved health and disease prevention. An overriding emphasis on any one part of the spectrum, or the exclusion or neglect of individual fields, would limit the benefits to be derived from scientific research. Even a brief review of the Interdisciplinary Cluster Reports of the Report of the President's Biomedical Research Panel reveals that promising advances are occurring in many areas of the health sciences, with both near-term and long-term payoffs expected for improved health status.

In short:

- The biomedical and clinical sciences have made extraordinary contributions to the quality of life and health in recent decades.
- A new profile of illness, which includes much behavior-related and chronic disease, now burdens the nation.
- We have grown in our understanding that many social, behavioral and environmental factors, including the organization of health care services, strongly influence health and disease; and we have begun to strengthen the science base to study these factors.
- It has become apparent that research advances in all components of the health sciences are needed to realize additional gains in health status.

The Support of Health Research

The goal of effective treatment and prevention of disease cannot be reached without the continued nurture and support of health research. This goal also cannot be achieved by crash programs nor can it be attained within a fixed schedule of years. The quest will not be productive if it is turned on and off arbitrarily, nor can it succeed if held at a standstill without opportunity for the growth necessary to develop new fields of study, to pursue new opportunities in existing fields, and to support, maintain, and renew research institutions. What is needed is decades of steady, hard work by skilled and imaginative investigators giving continuity to the research activity. This undertaking must be vigorously supported to insure that talented investigators will have the funds and facilities that are essential to the achievement of this goal.

The Committee realizes that such a program may be difficult to implement in an atmosphere of budgetary restraint. Health research, however, constitutes a very small part of health expenditures, and is the part most likely to enhance the quality of life and to lead to cost savings over the long-term by discovering improved ways of treating and preventing disabling and economically burdensome diseases. Moreover, there is ample evidence that research directed toward improving health is appreciated by the American people and has their strong support.

The Committee believes that resources now devoted to the health sciences are seriously inadequate in relation both to the need for the results of health research, and to the scientific opportunities in these fields. Health care should be based soundly in science. Yet in 1977, only about 3.4 percent of total health expenditures was devoted to health research*--a figure that, we are convinced, is insufficient and should be increased. We recognize that there is no simple answer to the question "how much is enough?" We believe, however, that with thoughtful study, it should be possible to determine a level of support for the health sciences that is both realistic in terms of the national economy, and sufficient to foster an enriched and highly productive national health research enterprise. Such policy analysis should be a significant element in the work of a permanent planning mechanism which we urge grow out of this current planning activity, as suggested below (see 22 and 23).

*Source: "Basic Data Relating to the NIH, 1978." Total national (public and private) health expenditures in 1977 were \$162.3 billion; total health R&D (public and private) was \$5.5 billion; total federal health R&D was \$3.3 billion.

In taking the position that current resources are insufficient, the Committee recognizes that it could be charged with promoting a self-serving interest. We believe nonetheless that health sciences research merits increased support due to its high social priority, which in turn is derived from its demonstrated productivity leading to extraordinary improvements in life and health, its long-term promise for diminishing the economic burdens of illness, and its enhancement of the quality and duration of life for our people. In advocating increased support, we also believe it is the responsibility of the health sciences community to assure that funds are spent efficiently and prudently, through careful research administration and such mechanisms as the peer review system, which operates to insure that only scientific projects and investigators who meet very high standards are supported.

The expanding opportunities in the health sciences, the current burden of illness, our growing appreciation of the many factors that affect health, and the strong support of the public for the social priority of research to improve health add further strength to our view that policies should be formulated which increase and make predictable the support for such work. The Committee therefore wishes to cite with approval the statement of the Panel on Health Regulation and Promotion, of the National Conference on Health Research Principles:

We do not accept the premise that resource limitations preclude significant expansion of the health research budget. That is a political judgment, not a reflection of economic necessity... [Current research expenditures are] a miniscule investment in relation to the size of the enterprise whose effectiveness rests upon it. Health research, basic, applied and related to the efficacy of preventive, therapeutic and regulatory services, provides major hope of improvements in the public health. It is penny wise and pound foolish to economize on the investment in obtaining the knowledge which can permit effective action for better health.

PART II

THE CURRENT PLANNING ACTIVITY FOR HEALTH RESEARCH

The Values of Planning

This Committee endorses the initiative of Secretary Califano and the DHEW leadership in directing that a multi-year strategy for health research be developed. In this effort, DHEW is being highly responsive to a number of factors affecting health research: widespread recognition that some areas of research have not been and are not being supported at a level commensurate with the need for results from these lines of inquiry; deep concern that the nation's commitment to fundamental research not waver; an appreciation that abrupt changes in research emphases at the federal level can cause wasteful dislocations in scientific programs; a recognition that funding priorities within applied health research do not necessarily reflect either the nation's profile of illness or scientific opportunity; and a general concern about the future of federal support for health research in an atmosphere of intense fiscal restraint. Given these many factors, long-term planning for health research is desirable and should be useful.

A well conceived plan should consider: the extent and distribution of current research efforts; the nation's burden of illness; the disciplines that show special promise for advancing the health of the public; problems inadequately studied; excessive duplication of activity; and areas where personnel and facilities must be developed further or better utilized. With such information in hand, it should be possible to address the perennial and difficult problem of establishing research priorities in an informed and constructive manner.

A well-designed health research plan should benefit the individuals and agencies involved in its preparation by fostering consideration in a deliberate and thoughtful manner of their roles and functions in health research. The missions of the individual agencies should become more crisply defined and areas of overlap and neglect more visible. The potential for increased interdisciplinary, multidisciplinary, and interagency research should become more apparent when all health research is arrayed in one plan at one time.

A comprehensive plan should also promote increase predictability and stability in federal support for health research--a goal which we strongly endorse. Federal funding of health research has often been erratic as a result of shifting priorities and budget levels, and of changing leadership, among other factors. Even outstanding scientists, in many areas of study, have suffered from the disruptions of fluctuating funding. The trend to shorter federal research funding cycles for centers, programs, and projects enhances the uncertainties and changeable character of research support. A hoped-for consequence of planning is increased predictability in funding and the possibility of longer-term funding, both of which would promote sustained attention to health needs. Research, by its very nature, is a long-term process that flourishes in a stable environment, particularly because scientific results are obtained at unexpected times and often through unanticipated channels.

Developing a research plan provides excellent opportunities to make information about health problems widely available and to foster communication among the public, its elected representatives, and the health sciences community about the nature, scope and goals of health research. The taxpayers who pay for research deserve to be provided with evidence that the research community is aware of the nation's health needs, and that it is pursuing new knowledge pertinent to these needs with vigor and excellence. Even though the results of research cannot be planned, the public has a right to know and debate broad priorities and emphases.

A comprehensive plan should also create an awareness of the role of the private sector in scientific inquiry. It could enhance the possibilities of integrating the efforts of the public and private sectors, so as to use existing resources more effectively, and to share the results of research in both sectors cooperatively and efficiently.

The Difficulties of Planning

The Committee also wishes to point out some difficulties associated with research planning generally and with this activity in particular. For example, planning may lead to inflexibility in research priorities, and may limit the ability of the government to adjust its research agenda to new social needs or scientific leads. We strongly urge, therefore, that the research plan eventually developed be reviewed and revised often in order to avoid the inefficiencies and missed opportunities that derive from inflexibility.

The great diversity and complexity in the many fields of study that comprise health research may be overlooked in the effort to develop a single plan for all of health-related research. Different types of planning processes, at different levels of specificity, are required for the various components of health research. For example, the essential value of fundamental research is to provide the advances in knowledge which form the science base for future progress. Major fundamental discoveries may change a field quite suddenly—a situation which demands flexibility in directions and resource allocations. As such, fundamental research can be "planned" only at a general level. In some areas, such as the environmental sciences, aspects of planning that encourage an interdisciplinary or multidisciplinary approach to problems are highly desirable. And in some areas, such as the last phase of developing a new drug, device, or technique, where the knowledge base is generally adequate, yet another type of planning which is more detailed and goal-specific may be appropriate. All components of health research are not alike, and therefore planning in each area may require different levels of specificity.

Another, more philosophical concern is that in developing a plan for health research, it is possible to gloss over the overwhelming extent of our ignorance about life, human behavior, social organization, and disease processes. Knowledge is lacking in many areas of health and behavior, such as the mechanisms of the aging process, the biochemistry of alcohol addiction, the role of our new chemical environment in cancer, the relationship of diet to health, the role of exercise in cardiovascular disease, effective techniques for health education, and the cost-effectiveness of many new technologies—the list is very long. It is important that in the effort to set research priorities, and to bring the sense of order to research that planning suggests, the great need for new knowledge about an almost infinite number of phenomena be kept clearly in mind.

An additional concern is that a plan may set up false expectations that the processes and results of research can be planned and produced "on schedule." While this may be true in some highly applied areas of study where a strong base of fundamental knowledge exists, many of the results of research appear in unpredictable and unexpected ways, and cannot be anticipated in an orderly sequence. Thus, planning for health research bears the

risk of erroneously suggesting to policymakers and other interested parties outside of the scientific community that desired goals (such as "a cure for arthritis") can be attained at specified times through careful planning. Needs for health research can be identified, broad research strategies can be planned, and crude estimates of scientific personnel needed in the future can be made. But the tangible results of scientific inquiry cannot always be defined or planned in advance. The more fundamental the science, the truer this statement is.

Implementation of a long-term federal research plan is, of course, hampered by the nature of governmental processes. The Congress appropriates money for health research yearly, not in five or ten-year blocks. Annual budgeting means that each year the federal approach to health research is reexamined, and often changed, sometimes only minimally and sometimes quite profoundly. The rapid turn-over of personnel in Congress and the Executive Branch also means that long-range plans are reviewed by an ever-changing group of policymakers, each of whom may wish to give a different emphasis to the forward plan.

There are also risks in planning health research that are unique to the present time and place and that may have serious future consequences. The current atmosphere of fiscal restraint may lead to a plan whose primary effect is to reduce funding for health research in the immediate future. It must be remembered that this plan is intended to guide health research from about 1982 to 1987--not this year or next. Thus, careful attention must be given to avoid having current fiscal constraints prejudice the future of support for health research.

A Permanent Planning Mechanism

Despite these numerous and generally obvious limitations on research planning, we reiterate that a multi-year plan for health research remains a desirable activity. We urge, however, that this planning effort lead to the development of a permanent planning mechanism for the health sciences as an important instrument for the determination of national health science policy. Such a mechanism will be needed at a minimum for the regular review and revision of this current plan in an orderly, efficient way. More generally, a permanent capability for long-term planning will provide a view of research support that extends beyond yearly budget cycles or current political pressures and will establish a clear locus for the needed consideration over time of such issues as the appropriate balance of fundamental and applied research, the relationship of the federal government and non-governmental research institutions, the role of research in regulatory agencies, mechanisms for coordinating health research throughout DHEW, approaches to establishing priorities within applied research and the many other

policy problems noted throughout this Report. The character and composition of this planning function need very careful thought, particularly with regard to the relationship of the planning mechanism not only to the health-related agencies of DHEW, but also to other federal agencies engaged in health research, and to the Congress, the Office of Management and Budget, and the Office of Science and Technology Policy.

The Process to Develop the Current Plan

The Committee wishes to make a few observations on specific aspects of the process being used to develop the requested plan.

- We support DHEW's commitment to public participation and open processes in the development of this plan, and encourage DHEW to assure that at each stage of the plan's development, opportunities be provided for commentary from many sectors. This includes review when the plan is implemented as well as in these planning stages. All parties need to give thought to finding ways of structuring this public discussion so that it is well informed and constructive.
- The October 1978 Conference on Research Planning Principles was commendable as an experimental effort to involve the public in research planning. Although conference participants were afforded a limited opportunity to express their views, we believe that the conference structure and time constraints did not allow for the useful interactions among the public, the scientists, professional societies, and others that the conference sponsors had intended.
- The preliminary, relatively easy aspects of research planning--namely, the development of general principles underlying health research--have taken many months. We agree that a statement of broad principles is an important first step. However, if the deadline for the completion of this plan remains the autumn of this year, the risk grows daily that too little time will remain for the more difficult and necessarily controversial task of establishing research priorities and sorting out agency missions to pursue these priorities. There are now only seven or eight months remaining until the autumn deadline--an interval that is inadequate for constructing a first rate research strategy, even if a process were already in place to reach this goal. In the present atmosphere of less than complete agreement on these principles, the purposes and scope of the plan, and even the process to produce the plan, the existing deadline becomes even more unrealistic.

- We suggest further that many important issues have not yet surfaced in this process or have been inadequately explored in the principles. Section IV of this Report highlights some of these issues.
- We are also concerned that if the most difficult questions are not addressed until late in the process, there will not be sufficient time for the public, the health research community, and other interested parties to discuss suggested policies and priorities thoughtfully before the plan is issued in final form. The first phase of developing the principles attempted to include such discussion, but the need for detailed review will be much more pressing in the later phases of the plan's development, when the numbers and priorities are on paper for all to see.
- By confining the scope of the plan to only those agencies within DHEW that support health research, important components of the total federal research effort pertinent to health are being omitted. The Veterans Administration for example, supported close to \$112 million of health research in 1977, principally through the Veterans Hospital system. The Departments of Defense and Energy also are involved in health research. During 1977, the Department of Defense spent \$124 million on health research, and the Department of Energy, \$203 million. Similarly, the National Science Foundation reported \$58 million of such research in 1977. The value of the DHEW plan would be enhanced if it were developed in relationship to the research activities and needs of these other agencies.
- We suggest that the long range utility of the plan will be enhanced if key leaders from Congress, the Office of Management and Budget, and the Office of Science and Technology Policy are kept apprised of the plan as it is developed.

PART III

THE RESEARCH PLANNING PRINCIPLES

General Commentary

The Committee has several general comments about the principles:

- A. The major message of the principles and of the October 1978 Conference during which they were discussed is a vigorous reaffirmation of existing federal support for the health sciences, and a clear call for an increased commitment to new and neglected areas. In neither the principles nor the conference was there a suggestion of rigidly limiting or reducing federal support of health research. We discern no themes in the principles or conference that suggest a major overhaul of the nation's health research commitment, except, as mentioned, to increase support for selected areas.
- B. A key feature of the principles is that they embrace a concept of the health sciences that is much broader than was the view as recently as ten years ago. Rather than equating health research with biomedical research only, the principles recognize the importance of such areas as epidemiology and biostatistics, environmental sciences, health services research, and the behavioral and social sciences for disease prevention and health maintenance; the Committee would add to this list biophysics and bioengineering, and clinically-oriented medical engineering and medical physics. The Committee regards this broadened concept as a desirable advance in policy formulation, and supports efforts to translate this perspective into tangible and adequate support for the full complement of the health sciences.
- C. The Committee also strongly supports the view expressed in various subsections of the principles--and throughout the conference report as well--that fundamental science is the cornerstone of health research, and that support for new and neglected areas of health science must not erode the core support of fundamental research.

- D. Throughout the principles and the conference discussions as well, the value of excellence in all areas of health research has been mentioned repeatedly. This Committee concurs that a commitment to excellence should be the prime determinant of support for health research. The public support of the health sciences enterprise demands that excellence be the ultimate criterion by which research allocations are made. Poor quality research is not worth doing, no matter how pressing the problem to which it is directed. The peer review system is a principal mechanism for assuring such excellence and should be applied as widely as possible to health research funding.
- E. Because of the generality and occasional ambiguity of the principles, we believe that they will be of only modest help in establishing detailed priorities and budgets and in sorting out the research missions of DHEW agencies. The difficult decisions needed to develop the actual research plan still lie ahead. We do not know what mechanisms will be used to translate these necessarily broad principles into a useful forward plan, or which set of decision-makers will actually set the five-year research priorities for DHEW. In the absence of such knowledge, we urge again that there be adequate opportunity for review and revision of the substantive decisions yet to be made in the light of these general principles.

The Five Sets of Principles

In the five sections below, the draft DHEW principles themselves are reproduced at the beginning of each section and enclosed in quotation marks. They have been numbered to assist in our review. After each set are presented the Committee's commentary and, where appropriate, specific discussion of individual principles. Differences in the nature of the commentaries on the five sets of principles and some overlap in the discussions are to be expected given the variability in style and some redundancy in the principles themselves; furthermore, this Committee was itself divided into five panels to review the principles, as listed at the beginning of this Report.

A. Principles Regarding Fundamental Research

"This focus addresses the need for fundamental research (the search for knowledge about fundamental processes of biology and behavior), the creative process that governs this type of research activity, and the role of fundamental research in improving public health and providing the essential knowledge base upon which other Department health missions rely. This focus also encompasses the issue of stability of research support and the relationship of fundamental research to other activities in the health research continuum.

- A1. Principle--A national commitment to fundamental research is essential to meet the full range of public health expectations.
- A2. The Federal investment in fundamental research must be maintained to develop the knowledge base essential to support the health research continuum that extends through applied research to the prevention, diagnosis, and treatment of disorders and diseases and to rehabilitation. This should be recognized as a long-term investment that provides the freedom for scientists to pursue diverse research topics that may not be immediately relevant to practical health problems.
- A3. This national commitment must include long-term, stable support for fundamental research. This support is essential for the maintenance and strengthening of the scientific knowledge base related to all DHEW health missions.
- A4. The development of new knowledge through fundamental research, and its application, has a significant impact in improving our ability to prevent disease and the effectiveness of treatment and rehabilitation.
- A5. The decision to fund fundamental research in a given area should be based upon an assessment of related ongoing research and new scientific opportunity. The peer review system must be regarded as an efficient and essential instrument in the conduct of research grant programs.
- A6. Investigator-initiated research proposals must continue to be emphasized in the conduct of fundamental research, and must be restored to their previous prominence as the primary mechanism in the allocation of funds.
- A7. Recognition must be given to a broadened concept of health factors and a research base developed to investigate them. This base should include studies in the behavioral sciences and population sciences such as epidemiology and biostatistics.
- A8. The Directors of NIH and ADAMHA should conduct annual program reviews to update projections and review amounts needed in fundamental research, to identify new areas warranting support, to curtail inappropriate distribution among areas already being supported, to monitor the allocation of resources to fundamental research, and to review the allocation of resources among the various fields."

Commentary

Central to any discussion of fundamental research is the issue of what is to be included in such research. We find the DHEW definition adequate,* particularly because it includes in the last phrase research which grows out of clinical problems, even though the goal of such inquiry may not be immediately applicable to diagnosis, treatment, or prevention of disease. We endorse a major theme of all the principles, that fundamental research is a component not only of the biomedical sciences, but also of the behavioral and social sciences, and population sciences such as biostatistics and epidemiology. We also suggest that fundamental research in these areas has not been adequately developed.

As we note at the beginning of Part III, we endorse the broadened definition of the health sciences, but emphasize here again that support for fundamental science must not be lessened in the effort to increase funds for new and neglected areas. Any dilution or further diminution in support of fundamental biomedical research in particular would be in direct conflict with the message of principle A1, which we find incontestable. Fundamental research, often without reference to, or motivation by, a specific health problem, has contributed the knowledge needed for major health advances. The Comroe-Dripps analysis** shows conclusively that more than forty percent of the crucial and decisive developments that underlie present capabilities in cardiovascular and pulmonary medicine and surgery derive from untargeted, fundamental research in the biomedical sciences. We believe that the germinal role of fundamental research would be similarly illuminated were comparable studies made of successful advances in other medical specialties. There is widespread agreement that long-term solutions to major health problems will not be forthcoming without

*"Fundamental Research - a search for new knowledge directed towards increasing our understanding of life, health and disease. The terms of reference are scientific inquiry into fundamental processes of biology and behavior. This science base includes both undifferentiated research tending to be isolated from a specific disease orientation, and clinically-oriented research focusing more on specific disease processes."

**Comroe, J.H., and R.D. Dripps. "The Top Ten Clinical Advances in Cardiovascular-Pulmonary Medicine and Surgery Between 1945 and 1975: How They Came About." Final Report, January 31, 1977. Supported in part by Contract 1-HO-1-2327 from the National Heart, Lung and Blood Institute, and grants from The Commonwealth Fund and The Burroughs Wellcome Fund.

a more detailed knowledge of the origins and mechanisms of disease, and the nature of human behavior and social interaction. Society's "burden of illness" is in fact a burden of ignorance. There is no alternative to fundamental research for eliminating that ignorance. Fundamental research is, indeed, the lifeline of medicine.

Principles A2-A5 emphasize that fundamental research is essential and must be fostered to support the entire range of health research that is encompassed by all DHEW health missions. As general statements they are laudable and should be affirmed. But the intent and impact of these statements, particularly as they bear on the specific budgetary decisions yet to come, are obscure. These statements could be signaling a commitment to develop or foster new, improved mechanisms for utilizing basic research advances in all areas of DHEW's concerns. We would support such a commitment. An additional or alternative interpretation is that fundamental research should become more "targeted" to DHEW health missions, e.g., prevention, diagnosis and treatment of disease, rehabilitation, regulation, health education, and the like. Such targeting would misrepresent the essential nature of fundamental research, which is that it is not directed towards specific diseases or social problems. We support the notion that the results of fundamental inquiry are necessary to meet the multiple missions of DHEW, but not that such basic research itself should be more directed or mission-oriented.

During the October conference, and occasionally in the language of the principles themselves, the notion is raised of diffusing responsibility for administrative control of fundamental research to other agencies of DHEW beyond NIH and, to a much lesser extent, ADAMHA. As regards basic biomedical research only, we would not support such a diffusion. Were many other agencies to become involved in basic biomedical research, there would be an increasing likelihood and perhaps even inevitability that such research would be targeted to the sponsoring agencies' missions rather than remaining truly fundamental and therefore not mission-oriented. Furthermore, inevitable duplication of work, and the necessity for establishing a separate (though parallel) peer review system to assure high quality research would be wasteful.

With regard to the focus of administrative responsibility for fundamental research in such fields as the behavioral and social sciences, epidemiology, and biostatistics, the DHEW principles are not explicit. We recognize that a number of DHEW agencies beyond NIH and ADAMHA may wish to pursue such fundamental research in an effort to meet the long-term needs of their specific missions. The Committee believes that this important and difficult issue deserves much careful study so that the eventual decisions concerning the administrative loci for fundamental research in these areas will serve to assure excellence in research and high quality in peer review, and will minimize redundancy.

Principles A2 and A3 identify the costs of fundamental research as a "long-term investment" and argue that the nation must commit "long-term stable support" to that activity. Though commendable, these phrases are too vague to be evaluated in practical terms. Does this willingness to view fundamental research as a long-term investment take account of the budgetary requirements for:

- a. Training future generations of scientists, technicians and teachers; upgrading obsolete, inadequate laboratory/clinical facilities and equipment; providing the essential experimental animal facilities?*
- b. Assuring the health, integrity, and vigor of the universities and institutions in which the bulk of high quality fundamental research is performed?*
- c. Developing novel, imaginative mechanisms that would provide secure funding to meritorious, promising programs, to investigators of proven ability and accomplishment, and in a fashion that would also encourage and support the growing body of talented young scientists?
- d. Reducing the uncertainties inherent in present research funding patterns and eliminating the consequent starts, stops, and delays in research programs that are wasteful of research effort, time, and money?
- e. Relaxing the requirement for frequent renewals of research support for the most productive and successful scientists, while still retaining the capability of monitoring the quality of ongoing research and of evaluating new leads, challenges, and initiatives?
- f. Expanding sources of support, such as the Biomedical Research Support Grant (BRSG), that improve the capability of institutions and investigators to capitalize on new research opportunities and to transcend disciplinary barriers?

We urge that the planning activity take full note of these many issues when trying to implement the stated commitment to long-term, predictable funding.

Principles A6 and A7 discuss the problem of identifying the most promising investigators for research support and of ensuring that such research is of the highest quality and potential. We strongly support

*See also the comments regarding the principles on Research Capability

the view that investigator-initiated research proposals should be the primary mechanism for allocation of funds in fundamental research programs. The statement of the October Conference Panel on Fundamental Research, "This mechanism allows for the maximum expression of individual ingenuity and competence in the formulation of research strategies, and therefore ensures a freshness and diversity of approach that would be difficult to evoke by any other means," emphasizes the same preference. But there is also merit to considering alternative modes of investigator-initiated proposals for core grants, program projects, interdisciplinary programs, etc. These should be implemented when there is clear and convincing evidence that such mechanisms create opportunities, capabilities, and facilities that are not attained as well through competitively awarded grants to individual investigators. This is especially important where it is desirable to pool the strengths of various disciplines, as in fostering the vital interplay of the physical sciences, engineering, and the behavioral and social sciences with the biomedical sciences.

We also support strongly the October Conference Panel's conclusion that the peer review system is the most effective, cost-efficient administrative procedure for assessing the quality, opportunities and directions of the nation's fundamental research programs. Further efforts are needed to improve the peer review system throughout DHEW for both basic and applied research. Within the NIH in particular, the peer review system needs to be strengthened so that its evaluations are not compromised by unreasonable work loads or by marked lack of uniformity in priority scores and funding across the multiple institutes. We also suggest that while consideration of national need will inevitably affect the priorities of different research activities, diligence is required to guard against the support of low quality even when such research is apparently responsive to these needs.

Principle A8 calls for annual program reviews "to update projections and review amounts needed in fundamental research, to identify new areas warranting support, to curtail inappropriate distribution among areas already being supported, to monitor the allocation of resources to fundamental research, and to review the allocation of resources among the various fields." It is difficult to imagine how enterprises such as NIH and ADAMHA, overseeing huge expenditures and large numbers of scientists and facilities, could function effectively without such periodic review, and indeed considerable review and planning are currently performed already. In this regard we urge that the recommendation made by the October Conference Panel, that the NIH and ADAMHA Directors consult broadly with outside scientific bodies in making their assessments of ongoing or prospective research programs, be given serious consideration. An additional recommendation which we support is that the Directors of NIH and ADAMHA have sufficient discretionary funds to encourage and promote new areas of fundamental research e.g., convening conferences to stimulate

interest in new areas or the modest use of special funding mechanisms to catalyze direct involvement of investigators in a new field.

A word of caution concerning Principle A8 is appropriate: there is a possibility that annual reviews, curtailments, and re-distributions of resources could jeopardize or compromise the previously stated commitment to long-term, predictable support for investigators and research programs. We recognize that both goals are important; careful attention and creative administrative mechanisms are needed to balance the two. For example, rather than making abrupt changes when undertaking needed program redirections, and thereby violating the need for predictability and continuity, such changes should be phased in gradually.

In the context of the present commentary, it is important to raise an issue not addressed directly in any of the principles, but which nevertheless has substantial impact on the conduct of health sciences research. We are increasingly concerned about the escalating costs in time and money attendant upon compliance with the growing body of federal, state, and local regulations governing the conduct of research. Experimentation with human subjects and even with materials from human sources is at times unnecessarily burdensome. Similarly, excessive bureaucratic restrictions could impede recombinant DNA research and retard the advances that this powerful new methodology promises. We recognize that there are benefits as well as costs in regulatory processes related to research. The goals of protection of human subjects, and accountability in the uses of public funds are of great significance and value. Nonetheless, the costs of regulation to research have to be in reasonable balance with the benefits achieved. We suggest that an analysis be undertaken of the role of regulation in the health sciences to examine such issues as:

- the risks in research towards which regulation is directed--both the risks to subjects and to investigators, and the liability of investigators and institutions for injuries resulting from experimental procedures themselves or from the products and devices derived from such research;
- the various mechanisms available for handling such risks;
- the possibility that the aggregate effect of individual regulations may inhibit needed and valuable research; and
- the overall benefits and costs of regulation.

Such an examination should include the views of the public, those who conduct and participate in research, and those involved in its regulation.

B. Principles Regarding Clinical Applications and Health Services

Research

"This focus addresses the development of the knowledge base to support the health care function, the need to acquire, validate and apply new knowledge, the characteristics of and requirements for applied, problem-oriented research, and the need to retain and strengthen the Department's pluralistic approach to the support of applied research.

- B1. Principle--To improve the quality of health care, prevent disease and contain health care costs, the health care system requires, in addition to new knowledge developed at the fundamental level, the support of applied, problem-oriented health research.
- B2. The development of an adequate knowledge base for the fulfillment of health care missions must be supported. This includes strengthening fundamental research, as well as applied research approaches to the solution of health problems, in order to develop systematic ways to meet the needs of non-research health agencies for specific knowledge. This includes giving an appropriate priority for stable funding to certain research areas, such as epidemiology, biostatistics, toxicology and nutrition.
- B3. The health research agencies must be responsible for assisting the health regulatory, care and policy-making agencies, whenever a formal request for assistance is made which clearly falls within the mission of the research agencies. Consideration should be given to the resources necessary to comply with such requests. The many applied health research needs which cannot be filled through such a system should be addressed by applied, mission-related research funded through the budgets of the health regulatory, care and policy-making agencies. Coordination and dissemination of the required knowledge should be provided through interagency committees responsible to the Office of the Secretary.
- B4. The validation of preventive and therapeutic measures before their introduction into the health care system must be assured and standards for their application in medical practice determined. This includes the validation of new regimens in terms of their efficacy, safety, and cost-effectiveness.
- B5. After the introduction of preventive, therapeutic and diagnostic measures into actual use, monitoring programs should be employed to evaluate both their costs and benefits. This function should be part of a strengthened activity in health services research and technology assessment within the Office of the Assistant Secretary for Health. In addition, a fixed and adequate percentage of the budget of health care agencies should be devoted to these monitoring programs.

- B6. The conduct of fundamental and applied research to improve methodologies for statistical, epidemiological, sociological and economic measurements in the health fields must be supported. This includes a long-term commitment to continuation and expansion of applied measurement research in statistical and survey methodology to provide improved statistics on morbidity and mortality, disease prevalence and incidence, disability prevention, behavior, enhancement of quality of life outcomes, the organization, delivery and financing of health care services, and new methods to facilitate epidemiologic analyses of large health data files. Funding for such methodologic research should occur at a reasonable level independent of support for specific health programs.
- B7. A strategy must be adopted for funding health research which includes provision for specific program expansions for the support of clinical applications, clinical trials and health services research activities without diversions of funds from fundamental research. This includes the development and funding of multi-year, high-cost investigations and clinical trials as direct add-ons to specific agency programs where an adequate and available science base exists. If budgetary increases cannot be accomplished to provide such funds, then the health care dollar should be considered as a source. Priorities should be established for funding these activities, based on the state of the science base related to each effort, the feasibility of each effort, based on the state of the knowledge and available resources, the potential impact of the trial on research, health care, the burden of illness, and various ethical considerations. The public sector, academic centers and appropriate elements of the private sector should be an integral part of this process.
- B8. The scientific merit of proposals for clinical investigations, clinical applications and health services research is a necessary condition for support. Each agency sponsoring such research should administer a peer review process to determine the scientific merit of each research proposal, and the reviewers should include nongovernment persons from appropriate disciplines.
- B9. The systematic dissemination of health services research results to providers of health services requires more emphasis, so that advances in knowledge are applied by the health care system as promptly and effectively as possible. However, care must be taken to avoid premature introduction of unproven new health technologies. Further research and evaluation are needed to determine the most efficient and effective methods of technology transfer.
- B10. Consensus development approaches for providing information and technical transfer should be strengthened to assure the involvement of all constituencies relevant to the specific health technologies addressed.

B11. Priorities for health services research support must be defined, and the social value of anticipated findings should be a determining factor in this process. In defining priorities, the following should be considered:

- State of the science base and the feasibility of each proposal, in terms of the state of knowledge and available resources;
- Demand for the information likely to be generated by the study--the probability that it will be put to use--in terms of the potential impact on health care, the burden of illness, and various ethical issues.
- Likelihood that the research will test assumptions on which current policies and delivery practices are based, provide the basis for developing new options for health services delivery, or provide the means for monitoring performance of the health care system;
- Provision of flexibility for innovative proposals;
- Participation in the process by those responsible for providing the research support, as well as those directly associated with the problems and needs;

B12. Planning and coordination of applied health research activities among DHEW agencies need to be strengthened, although the Department's present pluralistic approach to the support of clinical applications and health services research must be maintained.

B13. Planning and coordination can best be accomplished by establishment of a committee at the level of the Office of the Secretary, which includes representatives of all DHEW agencies involved in applied health research. The committee would serve generally to monitor the Department's commitment to provide an applied research capability, evaluate priorities and identify gaps and duplications of effort. Authority for program-specific research should remain within each agency. General health services, which is primarily the function of the National Center for Health Services Research, should be maintained as such, and the Center should become the operational arm of the committee. Coordination must also be increased between HEW and private industry, particularly in the area of developmental research."

Commentary

These principles highlight a perspective to which we give strong support and endorsement: "A strategy must be adopted for funding health research which includes provision for...expansions for the support of clinical applications, clinical trials and health services research activities without diversions of funds from fundamental research." (B7) We find it highly significant that this theme has been stated repeatedly in these principles, at the October 1978 conference, and in the panel reports of that conference as well--not only by fundamental science constituencies, but also by those concerned with applied health research. We express support both for the idea of guarding against erosion in fundamental research support, and for a strengthening of applied research--two related, but distinct concepts.

It is not easy to "strengthen" various components of applied research, however, and the principles do not discuss adequately how to do so. It is not simply a question of directing more money to specific research areas, although in some fields where the science base is strong, that may be adequate. More typically, there are problems in the institutional and personnel base of these fields that require resolution. In epidemiology, biostatistics, and toxicology, for example, there appear to be shortages of adequately trained scientists to meet existing needs. Although the reasons for these shortages vary, a simple increase in program funding for research in these areas without addressing the more fundamental institutional and personnel problems would be an inadequate strategy.

We also suggest that the applied health sciences require a long-term commitment to developing their fundamental concepts and tools. Principle B6 accurately pinpoints selected methods and measurements in need of refinement. Such "discipline building" requires durability of support over the long term, not only for research on specific problems and health needs, but also for meeting the personnel and institutional requirements of these disciplines.

Several of the principles (B3 especially) discuss the responsibilities of the health research agencies to the regulatory, care and policymaking agencies. Our Committee did not try to resolve what such responsibilities should be, or the parallel issue of whether these agencies should themselves develop stronger research capabilities. However, there was a consensus that the principles should not attempt to settle these questions prematurely in the absence of the detailed consideration which issues of this magnitude deserve. We suggest, for example, that the demand process outlined in B3--whereby the regulatory, care and policy agencies simply request certain research from the research agencies

and the latter are required to respond--is too simple and perhaps not feasible. There is no question that mechanisms need to be established to assure the development of the knowledge base required by these agencies to meet their responsibilities. But as the principles now stand, it appears that many nuances of this need have not been analyzed. For example, as regards the important research needs of the regulatory agencies in particular:

- it is possible that requests from regulatory agencies could overwhelm the research agencies and seriously compromise existing programs in such agencies;
- the knowledge requirements in the regulatory agencies are of many types--some very short term and immediate, others more fundamental (as in the search for appropriate animal models); it is likely that research mechanisms to address such different needs will have to be more multifaceted than the principles suggest;
- the role of the private sector in providing more of the knowledge needed by, for example, EPA and FDA merits exploration.

A comparable list related to the health care and policy agencies could also be formulated. We have not discussed such issues in detail, but suggest that these questions and others require more thorough consideration--perhaps through the permanent planning mechanism suggested earlier--than is possible here before DHEW acts on these issues.

The principles call attention to the issue of validating preventive, diagnostic, and therapeutic measures before their introduction into the health care system. Much concern has recently been expressed about the problem of premature dissemination of developments; this Committee shares the concern. However, the principle addressed to this problem (B4), if taken literally, raises the possibility of the reverse problem. This all-but-explicit endorsement of routine recourse to randomized clinical trials not only challenges the conventional pattern of innovation in human medicine but will require considerable expense and, frequently, a great deal of time. In the end, much needless consumer expenditure for ineffective treatment may be eliminated, but a substantial front-end cost and considerable political controversy will be encountered. The probable intent of the drafters of this principle, and our view as well, is that studies on risks and benefits especially are required before the wide-spread introduction of a new procedure throughout the health care system. We are concerned about the spread of fads, and the development of habits in health care practice which lack a solid basis in scientific evidence. But the clinical studies

needed to produce such evidence must not be structured as obstacles to responsible clinical innovations; it is obviously in the public interest to encourage a steady flow of well-considered new developments. We suggest, therefore, that Principle B4 be tempered to address this perspective. The critical issue in our view lies more at the level of widespread utilization and reimbursement for new procedures than at the point of innovation.

In Principle B7, the notion is raised of using the health care dollar to help support large scale clinical trials, health services research, and other applications research. We presume this specifically means that the budget of the Health Care Financing Administration (HCFA) is a possible source of support for the applied health sciences, particularly if an increase in funding for this area is intended. The Committee finds this a reasonable suggestion--as a way to find new funding sources, to protect the fundamental sciences, and to link health care services and research more closely. An agency such as HCFA has a clear need for the information generated by applied inquiries about the services and systems it is supporting. The "health care dollar" goes beyond HCFA, however, private insurers and purchasers of health care (employers and employees) also have a potential role in supporting applied research and should be involved in discussions about this important financing possibility.

We are not certain about the preferred locus for large-scale clinical trials. These efforts benefit from a special blend of managerial expertise and scientific/technical competence, and require substantial funding--a combination that is not easily found. In undertaking such large-scale studies, it may be desirable to have joint ventures between the Public Health Service (PHS) and HCFA; for example, HCFA might well finance such studies and PHS conduct them. This is yet another policy option in need of study, and with some urgency. Agencies and institutions that pay for health services are likely to be increasingly concerned about what they are paying for in health care, particularly as worries about cost control grow.

Additional comments on specific principles follow:

- In cautioning that needed increases in support for "clinical applications, clinical trials and health services research should not erode support for fundamental research" (B7)--a principle which we endorse--it would be useful to recognize that the costs of each of these neglected areas vary widely. Large scale clinical trials may each cost many millions of dollars, (even though some of these costs are not associated with the

trial itself and are instead costs of care that would have been purchased anyway), whereas needed support of health services research, for example, is probably of a smaller magnitude than the aggregate cost of all desirable clinical trials.

- The value placed on peer review and excellence (B8) is endorsed by this Committee here and elsewhere.
- Principles B9 and B10 speak inadequately to problems of knowledge dissemination and technology transfer. It will be important to consider not only the dissemination of information, but also methods to assure proper and adequate utilization of new information in the field. This area, too, will require much effort over a long period of time.
- As regards "consensus development approaches," (B10) we assume these refer to recent NIH workshops on health interventions of uncertain or controversial risks and benefits (such as mammography). Although we agree that it is useful to bring together experts and experienced practitioners from time to time to summarize the current state of knowledge regarding specific health technologies, such meetings are no substitute for needed evaluation of health care interventions through rigorous research.
- The task of establishing priorities for applied research is discussed in Principle B11. We agree that many of the factors listed are proper issues to be weighed in setting priorities. The principle, however, is silent on the subject of who is to set the priorities. Without further discussion of this fundamental question, the principle avoids a very important set of issues that pertain, among other things, to this current planning activity. As we ask in Part II of this Report, after all the principles are in hand, what set of decision-makers will actually set the five-year research priorities for DHEW?
- Coordination of health research in DHEW is the subject of B12 and B13. Although the phrase "pluralistic approach" is ambiguous, we are generally supportive of the idea that research areas may be overlapping. Multiple approaches to similar problems are often productive. We are more concerned about the recommendation for a

Secretary-level committee to "coordinate" DHEW applied health research and the confusing suggestion about NCHSR becoming the "operational arm" of this Committee. We do not have sufficient insight into the administrative workings of DHEW to know whether or not this is a good idea. Perhaps the Committee would be better located in the Office of the Assistant Secretary for Health or elsewhere. In any event, this issue requires more careful study--preferably within the context of our suggestion for a permanent health sciences planning mechanism--and should not be settled prematurely in a statement of principles.

- The very last sentence of the last principle in this section states that "coordination must also be increased between DHEW and private industry, particularly in the area of developmental research." In our view, one of the major deficiencies of the principles is that public-private sector relationships are neglected. This single statement is inadequate for the importance of the issue. For example, the principles do not speak to the role of private industry in supporting large-scale clinical trials, in developing prototypes of medical products or devices based on advanced research carried out in academic or government research institutions, or in promoting health education and information dissemination. A fully adequate five-year plan for health research should include consideration of such matters.

C. Principles Regarding Health Regulation and Promotion

" This focus addresses the further development of the knowledge base necessary for regulatory decisions and preventive and control measures, the need to communicate effectively the nature and inherent constraints of the regulatory process, and the need to explore more structured and creative interactions between the health research agencies and the agencies responsible for health promotion and regulatory activities.

- C1. Principle--The knowledge base necessary to protect the public health through the establishment of preventive measures, the conduct of health education and promotion activities, and the formulation of regulations must be further developed.
- C2. Progress in health regulation and promotion requires an increased commitment to health research, both basic and applied. The behavioral sciences are an integral part of this effort.
- C3. Support of fundamental research should continue to be the responsibility of NIH. The NIEHS and NIOSH have a special role in adding to and exploiting basic knowledge to improve our understanding of environmental and occupational hazards. The support of applied research that is necessary to convert limited information into scientifically acceptable regulatory and control options should continue to be pluralistic.
- C4. New approaches must be explored to assure that the knowledge needs of the regulatory agencies are clearly and systematically communicated to the health research agencies and that health research is responsive to these needs.
- C5. The public should be informed about the nature of the regulatory process, its strengths, and limitations, including the constraints imposed upon it by the frequent need to make immediate decisions based on available knowledge.
- C6. Research (most of it basic) should be supported to determine the most effective means of health promotion and disease prevention, the best ways of transmitting information to effect changes in behavior, and how specific measures can be most effectively directed to different populations. Programmatic approaches for health promotion research should stress the total range of interrelated health conditions.

- C7. The public must be encouraged to improve health by adopting preventive measures and, when necessary, altering nutrition, environments, lifestyles, and behavior to reduce the risk of disease, disability, and premature death. Such measures are more beneficial and less costly in the long-run than pursuing curative or rehabilitative approaches. More reliable data bases should be developed to help guide such decisions.
- C8. Research is needed to provide broader and more accurate data bases and assessments of well-being and effective social function as well as more accurate measures of the burden of illness.
- C9. In order to promote better health and to prevent illness, intensive and innovative cooperative efforts must be pursued by the government, health professionals, voluntary health organizations, and others in the private sector so that the public may be better informed and educated about the application of knowledge gained through research.
- C10. An expanded effort to support large-scale epidemiologic studies should be initiated as an approach to health protection. Such studies should include the natural history of disorders and the identification and quantification of both risk and protective factors.
- C11. The Secretary, DHEW, should be empowered to maintain an undesignated research fund to be allocated by an interagency coordinating committee with representation from NIH and the regulatory and service agencies for the purpose of dealing with urgent problems that arise unexpectedly in the health protection and health promotion areas."

Commentary

Regulation and promotion of health are activities not ordinarily considered when one reviews the research enterprise. However, as concern grows about the toxic effects of environmental pollutants, and the importance of health-enhancing behavior receives greater recognition, it is clear that further research in health promotion and regulatory activities is necessary. We endorse the explicit attention in the principles to these issues.

The historical basis of regulation in health has been well described. The sanitary movement of the 19th century occupied the energies of several generations of reformers and social activists and may have been largely responsible for the declining death-rates at the end of that century. Child-labor, sewage disposal, food and drug safety, work-place hygiene and water purification are only some of the health issues that required regulatory intervention. The conflict between the health of the consumer or worker and the desire for profit by the manufacturer has often been reconcilable only by regulation. Health promotion has an even more ancient basis, and in many societies, behavior detrimental to health has been recognized and actively discouraged--alcohol and drug abuse, over-eating, and smoking being prime examples of harmful behaviors. Given this historical perspective, we find it most appropriate that these DHEW principles give explicit attention to the interplay of health with regulation and behavior.

Several themes related to the principles which we wish to highlight with approval include:

- The appreciation that we need to know more about personal behavior related to health, and how to modify such behavior. We have learned well that admonitions to behave in certain health-enhancing ways are not enough. A great deal more research, much of it basic, will be required if modifications in personal lifestyle are to be encouraged successfully.
- The discussions of epidemiology, biostatistics, and other population-based sciences as principal tools in the area of health promotion and disease prevention.
- The specific attention to the research needs of the regulatory agencies.
- The recognition that improved measures and methods are needed within the science base of health promotion and disease prevention. For example, survey data of many types are needed, and we require more sophisticated measures of health status than existing mortality and morbidity indices provide.

The discussion of the research needs of regulatory agencies is particularly important. There are unfortunate past examples

of a lack of cooperation between research agencies and regulatory agencies. There needs to be a resolution of whether or not regulatory agencies should increase their research capacity at many levels in order to meet their responsibilities. As noted earlier, we urge that DHEW examine this issue very thoughtfully before a decision is made, and that such examination distinguish clearly between fundamental and applied research. We have already stated our view that fundamental biomedical research should remain the responsibility of NIH and, to a much lesser extent, ADAMHA. However, we reiterate that there is need for further analysis of the responsibility of various DHEW agencies, including the regulatory agencies, for fundamental research in fields other than the biomedical sciences.

The last sentence of C3 states: "The support of applied research that is necessary to convert limited information into scientifically acceptable regulatory and control options should continue to be pluralistic." We are not sure what "pluralistic" means in this context, but we are sympathetic to the idea that regulatory agencies must be able to meet their needs for the results of short-term, applied research, on the condition that funds for such work are specifically provided and earmarked.

Principle C7 discusses the goal of modifying personal behavior to enhance health. We find this perspective important and support the need for basic research about behavior (C6). We contend, however, that social institutions also figure prominently in health-related behavior. For example, the food and advertising industries share the responsibility for the poor nutritional and diet patterns in the population. In efforts to prevent disease and promote health, we should encourage institutional change also, and not focus exclusively on individual behavior. Principle C9 speaks of the need for "intensive and innovative cooperative efforts...by the government, health professionals, voluntary health organizations, and others in the private sector" to educate and inform the public about new knowledge regarding health promotion and illness prevention. These "cooperative efforts" should also be directed towards changes in organizations and social institutions so as to create a milieu favorable to personal health.

Additional comments on individual principles follow:

- C5 correctly suggests that the public needs to know more about the process of, and rationale for, regulation. We note that in the current climate of debate and controversy regarding regulation, there are those who argue for less regulation and attempt to trivialize the adverse effects of regulated products; there are others who argue that regulatory agencies are not adequately protecting the public interest. In this atmosphere of tension resulting from such divergent views, the public needs to be better informed about the concepts and

practices of regulation, and the data on which regulatory decisions are based, so that disagreements about various aspects of regulatory activity may be debated and resolved wisely.

- The first sentence of C3 does not acknowledge the presence of ADAMHA in supporting fundamental biomedical research, or the need for additional consideration regarding the administrative locus for fundamental research in disciplines other than the biomedical sciences (see page 29 for a fuller discussion of this issue).
- C6 mentions "interrelated health conditions." This phrase acknowledges that, particularly with the emergence of chronic disease as a major part of the burden of illness, health problems are now understood to have multiple causes, and multiple connections with other health and even social problems. Consequently, a wide range of approaches is required for their diminution or prevention. However, multidisciplinary and interdisciplinary studies often do not fit conveniently within the disease specific institutes of NIH, for example, and may not be funded adequately due to such institutional barriers. The mechanisms for funding multidisciplinary research within DHEW need additional attention.
- C10 is, as noted, most valuable for its strong endorsement of epidemiological studies. However, the term "large-scale" may be misleading. Some epidemiological research is quite small in scale, but also in need of greater support. We note that epidemiological teaching and research in medical schools are particularly neglected.
- Principle C11 proposes that an "undesignated research fund" be maintained by the Secretary for urgent needs related to health protection and health promotion. We suggest that the problem of establishing mechanisms to fund research that responds rapidly to suddenly appearing needs without abandoning quality standards is a more complex one than can be solved by a single committee or mechanism. Flexibility and more rapid response to new needs for research would be valuable in all areas—not solely health protection and health promotion. Deciding on the best mechanism to provide such flexibility will require a detailed review of, for example, the grant and contract award processes in all health-related agencies, alternative mechanisms for allocating flexible funds (using what priority system?), and the strengths and limitations of centralizing control of such funds in the Secretary's office; other loci might be more appropriate.

In our view, several areas were not given adequate prominence in this set of principles:

- The importance of establishing specific funding mechanisms for epidemiological studies.
- Research on the processes and practices of regulation. What are the benefits, costs, and conflicts inherent in regulation directed towards protecting the health of the public?
- The need for better "early warning systems" to identify occupational and environmental health hazards.
- The tension between private economic interests and the protection of the health of the public in a democratic society.

D. Principles Regarding Research Capability

" This focus addresses the need to assure that the resources, both physical and human, necessary for the conduct of research are available.

- D1. Principle--Present research capabilities must be sustained and enhanced to assure future health gains.
- D2. Programs designed to enable capable young women to compete successfully for research support should be provided.
- D3. It is essential to bring into the research community new investigators with new and innovative ideas and to provide them with support to capitalize on opportunities.
Individual peer-reviewed project grants, institutional fellowships and some new and innovative highly targeted programs are some of the mechanisms through which this could be accomplished. This is necessary to train and maintain the next generation of investigators. Research careers must be kept competitive with other pursuits in order to attract and train outstanding individuals.
- D4. Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and medical careers. Support at both the pre- and postdoctoral levels are necessary to accomplish this.
- D5. Recruitment of young researchers to areas of greatest national need and scientific promise must be encouraged. Mechanisms that may aid in doing this are individual research career development awards, individual and institutional fellowships, and new and young investigator and academic awards.
- D6. Clinical research depends upon providing opportunities for promising clinically trained individuals with aptitude for research to develop into independent investigators as well as for Ph.D.'s to enter clinical and other research disciplines.
- D7. It is essential to provide opportunities to individuals who have just obtained health professional or research degrees to embark on academic and/or Federal research careers.
- D8. Investigators of proven productivity should be able to depend on stable research support during their demonstrably active careers and should be buffered against radical short-term changes in policy.
- D9. Programs to encourage the research training and research grant support of minority investigators and institutions should be continued and expanded.

- D10. Programs designed to enable capable young women to compete successfully for research support should be provided.
- D11. Programs to support multidisciplinary, collaborative research approaches must be available.
- D12. Programs need to be established and/or expanded in research areas currently undermanned, such as biostatistics, epidemiology, demography, sociology, environmental and occupational health.
- D13. Major research activity at research and academic institutions such as health professional schools, graduate schools and Federal and National laboratories, such as the NIH intramural research program, must be fostered, and research support provided in a stable manner. Performance of research is inseparable from the learning process, enriching both directly and indirectly the quality of health care:
- D14. Investigators and institutions need some measure of stability and should be buffered against radical short-term changes in policy.
- D15. It is essential to provide an adequate level of long-term support to assure stability of training programs concerned with fundamental and clinical research in biomedical and behavioral disciplines.
- D16. Physical resources must be renewed and maintained. This requires giving attention to both equipment and facilities, since both are major determinants in the productivity of capable scientists.
- D17. Resources should be conserved through sharing, methods developed to stimulate greater ingenuity in the design and construction of laboratories and buildings, and support for health science libraries and other biomedical communication resources continued and expanded.
- D18. Grants for improvement of existing and construction of new animal facilities must be continued and expanded, as well as support for breeding and base-line characterization of needed research animals. The potential for preservation of stocks of organisms in the dormant state should be explored, as should reliable methods for frozen maintenance centers and distribution of stocks when called for.
- D19. A continuous assessment of ongoing needs and resources should be pursued. Additional studies of the future of junior faculty positions are needed, and the employment model used in estimating needs for the number of trained individuals and disciplines should be expanded into a more complete job market. Data to evaluate and monitor the condition of existing facilities and equipment are needed."

Commentary

In general, we endorse this set of principles, although as a beginning, it would be wise to distinguish clearly among human resources, physical resources, and animal resources (see paragraph D19) because different considerations come into play in planning for each. Human resources are the most important and merit the highest priority in funding.

A number of problems make it difficult to plan for meeting human resource needs. The course of science is difficult to predict, and the talents of well-trained scientists can be flexibly and diversely employed. The idea that one can predict "needs" for a particular number of persons trained in a specific scientific discipline is, accordingly, inappropriately narrow. Yet we can forecast confidently that a steady flow of young scientists is required to maintain the vitality of the nation's research enterprise. Current data on demand for and supply of scientific research personnel are inadequate, and we have insufficient and incomplete knowledge about the course of research careers in health science. The needs for research personnel seem intimately linked to the level of federal funding; yet short-term fluctuations in that level must not be matched by attempts to narrow and widen the flow of trainees, for research training is a long-term enterprise. The time interval from the decision to enter a research career to the achievement of independent investigator status is about a decade. The full effect of moves to encourage or discourage entry into research careers will not be felt for 15 to 20 years, but the effect will be irrevocable. If we make the mistake of skipping a generation in the 1980s, health research will suffer severely, for young scientists are "not only essential for the future, they are also indispensable for the work that has to be done today," as the Report of the President's Biomedical Research Panel asserts.

Scientific research is a career that requires particular talent, temperament and motivation, as well as specialized preparation. Many early aspirants to research careers soon find that they do not possess one of these attributes and willingly turn to other pursuits. It is thus important both to expose potential research scientists early to the opportunities as well as to the rigors of the career in order to help them make an appropriate choice, and to facilitate their progress along a pathway that may be long and difficult.

The principles are valuable in calling attention to the special needs of training clinical investigators (D6) - an issue that has been raised by the observations of the NAS-NRC Committee on National Needs for Biomedical and Behavioral Research Personnel and by the Institute of Medicine's Committee on Health Sciences

Policy. There is agreement, so far, only on the existence of a problem--namely, the apparent undersupply of candidates qualified to pursue clinical research careers. There is less agreement on the reasons for this situation, which may include:

- the disincentives of relatively low stipends for trainees and the burden of payback requirements;
- the economic unattractiveness of a career in research compared to the practice of specialty medicine;
- the current shortage or instability of research grant funding--especially for new (hence unproven) investigators;
- the dearth of research oriented internships and residencies for newly graduated MD's and especially for M.D.-Ph.D. graduates;
- current public attention and policy emphasis upon needs for primary care;
- a significant motivation toward non-research directions arising from the requirements of medical specialty board certification, and recent changes in medical school curricula.

Any or all of these explanations may have some merit. If the field of clinical investigation is to be strengthened, as we have advocated, it will be important that the relative significance of these various factors be analyzed, and that policies to enhance the attractiveness of this field be implemented.

In the interim, there are some readily apparent counter-measures that are worth pursuing. There appears to be a consensus that the Medical Scientist Training Program of NIH is effective in attracting talented medical students into clinical research. Some successful attempts have also been made to provide clinical experience in medicine to Ph.D. scientists with the aim of focusing their attention on clinical research. Such programs deserve further analysis to determine their benefits and limitations.

We note that--just as we are calling attention to the field of clinical investigation--the principles themselves (especially D12) attempt to specify certain scientific areas requiring nurture. Based on the aforementioned NAS Committee on National Needs, we would agree that toxicology, biostatistics, and epidemiology appear to be shortage areas. Conversely, there seems to be an oversupply of doctoral level biomedical

scientists in relation to available positions for such individuals, due primarily to demographic factors that are leading to no growth in higher education enrollments, and to budgetary decisions that have slowed or stopped growth in research funding. However, it is important to recognize that, for all these areas, there are many difficulties in determining national needs in scientific fields, or in developing evidence for oversupplied or undersupplied areas. The match between available positions and personnel is a complex mixture of economic, social, and educational factors. For example, oversupply may mean both that the nation is not providing adequate career opportunities in needed areas for properly trained scientists, and/or that there is a true excess of trained individuals given both the needs and opportunities in a given area. As regards the reverse problem, we suggest that if an undersupplied area is identified, remedies will likely include a combination of training support and project support—often in combination—to ease the shortage.

Several of the principles speak about institutional stability, which the Committee views as a central issue in research planning. We believe that a national strategy for health sciences research should explicitly and clearly recognize the role of the institution in which individual investigators work and its needs for stability. It is not enough to ask for stability of funding for investigators. It is also essential to provide for institutional integrity and freedom from disruption by radical short-term changes in policy. The university assumes responsibility for the support of teacher-investigators when they join its faculty, and assumes responsibility for seeing that facilities and equipment are provided, responding in good faith to governmental requests for research. The institution deserves some buffering from the inordinate number of program re-directions, eliminations, new initiatives, and expansions that have characterized recent federal programming. Institutions also require reimbursement for the indirect costs of research (overhead) which truly compensate them for the actual costs of supporting the research and the research environment e.g. animal facilities and libraries. Training programs (D15) share this need for stability. Program and funding disruptions lead to inefficiencies in the use of funds, to depleting institutional resources, and ultimately to discouraging the talented individuals who would undertake research careers.

The principles might usefully recognize the significant part now played by the Biomedical Research Support Grant (BRSG) in fostering institutional stability and helping the research institution to fulfill its obligations. Such funding provides

start-up support for new investigators and exploratory work on untested research strategies, smooths out some of the discontinuities that seem inevitable in the current pattern of project grants, and economizes on total system effort in the assessment of small-scale innovative inquiry.

A possible contradiction threads throughout the principles. The call for stability of support for productive investigators during their active careers, and the notion of providing for new investigators and fresh talent may be in conflict, particularly if an environment of sharply limited research support exists. This conflict is not easily resolved and is therefore identified in Part IV of this Report as an area requiring careful study.

One issue not adequately discussed by the principles is whether training programs--like aspects of applied research--should be mission-oriented or problem-specific. Our view is that training, even more than research, should not be "targeted" on current health problems although it is clearly appropriate to select certain disciplines for special support. The long interval required for training scientists suggests that efforts to focus training programs on special health problems is usually inappropriate, except, perhaps, in a very few scientific areas or in the later stages of training.

The need to provide adequate physical facilities and equipment is appropriately highlighted in the principles (D16 and D19). However, we require better information on facilities and equipment to plan rationally for their renewal (as emphasized in D19).

Although not specifically mentioned in the principles, we suggest that it is important to maintain clinical research centers. The metabolic ward model is not the only or even the most significant type of needed clinical research facility; nevertheless it serves an important purpose, particularly in studies of chronic disease that require environmental and dietary control and continuous monitoring of patient functioning. Other types of clinical research facilities are important for other types of problems--e.g. the scattered facilities for the study of acute, severe disease, and outpatient facilities for ambulatory conditions.

We are also concerned specifically that the animal resources required for selected aspects of health sciences research be maintained and increased as needed. The October Conference Panel report on research capability outlined this issue adequately, pointing out the need for the ready availability of genetically controlled, well-characterized stocks of a wide variety of research organisms, the need to support improved animal research facilities

and to search continuously for new animal homologs of human diseases, and the importance of maintaining existing animal models—e.g. non-human primates.

We comment additionally on three specific principles:

- We strongly endorse the prominence given in Principle D11 to multidisciplinary, collaborative research programs, particularly in applied research. Health problems, by their very nature, are often complex and are not readily resolved by unidisciplinary research. There is need to facilitate the multidisciplinary collaboration advocated in the principle, so that scientists may join in generating research programs that are of a scale suited to the dimensions of many of our health problems. This principle, incidentally, probably belongs in another section, perhaps "unifying concepts."
- Principle D17 states that: "Resources should be conserved through sharing, methods developed to stimulate greater ingenuity in the design and construction of laboratories and buildings, and support for health sciences libraries and other biomedical communication resources should be continued and expanded." The need for greater sharing within and among institutions of expensive or precious resources is a highly significant issue. Computer centers and animal research facilities are examples of such resources that should be shared to avoid unnecessary expense and duplication of effort. Much could be learned from the field of high energy physics in which expensive facilities are routinely and efficiently shared. More specifically, as this principle is phrased, it misses the point of the panel comment from the October conference, namely: ingenuity in design in order to achieve greater flexibility in usage. Also, it is unclear why only libraries and communication resources are singled out specifically for "continued and expanded support," but not for the application of ingenuity or conservation through sharing.
- D19 calls for the expansion of the employment model used to estimate research personnel. Although this sounds plausible, the expansion may be difficult and costly because of the dearth of data; and the result may not be worth the effort since the fragmentary evidence available suggests that all but a small fraction of biomedical and behavioral research related to health is performed in universities, federal and state governmental agencies. D19 also asks for additional information on the number of junior faculty positions needed in the future; we agree that such data are desirable.

E. Principles Regarding Unifying Concepts

" This focus deals with concepts that provide the basis for consideration of the philosophic base for public funding of health research and the interactions among the different parts of the research continuum necessary to move from the development of new knowledge to the application of research findings. Considerations include the need: to reaffirm the Federal support of health research; to fulfill public expectations regarding a return on the public's investment in health research; to communicate effectively the nature of the scientific process, its limitations and benefits; to develop bridges between fundamental and applied research; and to explore new interactions and processes.

- E1. The Federal Government should support health research, and the rationale for such support should be clearly presented to the public which makes such support possible.
- E2. There should be long-term stability in the funding of health research, but within this stability of funding there should be sufficient flexibility to allow for a rapid response to promising new research opportunities.
- E3. Fundamental research should be defined broadly and the need for a science base (or basic research) should be reaffirmed.
- E4. The funding and training of young investigators are essential to the future of health research.
- E5. The decision-making process in the formulation of health research policy should be both open and accountable.
- E6. Health research policies should be formulated in the light of a gradually evolving set of ethical and legal standards for the conduct of such research.
- E7. Efforts to involve previously underrepresented groups in health research should be continued.
- E8. DHEW agencies can perform an important matchmaking function by identifying mutually relevant and reinforcing research efforts.
- E9. The criteria for setting health research priorities among various fields and approaches should not be rigidly defined, but should consider a variety of factors ranging from research opportunity to social need."

Commentary

These principles, which touch on many basic philosophical and policy issues, represent a substantial condensation of earlier versions of the principles, particularly as compared to the September 15, 1978 draft. The process of wringing out possible controversy resulted in language that is so general that it is difficult to be sure which choices are being advocated. Thus, the comments in this section are intentionally less directed to the explicit language of the draft principles than is true for the four preceding sections.

These current unifying principles are altogether commendable. What is left out is the means by which health research can be made more effective; especially by bridges between fundamental and applied research.

The draft gives no hint of how poorly informed we are about the processes of creative discovery and its fruitful applications. There is little room to quarrel about the overall relationship of research and innovation, nor about the high return of benefits from health research investment. When it comes to finer details like the resilience of research motivation in the face of external regulation (accountability) or the optimal structure and allocation of research effort (by discipline or by immediacy of application), we are relying on common sense and personal belief. We should not confuse intuitive pronouncements on how best to do science with the better validated products of scientific inquiry.

Appropriate policies for scientific research could perhaps be elucidated through further systematic analysis of the history of research. Except for the work of Comroe-Dripps, most of our current knowledge about the scientific process is fragmentary anecdote. In many cases we would not know how to answer either "could the time to discovery be shortened?" or "could fruitful applications have been accelerated?"

A key fact that must illuminate public expectations of contemporary health research is the difference in the research tasks posed by infectious versus the degenerative diseases which are our principal challenge in health today. The latter entails laborious search for deep knowledge of the human organism far more complex and less accessible than the biology of the known parasites. Nevertheless, the stock of fundamental biological knowledge acquired during the last 25 years has implications for revolutionary advances in the improvement of health during the next 25.

Even for applied research, a cardinal principle should be: "How can we best exploit the most creative minds--how to identify, encourage, guide, and support rather than frustrate them? And how can we improve the most effective interplay of knowledge gained through both fundamental and applied research?"

The articulation of fundamental science with applied science requires the most thoughtful attention. Linkages are usually accomplished through a variety of institutions, notably the research universities and medical research institutes. In the name of accountability, many obstacles are placed in the way of such organizations and of efforts at integration; and little is done to relieve innumerable fiscal, political, and administrative stresses that tend to splinter into microscopic projects the activities that should be integrated.

At some point, accountability as an end in itself can defeat the underlying purpose of the enterprise. The greatest pressures for accountability arise when grants are based on overly narrow precepts that do violence to the service institutions that receive and administer the grants. Accountability should be tempered to meet reasonable public aims and to avoid fraud, not to lockstep each grantee to the bureaucratic rigor of the funding agency.

The linear continuum of research expressed throughout the principles is an over-simplified mode. In many cases, clinical observations or puzzles arising from practice have inspired the most fundamental inquiries. For example, the work that led to the discovery that DNA was the hereditary substance arose out of the most practically motivated efforts to develop vaccines for the prevention of pneumonia. The progressive compartmentalization of scientific inquiry into narrowly defined projects tends to frustrate the feedback along the research continuum which is necessary for the most vital exploitation of unpredictable opportunities.

The facilitation of communication among investigators who work at different points on the research continuum is preferable to centralized mandates for the pursuit of specific objectives by different actors. Funding mechanisms should facilitate productive interactions and communications between basic and applied scientists and between investigators in different disciplines, and should enhance the interplay of research and training.

Beyond these more general observations, we wish to discuss several individual principles:

- El discusses both the role of the federal government as the major supporter of health research and the need for taxpayers to be provided with a cogent "rationale" for such support. We wish to amplify this important principle. There are few alternative sources of support for health research outside of the public sector, as private sector research pertinent to health is governed by considerations other than national need. And although the private, non-profit sector provides important support for selected areas of health research, its resources are in no way comparable to public sector capabilities. The importance

of this federal role and responsibility cannot be emphasized enough. We also suggest that the rationale for such support has in fact been presented on numerous occasions--most recently in selected appendices to the President's Panel Report. We nonetheless endorse strongly the idea that the rationale should be presented frequently, in order to provide the public with an informed basis for deciding whether its trust and support are merited. This does not suggest that the public is wavering in its support of health research. Indeed, it is essential to this entire planning activity to recognize that public support for research in general, and research to improve health in particular, is high and strong. This is one important reason why policymakers should have little reluctance to take actions to extend and enhance the health sciences.

- We support the philosophical allegiance to openness in policy formulation, as stated in E5. Both the courts and public opinion support this approach. Yet we have much to learn about mechanisms to provide for such openness in a constructive fashion. The limited success of the October 1978 Conference on Health Research Principles demonstrated that much careful attention is needed to the problem of how best to structure public involvement.
- E6 quite properly asserts that research, like all other social endeavors, should comply with existing legal and ethical norms. If this principle speaks indirectly to regulation of research, we refer back to and endorse the discussion of regulation at the end of the discussion on the Fundamental Research principles.
- Principle E9 states that "the criteria for setting health research priorities among various fields and approaches should not be rigidly defined, but should consider a variety of factors ranging from research opportunity to social need." An earlier version of this principle which appeared in the September 1978 draft was more illuminating, and we therefore restate it below:

"Investments in areas of health research should be guided by many factors, including research opportunity, burden of illness measures, demographic trends, public perceptions of the relative importance of different health areas, current state-of-the-art, previous investment and return experiences, near term potential for new breakthroughs, problem areas identified through

disease surveillance and investigation of disease outbreaks, interrelationships with other research problems, benefits which may accrue by elimination or improved treatment of disease, the perception of those concerned or involved in dealing with social problems or needs, and a continuing retrospective assessment of health benefits attained through research expenditures. The relative importance of the above factors in allocating resources should vary between basic and applied research."

PART IV

TOPICS FOR FURTHER STUDY

The Committee wishes to call attention to an additional concern that transcends earlier comments about the process being used to develop the plan and about the individual principles. Several significant aspects of the federal role in health research have not yet been raised in this activity. There are also some issues that have been raised, but have been inadequately discussed or resolved.

Given the time available for this review, the Committee cannot analyze these issues or make specific suggestions about how they should be handled in a comprehensive five-year strategy for health research. Nonetheless, it is our view that these issues are central to the task of planning for health research. To exclude careful consideration of them in the current activity runs at least two risks: 1) that federal support of health research for the future will be planned without having addressed these fundamental issues--a shortsighted approach that overlooks challenges and problems facing the research enterprise; and 2) that these issues will be resolved or settled all too quickly in the last stages of this planning activity, with only superficial analysis, and therefore without an adequate basis for effective and wise action. As we have noted earlier and frequently, the Fall 1979 deadline for the completion of the plan does not seem likely to allow for the detailed inquiry these issues require--a possibility that adds to concerns expressed earlier about the process being followed to construct the plan.

Several of these fundamental issues are listed below:

- The development of an appropriate equilibrium between the requirements of stability for support of research, and the need to provide opportunities for young investigators. What are the approaches that may provide for continuity of support for proven senior investigators and yet not so limit the opportunities for newly trained scientists that the flow of bright young investigators slackens? Is it possible, through a variety of support mechanisms and through careful administrative tuning, to achieve both goals?

- The administrative locus for, and financial support of, clinical trials, particularly large-scale trials. Which institutions are best suited to organize and conduct large-scale clinical trials in a way that provides for both scientific and management expertise? Is it possible for several DHEW agencies to participate in the support of clinical trials? How are such trials to be financed, and is there a role for combined private and public support of such activities? How can new sources of funding be developed? By what guidelines are specific trials to be selected from the universe of all possible trials?
- An institutional home for modern "public health research." Is there a need for a new administrative locus for a constellation of scientific areas which are currently scattered and undersupported throughout DHEW—including epidemiology and biostatistics, health services research, and prevention research? Given our growing understanding of the need for, and contribution of, research in these areas, how best can these areas be nurtured and invigorated?
- Organizational aspects of the NIH, including both its intramural and extramural program. An incisive review of DHEW's health research activities should include analysis of such items as: the desirability of categorical institutes; the effects of the categorical labels on public understanding of health research and on support for non-categorical missions such as those embodied by the National Institute of General Medical Sciences; the relationship of the NIH intramural program to its extramural activities; the limited peer review of the intramural program; and the differences in career paths afforded scientists in the intramural as compared to the extramural program. An analysis of such issues, however, should occur within a framework that recognizes the value of the NIH and defends its administrative and functional integrity. The flexibility of the NIH must be maintained and its successful record acknowledged and reaffirmed.
- The coordination of public and private health research activities. What should be the relationship of these two sectors, particularly regarding development needs growing out of fundamental and applied research? What is required to take a scientific advance and translate it into an effective application in health care, particularly

when the public sector is reluctant to become involved in development activities, and private industry tends to work only on those products likely to be profitable? How can the federal government better stimulate innovation, the transfer of innovations into practice, and the ongoing evaluation and monitoring of new interventions?

- The introduction of new diagnostic, therapeutic, and preventive procedures into the health care system. At what stage are clinical trials to be mounted and under the auspices of which agency? In practical terms, how can monitoring and evaluation of technology occur in a way that does not stifle innovation but also assures that widely used procedures are of known risks and benefits? What is the role of third party insurance reimbursement mechanisms in assuring that only procedures or products that have received appropriate clinical evaluation are reimbursed?
- Providing for an adequate pool of clinical investigators. The Committee notes with concern the growing difficulty in attracting and retaining an adequate pool of researchers who span the fields of fundamental research and clinical practice--a critical link essential to the mutual stimulation of both areas of science. What are the causes of the diminution of physician interest in the field of clinical investigation? How might training programs, career paths, support mechanisms and other factors be modified to increase the number of highly competent clinical investigators? What are the institutional barriers to vigorous exchange between and among the fundamental and clinical sciences and how might these be eased?
- Systematic sharing with other nations of ideas, information, and resources pertinent to health research. Are current mechanisms adequate for such international cooperation and coordination? If not, how may they be improved?

We also reiterate that several issues raised in the principles should be studied further before action is taken. These include such matters as the relationship of DHEW research agencies to the regulatory, health policy, and health care service agencies; mechanisms within DHEW to coordinate applied health research; and the administrative locus for fundamental research in areas other than the biomedical sciences.

Research Needs for Research Planning

In coming years, planning for research will probably increase. Good planning for health research, however, is hampered by the lack of adequate information on a variety of issues which should all be weighed carefully in developing a plan. Some of these needs for "research on research" are listed below and are suggested as topics on which information should be collected in order to improve the data base for future planning:

- Past patterns of research support (including financial, institutional, and personnel dimensions) that have proved to be especially productive, as a guide to preferred patterns of support for the future. The Comroe-Dripps study is an excellent beginning for this area of study related to the biomedical sciences; for other fields, such as biostatistics, epidemiology, and the behavioral sciences, such historical data need to be developed.
- Analytic work on the general problem of establishing research priorities, including the development of methods for assessing the state of a science and outlining areas of scientific opportunity.
- The burden of illness nationally and internationally, utilizing many measures beyond mortality to assist in establishing research priorities.
- The incentives and disincentives facing individuals who have elected careers in health research, particularly those in the area of clinical investigation.

Senator KENNEDY. The subcommittee stands in recess.
[Whereupon, at 12:30 p.m., the hearing was recessed, to be recon-
vened Wednesday, May, 2, 1979.]

HEALTH SCIENCE PROMOTION ACT OF 1979

WEDNESDAY, MAY 2, 1979

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, at 10:10 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Schweiker, and Javits.

OPENING STATEMENT OF SENATOR SCHWEIKER

Senator SCHWEIKER [presiding pro tempore]. The Health and Scientific Research Subcommittee will please come to order.

I am pleased to be present this morning, as our subcommittee continues hearings on legislative and oversight aspects of biomedical research.

The health research community and our academic institutions have made enormous contributions to the health and prosperity of our Nation, but new challenges await the health scientists.

Senator Kennedy and I have recently introduced Senate Bill 988, the Health Science Promotion Act of 1979, in the hope that this legislation will assist the health sciences as they face these challenges.

In the hearing last week, we heard representatives of the administration address our legislative proposal and the status of Federal biomedical and behavioral research programs.

Today, we look forward to receiving testimony from the academic institutions and private foundations that support and perform health research. I am interested in your perception of the current state of health research and the problems or roadblocks that threaten progress in the health sciences. We will welcome your evaluation of Senate bill 988, and I hope that you have constructive suggestions for strengthening or improving this legislation.

The administration, the Institute of Medicine, and a number of organizations representing the scientific community have endorsed the concept of a national policy for health research and comprehensive, long-range planning for the health sciences. The administration disagrees with the planning mechanism that we propose. But I think we all agree on the problems that such an activity addresses. These problems include: The lack of predictability and continuity in funding for biomedical research—I might say we are struggling with that problem right now in the Labor HEW Appropriations Subcommittee, in which I am ranking, because of the proposals that are presently pending on budget cuts—poor integration

of the many and varied components of health research; and the difficulty of allocating research funds in an equitable fashion in a period of fiscal austerity.

It seems appropriate that Congress play a role in the establishment of research policy and a planning mechanism, in order to provide some permanence for these activities, and, more importantly, so that the planning process can effectively interact with the congressional budget process.

In closing, I would like to address an important problem, namely, the heavy burden of regulation imposed by Government on the scientific community. Individual investigators and their institutions must remain accountable, obviously, for the use of public funds that currently provide the bulk of their research support. Nevertheless, the oppressive paperwork burden resulting from regulation must be limited before irreparable harm is done to the health sciences. The productive atmosphere of trust and freedom that existed between academia and government has already been replaced by an adversarial atmosphere that threatens scientific freedom and innovation. The Health Science Promotion Act contains provisions for the NIH Director to experiment with new methods of accounting and reporting for research grants. We hope that these trials will provide the initial step in redefining the Federal academic relationship, perhaps a new, more positive role.

At this point I will ask that Senator Kennedy's opening statement be inserted in the record.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. Today, the Subcommittee on Health and Scientific Research continues its hearings on the Health Science Promotion Act of 1979. Last Thursday we heard comments from the administration and from a number of Federal research administrators. We move on this morning to hear the views of individuals and organizations representing elements of the research community.

As I emphasized last week, we view S. 988 as an expression of our commitment to promoting the health sciences in this country. I think our Federal health science institutions are fundamentally sound. But those of us who are committed to maintaining those institutions must also recognize that they face a number of important problems which need to be addressed.

In 1974, the President's biomedical research panel, after 2 years of intensive study, concluded that the Congress and the executive branch need more and better advice on the conduct of their health science programs. I think that need persists today.

Just last month, the Institute of Medicine issued a report stating that improved planning in the health sciences could increase the effectiveness of our health science expenditures. I agree.

I think it would be useful to strengthen the office of the Director of the NIH so that he and his organization can respond more rapidly to changing health science opportunities.

I think the Congress needs to commit itself squarely and openly to the support of investigator-initiated research.

I think our peer review system is overworked and understaffed. We need more peer review groups, and we need to be constantly alert to ways our peer review system can be improved.

I think it is essential to reduce the burden of paperwork on researchers in this country and to restore the atmosphere of mutual respect which once prevailed in the relationship between health scientists and their Federal patrons.

These are some of the problems we confront. Whether the solutions proposed in S. 988 do the job remains to be determined. We are here to discuss where they are on target and where they miss the mark. Above all, we are here to begin an open and vigorous exchange on the ways in which our health science institutions can be strengthened and improved to meet the challenges they will confront over the next decade.

Senator SCHWEIKER. We are very pleased to have as our leadoff witness this morning Dr. David A. Hamburg, president, Institute of Medicine.

Dr. Hamburg.

STATEMENT OF DR. DAVID A. HAMBURG, PRESIDENT, INSTITUTE OF MEDICINE, ACCOMPANIED BY SARAH SPAGHT BROWN, STAFF DIRECTOR, DIVISION OF HEALTH SCIENCES POLICY, INSTITUTE OF MEDICINE

Dr. HAMBURG. Thank you very much, Senator. I am delighted to be back with this committee again.

I would like to introduce on my right, Sarah Spaght Brown, the Staff Director of the Division of Health Sciences Policy in the Institute of Medicine, who was instrumental in the completion of our recent report on this subject.

I am very pleased to have the opportunity of testifying today before this committee, for which I have profound respect. I greatly admire the farsighted leadership and stimulation that this committee has provided for many years.

As you may know, the issue of research planning has been a topic of special interest within the Institute of Medicine. The most recent Institute activity centered on research planning is a review of DHEW's research planning principles conducted by an Institute committee.

This study was part of an ambitious initiative within HEW to formulate a comprehensive multiyear plan, involving all of the HEW health agencies—and I emphasize “all”, Senator, because I think that was an important innovation.

The initiative was, in my judgment, an admirable innovation. I believe that, during his testimony before the committee, Dr. Richmond last week described the activity in some detail, and we need not repeat that here.

From our perspective, the important component was the independent review and analysis which the Institute of Medicine conducted on the set of principles, and we raised some questions that go beyond those principles, looking to the future.

We are very fortunate to be able to mobilize an extraordinary committee. It produced a report of exceptional breadth and caliber in a few months' time. The chairman of the 22-person committee was Dr. Irving London, who regrets very much that it was impossible for him to be here this morning. Dr. London is the director of the Harvard-MIT Division of Health Sciences and Technology. We also had panel chairmen on the specific issues that were laid out in

the HEW principles. Those panel chairmen were Paul Berg, Willson professor of biochemistry at Stanford; Keith Brodie, professor and chairman of psychiatry at Duke; Paul Stolley, professor of research medicine at the University of Pennsylvania; and Henry Riecken, professor of behavioral sciences, also University of Pennsylvania, and Joshua Lederberg, president, Rockefeller University.

In the process of commenting on the principles, the committee took the opportunity to discuss some more general issues of research planning and to identify a range of policy matters pertinent to the health sciences that are of great significance and require resolution.

Now, one of the principal recommendations of our committee was that a permanent planning mechanism for health research supported and conducted by the Federal Government needs to be established. This recommendation has obvious relevance to title I of the health sciences promotion of 1979, S. 988, being considered by this Committee.

However, before I discuss this particular title of the bill, I would like to take the opportunity to summarize briefly some of the main points made in the Institute review not only because these points are relevant in and of themselves to health science policy, but also because they provide a framework for the specific recommendations of title I of the President's Council.

Let me quote briefly from the summary of our report.

This committee strongly endorses the introduction of long-range planning for health research. We believe that health research planning, when well performed, will prove to be a valuable mechanism for developing sound and productive national health research policy. Well conceived and executed planning is the Nation's best assurance that there will be optimal allocation of resources for health research and that precious resources will be utilized efficiently.

A long-range plan for health research and the policies growing from it should take into account the past productivity and future promise of the health sciences; our growing understanding of the many factors—

And I would emphasize "many factors"—

That affect health; the essential need for research across the full range of the health sciences to permit further advances in the diagnosis, treatment, and prevention of disease; the heavy burdens imposed by illness on society; and the strong support of the public for health sciences research.

The plan should also reflect the challenge and opportunity afforded the U.S. health sciences community to continue providing leadership in the development of knowledge needed to prevent disease and promote health, not only in this Nation, but in many other nations as well.

I would underscore the emphasis we place there on prevention research and on the worldwide significance of research conducted in this country, particularly the developing countries of the world, as you discussed, Senator, at our recent meeting.

To continue quoting from the report:

We support fully the major message of both the research principles presented to this committee for review and the October 1978 Conference at NIH during which the principles were discussed: namely, a vigorous reaffirmation of Federal support for the health sciences, and a clear call not only for an increased commitment to existing programs of high quality, but also for expansion to important new and neglected areas.

And I would add, Senator, that there is today in the scientific community, as well as in the Congress, a greater concern about searching out new and neglected areas that deserve support and attention.

In neither the principles nor the Conference was the notion advocated of limiting or reducing Federal support of health research.

Further, we support without reservation another message of the principles and of the conference, that fundamental science is the cornerstone of health research, and that support for new and neglected areas must not erode existing support for fundamental research.

Another important point—and I quote—

An additional perspective which we endorse is a broadened concept of the health sciences. Rather than equating health research with biomedical research only, the principles recognize the importance of such areas as epidemiology and biostatistics, environmental sciences, health services research, and the behavioral and social sciences as they relate to health and prevention of disease.

In addition, we wish to emphasize the importance and promise of the physical and chemical sciences and engineering for advancing our understanding of biological and medical processes and for achieving successful and practical solutions to difficult problems in fundamental biology and in clinical medicine.

That ends the quotation. I do want briefly to highlight a few points, rather than read all of them that are listed in my written statement.

Our committee was in substantial agreement with the main thrust of the principles. There were major themes in the principles which we found particularly significant and pulled out of the principles these themes.

My written statement, Senator, contains 16 points which we regarded as particularly significant. I would appreciate it if all of these could be part of the record, but I do not want to repeat all of them now.

Senator SCHWEIKER. Without objection, we will put your complete statement in the record, Dr. Hamburg.

Dr. HAMBURG. Thank you very much.

There are two or three that I personally would like to emphasize. One is the vital role of clinical investigation as a bridge between fundamental research on the one hand and medical practice on the other, and the need to strengthen the field of clinical investigation. That seems to me a terribly important point at the present time.

Another is the need for interdisciplinary research. The Nation's health problems are really very complex. In some ways, they are more complex and difficult than they were 20 or 30 years ago. They do not come in packages, Senator, that fit the historical accidents of the traditional disciplines. To really address the complex chronic disease problems adequately, for instance, we need to find ways to bring disciplines together, and we have not been terribly successful in doing that so far—

Senator SCHWEIKER. Doctor, let me ask you this, do you have a specific mechanism as to how we might consider doing this in the future?

Dr. HAMBURG. Well, one of the mechanisms pertinent to this matter is any form of general research support for the institutions that foster the health sciences with some kind of encouragement for those institutions to use the funds to bring disciplines together.

Now, there are certain specific forms that are useful. For example, the general clinical research centers—in my judgment—and I think it was the consensus of our committee—that those clinical research centers have tended to bring people together from quite different backgrounds and to create a pool of information and ideas that is very stimulating.

Those are two examples, Senator, of ways in which legislation can encourage interdisciplinary efforts. But it is a difficult problem, and I think more attention needs to be given to that.

Institutional support mechanisms are important for a variety of reasons, but I would always tend to press the institutions somewhat to use a significant part of those institutional grants for fostering interdisciplinary research.

Now, another point I would like to emphasize——

Senator SCHWEIKER. I might add, that in looking over some of the colleges with my college-age children that there seems to be a lot more emphasis on interdisciplinary curriculum and training. I think that I saw in some of the institutions a lot more emphasis on interdisciplinary sciences and related things that probably did not exist even 5 years ago.

Dr. HAMBURG. That is right. It was my privilege when I was at Stanford University before coming to the Institute of Medicine to help to create a program for undergraduates in human biology, which pulled on people from the medical school and from arts and sciences, a variety of disciplines working effectively together to give a life sciences perspective to undergraduates in an integrated way that we would not have ever imagined when I was a student. I think that is spreading, that kind of thing, throughout the country; you are quite right.

Senator SCHWEIKER. I think you make a very valid point. Please continue.

Dr. HAMBURG. Another point of some importance in the principles is the recognition that the policy agencies and the health care agencies and especially the regulatory agencies within HEW have research needs that are not adequately appreciated and must be attended.

In a way, the major part of what this HEW exercise was about was to ask the question, what kind of information needs do the various agencies have in order to fulfill their missions, and the most dependable way to get information is through scientific research. So there was an examination of the extent to which the different agencies would benefit from having the results of good research, and that goes beyond the traditional research agencies of NIH and ADAMHA. That seemed to our committee an important departure.

Now, our committee also noted a number of important issues, Senator Schweiker, that were inadequately resolved in the principles as formulated so far.

The time has really been very short since this initiative began. The issues are very complex. Our own committee had only a few months. And so there has not been time to grapple adequately with some issues that are vital to the Nation's health. In my statement, there are many of those listed.

I would really like at this point to mention just one or two. One is—and I think very important—to analyze the strengths and limitations of the possibility that a portion of the health care dollar might be used to support health care research. I know that last year, this committee was seriously considering how to upgrade and strengthen health care research. We are as a Nation going to spend very close to \$200 billion on health care this year, and it seems

very logical to ask how the health-care dollar could be linked to health care research.

And then finally, in the unexplored issues that we feel ought to be pursued is a systematic sharing with other nations of ideas, information and resources, including funds pertinent to health research.

In that connection, Senator, we had a fascinating meeting at the Institute of Medicine last Friday with the officers of the European Medical Research Councils. That meeting was made possible through the courtesy of Dr. Frederickson, the Director of NIH. There are so many interesting things they are doing that are pertinent to this bill that it seems to me that it is something that we ought to pursue more systematically in the future.

We were struck with innovations, for example, in Sweden, Finland, Belgium, France, Holland, that have elements of dealing with the issues that our report addressed and this committee is addressing, that makes me think that that ought not be left on a sort of a chancey basis for the future.

As I said, our committee advocated the establishment of some sort of permanent planning mechanism, and I would like to come back to that now.

The committee said:

We urge that this HEW planning effort lead to the development of a permanent planning mechanism as an important instrument for the determination of national health science policy.

Such a mechanism will be needed at a minimum for the regular review and revision of this current HEW plan in an orderly, efficient way. More generally, a permanent capability for long-term planning will provide a view of research support that extends beyond yearly budget cycles or current political pressures, and will establish a clear locus for the needed consideration over time of such issues as the appropriate balance of fundamental and applied research, the relationship of the Federal Government and nongovernmental research institutions, the role of research in regulatory agencies, mechanisms for coordinating health research throughout HEW, approaches to establishing priorities within applied research.

The character and composition of this planning function need very careful thought, particularly with regard to the relationship of the planning mechanism, not only to the health-related agencies of HEW, but also to other Federal agencies engaged in health research.

I would like to highlight two aspects briefly. One is that our committee sees this planning mechanism as a possible outgrowth of the HEW planning activity. Our committee was not willing to prejudge the value of the HEW initiative before it has been completed, for providing guidance to health research. The issue is left open whether or not the HEW process currently under way might itself evolve into the recommended mechanism or whether some new body and process are needed.

Second, the committee does not recommend a particular form that this permanent planning function should take, but instead cautions that various options should be considered carefully before a single arrangement is instituted.

It is in this framework that I would like to make a few individual comments in closing.

Senator SCHWEIKER. Dr. Hamburg, since the planning mechanism is an issue between the committee and the administration, I would just like to pursue one or two more points.

Was there a divided opinion in your group as to how planning should be accomplished or was this something specifically that the

group felt they should not make a judgment on? I am not clear on what you are saying.

Dr. HAMBURG. I will ask Sarah Brown to check me on this, since she was involved in every single moment of deliberation of that committee and visited many members in their natural habitats, as well.

But my recollection from my participation in the committee is that it simply was not addressed. The feeling was that we did not have time to address it. We would have liked very much to have considered several main options, but the feeling was that we had our hands full with the task in hand, and we had better defer that to the future.

Is that accurate, Sarah?

Ms. BROWN. Yes.

Dr. HAMBURG. Yes, it is.

Senator SCHWEIKER. Let me ask one further question. One of the other issues on this point is how much of this planning mechanism is in place now—aside from the top layer—would you give an estimate as to whether we are beginning to do planning in the middle and lower levels of the Government agencies responsible for biomedical research to any great extent. Is there a great need here, or how do you assess the middle and lower levels of government biomedical research planning?

Dr. HAMBURG. Well, I think it is spreading; under the stimulus both of this committee and of the HEW planning effort, a number of the agencies are conducting their own multiyear planning efforts. There was a meeting last week of the Alcohol, Drug Abuse, and Mental Health Administration, convening a group from around the country, together with their own key staff, to consider a draft of a multiyear strategy. NIH has done the same. I do not know how many agencies have done the same. There has been, I believe, somewhat similar thinking at CDC. I am simply not sure how many. But I have a definite sense that that effort is spreading among the research-oriented agencies.

Senator SCHWEIKER. Go ahead.

Dr. HAMBURG. There are a couple of things that I would like to say as an individual. I think that the title I really demonstrates a great deal of understanding of the policy and organizational problems that currently burden health research. These are the very difficult problems of continuity and predictability; the very human and vivid and poignant pressures involved in the so-called disease of the month syndrome; the need for sustained studies of research priorities in relation to scientific opportunities, national need and other indices; the need for more research on research itself is emphasized in this bill, I think wisely, and other policy issues are recognized in the bill, which were indeed enumerated in the recent report. I think that it is a creative attempt at a solution of the problem.

Now, whether or not the specific suggestion of a Presidential Council is the best option available is just unclear to me at the present time. We do not yet know whether the HEW activity currently in midstream will successfully address itself to the set of problems slated for study by the proposed Council.

It might be prudent to observe this initiative to its conclusion before determining that additional remedies are warranted.

Also, I am not certain about the administrative feasibility of some aspects of the Presidential Council, although members of the committee are better qualified to judge that than I am. I do wonder whether a part-time body that is advisory could in practice exert the kind of influence envisioned in title I.

In my judgment, this option does deserve serious consideration over a period of time, along with other options for long-term planning.

But I do want to make it clear that I personally share the Institute of Medicine Committee's view that a permanent planning mechanism is needed. The question is what form this mechanism should take, if it is to be socially useful and efficient for many years to come. And I do think we have to be thinking in terms of many years to come, not present circumstances or present incumbents or present situations only.

Now, in view of the ongoing HEW initiatives and the concerns expressed in testimony before the committee about the Presidential Council option, I respectfully suggest that an additional few months time be invested in a thorough study of the possibilities available for providing the long-term planning function.

Let me mention very quickly, six options.

One is a means of building upon the current, present HEW activity and its evolution into the permanent planning mechanism.

The second is the formation of a new intergovernmental-inter-agency group under the leadership of the Surgeon General or, for that matter, of a Secretary of Health, if the Department is ever reorganized on a DOD model.

Senator SCHWEIKER. I would like to interrupt for one minute, Dr. Hamburg.

We went into this very specifically at the last hearing. I agree with you. I think there is enough honest difference of opinion concerning the planning mechanism, that we ought to hear out the administration and wait several months and see what they propose or how they start planning for health research. And I, for one, have a very open mind about it.

But what disturbed me a little bit, and I think threw the committee for a loss, is that Dr. Richmond subsequently said that it might be as much as 2 years before we get some mechanism in place and really get going on health research policy and planning. As you know, that would very likely kill the process. I pointed out to him that most Assistant Secretaries of departments usually last about 2 years around here; that is the average turnover time, 22 to 24 months. So I agree with your point, and I hope that the HEW Department does too, because I think they could play a very constructive role. I have an open mind about either accepting some of HEW's suggestions or perhaps combining the two ideas in some unique way.

But obviously, if they are going to stretch out the preliminary planning phase over a 2-year period, then we may have to go on our own, which I would just as soon not do. So I think your point is very valid, and I hope HEW takes it to heart.

Dr. HAMBURG. My time scale was months, not years.

A third possibility is a role for the Congress own Office of Technology Assessment.

A fourth is the Presidential council option in this bill.

A fifth is a council option similar to title I, but appointed by the Secretary of HEW.

Sixth would be the use of the Institute of Medicine or other nongovernmental organizations for continuing analysis of health sciences policy.

This is only a partial list of options, and they are not mutually exclusive. You could combine a couple of these in a way that might be worthwhile.

In any event, for an issue of such extraordinary importance to human life and health as long-range planning for health research, we must be exceedingly careful that our initiative is the very best available.

My own judgment is this is one of the most important issues in the American society, and my belief is that the American people feel similarly about the importance of the priorities we are discussing here.

Above all, I believe that in considering this bill, the committee is addressing questions of absolutely fundamental importance to the Nation.

It is my belief that there is much common ground between this committee and HEW, in basic concern, in values, and general policy directions in the health sciences.

I am hopeful that careful consideration of the present bill will help us all to move in directions that will be of long-term benefit to the health of the American people.

Thank you, Senator, I will be happy to try to answer questions.
[The prepared statement of Dr. Hamburg follows:]

STATEMENT OF DAVID A. HAMBURG, M.D., PRESIDENT, INSTITUTE OF MEDICINE

Mr. Chairman and Members of the Committee:

I am most pleased to have the opportunity of testifying today before this Committee for which I have profound respect. I greatly admire the far-sighted leadership and stimulation that this Committee has provided over the years. As you may know, the issue of research planning has been a topic of special interest within the Institute of Medicine's Division of Health Sciences Policy. The most recent Institute activity centered on research planning is a review of DHEW's research planning principles conducted by an Institute Committee. This study was part of an ambitious initiative within DHEW to formulate a comprehensive multi-year plan, involving all of DHEW's health agencies, for the health sciences research supported by that Department. This initiative was, in my judgment, an admirable innovation. I believe that, during his testimony before this same Committee last week, Assistant Secretary for Health, Dr. Julius Richmond, described this departmental activity in some detail. As he noted, the Institute of Medicine was asked last Fall to conduct an independent review and analysis of a set of principles designed as a foundation for national policy with respect to health-related research. As Dr. Richmond explained, these principles were developed by DHEW after wide consultation with hundreds of organizations, institutions, agencies and individuals interested in health sciences policy. Between December and February, a committee of the Institute of Medicine completed the requested review and delivered its report to DHEW Secretary Califano on March 1, 1979.

We were very fortunate to be able to mobilize an extraordinary committee. It produced a report of exceptional caliber and breadth. The chairman of the 22 person committee was Dr. Irving M. London, Director, Harvard-MIT Division of Health Sciences and Technology; panel chairmen within the Committee were: Paul Berg, Ph.D., Willson Professor of Biochemistry, Department of Biochemistry, Stanford University; Keith Brodie, M.D. Professor and Chairman, Department of

Psychiatry, Duke University; Paul Stolley, M.D., Professor of Research Medicine, University of Pennsylvania; Henry Riecken, Ph.D., Professor of Behavioral Sciences, University of Pennsylvania; and Joshua Lederberg, Ph.D., President, Rockefeller University. In the process of commenting on the principles the Committee took the opportunity to discuss more general issues of research planning and to identify a range of policy matters pertinent to the health sciences that are of great significance and require resolution.

One of the principal recommendations of this Committee was that a permanent planning mechanism for health research supported and conducted by the federal government needs to be established. This recommendation has obvious relevance to Title I of the Health Sciences Promotion Act of 1979 (S.988) being considered by this Committee. However, before discussing this particular title of the bill, I would like to take this opportunity to summarize for you some of the major points made in the Institute review of DHEW's research planning principles--not only because these points are relevant in and of themselves to any general review of health sciences policy, but also because they provide a framework for the consideration of the specific recommendations in Title I of S.988 regarding a proposed "President's Council for the Health Sciences."

The summary of our report stated:

"This Committee strongly endorses the introduction of long-range planning for health research. We believe that health research planning, when well performed, will prove to be a valuable mechanism for developing sound and productive national health research policy. Well conceived and executed planning is the nation's best assurance that there will be optimal allocation of resources for health research, and that precious resources will be utilized efficiently.

"A long-range plan for health research and the policies growing from it should take into account the past productivity and future promise of the health sciences; our growing understanding of the many factors that affect health; the essential need for research across the full range of the health sciences to permit further advances in the diagnosis, treatment, and prevention of disease; the heavy burdens imposed on society by illness; and the strong support of the public for health sciences research. The plan should also reflect the challenge and opportunity afforded the U.S. health sciences community to continue providing leadership in the development of knowledge needed to prevent disease and promote health not only in this nation, but in many other nations as well.

"We support fully the major message of both the research principles presented to this Committee for review and the October 1978 Conference at NIH during which the principles were discussed: namely, a vigorous reaffirmation of federal support for the health sciences, and a clear call not only for an increased commitment to existing programs of high quality, but also for expansion to important new and neglected areas. In neither the principles nor the conference was the notion advocated of limiting or reducing federal support of health research. Further, we support without reservation another message of the principles and of the conference: that fundamental science is the cornerstone of health research, and that support for new and neglected areas must not erode existing support for fundamental research.

"An additional perspective which we endorse is a broadened concept of the health sciences. Rather than equating health research with biomedical research only, the principles recognize the importance of such

areas as epidemiology and biostatistics, environmental sciences, health services research, and the behavioral and social sciences as they relate to health and prevention of disease. In addition, we wish to emphasize the importance and promise of the physical and chemical sciences and engineering for advancing our understanding of biological and medical processes and for achieving successful and practical solutions to difficult problems in fundamental biology and in clinical medicine.

"We believe that current resources devoted to health research are seriously inadequate in relation both to our society's need for the results of health research and to the highly promising opportunities emerging in the health sciences. In 1977, for example, only about 3.4 percent of total national health expenditures was devoted to health research—a figure which, we are convinced, is insufficient and should be increased, particularly since health care should be soundly based in science. An effective plan for DHEW's support of the health sciences requires that health research be adequately appreciated and valued in the competition for resources, and that the need to build as well as to preserve the capability for this vital work be recognized. We are deeply concerned that excessive emphasis on the limitation of resources for health research may lead to a plan of inferior quality and limited utility.

"In taking this view, the Committee recognizes that its position may be dismissed as just another example of special interest pleading. We believe nevertheless that health research merits increased support because of its demonstrated contributions to improving health care, its long-term promise for diminishing the

crushing personal and economic burdens of illness, and its enhancement of the quality and duration of life--all of which are of high social priority. We also endorse fully the responsibility of the health sciences community to assure that funds are spent efficiently and prudently, through careful research administration and mechanisms that operate to insure that only scientific projects and investigators which meet very high standards are supported.

"We are in substantial agreement with the main thrust of the principles. Major themes in the principles which we found particularly significant include:

- the essential contribution of fundamental research to the prevention, diagnosis, and treatment of disease;
- the need for long-term, predictable support for the health sciences;
- the vital role of clinical investigation as a bridge between fundamental research and medical practice, and the need to strengthen this field;
- the need for research on personal and group behavior as significant factors determining the success or failure of programs directed toward health promotion and disease prevention;
- the important role of health services research in studying the structure, processes and effects of the health care system;
- the importance of developing improved, efficient mechanisms for technology transfer and information dissemination to facilitate the applications of research;
- the need for analysis and evaluation of the costs, risks, and benefits of new and existing health care interventions, without impeding desirable clinical innovations;

- the need for interdisciplinary and multidisciplinary programs in the health sciences to address the nation's health problems, many of which are highly complex and require the interaction of many scientific disciplines for their resolution;
- the importance of investigator-initiated proposals as a principal mechanism for research grant funding;
- the critical role of excellence as the ultimate criterion by which research should be supported, and the high value of the peer review system in helping to assure such excellence;
- the essential role of training programs to supply qualified research scientists on a continuing basis to all the health sciences;
- the pressing need to attend to the stability, maintenance, and essential physical renewal of the institutions within which much of health research occurs;
- the need to exercise care when changing research priorities in order to avoid wasteful disruptions and dislocations in scientific programs and institutions;
- the recognition that the policy and health care agencies, and especially the regulatory agencies within DHEW have research needs that are not adequately appreciated and must be attended;
- the recognition that the public needs to be better informed about the concepts and practices of regulation in the health area (such as the regulation of foods, drugs and devices), and the data on which regulatory decisions are based, so that public debate on the relevant issues will be conducted with more knowledge and wisdom;

- and the importance of having the scientific community inform the public about the accomplishments derived from public support of the health sciences."

Mr. Chairman, the report also noted a number of important issues that are inadequately resolved in the principles as formulated so far. Time has been short for consideration of such complex issues. They are vital to the nation's health and deserve serious consideration in the future. Such issues as identified by our Committee include:

- mechanisms to meet the research needs of regulatory agencies without overwhelming existing health research agencies such as NIH;
- the extent to which health service, policy and regulatory agencies should themselves become heavily involved in conducting or supporting research, in order to pursue their missions on the basis of scientific evidence, insofar as possible;
- the preferred administrative locus for the support of fundamental research in areas other than the biomedical sciences (such as epidemiology);
- the strengths and limitations of the possibility that a portion of the health care dollar might be used to support health research;
- the development of an appropriate equilibrium between the requirements of stability for support of research conducted by proven, senior investigators, and the need to provide opportunities for young investigators;
- the preferred administrative locus for, and financial support of clinical trials, particularly large-scale trials;
- organizational aspects of the NIH, including both its intramural and extramural programs;

- the coordination of public and private health research activities;
- providing for an adequate pool of clinical investigators;
- the rational and appropriate introduction of new diagnostic, therapeutic and preventive procedures into the health care system; and
- the systematic sharing with other nations of ideas, information and resources pertinent to health research.

As mentioned above, the Committee also advocated the establishment of some sort of permanent planning mechanism for health research. They stated:

"We also urge that this DHEW planning effort lead to the development of a permanent planning mechanism as an important instrument for the determination of national health science policy. Such a mechanism will be needed at a minimum for the regular review and revision of this current DHEW plan in an orderly, efficient way. More generally, a permanent capability for long-term planning will provide a view of research support that extends beyond yearly budget cycles or current political pressures, and will establish a clear locus for the needed consideration over time of such issues as the appropriate balance of fundamental and applied research, the relationship of the federal government and non-governmental research institutions, the role of research in regulatory agencies, mechanisms for coordinating health research throughout DHEW, approaches to establishing priorities within applied research, and the many other policy problems noted throughout this Report. The character and composition of this planning function need very careful thought,

particularly with regard to the relationship of the planning mechanism not only to the health-related agencies of DHEW, but also to other federal agencies engaged in health research, and to the Congress, the Office of Management and Budget, and the Office of Science and Technology Policy."

I would like to highlight two aspects of this statement by our Committee. First, note that the Committee sees this planning mechanism as a possible outgrowth of the DHEW planning activity. The Committee was not willing to prejudge the value of the DHEW initiative, before it has been completed, for providing guidance to health research. The issue is left open whether or not the DHEW process currently underway might itself evolve into the recommended mechanism or whether some new body and process are needed. Second, the Committee does not recommend a particular form that this permanent planning function should take, but instead cautions that various options must be considered carefully before a single arrangement is instituted.

It is within this framework that I would like briefly to discuss Title I of the "Health Sciences Promotion Act of 1979." In so doing, I strongly emphasize that I am speaking as an individual only, and not on behalf either of the Institute of Medicine or of the Committee that reviewed the DHEW principles.

The presence of Title I in this bill demonstrates exceptional understanding of many of the policy and organizational problems currently burdening health research. I believe that in formulating this provision, the sponsors of Title I have shown clearly that they are deeply concerned about the pressures and needs impinging on federal efforts in health research, such as the need for continuity and predictability in research support; the vivid and poignant pressures involved in the so-called "Disease of the Month"

syndrome; the need for sustained study of research priorities in relation to scientific opportunities, national need and other indices; the need for more "research on research" in order to invest wisely in future health research programs; and many of the other policy issues in the health sciences enumerated by our recent Institute report. Furthermore, I find the creativity evidenced by Title I most commendable. We know well at the Institute of Medicine that it is far easier to define sets of policy problems than to formulate appropriate and feasible solutions to these problems. Title I represents a thoughtful attempt to resolve a number of such problems well known to us all and I respect its main thrust. It is particularly significant that the Title provides for a vigorous program of "research on research"--a set of studies greatly needed for the formulation of health sciences policy.

Whether or not the specific suggestion of a Presidential Council is the best option available is unclear to me at present. We do not yet know, for example, whether the DHEW activity currently in midstream will successfully address itself to the set of problems slated for study by the proposed Council. It might be prudent to observe this initiative to its conclusion before determining that additional remedies are warranted. I am not certain that the Council proposed in the bill is administratively feasible, although members of this Committee and others who have testified before it are more knowledgeable about this than I. I wonder whether a part-time body that is advisory only could in practice exert the kind of influence envisioned in Title I. In my judgment, this option should be considered over a period of time along with other options for long-term planning. Nonetheless, I want to make it clear that I share our Institute of Medicine Committee's view that a permanent planning mechanism is needed. The question is what form this mechanism should

take if it is to be socially useful and efficient for many years to come.

In view of the ongoing DHEW initiative, and the concerns expressed in testimony before this Committee regarding the Presidential Council option, I respectfully suggest that an additional few months time be invested in a thorough study of the possibilities available for providing this long-term planning function. Options to be considered include:

- a means of building upon the current DHEW activity and its evolution into a permanent planning mechanism;
- the formation of a new intergovernmental/interagency group under the leadership of the Assistant Secretary for Health;
- a role for the U.S. Congress' Office of Technology Assessment (OTA) in this area;
- the Presidential Council option outlined by Title 1; and
- the use of the Institute of Medicine or other non-governmental organizations for continuing analysis of health sciences policy.

This is only a partial list of options, and they are not mutually exclusive. For an issue of such extraordinary importance to human life and health as long-range planning for health research, we must be exceedingly careful that our initiative is the very best available.

Above all, I believe that in considering S.988, this Committee is addressing questions of fundamental importance to our nation. It is my belief that there is much common ground between this Committee and DHEW in basic concerns, values, and policy directions in the health sciences. I am hopeful that careful consideration of the present bill will help us all to move in directions that will be of long-term benefit to the health of the American people.

Senator SCHWEIKER. Thank you, Doctor.

We realize that many options are available in designing a planning process, and I think you very knowledgeably listed several alternatives that we certainly ought to look at.

In your opinion, what are the essential components in terms of personnel, resources, and administrative structure and responsibilities that are needed to be successful in health research planning?

Dr. HAMBURG. Well, in the first place, I think that it is important that this planning mechanism have continuity. You need, obviously, to rotate members so that there is not too much power in any particular group, but each member should have a rather long term—I would think on the order of perhaps 4 or 5 years, because it will take a great deal of learning, no question, to understand thoroughly and to become sufficiently educated about different perspectives, no matter how brilliant the individual. So that is one thing, continuity, and rather long terms for individual members, and rotation of membership.

Second, maybe I really should have put this first, is the excellence of the people involved. I think the selection requires great care and should have really close scrutiny by the Congress, not necessarily formal approval, but very close scrutiny, because one really needs not only very gifted people, but very broad gaged and openminded people who are willing to take into account different bodies of evidence and different kinds of ideas, who are not locked into the patterns of the past, however successful they may have been. So the selection of people is terribly important.

The diversity of composition is terribly important. I do not care how brilliant any one individual is, no single perspective, no handful of perspectives will be adequate to get around the contours of these enormously important problems.

So the excellence and the diversity of the membership seem to me crucial factors.

The final point I would mention is touched on in the bill, and I think is crucial. There must be a staff. Wherever it is placed, there must be high-quality, full-time staff supporting the work of this planning body; even if the planning body consists of full-time officers of the Department of HEW, they have many different things to do besides the long-range planning. In fact, their day-to-day firefighting is a very heavy burden of responsibility. So that, wherever it is placed, there must be full-time staff available. That, perhaps, is even more crucial if some part of the membership of the body, or all of the membership were to come from outside government. So I would finally emphasize full-time, high-quality, broad gaged staff.

Senator SCHWEIKER. How can we assure that the expertise and advice of the private sector are utilized in Government planning for research. It seems to me that one of the problems is that we have to make sure that whatever mechanism we have, there is easy access and input from the private sector, so that it does not become a self-contained Government unit, which I think would not be advantageous.

Dr. HAMBURG. I agree very strongly. Indeed, that is referred to at two points in our report, that issue is one of the unresolved issues. As you recall in our recent Conference on Pharmaceuticals for

Developing Countries, one of our main objectives, in which I am happy to say, I think we succeeded, was to get some rational discourse rather than polemics between pharmaceutical industry, academic science and Government policymakers.

I think the private universities, the private foundations, the pharmaceutical industry and other private sector organizations—clearly, a sampling of industry and labor, as we do in the Institute of Medicine study groups, usually, Institute of Medicine conferences—I think it can be done. I think we are developing ways of fostering it, but so far, it is a very problematical area, and I am glad you draw attention to it.

Senator SCHWEIKER. What about input from the lay population? In other words, should such a panel have lay members or consult with the general public?

Dr. HAMBURG. Yes; I think it should, unequivocally; even if it were to be placed entirely in HEW, which is an option that I am quite sympathetic toward, I believe that it should have some lay members.

Now, there are lay members and lay members. I think it is critically important that the lay members be people who have a deep, sustained, long-term interest in health matters. We have such members not only in the Institute of Medicine, but on our council. Our charter requires that they be on our 21-person governing council, and I can assure you that they participate as fully and are as influential as our scientific and clinical members. But that is only made possible by the high quality of those people and their devotion to learning about health problems in great detail.

So the selection and preparation and staff support for the lay members strikes me as critically important.

Senator SCHWEIKER. Do you think there is any danger, or do you think scientists will be concerned that such a planning unit might put a cloud over the scientific freedom of scientists and innovators in this country in some way? Do you see that as something to be concerned about?

Dr. HAMBURG. Yes. I think there is palpable concern in the scientific community about that kind of issue. I think it all depends on how it is handled, Senator. I think if it is handled well, that that concern can readily be allayed.

Scientists generally recognize that they are accountable to society, that they are not some kind of superset within society. They also recognize that technical problems require technical depth of knowledge. And I think there are reasonable ways to deal with this problem.

Senator SCHWEIKER. You have some concern about the planning council concept that the committee proposed, and I would like to ask you to elaborate a little bit. What do you see as some disadvantages of the approach the committee has taken?

Dr. HAMBURG. Well, let me state briefly both some advantages and some disadvantages that I see, not so much from any depth of study, but from my own reflection and experience.

One has to do with who appoints. Let us think for a moment about the appointment of such a council. Let us assume a council something like this, but let us contrast the appointments being

made by the President with the appointments being made by the Secretary of HEW over about the next 10, 20, 30 years.

The advantage of Presidential appointments, as I see it, first it calls attention to the health field. It says in effect that the health field is terribly important, and these problems are of top priority to the American people, or very high priority, anyway.

Second, it lends the prestige of the Presidency to the appointment process so that it may increase somewhat the probability that very busy and distinguished people in different walks of life will accept the appointment and work hard at the task.

Third, it does provide for some kind of Government-wide view of health activities, say, in the Department of Defense, in the Veterans' Administration, as well as HEW, and those are formidable advantages.

On the other hand, I think there is a limitation in that on the average, my assessment going back, let us say, to the end of World War II and up to the present, on the average, I think Presidents have been less close to and less concerned with health matters than Secretaries of HEW. And it is almost inevitable and with rare exceptions; the President has so much to worry about around the world, and so many issues, that it is unusual for him, or even his staff, to have the knowledge and the commitment, the involvement with health issues that the Secretary of HEW would have.

I think that may be a significant disadvantage. That may be even more true if a Department of Education is created. I see that the Senate has approved a Department of Education. Should that come to pass, H and W are left. I suspect that any Secretary of HEW would devote a very large part of his time and energy to H, to Health. Therefore, it seems to me that you might well have, in the long run, better judgment exercised, and more support provided, and less tension created if the council were to be selected by the Secretary rather than the President.

Senator SCHWEIKER. I think that is a valid point, but isn't there a reverse side of that? In other words that by going outside the Federal health establishment, you achieve some diversity and a heterogeneous trend of thought, and you are a little more assured of outside input.

Dr. HAMBURG. Yes. That, I think, can, and in my judgment, should be done, regardless of whether the President were to make the appointment or the Secretary were to make the appointment.

Let me briefly mention two models that sort of flow out of HEW, both of which in my judgment should have members from outside the Federal health establishment.

The argument, incidentally, for having a corps of people from within the Federal health establishment is that they have the responsibility; they also have to have a good deal of the authority.

I am concerned about making it unattractive to get first-rate people to head NIH or FDA or what-have-you, if a great deal of their authority is removed. So I want to have them there, but I want to have more. I would like to have people from outside the Federal health establishment to bring in additional perspective.

Now, one way you could do that is a model that might be called a council of councils. By that, I mean you build on the councils that already exist for the various institutes—NIH has the equivalent of

a council; ADAMHA does not, but could readily have one—and you could then, building on those, have a secretarial council that would have representatives from each of the councils. Now, those councils presently have people from outside the Federal health establishment. You could thereby construct a mixed council—mixed in the sense of full-time, high level Federal health officials and nongovernmental people—and that way, construct the secretarial council as a council of councils.

Another way to go would be what you might call an augmented HEW steering committee. The current HEW steering committee which has been instrumental in the present planning effort involves the Secretary and the Assistant Secretary for Health and the heads of the health agency.

Now, they have from time to time augmented that body with outside people. I have attended some of those meetings, for instance, as a nongovernmental person. And that kind of augmentation could be made much more systematic, to have a sampling of nongovernmental people from around the country, from different fields, augmenting the government officials. That is what I mean by an augmented HEW steering committee model. Those are two models, both of which would include people, as you say, from outside the Federal health establishment.

Senator SCHWEIKER. You mentioned that your European counterparts were recently here. My question to you is what do they do in this area? How do the European health science communities solve their planning programs? What are their prototypes?

Dr. HAMBURG. Well, it is interesting that a number of them indicated they had long term, roughly 5-year forward plans. Several of these were rolling plans, updated each year. They did not seem to be shocked or horrified by that. These are the Western democratic societies. We are not now talking about totalitarian societies, which seem to do all kinds of 5-year plans.

There was a fairly high level of satisfaction with the long-term planning efforts among our European colleagues—not that they found the task easy; they did not.

It is also interesting that they found it possible to include inputs from parliament and from the general public, sometimes by having public members on the planning bodies, and sometimes through other mechanisms.

In Finland, a particularly interesting thing to me is that they have a deliberate, systematic scanning each year for new and neglected areas—burdens of illness that have not been adequately addressed, as was the case a few years ago with diabetes, or scientific opportunities that are just emerging and that maybe have not been adequately nurtured. And when they detect such areas, they have a definite procedure by which they try and clarify whether the opportunity is real, what the nature of the opportunity is, and ways of stimulating research in the new or neglected area. I found that to be a very progressive development.

Senator SCHWEIKER. The National Research Service Awards Act has authorized the National Academy of Sciences to study the manpower needs of biomedical and behavioral research and to make 3-year projections for training needs. Is this the kind of

activity that really ought to be included in a health research planning process?

Dr. HAMBURG. That is a very interesting point. It might very well be included. The process of research training is so vital to the whole enterprise. One of the deepest concerns in our report, and I think one of the deepest concerns of the scientific community in general is that we may be running some risk of letting that supply dry up. And it is not easy to turn it on again. So that is a critical part of the whole research enterprise, and therefore, offhand, I would be favorably inclined toward linking it in with the research planning effort, either as an integral part, with some explicit bridge that would tie the Academy activity on a regular basis to the rest of the planning mechanism.

Senator SCHWEIKER. Dr. Hamburg, thank you very much, we certainly appreciate your constructive contributions.

Dr. HAMBURG. Thank you very much, Senator. I appreciate the privilege of the discourse with you.

Senator SCHWEIKER. Thank you.

Now, we will go on to our second panel, Dr. Richard Ross, dean, Johns Hopkins School of Medicine, representing the Association of American Medical Colleges; Dr. Thomas Bartlett, president of the Association of American Universities; and Dr. Federico Welsch, executive director of the Worcester Foundation for Experimental Biology.

Why don't we go ahead. You have three individual statements, I assume, and if you could each present a summary, we will go on to questions.

Dr. Ross, go ahead.

STATEMENT OF THOMAS A. BARTLETT, PH. D., PRESIDENT, ASSOCIATION OF AMERICAN UNIVERSITIES; RICHARD ROSS, M.D., DEAN, JOHNS HOPKINS MEDICAL SCHOOL, REPRESENTING THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES; AND FEDERICO WELSCH, M.D., PH. D., VICE PRESIDENT AND EXECUTIVE DIRECTOR, WORCESTER FOUNDATION FOR EXPERIMENTAL BIOLOGY, A PANEL

Dr. Ross. Senator Schweiker, members of the committee, I am Dr. Richard S. Ross, dean of the Johns Hopkins University School of Medicine. I appear before the committee today to testify on behalf of the Association of American Medical Colleges on the recently introduced Health Sciences Promotion Act. It is a great honor and privilege for me to have an opportunity to discuss this proposal before this committee, because it is designed to increase the effectiveness of research in the biomedical sciences.

Senator SCHWEIKER. Doctor, let me say for the entire panel that we will enter your full statements in the record but if each of you could summarize in 5 to 10 minutes, I think it would allow a little more time for interchange.

Dr. Ross. All right. The Association of American Medical Colleges has begun a detailed analysis of what we view as a sweeping legislative proposal with many implications and consequences, not entirely obvious without careful study.

The remarks that I present today are in essence a summary of our preliminary observations on this legislation, and we would

hope that in the future, we might be able to prepare a more in-depth analysis and make that part of the record at a later time.

I would like to divide my testimony into three parts and first deal with title I of the proposed legislation which is, as we all know, for the creation of a President's Council on the Health Sciences.

Now, the law prescribes that the duties of this body are to provide advice to the President, to the Secretary of HEW and to the Congress and to recommend research priorities and allocations of funds across the entire range of DHEW supported health science research.

The mechanisms to accomplish these objectives would be the development of a rolling annual 5-year plan, and the analysis and critique of the plans and allocations arising out of the parallel processes in the executive branch.

Now, the association strongly endorses the principle that decisions by all branches of government on the Federal expenditure of funds for research in the health sciences be based on the most sound technical advice and professional wisdom that can be mobilized for this purpose.

Therefore, if the intent of title I is to create machinery to provide the Congress with high quality scientific advice, and to offer this body seasoned and wise judgment on the relative importance of scientifically sound programs for the needs and aspirations of our people, it is coincident with the position taken by the AAMC in 1976, in response to the President's Commission on Biomedical Research.

There is nothing we view as more in the public interest than the informed and effective process for allocation of public funds.

Now, having endorsed a principle, let me state that without further analysis, the AAMC is unable to decide whether the device proposed is the only or the best way to transform this principle into practice. At the same time, we would also wish to raise some questions that in our view need further clarification or explanation.

The first question has to do with the concept of planning. Although the basic process of planning is highly desirable, we caution that planning in biomedical research is not quite as simple and straightforward as it is in the physical planning of buildings, or the planning for the financial status of corporations.

As you well know, and as Dr. Hamburg has testified, research is the cutting edge of science and is always on the frontier; no one knows what lies beyond that frontier, and certain reservations must be held about trying to predict what will happen and setting a firm framework for the future.

The association would also be of the view that no group of the size proposed for the President's Council, no matter how distinguished, experience and wise——

Senator SCHWEIKER. Doctor, it seems that you are suggesting that the planning council might over-structure or straightjacket the research enterprise. Is that your concern?

Dr. Ross. Yes, sir. I would be happy to dilate on that a minute. I was shortening it for the sake of time.

Senator SCHWEIKER. Do not be afraid of hurting our feelings. We are here to learn.

Dr. Ross. Well, I think it is important to realize that science is different from financial planning and engineering planning. On the other hand, broad areas of potential reward can be identified, and funds allocated, resources allocated in that direction. But you have to be careful not to try to plan too tightly so as to exclude the random discovery which may change the whole map of the terrain beyond the frontier. We talked about the frontier.

So I think you have to be careful, but that does not mean that broad allocations to areas cannot be done, if it is done by wise people who have experience with the scientific process.

Senator SCHWEIKER. Let me ask you, would that criticism apply whether the planning body was located in HEW or as an independent Presidential Council? Do you see more concern if it is located one place or the other?

Dr. Ross. I think it is equally true, Senator Schweiker, irrespective of its location. It is just the nature of science that dictates that planning not be too tight, if it is to be rewarding.

Senator SCHWEIKER. Very well, Go ahead.

Dr. Ross. We also have some problems with the composition of the President's Council, and I understand from Dr. Blumenthal that that indeed may be changed in subsequent developments.

But if it is to do what it is supposed to do, namely, go over the budget, prescribe the plan, it would require an extensive apparatus, a permanent staff, and intermediate consultants to develop the plans, establish the priorities envisaged in the proposed legislation.

To effectively perform the task of developing an independent assessment of health science expenditures, an apparatus essentially equivalent in size and talent to that already existing within the HEW would be required, and would therefore represent redundancy.

Now, it is pointed out in this testimony that in certain situations, redundancy is worthwhile. There are two hydraulic systems on a 747 for good reason, and the cost is well-justified. However, we leave that to your judgement whether in this particular area, this very expensive redundancy is necessary. It must be recognized for what it is.

Now, the final point the association would like to mention in this preliminary reaction to the proposal—and I point out again this is a preliminary reaction—relates to whether the proposed function would be best performed in the organizational and administrative context stipulated in the bill.

This is the same point that Dr. Hamburg raised in his testimony. There are other possible ways this might be done. It might be in the Office of Technology Assessment, the Congressional Budget Office, or the Library of Congress.

Another alternative would be for the Congress to arrange directly or through the Executive for the National Academy of Sciences, the National Research Council and/or the Institute of Medicine to do the job.

Would it be feasible and/or desirable for the Congress to contract with the private organizations—a consortium of universities, a

quasi-government organization such as the Corporation for Public Broadcasting, or a private corporation to perform the task?

Without being able to specify them completely or weigh their significance accurately, there are obviously advantages as well as disadvantages to the proposal presented. The association would merely recommend a careful study of the pros and cons be carried out.

And finally with regard to title I, we would say that it seems to hold real promise for establishing an advisory mechanism that will provide continuity of oversight to the research enterprise and sound recommendations on the allocation of funds across a broad spectrum of programs.

The objective is splendid, and the association endorses the principle. However, without more careful study, we are uncertain about the best mechanism to achieve the goal.

Now let us turn to title II, which has to do with the National Institutes of Health.

We have no strong feelings about this. We would, however, point out that the NIH has functioned for a long time without explicit statutory authority. The position has clearly permitted effective performance. So we say what are the significant advantages expected from this proposal, and ask is it really necessary.

We would also like to comment on some of the language dealing with the stimulation of neglected or underfunded research areas and the selection of unconventional or innovative research proposals.

At least at first glance, we have some difficulty with this, because after all, the study sections do their best to identify innovative and unconventional research proposals. That is their job, and one wonders about the wisdom of attempting to fund proposals to which these advisors accorded less than full merit.

Moreover, a backup capability already exists in the National Advisory Council. I served as a member and chairman of the study section and as a member of the National Advisory Council for the Heart and Lung and Blood Institute, and I think that at all levels, there is awareness of the importance of identifying, selecting and funding the innovative and unconventional.

The next point has to do with the appeals process. I think that unless this were constrained in scope, it could result in an enormous administrative overload.

Now, the process at the NIH has already been considerably liberalized with the release to applicants of formerly confidential reviews and with the increased availability of staff for counseling.

National Advisory Councils with their lay members have become increasingly sensitive to the problem proposals and areas of great public concern and more frequently request a second review.

In my recently concluded experience on the Council, I have seen this many times, in which an area of great public interest would be identified, where a grant had been turned down, and one of the lay members would call this to the attention of the group, and a re-review would be organized.

We would also like to comment about the provision in some of the specific institute parts of the proposed legislation about clinical training.

We feel that this is a regressive step. To reinstitute such clinical training programs in 1979 would be an inconsistent turnabout in policy which this Subcommittee expressed in the National Research Service Award Act of 1974.

The mission of the National Institutes of Health is and ought to be research and research training. Clinical training should be supported in its own right in relation to health care delivery.

We also wonder about the sunset provisions. We think this is in general a good idea in government, but if the objective of this legislation is to provide stability and confidence that the Congress and the nation in general supports research, we do not feel that the sunset provision on the Institutes is conducive to that sort of confidence and security.

We think that anything that can be done to reduce paperwork is a very good idea.

And finally, in summary, we feel that the greatest virtue of the proposed legislation is that it is a visible and tangible symbol of the concern of the Congress to sustain the momentum of progress and the advancement of knowledge in the health sciences. This is heartening news for the scientific community and should also be to the general public, which stands to reap the ultimate benefit.

We would like to close also by suggesting some other things that might be important for this group to consider. One of them is the process for exploring ways to preserve competent, high level people in the management of the health science enterprise in government.

We feel that there is a problem with the deteriorating capital resources for research. Essentially no Federal funds have been available for the construction of health research facilities in a decade, and the basic statutory authorization for this type of assistance was repealed 3 years ago. There are obvious examples of need in this area. For example, at my own institution, there are two Nobel Prize winners who are in need of improved facilities. They can get adequate support for program, but the facilities support is a big problem, and that is something that might well be addressed.

The problem of creating opportunities for stable academic careers for young faculty is assuming crisis proportions. Dr. Hamburg mentioned earlier, it is important that this stream of talent continue to flow into the research enterprise.

I think I can conclude my formal statement at this point. I would be happy to respond to any questions. And I would also point out in conclusion that the AAMC will at a later time submit a more detailed response to the specific items in the bill. We hope that this will be made a part of the record.

Thank you.

Senator SCHWEIKER. Thank you.

[The prepared statement of Dr. Ross follows:]

TESTIMONY OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES
ON THE HEALTH SCIENCES PROMOTION ACT OF 1979*

Senator Kennedy, Members of the Committee:

I am Dr. Richard S. Ross, Dean of the Johns Hopkins University School of Medicine. I appear before the Committee today to testify on behalf of the Association of American Medical Colleges (AAMC) on the recently introduced "Health Sciences Promotion Act of 1979".

It is a great personal honor and privilege for me to have the opportunity to discuss the proposal of this Committee to increase the effectiveness of research in the biomedical sciences. I would wish to acknowledge, Senator Kennedy, the many and significant contributions to the public policy framework for health research made by you personally and by this Subcommittee collectively. The members of the Association are keenly aware and deeply appreciative of your efforts. My appearance here today attests to the willingness of our Association to continue to work with you for the promotion of the health sciences.

The AAMC, as you well know, since its founding in 1876 has steadily expanded its horizons, so that today it represents the whole complex of individuals, organizations and institutions charged with the undergraduate and graduate education of physicians. It serves as the national voice for all of the 125 operational U.S. medical schools and their students, more than 400 of the major teaching hospitals, and over 60 academic and

*Presented by Richard S. Ross, M.D., Dean, Johns Hopkins University School of Medicine, Baltimore, Maryland before the Senate Subcommittee on Health and Scientific Research on May 2, 1979.

professional societies whose members are engaged in teaching, in patient care and in biomedical research.

The Association has begun a detailed analysis of what we view as a sweeping legislative proposal with many implications, the consequences of which are not entirely obvious without careful study. We will develop a position for consideration by the Association's Executive Council as soon as possible and would like to request that this more deliberately formulated analysis be included in the public record. However, a number of tentative comments on the principles embodied in the bill seemed appropriate, and constitute the essence of my testimony.

TITLE I: ESTABLISHMENT OF A PRESIDENT'S COUNCIL ON THE HEALTH SCIENCES

Title I proposes the creation of a "President's Council on the Health Sciences" and prescribes as duties of this body to provide advice to the President, the Secretary, HEW and the Congress and to recommend research priorities and allocations of funds across the entire range of DHEW supported health science research. The mechanisms to accomplish these objectives would be: the development of a "rolling" annual five year plan; and the analysis and critique of the plans and allocations arising out of the parallel processes in the Executive Branch.

The Association strongly endorses the principle that decisions by all branches of government on the Federal expenditure of funds for research in the health sciences be based on the most sound technical advice and professional wisdom that can be mobilized for this purpose.

Therefore, if the intent of Title I is to create institutionalized machinery to provide the Congress high quality scientific advice and to offer this body seasoned and wise judgment on the relative importance of scientifically sound programs to the needs and aspirations of our people, it is coincident with the position taken by the AAMC in its response in 1976 to the Report of the President's Commission on Biomedical Research. There is nothing we view as more in the public interest than an informed and effective process for allocation of public funds for scientific research.

Having endorsed a principle, let me state that without further analysis, the AAMC is unable to decide whether the device proposed is the only or the best way to transform this principle into practice. At the same time, we would also wish to raise some questions that in our view need further clarification or explanation.

- The essential function of the President's Council is to reach a set of judgments on resource allocation based on a carefully developed and detailed five-year plan, annually reviewed and updated. This basic process---planning---is desirable and, in commonsense terms its value is virtually self-evident. However, let me raise an important caveat. Planning to acquire new scientific knowledge through research is not as simple and straightforward as: the strategic planning of corporations; the physical planning of builders and engineers; the land use, transportation, zoning, etc. planning of urbanologists; and a host of other types of planning. In research, the cutting

edge of knowledge is always on a frontier. No one knows what lies beyond that frontier, and therefore, it is impossible to plan the course that will be followed after the frontier has been crossed. A scientist must get an idea, formulate a hypothesis, test it and make a discovery which completely changes the direction of progress and indeed, the map of the terrain ahead.

An excellent example of this can be taken from the story of the discovery of the structure and function of DNA. Within weeks of the publication of the paper by Watson and Crick in Nature, hundreds of scientists throughout the world had radically altered their thinking and their work, and within a year, the same could be said of thousands.

It seems to me that the evolution of scientific knowledge is most frequently determined by unpredictable randomly occurring discoveries, some of which turn out to have very significant survival value; in short, a process akin to natural selection. This is a far cry from the deliberately proposed changes based on application of a solid knowledge that characterizes planning in the more conventionally understood meaning of the word. For this reason, scientists tend to be somewhat wary of the value of planning in the domain of the search for new knowledge.

• The Association would also be of the view that no group of the size proposed for the President's Council, no matter how

distinguished, experienced and wise, could of themselves conceivably discharge the awesome task proposed. This is especially true for the proposed advisory body, in which experienced biomedical scientists are seriously underrepresented. In my view, the composition of the Council should be seriously reconsidered. An extensive apparatus of permanent staff and intermittent consultants would have to be created to develop the plans and establish the priorities envisioned in the proposed legislation. To effectively perform the task of developing an independent assessment of health science expenditures, an apparatus essentially equivalent in size and talent to that already existing within the DHEW would be required. Engineers have long been accustomed to incorporate redundancy deliberately into systems to assure optimal performance. The additional cost of this type of design is viewed as warranted by the anticipated benefits, including avoidance of the consequences of malperformance. I would leave to your expert judgment the question of whether the legislature would find the independent advice sufficiently helpful to justify the additional cost.

● The final point that the Association would like to mention in this preliminary reaction to the proposal in Title I relates to whether the proposed function would be best performed in the organizational and administrative context stipulated in the bill. It seemed to us that it would be worthwhile exercise to explore the advantages and disadvantages of alternatives. Could this function be set up within the legislature itself---

in the Office of Technology Assessment, the Congressional Budget Office, or the Library of Congress? Could the Congress arrange, directly or through the Executive, for the National Academy of Sciences/National Research Council and/or the Institute of Medicine to do the job? Would it be feasible and/or desirable for the Congress to contract with the private sector---a consortium of universities, a quasi government organization such as the Corporation for Public Broadcasting, or a private corporation to perform the task? Without being able to specify them completely or weigh their significance accurately, there are obviously advantages as well as disadvantages to the proposal presented. The Association would recommend a careful study of the pros and cons of alternatives.

Title I then seems to hold real promise for establishing an advisory mechanism that will provide continuity of oversight to the research enterprise and sound recommendations on the allocation of funds across a broad spectrum of programs. The objective is splendid and the Association endorses the principle. However, without more careful study, we are uncertain about the best mechanism to achieve the goal.

TITLE II: THE NATIONAL INSTITUTES OF HEALTH

The Association, as a tentative position, has no serious reservations about most of Title II of the bill, which establishes the National Institutes of Health in statute, defines its mission, establishes the position of Director, NIH and defines the authorities of that office.

However, in this context of general acceptability, a few questions seem appropriate and several specific objections must be raised.

The NIH has functioned for a long time without explicit statutory authority. That position has many advantages and has clearly permitted effective performance. What are the significant advantages expected from this proposal? Is it really necessary?

One obvious omission from the mission statement is the traditional NIH responsibility to assure an adequate supply of research manpower through training programs. While we recognize that research training authority has been in a separate Act since 1974, we believe it would be wise to incorporate the training authorities of the NIH in the Health Promotions Act.

The implementation of such concepts as "neglected" or "underfunded" areas and "unconventional" or "innovative" research proposals, at least at first glance, presents some difficulties. After all, the Study Sections do their best to identify innovative and unconventional research proposals, and one must wonder about the wisdom of funding proposals to which these advisors accorded less than full merit. Moreover, a back-up capability already exists in the National Advisory Councils.

The requirement to set up an appeals process, unless constrained in scope, could result in an enormous administrative overload. The policy has already been considerably liberalized, with the release to applicants of formerly confidential reviews and with increased availability of

staff for counseling. National Advisory Councils with their lay members have become increasingly sensitive to problem proposals and more frequently request a second review.

The Association's initial reaction to the revisions of the statutes for the separate National Institutes of the NIH is again one of general acceptance, with two major and serious reservations.

- Firstly, we view the inclusion of authority for clinical training as a regressive step. To reinstitute such clinical programs in 1979 would be an inconsistent turn-about in the policy which this Subcommittee expressed in the National Research Service Awards Act of 1974 and reiterated in the Health Manpower Amendments of 1976. The mission of the National Institutes of Health is, and ought to be, research and research training; clinical training should be supported in its own right in relation to health care delivery but not as part of the NIH mission.
- Secondly, despite the understandable rationality and popularity of "sunset" provisions in many statutes, the Association views them as without merit in the case of biomedical research, a critically important national enterprise that is virtually totally dependent upon Federal support. The basic concept is unsound and could have a disastrously demoralizing impact on the research community. While each of us fervently hopes that the millenium for the complete conquest of disease will be at hand in 1984, that is very unlikely and all of the Institutes will surely be needed for the foreseeable future. Nor is it likely that research on

any category of disease will go on mindlessly, once it has been conquered, due to failure of anyone to recognize that the objective has been attained. The spectre of renewal of research authorizations getting caught in an end of session legislative logjam is not just an improbable bad dream.

TITLE III: PAPERWORK

Under Title III, the Director of the National Institutes of Health is instructed to undertake a series of experiments designed to reduce paperwork associated with investigator initiated grants. The AAMC supports any effort to reduce the burden of paperwork and believes that the proposed experimental approach is to be preferred because it gives the flexibility needed to find the best and most workable solution to the problem. We feel, however, that it is mandatory that the experiments be high quality with the best possible management advice and that they must be cooperative experiments involving the best of both Federal and institutional research management personnel.

Overall Significance of the Health Promotion Act

The greatest virtue that the Association perceives in the proposed legislation is that it is a visible and tangible symbol of the concern of the Congress to sustain the momentum of progress in the advancement of knowledge in the health sciences. This is heartening news to the scientific community and should also be to the general public that

stands to reap a rich harvest from our national investment in research. Since World War II, the United States has emerged as the undisputed leader of an awesome assault on nature's secrets that has started a profound revolution in biology and in medicine. The impact on biology is already widely obvious though by no means fully perceived. The length of the pipeline before applications can mature is longer; thus the benefits to medical science and to the health of the public are just beginning to be realized. I could recite a long list of successful applications that have eliminated or ameliorated disease, enhanced the quality of life, prevented premature death, and extended vigorous and useful existence to millions of our citizens. But progress against problems that have been intractable for centuries remains slow; it has to be evaluated over a longer epoch than a year or even a decade. In this connection, a colleague of mine recently called my attention to a floor speech of Senator Joseph E. Ransdell's delivered in 1930, in support of the bill which later became P.L. 71-251 and really established the modern NIH. I would like to quote briefly from that speech.

"Disease is the greatest and most formidable enemy of human life.... There are millions of sufferers from painful, consuming disease ... about the nature, origin, and cure of which little or nothing is known, and which causes more deaths and economic waste than any other; as influenza, before which modern medicine remains impotent; measles, the offending organisms of which have not as yet been definitely proven; pneumonia, which is still unconquered; tuberculosis and cancer, which baffle the skill of scientists; childhood sickness so fatal to mothers; infantile paralysis, which remains a curse to childhood; Bright's disease, which is so prevalent among adult men; mental troubles, heart lesions, and venereal diseases, all of which take heavy toll of human life"

It is an astonishing fact that most of the diseases that Senator Ransdell found so prevalent and threatening are now not only well understood

but rare and easily controllable. Progress cannot be evaluated day by day or year by year. Clearly giant strides have been made in the last half century and every indication is that progress is accelerating.

But health research in this nation is at a critical crossroads today. The needs are many. Some fall within the purview and jurisdiction of this Committee and the bill now before us focuses on several important matters that are essential or at least desirable for continued progress--- a sound planning process; an effective and informed allocation process; the vesting of expanded authorities in the Office of the Director, NIH; a process for thoughtfully exploring ways to preserve responsible management of and strict accountability for expenditure of public funds, without at the same time diverting scientists from what they do well--- research---and converting them into full time administrators. Perhaps there are other authorities that this Committee might appropriately devise to achieve our mutually desired goals.

One that occurs immediately to me relates to the deteriorating capital resources---plant and equipment---for research. Essentially no Federal funds have been available for the construction of health research facilities in a decade and the basic statutory authorization for this type of assistance was repealed three years ago. Research funding has barely kept up with inflation since 1968. Thus investments in equipment, especially of the type which embodies advanced technology have been limited and are likely to be manifesting increasingly serious consequences for progress.

The problem of creating opportunities for stable academic careers for young faculty is assuming crisis proportions. The appointment of young scientists and scholars to medical school faculties is the primary device of universities for self renewal. A mechanism to re-establish the flow of these young scholars to university faculties, slowed to a trickle by the prevailing financial exigencies, is imperative.

Finally, any statutory provision that would facilitate the recruitment and retention of high quality Federal officials in the health science research agencies would be most welcome.

Ironically, as past investments in research are paying off and as marvelous opportunities for exploiting them dance before the eyes of superbly trained scientists---young and mature---money for fundamental research is becoming extraordinarily scarce. I am well aware of the fact that this Committee, as a Committee, has no jurisdiction over appropriations, but I would be remiss in my responsibilities to the academic medical centers, to the biomedical research community, and to the general public, if I did not point out that the prevailing Federal parsimony is responsible for the loss of important opportunities in the struggle to attain mastery over the health problems of our country.

This concludes my formal statement, Senator. In the ensuing discussion, I would be happy to respond to questions or to extend, amplify, and clarify any of the assertions contained in my statement. Again, a more detailed response to many specific items in the bill is being prepared by the AAMC, and will, with your approval, be submitted later for the record.

Senator SCHWEIKER. We will go ahead and hear all the opening statement before we go to questions.

Dr. Bartlett?

Dr. BARTLETT. Senator Kennedy and Senator Schweiker, I am very grateful for this opportunity to testify on the Health Science Promotion Act. I am testifying on behalf of the Association of American Universities, whose members are America's predominant research universities.

Most of them have substantial academic health centers, and each of them obtains critical research support from the National Institutes of Health.

With the committee's permission, I should like to request, as Senator Schweiker suggested earlier, that my complete testimony appear in the record, and then I will try to be as brief in summary as I can.

Senator SCHWEIKER. All right.

Dr. BARTLETT. Most of my remarks will be devoted to title III, which is the section on the reduction of paperwork, but let me begin with just a brief comment on the proposed President's Council on the Health Sciences.

Those of our members who have commented on the proposal for a President's Council for Health Sciences are gratified at this recognition of the need for stability in the funding and in the priorities of health research. They are in agreement with your floor statement, Mr. Chairman, which recognizes "the need to increase continuity, stability, and predictability of Federal support for health research."

We are also aware of the various recommendations for an improved planning process, such as those mentioned today by David Hamburg earlier in the testimony.

The President's Council on Health Sciences could provide the needed improvement. We are also considering suggestions that we would like to make for your later consideration, suggestions which would support the institutional base of biomedical research.

But our initial reactions to title I include agreement with the subcommittee that the planning and appropriations processes could be significantly improved by long range planning.

The mechanism proposed, an advisory Council whose recommendations would not be binding, but would be based upon broad input and professional expertise, is an attractive idea.

The Council as construed in the bill will stand or fall on the merits of its recommendations, as is proper. Such a mechanism deserves careful consideration as one of the possible means to accomplish long range planning.

We do have some concern about the composition of the Council, as Dr. Ross mentioned in this testimony. In light of the preponderance of biomedical research funded by NIH, we believe that the Council should include more biomedical researchers.

We also hope that the Council would be more clearly directed to take into consideration in its planning processes the needs of basic research, which, although often not as glamorous as some other kinds of research, clearly provides the groundwork for all other work.

Moving on to title II very briefly, while again we need more time to consider its broader implications, we have two reservations which I would just like to mention. We are not certain that it is necessary or productive to include a sunset provision for the Institutes, given their peculiar functions.

While we are not convinced that congressional oversight is significantly enhanced by putting legislative programs of this sort under that kind of a gun, we are also wondering whether the missions of the Institutes would be enhanced by their being in such a precarious position.

On another rather minor but potentially important point, we are not convinced that the membership of laypersons will add to the extremely technical tasks of the peer review panel, which is also provided in the draft legislation.

As you would expect from a group of academicians, we have some points of difference and some suggestions, but fundamentally, we are supportive of the concepts in the bill.

We wish to commend the subcommittee's concern for basic research in the past and now again in this legislation. And, Mr. Chairman and Senator Schweiker, we particularly would applaud the remarks in your floor statements on the introduction of this bill, which we think carry us forward very clearly.

Now let me turn to title III. Appended to our long testimony on title III is a letter to me from the Committee on Governmental Relations of the National Association of College and University Business Officers. That COGR letter spells out in detail reaction to the provisions for experiments mandated in the legislation.

I have brought with me Robert C. Bowie, who is the vice president for finance and management systems at Johns Hopkins University, to whom you may wish to address very technical questions on those issues that title III raises.

The administration, as we understand it, maintains that title III is unnecessary because there is ample authority in law for reducing paperwork and for modifying the regulatory burden on universities.

Well, that does appear to be so in the sense that the administration can mandate financial reporting requirements, and presumably, the administration could modify them.

However, we believe that legislation in this area in fact can serve a useful purpose and is desirable. The committee is aware, I am sure, that OMB recently published revised cost principles for educational institutions, OMB Circular A-21. That publication was produced after 2½ years of negotiations. University spokesmen at various levels repeatedly recommended changes that would accomplish the implied intentions of title III, but to a significant degree, we were unsuccessful.

Title III is needed not because the administration does not have the authority for experimentation, but because the Office of Management and Budget apparently feels caught among competing pressures, and therefore unable to consider important changes in the cost principles.

If we can show through carefully controlled experiments that both the universities and the Government can continue to be accountable to the American people with the changes suggested by

title III, then presumably OMB will be willing to listen more sympathetically when we revise A-21 again.

Recent Government audits of federally sponsored research in America's leading universities have produced audit reports that are disturbing. The Government-university partnership thrived for 25 years largely because Federal rules were applied to universities with perception and sensitivity. That sense of trust and common mission seems to be gone. Now we are required to live up to the letter—as well as the spirit—of rules which are often not appropriate to university research purposes.

The principal message of my testimony on this point is that the literal application of Federal reporting requirements to universities is harmful to the research environment and to the scientific process within universities. That is particularly true in the areas of: One, the transfer of funds among projects and two the requirement for personnel effort reporting.

The experiments mandated on precisely these points by title III, we believe, may enable us to show OMB and the administration generally that there are ways of demonstrating accountability that are compatible with the ways universities conduct the business of education, research, and public service.

Let me emphasize a point that needs to be made over and over again. The arguments that come out of audit reports are not about personal fraud. They are technical arguments over what costs universities should recover and over what documentation is necessary. They are arguments among accountants and auditors over procedures.

Let me conclude these hurried summary remarks by suggesting that we may have another area of experimentation which would be desirable. There are some others proposed in the letter from COGR, which I have included as part of my longer testimony.

One other suggestion is that the Government experiment with differentiating its reporting requirements for recipients who have demonstrated that they can be responsible custodians of public funds. Persons in our society who have established themselves as good credit risks in commerce typically have fewer requirements placed upon them than poor credit risks. Similarly, we believe that universities which have demonstrated responsible management of Federal funds might be given latitude in how they will meet Federal objectives. Such universities might be allowed to develop their own financial management procedures, ones that would indeed fit the particular circumstances as well as the necessity of accountability.

Not all will achieve Federal purposes in the same way, because not all universities have the same missions or the same history or the same facilities, and surely, it is in the national interest to encourage as much diversity as possible, compatible with good stewardship of public funds.

Those are the comments that I would make in summary of our larger testimony.

[The prepared statement of Dr. Bartlett follows:]

Prepared Statement of Thomas A. Bartlett, President,
Association of American Universities

Mr. Chairman, members of the Committee, I am Thomas A. Bartlett, President of the Association of American Universities. I am pleased to testify on behalf of the AAU membership--48 U.S. universities that are affiliated on the basis of their commitment to basic research and graduate study.

The proposed legislation before the Committee is important and deserves more attention than we have been able to give it since it arrived last week. The academic health centers at AAU universities will want to comment on the proposals for long-range planning and for authorizing in law the unauthorized Institutes.

I will confine my comments to Title III, Reduction of Paperwork. I endorse the objectives of the Title wholeheartedly and without reservation.

The Committee on Government Relations (COGR) of the National Association of College and University Business Officers have commented in a letter to me on certain technical aspects of the legislation. I would like to submit that letter for the record and devote my comments to a discussion of the relationship between the federal government and the universities, what is healthy about the relationship, what is in poor health, and where the experimental approach in the Committee bill fits in.

Despite some ominous problems, the government-university partnership for research continues. I will deal with some of the problems in a minute, but it is important to note that the partners--the universities and the government--agree completely on the importance

of basic research to our national interest. Not only are we committed to the discovery of new knowledge for its own sake, but we recognize that future technological progress is dependent on the knowledge generated by basic research, and the principal instrument for basic research is our universities.

The second important basis for the partnership is the principle that both the universities and the government must be accountable to the American people for the use of public funds. I think we can be true to that principle and at the same time reduce the regulatory burden on the universities. That, I believe, is the purpose of Title III. Our universities maintain that changes can and should be made in federal reporting requirements and that those changes will make the system even more productive and thereby enable us to account in the most fundamental way for use of taxpayers' money.

The government-university partnership, then, is based on our agreement that basic research is essential to the national interest and that both the government and the universities must be accountable. What are the strains? And what is causing them? Finally, what can the experiments proposed in the Committee bill hope to accomplish?

The basic problems in the university-government relationship arise from two sources. One is the accounting rules by which we are required to live; the other is the manner in which those rules are enforced. Let me dispose of the second quickly and dwell on the first, because it is the rules themselves that this legislation addresses. Moreover, if the rules are altered, their mode of enforcement should become less of a concern.

More than 90% of U.S. colleges and universities are audited by HEW. In recent years, the Department has made the conscious decision to enforce the letter as well as the spirit of the rules. Pre-1970 government auditors recognized that the nature of the university and the nature of the research process require a certain amount of flexibility in applying traditional accounting practices. The auditors made certain that federal accounting objectives were met, but they applied the rules so that accounting would not interfere with the research environment of the universities. The rules are no longer adapted to the needs of research. Quite the contrary, research is now expected to adapt to the rules.

It is in the nature of a great bureaucracy that regulations ultimately will be literally applied. Robert H. Bork, former Solicitor General of the U.S., has tried to help us understand the bureaucrat:

Bureaucrats are as well-intentioned a group as I have ever seen, but they move according to bureaucratic imperatives of which they are not even aware. We tend to create a new bureaucracy for every principle we wish to enforce. That means every such organization has one principle: health, safety, clean environment, racial equality, sexual equality, whatever. No single principle is fit to live with. At some point, every principle becomes too expensive--in terms of other values--to be pushed further. But most of us would recognize the stopping point much sooner than would an equally intelligent person whose career is defined entirely by the single principle, and so bureaucracies thrust past the balance point to produce results that are disastrous to institutions and processes that depend on a balance of principles.

Let me turn now to the substance of our concerns, the real sources of strain in the partnership. Costing rules and uniform reporting requirements are written so that both the government and

the universities know what research costs may be recovered and how those costs must be documented. The process of documenting allowable costs has come to be equated with accountability. If a university claims only allowable costs, and if it documents its claims, it is considered to be meeting its responsibility to be accountable. Of course, that is one measure of accountability. At least we know by that measure that no one is absconding with federal funds. But our problem of accountability is not embezzlement, the examples of that are so rare as to be trivial.

A more fundamental measure of accountability asks what product or service of value the government got for its money. Was the money effectively spent? The Committee bill authorizes an experiment that would shift from the first measure of accountability to the second. The Director, according to Title III, may eliminate or modify the requirement for effort reports (which are required as documentation for allowable personnel costs) in exchange for a determination that the research was of high quality.

I want to underline the urgency of modifying the rules by which we are required to account for our use of federal funds. As background let me make three points for the record. First, I would like the hearing record to include a description of the experiment that the National Science Foundation and the AAU have initiated with certain universities. If the Committee will not have separate testimony on that experiment, it may wish the record to include a paper on the subject prepared by Mr. George Piliranos, Deputy Assistant Director for Administration, National Science Foundation.

The ground rules for the AAU-NSF experiment provide that for now we shall leave the project proposal and review process untouched, but the universities will be willing to experiment with post-award documentation and reporting requirements. To date, the NSF has signed agreements with three universities and is negotiating agreements with five others. The Piliranos paper is a good description of the experiment, its rationale, and the provisions of the various agreements.

Second, as I urge changes in federal reporting requirements, it should be understood that I represent a notably diverse group of universities. Requirements that are troubling to one institution are tolerable to another. The scholarly environment of a university is the product of a unique combination of organizational, physical, and intellectual influences that cannot be repeated elsewhere. Some universities would rather document effort than research progress, and others believe that effort reports are disruptive to the research process.

Third, I would like to note that while most universities do an excellent job of complying with federal financial reporting requirements, a further tightening of the rules will undoubtedly cost more than the potential gains. There comes a point of no return, where to get 5% more accurate reporting, you must spend 20% more to revise procedures.

The Committee Bill proposes experiments that ultimately may reduce the reporting burden on the universities. We applaud the Committee's initiative because we fear that current federal requirements, if tightly enforced, can seriously damage the research environment of the university.

Let me briefly describe what I mean by a research environment. It is an environment that provides an opportunity for individual scientific initiative. The researcher is able to devote time to aspects of science that excite his or her own interests. There is time to follow studies and ideas to their logical conclusions. The scientist has the security of knowing that mistakes are part of the process of the search for new knowledge, not errors of judgment.

A good research environment includes colleagues, both peers and students, with whom the scientist interacts and who challenge poor ideas, as well as good ones. Finally, the environment must facilitate the research process by the provision of equipment and information sources that add a measure of efficiency.

Federal costing principles have been adapted primarily from commercial cost accounting standards. Many of those standards, when rigidly applied, are incompatible with the way universities are organized and with the manner in which research is conducted. Universities are structured horizontally, not vertically or hierarchically like most commercial and government organizations. Universities are assemblies of individuals who have great autonomy in their work. The presidents, chancellors, provosts, deans, and department heads serve the processes involved by providing a measure of order for the enterprise. This unique organization evolved because intellectual labor requires individual initiative, which can be stifled by "management". The unique characteristic of organizations that provide for intellectual innovation is that there is great creative autonomy for those who are responsible for producing that innovation. In the case of universities, it is the

faculty; at the Bell Laboratories, it is the Scientists; and at Brookings, it is the Fellows. Perhaps in Congress, it is the Members themselves. In none of these organizations will an administrator attempt to manage the time, the style, or the judgment of the responsible individuals. Now there are indications that federal reporting requirements are altering the structure of universities; they are forcing organizational changes that may reduce the productive capacity of university scientists.

The project grants system for supporting research has developed over the years as an effective way of meeting national requirements for research excellence wherever it may be found. The system, however, requires that major research universities administer anywhere from 1,000 to 3,000 projects simultaneously. When one considers that universities also have "non-federal" functions of teaching and service, and that those functions are conducted by the same people in the same facilities as sponsored projects, the complexities of the management problem become apparent.

Federal accounting rules are designed to isolate allowable federal costs from non-federal costs. The rules provide for the type and amount of documentation that should be available for every cost charged to the government. The university office responsible for meeting federal reporting requirements is the business office. The business office has changed dramatically in the last decade, principally because of the growth of federally-sponsored research and because of the increasing number of federal requirements and the rigor with which they are enforced. Typically, universities have employed professional cost accountants, many from

government agencies. The accountants oversee the management of multiple grants in a joint-product environment that is further complicated by the fact that each federal agency adds its own unique reporting requirements on top of government-wide requirements. The most sophisticated university business offices are as qualified as any in industry or government.

Significantly, the twin bureaucracies in government and the universities, the ones that make the rules and the ones that comply with the rules, have become the principal negotiators of the rules. I do not want to imply that there is or was a conspiracy. Policy members in government and academia directed their business officers to seek certain results: for example, for the government, that the government pay only for costs that benefit its federally sponsored projects; and from the university point of view, that federally-sponsored agreements be burdened with their real share of university indirect costs. Through their Washington professional associations, university business officers with their government counterparts have developed accounting procedures that set a very high standard for federal recipients, and which, when implemented properly, isolate allowable government costs from other university costs.

It may have been intended that the business office would shield university scientists and artists from enervating bureaucratic demands, but it does not work out that way. Increasingly, department heads and research leaders must require that academic researchers comply with federal requirements. Academic leaders, therefore, assume a supervisory or management role, which can stifle creativity. It is clear that vertical bureaucratic lines are developing within some

academic departments in some universities. With no malice on the part of anyone, and with every intention of furthering scientific investigation, accounting professionals in government and the universities have created a system of accounts that threatens the quality of the product for which these costs are incurred.

Collins, Sessions, and Orbach of UCLA examine the same phenomenon from another perspective in a paper entitled, "Federally Sponsored Research at Educational Institutions: A Need to Account for Accountability," (April 1, 1979). The authors point out that:

"...the basic research process is characterized by uncertainty, unpredictability, complexity and intermittancy. The wrong turns and dead ends could, in a simplistic accounting framework, appear to be inefficient. In fact, the scientist learns from these "failures" and is able to chart a more promising course as a consequence. Research cannot be structured, forced, or reliably predicted in any detailed way. And this is fundamentally why basic research and strict accounting do not fit together well. The strict accounting perspective seeks to minimize unpredictability, inefficiency, intermittancy, complexity and lack of structure. There is a fundamental incongruity between the creative process and the structured and well-defined world the accountant and auditor seeks." (page 35)

It is the point of this testimony that among other ills, government reporting requirements threaten to bureaucratize the university with serious consequences both for basic research and, not incidentally, for the education of youth.

How can the Committee bill help resolve these problems? The bill offers hope of relief by authorizing experiments to determine whether or not the more debilitating financial reporting requirements are necessary.

Federal officials criticize universities principally for the improper allocation of indirect costs, for improper fund transfers within and between projects, and for improper attribution of personnel costs among projects. Often, however, auditors find nothing improper; they merely cannot find adequate evidence that costs were incurred. University scientists do not, according to the auditors, properly document what they do. This is labelled "abuse of federal funds." It is important to understand how the rule makers define "abuse". If those who devise the rules, devise rules with which we cannot comply, we necessarily end by abusing federal funds. Let me re-emphasize, incidentally, that the problem is not fraud for personal gain. It is a dispute over accounting definitions.

I am pleased that the Committee bill deals with the very same issues that plague the universities and the federal auditors. Any of the principals will tell you that fund transfers and personnel effort reports cause most of our difficulties. Improper fund transfers occur when purchases are made for one project with the money granted for another project. Effort reports are supposed to indicate the percent of total effort that a scientist has devoted to a sponsored agreement.

It is significant that the two issues which cause the most difficulty, fund transfers and effort reports, are also the ones over which scientists themselves exercise most control. If we are

to satisfy requirements for bookkeeping neatness, we may have to reduce the scientists' degree of control and increase someone else's. The dangers are obvious.

I have several comments on the issue of fund transfers and why they are a problem for our scientists and administrators. The basic problem is that university research laboratories and scientists undertake programs of research which tend to be long-term and cumulative in their results; government funds, on the other hand, are given for relatively short-term projects, most of which fit into the overall program. Funds granted for equipment and materials purchases are project-specific, but the equipment may be useful for a number of projects within the program. Given the appropriations process, government awards often arrive after the starting date of the project; strict accounting would require that the project get turned off and then cranked up again when the funds arrive, but research must be a continuous process. The scientist who may be principal investigator for three or four related projects is thus tempted for reasons of continuity and efficiency to use the funds provided for one project to support work done for another. Within limits, we believe that is what should occur, as long as such flexibility is in support of approved scientific objectives. It is what the NSF experiment referred to above will allow, among all projects awarded by a given governmental division within a broad program in a university. It promotes productivity and efficiency and good research. But strictly speaking, such good stewardship of public resources is illegal under current cost-accounting regulations. The Committee's bill would allow the universities and the agencies

to explore together more effective ways of assuring the government that its funds are used to push back the frontiers of knowledge, while not constraining the scientists to account for each dollar spent within the tightly limited bounds of the individually funded project.

The problems with effort reporting are similar to those with fund transfers. Current regulations require that all professionals who are paid under project grants report the percentage of their "total effort" devoted to the particular project. But scientists are, for the most part, unable to estimate accurately the portion of their effort that is spent on one sponsored project. Partly this is because it is impossible to separate "research" on a project from the teaching of graduate students that is going on simultaneously; partly it is because a number of projects in which the scientist is involved may all be part of a total research program. Therefore, scientists tend to report the effort that they had predicted they would spend when they prepared their original proposals. Some months their reports are accurate and some months they are not, but not even the scientists know which is the accurate month and which is the inaccurate one. Many of us believe that it is a corrupting influence to require that scientists, whose lives are devoted to the analysis of accurate data, be forced to deal with reports in such a conjectural manner to meet the demands of the accounting system.

There is wide agreement that effort reporting requirements are the principal source of much of the malaise that has come to characterize the government-university partnership. Nearly all

government officials who are responsible for policy development or for the implementation of rules agree with us that until we solve the problem of accounting for personnel costs, we will be unable to iron out our difficulties. The AAU presidents, when they met last month, once again identified effort reports as a serious issue between the universities and the government. They were not quite sure that "research progress" is the proper substitute. But they are confident that the system would work better without effort reporting as we know it. They are, therefore, encouraged by your proposal to permit investigation of new methods of accounting for personnel time.

Incidentally, I have been advised that perhaps NIH already has the authority to experiment with paperwork requirements. It would appear that since the Executive Branch prescribes the reporting requirements that cause us trouble, the Executive Branch should be able to experiment with and perhaps change those requirements.

We are delighted with the willingness of NSF to experiment, and we are pleased with recent indications that NIH may wish to try out new procedures. However, ultimately the universities are subject to the pleasure of the Administration, whether it be through NSF, NIH, or any other agency, because the Administration controls the purse strings. During the past two and half years, we have been negotiating with the Administration over the Cost Principles for Educational Institutions (OMB Circular A-21). The Administration accommodated many of our wishes, but steadfastly declined to alter certain provisions, especially some of those addressed by Title III of your bill. On the basis of our recent experience, I believe that

we should have legislation that requires experimentation, so that the Congress can join with the Administration and the universities in helping to re-cast accountability.

Whether or not the Committee bill becomes law, the government will have the cooperation of America's research universities in strengthening the federal-university partnership. It is significant, I think, that the Committee has identified the principal irritants.

We conclude this testimony with a proposal for one other reasonable objective that both the universities and the government should pursue as we attempt to improve our relationship. We propose that our long-range goal be one of sorting out the "high risk" recipients from the "low-risk" recipients. Federal rules are made and applied so that taxpayers can be assured that their money is not misspent. Our institutions cannot benefit by mismanagement of federal funds. When the rules are rewritten, with the help of legislation like that proposed by this Committee, so that we can comply, and when universities demonstrate that they have the internal financial control to prevent real abuses, then the institutions should be required only to meet accountability objectives that are mutually agreed upon. Universities which have proved to be good managers should be given requirements which they can meet by using any procedure that is compatible with their own unique circumstances. Government-mandated procedures could be retained for those recipients who have not yet demonstrated adequate internal controls. We believe that experiments in this area could help to reduce the overwhelming burden of the costs of the present regulations, both to the universities and the government.

The bill before you has the great value of giving the granting agencies and the universities an opportunity to look at the validity of different approaches to ensure accountability. We strongly endorse that objective.

I thank the Chairman and the Committee for this opportunity to share with you the views of the Association of American Universities.

COMMITTEE ON GOVERNMENTAL RELATIONS

National Association of College & University Business Officers

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APR 27 1979

April 27, 1979

Dr. Thomas Bartlett
 President
 Association of American Universities
 #1 Dupont Circle, Suite 730
 Washington, D.C. 20036

Dear Dr. Bartlett:

Pursuant to our discussions of non-budgetary constraints on research, we are providing comments and suggestions pertinent to Title III of the proposed Health Sciences Promotion Act of 1979.

The cumulative effect of the growing burden of complying with the ever increasing number of Government regulations is a matter of serious concern to our constituent institutions. It is most encouraging that the Senate Health Subcommittee has taken notice of the regulatory demands placed on educational institutions and would reverse this trend in the proposed Health Sciences Promotion Act of 1979.

The Committee on Governmental Relations applauds this effort to reduce the paperwork burden currently imposed on research scientists. We understand that AAU also supports Title III of the proposed Act, and will present testimony to this effect.

The COGR wishes to offer suggestions for revisions to the proposed bill. We believe our recommendations will enhance grants management improvements that could be achieved by the proposed legislation. Our suggestions follow sequentially, the numbering order of the proposed legislation.

Section 301(a)(1)(A) & (B) is apparently intended to assure that grants covered under the Directors experimental program receive a review. Such a review can be accomplished by a random audit and periodic peer review as stated by the present language. However, these provisions are better placed at the end of Title III as Section 301(b) in place of lines eleven through thirteen on page 90.

We recommend the carryover provision of Section 301(a)(2)(A) be modified to permit the expenditure of 115 percent of grant funds in any one year rather than only permitting carryover from previous awards. Often times a research project can produce promising results earlier than anticipated. In these instances, a timely outcome depends on the ability to spend grant funds at an accelerated rate. The technique of advanced authorization for expenditures is used by the Department of Energy in its Special Research Support Agreements. It is a funding procedure that has been used for several years by the Department's predecessor agencies, AEC and ERDA. This provision carries with it an understanding that the grantee is liable for the fifteen percent advanced spending, should a follow-on award not be made.

We suggest modifying Section 301(a)(2)(A) by adding the following language:

or charges to NIH for a specific grant period may not exceed 115 percent of the amount authorized for that grant award, except as approved by the Director, NIH.

Section 301(a)(2)(B) as proposed is more restrictive than the current NIH transfer policy which does not place a 10 percent limit on transfers nor does it restrict transfers where the investigators on both grants are not the same.

A new Section 301(a)(2)(B) is needed to permit the grouping of individual research grants into a single entity called a master grant, for purposes of administration. This master grant would make available to the investigator the option to interchange funds as necessary and appropriate (in the investigator's judgment) to best carry out the work on NIH grants for related projects or for projects in the same academic department.

Present constraints force investigators to treat each grant as a distinct entity, cost of which are to be kept separate from those of other grants. These largely, artificial boundaries arise from the assumption that grants are by definition discrete projects which should be kept separate from other grants (projects) carried out in the same laboratory or academic department. This discrete project assumption obliges university investigators to break their overall research program into projects, which in many instances, are defined exclusively by the amount of money from a given agency or grant. In many instances there are very real differences in the work done under different grants in the same laboratory and thus grant boundaries and project boundaries coincide.

Problems occur when the investigator views his research as a general research undertaking which must be broken into separate pieces with different titles. Unless the investigator documents very precisely appropriate portions of people, supplies, equipment, travel, etc., on each grant, questions are raised about "relatedness" of particular expenditures to particular grants.

Discussions with auditors on these questions are frequently unrewarding, because the auditors insist on documentation or "proof" of relatedness (such as effort reports, receipts, or other paperwork that substantiates relatedness). With audits conducted three or more years after a particular line of research is completed, there is simply no way an investigator can record circumstances to the satisfaction of the auditors. All of this is complicated further by agency program officers who monitored the project and may have left the agency. Therefore, we propose a new Section 301(a)(2)(B) as follows:

(B) grouping of individual research grants into a single entity called a master grant, for purposes of administration.

Section 301(a)(3) mandates alternative methods to document compliance with requirements for cost sharing. Any documentation of cost sharing does nothing to improve accountability and only adds to the paperwork burden unnecessarily.

A brief excerpt from the Report of the Commission on Government Procurement best states the case:

"The Government R&D procurement process thus suffers from increased performer costs, increased agency administrative costs, and a consequent decrease in the Federal research yield per dollar expenditure. Above all, these restrictions in the system do nothing to increase the total yield of research performed; they merely rearrange it in a bookkeeping fashion, at considerable cost."

The appropriations bill for the Departments of Labor and Health, Education and Welfare for thirteen years has required cost sharing in research grants. The HUD-Independent Agencies Appropriations Bill likewise requires cost sharing. The concept was originally intended to save paperwork and reduce administrative burdens. Subsequent experience has fallen short of this expectation to the extent that both the Commission on Government Procurement and the Commission on Federal Paperwork have studied the matter and reached the same conclusion. We propose, therefore, that the Senate Health Subcommittee urge deletion of the cost sharing language from the appropriations bills.

Modification to Section 301(a)(3) is needed to permit NIH to explore alternative means to document cost transfers, equipment purchases, and other expenditures made with grant funds. It is necessary to simplify documentation requirements because investigators are not able to "prove" project relatedness nor are they able to provide documentation "sufficiently precise" to satisfy auditors. Our earlier discussion concerning artificial project boundaries is pertinent here.

Some experimentation proposed by the legislation is already permitted by NIH policy. For example, the 10 percent transfer provisions have been available to investigators for a number of years. The difficulty, in making transfers under NIH policy, is the problem described earlier in regard to providing sufficiently precise documentation. Without the ability to explore alternative means for documenting project relatedness or reasonableness, the experiments proposed here may well be the victim of what we are attempting to overcome.

It is proposed therefore, that Section 301(a)(3) be amended as follows:

(3) the development of alternative methods to document compliance with any requirements for cost sharing, *cost transfers, equipment purchases and other expenditures.*

We suggest that Section 301(a)(4) be modified to eliminate any obligation of recipients of grant funds to account for non-expendable equipment, where the original cost of the equipment was less than \$5,000. Relief from accountability for equipment up to \$1,000 where title vests in the grantee, has recently been granted by DHEW through its implementation of OMB Circular A-110. A survey undertaken by NACUBO/COGR indicated that:

"If such recordkeeping responsibilities were limited to property with a unit cost of \$5,000 or more, the number of items would drop by more than 90 percent while more than 55 percent of the total dollar value would remain on the list. If the accountability level were increased only to \$1,000 the number of items on which record-keeping was required would drop by 63 percent, while more than 82 percent of the dollar value would be retained." (From the Report of the Commission on Federal Paperwork).

It is necessary to raise a more fundamental question here. The paperwork burden resulting from this regulation can be justified only if accountability serves a useful purpose. Accountability of equipment where title vests with the grantee, is now required for the period of the grant plus 120 days to give NIH the right to require transfer to a third party. We are unaware that this right has been exercised in any significant way; meanwhile, grantees are spending considerable sums to account for and track this equipment.

It is more sensible for the recipient to use non-expendable equipment on the project or program for which it was acquired as long as needed, whether or not the project continues to be supported by federal funds. When no longer needed for the original project or program, the recipient should be permitted to use the equipment in connection with its other educational activities.

We believe these arguments support waiver of accountability for all research equipment, where title vests in the grantee. For the reasons cited, and because of significant inflation, raising the accountability threshold to \$5,000, might give grantees an opportunity to demonstrate whether restrictions imposed for equipment accountability serve a useful purpose or whether the restrictions should be lifted altogether.

In addition to our comments on specific sections of the proposed legislation, we would like to propose some additional experimental ideas and concepts.

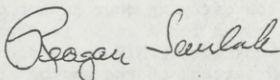
First, we recommend NIH consider expanding its present institutional prior approval program. A number of grantees have expanded their computer capability in a way that would allow them to provide different kinds of useful administrative/financial data to NIH through computer terminals as opposed to the more conventional ways.

Second, there are discussions underway regarding advance certification of financial systems as a way to reduce both audits and financial disallowances for grantees. We believe experimentation is called for in this area. This advance certification concept is untried and very preliminary. It is used here only as an example of an innovative approach that might be encouraged by the NIH. We are supportive of the Subcommittee's efforts to mandate experimentation. We hope the Subcommittee is of the view that the notion of experimentation should be broad and not limited specifically to those examples cited in the proposed legislation.

For clarity, a revised version of Title III is appended to this letter.

We believe improvements can be realized from the proposed experimentation. These improvements will accrue to the benefit of the government, universities and the public at large.

Sincerely,

A handwritten signature in cursive script, reading "Reagan Scurlock". The signature is written in dark ink and is positioned above the printed name.

Reagan Scurlock

TITLE III - PAPERWORK

REDUCTION OF PAPERWORK

Sec. 301. (a) In order to increase the productivity of research undertaken and supported by the Department of Health, Education and Welfare, while at the same time maintaining adequate accountability for the funds expended for such research, the Director of the Institutes shall conduct experimental programs to reduce paperwork associated with the application for, and administration of, research grants. Such experimental programs may include--

(1) the elimination or modification of effort reporting by investigators for selected grants and the utilization of alternative indicators of work performance.

(2) the delegation, to non-profit and public entities engaged in health sciences research to approve--

(A) the carrying over of not more than fifteen percent of the grant award for a given year to the next year of the grant; or charges to NIH for a specific grant period may not exceed 115 percent of the amount authorized for that grant award, except as approved by the Director, NIH.

(B) grouping of individual research grants into a single entity called a master grant for purposes of administration.

(3) the development of alternative methods to document compliance with any requirements for cost sharing, cost transfers, equipment purchases and other expenditures.

(4) the elimination of any obligation of recipients of grant funds to account for nonexpended equipment when the original cost of the equipment was less than \$5,000 and

(5) the elimination of all reporting requirements, other than a final report, for individual investigators for grants, the applications for which were unsolicited.

(b) The aggregate total of all the awards for grants under subsection (a)(5) shall, in any year be no more than one-half of one percent of all funds expended by the Institutes. In order to assure adequate accountability for the funds expended to support such grants--

(1) a periodic review to determine the extent to which research projects have achieved their intended purpose

(2) audit of individual grants, on a random basis, to assure that grant funds were expended appropriately.

SUPPLEMENTAL TESTIMONY ON S. 988

This statement is submitted for inclusion in the record of the public hearings on S. 988, the Health Science Promotion Act of 1979, as a supplement to the oral and written testimony which I provided for the Committee at your hearing on May 2.

At that time, I dealt largely with the provisions of Title III. My general remarks regarding Titles I and II stand as I delivered them, but I want to address some of the specifics of these Titles in this supplementary statement.

Of its 50 member institutions, the Association of American Universities represents a large proportion of the nation's academic health centers. Each of these centers is engaged in a thriving research partnership with the National Institutes of Health. Our members who have commented on S. 988 are pleased with the recognition of the need for stability in the funding and in the priorities of health research. They agree with your floor statement, Mr. Chairman, which recognizes "the need to increase continuity, stability and predictability of Federal support for health related research."

Let me begin with some comments on the proposed President's Council on the Health Sciences.

We are aware of the Institute of Medicine's recommendations for an improved planning process. The President's Council on the Health Sciences may well provide needed improvement. We agree with the purposes of Title I, because it would improve long-range planning in the authorization and appropriations processes. The proposed Advisory Council, whose recommendations would not be binding but would be based on broad consultation and professional expertise, is an attractive idea and deserves careful consideration. We believe that the merits of the Council will best be determined by a measurement of the quality and effectiveness of its recommendations over time, and we do, therefore, support the sunset provision as it relates to the Council's life.

We are concerned about the composition of the Council. In light of the preponderance of biomedical research funded by NIH, we believe the Council should include persons with expertise in biomedical research. In addition to increasing the number of biomedical researchers on the Council, we would suggest lengthening their terms to at least four years to promote the desired continuity and stability of planning. As to the lay members of the Council, we support the suggestion of Dr. Hamburg (of the Institutes of Medicine) that these members be chosen because of a deep sustained interest in the health sciences. We also recommend that the Council staff consist of recognized professionals in health sciences research, and that the Council stand free of federal agency oversight and control.

We believe the Council's mandate should include broad assessments of "the state of the art" of health research, not detailed budget recommendations; an emphasis of the needs of basic research; and an assessment of research capability. We believe the Council may be able to provide Congress with a more accurate picture of the state of research facilities; an assessment of the condition of physical plants dedicated to health research; a description of the adequacy and condition of research equipment and instrumentation; and provide an assessment of that which is necessary to maintain research capability.

We believe the Council should be directed to consult with the Director of NIH and with the Institutes themselves as they engage in their own internal planning process. In emphasizing the advisory nature of the Council, we also ask recognition of the inherent quality of research: that of breakthroughs and innovation which demand that the planning process not be rigid, but rather allow for a degree of flexibility to reassign resources in areas of new promise with the necessary immediacy.

As for Title II, we are concerned with the "sunset provision" for NIH; we are not convinced that such a provision would improve or promote Congressional oversight. In addition, such a provision might distort the research effort, creating undue pressure to "find a cure to insure reauthorization." We applaud the recognition of the importance of basic research reflected in the provision for 45 percent of funds to be expended on investigation-initiated research, but we are not certain that such a rigid mechanism, in a variable appropriations environment, would work all the time for the benefit of research.

The experiments for lay persons on peer review panels has produced mixed comments from our member institutions. While there are those members who believe that such an experiment might end undue suspicion of the peer review system, others believe that it is not only unnecessary, but also unwise. The major problems we foresee with such an experiment are that: it may not be evaluated within a reasonable time and halted if deemed a bad idea; and that lay persons in peer review is a contradiction in terms and could dilute the efficiency and effectiveness of the peer review panels.

Finally, the provision for an appeals process also has been met by mixed reviews. The criticism is centered on the belief that such a process would overload an already overburdened system. We believe that an appeals process is just and necessary, but that it must be carefully constructed to avoid an "automatic" appeal for every grant which is unfavorably reviewed. We hope that any new appeals process would allow fair review and avoid becoming an "invitation to litigate."

In conclusion, Mr. Chairman, we are gratified at the range of problems addressed in this bill. We look forward to continuing to work with you and your staff to help improve the nation's health sciences research effort.

Senator SCHWEIKER. Dr. Welsch.

Dr. WELSCH. Mr. Chairman, Senator Schweiker, the Delegation for Basic Biomedical Research appreciates the opportunity to offer views on the Health Sciences Promotion Act of 1979.

The views I will express this morning are necessarily Dr. Hoagland's and my own, since the bill has not been available long enough for study and consensus development between all the members of our delegation.

We wish to request, therefore, that the other members be given an opportunity to submit their written comments for the record.

Future medical progress demands free exploration of nature—if you wish, basic research—and that the conquest of illness go hand-in-hand.

The National Institutes of Health stand as the living testament to: (1) The unprecedented success of the science-medicine marriage, and (2) to our Nation's commitment to continue the search.

The NIH system of biomedical science support integrates public need and professional know-how in a remarkably effective way. It achieves not a perfect but a reasonable distribution of resources between intramural and extramural research and between basic and applied research.

It insures that the award of resources is based on merit. Its advisory councils seek synthesis between public expectation and scientific capability, and the NIH Director is provided with broad policy input from his own advisory council.

The Health Science Promotion Act addresses a set of problems which both legislators and scientists agree remain unresolved.

The most important of these are: (1) The instability of science support and (2) the shifting emphasis in science priorities.

This points out the need for science policy planning over a time-span exceeding 1 year.

The central question posed by the bill is, can a large, high level policy and budget-setting committee of the composition proposed in Title I significantly improve the planning process. Can it improve upon the present, unstructured, pluralistic, flexible process which is wide open to concerned scientists, health care professionals and the public through access to Congress, administration, and the NIH directorate?

It is our belief that the proposed council is more likely to restrict access to the system and impede planning. First because it would be imposed legislatively at the top of a basically healthy functioning system, and second, because its composition does not reflect the present or near future potential of science to contribute to medical advance.

Science representation on the committee effectively determining policy for NIH must be only partly a reflection of public concern or interest. Representation must also reflect the current state of the Nation's science potential, its capability of making discoveries that will help solve human health problems.

It must depend heavily upon decisions made by scientists representing those areas of research that have an established record for producing knowledge.

Some medical problems are ripe for study and solution; others are not. And science must decide which is which. By these criteria,

a council of the composition proposed is inimical to the intent to bring the best of science to bear on health problems.

Only 3 seats of 15 are designated for the biomedical sciences: those disciplines such as microbiology, physiology, biochemistry, molecular and cellular biology, immunology, et cetera, that have brought us to the point of medical advancement we enjoy, those disciplines which have accumulated a solid knowledge base from which future progress must inevitably flow. Behavioral sciences, allotted three seats, is a young discipline addressing important problems, but it has not yet the potential for contributing in a major way to health care advance, though it may do so in the future.

Social science, allotted three seats, also addresses major societal issues, but since it is not truly a science, would effectively add to the ranks of the membership appointed from the general public.

Thus, the council could not, in our view be effective in making wise decisions at the science/medicine interface.

It occurs to us to ask, in the interest of making effective use of advantages we already have, why the NIH Director's Advisory Council could not be used for policy development.

Could not the Advisory Council report be available to Congress?

Secretary Califano has recently completed an extensive study of the NIH science support system. The Institute of Medicine, as we heard this morning, of the National Academy of Sciences, has reviewed the study and made recommendations with regard to planning mechanisms.

It is expected that the Director of NIH will be implementing these recommendations. Congress could help the NIH planning function by: (1) Recognizing the need for science support stability on a multiyear basis, and (2) projecting appropriations accordingly.

I will now shortly comment on certain provisions of title II.

We are opposed to the requirement that the Director of NIH experiment with the peer review process by including on peer review groups lay persons, social scientists, and other individuals lacking expertise for judging the scientific merit of research proposals.

The peer groups have a proud record of expert evaluation of research proposals on the basis of scientific merit, entirely apart from social, political, or economic considerations or influences.

No one has yet devised a better way to do this vitally important job. Study section members are qualified members in very restricted areas of scientific research, and they evaluate highly specialized proposals.

A professionally unqualified member of such a panel would be nothing more than a drag. He or she would be completely lost in the discussions, and the qualified members, out of courtesy, would spend valuable hours trying to bring the outsider to some participatory level of comprehension.

Since there is already substantial lay membership on the NIH Councils, the need for the bill's provision is, in our view, not justified.

We are not in favor of the legislatively mandated grant appeals process. We believe that the present informal peer review appeals process is satisfactory. If added safeguards are deemed necessary by

the NIH Director and his advisors, let them be instituted by the NIH administration.

I regret that I have been rather negative up to this point, but I will end on a more positive note. The provision that not less than 45 percent of all NIH funds be reserved for scientist-initiated project grants is an excellent one, and would have, I believe, the strong support of the basic scientific research community.

We are heartily in favor of the title III provisions aimed at reducing the burden of paperwork carried by our scientists and institutions that depend on the NIH project grant support system.

We also applaud the intentions of the bill as they relate to providing the NIH Director with the 0.5 percent of the NIH budget as discretionary funds, the opportunity to charter committees including peer review groups, and to steer NCI back under the over-all umbrella of NIH.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Hoagland, as presented by Mr. Welsch, follows:]

Comments by Mahlon B. Hoagland, President and Scientific
 = Director, Worcester Foundation for Experimental Biology,
 and Spokesman, Delegation for Basic Biomedical Research.

Mr. Chairman, members of the Subcommittee on Health and
 Scientific Research, I very much appreciate this opportunity
 to offer my views on the Health Sciences Promotion Act of 1979.
 My views this morning are my own since the bill was not avail-
 able long enough to distribute to my Delegation colleagues.
 I wish, therefore, to request that they be given adequate time
 to study the bill and to submit their comments for the record.

Science is the motive force in the evolution of modern
 health care theory and practise. Lewis Thomas has pointed out
 that prior to the merging of medicine and science, doctoring
 was a dismal and terrifying occupation in terms of its impact
 upon the patient. The dawn of science's influence came when
 physicians stretched their curiosity and compassion sufficiently
 to ask "What would happen to my patient if I left him alone?"
 That simple beginning led quickly to the discovery that humans
 are basically self-curing machines and then, in time, to many
 discoveries that made it possible to prevent, cure or alleviate
 a steadily increasing number of diseases.

Future medical progress then demands that we acknowledge
 biomedical science's critical role in bringing us to the present
 state of health care capability; that free exploration of nature
 and the conquest of illness go hand in hand. The National

Institutes of Health stand as the living testament to the unprecedented success of the science-medicine marriage and to our commitment to continue the search. The NIH system of biomedical science support integrates public need and professional know-how in a remarkably effective way; it achieves a reasonable distribution of resources between intramural and extramural and between basic and applied research; it insures that award of resources is based on merit; its Advisory Councils seek synthesis between public expectation and scientific capability; and its Director is provided with broad policy input from his own Advisory Council.

The Health Sciences Promotion Act addresses a set of problems which both legislators and scientists agree remain unresolved. The most important of these are instability of science support and shifting emphasis in science priorities, pointing to the need for science policy planning over a time span exceeding one year.

The central question posed by the bill is: can a large high level policy and budget-setting committee of the composition proposed in Title I significantly improve the planning process? Can it improve upon the present unstructured, pluralistic, flexible process which is wide open to concerned scientists, health care professionals and the public through access to the Congress, administration and the NIH directorate? It is my

belief that the proposed Council is more likely to restrict access to the system and impede planning. First because it would be imposed legislatively at the top of a basically healthily functioning system and second because its composition does not reflect the present or near-future potential of science to contribute to medical advance.

Science representation on a committee effectively determining policy for NIH must be only partly a reflection of public concern or interest: i.e., perceived need. Representation must also reflect the current state of the nation's (indeed the world's) science potential, its capability of making discoveries that will help solve human health problems. It must depend heavily upon decisions made by scientists representing those areas of research that have an established record for producing knowledge.

Some medical problems are ripe for study and solution, others are not; and science must decide which is which. By these criteria a Council of the composition proposed is inimical to the intent to bring the best of science to bear on health problems. Only three seats of 15 are designated for the biomedical sciences, those disciplines such as microbiology, biochemistry, physiology, molecular and cell biology, neurobiology, immunology, that have brought us to the point of medical

advancement we now enjoy and have accumulated a solid knowledge base from which future progress must inevitably flow. Behavioral science, allotted three seats, is a young discipline addressing important problems, but it has not yet the potential for contributing in a major way to health care advance, though it may in the future. Social "science", allotted three seats, also addresses major societal issues, but since it is not truly a science would effectively add to the ranks of the membership appointed from the general public. Thus the Council could not in my view be effective in making wise decisions at the science-medicine interface. It occurs to me to ask, in the interests of making efficient use of the advantages we have, why the Director's Advisory Council could not be used for policy development. Could not its report be available to Congress?

Secretary Califano has recently completed an extensive study of the NIH science support system. The Institute of Medicine of the National Academy of Sciences has reviewed this study and made recommendations with regard to planning mechanisms. It is expected that the Director of NIH will be implementing these recommendations. Congress could help in this planning function by recognizing the need for science support stability on a multi-year basis and projecting appropriations accordingly.

My final comments apply to certain provisions of Title II.

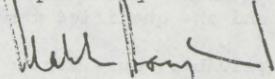
I am strongly opposed to the requirement that the Director "experiment" (p. 18 lines 11-15) with the peer review process by including on peer groups lay persons, social "scientists" and other individuals lacking expertise for judging the scientific merit of research proposals. The peer groups have a proud record of expert evaluation of research proposals on the basis of scientific merit, entirely apart from social, political or economic considerations or influences. No one has yet devised a better way to do this vitally important job. The Study Section members are qualified experts in very restricted areas of scientific research and they evaluate highly specialized proposals. A professionally unqualified member of such a panel would be nothing more than a drag. He/she would be completely lost in the discussions and the qualified members, out of courtesy or pity, would spend valuable hours trying to bring the outsider to some participatory level of comprehension. Since there is substantial lay membership on the NIH Councils, the need for the bill's provision is not justified.

I am also opposed to a legislatively mandated grant appeals process. I believe the present informal peer review appeals process is satisfactory. If added safeguards are deemed necessary by the NIH Director and his advisors, let them be instituted by the NIH administration.

I regret that I have had to be rather negative about major provisions of the bill. I will end on a more positive note by stating my view that the provision that not less than 45% of all NIH funds be reserved for scientist initiated project grants is an excellent one and would have, I believe, the strong support of the basic scientific research community.

I am heartily in favor of the Title III provisions aimed at reducing the burden of paperwork carried by scientists and institutions that depend on the NIH project grant support system. I also applaud the intention of the bill as it relates to providing the NIH Director with an 0.5% of the NIH budget as "discretionary funds", the opportunity to charter committees including peer review groups and to steer NCI back under the overall umbrella of the NIH.

Respectfully submitted,


 Mahlon B. Hoagland, M.D.

Senator KENNEDY [presiding]. Thank you very much for your comments, and thank you to the whole panel.

Dr. Welsch, we are not wedded to any particular percentage of representation on the council. There is a good deal of flexibility in the thinking about the membership of the Council itself.

But as you well understand, the Council itself is to not only represent NIH, but it is also to represent the National Institutes of Mental Health, the Institute of Drug Abuse, the Center for Health Service Research, in terms of the scientific policy shaping of those particular organs.

It would be difficult to have their interests represented without the behavioral scientists, without social scientists.

I gather that you are all reasonably satisfied with the way things are running at the present time.

It seems to me, at least, I was always under the impression that what the researchers and science policy personnel are really looking for is a degree of certainty, predictability, and some forward-looking in terms of allocations of research and planning.

And what we have seen, and increasingly so, is that those decisions are being made not from the basis of scientific judgments, not even by OMB; they are basically being made up here in the Congress, in terms of the allocations of resources in the appropriations process. That is the hard reality, and the reality is that that is

going to continue over a period of time with short budget allocations.

With all the mechanisms that have been established with advisory committees, in NIH, basically, the priorities are going to be decided in terms of appropriations.

If you look either at the testimony before the Appropriations Committee or the nature of the debate and discussion on the floor of the U.S. Senate when we come to allocating these resources in scientific research, I daresay that the preparation and understanding of priorities is fairly minimal, to be very charitable about it.

The question that we are trying to grapple with, is how we come up with some kind of mechanism by which we can establish some measuring devices for responsible action in the Congress over any period of time. Whether that is going to have an impact at the time when the actual allocation of the budget takes place may be an entirely different issue. But at least those thoughtful men and women who serve in the Congress, the Senate, might be able to say, "Look, the Council, which is truly attempting to consider the various scientific research in all of these areas has worked its will in these areas, and they have made these recommendations." To have that kind of factor included in the debate, it seems to me, would have some advantage in appropriately representing what is the best in terms of science research.

The point that troubles me and I sense troubles you also, is that the future in terms of appropriations and priorities is going to be disjointed unless we come to grips with it soon. I know the universities share this concern.

But I think we need a good deal of help and assistance in this area, and I just do not know how we can deal with it as business as usual.

Yes, Dr. Bartlett.

Dr. BARTLETT. I think Dr. Welsch and I both want to respond. But let me say, sir, that if there is uncertainty you are hearing, I do not think it reflects disagreement with the fundamental notion that the planning process needs to move beyond where it is. I think there will be a great deal of support for that notion.

The uncertainty, as much as anything, is a procedural one. We are speaking for people in many parts of the country, with all kinds of interests, and they in turn are considering new ideas. It will take a bit of time for views to emerge.

But from the initial responses of which I am aware, you will get support and sympathy for the basic purpose and some concerns about the details. Your comment on membership of the Council, for example, is a very important one from the point of view of those of us who work in the biomedical research system, because we are concerned that the largest part of the problem will be in the biomedical scientific area, and that area clearly is underrepresented in the Council membership as originally proposed.

Senator KENNEDY. We are wide open on any aspects of the legislation. What we are trying to do, very frankly, is find alternative ways of trying to achieve this common desired end.

But I think what we have been pressed with is the increasing failure of the science policy function in terms of establishing the standard by which the American people, and the Congress can

make judgments, and that really is something that is going to be increasingly a problem.

Dr. Welsch?

Dr. WELSCH. Mr. Chairman, I wonder if because one dwells perhaps a little bit too much on the negative points, the impression has not come through erroneously that there is a lot of support for the intent of the bill.

There is no question that the planning function has to be improved, and there is no question that long-range plans have to be expressed some way in the form of a multiyear appropriation or goal in appropriations, or whatever it is. I think that that is the only statement I wanted to make.

There is a lot of support for aspects of the bill; there is concern about other aspects of the bill.

Dr. Ross. The same thing, Senator Kennedy. In our testimony, we said that we heartily endorsed the principle of long range planning, allocations, decisions on the basis of the best scientific information. We are concerned only with the mechanism.

Senator KENNEDY. How else can we do it? We need a good deal of help. Our committee is dealing with 8 or 10 different health policy questions constantly, and we need some help in this.

You people have the experience, you have devoted your lives to the various aspects of this problem. You have obviously given thought to it. How else would you do it? If you agree about the importance of planning, the concept, you agree with the necessity for it, how else can we do it? Do you have suggestions?

Dr. WELSCH. Senator, this morning, Dr. Hamburg made the suggestion, for instance——

Senator KENNEDY. I know he made a number of excellent recommendations.

Dr. WELSCH [continuing].—One of them was the creation of a council of councils. The 5-year forward planning is something which already exists in most Government agencies.

Senator KENNEDY. And very little is paid. You know, I want to read more closely Dr. Hamburg's thoughts on this, because they can be very helpful.

What is your reaction to that, to the earlier suggestions that were made?

Dr. WELSCH. I think that that is one suggestion that should be taken very seriously into consideration. What I wanted to add is that there already is 5-year forward planning in many of the agencies.

If advisory councils like the NIH Advisory council could pass on in a formal way to Congress their recommendations without having them screened by the administration, I think that that would be a very healthy step, too.

Senator KENNEDY. Of course, the cancer panel does that, and there is question within the NIH whether that is an appropriate mechanism. I think we have been extremely fortunate in the people who have served on that panel. It has been enormously valuable, quite frankly, to have their recommendations before the committee. We ought to be able to get those kinds of recommendations.

Dr. Ross. I think one of the problems is that you want to be sure that you do not just elevate to this Council level the competing disease of the month philosophy that so often is apparent at the appropriation hearings.

Senator KENNEDY. That is right.

Dr. Ross. So you have to have a broad-based panel, with people who can be above and apart from their own parochial interests.

Senator KENNEDY. Well, that is clearly the purpose and what we hoped to achieve, and also, then, representatives of the various groups that would be involved. But there are so many science policy issues which are shaped and that impact HEW. I have not been impressed by the establishment of the planning mechanism, the establishment of the priorities, the establishment of planning, the presentations of alternatives and how these things are going to be; it really does not exist.

I listened with great interest to Dr. Frederickson, and the process which works at the NIH. He has made very important changes to include a number of planning mechanisms in the NIH which have been impressive. But I still think what we are talking about is a broad based science policy.

Dr. Bartlett?

Dr. BARTLETT. I think there is another point which grows from a statement by Dr. Ross. In dealing with the disease of the month problem, one of the critical elements is the political and public opinion aspect. And one of the advantages of a council of this sort can be that it can deal at a level of public opinion and public policy which may enable it to be a counterweight against the wind that blows first in this direction and then in another. I think the council can bring an important new element of stability and reflection.

Senator KENNEDY. In one other area, in terms of the peer review system, why wouldn't it be useful for a limited period of time, limited circumstances, to experiment with lay personnel serving on these panels, to try to put to rest for once and for all, if that is going to be the result, whether there is a function and whether there is a utility that can be served by their involvement and their purpose?

Dr. Ross?

Dr. Ross. I would like to respond to that. I see nothing wrong with that as an experimental procedure. It would seem to me that its chief advantage would be that it would allay the anxiety and suspicion that at the study section level, there is cronyism and backscratching, which is undesirable.

In the national heart and lung council level, the lay people have gone on site visits; some of them have been taken by study section secretaries to informally sit in on study sections, and they have all come away feeling the process works pretty well, and it is of high quality. And I think that would be the chief role that this would have, namely, to let them see what goes on.

I doubt that the review of actual proposals would be particularly useful, either for them, and indeed, it might slow down the action of the study section and interfere with the progress on a terribly big workload.

Dr. WELSCH. And since the process is already happening that lay members and invitees are attending study section meetings, it is not necessary to mandate it by law.

Dr. BARTLETT. I think it is important to draw the distinction of functions here. When one is dealing with a peer review panel process, one is dealing with very close examination of very technical papers and statements. And, as Dr. Welsch pointed out in his opening testimony, a layman coming into that process is going to have to be taken through by the hand to understand even what the words mean, because of the degree of technical specialization that exists at any given point on the frontier of biomedical research.

It is a different kind of role from the role of the layman in trying to appraise value issues and priorities. That latter role comes into play at several other points apart from the peer review process, and is the appropriate one.

Therefore, I would support Dr. Ross' comment, which it seems to me makes the same point. The only thing that will come out of the participation of a layman at that point, in all likelihood, is a revalidation of the process. It makes little difference in substance.

Dr. WELSCH. Senator, if an invitee attends a study section meeting, the invitee does not vote on the priority score for approval or disapproval of that application, and I really do not think it would be appropriate for a lay person to decide if an application should or should not be approved on scientific merit and what priority that individual is going to get, or the application is going to get. That is something for scientific peers to do.

On the other side, to attend a meeting as an invitee, there is no problem whatsoever, and as you have heard, it is already happening.

Senator KENNEDY. Well, I hope you will continue to give some thought to this problem and what we are attempting to achieve with this legislation. Please keep us informed of your thoughts on it, because it is an issue which I do not think is going to go away. I think we are going to be faced with increasing intensity on this over the period of years. And to try and develop some kind of mechanism—this may or may not be it—but to develop some kind of mechanism to try and cope with these problems, I think, is going to become increasingly apparent. We are going to need a lot of help and assistance from all of you and many others' to try and deal with the problem.

Dr. BARTLETT. I do hope that the title III section of the bill will not be lost as we concentrate on these other issues, because title III is an area where I think you will find strong agreement and real prospects for increasing efficiency and/or cost saving.

Senator KENNEDY. Do the others wish to make a comment on the paperwork provisions?

Dr. WELSCH. As I stated before, we are in favor of reducing the paperwork as much as possible, no question about that.

Dr. Ross. I agree.

Senator KENNEDY. OK. Thank you very, very much.

Our next panel includes John Eckstein, president of the American Heart Association; Frank Raucher, senior vice president for research of the American Cancer Society; Eugene Jacobson, chairperson, National Commission on Digestive Diseases.

It is a pleasure to have all the members of the panel. We welcome you back. We have always benefited from your comments. Please begin, Dr. Raucher.

STATEMENT OF DR. JOHN ECKSTEIN, PRESIDENT, AMERICAN HEART ASSOCIATION; DR. FRANK RAUCHER, SENIOR VICE PRESIDENT FOR RESEARCH, AMERICAN CANCER SOCIETY; AND DR. EUGENE JACOBSON, CHAIRPERSON, NATIONAL COMMISSION ON DIGESTIVE DISEASES, A PANEL

Dr. RAUCHER. Thank you, Mr. Chairman. It is a very real privilege and pleasure to be back with you and with this committee, and I appreciate the opportunity.

In order to save time, may I request that our statements be entered in the record?

Senator KENNEDY. They will all be printed in the record.

Dr. RAUCHER. I will take just a few minutes to express a concern about the categorical nature of the disease that I represent, namely, cancer.

We think that the bill provides many opportunities for better coordination of health resources, and as you pointed out, there is a very real need on the part of the Congress to compare competing priorities, for that matter.

Our concern is only that whatever does come out in this bill that the priority that you, through your leadership in 1971 afforded cancer, not be reduced.

We have been into this program now for some 7 years, and I think by any parameter of measurement, it is an excellent program. It works, and it works very well.

I believe that a very important reason that it works is because of some of the separate authorities, special authorities—even privileges, if you will—that were provided to the Cancer Institute and the national cancer program at the beginning in 1971.

I believe that the appointment of its Director by the President should continue. This has helped me during my 5 years as Director on many occasions, particularly in relating and trying to work with other Government agencies.

During that period of time, we effected, I think, very good agreements with the Soviet Union, with France, with England, with Japan, and other countries. And without question, one of the reasons that that worked so well, I believe, is that a Presidential appointee can relate at a seemingly higher plane, and I believe this is extremely important to those countries as well.

The President's Cancer Panel, as you pointed out before, I believe should continue and should continue as a Presidentially appointed group. There is no question that Ben O. Schmidt and others have provided a very important service, I believe, to the Nation, to the entire cancer community.

Budgetary bypass. This is something that has been controversial, as you very well know, but I think is one of the most important factors in moving the cancer program as quickly as possible.

There were many occasions in the past 5 to 6 years in which, when additional funds or additional authorities were needed, we could at least get decisions on these issues very quickly.

You will recall that from time to time, the Secretary of HEW felt that training was no longer desirable. Because of the special authorities in the Cancer Act, we were allowed to continue to train pathologists, epidemiologists, and other very hard to come by categories, categories that are still scarce. Our construction authority was safeguarded, I believe, by the budgetary bypass provision of the act.

So too with information dissemination. From time to time, there are policies coming out of HEW or OMB that preclude effective communication with the public. I believe that that was not a major problem with the cancer program because of the authorities you and your colleagues wrote into the bill in 1971.

Well, again, to be very brief, my plea is that we do whatever can be done to maintain this priority. We have got a long way to go. We have had great success in cancer, but we have much more to do, and I respectfully submit that now would not be the time to even think of diluting those special authorities.

Senator KENNEDY. Thank you very much, Dr. Raucher.

[The prepared statement of Dr. Raucher follows:]

STATEMENT OF FRANK J. RAUSCHER, JR., PH. D., SENIOR VICE
PRESIDENT FOR RESEARCH, AMERICAN CANCER SOCIETY

Mr. Chairman, I am Frank J. Rauscher, Jr., Ph.D. I am Senior Vice President for Research, of the American Cancer Society. It is a pleasure to appear once again before this Committee, an activity I had the privilege to perform many times in the recent past when I was Director of the National Cancer Institute.

I am here to represent concern about Senate bill 988 from two points of view. First, I am here to testify to the position of the American Cancer Society on several aspects of the bill which, in our opinion, impact directly on the National Cancer Program, and the position of the National Cancer Institute in the bureaucratic structure. Secondly, I am here as an individual, to express my concerns about certain aspects of the bill that relate to the cancer program, from the very special perspective of having been the administrator responsible for using the special authorities Congress gave the NCI to get the national effort against cancer accelerated, and keep it moving in the dynamic mode it has maintained over the past seven years.

It is of critical concern to the American Cancer Society that the priority status voted by the Congress for the National Cancer Program in the National Cancer Act of 1971 be continued. The unique position that Congress gave to the National Cancer Institute in that act and in the two succeeding statutes that extended the program in 1974 and 1978 reflected the legitimate concern of Congress, the President and the American people that the efforts formerly made to eradicate the most dreaded of all diseases had been inadequate and that a renewed war on cancer mobilizing all of the resources of government of the private sector was necessary. The Congress' own language for the effort was "The Conquest of Cancer" program.

The proposed bill is regressive in its attempts to modify the status of the National Cancer Institute and would serve to jeopardize the programs with which it has been so successful. Its effect is to repeal the National Cancer Act and not to extend it, and therefore the American Cancer Society must oppose the bill.

In its realization of the need to embrace a total commitment to the conquest of cancer, Congress gave the NCI its current status as a bureau within the National Institutes of Health with both its Director and the National Cancer Advisory Board appointed by the President and its annual reports submitted directly to him. Most important, budgeting requests were to be submitted directly to the White House. The NCI has been able to act and react quickly, effectively and free of political constraint because of its special structure.

The new bill would make future progress more difficult. NCI would no longer maintain its prioritized status under a Director, a step removed from the President. Budget requests and annual reports would be submitted first to the NIH and then to the Secretary of Health, Education and Welfare and members of the National Cancer Advisory Board would be appointed by him, rather than by the President.

Practically speaking the NCI would no longer retain its close statutory relationship to the President and the sense of total commitment, flexibility of action and public image of NCI would be undermined. No longer would the intent of Congress that NCI be an equal partner with NIH in a joint effort to conquer cancer be realized. Indeed, the bill would contravene the expressed purpose of the National Cancer Act which was to enlarge the authority of the National Cancer Institute in order to advance the national effort against cancer most effectively.

The budget by-pass authority is perhaps the most important special authority given the NCI. More important than the special access it assures regarding the NCI budget, is the special access it guarantees, when needed, to the highest levels of the Executive Branch on behalf of the National Cancer Program. This authority gives the President's Cancer Panel -- another vital element of the Program -- legal authority to work directly in behalf of the national cancer effort with the Congress as well as the White House.

For instance, early in the National Cancer Program, an HEW Department-wide order went out curtailing information office activity by Departmental agencies just at the

time when Congress, and the National Cancer Plan (originated by non-government scientists) determined that a prime way to reduce cancer deaths was to provide the public, and the medical profession more information. Another instance was the HEW Department-wide move to reduce training programs, particularly the training of research personnel, on the theory that the more trained personnel there were, the more requests there would be for research grants. This came at a time when severe shortages were foreseen in epidemiologists, pathologists, and certain other areas of specialization. Many of these shortages are even worse today as a result of increased federal regulatory efforts.

Benno Schmidt and the President's Panel were successfully able to appeal these departmental decisions on behalf of cancer. That kind of action has repeatedly proven the efficacy of the Congressional priority for cancer. I repeat, even when money was not the issue, the Panel-directed, cohesive, goal-oriented National Cancer Program was, and is something more than a government-as-usual activity. It has top flight, experienced overseers exercising oversight and administrative functions that most other government programs don't have, and such work cannot be done without the authority for direct access to top Executive Department Administration. The authority for budget by-pass of the many levels of bureaucratic review and revision is the keystone of the National Cancer Program, and ^{for} its success, thus far. Cancer administrators have not abused this special authority. They have used it discretely, and with consideration of other health goals. They have used it as the Congress originally intended it to be used. To remove it because of apparent disuse would be action based ^{how it was exercised and would contradict} on a lack of intimacy with ^{the} original intent of the Congress. It would remove a vital tool, essential to the continued dynamism of the national cancer effort.

As to the power to appoint, we believe that the kind of administrator and overseer I alluded to above cannot be lured into government service by anything less than a Presidential appointment. Money won't bring them in. The routine advisory committee position won't, either.

The proposed bill would extend spending authority for the next three years but in view of unprecedented inflation and the demonstrated needs of NCI the amounts allocated to it are insufficient.

We feel that the amounts suggested in the bill for NCI the years 1980 through 1983, although providing increases in line with current budgetary restraints, do not come near to the amounts conceived in the original legislation, and cannot support, today, the program as it was conceived then. At the bare minimum, a cost of living factor should be included in these projected authorizations.

A new President's Council on the Health Sciences is proposed. Although its members would be appointed by the President, its major function would be to advise the Secretary of Health, Education and Welfare, and Congress about resource allocation in the health sciences within the Department. Instead of facilitating the operations of the NIH and increasing its effectiveness, it would appear only to serve as another agency to further review the budget and operations of the NCI and act as a veil between it and the President in derogation of the expressed Congressional intent. It is difficult to see how a bill which has as its purpose the simplification and reduction of procedures can provide for another bureaucratic barrier.

In opposing the legislation the American Cancer Society asks for nothing more than the retention by Congress of the current status of the NCI with its close statutory relationship to the White House as expressed in the National Cancer Act.

There could well be a Council such as this bill would provide, to apply a rational process to the allocation of appropriations among various categorical diseases and research areas. And we are aware of the difficulties faced by Members of both houses of Congress in arriving at proper allocations. However, ultimately, the process is rightly political, and we think that the Congress has made the right political judgments with regard to the Cancer Program, thus far. Cancer is most likely the costliest of all diseases, economically, emotionally, and socially. In any case, the American

Cancer Society is more than willing to submit its views on proper federal spending on categorical diseases to a rational forum. We are convinced that Congress' earlier decision would be supported by any fair set of data. If such a Council is created, however, it should not be done with the hope that the political process would be by-passed. Congress is the ultimate forum for many health questions which, in different times and places have been the prerogatives of priests, or educators, or parents, or others to debate and decide. Ultimately Congress will decide health appropriations, and no such Council can replace Congress' decision-making process.

Mr. Chairman, you, and a number of members of this Committee were the Congressional leaders who in early 1971 took the Senate Panel of Consultants' report, and created the original bill for a national cancer effort. I well remember just a little over 8 years ago your introduction of S.34 was one of your very first actions as Chairman of this Committee. I give you my personal, as well as my professional judgement and conviction that the tremendous investment you made yourself, and you guided the Congress into making has accomplished its objectives to this point in time. The returns have been coming in in terms of lives saved, and in terms of man's ability to control, and in some cases, cure cancer. In addition to these "people-profits", a conservative estimate of the economic mortality savings in terms of people now living and working - disease-free - who have had cancer, totals more than \$11 Billion a year.

I urge this Committee to allow the great cancer program that the Congress created be given the continued opportunity to function as the Congress intended it to, with out alteration of its special authorities.

Thank you.

Senator KENNEDY. Dr. Eckstein?

Dr. Eckstein. Thank you, Mr. Chairman. On behalf of the American Heart Association, I will comment very briefly with respect to title I.

The American Heart Association endorses the formation of a body to give top level health sciences advice to the Congress.

Such a council could enhance the scientific progress by attention to several important issues: institution of a long range plan for health sciences research; continuity in funding of biomedical research; predictable mechanisms for insuring support of promising research initiatives; and a vehicle to provide the Congress with rational budgeting advice.

Moreover, the additional visibility given to the health sciences mission could be very beneficial. It might also provide continuity of advocacy for health sciences research in Government.

The American Heart Association therefore supports the establishment of an effective council which can achieve these desired ends.

One or two comments about the Council. We would like to see an overall health sciences policy advisory council which would include more Government agencies to conduct health sciences research, but we recognize the complexity of achieving all that in a single bill.

We recommend changes in the Council, the proposed composition of the Council, as others have. We do believe that the Council's deliberations should be open to public scrutiny and that the Council should be sensitive to the expressed needs of the public.

But our position is that the demanding assessment of scientific priorities should depend primarily on the wisdom of scientists and that the majority of the Council should be active biomedical research scientists.

Title I does propose to initiate an extraordinarily demanding task, of planning a health sciences policy and the planning, and the Council certainly will need substantial assistance, cooperation, and staffing if it is to perform its intended function.

To summarize our points thus far, the heart association endorses the establishment of a council to provide the congress with rational planning mechanisms to guide the accomplishment of the health sciences mission.

With respect to title II, we agree with the missions for the institutes defined in the proposed section 400(b). All of these missions are important, and we suggest that none needs to be given unusual precedence.

Thus, in section 400(b)(5), we would suggest deletion of the special priority which seems to be given to prevention and maintenance of health, recognizing that this is a very distinct and important priority.

We endorse the discretionary fund provided for the Director, and we believe it should be at the level recommended.

We would advise modification of the provision dedicating not less than 45 percent of all NIH funds to the support of unsolicited research grant proposals. A percentage requirement such as this may tend to become a spending ceiling, as well as a floor, and that could limit flexibility in the future.

We have a suggestion regarding the grant appeals process. We recognize its importance, but we hope that it will not become unduly burdensome, and I think care will have to be given to the planning for that.

The association strongly supports the peer review system as it exists. We would also encourage some experimentation with alternative methods for conducting peer review of research projects, but we cannot endorse the proposals that laymen be voting members of the peer review committees.

We think it is important that peer review judgment should represent the opinion of scientists with respect to scientific projects. We have no objection to experimenting with participation on a nonvoting basis, and we do so in our own organization.

We have an interesting recommendation that we would like to make concerning the responsibility of the Secretary in appointing the Chairman of the Advisory Council.

The American Heart Association has had years of experience with a system in which the chairmen of its two principal scientific policy bodies are elected by the body.

It has worked very well, and we would suggest that you give it consideration.

Finally, with respect to title III, we are enthusiastic about the general idea of reduction of paperwork. However, we would encourage some kind of provision for early termination of any experiment which proved in application to threaten increases rather than decreases in the amount of work that has to be done.

Finally, we were tempted to comment on the matter of the sunset provisions. I am not sure what was intended, and we chose not to do so.

[The prepared statement of Dr. Eckstein follows:]

PREPARED STATEMENT OF JOHN W. ECKSTEIN, M.D., PRESIDENT OF THE
AMERICAN HEART ASSOCIATION

Mr. Chairman:

Thank you for the privilege of testifying before the Committee today. I am John W. Eckstein, M.D., and I am appearing on behalf of the American Heart Association in my capacity as President of that organization.

The American Heart Association is a voluntary health agency which enjoys the dedicated support of two million active medical and nonmedical volunteers. The American Heart Association receives contributions from approximately thirty-five million adult Americans. The organization has been concerned since its founding in 1948 with vigorously fighting the battle to prevent or cure the consequences of diseases of the heart and blood vessels.

I also bring to this Committee's hearings a deep personal commitment resulting from long association with the research enterprise examining the vascular system. Since 1970, I have served as Dean of the College of Medicine at the University of Iowa. Prior to that time during my entire professional career I was actively associated with cardiovascular research both in connection with projects sponsored by the American Heart Association and projects sponsored by the federal government. I have recently completed my term of service as member of the Advisory Council of the National Heart, Lung, and Blood Institute.

First, we would like to consider with you the viewpoint of the American Heart Association regarding Title I of the Act, "The President's Council on Health Sciences." The American Heart Association recognizes the need for the generation of a long-range plan determining health sciences policy. The proposed President's Council represents a promising idea which could lead to this desirable result.

Thus, the American Heart Association strongly endorses the formation of a body to give top level health sciences advice to the Congress. Such a Council could enhance scientific progress by dedicated attention to several crucial issues, such as: institution of a long-range plan for health sciences research; continuity in funding of biomedical research; predictable mechanisms for ensuring support of promising research initiatives; and, most significantly, a vehicle to provide the Congress with rational budgeting advice. Moreover, the additional visibility given to the health sciences mission would prove beneficial.

The American Heart Association, therefore, supports the establishment of an effective Council which can achieve these desired ends.

However, the Association has important concerns about some features in this bill as presently constituted. First, we notice that while the bill relates to the organization of the health sciences mission of the federal government, the legislation refers mainly to the Department of Health, Education and Welfare. We are concerned that substantial portions of the health sciences investment of the federal government relates to programs under the aegis of the Veteran's Administration, the Department of Defense, and of the National Academy of Sciences, among others. A comprehensive plan to accomplish the health sciences mission will not be complete unless it involves all of the agencies involved in this mission.

Second, the American Heart Association strongly recommends changes in the proposed composition of the President's Council. Our position is that the demanding assessment of scientific priorities should depend primarily on the wisdom of scientists. The findings by the President's Council should reflect sober, unemotional, critical evaluation of optimum prospects for scientific productivity which will serve the future health of this country. The Council's deliberations should be open to public scrutiny and should be sensitive to the expressed needs of the general public. Inasmuch as the final recommendations of the Council relate to technical scientific decisions they should be most heavily influenced by the judgment of research professionals. Based on this general philosophy, therefore, the American Heart Association strongly recommends that the composition of the Council be reordered such that a majority of the Council comprises active biomedical research scientists. A suggested distribution is eight distinguished biomedical scientists; two behavioral scientists; two social scientists and three members from the general public.

Title I proposes to initiate an extraordinarily demanding task of planning a health sciences policy. The Council will need substantial assistance and cooperation if it is to perform a useful function. The American Heart Association has recently participated in the Conference organized by the Secretary of Health, Education, and Welfare, pointed toward the generation of a five year plan for research priorities. As you are well aware, the scientific community participating in this Conference is in accord with the goals of stability and predictability in research funding, but it is extraordinarily concerned that a rational, unbiased process to determine scientific priorities has not been developed. If it is to succeed, the Council must generate such a process.

For example, its primary source of information will be reports from existing agencies. The Council must be given access to analytical, statistical and planning techniques superior to those currently applied or the determination of priorities by this body will be no more helpful than those which influence the current process.

To summarize our points thus far, the American Heart Association endorses the establishment of a Council to provide the Congress with a rational planning mechanism to guide the accomplishment of the health sciences mission.

From the Association's review of Title II, we have several comments. We support the codification of the Public Health Service Act through language authorizing and providing a mission statement for the National Institutes of Health. We agree with the missions defined by proposed Section 400(b). All these missions are important and we suggest that none needs to be given unusual precedence. Thus in Section 400(b)(5) we would recommend deletion of the special priority.

We endorse the discretionary fund provided for the Director in proposed Section 400A(c). It is our opinion that the level of funding at one-half of the percent of 'the Institutes' budgets is a reasonable value and should remain at this proportion.

We would advise a modification of the provision dedicating not less than 45% of all NIH funds to the support of unsolicited research grant proposals (section 400A(d)). A percentage requirement such as this may tend to become a spending ceiling as well as a floor, which could limit flexibility to meet changing needs.

We emphatically support the point of view that substantial investment in investigator-initiated research promotes the greatest productivity in the use of research funds. Therefore we urge that other language be devised which will assure proper attention to this kind of funding both in the National Institutes of Health and for each of the individual Institutes.

We have a suggestion regarding the grant appeals process authorized in proposed Section 400A(f). We recognize the fairness of reporting the records of peer review group deliberations to applicants and giving all applicants an opportunity to respond. The current process, however, has imposed a substantial burden both on the staff of the National Institutes of Health, and on the peer review and advisory groups. Consideration of appeals has been unscheduled with respect to the grants cycle and has consequently interfered with the regular review of applications. We recommend that the appeals system should specifically be required not to encumber the regular review cycle and not to become overly burdensome.

The Association strongly supports the peer review system as it exists. We would also encourage some experimentation with alternative methods for conducting peer review of research projects but we cannot endorse either of the two specific experiments proposed in the bill (proposed Section 400A(g)). The Association has no reluctance to permit non-biomedical scientists to witness all processes of peer review. However, we think it is extraordinarily important that peer review judgments should represent the opinions of scientists with respect to scientific projects. The inclusion of non-biomedical scientists as voting members of peer review groups can only decrease the credibility of these groups and the reliability of their judgments.

We have a major recommendation to make concerning Section 204(f), which continues the authority to the Secretary of Health, Education and Welfare to appoint the Chairman of the Advisory Council of the National Heart, Lung, and Blood Institute. The American Heart Association has had years of experience with a system in which the chairmen of the two principal scientific policy bodies are elected. Coordination with the staff has been efficient and productive. Therefore we strongly recommend that the bill provide for the election of the chairman of each advisory council by the council itself. We believe this measure will materially enhance the effectiveness of these important planning groups.

Finally, with respect to Title III, the Association, on behalf of its constituent research scientists, is enthusiastic about the general idea of the reduction of paperwork. The approach described in Title III to stimulate experiments to develop alternate methods for accountability, is reasonable. Rather than comment in detail on the several suggested methods in this section, we would offer one general caution. In order to achieve the goal of the title, the experimental design clearly must be less cumbersome and time-consuming than current methods. We do not find anywhere in the language of the bill the requirement that the suggested experiments be designed to be less cumbersome than existing methods. Further, we would urge the inclusion of language providing for early termination of any experiment which proved in application to be unduly complicated and which threatened serious increases, rather than decreases, in paperwork.

I greatly appreciate having had the opportunity to speak before the Subcommittee today regarding this important measure. Thank you, and good day.

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Senator KENNEDY. Thank you very much.

Dr. Jacobson?

Dr. JACOBSON. Senator Kennedy, Senator Schweiker, my name is Eugene Jacobson, M.D. I am associate dean of the College of Medicine of the University of Cincinnati. I am also here representing the American Gastroenterological Association, an organization of more than 2,000 physicians who are in practice and dedicated to combating digestive diseases.

I was also the chairperson of the recently terminated National Commission on Digestive Diseases.

I want to express my appreciation to Senator Cochran, who arranged for me to be speaking here today in behalf of his bill, S. 376, which deals with several of the provisions of the report of the National Commission that require new authorizing legislation.

In 1976, the Congress mandated the National Commission on Digestive Diseases and charged the Commission with conducting a 2-year study of digestive diseases as a national health problem, and with coming back to the Congress with a report to indicate not only its findings, but also, a long-range plan for the Congress to better combat digestive diseases in this country.

In January of this year, the report was submitted to the Congress. There are a large number of findings in this report, but there are two which stand out significantly.

The first is that digestive diseases in this country constitute an enormous national health problem. This problem is of the first order, whether measured in terms of the numbers of people afflicted or in terms of the dollar drain on our society to combat these disorders.

An indication of the magnitude of this problem is found in the following few statistics.

Last year in this country, there were 14 million Americans who suffered from acute digestive diseases. These ranged in severity from something as mild as turista, which ruined a business trip or a vacation, to hepatitis, which killed someone.

In addition to those individuals, there were another 20 million Americans who were suffering from chronic digestive diseases, relatively interminable types of disorders that go on for years, very common diseases like ulcers, spastic colon, ulcerative colitis, cirrhosis of the liver, and the like.

The magnitude of the problem is equally impressive if you look at the economic impact. Last year in this country, digestive diseases cost our society \$17 billion for the direct expense of caring for these patients, and cost our society an additional \$18 billion in lost wages due to disability and death from digestive diseases.

As a rule of thumb, one might say that digestive diseases cost our country 10 cents on every dollar that is spent to combat all illness.

The second salient finding—

Senator KENNEDY. Dr. Jacobson, that is a 5-minute warning bell, and I am going to have to excuse myself from the hearing.

I would ask Dr. Blumenthal to take the remainder of your testimony, if you would, for the record.

Please continue, Doctor.

[Whereupon, Dr. David Blumenthal assumed the Chair.]

Dr. BLUMENTHAL. Please continue.

Dr. JACOBSON. A second salient finding in the Commission report is the lack of awareness of the magnitude of the problem posed by digestive diseases. This lack of recognition of the significance and size of the public health problem is a lack of awareness that is shared by the American people, by their elected representatives, and even by the bulk of health professionals in this country.

One consequence of this lack of awareness, as an example, is the following fact. Last year, digestive diseases cost the American public more money than cancer did, yet last year, the American Government spent more than 10 times as much money in research on cancer as it did in research on digestive diseases.

The long-range plan that the Commission has put forth to better combat digestive diseases is composed of 23 recommendations. There is not time this morning to amplify on those.

Let me just make some brief comments about the recommendations. They can be grouped broadly into four categories. The first category has to do with education about digestive diseases—not just education of health professionals, but also education of patients and of the public-at-large.

The second category of recommendations have to do with improving health care delivery for digestive diseases. This would include recommendations such as determining cost effectiveness of currently employed techniques to diagnose or treat digestive diseases.

A third category of recommendations have to do with enhancing the effort to conduct research on digestive diseases—not just test tube research in the laboratory, but also research on patients who have digestive diseases and translational research, to bring the findings of the laboratory and the university hospital into the community practice of medicine that has to combat digestive diseases.

There are also recommendations relating to research into causes of digestive diseases, because if we can determine the causes of some of these disorders, we have some chance of preventing them; such potential preventable causes include dietary, environmental pollutants, and even psychosomatic factors.

Finally, there are recommendations by the Commission that relate to better coordination of current Federal efforts to work in the area of digestive diseases.

Three of the recommendations, which require new authorizing legislation and are covered in Senator Cochran's bill, include the 1st, 3rd, and 21st recommendations.

The first recommendation has to do with establishing an educational clearinghouse to prepare, evaluate, and disseminate information and informational material relating to digestive diseases, both on a public scale and on a professional level.

The third recommendation has to do with beefing up current potential in medical schools for teaching digestive diseases. At the present time, there are a sizable number of medical schools in this country which are lacking in trained individuals who can teach about digestive diseases. Thus, for example, less than 1 percent of M.D. faculty members in American medical schools have had training in gastroenterology. Yet these faculties are going to have to

teach the primary care physician, whether general practitioner or internist or pediatrician, about digestive diseases.

The last recommendation requiring new authorization has to do with establishing a Digestive Diseases Advisory Board. At the present time, Federal efforts in the research area in digestive diseases are spread out among nearly a dozen different institutes. This situation promulgates overlap and duplication, and there is need for an overseeing body which can answer to Congress and the Secretary of HEW.

In conclusion, it is my hope and the fervent hope—perhaps the only hope—of people who are seriously ill with chronic digestive diseases that this Congress will see fit to implement the recommendations of the National Commission.

Thank you.

Dr. BLUMENTHAL. Thank you, Dr. Jacobson, Dr. Eckstein, Dr. Raucher.

The Senator asked me again to express his gratitude for your comments.

At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

[The prepared statement of Dr. Jacobson and material referred to follows:]

TESTIMONY OF EUGENE D. JACOBSON, M.D.

College of Medicine, University of Cincinnati

In October, 1976 the Congress of the United States passed Bill 94-562, Title III creating the National Commission on Digestive Diseases. The Congress charged the Commission with conducting a two-year study of digestive diseases as a national health problem and with providing the Congress with a report which would contain not only the findings of the study but also a long-range plan to better combat digestive diseases in this country. In January of this year the Commission submitted its report to the Congress.

The report of the Commission is extensive and lists many findings. There are two findings of greatest importance in this report. The first is that digestive diseases constitute an enormous national health problem. The magnitude of this problem is of the first order whether one counts the numbers of individuals afflicted with digestive diseases in our society in any given year or whether one determines the dollars drained from our society to pay for digestive diseases. Thus, for example, last year there were 14 million Americans who suffered from acute digestive diseases, which ranged in severity from something as mild as a case of tourista that ruined someone's business trip or vacation to something as severe as hepatitis which killed someone. Besides these people there were another 20 million Americans suffering from chronic digestive diseases--common illnesses which last for years such as ulcers, gallstones, functional bowel disease, ulcerative colitis, cirrhosis, and the like.

The picture is the same if one measures the magnitude of digestive diseases in our country in terms of economic cost. Last year the direct cost of taking care of people sick with digestive diseases amounted to \$17 billion. In addition there was an indirect cost, namely another \$18 billion due to loss of wages from disability and death attributable to digestive diseases. As a rule of thumb digestive diseases cost our country ten cents out of every dollar spent on illness.

The second major finding of the Commission is that, despite the enormity of the problem posed by digestive diseases, there is a lack of awareness of the importance and magnitude of the problem. This lack of awareness is shared by the American people, their elected representatives, and even by the majority of health professionals. One consequence of this lack of awareness is the following fact: last year digestive diseases cost our society more money than did cancer; however, last year the federal government spent more than ten times as much money on research in cancer as was spent in research on digestive diseases.

The long-range plan to better combat digestive diseases proposed by the Commission in its report to the Congress consists of twenty-three specific recommendations. There is not time in my presentation to detail these numerous recommendations. Some brief comments are in order, however. The twenty-three recommendations of the Commission can be grouped broadly into four main categories. There are several recommendations relating to education about digestive diseases, not only education of health professionals but also education of patients afflicted with digestive diseases and education of the public as well. There are another group of recommendations which are directed toward improving health care delivery in the area of digestive diseases. Thus, for example, one recommendation deals with assessing the cost/effectiveness of currently employed diagnostic and therapeutic procedures used to manage patients with digestive diseases. There are a number of recommendations which relate to intensifying our efforts to conduct research in digestive diseases. These have to do not only with test tube research in the laboratory but also with research on patients suffering from digestive diseases and research which would translate the findings of the laboratory and the University Hospital into the community practice of medicine which has to handle most patients with digestive diseases. There is also research recommended to uncover the causes of many digestive diseases, for only if we know the causes can we hope to

prevent digestive diseases. Promising areas to investigate which may be causes of digestive diseases include nutrition, environmental pollutants, and psychosomatic factors. Finally, there are a group of recommendations which are directed toward better coordination of current federal efforts to deal with digestive diseases.

There are three recommendations of the Commission report which require authorizing legislation, and a bill has been introduced into the Congress to provide the authorization. Let me address these three recommendations briefly.

The first recommendation requiring new authorization is the establishment of a National Digestive Diseases Education and Information Clearing House. There is precedent for this type of federal organization in other disease areas, such as arthritis and diabetes. The Digestive Diseases Clearing House would provide information and education to medical schools, health professionals, patients and the public. The success of the high blood pressure public educational effort would serve as a model to emulate.

The third recommendation of the Commission, namely to strengthen professional education in digestive diseases also requires authorization. Implementation of this recommendation would involve provision of teaching awards to American medical schools where there is an absolute shortage of individuals trained specifically in digestive diseases who are needed to teach other health professionals critical aspects of the subject. This recommendation would also provide support for visiting faculty to teach in medical schools which do not currently have experts in digestive diseases.

The twenty-first recommendation of the Commission urges establishment of a National Digestive Diseases Advisory Board which would review, advise on and facilitate coordination of Federal activities in digestive diseases. Currently there are nearly one dozen different Federal agencies which conduct research in digestive diseases. The chances for overlap and duplication are obvious. The Advisory Board would report directly to the Congress and to the Secretary of the Department of Health Education and Welfare.

In summary it is my hope, and the fervent hope, perhaps the only hope of patients seriously ill with digestive diseases (a hope that was expressed often by some of these patients at public hearings the Commission held in nine different American cities) -- it is our hope that this Congress will implement the recommendations of our National Commission.

EDJ/gh/0085B

FASEB

FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

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AMERICAN PHYSIOLOGICAL SOCIETY
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EUGENE L. HESS
Executive Director

JOHN R. RICE, C.P.A.
Comptroller

June 12, 1979

The Honorable Edward M. Kennedy
 Chairman, Subcommittee on Health
 and Scientific Research
 Committee on Human Resources
 310B Senate Courts Annex
 Washington, DC 20510

Dear Mr. Chairman,

The purpose of this letter is to offer preliminary comments, on behalf of the Public Affairs Committee of the Federation of American Societies for Experimental Biology, on S. 988, the Health Science Promotion Act of 1979. The six learned Societies comprising the Federation represent basic research disciplines in the biological and medical sciences and have a combined membership of 18,000 Ph.D. and M.D. research scientists.

The Committee is happy to note that:

1. The Chairman has repeatedly invited the community to comment on and suggest revisions to the bill.
2. Ample time in advance of a legislative deadline has been allowed for detailed examination of the bill, for clarification of intent and for resolution of differences and ambiguities.
3. A member of the Federation staff was given the opportunity to discuss the bill with members of the Subcommittee staff, subsequent to its introduction and hearings on it.
4. The bill addresses a broad array of long-standing problems of direct concern to investigators, who, collectively, represent the heart of the biomedical research enterprise.
5. Many of the solutions put forward in S. 988 reflect, in concept if not in detail, broad agreement already reached in the community and recorded in such documents as the Report of the President's Biomedical Research Panel (April 1976) and the Report of the NIH Grants Peer Review Study Team (December 1976). For example:
 - a. The Report of the President's Panel (page 11) dwells on "the absence of an explicit mechanism for providing advice to the highest levels of government in the formulation of federal policy for support of biomedical and behavioral research," and states, "there was broad agreement for the need for this function."

PUBLISHER OF FEDERATION PROCEEDINGS

The Honorable Edward M. Kennedy

June 12, 1979

Title I of S. 988 creates a permanent independent advisory planning mechanism, to be known as the President's Council for the Health Sciences, for the principal purposes of setting priorities in the health sciences and outlining a proposed rolling 5-year budget.

- b. The Panel Report (page 16) deplors the "extremely limited statutory authority" of the Director, NIH, "to achieve agency goals."

Title II of S. 988 confers specific statutory authorities on the Director, NIH.

- c. The Panel Report (page 5) states: "Before there can be intelligently conducted applied research, before there can be demonstrations or clinical trials, or before there can be public dissemination of techniques, there must be enough productive basic research to provide the fundamental science from which these efforts flow. Strong stable budgetary support for the basic science programs of the NIH is, therefore, essential." (Dr. Arthur C. Guyton, then President of FASEB, stated in testimony to the Panel: "There should be official recognition of the necessity for basic research. National policy should commit to the support of basic research a fixed minimum share of the funds appropriated for the National Institutes of Health.")

Title II of S. 988 requires the Director, NIH, to assure that not less than 45 percent of all funds expended by NIH shall be for investigator-initiated basic research.

- d. The Report of the NIH Grants Peer Review Study Team (page 193) recommends that "a formalized NIH Grants Peer Review Appeals System be established to correct or eliminate the deficiencies noted." (This was the reform in the peer review system most frequently requested by the community, which was thoroughly circularized by NIH.)

Title II of S. 988 requires the Director, NIH, to establish an appeals process for individuals and institutions whose applications for grants under this title have been denied.

- e. The Report of the NIH Grants Peer Review Study Team (page 132) recommends that authority to establish or discontinue initial grant review groups, as the workload dictates, be delegated to the Director, NIH. The Report of the President's Panel (page 18): "The difficulty in chartering additional Study Sections must be eliminated."

Title II of S. 988 authorizes the Director, NIH, "to appoint one or more advisory committees." In introducing the bill, the Chairman said, "It is our specific intent that he use this authority to help bolster the peer review system by appointing new groups as the need arises."

- f. The Report of the President's Panel (page 16): "The Director, NIH, should have a discretionary fund included in the NIH appropriation amounting to not more than one percent of the NIH budget, which he could assign to one or more Institutes for correcting imbalance, for exploiting new scientific opportunities, and for contingencies."

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Title II of S. 988 grants discretionary authority to the Director, NIH, to expend, for innovative research and related purposes, one half of funds set aside originally in Section 513 of the Public Health Service Act for evaluation of programs.

- g. The Report of the President's Panel (page 14): "The legislative provision now allowed by statute that permits two of the Institutes of the NIH to award grants of less than \$35,000 (direct costs only) without approval by National Advisory Councils should be extended to all of the Institutes of the NIH and ADAMHA."

Title II of S. 988 authorizes all Institutes to make grants of less than \$50,000 (direct costs only) without reference to National Advisory Councils.

- h. The Report of the President's Panel (page 14): "The excessive politicizing of the National Advisory Councils and the delays in securing appointments of nominees to vacancies on the National Advisory Councils have created a situation that adversely affects the proper functioning of these advisory groups."

Title II of S. 988 requires the Secretary to fill vacancies on National Advisory Councils within 90 days.

- i. The Report of the President's Panel (page 16): "In the total range of its recommendations, however, the Panel is seeking to strengthen the character and operation of all the Institutes of the NIH with a view of assuring that, in the future, high-priority biomedical research and related action programs can be pressed effectively by the NIH within its own management structure without the need for the Congress to provide special arrangements. The Panel believes that the Director, NIH, should be the central figure at the NIH accountable for planning and decisionmaking. It does not recommend that the special status of the NCI be changed at this time."
(April 1976)

Title II of S. 988 eliminates the NCI budgetary bypass authority and provides that the Director, NCI, and members of the National Cancer Advisory Board henceforth be appointed by the Secretary rather than the President.

The FASEB Public Affairs Committee has no reason to disown or second guess the recommendations enumerated above of the President's Biomedical Research Panel and the NIH Grants Peer Review Study Team. The Federated Societies were abundantly represented in the work of the Panel: 2 of the 7 members of the Panel were members of FASEB Societies, as were 5 of 10 members of the Overview Cluster, and 75 of the 149 members of the Interdisciplinary Clusters. FASEB was likewise well represented in the work of the NIH Grants Peer Review Study Team, in the course of which the entire community was thoroughly canvassed.

Title III of S. 988 directs limited "experimental programs to reduce paperwork associated with the application for, and administration of, research grants," including elimination or modification of effort reporting by investigators, carrying over grant funds from one year to the next, and transferring funds from one grant to another. No documentation of FASEB or community consensus on the burden of paperwork is offered because none is required. In recent years the groundswell of dismay at proliferating paperwork requirements has been universal and self-evident.

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While the Public Affairs Committee is happy to see a bill that addresses so many long-standing problems of the community in ways that have the documented consensus of the community, the Committee does have comments and questions on specific points:

1. The 15 members of the President's Council for the Health Sciences are to include 6 public representatives, 3 social scientists, 3 behavioral scientists and 3 biomedical scientists.

This proposed composition begs for rejection. In view of the nature and scope of the mission and the span of scientific expertise required, the quota for biomedical scientists is inadequate by inspection.

2. Title II directs experiments with 1) inclusion of nonbiomedical scientists on selected peer review groups and 2) inclusion of lay persons on at least five peer review study groups.

In introducing S. 988 the Chairman said the first of these two experiments was "consistent with recommendations of a panel which recently completed a comprehensive review of NIH's peer review system" presumably the NIH Grants Peer Review Study Team. A review of the Study Team Report does not indicate this idea was addressed. Of the second experiment, the Chairman said, "Our hope is that this latter initiative will shed some light on the continuing controversy concerning whether such lay input would be useful at the level of initial grant review." The parties to this "continuing controversy" are not known to FASEB. The fact is that when a grant application has been reviewed for scientific merit by scientific peers it is then referred to the appropriate National Advisory Council, which includes lay persons and may include nonbiomedical scientists, for review for program relevance. Review of a sort could be carried out by a Study Section of mixed composition, but it could no longer be called peer review. If the intent is to symbolize the openness of the system, there should be more effective ways of doing it. But, perhaps, the essential purpose to be served by the experiment is to prove that no useful purpose would be served.

3. Title II provides that each of the Institutes (except Cancer and Heart, which are separately authorized under Section 301 of the PHS Act) "shall cease to exist on September 30, 1983," unless, of course, Congress acts to renew authority for it and its programs. Unlike Cancer and Heart, the other Institutes, under this provision, could not be funded under a Continuing Resolution in the event Congress failed to meet the deadline for renewal of authorizations. The Institutes and their programs would, in fact, cease to exist.

In presenting the bill, the Chairman said of this provision, "It is consistent with the general trend toward requiring Federal institutions to justify themselves to the Congress and the American people on a periodic and regular basis. I find it inconceivable that the Congress would ever fail to renew the mandates of these essential health care facilities. However, I think the requirement for periodic congressional and administrative oversight is healthy and necessary, and is in keeping with the general mood of the country at this time."

No one will quarrel with the principle that all Federal institutions be required to justify their continued existence. No one will deny the salutary effects and potential gains from periodic congressional and administrative oversight. However, since Congress can establish and

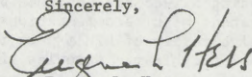
The Honorable Edward M. Kennedy

June 12, 1979

disestablish institutions at its own option and conduct oversight when it chooses, isn't there some less lethal way of reminding the Congress that it has forgotten or neglected something? It will be recalled that it was long after the eleventh hour of the last session when Congress managed to reauthorize the Cancer and Heart Institutes. Is it going to be any easier with eleven than it has been with two? In a bill that aims at creating stability and predictability in the biomedical research enterprise, which all agree demands a long-term commitment, it is curious that this form of Russian roulette and sudden death should be introduced.

The Public Affairs Committee of the Federation is pleased to submit these initial comments on a bill that has much to commend it. Through its Newsletter the Federation has urged all members of the six Societies to obtain a copy of the bill and make their views known. The Committee plans to offer further comment at a later time and will be happy to assist in any way possible with revisions.

Sincerely,



Eugene L. Hess
Executive Director

Copies to Senator Williams
Senator Schweiker
Senator Javits

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OFFICE OF THE PRESIDENT
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May
8
1979

Dr. David Blumenthal
Professional Staff Member
Subcommittee on Health and
Scientific Research
Committee on Human Resources
United States Senate
Washington, D. C. 20510

Dear David:

Thank you for your letter of April 27, 1979, along with a copy of the Congressional Record transcript containing Senator Kennedy's opening remarks and the text of S.988, the Health Science Promotion Act of 1979.

I have reviewed this material and would state that I am in accord with the general thrust of the bill. There are, however, certain comments and suggestions I would like to make.

First, regarding Title I, the President's Council on Health Sciences, consists of 15 members, of whom six are to be laymen, and of the remaining, only three are to be drawn from the biomedical sciences. In my opinion and in light of the great importance of the biomedical sciences (which I presume include the clinical sciences) to the whole research endeavor, I believe that there should be a higher representation of the biomedical sciences to perhaps six or seven. Also, in light of the fact that the Council has some responsibility to Congress, it may be desirable to have Congress nominate a certain proportion of the members of the Council.

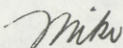
Second, regarding Title II Sec. 204 (D) (2), which is concerned with authorization levels, I believe that the figure for 1981 of 592 million dollars for the National Heart, Lung, and Blood Institute is relatively low. Indeed, this increase hardly compensates for inflation. During the past few years, this Institute has been inadequately funded (I realize, of course, that the authorized levels do not necessarily mean the funding levels) and actually has been greatly handicapped in its ability to expand and intensify its research potential, particularly since

it has been given responsibility to support research activities in blood and pulmonary areas in addition to the cardiovascular area. In light of the fact that cardiovascular disease alone accounts for more deaths than all other diseases combined and for an enormous toll in disability, and in light of the demonstrated great progress that has been made in this field of endeavor, I believe its authorization levels should be considerably higher and should more closely approach the levels authorized for cancer.

Finally, regarding Title III Reduction of Paperwork, I can only say "hallelujah." This has become increasingly burdensome and costly, and there is great need for correction.

My best wishes.

Sincerely,



Michael E. DeBakey, M. D.

lm

American Nurses' Association, Inc.

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Barbara L. Nichols, M.S., R.N.
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May 11, 1979

The Honorable Edward M. Kennedy
United States Senate
2241 Dirksen Senate Office Building
Washington, D. C. 20510

Dear Senator Kennedy:

The intent of the following is to join in the dialogue which you called for in the preamble of S. 988, the Health Sciences Promotion Act of 1979. We ask that this letter be made part of the hearing record.

The Commission on Nursing Research and the Council of Nurse Researchers of the American Nurses' Association strongly endorse your contention that:

"... investment in the health sciences is the bedrock upon which our health care system rests, and that a strong, stable, and continuing commitment to the health sciences must remain a fundamental tenant of national health policy."

We recognize the importance of continuity in federal support for the health services and the need to expand that support based on the results of ongoing planning. We want to commend the committee for considering the difficult issues of continuity, stability, and predictability for federal support for health related research.

Although we are in accord with the intent of Title I, which is to establish an institutionalized mechanism for planning related to health research, we have reservations about the proposed President's Council. Rather than establishing such a council at this time, we would favor proceeding with plans set in motion by the health research principles conference convened by Secretary Califano. Members of our organization participated in that conference as panel members and in providing testimony, and we feel it was a positive initiative. We would now like to see HEW move aggressively ahead to institutionalize a permanent health research planning mechanism with the elements recommended in the Institute of Medicine of the National Academy of Science's Critique of the Revised Statement of the Health Research Principals. Because of the complexity of such a planning activity we believe that this mechanism should provide (1) for full time involvement from eminent research professionals and (2) ongoing input from relevant

scientific and lay groups. At both levels we see need for the involvement of nurse scientists because of their expertise in research dealing with the scientific assessment of preventative and care strategies.

They could also be helpful in identifying and planning for areas of research which have potential but are in need of further support, a need which is expressed in Section 492 of S. 988.

On other aspects of the proposed legislation:

- (1) We favor the provisions of Title II to strengthen the office of the NIH director.
- (2) We recognize the value to maintain a balance between investigator-initiated research and that initiated within federal agencies; however, we question the need to specify a percentage, such as 45%.
- (3) We support the peer review process as essential to promote high quality research, thus, we are in favor of the proposed initiative which would seek ways to further refine the peer review process.
- (4) We oppose the sunset provisions and concur with Assistant Secretary Richmond's position on this matter (testimony presented on April 26, 1979).

We applaud the effort to reduce paperwork related to grants and support initiatives which would place increased regulatory authority within the hands of universities.

Sincerely,

Carolyn Williams

Carolyn Williams, Ph.D., R.N., F.A.A.N.
Chairperson, Legislative Coordinating
Committee
Commission on Nursing Research
and
Council of Nurse Researchers

CW:mm

AN EXPERIMENT IN GRANT ADMINISTRATIONGeorge Pilarinos*

On January 9, 1979, the Director of the National Science Foundation (NSF) and the President of the University of Florida entered into an agreement that could have a profound effect on the way research projects are managed in universities throughout the country and on the relationship between the Federal Government and the academic community. Dr. Richard C. Atkinson of NSF and Dr. Robert Q. Marston of the University of Florida agreed to experiment with a grant administration system that provides great flexibility to the University, permits most management decisions to be made locally, yet (paradoxically to some) improves accountability for the use of public funds. Seven other large universities have since signed similar experimental agreements or have expressed an interest in doing so.¹

These agreements are the culmination of a one year reexamination by NSF of the way it does its grant business. One impetus for the reexamination was a negative one: the increasingly acrimonious debate over Federal control or "interference" in the affairs of universities and the perception that a long and fruitful partnership relationship had deteriorated. Another impetus was positive: the passage of PL 95-224, the Federal Grant and Cooperative

Agreement Act of 1977. PL 95-224 specifically seeks a clarification of the relative roles of Federal funding agencies and the recipient institutions and calls for a government-wide study of the appropriate uses of the grant mechanism as compared to others. On still another level, NSF management officials had been concerned for some time about the proper balance between accountability and the growing paperwork burden. These forces came into focus during 1977 and led to the idea of carrying out some experiments.

The Association of American Universities learned of the project at its inception and volunteered to assist. The AAU-NSF experiment, as it was soon named, began by calling on groups of university research administrators to meet and discuss the problems associated with the present grant administration system and to suggest possible improvements that could be part of an experiment.² The only guidelines supplied by the NSF representatives were:

1. The experimental design should focus on the system for post-award administration. The pre-award project grant/"peer review" system had already been studied in depth as a separate

effort by the Congress and others and had been found to be basically sound.³ Various suggested improvements resulting from these studies were being implemented.

2. The experiment should be limited to NSF grants and, to keep it manageable at the start, to a single research discipline. (The NSF Chemistry Division volunteered itself for the purpose.) While the new procedures would probably find application to the grant systems of other agencies, the expansion of the experiment into a multi-agency effort would cause too great a delay. On the other hand, a successful experiment with NSF grants might be picked up by other agencies once the data became available.

3. The statutory requirements of the Federal fund appropriations system would have to be observed. For example, the identity of appropriated funds passed by NSF to grantee institutions would have to be maintained. Statutory restrictions on grant payments for principal investigator salary and statutory cost sharing requirements would also continue to be imposed. It would simply cause too great a delay to attempt experiments that required legislative changes.

After several meetings and rounds of correspondence, the broad outlines of the experiment took shape and an NSF-AAU team visited the University of Florida to flesh out the agreement that was finally approved.⁴ In order to put the specifics of the agreement in perspective, a short digression to discuss "project" vs. "block" funding may be useful.

Broadly speaking, Federal support for science can be provided through "project funding" or "block funding." In "project funding," individual scientists develop their ideas and submit them to the interested Federal agency with the concurrence of their institutions. If the proposal is approved, the agency awards funds to the institution to permit the proposed work to be carried out by the applicant scientist. After award, each project must be accounted for as a discrete entity. Although several projects are normally underway simultaneously and available resources are in fact shared, for accounting purposes the portion of the resources used by each project must be separately documented in isolation from all others. In "block funding," an institution submits an application describing the broad purposes or an outline of inquiry for which it would use the funds, without specifying the details of the investigations down to the project level of organization. Block funding can range from simple formula grants that do not

require the applications to contain detailed programmatic descriptions of work, to the funding of centers, departments, or other large units of organization based on proposals with considerable programmatic content. After award, accounting documentation is permitted at a high level of aggregation and the institution may routinely shift resources and funds from one subactivity to another.

Although examples of block funding can be found in the NSF, the principal mode for its support of scientific research is the project grant system with "peer review" of individual project proposals to determine which are the most meritorious. A detailed comparison of the relative advantages and disadvantages of the project system vs. the block system is beyond the scope of this paper. Suffice it to say, however, that most analysts agree the project grant and its associated peer review system are the best mechanisms for identifying the most meritorious research ideas to be supported.⁵ On the other hand, after award the block grant system has a potential for more coherent and efficient administration by grantee organizations, because of its strong reliance on local decisionmaking and the broader scope of its approved work. The experiments NSF is undertaking have the effect of combining the best elements of the project grant

system, i.e., the pre-award evaluation and selection features, with the unique post-award management benefits of the block grant system.

The experimental grant agreements have three principal components: a "master grant" concept; a specially tailored "organizational prior approval system" (OPAS); and a set of special grant clauses not normally included in typical NSF grants.

Master Grant Concept

After award, the narrow scope of the project grant is a drawback because of the need to account for project expenditures in isolation from the work going on around it. The problem has been compounded in recent years as grants have come to be treated more and more as if they were cost-reimbursement contracts. The effect of this shift has been to require of the grantee institution much more documentation and the installation of detailed cost accounting systems to allocate charges accurately to the project level. These constraints increase the administrative cost of managing the grants and often impose administrative tasks on the scientific investigator, reducing the time available

for the research. Three examples may help illuminate the problem:

- o A University department has ten NSF projects with a total value of \$500,000. Each project uses specialized glassware. During the year the total used by all the projects amounts to 500 pieces costing \$5,000. As the glassware is ordered, separate documents are required for each project, certified by the investigator and separately entered in the university accounting system to show the exact quantity, nomenclature, property classification, and price. Is this level of detail worth the extra administrative costs involved? Probably not. Departmental, rather than project records would serve the same purpose. Yet, the use of a discrete grant to fund each project leads to such a requirement.

- o Each of the ten projects has \$5,000 approved for measurement instrumentation. Each investigator buys the specific device needed for the work of that project--a total of \$50,000. Each purchase is entered in the accounting system and the project grant administration system is satisfied. However, there exists a device, costing \$35,000 that can perform all the functions needed

by all the projects. Clearly, a broader approach to the procurement would be more efficient and economical, but the project system does not promote such cooperative administration.⁶

o A research assistant works several hours each day on five of the projects for a total of 40 hours per week. The payroll time card for that week must indicate the project account code and the actual number of hours spent on each project. This recordkeeping becomes especially burdensome if the time spent on each project varies from day to day. Obviously, the substitution of a single account code for the composite of all five projects would simplify matters greatly, but this is not permissible if each project is a separate grant.

The NSF experimental program seeks to overcome these difficulties by grouping individual approved research projects into a single entity called a "master grant" for purposes of administration. Under the master grant concept, the scope of work is defined as the aggregate of the scopes of all new projects approved for support at a university department during one fiscal year.⁷ At the start of the year, NSF establishes an empty, skeleton master "grant" with a unique grant number and a

dollar value of zero. Proposals from the investigators at that department are received and evaluated in the usual manner. When the first project is approved for support, it is awarded to the university as amendment no. 1 to the master grant. A project list attached to the grant letter gives the basic identifying information about the project award such as the investigator's name, the effective date, the expiration date, the dollar amount awarded, and so on. As subsequent projects are approved, they too, are awarded as amendments with revised project lists attached reflecting the expanded set of covered projects. Each of these projects has an approved level of effort represented by the description of work in the proposal and the approved line item budget. As each project is added to the master grant, however, an aggregate line item budget is created. It is at this aggregated level that NSF requires the institution to account for its funds. Universities may, of course, maintain accounting records and expenditure controls at the project level of detail for management purposes. Investigators will want to know how their projects stand financially. University officials will want controls in place to assure that projects are

carried out in accordance with the schedule and level of effort approved by NSF.

Such project accounting is for the convenience of the institution and may be designed to meet those needs exclusively. The allocation of costs to projects may be by estimation or other methods less precise than would be required if each project were a grant. The significant point is that for reporting to NSF and for accounting to Federal auditors, the university is required to support its expenditures at the master grant level of detail.

Organizational Prior Approval System

While the aggregation of projects under master grants can significantly simplify accounting and reduce paperwork, it does not in itself increase flexibility for local decisionmaking. NSF post-award policies require prior approval by NSF for various changes in the administration of projects such as the purchase of an item of equipment that differs from one in the approved proposal. In the example cited earlier, if the ten investigators agreed to cooperate to purchase one device costing \$35,000 rather than ten devices costing \$50,000, each would have to write to the NSF program officer responsible for that project. The ten letters would have to be sent via the institutional review structure

of the university and be countersigned by an "authorized institutional representative." At NSF, the letters would be reviewed by each of the several program officers involved. Assuming concurrence in each case, letters would be written to each investigator. Copies would be sent to the NSF Division of Grants and Contracts for inclusion in the administrative files for each project.

Clearly, a good deal of paper is involved in this process and weeks of delay can result. Other types of changes are even more complicated, requiring approvals by both the program officer and the grants officer for the project and a formal amendment to the grant.

This is not to say that NSF rules are especially cumbersome. On the contrary, NSF procedures are some of the simplest in the Federal Government. In its Grant Policy Manual issued October 1, 1977,⁸ NSF provided for delegating certain of the approval authorities to institutions if the institutions established "Organizational Prior Approval Systems" (OPAS) in accordance with guidelines supplied in the Manual. The OPAS approach was originally devised by the National Institutes of Health and most of the institutions doing business with NSF had such systems in place. The

adoption of the concept by NSF and the delegations of authority went a long way toward simplification of grant administration.

The success with the OPAS concept made it the logical mechanism for carrying out additional delegations of authority envisioned for the experiment. The Foundation informed the participating institutions that if they had in place, or agreed to establish, an organizational prior approval system acceptable to NSF, then NSF was prepared to delegate authority for all prior approvals except changes in project scope of work, level of effort or principal investigator. These delegations would become a part of the Grant Administration Agreements to be negotiated with the institution and would be accompanied by the guidelines for making the decisions and the standards for documenting them. The guidelines are the same as those that NSF officials would use to make prior approval decisions.

Even without the master grant concept, the delegation of these authorities would have an important impact on institutional flexibility and on the paperwork associated with processing changes. The combination of these delegations of authorities with the aggregation of all projects into one master grant greatly amplifies the

effect because for purposes of delegation, the "grant" being administered is the master.

A brief excerpt from the agreement entered into with the University of Illinois gives the flavor of the flexibility derived from the combination of these concepts:

"Fund Transfers. (1) The University may transfer funds provided under a master grant among the projects included within the scope of the master grant. (2) The University may reprogram funds between the line item categories of the aggregated master grant budget. (3) The University may make cumulative expenditures for equipment or domestic travel which exceed by 25% the aggregated amounts budgeted for these items..."

As noted earlier, this sort of flexibility is normally associated with block funding. It is achieved in the experimental agreements by systematically unravelling the web of post-award restrictions attached to the project grant and reweaving an accountability structure at the master grant, or departmental level of detail.

Special Clauses

During the exploratory discussions with university representatives at the early stages of experimental design, they were asked to identify particular problems in research project administration that could be addressed as part of the experiment. Most have been accommodated by the master grant concept and the OPAS delegations of authority. Several clauses added to the grant administration agreements warrant special mention, however.

A. Pre-Award Costs. Normally, NSF does not permit grantees to charge against a grant any costs incurred before the effective date of the grant. This restriction, made for sound reasons, can cause problems in certain situations. The most typical case is the funding hiatus that can sometimes occur when a renewal of an existing project is somehow delayed resulting in an unfunded gap of several weeks or, more rarely, months. In order to keep the project viable, the grantee resorts to a variety of stopgap funding measures, some of which are technically in violation of Federal regulations and lead to audit disallowances. Yet, obviously, it would be inimical to science and to the economical use of public funds to disband a project, fire the

staff, turn in supplies and equipment, and so on, only to start it up again a few weeks later. To deal rationally with this and other cases in which pre-award expenditures would be beneficial to the research, specific provisions have been included in the grant administration agreements permitting the OPAS to authorize such charges for a prescribed period of time before the effective date of awards.

B. No-Fund Extensions of Time. A similar problem occurs at the expiration date of grants. If the researcher needs more time, a letter request must be submitted to the NSF program officer and if approved, the NSF grants officer issues a formal amendment extending the original funding period. Apart from the paperwork generated by these requests, which are almost always honored, delays can cause the same problem of project interruption as the "late renewal" problem. A special clause has been included in the experimental agreements to permit OPAS approval of extensions of up to six months for projects.

C. Monitored Workload Cost Allocations. The accounting method for allocating salary and wage costs under grants has been a subject of great controversy between academic institutions and the Federal government. A detailed discussion of this complex topic

is beyond the scope of this paper. Suffice it to say, a unique experiment has been authorized at one of the universities involving use of the "monitored workload" system for allocating costs for professional and nonprofessional project staff. Under this method, the distribution of salary and wage charges is based on budgeted and assigned workload updated to reflect significant changes in workload distribution. The experiment will seek to establish whether this method, favored by the academic community as being less costly to administer, can be as effective as the more detailed payroll distribution system required by the Federal government.⁹

Effect on Accountability

Although the experimental design reduces paperwork and increases management flexibility at the university, paradoxically it also improves accountability for the use of public funds. There are several reasons for this apparent contradiction. First, the "normal" pattern of delegations of authority of authority is largely accidental, having evolved for reasons peculiar to each provision, rather than as a coherent package. It is difficult to explain why one type of authority is currently delegated while another is not.

The effect of this fuzziness in rationale is to cloud the question of who is responsible for the management of the projects. By delegating to the university all of the miscellaneous authorities except those controlling changes in scope, level of effort, and principal investigator, NSF makes the University-NSF roles crystal clear and the university agrees to be held fully accountable for its actions. This clarification is a positive improvement in accountability.

Second, the mass of paper associated with "normal" project grant administration increases costs and may actually impair accountability. An NSF program officer reviewing and stamping forms for routine change actions has less time available to review the progress of the work and the quality of the research. By permitting the program officer to focus attention on substantive oversight, the reduction of paperwork may lead to greater program accountability without loss of administrative accountability.

Quite apart from these considerations, however, the experimental program can make a clearcut improvement through the effective use of the OPAS procedures. In the "normal" system, individual investigators deal with individual program managers at NSF. As in any large group, the effectiveness of

NSF program officers in administration and their awareness of all the policy considerations will vary from person to person. The small group comprising the institution's OPAS can be much more consistent in the application of policy standards.

Furthermore, the OPAS group will see all requests for change and will be better equipped as a result to consider each request within the context of the total work in progress and in the historical perspective of decisions made in earlier cases. The simple fact of physical proximity to the work of the people reviewing the requests is another positive element in arriving at good decisions.

Consider, too, the documentation system. Each month (or other regular frequency) the OPAS of each institution will report to NSF on all decisions made during the previous period. NSF will have in one package a record of all OPAS actions, available for review and analysis. The present system does not lend itself to such a coherent, orderly review. Each investigator's request is processed separately by individual program officers and grant officers and is filed in its own separate project folder.

The ability to examine all actions as a unit permits regular analysis by NSF management of types of requests, patterns of approvals or disapprovals, and frequency of good or bad applications of policy. Where the need indicates, corrective action can be taken by altering the delegations of authority or some other mechanism. Such analyses would be too difficult, cumbersome, and time consuming to carry out effectively in the traditional administrative system. For many of the same reasons, auditors will also find the centralized OPAS approval records a big help in their review of financial management practices.

Evaluation of Experiment

The experimental design includes provisions for evaluation. During the first year, records will be kept by NSF and the grantee in a way that will facilitate comparisons of "old" and "new" in terms of paperwork savings and project efficiencies. The people involved have also been asked to record their positive or negative impressions about the experiment from time to time.

After six months, a special review team including NSF and AAU representatives will visit to discuss advantages and disadvantages of the experimental approach and to measure tangible

savings to the extent possible. The review will include personal interviews with investigators to get their views and to determine if the expanded local authority has operated fairly and equitably to all investigators.

At the end of one year, another similar review will be conducted, but in greater detail and with an audit of the accounting records by the NSF Audit Office to assure that the accounting methods used during the experiment provide adequate fiscal accountability. Based on this review, the NSF and the participating universities will decide whether the experiment should be continued and expanded, should be modified, or should be terminated.

Whatever the outcome, an exciting period lies ahead for those of us committed to innovation in research administration.

Footnotes

- * Deputy Assistant Director for Administration, National Science Foundation. BA Economics, Queens College, 1953; MA Public Administration, George Washington University, 1964. Member ASPA, SRA, NAMA, ACM, DPMA, Philosophical Society.
- 1. The seven are: University of California, Los Angeles; University of California, San Diego; University of Illinois, Urbana; University of Wisconsin; Massachusetts Institute of Technology; Columbia University, and State University of New York, Stony Brook.
- 2. Representatives from the following organizations took part in these meetings: Duke University, University of Illinois, Princeton University, University of California, University of Rochester, University of Florida, Pennsylvania State University, Stanford University, Johns Hopkins University, Committee on Government Relations of NACUBO, and Steptoe and Johnson.
- 3. See in particular: Hearings before the House Subcommittee on Science, Research, and Technology of the Committee on Science and Technology, 94th Cong., 1st Sess., (1975) and the Report

resulting from those hearings: National Science Foundation Peer Review, 94th Cong., 2nd Sess., (1976).

4. In addition to the author, the members of the team included Dr. Richard Nicholson, Director of the NSF Division of Chemistry, Mr. Warren Hynes, NSF Deputy Audit Officer, Dr. Robert Newton, Senior Staff Associate, NSF Division of Grants and Contracts, and Mr. Newton Cattell, Director of Federal Relations of AAU.
5. For example, from Vol. 1, page 2 of the House Report cited above: "No method superior to peer review has been found for judging scientific competence of proposers." This view is by no means unanimous, however. For an excellent counter argument, see "The Burden of Competitive Grants" by A. Carl Leopold in Science, February 16, 1979, p. 607.
6. Of course, some researchers do cooperate and attempt to share resources for more effective project management. The present system places obstacles in the path of such cooperation, however, and makes them the exception.
7. The concept of "master grant" is an extension of an earlier innovation, developed by the National Science Board, named the "group grant." In the latter concept, researchers may submit

their requests for project support in one proposal. Each part gets peer reviewed, but for those approved, a single grant is made. Under master grants, project proposals can be submitted at any time during the year and are aggregated by amending the master. It might also be noted that broader definitions of scope than "one department-one year" are possible. However, this definition is the most manageable in that the work is closely related by scientific discipline and organizational association and is limited to the set of projects begun in a fixed time period.

8. NSF Grant Policy Manual, NSF 77-47, U.S. Government Printing Office, 1977.
9. The focal point for the controversy on time and effort reporting has been the proposed revision of Office of Management and Budget Circular A-21, "Cost Principles for Educational Institutions." The new version of this circular was published in the Federal Register, Vol. 44, No. 45, pp. 12368-12380, March 6, 1979.

TESTIMONY OF SENATOR THAD COCHRAN IN SUPPORT OF S.376,
"THE NATIONAL DIGESTIVE DISEASES PREVENTION, CURE AND
CONTROL ACT"

Mr. Chairman, I am pleased to present this testimony in support of S.376, the "National Digestive Diseases Prevention, Cure and Control Act." This bill is currently cosponsored by my distinguished colleagues, Senator Mathias of Maryland and Senator Bayh of Indiana.

In 1976 Congress commissioned a study of digestive diseases under P.L.94-562. The National Commission on Digestive Diseases was established to accomplish three major tasks:

- study the medical, social and economic problems attributed to digestive diseases;
- evaluate the present use of resources to control the problems identified;
- develop a long-range national plan for the organization and effective use of national resources to deal with digestive diseases.

On January 31, 1979, after extensive research, meetings, workshops and surveys, the Commission presented its findings to Congress along with a long-range plan to combat more effectively the immense problems presented by digestive diseases.

The Commission's findings are, to say the least, disturbing.

As summarized in its report to Congress, the Commission found that digestive diseases collectively represent:

- 10 percent of the total economic burden of illness in the United States, as defined by the National Center for Health Statistics;
- the primary reason for major surgery;
- the leading cause of hospitalization;
- 15 percent of all hospital utilization (43.4-million hospital days each year);
- the second most prevalent cause of disability among the employed;
- 20 million chronically ill individuals;
- 14 million persons who suffer acute episodes of illness each year;
- 190,000 deaths each year (counting only those for whom digestive diseases are identified as the immediate cause of death);
- \$17-billion in direct health care costs;
- \$35-billion in total annual economic loss,

or approximately 1.5 percent of the gross national product (1978 projection).

One out of 10 Americans ~~are~~^{is} affected with some form of digestive disease. And 17 out of every 100 individuals between the ages of 45 and 64, most of whom sustain family income in whole or in part, have some form of a diagnosed digestive disease.

Despite the prevalence of these diseases, the level of public and even professional awareness is low. Our commitment of national resources is extremely low. For every dollar of economic loss to society from various diseases, the following sum - in cents - was devoted to research:

- cancer - 4.7¢
- neurological, stroke, communicative
and eye disease - 2.0¢
- mental health - 0.8¢
- heart, lung and blood disease - 0.7¢
- kidney and urological disease - 0.4¢
- arthritis and bone disease - 0.3¢
- digestive disease - 0.2¢

This dramatically illustrates the imbalance that exists between the impact of digestive diseases and our ~~re~~^{is}ponse to it.

The bill that I am sponsoring attempts partially to alleviate that imbalance. My bill would implement three key recommendations of the National Commission on Digestive Disease:

- establishment of a National Digestive Diseases Advisory Board to oversee implementation of the Commission's long-range plans;
- establishment of a National Digestive Diseases Education and Information Clearinghouse to serve as a public and professional information source;
- authorization of a grant program through the National Institute for Arthritis, Metabolism and Digestive Diseases to improve medical education in digestive diseases.

The total 3-year authorization called for is \$5,665 -million. This is a small sum for such a significant endeavor. The largest share of this authorization would go to the clearinghouse. This is justified, in my view, by the fact that the main thing we need to do is to raise the level of awareness throughout the country of the urgency of the medical problem.

The Commission made 23 major recommendations in its report to Congress. My bill implements three of those recommendations. Six others require administrative action and eleven others require appropriations. Two others require long-term legislative action. My bill will be a real first step toward accomplishing these goals.

Mr. Chairman, I hope that this committee will act expeditiously and favorably in its consideration of this bill.

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OFFICE OF THE DEAN

Dear Senator Kennedy,

I have had the opportunity to review your proposal entitled The Health Services Promotion Act of 1979. I found the effort to be a refreshing approach to many of the issues which have, for several years, surrounded the federal biomedical and behavioral research support effort. While I cannot agree with every provision in its current form, I found several provisions particularly appealing. For example, defining the authority of the Director, NIH to appoint experts and consultants, to charter committees, including peer review groups, and to use set-aside funds for support of neglected, underfunded and innovative research proposals are ideas which should be implemented promptly.

The intention to stabilize funding of investigator initiated research is also commendable. To achieve it by mandating a fixed percentage of the budget might take a phase-in period and would need some refinement, I think, to clarify some discrepancies between various Institutes.

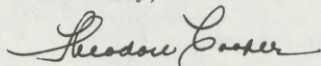
I also recognize an intent to stabilize research support through the proposed planning effort with the President's Council. I would be concerned with the practicality of the provision. The staff work would have to be tremendously effective. The program would be saddled with another set of required reporting and time tables and I would question whether the group could be viewed as having credibility. One of the greatest frustrations in the planning efforts of the past has been the regulation that every few years, as the actors change, plans are cast aside. The fact that the basic budget process is annual also makes the planning effort difficult. Perhaps you should consider committing a budget for 3 to 5 years and perhaps adjust it annually. Undoubtedly some would interpret this provision as reflecting lack of confidence in the staff of the Department of Health, Education and Welfare, including NIH.

The "sunset" provision could be looked upon as a device to eliminate categorical Institutes. I doubt whether this approach will gain confidence of the community.

I am delighted with your ideas on paperwork. The approach is realistic and could be productive. This section is particularly creative and should be tried soon.

These proposals should provoke needed discussions on improving our system. I believe things can be improved and I hope you are successful in your efforts.

Sincerely,

A handwritten signature in cursive script, reading "Theodore Cooper".

Theodore Cooper, M.D., Ph.D.
Dean

Senator Edward M. Kennedy
Russell Senate Building
Washington, D.C. 20510

May 9, 1979

Dr. BLUMENTHAL. The subcommittee stands adjourned.
[Whereupon, at 12:15 p.m., the subcommittee was adjourned.]



The following table shows the results of the experiments conducted at the University of California, Berkeley, in 1901.

TABLE I

