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NATIONAL BIOMEDICAL HEART, LUNG, BLOOD, BLOOD
VESSEL, AND RESEARCH TRAINING ACT OF 1975

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HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON
LABOR AND PUBLIC WELFARE
UNITED STATES SENATE

NINETY-FOURTH CONGRESS

FIRST SESSION

ON

S. 988

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REVISE
AND EXTEND PROGRAMS OF THE NATIONAL HEART AND
LUNG INSTITUTE AND NATIONAL RESEARCH SERVICE
AWARDS

MARCH 17, 1975



Printed for the use of the Committee on Labor and Public Welfare

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NATIONAL BIOMEDICAL HEART, LUNG, BLOOD, BLOOD VESSEL, AND RESEARCH TRAINING ACT OF 1975

MONDAY, MARCH 17, 1975

U.S. SENATE,
SUBCOMMITTEE ON HEALTH OF THE
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittee met at 10:12 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman), presiding.

Present: Senators Schweiker, Nelson, and Stafford.

Committee staff present: LeRoy G. Goldman, professional staff member; and Jay B. Cutler, minority counsel.

Senator KENNEDY. The Subcommittee on Health hearing will come to order.

Today the subcommittee begins hearings on the National Biomedical Heart, Lung, Blood, Blood Vessel, and Research Training Act which I introduced earlier this month along with my colleagues, Senators Javits, Williams, Schweiker, and Stafford.

These important authorities of the National Institutes of Health expire June 30, 1975. Our bill proposes a 2-year straightforward extension of these programs. This is in anticipation of the work now underway by the President's Biomedical Research Panel, which grew out of legislation which Senator Javits and I authored last year.

I believe this Panel has now undertaken the most important evaluation of the National Institutes of Health and its programs since the Agency's inception 35 years ago. I and the members of my subcommittee eagerly await the Panel's report, and I would hope that that report, coupled with the expiration of the Heart Act, the Cancer Act, and the Research Training Act of 1977, will create the conditions which will bring about the reformation of the National Institutes of Health.

In the interim, it is necessary that we reauthorize and maintain these expiring programs.

Heart and blood vessel diseases kill more than 1 million people each year; myocardial infarctions kill some 600,000 people annually. More than 12 million Americans will suffer some kind of heart attack in the next 10 years.

Lung diseases are deadly killers and debilitators. Approximately 20 million Americans are disabled with diseases of the lungs. Death from emphysema is rising at a rate unparalleled by any other disease.

Enormous numbers of people are being killed and disabled by thrombosis. This disease, consisting of the formation of blood clots in the vessels, is responsible for most of the suffering and death caused by the 200,000 strokes occurring annually in the United States.

I believe S. 988, with whatever additional amendments the committee may wish to make, will continue the viability of these authorities, and I look forward to the testimony we'll have this morning.

Senator Schweiker.

Senator SCHWEIKER. Thank you very much, Mr. Chairman.

In 1972 the Congress enacted the National Heart, Blood Vessel, Lung and Blood Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases. Today we have an opportunity to review the Federal activities under that act, to assess the progress we have made, and to begin our consideration of its renewal.

I am pleased to have joined the chairman and several of my colleagues on this subcommittee in sponsoring the legislation extending for 2 years both the heart and lung program as well as the research training authority of NIH.

In 1972 I introduced a bill which sought to implement certain of the recommendations of the National Heart and Lung Institute task force report on arteriosclerosis. The task force urged leadership by the Federal Government in a major Federal commitment for the prevention and control of cardiovascular diseases, the Nation's No. 1 killer.

The three major provisions of the proposal established national centers for the prevention of arteriosclerosis, cardiovascular disease prevention clinics, and an office of health and education within the Heart and Lung Institute. In concept, these proposals were preserved in the Heart, Lung and Blood Act which the Congress enacted.

I am particularly interested, therefore, in examining the success of the efforts of the assistant director for health information programs of the National Heart and Lung Institute, particularly the special emphasis required in the law on the dissemination of information regarding diet, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis, cardiovascular and pulmonary diseases.

Also required under the act, which expires June 30, is a requirement that in addition to research, training, and demonstrations, the centers established around the country by the Institute would be utilized for programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular disease, improved methods of intervention against those factors which cause individuals to have a higher risk, and development of health professions and allied health professions personnel highly skilled in prevention.

I was particularly interested, Mr. Chairman, in the National Heart and Lung Institute response to the provisions of the act which you inserted in the record indicating that both of the provisions I have mentioned have been implemented. However, the brief response of the Institute did not provide the detailed information which I hope the committee will receive today.

One further area which I think we should explore involves the precedent we established in the recently enacted Diabetes Act in which we placed the control and prevention program under the jurisdiction of the Center for Disease Control in Atlanta, rather than in the National Institute for Arthritis, Metabolism, and Digestive Diseases. I will be

interested in determining whether we should consider a similar provision in the extension of the present act, and I hope the committee will be provided some guidance in that regard.

With respect to the National Research Service awards authority which we established last year and which is extended in the bill before us, I just want to confirm my view that direct support of the training of scientists and careers in biomedical and behavior research is an appropriate and necessary role for the Government and it is essential that we continue the program as we designed it last year by consolidating then existing research and training and fellowship authorities into a single National Research Service awards program.

[The text of S. 988 follows:]

94TH CONGRESS
1ST SESSION

S. 988

IN THE SENATE OF THE UNITED STATES

MARCH 6, 1975

MR. KENNEDY (for himself, MR. JAVITS, MR. WILLIAMS, MR. SCHWEIKER, and MR. STAFFORD) introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To amend the Public Health Service Act to revise and extend programs of the National Heart and Lung Institute and National Research Service Awards.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*
- 3 That this Act may be cited as the "National Biomedical
- 4 Heart, Lung, Blood, Blood Vessel, and Research Training
- 5 Act of 1975".

1 TITLE I—NATIONAL HEART AND LUNG
2 INSTITUTE

3 REPORT AND PLAN OF THE DIRECTOR OF THE INSTITUTE

4 SEC. 101. Paragraph (2) of subsection (b) of section
5 413 of the Public Health Service Act is amended to read as
6 follows:

7 “(2) The Director of the Institute shall, as soon as
8 possible after the end of each fiscal year, prepare in con-
9 sultation with the Council and submit to the Secretary of
10 Health, Education, and Welfare for transmittal to the Presi-
11 dent and the Congress simultaneously a report on the activi-
12 ties, progress, and accomplishments under the program
13 during the preceding fiscal year and a plan for the program
14 during the next five years. The plan shall also project the
15 staff required by the Institute to carry out the program
16 and recommendations for appropriations for the program.

17 ALTERATION AND RENOVATION OF FACILITIES

18 SEC. 102. Paragraph (2) of subsection (c) of section
19 413 of such Act is amended by striking “operate,” and
20 inserting in lieu thereof “operate, alter, renovate,”.

21 ASSISTANT DIRECTOR FOR PREVENTION AND EDUCATION

22 SEC. 103. Subsection (d) of section 413 of such Act is
23 amended by striking “Assistant Director for Health Infor-
24 mation Programs” each place it appears and inserting in lieu
25 thereof “Assistant Director for Prevention and Education”.

1 EXTENSION OF PREVENTION AND CONTROL PROGRAMS

2 SEC. 104. Subsection (b) of section 414 of such Act is
3 amended by striking "and \$45,000,000 for the fiscal year
4 ending June 30, 1975" and inserting in lieu thereof "and
5 \$45,000,000 for the fiscal year ending June 30, 1975, and
6 for each of the two succeeding fiscal years".

7 PREVENTION PROGRAMS IN RESEARCH AND
8 DEMONSTRATION CENTERS

9 SEC. 105. Paragraph (2) of subsection (a) of section
10 415 of such Act is amended as follows:

11 (a) by striking "paragraph (1) (A)" and inserting
12 in lieu thereof "paragraph (1) (A) and (B)";

13 (b) by striking "cardiovascular diseases" and in-
14 serting in lieu thereof "cardiovascular, lung, and blood
15 diseases";

16 (c) by striking "cardiovascular disease" in sub-
17 paragraph (A) and inserting in lieu thereof "such
18 disease"; and

19 (d) by striking "disease" in subparagraphs (B),
20 (C), and (D) and inserting in lieu thereof "diseases".

21 LIMITATION ON PAYMENTS TO CENTERS

22 SEC. 106. Subsection (b) of section 415 of such Act is
23 amended by striking the first sentence following paragraph
24 (4) and inserting in lieu thereof the following: "The aggre-
25 gate of payments (other than payments for construction)

1 made to any center under such an agreement may not ex-
2 ceed \$5,000,000 (excluding indirect costs) in any year,
3 except that such aggregate may exceed such sum in any year
4 to the extent that any excess amount is attributable to in-
5 creases in appropriate costs as reflected in the cost of living
6 index published by the Department of Labor for such year.”

7 CORRECTION IN DESIGNATION OF DIRECTOR OF THE

8 NATIONAL SCIENCE FOUNDATION

9 SEC. 107. Paragraph (1) of subsection (a) of section
10 417 of such Act is amended by striking out “Director of the
11 Office of Science and Technology” and inserting in lieu
12 thereof “Director of the National Science Foundation”.

13 REPORT OF NATIONAL HEART AND LUNG ADVISORY

14 COUNCIL

15 SEC. 108. Paragraph (2) of subsection (b) of section
16 418 of such Act is amended to read as follows:

17 “The Council shall submit a report to the Secretary
18 of Health, Education, and Welfare for transmittal to the
19 President and to the Congress simultaneously not later than
20 November 30 of each year on the progress of the program
21 toward the accomplishment of its objectives during the pre-
22 ceding fiscal year.”.

1 EXTENSION OF PROGRAMS OF NATIONAL HEART AND LUNG
2 INSTITUTE

3 SEC. 111. Section 419B of such Act is amended by
4 striking "and \$475,000,000 for the fiscal year ending
5 June 30, 1975" and inserting in lieu thereof "and \$475,-
6 000,000 for the fiscal year ending June 30, 1975, and for
7 each of the two succeeding fiscal years".

8 TITLE II—NATIONAL RESEARCH SERVICE

9 AWARDS

10 TRAINING IN FEDERAL INSTITUTIONS

11 SEC. 201. Section 472 (a) (1) (A) (iii) of the Public
12 Health Service Act is amended by striking "non-Federal".

13 COMBINATION OF HEALTH RESEARCH AND HEALTH

14 TEACHING

15 SEC. 202. (a) Section 472 (c) (1) (A) (i) of such Act
16 is amended by striking "health research or teaching" and
17 inserting in lieu thereof "health research or teaching or any
18 combination thereof which is in accordance with usual pat-
19 terns of academic employment"; and

20 (b) Section 472 (c) (2) (A) of such Act is amended by
21 striking "health research or teaching" and inserting in lieu
22 thereof "health research or teaching or any combination
23 thereof, which is in accordance with the usual patterns of
24 academic employment,".

Senator KENNEDY. Thank you very much.

Our first panel of witnesses this morning will represent the views of the administration of the measures we're deliberating on this morning.

Dr. Cooper is Acting Assistant Secretary of Health for the Department of HEW; Dr. Ronald Lamont-Havers is the Acting Director of the National Institutes of Health; Dr. Robert Ringler is the Acting Director of the National Heart and Lung Institute.

I want to welcome all of you. I want to make the observation that you're all acting in these positions. I am sure you are all fulfilling your responsibilities ably and well, but we cannot let the moment pass without recognizing, both in fairness to you and to the program itself, that it is terribly important that these positions be made permanent.

Obviously, you are all to be commended for assuming these responsibilities, and we welcome you here as people who can speak with a good deal of authority and responsibility.

We welcome you, Dr. Cooper.

STATEMENT OF THEODORE COOPER, M.D., ACTING ASSISTANT SECRETARY, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, ACCOMPANIED BY FRANK E. SAMUEL, JR., DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DHEW; RONALD W. LAMONT-HAVERS, M.D., ACTING DIRECTOR, NATIONAL INSTITUTES OF HEALTH, DHEW; ROBERT L. RINGLER, M.D., ACTING DIRECTOR, NATIONAL HEART AND LUNG INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DHEW; JAMES D. ISBISTER, ACTING ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION DHEW

Dr. COOPER. Thank you, Mr. Chairman.

Besides the two other "actors" that you mentioned, I have another "actor" with me, Mr. James Isbister, the Acting Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, whose activities come under the purview of title II of this act, and Mr. Frank E. Samuel, Jr., the Deputy Assistant Secretary for Legislation.

I might begin by wishing you and the members of the committee, sir, a happy St. Patrick's Day, and I would suggest, if it is OK with you that instead of reading the detailed statement, that I summarize the statement, and then my colleagues and I could respond to your questioning.

Senator KENNEDY. That will be fine. We will have it printed in its entirety in the record at the conclusion of your testimony.

Dr. COOPER. Thank you.

With respect to title I, the administration does not expect to submit a proposal for legislation extending the National Heart, Blood Vessel, Lung, and Blood Act of 1972. However, we would not oppose an extension of this act. We would suggest that the extension in its authorizations conform to the levels of the President's budgetary plans.

We would also suggest that no additional mandates or new categorical activities be added to the act, as you have said, until the Presi-

dent's Panel for Biomedical Research makes its report. We do feel that the activities in this particular program have been done productively.

It has been a good program, effectively carried out.

I would like to briefly just highlight some of the advances that have been made and some of the findings which you are probably aware of in this field that reflect continuing success in the efforts to combat heart, lung, and blood vessel and blood diseases.

I think the most significant finding in the last 2 years has been the report from several investigators, confirmed by our own Institute, that the so-called epidemic in coronary artery disease, the problem of heart attack, in particular, has stabilized. We are pleased to join those whose interpretation of the vital statistics data point out that since 1968 there has been a downward trend, which we think is a real statistical trend in the incidence of the death rate from heart attack in this country.

Senator KENNEDY. You will give us the figures or these statistics?

Dr. COOPER. Yes, sir.

[The information referred to follows:]

Downward Trends in Heart and Lung Diseases

Age-Adjusted Death Rates/100,000 Population

	<u>1940</u>	<u>1950</u>	<u>1960</u>	<u>1965</u>	<u>1968</u>	<u>1973</u>
Coronary Heart Disease	207.2	226.4	238.5	237.7	241.6	218.9
Stroke	105.0	88.8	79.9	73.3	71.3	63.7
Hypertension	69.3	56.0	29.6	22.4	9.5	6.3
Rheumatic Heart Disease	20.5	14.0	9.7	7.5	7.2	5.4
Emphysema	N/A	0.7	4.2	7.6	9.2	7.7
Bronchitis	N/A	1.3	1.8	2.5	2.4	1.9

% Changes in Age-Adjusted Death Rates

	<u>1940 - 1950</u>	<u>1950 - 1960</u>	<u>1960 - 1965</u>	<u>1968 - 1973</u>
Coronary Heart Disease	+ 9.3	+ 5.3	- 0.3	- 9.4
Stroke	- 15.4	- 10.0	- 8.3	- 10.7
Hypertension	- 19.2	- 47.1	- 24.3	- 33.7
Rheumatic Heart Disease	- 31.7	- 30.7	- 22.7	- 25.0
Emphysema	N/A	+ 500.0	+ 81.0	- 16.3
Bronchitis	N/A	+ 38.5	+ 38.9	- 20.8

Senator KENNEDY. I would like all of that material.

Dr. COOPER. We will give you the actual numbers on these. I think in both cases it appears like an annual reduction rate of 1½ to 2 per cent. It is a consistent pattern.

We think this is most important and most significant.

At the recent meeting of the American Heart Association, these figures were reported as.

Senator KENNEDY. What do you attribute it to?

Dr. COOPER. Well, there has been some controversy as to what the actual cause—the reason why we are successful. My own view is it a result of several factors. First, the program on hypertension. Since hypertension that it is a real risk factor when coronary artery disease has taken hold, I think our 15-year experience with the reduction in complications is now beginning to make an impact on coronary artery disease itself in its initial expression.

Second, I think we are beginning to see the results of successful emergency treatment and in coronary care in the early stages of post-myocardial infarction. I think there is some successful addition of knowledge of some of the other factors that are known as risk factors besides hypertension in field of coronary artery disease.

These are the questions that Senator Schweiker mentioned in his statement about diet, smoking, and exercise. Although we are not uniformly successful in educating the public and the profession about the importance of continuing attention to these risk factors, I think, in the aggregate, we are beginning to see some progress on the prevention side, some very good progress on the treatment of hypertension, some very good progress on the treatment of acute myocardial infarction itself, and, therefore, the initial event is not as detrimental in a statistical sense as it used to be.

I think our ability to treat shock which is a significant cause of the deaths from acute myocardial infarction, is coupled to some of the other advances that we are seeing in the treatment of the acute myocardial infarction. This is the most significant finding.

In that regard, I would point out that there have been some additional diagnostic developments with the use of echocardiography, with the extension of the use of electrophysiological phenomena, enzyme biochemistry to limit or delimit the extent of injury to the heart after a coronary occlusion. I think our ability to do these kinds of things will further enhance our ability to save people after the initial insult, but the best progress will still be made if we are more successful in primary prevention.

I think we are seeing a great deal of success in relief of symptomatology when the operation known as coronary artery bypass is applied to patients with significant arteriosclerosis of their coronary arteries. I think we are beginning to see some of the effect on our statistics on an age-adjusted and yearly basis of the application of this particular technique.

So I think across the board here I am optimistic that we are on the right track in treating coronary artery disease and preventing coronary artery disease.

Our efforts on high blood pressure, as I mentioned, have been significant. I think the public is more aware of this problem. The profession has increased its efforts in detecting and treating high blood pressure and we now believe that there is no such thing as benign

high blood pressure. I think this awareness, based on studies that were done in the last decade by the Veterans' Administration, as well as the Department, and programs supported by both in the community, means that the problem of hypertension, which is a huge one—23 million Americans—will be coming under control.

One of the other important risk factors associated with this, and also mentioned by Senator Schweiker, is diabetes. I think we might have been remiss in the past in not emphasizing the importance of the association of diabetes with the problem of arteriosclerosis. We have stepped up our activities in this regard and I think we can expect some further advances in this field as these activities clarify the association between diabetes, arteriosclerosis, and a variety of cardiomyopathies.

We will look with interest toward the recommendations of the Commission on Diabetes which is due in the next several months, and I am sure that the Department and the Institute, in particular, will be pleased to try to implement the recommendations that come forth from the Commission in combating that risk factor in arteriosclerosis.

There have been other advances in several fields of cardiovascular disease. I have only mentioned the most important from the statistical standpoint.

I would emphasize, as you pointed out, that all advances in the early detection treatment of lung disease and have also been reflected in an improvement in the statistics, and we will provide the detailed numbers on those for the record, but perhaps one of the more encouraging things on the lung aspect of the National Heart and Lung Institute's program has been the ability to bring into the study of lung disease the modern technology of molecular biology, cytology, biochemistry.

For so many years the study of the lung was concentrated on the aspect what used to be called "plumbing function" of the lung, the transmission of air in and out, which is the most vital function at its input. That is the end result, sort of like a passive system.

It is now recognized that we can separate from the lung itself perhaps 40 different cell types. We are just beginning to learn what the importance of these various cells are to the normal function of the lung and the response to environmental agents which prove to be noxious, infectious agents. We think that this will be a situation in which there will be a great burgeoning of new information about diseases of the lung which will give us the opportunity for new treatments and prevention.

Specifically, there have been great advances in the treatment of the respiratory disease syndrome of infants, much better treatment by positive pressure breathing. We have been able to reduce by half the death rate in the premature infant from the application of these techniques.

Senator KENNEDY. Has fetal research played any role in that?

Dr. COOPER. Yes, sir. One of the interesting findings in this regard is the ability to detect by the process known as amniocentesis those infants that may be at risk of having respiratory distress syndrome after birth or after premature delivery. This relates to the chemical findings of the fluids and the cell types which are identified after the amniocentesis. This would be classified as a category of fetal research which is, as you know, under study by the Ethics Commission.

We expect to have their initial recommendations on the whole area covered by fetal research by May 1, and it is my understanding that these recommendations will be on schedule.

Senator KENNEDY. Maybe you could explain the procedure, just as a practical matter? Do they examine the fluid?

Dr. COOPER. They examine the fluid in the sac which surrounds the fetus and from that they can determine what the likelihood might be of the premature infant of having respiratory difficulty upon delivery.

Senator KENNEDY. So if they know that before, what does this mean?

Dr. COOPER. If they know that beforehand, there are two avenues for dealing with it in a very positive way. It opens the opportunity for medical treatment of the mother, within certain ages, which might improve the structural function and the capability of the lung to respond on reaching the ambient environment outside the mother's womb. And there are some studies going on now which relate to the use of certain agents like steroids in that regard.

And, second, it alerts the physician and the care team to those infants that ought to be very promptly treated with the most modern techniques of both monitoring and ventilatory support of the type that I mentioned earlier.

In the area of blood diseases, I think there have been significant improvements in the last few years as a result of the new activities in sickle cell disease and the new possibilities for techniques to combat the thromboembolic crisis, the basal occlusive crises which are associated with it.

We are learning more about the treatment of hemophilia. We think we can improve the production of blood fractions and at a much lower cost for the treatment of the hemophilic.

We think that there are better technique and a better understanding now of the problem of blood transfusion and hepatitis. One of the interesting things here is that where we simplistically used to think that hepatitis caused by blood transfusion was transmitted by one specific agent that used to be called hepatitis B, we recognize now that a lot of hepatitis can be transmitted by agents other than just the A and B that was identified previously. This has proven to be a significant percentage of hepatitis. But the ability to identify in the screening process people who may transmit this disease blood donation is a significant advance.

So I think in all these areas there are very practical outputs which are coming forth as a result of this program, and a result of the research for the 20 years before that have been very productive for the control of the diseases which this act is meant to combat.

In addition, I would point out, in response to Senator Schweiker's comments that we did institute a reorganization of the Institute following the enactment of the act in 1972. There were organizational changes which were designed to facilitate the implementation of the act.

The Institute now has specific divisions for heart and vascular disease, lung disease, and blood diseases. We did appoint an Assistant Director who would have responsibility for the informational, educational, and prevention programs. His name is Dr. Jim Shields.

Since you were interested in that particular facet of the activity, I would like to point out that the most intense activity of that new effort was directed toward the problem of hypertension. Then-Secretary Richardson in July of 1972 did initiate a high blood pressure educational program. This was subsequently reendorsed by Secretary Weinberger last year, and this activity has been effective in bringing to the public and to the profession a new awareness on both the problem of high blood pressure and what can be done about it, because this is the most important feature of the problem of hypertension at the moment. It is not only a big problem with its severe consequences, but it can be detected rapidly with a very simple and inexpensive technique.

There are good therapies available and we have the data from clinical trials which emphasize the point that if you do something about it, you will prevent the catastrophic consequence of hypertension.

New educational activities have also been initiated in the lung disease area, and these are related basically to the necessity of giving the professionals and paraprofessionals the newest information on how to give respiratory support because we are very much aware that the success in emergency treatment and support of respiratory treatment depends on how it is done. The administration of oxygen, positive pressure, and other things which are characteristic of that therapy can also be detrimental, so we are actively engaged on a campaign which is designed to improve not only the scope of application, but also the proper application of this type of therapy.

In the blood area we have a significant effort which was initially begun on the problem of sickle cell disease in which the effort was basically to clarify the difference between a carrier of the trait and the patient with the actual sickle cell anemia itself. The need for this clarification was urgent because in several instances it created confusion within the community as to what having the trait meant. The resulting misapplication of that information could have been a massive abuse of personal liberties of many people who were not ill but who would be subject to certain tests and implications from those tests which would deprive them of job opportunities and other forms of security.

So we think in this area the new program has been both effective and active in this regard. There have been both organizational changes along that line. The Institute did also implement the requirement to spend 15 percent of its resources on lung disease and 15 percent of its resources on research on blood diseases. This has been accomplished within this period of time as well and has made a significant contribution to the expansion of the pulmonary research activities and the researches in the blood field.

So I think along those lines we have carried that out.

The requirements to initiate the comprehensive centers was begun. Three centers have been initiated, one in cardiovascular disease, one in pulmonary disease, and one in blood diseases. The one in cardiovascular disease is in Houston, Tex.; the one in pulmonary disease is in Vermont; and the blood resources center is in Seattle, Wash.

Senator KENNEDY. That's three; is that right?

Dr. COOPER. Yes, sir.

Senator KENNEDY. And didn't the act call for 15 heart and 15 lung?

Dr. COOPER. Thirty; fifteen heart and blood and fifteen lung.

Senator KENNEDY. And you have only got three?

Dr. COOPER. Yes, sir.

Senator KENNEDY. What is the problem?

Dr. COOPER. There are two determinants of that number. After consultation with the Advisory Council and within the Institute, we felt that the pace of developing these centers should be a reflection of finding out the best way to do it. It is not as simple in diseases with the scope of people that need to be addressed as with some other disease situations where there are lesser numbers of individuals that can be affected.

For example, in the problem of high blood pressure you are dealing with 23 million people, whereas, let us say, certain forms of specialty diseases such as leukemia, you might be dealing with several thousands of people. We felt that it would be wise management of the program if we could find out how to incorporate the total span of activities of basic research through clinical investigation, through community education and professional education that is called for in the law.

The second determinant, of course, was the availability of resources, and within those two constraints we were able to initiate three centers. In our initial competition we received applications from 49, of which the National Advisory Council recommended those three.

Senator KENNEDY. That might serve as an explanation if you had set up 20 out of the 30, but three—3 out of the 30—I do not think that is a terribly satisfactory response.

Dr. COOPER. I am not aware of the exact number, but I think that is correct.

Senator KENNEDY. And the Congress has expanded that to go up to 35, and we have 30 here and only 3 are in place. That is one a year. That is not very good. What are you planning now?

Dr. COOPER. Well, with respect to that, let me point out two different things, Mr. Chairman: That the amount of resources available to the National Cancer Institute for implementing that program was probably of the order of nine to 10 times greater than they called for in the authorizing legislation. The same general specifications, if you will recall, said \$5 million as to the upper limit of operating costs for each center, and within the cancer budget, because of the initial increment that was made available to them at that time, they were able to allocate a much larger amount of dollars.

The second point I would make in that regard is that the actual expansion to that number of centers occurred toward the fourth year of the program after the initial guidelines had been discussed and the initial competition had been made. So that as you entered the third year they were not really that much farther along than at our time, and they actually just designated those that were already centers.

Our ability to move forward on that would depend on the resources available.

Senator KENNEDY. Why don't you tell us about your fourth year? This will be 3 years.

Dr. COOPER. Our fourth year will not allow us much opportunity for expansion because, as you know, the President has asked us to constrain new developments and new starts, and his budget request for 1976

would not provide the resources that would enable us to expand on that program.

Senator KENNEDY. So how many will you build? Will you not build any?

Dr. COOPER. We have no plans for competition for 1976.

Senator KENNEDY. That is belt tightening.

Dr. COOPER. If there are any questions about title I, I would be glad to go on with a reiteration of the details, unless the committee—

Senator KENNEDY. On the whole issue of the prevention and control program, why has that been so slow in getting moving?

Dr. COOPER. We don't think it has been terribly slow in the high blood pressure area. I think when you get down to the dietary question, which is the next major item that was recommended in our arteriosclerosis effort, we come down to the need for actual, more definitive data because of the great economic—potential for economic—impact some of the recommendations would have on many segments of the community. I think to that end the Institute has—and the administration has—endorsed the advancement of the necessary clinical trials for getting that particular information. There are two programs in progress right at the minute which are addressed to that point, one is called the lipid research program and the other is multiple intervention trial. In these particular programs we are trying to get the definitive information which would allow us to make recommendations of diet uniformity to people and determine the importance of the cholesterol and fat features of the diet, as well as the combined risk factors.

I think, as—

Senator KENNEDY. When will we know that?

Dr. COOPER. The actual studies are now recruiting these patients. Because of the nature of the disease, we do not think we see evidence of pro or con about this feature before 1977 and probably 1979. It requires a huge screening of hundreds of thousands of people country-wide to get the actual cohort and to get them to participate over an individual period for each of about 5 years.

Dr. RINGLER. Or even a little later.

Dr. COOPER. 1980, depending on the rate at which we can get the actual cohort completely recruited.

Senator KENNEDY. Can't you make some preliminaries? Is this on diet?

Dr. COOPER. Let me give you a point of reference which will help put this in perspective. Just recently the Institute reported on 55 groups of investigators nationwide who reported in the *Journal of the American Medical Association* the results of what was called the coronary drug project. This was a program that was initiated in the early 1960's in which patients were followed for between 5 and 8 years. It was supported as a line item by the Congress and it addressed the question of whether lowering the blood fat by drugs would prevent coronary artery disease or heart attacks. We found in that study, that we could establish no statistical proof that lowering the lipids by these particular drugs provided protection against subsequent attacks or death by myocardial infarction. That is a simplification of a large amount of data, but is a reflection of what the time required and the resources required for getting this kind of information on a chronic disease.

At the present time we are pleased with the amount of technical data we are getting on patients nationwide with lipid abnormalities, high cholesterol, and that sort of thing.

But I think it would be premature to try to guess what that answer would be. These are situations which affect a different population of patients, and more relevant to the question of primary prevention.

Senator KENNEDY. But are there not just some broad, general inference that people who are overweight, are going to have heart disease a good deal more quickly? Can you not develop a program that is defensible statistically and, you know, take a major bite out of the apple, so to speak, in terms of prevention. Should you not be doing that rather than just waiting to get all the answers with regard to diet, which you say, may take 5 to 7 years or maybe more?

Dr. COOPER. Yes, I think there are some general principles that can be addressed, and this is general weight control. The institute has, with the Department's endorsement, put out this general kind of statement and general kind of recommendation, and this relates to the idea that overweight in itself is not a good thing; a prudent program of activity is a good thing. We have been advocates of the abolition of smoking for some time.

I think what the profession and what the public are looking for however, to buy a general program or just for prudence, is the definitive data. I think what we lack here is a way to be effective in getting ideas across that you should not eat so much and you should not do some of these other things as a style of life. That is a very difficult type of program to implement in a successful way without definitive data, but we should try harder, and we will.

Are there any other questions about title I before I go on to title II?

Senator KENNEDY. What kind of reaction do you have to transferring prevention and control to the Center of Disease Control?

Dr. COOPER. I have a negative reaction to that, Mr. Chairman. I think one of the strengths of the high blood pressure effort that we have made has been its association with the seat of expertise within the program itself. As this committee and the Appropriations Committee have said many times, they would like to find a way to expedite the translation of research information into standards of practice. I think, personally, that the best way to do this is to not exclude the relevant expertise of the Institute and their programs themselves for that purpose. Now, in some instances where it is either so fragmented or it is not addressed in a categorical program to get the work done, then I think there is a basis for the CDC filling the gap and coordinating overall activities. But in this specific area where there is a great deal of expertise, a great deal of respect and appreciation in the scientific and medical community for the opinion of the Institute, it should rest there.

Senator KENNEDY. Senator Stafford.

Senator STAFFORD. Mr. Chairman, thank you.

First I want to say that I am pleased to be a cosponsor of the legislation which we are considering this morning, S. 988, and then, as a comment and not a question, to say that I have two grandsons alive and well today, each of whom was born quite prematurely, and I think the fact that they are alive and well is due to the advances over the

last 15 or 20 years in medical science. Otherwise, neither would have lived.

And, finally, since the Senate committee system runs the way it does, I am the ranking member of another subcommittee that is meeting that I have to attend at 11 o'clock, and I am disappointed that I will not have a chance under these circumstances to welcome Dr. Green.

Is Dr. Green here? He is from Vermont, and I was pleased to hear that the Lung Center is in Vermont.

So may I, Mr. Chairman, commend Dr. Green and his testimony to you and my colleagues on this committee and apologize to him for the fact that another committee will require me to leave in a few minutes.

Senator SCHWEIKER. Mr. Chairman, I want to pursue this question on title I of involving the Center for Disease Control, if I may.

Dr. Cooper, it is true that in the Diabetes Act we did set a new precedent in moving the control program to Atlanta, and I am interested in your reactions to Senator Kennedy's question and also my initial statement.

I just wonder if we are not asking too much of NIH. In other words, by adding to the research program an infield program of prevention and control, is this not a little too much to expect of NIH? Is this one of the reasons why the program of education and prevention is behind schedule and not what it could be?

I am not saying that the Atlanta Center for Disease Control is necessarily where to put it. I think one of the problems that you run into at NIH in administering a program like this is you immediately have some fragmenting between the different Institutes or agencies and divisions, so you immediately have to begin to coordinate. It is particularly true in diabetes. It may not be as true in the heart and lung program.

So I am wondering if institutionally we are not asking too much to expect a prevention and control program to be meaningfully administered out of NIH.

Dr. COOPER. Let me answer that yes and no.

Senator SCHWEIKER. I can see why you are being considered for that slot in the Department. [Laughter.] You are doing very well so far.

Dr. COOPER. I would be extremely reluctant to recommend that the National Institutes for Health have its research resources diluted to the point where the actual implementation of all kinds of control and community activities would be their responsibility both because of a constraint on resources and because the type of personnel that they have traditionally related to in their own specific interests.

The other key statement that you made and I mentioned to Senator Kennedy was that basically if the program is greatly fragmented, and the diabetes program is in seven or so institutes, then in this situation it is appropriate to try to bring together in one focus the type of activity that can be applied to community activity or to so-called control activities.

The third point depends on what you mean by control activities. Now, if you really mean, as is proposed in the Health Services Act, taking the 314(d) funds and assigning part of that to, say, a disease like hypertension or diabetes or something of that order, that kind of activity is not well administered by NIH because it is not the Agency that has the relationship with the State governments. On the other hand, it would be inappropriate to ask CDC to develop a team

of experts to evaluate research to develop the information that needs to be used in that system.

So I think NIH has a role up to that point in making the clinical evaluation of the research data to the point where it is ready for a standard of practice, and then, under guidelines prepared by them, another agency, depending on what you mean by control, can interact with the community network to try to get it done.

So I think, even in the case of the Heart and Lung Institute, where there may be a need depending on what the future of that legislation is, or even in the field of hypertension for a different order of activity that the non-NIH portion of the health agencies need to be involved. I have no difficulty with having a health education program and prevention activity in CDC.

I think the key is the relationship between all the agencies, whether it be ADAMHA or NIH or any of the others, with the particular objective that is spelled out in the law. I think they are both compatible, and the specific responsibilities for each can be delineated.

Senator SCHWEIKER. Maybe, Doctor, we could combine your yes and no answer to start programs of this nature and produce guidelines within NIH and then, after a certain point, turn it over to Atlanta. Maybe we could try something halfway between what we are doing for heart and what we are doing for diabetes. I do not know. Just in view of what you tell me, maybe they both have something to contribute. I am just raising that possibility.

Dr. COOPER. I think, in fact, that that is what the activity should be and, in this particular case, is. I think your concern for diabetes has been a concern of fragmentation, lack of cohesion, which I think will now be addressed. In the RMP legislation the idea was to try to address that question, also. The weakness of trying to build two different loci of expertise for heart disease programs in many different agencies. It did not work out well in that case.

So I think some appreciation of the role of bringing it up to a standard of practice is an appropriate one.

Senator SCHWEIKER. That is all I had on title I.

Senator KENNEDY. Senator Nelson, we just were doing title I, and we could continue with Dr. Cooper unless you have some specific questions.

Senator NELSON. At some stage I want to ask a question about the confidentiality of grant applications. Has that issue been addressed?

Senator KENNEDY. Why not do that at the end?

Dr. COOPER. Why do we not then address ourselves—before we leave title I, Mr. Chairman to a few more technical points. Where we talk about blood diseases, it would help for clarification if we also said “and blood resources,” and if there is need for any specific indication of where that might be, we would be pleased to show you where we would make that recommendation, in sections 104, 105, and 415 and 413.

I would also like to comment on section 109(a)(4), where it specifies that the Advisory Council approve the percentage of the Institute's budget which may be expended for contracts. We think that this provision is undesirable and the Institute should have the flexibility to choose the appropriate funding instrument to get

the research done in the best way. Very often in the practical world this could be done in relationship to the budget cycle, when we actually do have to come back to the Appropriations Committee anyway when significant rebudgeting of resources from these categories would be needed. We would propose that the Advisory Council review here was presented publicly in a previous report on mechanisms of support and that the Council should review the Institute's whole program and comment on the total balance of the program. But specific budgetary lines, particularly in years like this where the funding levels are very difficult, would limit the flexibility to be responsive in the area of getting the best research awards out based on the principle of merit or objective.

Can we go on to title II? In title II we will be submitting, hopefully by the end of the week, our recommendations for extension of the National Research Service awards authorities. We will be recommending 3 years of support. We will recommend, in addition, limiting the awards to postdoctoral fellowships and clarifying language to indicate that the National Academy of Sciences study be advisory to the Secretary.

Those are essentially the three main features of the proposal that we will make. We do recommend extension.

I would additionally point out that the requirement in the act to have the recommendations of the National Academy of Sciences study in by the end of this month and having the information necessary for next year for identifying only those areas for award which are needy or shortage areas will not be met.

Upon passage or enactment, there were discussions with the National Academy of Sciences. They indicated, as I understand it, that there was a need to assess whether in fact it was feasible to respond as the Congress had mandated. This feasibility study has been concluded or completed and, in fact, they have determined that it is possible. It is my understanding that they have now proposed the necessary activity that would be needed to get the information called for. An interim report should be available on the specifics of the detailed information needs in July, around the 1st of July.

We will be pleased to send forward in a short period of time the feasibility study that the Academy completed.

I think I should alert you to the fact that we will not be able to come forward with the design of a research fellowship program that will respond to the mandates of the first year's enactment on the time schedule that was mandated in the law.

[The information referred to and subsequently supplied follows:]

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R E P O R T

of the

COMMITTEE ON A FEASIBILITY STUDY OF NATIONAL NEEDS
FOR BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

* * *

COMMISSION ON HUMAN RESOURCES

NATIONAL RESEARCH COUNCIL

*

February 1, 1975

P R E F A C E

The National Research Service Award Act of 1974 articulates the view of Congress that direct support of training for careers in biomedical and behavioral research is an appropriate and necessary role for the Federal Government. It signals at the same time the importance of careful planning for an era in which the growth of research training programs is likely to be more limited. In this connection, a novel element in the legislation is the stipulation that training awards by the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration are to be restricted, after July 1, 1975, to subject areas for which there is a need for personnel. The vehicle for determining personnel needs is to be a continuing study, the objectives of which are prescribed in the law.

The present report, prepared in response to a request from the Secretary of Health, Education, and Welfare, describes the rationale for the Committee's conclusion that such a study is feasible of accomplishment. In proposing a course of action for consideration by the Governing Board of the National Research Council, the report identifies the initial steps that can be reasonably undertaken within the limitations of the current data base and available methodology. In addition, it outlines an organizational framework and formulates a first-year budget tied to explicit assumptions as to distribution of responsibility between the National Research Council and the two operating agencies.

Although the report highlights a number of questions concerning the difficulty of projecting needs, the Committee acknowledges that some must be left to be discussed by the continuing study. The report, however, expresses the Committee's belief that training programs in the biomedical and behavioral sciences can be usefully guided by such study of future requirements. Consistent with that belief, the Committee recommends an early start toward developing the informational and judgmental basis that must undergird a continuing study.

In carrying out the feasibility study, the Committee received help from many quarters. Members of the eight advisory panels, despite severe time constraints, were able to shed considerable light on problems of methodology and issues unique to the various categories of biomedical and behavioral sciences. Many individuals and professional associations were helpful in making suggestions and in sharing the lessons derived from their own experiences in the performance of manpower studies. The National Institutes of Health provided support for the study, and the assistance of members of the NIH/ADAMHA staffs in providing data is gratefully acknowledged. The Committee's deliberations were greatly enriched through the guidance and advice provided throughout the project by Dr. Robert A. Alberty and Dr. William C. Kelly. Finally, it is a pleasure to acknowledge the contributions of Dr. Samuel Herman, who served as staff director for the project, as well as those of Mr. Robert G. Lindee in his capacity of consultant for the study.

Robert J. Glaser, M.D.

February 1, 1975

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I. INTRODUCTION

This report concerns the feasibility of estimating national needs for research personnel in the biomedical and behavioral sciences. The President on July 12, 1974, signed the National Research Act (P. L. 93-348), Title I of which* amends the Public Health Service Act "to establish a program of National Research Service Awards to assure the continued excellence of biomedical and behavioral research".

The new legislation authorizes awards for predoctoral and postdoctoral research training both to individuals and to non-Federal public or nonprofit institutions (which will select individuals for such awards). Not less than 25 percent of the amount appropriated must be made available directly to individuals. Award recipients must give assurance that they will meet a service requirement---engage in health research or teaching or, alternatively, (1) serve as a member of the National Health Service Corps, (2) serve in his or her specialty in a geographic shortage area in that specialty or in a health maintenance organization which offers care in a medically underserved area, or (3) serve in an approved health-related activity. Guidelines now in preparation will specify the period of time within which repayment may be made; the type of research and teaching which qualify as payback, and other matters relating to service payback. Recipients who fail to comply with the service requirement must repay the amount of their awards plus interest, less proportionate credit for half of the months they actually served.

Effective July 1, 1975, awards under Title I may be made for research training only in those subject areas in which there is need for personnel, as determined by a continuing study which the Secretary of Health, Education, and Welfare is to request the National Academy of Sciences to conduct. As described in the legislation, the continuing study is "to establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel". Also to be derived from the continuing study is an assessment of current training programs, as well as identification of the kinds of research positions available to and held by recipients of National Research Service awards. An annual report of the continuing study is to be submitted by the Secretary to the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare not later than March 31 of each year.

In response to a request from the Secretary, the Governing Board of the National Research Council (NRC) voted on September 16, 1974, to authorize the Commission on Human Resources to explore the feasibility of a continuing study. The feasibility study was initiated shortly thereafter with contract support from the National Institutes of Health (NIH), to which agency lead responsibility had been assigned by the Secretary for developing a plan to implement the provisions of Title I of the Act.

*Title I, cited as the National Research Service Award Act of 1974, repeals existing research training and fellowship authorities of the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Henceforth, research training activities of these agencies will be carried out under a consolidated authority contained in the new law. Title I does not address clinical training, nor does it affect authority available elsewhere in the Public Health Service Act under which the Secretary may enter into contracts with public and private entities and individuals for health services research and health statistics training.

Following discussions with representatives of the Assembly of Behavioral and Social Sciences, the Assembly of Life Sciences, and the Institute of Medicine, a Committee on a Feasibility Study of National Needs for Biomedical and Behavioral Research Personnel (Appendix A) was appointed to supervise conduct of the feasibility study. To advise the Committee, panels were established for the following five disciplinary areas into which were grouped the various fields of research training support by NIH and ADAMHA: Basic Medical Sciences, Basic and Applied Biology, Behavioral Sciences, Clinical Sciences, and Health Services Research and Evaluation (Appendix B). In addition, three panels concerned with methodology were set up under the following titles: Data and Analyses, Supporting Studies, and Impacts of Training (Appendix B). Administrative support for committee and panel functions has been provided by staff of the Commission with the assistance of a consultant who was available on essentially a full-time basis. To prepare the ground for committee operations, discussions were held with staff of the cognizant Congressional Committees, professional and education associations, Sections of the National Academy of Sciences, and NIH/ADAMHA representatives. Liaison officers designated by NIH/ADAMHA provided a substantial body of program data, as well as interpretation of policies and procedures of the two agencies.

Completion of the report was targeted for December 31, 1974. In light of the complexity of the overall task, however, the request for support of the feasibility project anticipated a possible need for extension of time to February 28, 1975, with the feasibility report itself to be completed in early February. Consideration of the report by the Governing Board of the National Research Council would then lead to a decision concerning acceptance of the request to conduct a continuing study.

II. EARLIER EFFORTS TO ESTIMATE NATIONAL NEEDS

Various Federal agencies have attempted to forecast the goodness of fit between supply and demand, to project supply and/or demand, and to estimate the personnel requirements for subject fields in broad and fine detail. The Bureau of Labor Statistics has projected requirements from 1968 to 1980 for doctoral scientists and engineers in private industry, based on a questionnaire study of major employers (1). It also has made projections of long-term trends in industrial and occupational growth based on a seven-step projection model which incorporates factors affecting the whole economy.

The National Science Foundation has completed two studies---and has a third in preparation---on the projected relationship between supply and utilization of science and engineering doctorates, based upon supply trends for six preceding years and explicit assumptions concerning rates of increase in the Gross National Product, funds to be expended on research and development, and employment requirements for academic and nonacademic positions (2).

In terms of direct relevance to the present area of inquiry, several publications of the National Institutes of Health merit special attention. Two reports, issued in 1963 and 1968 respectively, used an "updated" benchmark approach (3,4). A base-year employment benchmark was established separately for government, industry, and non-profit institutions, classified by level of training. Annual projections of undergraduate and graduate enrollment and of M.D. candidate enrollment were used to extend the benchmark figures, with stated assumptions as to degree completion rates, educational progression rates, and age-cohort survival rates.

In January, 1970, the National Institutes of Health published projections for the period 1972-1980 to show trainee populations required to sustain several assumed alternate growth rates of research funding, with provision for deaths, retirements, and shifts to other activities (5). The essential contribution of this model was its use of separate estimates for research, teaching, service, administration, and other functions. A more sophisticated version of this model, including estimates of prospective demand for biomedical scientists through FY 1983, was released in 1972 (6).

Numerous studies in the private sector have also been addressed to these problems. Cartter has made the most detailed analysis of expected faculty needs for holders of the Ph.D. He has projected, by five-year intervals, the number of doctor's degrees to be awarded, the number of new faculty members who should hold that degree to match the increasing enrollment and to maintain the current percentage of doctorate holders in the Nation's faculty, and the percentage of new doctorates of each five-year period who would be required for such faculty appointments (7). Freeman has made projections for various fields with a market model that takes into account the behavioral characteristics of performers in the labor market (8). The status of such labor market forecasts for doctorates is discussed in a report of the National Board on Graduate Education (9). In addition, Freeman and Breneman have examined current forecasting techniques against a background of past forecasting failures, and have described a methodology for making "response adjusted" projections, based on student career decisions, experienced personnel supply behavior, employer decisions, and salary determinations (10). The National Planning Association has undertaken a pilot study to assess the potential for anticipating the scientific manpower requirements likely to be generated by expenditures in pursuit of national goals in the private economy in the next five-ten years. A special NPA case study concerns requirements in the 1980's for scientists and engineers for the abatement of air, water, and solid waste pollution (11). Also of interest in this connection is a demand survey for industry which was sponsored in 1972 by the Industrial Research Institute (12).

A careful review of these diverse efforts leads to several observations and conclusions:

1. Projections must be distinguished from predictions. Derived from models based on trends and awareness of current developments, projections offer a range of possible future events based on explicit assumptions and no significant break in trends. It is important that no false sense of precision be attributed to projected numbers in view of the limitation of the data and methodologies, the complexity of manpower utilization, and the unpredictability of future events.
2. Projections of forecasts of supply and demand for highly trained manpower have focused on numbers and given relatively little attention to quality ---quality of instruction, research, or of the Ph.D.'s themselves. Assaying quality is a difficult problem. There are at present only rough methods for taking this attribute into account, such as assuming that the quality of institutions or departments can be measured, and that on the whole institutional quality is related to the quality of those who are awarded degrees.

3. The results of attempts to produce supply and demand forecasts by field and discipline have been spotty. Sizable differences between projected estimates and actuality are not uncommon. Although relatively sophisticated analyses have been made by some professional associations---in physics, in surgery, and in pharmacology and experimental therapeutics, for example---many lack the resources to undertake these activities. Further studies of forecasting for specific fields are clearly needed to throw light on the conceptual, methodological, and practical problems of forecasting by discipline.
4. One of the central problems of projections is the difficulty of formulating generally acceptable concepts of underemployment. Specifically, there is a need to determine the criteria by which underemployment is to be defined, and to attach quantities to the criteria to permit enumeration of the underemployed. A number of criteria could be used, such as differential income and extent of utilization of maximum skills.
5. In addition to methodologic complexity and data shortcomings that plague the projector, there is the well-known fact that published projections are viewed as predictions by the public and the market moves to defeat the predictions. Employers and prospective employees note where "shortages" or "overages" are forecast and shape their strategies accordingly.
6. A significant development in projecting the supply of, and demand for, high-level manpower has been the increasing attention paid to market forces and the behavior of individuals and institutions in the market. Extension of this work has a high potential for the improvement and refinement of projections.

III. PRINCIPLES

A number of general principles have emerged from the Committee's discussions and have been found helpful in guiding its recommendations.

A. Numbers

Assessment of the Nation's needs for biomedical and behavioral research personnel is a necessary task in view of the large national interest in this area and the need to use national resources wisely. It is also a difficult task that must be approached with a clear recognition of the difficulties. The Committee and its panels believe, however, that the present methodology and data base are adequate for developing a strategy and for making a start toward forecasting aggregate manpower requirements for biomedical/behavioral research. Even though use of particular assumptions may introduce an appreciable margin of error at the outset, available methodology and the data base are adequate to indicate the direction of change.

In contrast to the problem of forecasting aggregate manpower in large fields, estimating needs by fine fields is exceedingly difficult. Boundaries between disciplines have become less distinct with the increase in emphasis

on study of biological phenomena at the molecular level. Titles of narrow disciplinary fields have therefore lost some meaning for the purposes of forecasting. The problem is compounded by the difficulty of predicting major scientific developments and their impact on manpower requirements. Moreover, many aspects of the dynamics of the manpower pool are not clearly understood, and hence any supply/demand/model that can be developed will have limitations for determining the need for disciplinary specialists. These limitations, the Committee believes, are offset largely by the breadth of training and the adaptability of biomedical/behavioral scientists and their capacity for mobility within and across fields. This is especially true for transfers from more fundamental to applied fields. Further, postdoctoral training often makes possible a transfer to a related field where shortages may exist. As noted in The Life Sciences, a report published by the National Academy of Sciences, a large percentage of those pursuing postdoctoral training seek this experience in a discipline other than that in which they received their graduate education (13). Moreover, most do so in laboratories other than those of their original research mentors, engaging in fields of research distinctly different from those in which they had been trained in the first instance. These facts underscore the importance of postdoctoral study as a mechanism for responding to new opportunities.

B. High Quality and Stability

In addition to a concern with adequate numbers of personnel, NIH/ADAMHA has a pivotal role in helping to maintain high-quality training programs. This dual role, the importance of which is underscored in the declaration of purpose for Title I of the law, requires continuity of support for its proper fulfillment. Since it takes many years to complete the training of an individual--- five or more years of post-baccalaureate training for Ph.D.'s working in the basic biomedical and behavioral sciences---the process cannot be turned on and off abruptly without damage to quality and training capability. Persistence of the stop/start pattern of support that has occurred in recent years could lead to erosion in the quality of the training structure. In this regard, the Committee believes the continuing study should include an historical survey of factors that have contributed to instability and should document the effects of instability on faculty and the scientific environment, physical facilities, and the recruitment and retention of promising trainees. It may be possible, independent of the level of support, to design experimental situations to test the effectiveness of alternative funding arrangements in promoting stability.

C. Flexibility

It will continue to be important to foster flexibility in the organization of training activities to ensure responsiveness to the changing character of the research scene. Change must not only be permitted but encouraged to allow appropriate response to the dynamic character of biomedical/behavioral research and its changing manpower requirements. Within funding levels tied to specific fields and numbers, how are resources to be mobilized to allow ready responsiveness to emerging opportunities? This is a key question requiring the development of a sensitive monitoring system, as well as the introduction of modifications and the design of experimental training programs. Study approaches could include a comparison of disciplinary versus interdisciplinary programs as a means of responding to changing manpower needs.

Flexibility in this context has implications which the Committee believes will merit consideration in a continuing study. A key issue relates to the capability of institutions to adjust their resources---faculty, students, and facilities---to a changing manpower outlook, as in the case of fields approaching a point of saturation.

D. Concern for Excellence

The new law assigns to the continuing study the task of assessing NIH/ADAMHA training programs---a further indication of the concern for excellence. The study will be expected to evaluate the impact of training programs on the total scientific environment of institutions. Basic approaches to implementing this responsibility will be to identify areas of program success for retrospective examination of effects, such as encouragement of programs that cut across traditional departmental lines; stimulation of interaction of faculty, trainees, and persons from other departments and institutions; and increase in the quality of advanced courses. Other questions warrant investigation. Is quality more effectively fostered by concentration on a limited number of programs than by providing broad support for training? Is it possible without NIH/ADAMHA support to build the types of curricula that permit quality training in special fields? How effective have these programs been in attracting superior personnel into areas lacking a tradition of research?

E. Shared Responsibility

Though it should be a truism, the point merits repetition that NIH/ADAMHA are not---and should not be---responsible for the support of all biomedical and behavioral research training. That responsibility is shared with other elements of American society---the states, industry, the foundations, private donors, and the universities themselves---which will continue to rule their individual contributions. NIH/ADAMHA are indeed responsible, as affirmed by the new law, for providing sufficient support to ensure that the overall training effort will produce the numbers and quality of research scientists which forecasts suggest will be required in the future. This presupposes that NIH/ADAMHA will continue to bear a substantial share of the costs of graduate education in the biomedical/behavioral sciences with provision for adjustment in the face of evidence of excessive or insufficient training effort.

IV. A CONCEPTUAL FRAMEWORK

The Committee focused its attention on an eclectic, pluralistic approach designed to bring together information and seasoned judgment from a number of different sources to permit testing of tentative findings of national need and eventual formulation of recommendations. Although there are promising developments in forecasting personnel needs, particularly in the use of models that take market forces and individual and institutional behavior into account, the Committee is not convinced that the outputs of such comprehensive models are as yet sufficiently reliable to fulfill requirements of the law.

To illustrate the Committee's approach, the relationships among a number of possible sources of information and types of analyses are shown in a block diagram (Figure 1). Although the arrows suggest a cybernetic approach, the diagram is in reality less precise than this since many of the units have multiple connections that are not depicted and since the units themselves are quite complex. The types of activity represented by the individual blocks may be outlined as follows: . . .

● Background Studies

- Demographic analysis of trends in university and professional school enrollment rates and on anticipated sizes of groups from which enrollment will be drawn---to establish the need for new faculty.
- Identification of new and emerging research areas with potential impact on manpower requirements---e.g., research on biological effects of environmental chemicals as a basis for establishing criteria and standards.
- Examination of manpower utilization patterns in research.
- Examination of trends in expenditures for research and development---the single most important determinant of demand for research personnel.
- Cost/benefit analyses to try to determine the returns on investment in graduate education.

● Projections

- Consideration of "fixed coefficient" models of the education/manpower system.
- Development and testing of "market" models that take into account student choices of fields of study and initial job decisions; decisions of persons already in the work force; employer hiring, firing, promotion and retirement policies; salary data; and governmental initiatives and responses.

● Pipeline Studies

- Flow of personnel through graduate and postdoctoral education into employment, including analyses of enrollment data, degree attainment, attrition, field switching, and turnover and aging of the research work force.

● Labor-Market Studies

- Monitoring of various job placement services.
- Demand surveys of industry and other employment sectors.

*Labels correspond to those in Figure 1.

- Monitoring of fluctuations in the Engineer/Scientist Demand Index (ESDI) reflecting the volume of recruitment advertising in technical journals and newspapers.
- Assimilation of the results of employment studies such as the National Research Council's Survey of Doctoral Scientists and Engineers and the surveys made by professional societies.

• Impact Studies

- Studies of the impacts of these and other support programs on the market undertaken in collaboration with education and professional associations and other agencies. Also, studies directed toward identifying the effects of NIH/ADAMHA training programs on faculty, curriculum, physical facilities, development of interdisciplinary programs, baccalaureate-to-doctorate time lapse, Ph.D. attainment rate, and post-training career outcomes.

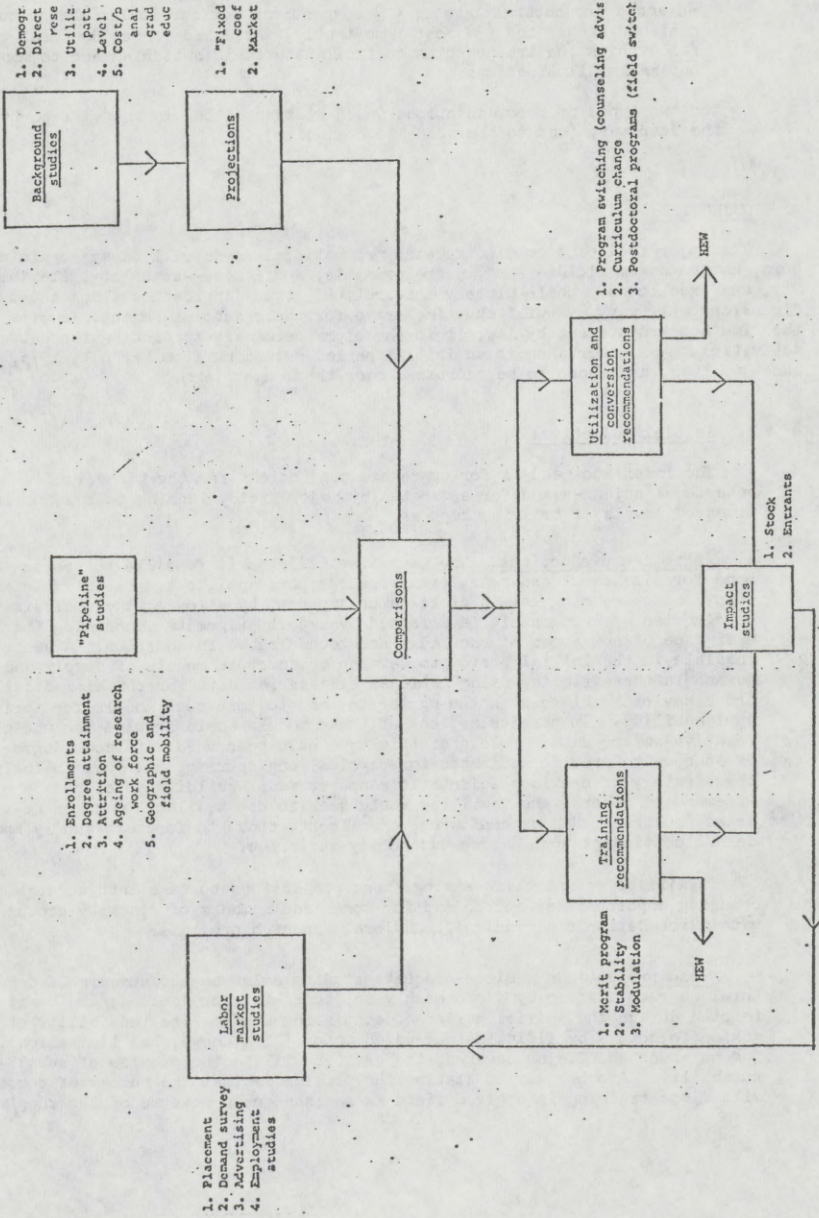
• Comparisons

- This block encompasses the principal function to be performed by the committee for the continuing study and the committee's panels. Within the framework shown, the Committee would be expected to draft annually a "State of National Need" document which would be based on the results of the study outlined above. The end product would take the form of a description of field requirements that had been subjected to as many realistic tests as possible and that represented the best effort of the Committee in estimating needs for at least the near-term future.

• Recommendations

The comparison process would generate recommendations of two kinds:

- Training Recommendations would have to do with predoctoral and postdoctoral traineeships and fellowships to be awarded by the Federal government. Three principles might well be observed: (1) recognition of unusual merit or promise of individuals through a small, highly selective, nationally competitive fellowship program; (2) stability of support through an appreciably larger training grant program in which institutional needs would be recognized and field support changed relatively slowly; and (3) modulation of field support levels---e.g., fluctuations of an appropriate percentage consistent with the committee's perceptions as to where shortages or overages of personnel were occurring or likely to occur.
- Since the time needed for effecting change in output through the predoctoral support mechanism is approximately five years, a need exists for a mechanism that can respond to national needs more quickly---in one or two years. Utilization and Conversion Recommendations might therefore be made through the medium of (1) program advisories to encourage field switching at the postdoctoral and, to the extent possible, at the



advanced predoctoral levels; (2) suggestions for curriculum change to meet new needs; and (3) most importantly, the award of postdoctoral fellowships and traineeships to facilitate field switching and to smooth out market fluctuations.

The two types of recommendations would be transmitted in annual reports to the Secretary (and to the academic community).

V. OBJECTIVES

The major foci of a continuing study of national needs will be aggregate numbers, estimates by fields---and, where possible, subfields---stability, flexibility, and excellence. While closely interrelated, study approaches along these dimensions will vary, as will the time frame for their accomplishment. In view of the time constraints set by law, it is therefore necessary to distinguish between activities to be undertaken in an initial period extending from March 1, 1975, to June 30, 1975, and those to be addressed over the longer term.

A. Initial Objectives

The immediate need is for aggregate projections for the biomedical/behavioral sciences and for estimates by major field, leading to recommendations of levels of training support.

Aggregate projections. The Committee believes it feasible to project demand for biomedical and behavioral research personnel, based on suitable assumptions concerning levels of research support, by allowing the analysis to be directed by demographic factors and by expert judgments concerning the emergence of new areas of knowledge and technology. In addition, it seems feasible in the initial period to develop econometric models of supply and demand in these fields, using national time-series data for the biomedical and behavioral sciences in the aggregate, and to test such models for their applicability. In particular, one of these models would involve the use of relative-salary data. Models of this type have been used with some degree of success to provide estimates for physics, engineering, and law. Following the strategy of previous scientific manpower model-building developed by Freeman and others, the Committee would seek to use available data on degrees, salaries, R&D expenditures, enrollment, etc., to forecast supply and demand contingent upon exogeneous policy variables.

It will be essential in making these projections to take into account changing opportunities and demand for women and members of minority groups within the Nation's biomedical/behavioral research programs.

Field projections. Since adequate studies exist on the numbers of doctoral degrees awarded by field each year, short-term projections can be attempted during the initial period of continuing study. The feasibility of making forecasts by field, as suggested under III-A above, has limitations. The narrower the fields covered, the greater will be the problem of substitutability. Another way of stating the problem is that the number of those with first training in a given field is an inadequate measure of the supply

of persons capable of working in that field. Moreover, the further into the future that forecasts are made, the greater the barriers to measuring supply in narrowly defined fields.

The margin of error may be minimized through projecting by broad fields in contrast to aggregating subfields. Broad-field projections can be supplemented by judgments of expert panels to delineate rapidly growing fields and those showing a more modest or relatively slow growth or decline. Although not currently available, models analogous to those referred to above can be developed relatively early for selected fields and subfields and to a limited degree could be made to reflect the extent to which workers could shift among fields. This analysis would make use of field-switching data developed by the National Research Council and other organizations.

Levels of training support. Based on the foregoing projections and examination of current trends in supply---including the output of other training efforts---recommendations would be made for the levels of NIH/ADAMHA training programs in FY 1976. As in the case of the projections of demand, these would be made by broad field.

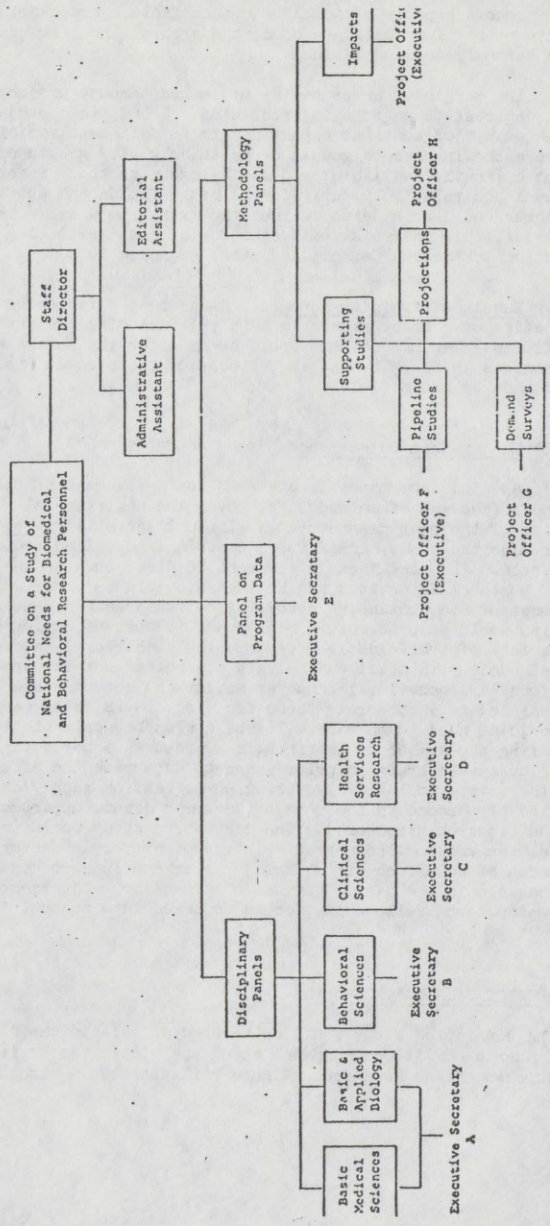
B. Longer-term Objectives

Special importance is attached to improvement of the data base and continued refinement of methodology. Over the next several years, the full potential of the plan diagrammed in Figure 1 seems likely to be realized and should provide the basis needed for increasingly detailed recommendations by the Committee. The usefulness of current studies, such as the NRC-maintained Roster of Doctoral Scientists and Engineers, could be significantly enhanced for purposes of the continuing study. A suitable enlargement of the survey sample size would help to ensure representativeness of employment data for a greater variety of subfields in the biomedical/behavioral sciences. With respect to methodology, a detailed analysis can be made of the specific features of the biomedical/behavioral manpower market and second-round model-building can be designed to incorporate these features. Studies of manpower flow in academic medicine need to be made. It would also be desirable to conduct a study comparing the number of the Ph.D.'s awarded as a percentage of the number of baccalaureate degrees in prior years to determine the effect of support programs. Other steps would involve bringing to bear on supply/demand problems the expertise of persons in the market (academic deans, department chairmen, students, and research directors). The continuing study would involve also a more careful analysis of the characteristics of different sectors of the market and modes of adjustment to changing market and support conditions than has been possible in the past. The use of non-salary adjustment mechanisms, such as postdoctoral fellowships, could be taken into account in the economic modeling.

VI. PROJECT ORGANIZATION

The continuing study would be carried out within the framework outlined in Figure 1 under a committee and panel structure within the National Research Council's Commission on Human Resources. Figure 2 illustrates a possible organizational plan.

FIGURE 2. AN ORGANIZATIONAL STRUCTURE.



The NRC would carry the sole responsibility for analysis of program data, supporting studies of several kinds, impact studies, "needs statements", comparisons with variety of test data, and recommendations. Under certain circumstances outside organizations may be engaged to perform selected tasks. The results would be communicated to the Secretary in a series of annual reports, to be transmitted to the Congress.

The Committee believes that the activities for which NRC has sole and shared responsibility could be carried out with an annual budget initially of about \$1 million (Table 1). The anticipated number of professional staff members required would be 12, and a supporting staff of 15 members would also be needed. The Committee would meet monthly at the start, and the panels at quarterly intervals.

TABLE 1. Estimate of Initial Annual Costs

Personal Services	\$435,000
Fringe Benefits	56,600
Consultants	12,500
Committee & Panel Travel	66,000
Consultant Travel	4,000
Staff Travel	10,000
Communications & Shipping	7,200
Materials & Services	7,200
Commissioned Studies	100,000
Data Processing	36,000
Indirect Costs	264,400
Total	\$998,900

Maintenance of administrative records of training awards would be the responsibility of NIH/ADAMHA. Extramural performers operating under NIH/ADAMHA or organizations conducting commissioned studies for the NRC would address other needs for data and analysis.

VII. RECOMMENDATIONS

- A. The Committee recommends that the National Academy of Sciences accept the invitation of the Secretary to conduct the continuing study mandated by Title I of the National Research Act. The recommendation is based on the belief: (1) that within the methodologic limitations outlined in this report a productive start can be made during the current fiscal year toward meeting the requirements specified in the law; (2) that improvements can be expected in ability to gather and utilize needed information as experience is gained over the next several years; and (3) that the National Research Council through the experience of its Commission on Human Resources and its ability to call upon the skills of the scientific community is the most appropriate agency to conduct the continuing study. The recommendation further assumes that sufficient agreement can be reached on the conditions for the study as outlined below.

- B. The continuing study is viewed as a long-term undertaking with major costs that may involve at least three-year obligations. It is the Committee's view, particularly in light of the single-year authorization contained in the Act, that discussions be conducted with Congressional and Departmental staff regarding a three-year commitment for continued support of the study.
- C. An appropriate level of effort for an undertaking of the magnitude envisioned in this report calls not only for the continuing study by the National Research Council but also for data collection by NIH/ADAMHA and extramural research by other organizations. The Committee believes that an amount up to one percent of the ceiling authorized by law can be justified to support such a level of effort, including a need in the initial year for approximately \$1 million to underwrite the National Research Council's continuing study.
- D. The current legislation contains several provisions with which NIH/ADAMHA has had little or no experience in the administration of training programs. The Committee recommends that the effect of these provisions on the program, notably the need for annual renewal of authorization, payback requirements, and the specification of 25 percent of the appropriation for direct award to individuals, be examined carefully by the committee for the continuing study. An additional point that will merit scrutiny is the 3-year limitation on support of any individual, particularly its impact on activities such as the Medical Scientist Training Program and most predoctoral graduate study programs.
- E. The present report calls attention to limitations in the adequacy of methods for projection of need for biomedical and behavioral research personnel and for determination of suitable levels of training support. The Committee believes that some of these limitations can be significantly remedied through further studies and that others can be offset by appropriate administrative measures affecting training programs, measures that are responsive to market forces and conditions.
- F. Since future requirements for personnel cannot always be predicted, the Committee recommends experimentation with programs at both the predoctoral and postdoctoral levels that can encourage the post-training movement of biomedical/behavioral scientists into specific research areas as opportunities arise, with due regard for individual desires and aspirations.
- G. The Committee has noted the National Research Council's current studies of the Nation's population of biomedical and behavioral research personnel and its studies of the number and type of graduate students planning careers as biomedical and behavioral scientists. It suggests the additional need to observe trends at the earlier stages of education as a means of detecting significant fluctuations in the supply of scientific manpower early enough to determine the reasons and permit appropriate policy decisions.

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Senator KENNEDY. We will look forward to getting your legislation up here. It is an area in which we are most interested and we want to move along. The earlier you can get it up here, the more chance we will have to evaluate it.

Senator SCHWEIKER. Are your recommendations in this report, then, based solely on budgetary constraints as opposed to what the definition of need might be in lieu of not having this study?

Dr. COOPER. Two points here, Senator Schweiker. The President has asked us to contain our programs, hopefully to current levels or less, and that is a consideration in the recommendations that will be coming forth. But, in addition, in the spirit of the intent of the act itself, we would like to see what the recommendations on areas of need are, what types of programs are needed as specified in the National Research Act, and we would also like to see what the President's Biomedical Research Panel is going to recommend along these lines, also.

As you are well aware, we are already trying to manage the phase in and phaseout of three different programs at one time, the present time, and this is a formidable challenge and responsibility. We would feel badly to have to add another variation with another short-time frame.

Now, it is not our inconvenience that is important here. It is the instability which this induces in the institutions which we serve, and I think that is an important consideration. We would like to stabilize this situation as much as we can in order that the institutions where this actual training has to be done—and we agree it has to be done—need to take place. I think to induce several changes over a short period of time is not an objective which we would support.

Senator KENNEDY. We will yield to Senator Nelson. This is a matter of great interest. We expect to hear from the AAMC as well. Both the Health Committee, and the Administrative Practice Subcommittee have run into this particular problem. We have been looking into the whole question of consent in areas of research. We are aware of court decisions that have been taken, and the filing of the AAMC amicus curiae brief in support of the administration's withholding information on experimentation.

So I would like to yield to Senator Nelson and I will get back to you a little bit later myself.

Senator NELSON. Well, Mr. Chairman, I have been assuming that this issue would be raised, and I just wanted to be sure it was. It involves the question of the confidentiality of protocols for research grants and contracts under the Freedom of Information Act. As everyone is well aware, the circuit court of appeals ruled that 11 of such funded NIMH projects were not specifically exempt under the Freedom of Information Act and, therefore, those protocols were a matter of public information.

I understand that many, at least in the scientific community, feel that there should be some time limitation in disclosure of these protocols that are funded unless the applicant wishes to disclose the protocols forthwith.

The court did not address itself, because the issue was not before it, to the question of protocols for nonfunded projects, which, I assume, at some stage will also become an issue.

The question I would like to pose for any of the witnesses appearing this morning who wish to address themselves to it is: What is your view as to whether or not there is some necessity for a time limitation on the disclosure of the protocols of these applications for grants or contracts, and why, if you so believe, should there be some period of time protecting the disclosure? Why you believe that is necessary?

Dr. COOPER. Dr. Lamont-Havers.

Dr. LAMONT-HAVERS. Senator Nelson, in conformance with the court decision and the Freedom of Information Act, we indeed are now making available award research grant applications on request. This also will apply not only to the awarded grants, but any submitted supplements or competing continuations which are for another period of time.

We do feel—I think certainly within NIH—that it would be within the best interest of science if there was a time constraint on the time when we make this information available. The projects which are submitted to the Federal Government are submitted with the idea at least by the investigator, that they will be held in confidence; they will be held confidential because these are his ideas, the ideas of the investigator, upon which his future reputation depends and his career and, therefore, it has always been a problem, the fact that these ideas of individuals may become available to others before he, in turn, really has the opportunity to develop them.

We also recognize, however, that any project which is supported by public funds should be made available to the public. We do feel, however, that in this respect a period of 6 months to a year elapsing from the time the award was made to the time that the information was made available would not in any way inhibit the public's right to know, but would indeed give protection to the investigator's concepts and ideas which are his own.

I would point out, however, also that the final project reports on all awards which are submitted are made public at the end of the project period itself.

Senator NELSON. I did not understand that. At what point are they all made public?

Dr. LAMONT-HAVERS. At the end of the project, whether it is 3 years or whatever, the final project report is made public.

Senator NELSON. But under the law—the ruling of the court—what is your current status?

Dr. LAMONT-HAVERS. Under the ruling of the court, the concepts of projects are made public even before it is begun, practically. As soon as the award is made, then the details of that project can be made available to anybody.

Senator NELSON. Now, an application is made to the study section and the study section then evaluates the application and then sends its evaluations to the advisory council of each institute—is that the way it goes?

Dr. LAMONT-HAVERS. That is right.

Senator NELSON. Did the court require any disclosure of anything that the study sections themselves did?

Dr. LAMONT-HAVERS. The court gave a specific judgment that the fact that the internal documents which reflect those opinions are not public.

Senator NELSON. That is, the opinions of the members of the study section respecting the quality or merits of the application, those opinions are not required to be made public?

Dr. LAMONT-HAVERS. That is right, sir.

Senator NELSON. Then the recommendations of the study section on some rated scale go to the advisory council, right?

Dr. LAMONT-HAVERS. That is right. They give a priority judgment.

Senator NELSON. Then the advisory council, based upon the recommendations and evaluations of the study section, makes a decision as to which of these applicants for grants or contracts, which protocols, shall be approved, right?

Dr. LAMONT-HAVERS. They make a recommendation of approval for funding, just a recommendation for approval.

Senator NELSON. And that final decision is—

Dr. LAMONT-HAVERS. The final decision as to which applicants are to be funded is the responsibility of the institute director.

Senator NELSON. And once the institute director has made a decision as to which of these grant and contract applications shall be funded, it is at that precise stage that the court said the applications shall be made public?

Dr. LAMONT-HAVERS. No. It is at the time that the applicant receives an award statement or a statement from the Government that indeed money is going to be given to that institution to pay for this project.

Senator NELSON. So it is not at the stage at which the director approves some or all of the advisory council's recommendations, but it is at the stage that the applicant is notified that his protocol for a certain project has been approved for funding?

Dr. LAMONT-HAVERS. And will be funded.

Senator NELSON. And will be funded.

Then, forthwith, under the Freedom of Information Act, the application is public information. Is that what the court said?

Dr. LAMONT-HAVERS. At that point, upon request, we will release that information.

Senator NELSON. Now, there has been no ruling on the question of grant and contract applications which are not approved by the advisory council; is that correct?

Dr. LAMONT-HAVERS. Except, sir, in the case of supplemental applications to a project which already has been funded or if the investigator comes in at the end of 3 or 4 years with a request for continuation of that project. In that case the court has ruled that those applications upon receipt, in effect, are open to the Freedom of Information Act.

Senator NELSON. But you do not know, do you—this is an inquiry. I do not know the breadth of the court's decision. They only ruled, of course, on the precise question which was before them, which covered grants that had already been approved. We do not know whether the court, if the issue is raised, will at some stage say that grant applications that were turned down by the study section, not recommended by the study section, or, if recommended, not approved by the advisory council, or if approved by them, not funded by the institute director at NIH, are subject to public disclosure. In any

event, the court did not address in any way the question of whether a protocol, if turned down, is exempt from the Freedom of Information Act, did they—or did they?

Dr. LAMONT-HAVERS. That is true for those applications which are submitted for the first time. In other words, that come in new.

However, if the investigator has a funded project from NIH for 3 years and he then wishes to come in with another application to extend that project for another 3 years, that application, whether it is reviewed or not or whether it is approved or not, regardless of anything else, comes under the Freedom of Information Act. But the application which comes in for the first time is not.

Senator NELSON. And they did rule on that precise question?

Dr. LAMONT-HAVERS. They ruled—

Senator NELSON. On the new application?

Dr. LAMONT-HAVERS. No, they did not rule on the new application. They ruled, rather, on the—

Senator NELSON. That is still an open question?

Dr. LAMONT-HAVERS. That is still an open question.

Senator NELSON. Now, given the whole concept that scientific investigation, scientific knowledge is world knowledge—and I am not talking about patents and that sort of thing, but scientific research is generally by scientists considered to be information that should be turned over to the world, all people, all scientists, all countries, through literature—you are now saying there ought to be some time limitation under which this disclosure should occur.

Now, you are not talking about findings; you are talking about a protocol or a concept that has been designed by some scientist.

Dr. LAMONT-HAVERS. That is true, not findings.

Senator NELSON. Now, what is the public interest involved here? That is to say, you have this kind of a question about a scientist deeply involved in an aspect of biomedical science affecting human health. I am trying to find out, is this a relatively typical kind of a case? A scientist or a group of scientists who have been working for many, many years on some specific problem in the field of biomedical science, after several years of work have designed a protocol for an investigation for which they want funding; they make their application to the Federal Government; and at the time they are funded, the protocols are disclosed to the public. Are scientists concerned that all kinds of other scientists with the same kind of expertise can forthwith begin investigations based upon this protocol? Is that the kind of problem you are worried about?

Dr. LAMONT-HAVERS. Yes; partially, sir. I think one has to recognize the rights of individuals and their aspirations and why they do things and, obviously, an individual in a scientific endeavor, the thought process is his life's work and it is that upon which his future depends. And, therefore, when he comes up with a concept developed from his own work, he wishes to be assured of the fact that at least he will have the opportunity to develop it if it is considered meritorious.

On the other hand, I think that our whole system, the whole system upon which we administer the public funds to get the best scientists, is based on the fact that the concepts which are developed within the applications are indeed capable of review.

Now, if the scientists ever think that they really are not going to give us their best ideas in order that we can judge them to find out whether we should fund them because somebody else might get in there first, then I think we might have a problem trying to judge indeed what is good science for us to fund, and I think that the period which we would consider, either 6 months to a year, gives that individual an opportunity to begin and get his concepts underway.

Senator NELSON. Is it your belief—you say 6 months to a year?

Dr. LAMONT-HAVERS. Six months to a year.

Senator NELSON. Would you vary it depending upon the project or are you just suggesting some arbitrary period?

Dr. LAMONT-HAVERS. Some arbitrary period. Not less than 6 months, and it would not need to be more than a year.

Dr. COOPER. Senator Nelson, the cases you mentioned, they were supported by ADAMHA. Perhaps Mr. Isbister would have some comments.

Mr. ISBISTER. I have nothing really to add to what Dr. Lamont-Havers has said, except to indicate that one of the problems faced by the court was that the Freedom of Information Act did not deal in its exemptions under the act, specifically with the kinds of cases that we are talking about. The reasoning process to protect the confidentiality of research grant applications is argued by extension from an exemption in the act which really has to do with trade secrets.

The other operative exemption under the act is the one which you referred to, Senator Nelson, which is designed to protect the confidentiality and, therefore, the candor of internal governmental deliberative processes. In that case the court accepted that the exemption applied, and it was on that basis that the opinions expressed by the initial review groups were determined to be exempt from disclosure under the Freedom of Information Act.

Senator NELSON. Now, there is no question in the court decision, is there, that if there were an assertion or a valid claim that some of the information sought were proprietary information or patentable, that it is exempt under the Freedom of Information Act? There was no question about that; that would be protected, right? Is that correct?

Dr. LAMONT-HAVERS. That is not clear. I think that we are—our own patent attorneys are going on the assumption that indeed if there is a patentable concept within the funded project, then that should not be disclosed without the consent of the individual.

Senator NELSON. Are you saying the court decision is not clear as to whether or not scientific protocols that may be considered patentable are protected?

Dr. LAMONT-HAVERS. I do not think it is clear.

Senator NELSON. What you are arguing here is that—I assume this is what you are arguing—that a scientific concept is entitled to some kind of protection similar to patentable information and trade secrets, and that the public interest is served by giving some kind of protection to such protocols for the same period of time? Is that the argument?

Dr. LAMONT-HAVERS. That is right, sir.

Senator NELSON. That is all I wanted to ask.

I will not be able to stay for the whole hearing, but I trust that some of the others will comment on this question. I have an amend-

ment designed to deal with this question, but I want to be sure that we can demonstrate that it is in the interest of the public and in the interest of scientific research and that it is right and proper that even though public moneys are involved, that some time period of protection be granted to the concept that is developed and designed over a period of time by some scientific applicant.

Senator KENNEDY. Is there any reason why either public interest groups should be denied this information?

I believe that that, at least in terms of the court cases, has been one of the prime interests of the various public interest groups.

Dr. LAMONT-HAVERS. No, we think that the public interest groups have every right to question anybody who is dealing with subjects with regard to consent procedures or anything else they have. It should be recognized, by the way, that there is a short synopsis of all funded applications available for the public through the Smithsonian Scientific Information Exchange.

Senator KENNEDY. Was that prior to the court decision?

Dr. LAMONT-HAVERS. This has been there for many years.

Senator KENNEDY. From that they can tell who is going to be experimented on?

Dr. LAMONT-HAVERS. They can detect from them the general outline of the study and the purposes of it. It is unlikely that that would go into great detail with regard to the protocol or the details with regard to the populations which are being studied. It would give these in a general way.

Dr. COOPER. I would say there, Senator, that if it is a clinical study that is involved with human subjects, there are other safeguards required besides the Freedom of Information Act as to the protection of the subject.

Senator KENNEDY. You certainly were not publishing in the Smithsonian, a report on the syphilis study and you were not publishing the sterilization study on work that was done in the poverty programs in Alabama. If there is scientific research that is in the public interest that is being funded by public funds, it has to be protected in terms of research. It cannot be used as an umbrella to prevent various concerned groups from finding out who those individuals are that are being involved in such an experiment. We must also insure that, besides the various consent procedures which have been initiated within the NIH—and they have been improved—that we permit other interested groups access to information on who these various individuals are and what procedures are being taken in terms of consent and notification.

As I understand, you are not suggesting any amendments at the present time on this particular issue?

Dr. LAMONT-HAVERS. No.

Senator KENNEDY. Finally, do you have any information as to the projects for which people have requested grant applications from HEW in the past 2 years?

Dr. LAMONT-HAVERS. At the present time for this year, during the present fiscal year, we have received approximately 2,800 applications for fellowships and about 1,000 applications for training through the institution-type award.

Dr. COOPER. Do you mean the freedom of information requests?

Dr. LAMONT-HAVERS. I am sorry.

Mr. ISBISTER. We have received a handful, I would say five or six in our Agency.

Senator KENNEDY. Who were those who have been doing it? Are those researchers or public interest groups?

Mr. ISBISTER. They have been public interest groups, including the public interest group that brought this particular suit. There have been in the last couple of weeks a couple of requests from individuals.

Dr. LAMONT-HAVERS. This is true for NIH, also, Senator. We have had a relatively small number of requests, and the total number of applications which have been requested in one lot was around 70 and in another, around 30.

Senator KENNEDY. How much of a problem is this, scientists stealing other scientists' work?

Dr. LAMONT-HAVERS. Whether it is a real problem or not, nobody really knows, but it certainly bothers some scientists. You know, it is one of those things that would be very difficult to prove if somebody actually had done it, but certainly a number of investigators get quite concerned about the availability or the wide dissemination of their concepts and thought processes.

Dr. COOPER. During the 6 years when I was Institute director, I think there were about three instances where individual scientists had contacted me as the Institute director, claiming that in the regular review process in which there is obviously exposure of the protocol, that there had been stealing of the idea by someone else.

Senator KENNEDY. How many scientists get an opportunity in the peer review system to review the work that is going to be done?

Dr. LAMONT-HAVERS. The normal study section is about 15 individuals, but at least they are known. Everybody knows who they are and, therefore, there is a check in the system with regard to disclosure of that information.

Dr. COOPER. And usually when the complaint comes in, it is specific to some individual that was linked to the review process.

Senator KENNEDY. Thank you very much.

Senator NELSON. May I ask one question on that?

Senator KENNEDY. Surely.

Senator NELSON. I think Senator Kennedy raises a very good question. The study sections are presumably made up of those scientists who are among the best qualified to judge the quality and value and significance of the application that is made, right?

Dr. COOPER. Yes, sir.

Senator NELSON. So then it is quite a bit to expect 15 scientists—or people in any walk of life, authorities in whatever aspect of some problem they are dealing with—who review all these applications, to go back home, and, in dealing with their most important daily pre-occupation, their scientific discipline, not to say to their colleagues, "That was a hell of a good proposal that Dr. So-and-So was making before the study section that I sat on".

It is like what an old politician told me, when I first got into politics: "You know, always keep in mind that there are no secrets in politics. I can keep a secret, but the people I tell it to cannot." If a fine idea has been proposed to a study section, isn't it possible that one of

the members of the study section is going to all of a sudden go back to his institute or university, and seek funds from that institute or university, and grab the protocol and start doing the same experiments that the applicant proposed doing? Certainly it is true that a good idea in solving a certain serious problem would spread around the country rather rapidly among those in the field.

Dr. COOPER. I can only say that first, scientists are human, Senator, and, second, to paraphrase Winston Churchill, that the system has defects, but it is the best system we have. It is the best there is. Yes, there is an opportunity for abuse. You can't remove from somebody's mind something that he has read, and it might affect something that he says to his colleagues subsequently thereafter.

I think the performance of that system over the last 25 years has been such to emphasize that, the amount of either advertent or inadvertent misappropriation of somebody else's ideas has been rare.

Senator NELSON. One more question. Are you saying that, within a discipline, a good idea will end up circulating around, among other distinguished colleagues, of whom there may only be 30, 40, 50 or 100 in the country. That is bound to happen, I take it?

Dr. COOPER. And also it is bound to happen that nobody has a market on the same idea. We can't be sure that only one person would not come up with the same idea either.

Senator NELSON. This gets to my next question. I think we know that is bound to happen because, if somebody designs a protocol to deal with a very important knotty, unresolved scientific problem in the field of health, it will be talked about; it is natural that it be talked about, and there is no way for it not to be talked about.

But you are saying that it is important that there be a time limitation to protect confidentiality of scientific protocols for a specific reason. I am assuming that the very detailed description of the protocol to be followed becomes an important aspect. Is that what you are saying?

Dr. COOPER. Exactly, sir.

Senator NELSON. You are not too much worried about protecting the idea that the investigator is engaged in, but you do feel he is entitled to the protection for some period of time as to the explicit detailed protocol, which he and his associates may have developed over a period of years.

Is that what you are talking about?

Dr. COOPER. Yes, sir.

Senator KENNEDY. As I understand it, AAMC, in their testimony, is submitting an amendment on this general topic area. Would you take a look at it and send us a note as to what your reaction to it is?

Dr. COOPER. We have not seen it, yes.

Thank you.

[The prepared statement of Dr. Cooper follows:]

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

OF

DR. THEODORE COOPER

ACTING ASSISTANT SECRETARY FOR HEALTH

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

MONDAY, MARCH 17, 1975

Mr. Chairman and Members of the Subcommittee:

I am here this morning to testify on legislation before your Subcommittee to extend the program authorized by the National Heart, Blood Vessel, Lung, and Blood Act of 1972. As you know, the appropriations authorizations for this Act expire at the end of FY 1975.

Introduction

I should like to begin by reporting to you about (1) the effect of heart, blood vessel, lung, and blood diseases on the American people, and the reasons why we feel justified in expressing cautious optimism concerning our efforts to combat them:

(2) some examples of recent advances in heart, blood vessel, lung, and blood disease diagnosis, treatment, and prevention.

Because of the numbers of people affected and because they spare no segment of our society, heart, blood vessel, lung, and blood diseases have remained among the most serious health problems in our country. Grim statistics tell the story of their destructive impact in terms of human suffering, disability and economic hardship for individuals and families. Collectively, more than 30 million Americans are affected. Heart and blood vessel diseases alone kill more than one million Americans each year, a rate equivalent to two deaths every minute. The total economic drain on society has been estimated at more

than \$40 billion a year. These statistics give a sobering overview of the magnitude and importance of heart, blood vessel, lung, and blood disease research.

Nevertheless, I am optimistic for the future because progress in research and treatment has improved the chances of reducing these dreadful statistics. At long last, the death rates from some of these diseases are either stabilizing or tending downwards. Improved diagnostic methods, treatments, and preventive measures have been developed and are now being applied by medical practitioners.

One reason for optimism is that our efforts have promoted interdisciplinary collaboration by creative and dedicated scientists. Ongoing activities encourage cooperative efforts at all levels of scientific inquiry and build upon the spectacular advances made in the basic biological sciences during the 1950's and 1960's. Developments in technology and the physical sciences and, in recent years, the social sciences, have made important contributions. The base of scientific information continues to expand, and the rate of scientific discovery continues to increase. As a result, we can anticipate further progress in research and treatment related to these diseases.

Another reason for optimism is that, after a steady 25-year increase, the death rate for coronary heart disease has not only stabilized but has trended downward in the past several years. This change is significant because even a modest decrease in this death rate represents thousands of lives saved.

In the case of emphysema, one of the priority lung diseases in our program, the death rate has declined. While emphysema was the fastest rising major cause of death during the 1950's and 1960's, the trend has declined at least two percent per year since 1968.

Recent Advances

Examples of recent advances in heart and blood vessel diseases include non-invasive and improved angiographic methods for detecting lesions in the heart and blood vessels, improved surgical procedures which permit correction of most congenital heart defects even in newborn infants, surgery for the repair of diseased arteries of the heart itself, methods for determining and minimizing damage to the heart following a heart attack, and many others, all of which argue for a substantially improved prognosis for patients afflicted with these diseases. New risk factors for heart disease are also being identified

and our understanding of the long-established ones like smoking, high blood pressure, and elevated blood cholesterol is being refined. These insights have improved our ability to prevent heart and blood vessel diseases, especially coronary heart disease and stroke.

Examples of recent advances in the diagnosis, treatment, and prevention of lung diseases include the ability to identify infants in utero who are likely to develop respiratory distress on delivery so that arrangements can be made for the mother to be transferred to a medical center equipped to care for these newborns. A new method for treating infants, called continuous positive airway pressure breathing, has significantly improved the survival rate for infants born with this condition. Other examples include a new diagnostic test for asthma, a method for early detection of changes in lung function and structure which appear to be the first sign of chronic obstructive lung disease, the identification of risk factors for emphysema, significant improvements in the understanding of the structure and functions of the lung in health and in disease, and the development of artificial lungs to treat acute respiratory failure.

Examples of prevention and treatment techniques in blood diseases and blood resources include enzymes which are

capable of dissolving life-threatening blood clots in the lung, new techniques for measuring abnormal tendency for the blood to clot, new approaches for the treatment of sickle cell crisis, improved treatment for hemophilia, better procedures for preventing the transmission of hepatitis during blood transfusion, and development of artificial materials for prosthetic devices which cause minimal damage to the blood at least on short-term exposure.

Department's Activities

Next, Mr. Chairman, I should like to describe the Department's activities in the two and a half years that have elapsed since the National Heart, Blood Vessel, Lung, and Blood Act of 1972 was signed into law. Our current program effort emphasizes three major approaches: Research to gain fundamental information necessary to improve understanding of the cause, prevention, and improved treatment of these diseases; evaluation of new findings through programs of clinical and applied research; and dissemination of these results through programs of professional and public education.

Soon after passage of the Act in September 1972, the National Heart and Lung Institute was reorganized into programmatic divisions. Three of these are categorical program divisions: The Division of Heart and Vascular Diseases, the Division of

Lung Diseases, and the Division of Blood Diseases and Resources. In addition, there is a Division of Intramural Research, which comprises the laboratory and clinical research conducted at the NIH, and a Division of Extramural Affairs, which is responsible for the services associated with scientific and technical merit peer review of applications for grant and contract support and grant and contract management functions.

Detailed reports on the National Program mandated by the Act were provided to the Congress in July 1973 and are updated by the annual reports of the Director of NHLI and the National Heart and Lung Advisory Council. The current National Plan identifies ten areas for special emphasis in heart and blood vessel diseases, eight in lung diseases, and four in blood diseases and blood resources.

An Office of Prevention, Control, and Education was also established. Through this Office and through its categorical program divisions, the Institute began to implement the prevention, control, and education programs provided for in the Act. The major prevention, control, and education programs are the High Blood Pressure Education Program, the Sickle Cell Disease Program, and an educational effort related to respiratory failure.

During the past year, the Institute initiated three National Research and Demonstration Centers--one in each of the three categorical areas. The Cardiovascular Center is located in Houston, Texas; the Pulmonary Center in Vermont; and the Blood Resources Center in Seattle, Washington. The programs of these centers include both basic and clinical research and demonstration as well as education projects designed to hasten the application of research findings.

The legislation expanded the membership of the National Heart and Lung Advisory Council and enlarged its responsibilities. In addition to reviewing applications for research grants, the Council plays an active role in the development, review, and evaluation of the National Program. Through a number of collaborative efforts with other Institutes, agencies, and organizations, and through the Interagency Committee mandated by the Act, the Institute has sought to utilize more effectively the national resources available for the Program.

Some of the other new activities initiated in recent years which have added significantly to the Institute's program are an expanded program in lung diseases; coordination of the sickle cell disease program efforts; establishment of 26 sickle cell screening and education clinics, and the establishment of 15 comprehensive sickle cell centers; development of the

high blood pressure education program; collaboration in the implementation of national blood policy; establishment of 49 specialized centers of research in arteriosclerosis, hypertension, pulmonary diseases, thrombosis, and ischemic heart disease; implementation of large-scale clinical trials in arteriosclerosis, hypertension, and myocardial infarction; and implementation of a five-year agreement for a cooperative health program between the USA and the USSR.

During this period of expansion in the Institute's programs, the Institute's obligational authority increased from \$160.2 million in FY 1970 to \$327.2 million in FY 1974, including released FY 1973 funds. A comprehensive account of the status of our program since 1972 and the updated five-year plan for all program areas in heart, blood vessel, lung, and blood diseases and blood resources have been presented in the Annual Reports of the Director of the Institute and the Advisory Council.

Mr. Chairman, since the time available for this testimony is limited, I have a small appendix highlighting program developments which I would like to submit for the record.

Conclusion

The Administration and this Subcommittee are, I believe, in

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full accord in our commitment to maintain the research momentum of the heart, blood vessel, lung, and blood research programs. These efforts have a high health priority in this Administration. Although we believe that extension is unnecessary to the continuation of these efforts, we do not object to extension of the heart and lung appropriation authorities provided that:

- the authorization levels are consistent with the President's 1976 Budget; and
- no new activities within these programs are mandated in extension legislation.

We disagree with the authorization level of S. 988 because of our need to consider these programs against the background of the total resources we have for other health research efforts and for other Federal programs as well. As for new activities, we urge that no new categorical research program authorities be enacted pending the conclusion of studies now underway by the President's Biomedical Research Panel. Subject to these understandings, we do not object to extension of the research and control programs in this area.

In summary, Mr. Chairman, the Administration is pleased with the progress made since the National Heart, Blood Vessel, Lung, and Blood Act was enacted. This progress is a reflection of Administration priorities for heart and lung research as well as of the enactment of this law. We are firmly

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committed to the support of these programs at the level of the President's budget.

Now, Mr. Chairman, I would like to direct the Subcommittee's attention to the proposed legislation extending NIH and ADAMHA research training programs.

Research Training

S. 988 would extend the National Research Service Award authorities for two years to continue the support of training of biomedical and behavioral research scientists. The Administration supports an extension of this important effort, provided it is amended in accord with the President's 1976 Budget. Before presenting our recommendations, however, I would like briefly to describe the current status of our research training programs and to report on our implementation efforts with regard to the present Act.

The budget authority for research training through NIH and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) was \$150 million in 1974, \$144 million at the revised 1975 level and \$136 million in the President's 1976 request. Currently, we are responsible for three types of research training support. The first is the continued support of the traditional training grants and fellowships that were initially awarded under the terms of the old program prior to

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January 1973. The present dimensions of the program include the impact of the released FY 1973 funds that were obligated in FY 1974 and are roughly equivalent to the FY 1972 program with obligations of about \$200 million. This amount supports about 12,000 full-time trainees and another 5,000 part-time trainees. The following table shows the budget authority in HEW for research training during the 1972 - 1976 period.

Funds for Research Training
(Budget Authority in \$ Millions)

	<u>1972</u>	<u>1973</u>	<u>1974</u>	<u>1975</u>		<u>1976</u> <u>Request</u>
				<u>Revised</u> <u>Budget</u>	<u>Appro.</u>	
NIH	160	177	131	132	156	124
ADAMHA	<u>18</u>	<u>18</u>	<u>19</u>	<u>12</u>	<u>20</u>	<u>12</u>
	178	195	150	144	176	136

In July 1973, Secretary Weinberger announced a new post-doctoral fellowship program. It was originally designed to provide \$30 million in awards the first year, \$60 million the second, and to level off at \$90 million the third year, and was limited to postdoctoral fellowships. A limited number of institutional awards were to be made under this program in shortage specialty areas where support was needed to provide training environments of types not in existence.

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The third type of training support was established by the National Research Act, enacted last July, which provided new, consolidated research training authority for NIH and ADAMHA. It superseded the previous research training authorities of NIH and ADAMHA which had been used for prior training programs.

The Act authorizes individual fellowships and institutional awards for biomedical and behavioral research and research training at both the pre- and post-doctoral levels. In return for Federal support, individual recipients must agree to a service payback obligation. The Act also required the Secretary to contract with the National Academy of Science for a study of research personnel and training programs to identify those specific subject areas in which there are shortages of research personnel. Effective July 1, 1975, research training awards are to be granted only to train investigators in shortage subject areas.

This year, then, has been a rather exceptional one for the NIH and ADAMHA training programs as the phase-out of the "old" research training grants and fellowships and of the new postdoctoral fellowships program has moved ahead with the implementation of the new National Research Service

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Awards program. We have had less than a year to determine guidelines and solicit applications under the new authorities. We have not yet actually granted any awards but we expect to do so by the end of the fiscal year. Although we are not now in a position to assess the long-range impact of the new program, we feel confident that, if amended, the National Research Service Award Act can provide an adequate foundation for the limited post-doctoral fellowship program that we believe is appropriate.

With regard to the study of research training needs required in the National Research Act, there was concern initially about whether such a complex study could be successfully carried out at all. A preliminary contract was made in October 1974 with the National Academy of Sciences to assess the feasibility of the task. This initial effort indicated that the Academy believes such a study is possible. The Academy now plans to undertake the full study mandated in the law. Their report to this effect was forwarded to us at the beginning of this month and is now being prepared for transmittal to the Congress.

In the 1960's, biomedical research grants grew at an average of about 22% annually. In the context of such rapid growth, a large amount of research training support was provided to

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attract and educate an increasing number of qualified individuals in a short period of time. However, the aggregate employment patterns, the training capacity and the numbers of qualified researchers available for the conduct of research in the mid-1970's are quite different. Institutional training capacity and student interest have grown to the point that the total number of researchers in the biomedical and behavioral sciences approaches and in some fields is believed by some to exceed the level of current need.

Accordingly, we believe that Federal expenditures for research training should now be directed more specifically to supporting a limited amount of training in those disciplines and areas of research in which there is a chronic shortage of highly qualified research personnel.

We regard this training support as an investment in the health and well being of the American people and, given both the current economic situation and the supply of researchers, there is need to make our investment choices even more prudently and efficiently than in the past.

The preparation of the 1976 Budget required a very stringent review of Federal programs and expenditures. The President has called upon the Congress this year to make extraordinary

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efforts to hold down Federal spending, and the Administration in its planning efforts has vigorously attempted to evaluate all programs in the light of need, efficacy, and appropriateness. With regard to research training subsidies, particular care was taken to take a fresh look at programs against the background of present and future needs. It is our position that, while at this time Federal assistance in certain aspects of the research training process is warranted, modification of the current program of assistance is necessary.

In light of these considerations, I would now like to outline the amendments to the present authority to be proposed by the Administration--amendments which we believe will strengthen the Federal biomedical and behavioral research training support programs by targeting assistance to areas of need.

We propose that fellowships be authorized for post-doctoral research training only. This amendment will provide a mechanism for recognizing outstanding post-doctoral level individuals without subsidizing training in areas in which there may already be sufficient numbers of research personnel.

The 1976 Budget decisions reflect:

- the inequity of providing substantial Federal subsidies (\$200 million annually) for students in the biomedical and behavioral sciences, but not in other fields;

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-- the existence of general predoctoral student support programs in the Office of Education.

The 1976 Budget limit of 1,100 new fellowships was selected because it brings the number of trainees roughly in line with the number of new researchers supported annually on research grants. Individual fellowship support was chosen because it is consistent with the Administration's general higher education policy of concentrating support on individual students as opposed to grants to institutions. Moreover, post-doctoral support does not further aggravate any problems of excess supply of researchers since training will be supported only in areas of need. This approach also avoids institutions becoming more directly dependent on Federal funds for faculty salaries.

An increasing problem with the biomedical and behavioral research training grants and fellowship program in recent years has been that they serve to increase the number of specialists in disciplines which already have sufficient manpower to meet national research needs and have not, in a selective manner, served to alleviate the problem of chronic shortages of certain high priority specialties. We feel that the more selective use of Federal support in these specialties may be more effective in this regard.

One of the key elements of the present authority is the National Academy of Sciences study, which includes an identification of specific areas in which there is need for additional research personnel. This study should provide a preliminary basis for the determination of where research training support can best be used. We are pleased the Academy has agreed to undertake this task and look forward to the results of this study and the recommendations. Under the present law, it is not clear that these recommendations are intended only to be advisory to the Secretary, although the NAS is assigned no responsibilities for their implementation. We will propose amendments to the language to clarify the fact that the Academy study is advisory in nature.

Our last proposed amendment relates to the provision of stability for the research training programs and the flexibility necessary to operate most efficiently. The extension of the research training authority proposed by S. 988 would continue the authority for two years at the 1975 authorization level of \$207.9 million. We recommend that the bill be amended to provide a three-year extension with appropriations authorizations of \$136 million.

The biomedical and behavioral research community over the last several years has been subjected to change and program shifts with respect to research training support. In order to provide a stable basis on which students and research training institutions can effectively plan for the future, we feel a three-year extension is in order. It is necessary in terms of enabling NIH and ADAMHA to more effectively plan program operations as well.

Conclusion

In conclusion, the Department will soon be submitting draft legislation regarding modifications of the existing research training authority. We feel the changes we have suggested will improve the ability of HEW to provide for the limited training of biomedical and behavioral researchers in the context of a realistic and equitable research manpower policy.

That concludes my prepared remarks, Mr. Chairman. My colleagues and I would be pleased to answer any questions you and other Members of the Subcommittee may have.

NATIONAL HEART AND LUNG INSTITUTE
EXAMPLES OF PROGRAM DEVELOPMENTS

Development of knowledge

● Identification of Risk Factors for Heart Attacks

Approximately 1,250,000 heart attacks occur in America each year. The five major and well-established risk factors for heart attacks are: age, male sex, high levels of blood lipids, high blood pressure, and cigarette smoking--and for two of these, cigarette smoking and high blood pressure, we know that decrease in the factor results in reduced risk.

● The Framingham Study

A 22-year follow-up has been completed on 5,209 participants. This study has contributed greatly to our understanding of the roles of different risk factors such as high blood pressure, cigarette smoking, high blood lipids, obesity, and diabetes, as well as several risk factors acting simultaneously.

● Determination of Blood Lipids

Methods for accurate and precise determination of blood lipids have been developed for effective and efficient risk factor detection and management.

● New Therapy for Heart Attacks

Recent investigations have shown that the patient's prognosis is directly related to the amount of dead heart muscle resulting from a heart attack. Drugs, oxygen therapy, and mechanical circulatory assistance are promising new therapies for limiting the amount of heart muscle damage from heart attacks. Recent studies in animals show that nitroglycerin, one of the oldest and best drugs for relief of the chest pain of angina pectoris, may be uniquely valuable in the treatment of acute heart attacks by reducing the amount of heart damage.

- Methods to Determine the Amount of Heart Muscle Damaged in Heart Attacks

New noninvasive methods have been developed for determining the amount of heart muscle damaged in heart attacks. These will be important in determining the benefits of various therapies in reducing heart muscle damage.

- Understanding Arteriosclerosis

Arteriosclerosis is responsible for about 85 percent of the deaths from heart and blood vessel diseases. Recent progress has been made in understanding this process. Preliminary studies suggest that each atherosclerosis plaque consists mainly of one colony of cells that have all arisen from a single cell in the artery wall.

- Detection of Pediatric Lung Disease Before Birth

Hyaline membrane disease (HMD), or respiratory distress of the newborn as it is frequently called, often leads to death within a few days of birth. Without special treatment, the majority of these babies will die. If these deaths could be prevented, the infant mortality rate in this country could be substantially reduced. As indicated previously, therapy is available. However, delay in diagnosis contributes greatly to the high death rate. A major diagnostic advance has occurred which allows detection of HMD before birth and initiation of treatment immediately at birth.

- New Therapy for Pediatric Lung Disease

Until recently, the usual therapy for HMD was artificial ventilation and other intensive care usually available only in large hospital centers. Unfortunately, this was not sufficient. A new therapy has been developed which results in a survival rate of up to 90 percent in some studies. This therapy is continuous positive airway pressure and is used in conjunction with artificial ventilation.

- Diagnosis of Asthma in the Asymptomatic Child

Asthma, which affects more than 8 million Americans, could be prevented or treated while still reversible if it were diagnosed sufficiently early. A diagnostic test which allows such early detection has been developed and is undergoing evaluation. It involves exposure to a substance called methacholine.

- Early Detection of Chronic Obstructive Lung Disease

Chronic bronchitis and emphysema are the major chronic obstructive pulmonary diseases. A new, and potentially more sensitive method (closing volume) has been developed for early detection of changes in lung function and structure which appear to be the first sign of chronic obstructive lung disease.

- Improved Understanding of Lung Disease

Technology is now at hand to relate structure and function at the cellular level. As this information develops, it should be possible to begin investigations into the molecular basis of lung disease -- an essential step toward effective prevention and treatment.

- Improved Treatment of Hemophilia

A procedure has been developed which will improve production of Factor VIII, which is used to stop bleeding in hemophiliac patients. This procedure will enable blood banks and laboratories throughout the country to obtain more potent and more uniform Factor VIII from donor blood.

- Development of Materials for Artificial Organs and Prosthetic Devices

Important progress has been made in developing techniques to impart blood compatibility to materials for artificial organs which come in contact with blood.

Evaluation of Knowledge

- Lipid Research Clinics Primary Prevention Trial

This is a study designed to test whether or not lipid lowering can prevent or delay the onset of coronary heart disease. It is being carried out in 12 Extramural Lipid Research Clinics located across the continent.

- Multiple Risk Factor Intervention Trial

This is another large-scale clinical trial conducted in twenty clinics throughout the country. This study will determine the impact on cardiovascular disease of controlling, simultaneously, the three major risk factors: High levels of blood lipids, high blood pressure, and cigarette smoking.

- Coronary Drug Project

The Coronary Drug Project has just been completed. This was a study of the effects of 5 lipid-lowering drug regimens in patients who have already had a heart attack. It was found that although these drugs lowered lipids they did not benefit the patients in terms of preventing further cardiovascular disease and deaths.

- Coronary Artery Surgery

A collaborative national program to determine the indications for and the long-term effects of coronary artery surgery in the management of coronary heart disease is about to be implemented.

- Artificial Lungs

Blood oxygenators for temporary support of the lung have been developed and are being tested in a clinical trial. All these devices are of a nonclinical type.

- Sickle Cell Disease

While clinical trials to evaluate urea as an anti-sickling agent have shown that it is not effective in the treatment of the sickle cell crisis, evaluation of other anti-sickling agents continues. Preliminary studies with sodium cyanate are quite promising.

- Hepatitis

A study is underway of the efficacy of hepatitis B immune globulin in the treatment or prevention of hepatitis B infection.

- Blood Clots in the Lung

A clinical trial has been completed of an enzyme capable of dissolving blood clots in the lung. Results indicate that the enzyme streptokinase (a relatively inexpensive and available preparation) dissolves blood clots in the lung just as effectively as the more widely publicized urokinase (another enzyme preparation), which is quite difficult to obtain.

Dissemination of Knowledge Through Prevention, Control and Education Programs

● National High Blood Pressure Education Program

Drug therapy to control high blood pressure reduces the incidence of strokes and heart failure among persons with moderate or severe hypertension. However, only about 12 percent of hypertensives in the United States are currently receiving adequate treatment. The National High Blood Pressure Education Program is aimed at bringing individuals with hypertension under effective treatment.

● Dissemination of New Knowledge in Lung Diseases

The establishment of a National Research and Demonstration Center at the University of Vermont will tie together and intensify efforts and resources for the control of respiratory disease in Vermont (a state with one of the highest respiratory ailment rates in this country). A primary goal of this Center will be to hasten the application of new research results.

● Sickle Cell Disease Screening and Education Clinics

The Institute supports 26 screening and education clinics which are designed to evaluate new screening techniques and demonstrate counseling and education methodologies.

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Senator KENNEDY. Our next panel of witnesses represents the views of three associations much interested in the American Lung Institute, Mr. Green, the president of the American Thoracic Society, Elliott Rapaport is the president of the American Heart Association. Dr. Hunt is the president of the National Kidney Foundation.

However you wish to proceed—we are going to run into a time problem on it, so I will ask you if you will submit all the statements.

STATEMENT OF GARETH M. GREEN, PRESIDENT, AMERICAN THORACIC SOCIETY, ACCOMPANIED BY ELLIOTT RAPAPORT, M.D., PRESIDENT, AMERICAN HEART ASSOCIATION AND JAMES C. HUNT, M.D., PRESIDENT, NATIONAL KIDNEY FOUNDATION

Dr. GREEN. Mr. Chairman, I think the Lung Association is scheduled to go first.

I am Gareth Green. I am president of the American Thoracic Society, which is an organization of over 6,000 physicians and scientists of the academic and practicing community responsible for the research, training, education and clinical care of lung diseases.

And as you might be confused by the name American Thoracic Society and the American Lung Association, I simply want to point out that this society also serves as medical and scientific adviser to the American Lung Association, which is the Christmas seal organization.

This association is grateful for the opportunity to testify before this committee and is strongly in support of the reenactment of the National Heart, Lung, Blood Vessel and Blood Act of 1972.

We are convinced that the Heart and Lung Act is essential to the acceleration of biomedical and scientific progress against heart, lung, blood vessel and blood diseases.

The act has identified and fostered a number of innovative approaches which improve communication among scientists, accelerate the rate of research discovery, and facilitate the dissemination of new research findings to the application of medical care at the community level. We believe time will show that these innovations will have the overall effects of decreasing disability, death and discomfort due to these diseases and do so in a more efficient manner than heretofore achieved under previous authorizations.

My testimony will address the achievements in the field of lung diseases under the act as my colleagues will address progress and needs in the heart, blood vessel and blood programs.

Now, I have a text before you. I am going to outline and summarize some of the major points from this text.

First: The first point I would like to make is that the National Heart, Lung, Blood Vessel and Blood Act of 1972 has had a profound effect on the field of lung research; the most important reason for its success is the fact that a comprehensive program plan has been developed and promulgated, and as I am sure you are aware, at the time the act was instituted, there was a survey of the resources and needs in the lung community. It was carried out, first of all, by the joint action of the American College of Chest Physicians, the American Thoracic Society, and the National Heart and Lung Institute.

Second: There was a task force report on problems and research approaches and needs in lung diseases. This formed the basis of the

program which has been begun under the National Heart and Lung Act.

It is this planned approach towards research problems and developing new and innovative management mechanisms for addressing these problems that has been a singular success of this piece of legislation.

The plan established problem areas and research priorities, and not only that, set criteria for measuring effectiveness.

Dr. Cooper has outlined the most dramatic area of progress in lung diseases in the past 10 or 15 years. That is in the area of progress dealing with acute respiratory distress syndrome in infants and newborns. I have outlined that in some—in some detail in the next section of the report, primarily to illustrate the aspects and process of conquering diseases.

This process depends on the development of basic knowledge, the development of new techniques for early diagnosis, the development of new methods to prevent those who do not have a disease from contracting the disease, the development of new treatments for those who have the disease, and the education of physicians in the community to recognize and treat the disease.

This area of respiratory distress in the newborn is a good example of how the various aspects of research and medical care development and regional organization can serve together in an integrated fashion to develop significant progress in a disease process.

The organization and utilization of regional medical centers is important to developing a group of expert and highly trained physicians and nurses and in acquiring adequate specialized equipment. Unfortunately, there are too few such specialized centers in this country so that even though effective treatment is available for many lung conditions, it is not effectively implemented in many of the medical care institutions in this country.

And that brings me to my second point, which is urging the establishment of additional regional centers under the research and demonstration component of the Heart and Lung Act. We would support the initial objective of 15 such centers for lung diseases. We note that the revised S. 988 proposes cutting in half, essentially, the number of such research and demonstration centers.

I would simply like to point out to you that that would probably have a more significant effect on the numbers of centers in the lung program than of the other institute programs.

Now, there are a couple of other innovations that I feel, that we feel are important in the Heart and Lung Act. These are specific provisions and authorizations to facilitate the research to application process. And it is this emphasis on the continuum of research to application that is important.

Thus, in section 414(a) there is a provision for prevention and control programs. Prevention and control programs should address the needs of additional specialized centers in many areas, and particularly in the area of acute and chronic respiratory conditions in infants and children, but, of course, no money has ever been appropriated for these program areas.

We would urge an expansion of these programs within the organizational area of the National Institutes of Health, and I can address that area more in response to questions, if you wish.

The prevention and control programs should attack aggressively respiratory diseases in children, in antismoking, and in cooperation with local voluntary and official health agencies should make epidemiological assessments of specific community hazards to respiratory health such as caused by local air pollution problems or certain specific environmental and occupational conditions.

In section 415 there is provision for 15 national research and demonstration centers for lung diseases. These centers incorporate in one setting all of the elements of research, development, training, dissemination of information, and application of new findings. This integration of the several steps of the research to application cycle is a major advance provided by the Heart and Lung Act. Unfortunately, the funding level for such centers has been sufficient to provide only one at this date in lung diseases. We continue to support the goal of 15 centers for lung diseases.

Finally, the act provides a mechanism for the coordination of all Federal health programs and activities related to heart, lung, blood vessel, and blood diseases, and provides for full communication and exchange of information necessary to maintain adequate coordination of such programs and activities. We believe this effort to integrate Federal programs in a disease-oriented fashion should be fostered and strengthened. It is important to recognize that these mechanisms have been made possible by the specific legislation contained in the National Heart, Lung, Blood Vessel and Blood Act of 1972.

Finally, I would like to address the issue of costs. Funding levels have fallen far short of what was anticipated in the original act of 1972 and yet much has been done with the funds that have been provided. In order to guarantee that the problems of lung disease receive a minimum level of funding, 15 percent of the National Heart and Lung Institute budget is identified for the lung programs in the act. Even those individuals not primarily engaged in lung research agree that the 15 percent set aside for lung diseases was a worthwhile investment in this underdeveloped research area. It is the consensus of the lung community that for the present, this designated percentage is the most sensible way to proceed given the importance to the Nation of lung disease problems and the early stage of development of most of the program addressing lung diseases.

Finally, I would like to address the issue of funding for training and development programs. There have been a number of innovative programs produced in the lung division to address the multiple needs of manpower development in pulmonary disease. I am sure that you are aware that this area of manpower support was woefully inadequate in the past 15 or 20 years at a time when lung diseases were multiplying extensively. Carefully developed and innovative plans and programs such as the pulmonary faculty training program have evolved. This latter program is designed to ensure good pulmonary teaching, research, and clinical care in each of 105 medical schools, and is performed—and is achieved by larger schools helping smaller schools in a spirit of constructive cooperation rather than destructive competition.

Much remains to be done. A recent survey to followup on the 1971 manpower report shows that in 103 of 114 medical schools pooled, the number of full-time equivalent faculty in pulmonary diseases has increased from 593 to 657, but there are still 260 funded vacancies and an additional 262 anticipated in the next 2 years.

Key to the future of the program is the interdisciplinary approach; coordinated lung training and research programs, including the SCOR programs, the specialized center of research program, have already demonstrated that the sharing of equipment and administration saves money, and that the sharing of recently developed knowledge in workshops and annual progress reports is an effective means of accelerating the process of scientific development and improving health care for patients with lung diseases.

And I think I need only call to your attention that difference in the format and the size of progress reports from the 1973 progress year to the 1974 progress year. This innovation for distributing the annual progress report, that is, progress reports annual, sharing them with other colleagues and scientists in the field is a major innovation that has greatly accelerated the rate of communication and distribution of ideas among the scientific community.

The American Thoracic Society and the American Lung Association strongly support the renewal of the National Heart, Lung, Blood Vessel and Blood Act because of the significant advances provided by the act and because this act provides substantial benefits to the American public.

Thank you.

Senator KENNEDY. Do you have any views on this training feature, whether it ought to be limited to postdoctoral training or should include predoctoral training? Do you have any set views on that or do you want to think about it, and let us know what your position is?

The administration has indicated that they just want postdoctoral.

Dr. GREEN. I certainly would support a predoctoral training. We find in academic centers that the interest and the talent is often recruited at a young age in science, generally. This is certainly true of the pulmonary disease area.

Senator KENNEDY. Dr. Rapaport?

Dr. RAPAPORT. Thank you, Mr. Chairman.

I want to express our appreciation for this opportunity to present the views of the American Heart Association on S. 988, and we certainly support this bill.

I have distributed earlier written testimony outlining our position and I only wish to take a few minutes to perhaps summarize some of the more salient points and perhaps express two or three concerns that we do have.

I know that you many are very well aware of the scope and magnitude of the problem of heart and cardiovascular diseases, and I shall not reiterate statistics to you. However, I think I should remind the committee that the number one cause of premature death and disability in this country still remains diseases of the heart and circulatory system, and number one, unfortunately, by a very large margin.

That, in itself, would not necessarily justify a national act nor the expenditure of hundreds of millions of dollars annually unless there was really hope that such legislation and the funds implemented could really be expected to make a profound impact on this problem.

We believe that, in fact, it will. It has done so in the past.

Now, specifically, I would like to comment on several areas. First: On the authorization levels which we have recommended on pages 4

and 5 of our written testimony. You will note that actually the authorization levels for the first year are less than that which are recommended in the committee's bill. We wish to point out that our recommendations of authorization levels are what we really believe are the appropriate appropriation levels at the present time. We have not presented authorization levels based upon some hope that some fraction of said authorization level will eventually be appropriated.

The figures which we have presented to you are figures which we believe are appropriate appropriation levels for the years in question.

The second issue I would like to discuss with you is contained within sections 413(d) and 414 of the previous act, which established the office for health information, and authorized the prevention and control programs. We share with you what I believe is your concern, as you expressed it in your questioning of Dr. Cooper, the lack of activity in this area of previous legislation.

We would call to your attention that section 414 had the authority for separate appropriation and, in fact, appropriations were never granted by the Congress during the life of the act in this area, so that it is to some extent understandable that there has not been more activity in the control and prevention areas that has in fact taken place.

When one subtracts the funds that have been expended for sickle cell anemia control from the total amounts appropriated since this act has been in effect, one finds that only \$2 million or \$3 million have in fact been utilized by the Office of Health Information in carrying out its activities and in the general area of control and prevention.

We do not believe that there is any real need for a statutory change in the language of the bills that direct this, but, rather, what we hope is that there would be sufficiently strong language in the committee's report such as to create legislative history that would encourage appropriations in the manner indicated in the bill to implement this section more effectively.

The next area I would like to discuss with you relates to the area of National Research and Demonstration Centers. Again, we share with you the concern that of the 30 authorized centers only three have in fact been funded, of which only one is in the important heart area, and in fact this one is having its dedication ceremonies next week at Baylor, so there has not yet been an effective movement in this whole area.

And, yet, we also, again, have to state our own understanding of the position of the National Heart and Lung Institute and it is a difficult position of trying to take moneys from other areas of this program to support the centers. These are costly endeavors and unless they can be funded adequately, then in fact they perhaps should not be put in the way they are in the legislation, because I think, in a sense, the biomedical community and the practicing cardiologist, lung, and blood communities have found themselves in the difficult position of planning, having many meetings, holding many conferences, in an attempt to develop the center concept for potential funding.

Let me give you one specific example: In the Chicago consortium which resulted in an application from Chicago for a heart center application, the Chicago Heart Association spent \$40,000 directly out-of-

pocket expenses and an estimated \$250,000 in time of personnel that were involved in attempting to plan and develop their center application. In fact, as was noted in the testimony of Dr. Cooper, some 49 center applications were received and yet only three could in fact be funded, and this is an enormous waste of scientific manpower, as well as direct out-of-pocket expenses and we would hope again that there would be some help for the center section of this bill, that sufficient funds be appropriated to carry out this activity.

I would finally indicate that we strongly recommend extension of the National Research Services Award Act. We also would support a view that perhaps some 25 percent of the funds under this title of the act be given to the discretion of the Advisory Council rather than to have the National Science Foundation be the sole determiner of the area of need in supporting funds for fellowship and training support. That is because there are times when situations change rapidly, in which an advisory council might be in a better position to respond quickly to such changing needs rather than be dependent on a long-term study of the National Science Foundation.

Finally, I would mention that we also support the Freedom of Information Act, but do feel that the confidentiality of grant applications is a significant problem. We would be supportive of the proposed amendment of the AAMC in this area.

In summary, Mr. Chairman, we strongly urge passage of this act. We believe that it has past performance and it has been, in terms of the activities of the National Heart and Lung Institute, meritorious and the act is very important for continuing this whole area.

Senator KENNEDY. We will come back to some questions.

Dr. RAPAPORT. Senator, if I may interject one little note that I made when I heard Dr. Cooper suggest elimination of section 109(a)(4) regarding the Advisory Council's role in the area of contracts, I would state that the American Heart Association's position is in support of the committee's bill and we would be opposed to the elimination of this section. We believe that the increasing emphasis on the contract mechanism as a way of supporting research requires the Advisory Council to have a prominent role in looking at the areas of involvement, and we, therefore, support the position of the bill.

Senator KENNEDY. Dr. Hunt.

Dr. HUNT. Mr. Chairman, I am Dr. James Hunt, the president of the National Kidney Foundation. I am a professor and chairman of medicine, Mayo Clinic and Mayo Medical School.

My prepared testimony for the American Kidney Foundation has been received, and I understand it will be submitted in the record.

If it meets with the approval of the chairman, I would prefer to just make several points from this testimony.

The National Kidney Foundation is a lay and professional volunteer health organization having some 55 affiliated divisions in most of the States in the United States. We come before the committee today primarily to serve in a supporting role on positions taken by Dr. Green and Dr. Rapaport from the Lung and Heart Association, respectively.

The Committee on Health and Scientific Affairs of the National Kidney Foundation has carefully studied the written testimony offered by Dr. Rapaport and his associates from the Heart Association and we

wish to strongly support the recommendations not only with respect to programs concerning renewal of the Heart and Lung Act, but also with respect to the necessity of following the guidelines outlined in the bill S. 988 concerning establishing a reality between authorization and appropriation.

We think that the Heart Association is very wise in defining a realistic request for authorization and appropriation.

The second point which I would wish to make is to mention the magnitude of the problem in terms of heart, lung, blood vessel, and kidney disease. Now, the diseases of the heart and circulation, clearly including heart attack, stroke, kidney failure, a variety of lung and blood diseases, account for more than 70 percent of the deaths in the United States each year.

The chairman in his opening remarks addressed himself to these important aspects. The disability and lost wages associated with disability of these diseases alone is an enormous financial drain on the United States each year.

Mr. Chairman, you also, from your opening remarks, are aware of the close relationship between diseases of the heart and circulation and the kidneys. The single more common cause of heart attack, stroke, and kidney failure is high blood pressure, and great emphasis has been placed on the magnitude and nature of this problem here earlier this morning by Acting Assistant Secretary Cooper.

The fourth point which I would like to make is that the American public, the volunteer health agencies, particularly the National Kidney Foundation, is quite aware that the Congress has been responsive to the public's needs not only through H.R. 1 with major emphasis on kidney disease and utilization of social security moneys through medicare and medicaid have advances been made from the standpoint of delivery of medical care, health care, but there have been generous appropriations made to the National Institute of Arthritis, Metabolism, and Digestive Diseases. There have been generous authorizations, but not necessarily appropriations to the National Heart and Lung Institute, and we feel it would be importance, as Dr. Rapaport stated earlier, to make these more in keeping one with the other.

The single most—the fifth point I would like to make, Mr. Chairman, is that the single most common cause of endstage renal disease is high blood pressure. Now, as stated earlier, we have made advancement in the treatment of kidney failure through dialysis and transplantation, but, Mr. Chairman, we have not made a great deal of progress despite those notations made by Dr. Cooper earlier this morning in utilizing the available knowledge, the available know-how, the available medications, the available approaches to nutrition and environment in the management of the high blood pressure problem.

Now, there are probably 25 million Americans who have high blood pressure. High blood pressure is the single most common cause of heart attack, stroke, and kidney failure, yet only 25 percent of the American public with high blood pressure is on any adequate or minimally active treatment program.

Dr. Cooper acknowledges in his statement this morning that probably not more than 12 percent of the hypertensive population has satisfactory blood pressure control, yet, Mr. Chairman, the amount

of moneys available through the Heart and Lung Institute utilized for the national high blood pressure education program have been extremely minimal, probably not more than \$2 million per year.

The National Kidney Foundation does acknowledge that probably the single most important accomplishment of the Heart and Lung Institute in demonstration programs has been—education programs—has been the national high blood pressure education program. We would submit, however, that the National Heart and Lung Institute could more effectively fund these programs and provide personnel for their development.

Indeed, since Dr. Cooper left the directorship of the National Heart and Lung Institute, this program has effectively been without a head—not even an acting head.

The new Public Law 93-641 defines a number of important areas of health priorities. Included in these priorities there is mention made of nutrition and environmental factors affecting health. We feel that the programs of the National Heart and Lung Institute, through the continuation of the Heart and Lung Act, certainly have an important role to play in this.

The Chairman earlier this morning asked about nutritional and dietary factors with respect to heart disease, lung disease and especially heart attack. Our suggestion is that reenactment or continuation of the act will strongly support these areas.

Mr. Chairman, there are several additional points that I have made in my testimony, but with attention to time and the saving of the committee's time, I would like to stop at this point, and perhaps during the discussion, if there are other points, address them.

Thank you very much for the privilege of appearing on behalf of the Kidney Foundation.

Senator KENNEDY. Thank you very much, Dr. Hunt.

I wonder if you agree with your colleagues about the training program, whether it ought to be limited to postdoctoral or whether it ought to also include the predoctoral training.

Dr. HUNT. Mr. Chairman, we would strongly support Dr. Green's statement that academic physicians and scientists begin their careers early. The training of such a scientist is long and involved and we, therefore, feel that predoctoral training is exceedingly important, sir.

Senator KENNEDY. Thank you very much. We appreciate your appearance.

[The prepared statements of Dr. Green, Dr. Rapaport, and Dr. Hunt follow:]

Testimony of the American Thoracic Society - American Lung Association in support of the National Heart, Lung, Blood Vessel & Blood Act to be presented by Dr. Gareth M. Green, President, American Thoracic Society, before the Senate Appropriations Committee, March 17, 1975.

Mr. Chairman, Members of the Committee, Ladies and Gentlemen:

I am President of the American Thoracic Society - an organization of over 6,000 physicians, teachers and scientists of the academic and practicing community responsible for research, training, education and clinical care of lung diseases. This Society serves as medical and scientific advisor to the American Lung Association, the national Christmas Seal organization dedicated to the prevention and control of lung diseases. This organization is grateful for the opportunity to testify before the Senate Appropriations Committee and is strongly in support of the re-enactment of the National Heart, Lung, Blood Vessel and Blood Act of 1972. We are convinced that the Heart and Lung Act is essential to the acceleration of biomedical and scientific progress against heart, lung, blood vessel and blood diseases. The Act has identified and fostered a number of innovative approaches which improve communication among scientists, accelerate the rate of research discovery, and facilitate the dissemination of new research findings to the application to medical care at the community level. We believe time will show that these innovations will have the overall effects of decreasing disability, death and discomfort due to these diseases and do so in a more efficient manner than heretofore achieved under previous authorizations. My testimony will address the achievements in the field of lung diseases under the Act as my colleagues will address progress and needs in the heart, blood vessel and blood programs.

Lung diseases are the most rapidly increasing cause of death in the U.S., they pose a staggering economic toll, and they are major causes of disability. Prior to the Act of 1972, medical science had been slow to recognize the seriousness of lung diseases as a national problem and to bring to bear the available knowledge and technology on respiratory diseases. The Manpower Survey completed by the ATS/ACCP/NHLI established the serious lack of manpower and the fact that the field of lung diseases had failed to attract its share of bright, productive young scientists and physicians necessary for future advances in an attack against respiratory diseases.

The National Heart, Lung, Blood Vessel and Blood Act of 1972 had a profound effect on the field of lung research; the most important reason for its success is the fact that a comprehensive program plan has been developed and promulgated.

The plan established problem areas and research priorities, and set criteria for measuring effectiveness. It was recognized that the complex problem involved in lung diseases required the mobilization of basic scientists with diverse interests to the study of lungs. It was also acknowledged that various lung diseases including emphysema, bronchitis, fibrotic and immunologic lung diseases, environmental and industrial lung diseases, pediatric lung diseases, asthma and cystic fibrosis involve processes which require similar basic scientific skills.

Because of the complex nature of the disease processes, a keystone to the "plan" has been the interdisciplinary approach to research. Mechanisms were developed to promote research by groups of workers from different disciplines working together. Of particular interest in this regard are the Specialized Centers of Research in Lung Diseases which have mobilized scientists with different skills and have encouraged them to integrate

clinical and research activities.

Let me illustrate the process of health care development and the inter-relationships of basic research, clinical investigation, health resources development, education, and improvements in medical care by drawing on an article on hyaline membrane disease written by Reynolds in the British Medical Bulletin in January of 1975. Hyaline membrane disease is a condition that develops principally in premature newborns and is characterized by extreme difficulty breathing, inability to provide oxygen to the tissues, the development of stiff lungs and, up until 2 or 3 years ago, death in 50-60% of those afflicted. Ten years ago there was no really effective therapy for this condition.

Approximately 18 years ago basic scientists discovered a fatty material in the lungs which keeps the lungs expanded. This material was called pulmonary surfactant. Sixteen years ago clinical investigators discovered that surfactant could not be found in the lungs of infants dying with hyaline membrane disease. Subsequent basic research revealed that surfactant is produced by a specialized (Type II) cell in the lung and that the reason for this deficiency is immaturity of those cells. The system normally matures at approximately 33 weeks of pregnancy after which surfactant is released into the fluids surrounding the fetus in the uterus. When the new diagnostic procedure called "amniocentesis" (which means sampling the uterine fluids), was developed by clinical investigators the presence or absence of this material could be diagnosed before birth; physicians can now diagnose the state of maturity of the fetus' lungs and predict the high risk infant. Very recent clinical studies have shown that the drug cortisone stimulates the production of surfactant and thus corrects the immaturity defect in these infants.

Not all infants destined to develop this disease, however, can be

diagnosed before birth. Using techniques of breathing support, based on basic and clinical research in pulmonary physiology, infants who have already developed the disease can now be kept alive in specialized regional intensive care units until the lungs can have a chance to mature either spontaneously or under responses to drug treatment. Now in these specialized centers, the survival rate of infants weighing more than 1,000 grams is almost 90% as opposed to 40-50% a short few years ago.

The importance of this story is that both aspects of diagnosis and treatment - surfactant and life support systems have depended on (1) the development of basic knowledge, (2) the development of new techniques for early diagnosis, (3) the development of new methods to prevent those who do not have the disease from contracting the disease, (4) the development of new treatments for those who have the disease, and (5) the education of physicians in the community to recognize and treat the disease. The organization and utilization of regional medical centers is important in developing a group of expert and highly trained physicians and nurses and in acquiring adequate specialized equipment. Unfortunately, there are far too few such specialized centers in this country so that even though effective treatment is available, thousands of otherwise entirely normal infants may die each year. This example is important to an understanding of the process of conquering disease. It is important now that we use the organizational and managerial innovations established under the Heart and Lung Act to achieve similar advances in the battle against emphysema, pulmonary fibrosis, asthma, occupational lung diseases, cystic fibrosis of children, and other acute and chronic lung diseases.

The importance of the Heart and Lung Act is that it contains specific provisions and authorizations to facilitate the research to application process. Thus, in section 414(a) there is a provision for Prevention and

Control programs. Provided adequate funding, Prevention and Control programs could address the needs of additional specialized centers for treating such disorders as hyaline membrane disease, could foster research into other disabling diseases of children such as asthma and cystic fibrosis, and could support training of physicians and scientists knowledgeable in the whole group of pediatric pulmonary diseases. Or, the Prevention and Control programs could attack aggressively the issues and problems in anti-smoking; or could, in cooperation with local voluntary health agencies, make epidemiologic assessments of specific community hazards to respiratory health such as caused by local air pollution problems or certain specific environmental and occupational conditions.

In section 415 there is provision for 30 National Research and Demonstration Centers which incorporate in one setting all of the elements of research, development, training, dissemination of information and application of new findings. This integration of the several steps of the research to application cycle is a major advance provided by the Heart and Lung Act. Unfortunately the funding level for such centers has been sufficient to provide only 1 at this date in lung diseases.

Finally, the Act provides a mechanism for the coordination of all federal health programs and activities related to heart, lung, blood vessel, and blood diseases, and provides for full communication and exchange of information necessary to maintain adequate coordination of such programs and activities. We believe this effort to integrate federal programs in a disease-oriented fashion should be fostered and strengthened. It is important to recognize that these mechanisms have been made possible by the specific legislation contained in the National Heart, Lung, Blood Vessel and Blood Act of 1972. This Act is needed because it provides a plan, it sets priorities, it provides for organizational changes which

allow the accomplishment of the aims, and provides machinery for measuring the effectiveness of the program.

Of course all this costs money. Funding levels have fallen far short of what was anticipated in the original Act in 1972 and yet much has been done with the funds that have been provided. In order to guarantee that the problems of lung disease received a minimum level of funding, 15% of the National Heart and Lung Institute budget was identified for the lung programs in the Act. Even those individuals not primarily in lung research agree that the 15% set aside for lung diseases was a worthwhile investment in this underdeveloped research area. It is the consensus of the lung community that for the present, this designated percentage is the most sensible way to proceed given the importance to the nation of lung disease problems and the early stage of development of most of the program addressing lung diseases.

The funds have supported high quality research and have fostered the training of many badly needed investigators and teachers in lung diseases. Carefully developed and innovative plans and programs such as the Pulmonary Faculty Training Program have evolved. This latter program is designed to ensure good pulmonary teaching, research, and clinical care in each of 105 medical schools by larger schools helping smaller schools in a spirit of constructive cooperation rather than destructive competition. Since lung disease is a local community problem, it is vital that every geographic area has trained physicians to deal with the problem. Such programs are beginning to develop groups of scientists capable of solving the problems facing them, but another three years at least are critical to the development of a core of scientists, teachers and adequate pulmonary programs around the country.

Much remains to be done. A recent survey to follow up on the 1971 ATS/ACCP/NHLI Manpower Report shows that in 103 of 114 medical schools polled, the number of full time (equivalent) faculty in pulmonary diseases has increased from 593 to 657, but there are still 260 funded vacancies and an additional 262 anticipated in the next 2 years.

Key to the future of the program is the inter-disciplinary approach; coordinated lung training and research programs, including SCOR programs, have already demonstrated that the sharing of equipment and administration saves money, and that the sharing of recently developed knowledge in workshops and annual progress reports is an effective means of accelerating the process of scientific development and improving health care for patients with lung diseases. The American Thoracic Society and the American Lung Association strongly support and urge the renewal of the National Heart, Lung, Blood Vessel and Blood Act because of the significant advances provided by the Act and because this Act provides substantial benefits to the American public.

Management of Hyaline Membrane Disease by E. O. R. Reynolds, in the British Medical Bulletin, Volume 31, Number 1, pages 18-24, from the Summary and Conclusions.

When hyaline membrane disease was last reviewed in the British Medical Bulletin, Strang (1963) was forced to conclude: "There is as yet no really effective therapy for this condition." Since then, major advances have been made. With greatly increased understanding of the abnormalities present in the illness and the application of soundly based therapeutic methods, a large reduction in mortality has been achieved. Probably very few infants born at gestational ages of 30 weeks or more should now die from hyaline membrane disease. Equally importantly, the survivors of intensive care methods, including those infants who have suffered from severe hyaline membrane disease, are proving to be normal children at follow-up (Rawlings, Reynolds, Stewart & Strang, 1971; Calame & Prod'hom, 1972; Stahlman, Hedvall, Dolanski, Faxelius, Burko & Kirk, 1973; Stewart & Reynolds, 1974). Yet facilities for providing this care in Great Britain as a whole remain totally inadequate (Lancet, 1974). ~~Let us hope that they will rapidly improve during the next few years, so that~~ their full impact on the reduction of mortality and morbidity can be felt.

TESTIMONY OF ELLIOT RAPAPORT, M.D., PRESIDENT, AMERICAN HEART ASSOCIATION,
CONCERNING THE EXTENSION OF P.L. 92-423, THE NATIONAL HEART, BLOOD VESSEL,
LUNG AND BLOOD ACT OF 1972

The American Heart Association urges the extension of Public Law 92-432, the National Heart, Blood Vessel, Lung and Blood Act, for three years, through June 30, 1978. We believe that the activities and accomplishments of the National Heart and Lung Institute (NHLI) in the past 2 1/2 years themselves justify the 1972 enactment and argue for the renewal of the national commitment to the conquest of cardiovascular disease in this form.

Furthermore, we are convinced that expenditures of this magnitude could have a significant impact on the epidemic of premature heart attacks this country has been experiencing. National mortality data for the most recent five years of record -- 1968 through 1972 -- indicate a downturn in the coronary death rate, averaging 8.7 percent for white men age 35-64 (11.4% for those age 35-44, 7.4% for those age 45-54, and 7.4% for those age 55-64). Downward trends were also recorded over this period for black men age 35-64, and for white and black women, age 35-64. This shows that investment in cardiovascular research and program activities, such as that sponsored since the Second World War, can have important pay-offs.

1. Evaluation of the Act

While the passage and terms of Public Law 92-432 raised some hopes which have not been fulfilled, these shortcomings can be reasonably traced to the disparity between actual appropriations and the authorization levels Congress considered necessary three years ago. Conversely, many of the achievements which followed the enactment of the National Heart, Blood Vessel, Lung and Blood Act were facilitated because the priority which the Act manifested helped NHLI avoid the more severe cuts inflicted on biomedical research in general during this time period.

The American Heart Association knows well the recent problems in research funding because our extramural research program tries to complement the support of federal agencies for cardiovascular and cerebrovascular research. In this way we hope to do our share in providing vitality and stability in the system for creating new biomedical knowledge. When the Administration sought to eliminate federal research training programs, for instance, we increased the number of new "Established Investigator" fellowships by 35 percent. (This AHA program is roughly equivalent to NIH's Career Development Award.) We also changed our grant policy so as to permit the use of grant funds for salary support of fellows recently entering their postdoctoral training. We have made other changes in our grant program, realizing that when research funds get tight, it can be hard for new researchers to get funds to cover the cost of equipment, supplies and technician time needed to carry out their scientific inquiry. Accordingly, our Research Committee has decided to give preference in the award of grant funds to the new investigator.

a) Institutional Effects

Returning to our analysis of the statute before us, it would seem that the Act helped improve the institutional setting for the federal effort in heart, blood vessel, blood and lung diseases. The National Plan called for by section 413(a), the revitalized Advisory Council, and the requirement for annual, public reports by both the Institute Director and the Advisory Council are expressions of a more systematic, rational approach to the generation and application of new knowledge.

b) Implications for the Patient

Did the Act make any difference for the patient?

First of all, the Act called attention to the importance of prevention. It also focused interest on testing major assumptions in this area. As a result, several clinical trials are currently underway to evaluate ways of preventing heart disease.

For instance, there is good scientific evidence associating certain "risk factors" -- including high blood lipids, high blood pressure and smoking -- with coronary heart disease. These trials are designed to determine whether controlling the named risk factors will affect the likelihood of a cardiovascular incident. Other trials are seeking information about the potential efficacy of drugs and surgical intervention in reducing the incidence of heart attack.

Much has already been uncovered with immediate relevance to the patient. The Coronary Drug Project, for instance, was a clinical trial to determine the preventive effect of lipid-altering drugs on patients who have had one or more myocardial infarctions. The study demonstrated the failure of some drugs in mass use to be of benefit in secondary prevention. Therefore, it facilitated a more rational approach to the use of these drugs.

A more hopeful advance is that methods for detecting the amount of heart muscle damage by a heart attack, and treatments for limiting such damage are being developed under Institute support.

(Both the Multiple Risk Factor Intervention Trial and the Coronary Drug Project are examples of programs of such size, complexity, and cost that they could never have been undertaken by a voluntary health agency; and are therefore indicative of the need for a substantial federal commitment to heart research. The Multiple Risk Factor Intervention Trial will eventually involve 12,000 volunteers. The Coronary Drug Project had a population of 8,400.)

c) Public, Patient and Professional Education

The scientific community must do a better job in translating research findings to the professional and the public. The 1972 Act took an important step in this direction by establishing the Office for Health Information in section 413(d), and authorizing the creation of 30 Research and Demonstration centers in section 415.

The Act provided new impetus for the planning and implementation of a National High Blood Pressure Education Program, a remarkably effective effort considering the limited resources available to it. Other activities have been hampered because there has never been Congressional appropriation of funds under section 414(a).

The Centers concept is a unique approach to developing a continuous flow of information from the researcher to the practicing physician and the public. The concept is so exciting that 42 applications were entered in response to the October 1972 solicitation. Since the NHLI budget did not have sufficient funds available, after supporting basic and applied research under traditional mechanisms, only three Centers could be funded (including one in heart). As a result, much valuable time and effort was lost in the preparation of unsuccessful applications and skepticism grew in the academic community.

2. Changes Indicated in the Act

The attachment reflects most of our suggestions for statutory changes which should be enacted in connection with the extension of the National Heart, Blood Vessel, Lung and Blood Act. These changes are perhaps not as comprehensive as they would have been if funding opportunities had permitted more experience with the Center concept, the control programs and the information and education activities authorized in the 1972 Act.

AHA is especially interested in seeing a major initiative by the Institute in prevention, education and control programs. We could not, however, think of any changes in the statutory language which would make this hope come true in the absence of specific appropriation of funds for these purposes. It is also imperative, in our estimation, that at least one National Research and Demonstration Center for heart and blood vessel diseases be established in each HEW Region. These approaches will help to advance the goal of translating discovery to practice.

Another one of our main interests -- indicated by our own commitment to fellowship programs over the years -- is in the area of research training. The Research Service Awards Act limits the support of research training to areas where there is a perceived need for additional manpower. We believe that the Advisory Councils of the various Institutes should have some role in determining this need. Accordingly, we suggest that approximately 25 percent of the funds available for manpower development be authorized for training awards which the Institutes consider absolutely necessary.

Thirdly, the experience recently gained in seeking replacements for Directors at various NIH Institutes shows that the compensation package available to prospective Directors is woefully inadequate. Although not included in the attached statutory treatment, we believe that the extension of the Heart Act might be an appropriate opportunity to legislate a salary raise for all Institute Directors.

Finally, we believe that the nation should celebrate our bicentennial anniversary by sharing our extraordinary knowledge about the prevention and treatment of cardiovascular disease, and rehabilitation from it, with other countries around the world. Therefore, American Heart suggests

that NHLI be given a special authorization for 1976 which will enable it to sponsor travelling fellows in cardiology. A travelling fellowship program should achieve the same level of information exchange as an international conference but at much less expense. Although we have not done so yet, we would be happy to supply wording for an addendum to the bill which would authorize such a program.

3. Levels of Authorization

Perhaps the most sensitive question in the renewal of the Heart Act is the level of authorization for the activities of the Institute, other than prevention, education and control programs. This is contained in section 419B.

We are aware of the need for fiscal restraint in these hard times. In addition, authorization levels which are unrealistic both in relation to needs and capabilities and also as to funding possibilities lead to public confusion and mistrust. On the other hand, there is need to restore stability and continuity to the biomedical research process if it is to survive and be productive.

With this in mind, we have taken great pain in calculating authorization levels which will:

- a) enable support of research programs which appear to have high cost-effectiveness, while
- b) funding the new programs which will improve patient care through the transmission of new knowledge, and
- c) provide for necessary maintenance of the infrastructure (manpower and facilities) necessary for a high quality research initiative.

With respect to the third point, very little money has been available from the federal government for the construction of research facilities in the past few years. Payment of construction money both for the development of National Research and Demonstration Centers and in conjunction with ordinary grant awards, will not only help to assure that the quality of our research installations does not fall below that of other countries but will also be a source of stimulus for the economy.

Here is a detailed breakdown of our recommendations for authorization levels:

<u>Category of Obligation</u>	<u>FY1976</u>	<u>FY1977</u>	<u>FY1978</u>
Research Grants and Program Projects	\$160,000,000	\$190,000,000	\$230,000,000
SCORs	40,000,000	42,000,000	45,000,000
Control Programs	20,000,000	30,000,000	40,000,000
Centers	20,000,000	46,000,000	70,000,000
Construction	15,000,000	25,000,000	29,000,000

<u>Category of Obligation</u>	<u>FY1976</u>	<u>FY1977</u>	<u>FY1978</u>
Manpower Development	32,000,000	35,000,000	38,000,000
Intramural Research	25,000,000	27,000,000	30,000,000
Contracts	80,000,000	86,000,000	98,000,000
Management & Program Services	18,000,000	19,000,000	20,000,000
TOTAL	\$410,000,000	\$500,000,000	\$600,000,000

DC/jb
ED/66



Am Art

To amend the Public Health Service Act to enlarge the authority of the National Heart and Lung Institute to conduct research on the causes and treatment of diseases of the heart and blood vessels, the lungs, and blood, and for other purposes.

As it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.
NATIONAL HEART, Lung, and Blood Act of 1972.

SECTION 1. This Act may be cited as the "National Heart, Blood Vessel, Lung, and Blood Act of 1972".

FINDINGS AND DECLARATION OF PURPOSES.

Sec. 2. (a) Congress finds and declares that—
(1) diseases of the heart and blood vessels collectively cause more than half of all the deaths each year in the United States and the combined effect of the disabilities and deaths from such diseases is having a major social and economic impact on the Nation;

(2) elimination of heart and blood vessel diseases as significant causes of disability and death could increase the average American's life expectancy by about eleven years and could provide for annual savings to the economy in lost wages, productivity, and costs of medical care of more than \$20,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years and are the leading cause of death in the United States, along being the fastest rising cause of death in the United States; Americans, emphysema an estimated one million, chronic bronchitis an estimated four million, and asthma an estimated five million;

(4) thrombosis (the formation of blood clots in the vessels) may cause directly or in combination with other problems, many deaths and disabilities from heart disease and stroke which may be prevented;

(5) blood and blood products are essential human resources whose value in saving life and promoting health cannot be assessed in terms of dollars;

(6) the provision of prompt and effective emergency medical services utilizing to the fullest extent possible advances in transportation and communications and other electronic systems and special medical equipment and techniques, and the employment of personnel can reduce substantially the number of fatalities and severe disabilities due to critical illnesses in connection with heart, blood vessel, lung, and blood diseases; and

(7) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart and Lung Institute, but advancement against such diseases depends on the availability of research programs and personnel to conduct the research programs of other research institutes of the National Institutes of Health.

(8) It is the purpose of this Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases.

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PROGRAM

Sec. 3, Part B of title IV of the Public Health Service Act is amended (1) by redesignating section 413 as section 413A, (2) by redesignating section 414 as section 418, and (3) by adding after section 412 the following new sections:

"NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PROGRAM
"Sec. 413. (a) The Director of the Institute, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung, and Blood Disease Program (hereafter in this part referred to as the program) to expand, improve, and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases (including the conditions in that section) and to coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases with the activities of the other departments of the National Institutes of Health to the extent that they have responsibilities respecting such diseases and shall provide for—
(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, nutritional, hormonal, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;
(2) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;
(3) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and applicable to, the diagnosis and treatment of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;
(4) establishment of programs that will focus and apply scientific and technological efforts involving biological, physical, and engineering sciences to all areas of heart, blood vessel, lung, and blood diseases with emphasis on refinement, development, and evaluation of techniques and devices for diagnosis, treatment, and diagnosis and treatment of those diseases;
(5) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;
(6) studies and research into blood diseases and blood and blood vessel conditions for the purpose of developing methods of collection, preservation, fractionation, and distribution of it and its products;
(7) the education and training of scientists, clinicians, and educators in fields and specialties (including computer sciences) requisite to the conduct of programs respecting heart, blood vessel, lung, and blood diseases;
(8) studies and research into the epidemiology, etiology, and prevention of blood diseases and the use of blood and blood products and the management of blood resources;
(9) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, and hemolytic and hemophilic

-2-

Change

62 Stat., 464,
42 USC 287-
287a.

NIH, coordination provisions.

"Sec. 413. (a) The Director of the Institute, with the advice of the Council, shall carry out the National Heart, Blood Vessel, Lung, and Blood Disease Program in accordance with a plan or plans developed with the assistance of advisory bodies. This program shall expand, intensify and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases (including its activities under section 412) and shall be coordinated with the other research institutes of the National Institutes of Health to the extent that they have responsibilities respecting such diseases. This Program shall include:

66 STAT., 680
66 STAT., 681

Reason

This section should be amended to reflect the completion of the plan as required by the 1972 Act.

The Institute should have authority to support both clinical and research training in addition to and separate from the training provisions of PL 93-438.

Section 413(a) (7) should appear in the Extension as it does in the 1972 Act.

-4-

Change

Assistant Director-
Information Programs

"(c) There shall be in the Institute an Assistant Director for Health Information Programs who shall be appointed by the Director of the Institute. The Director of the Institute, acting through the Assistant Director of Health Information Programs, shall conduct a program of research, training, and demonstration in the field of prevention with regard to the health and the health habits of the population with regard to cardiovascular and pulmonary diseases. In the conduct of such program, special emphasis shall be placed upon dissemination of information regarding diet, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary disease.

"HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS"

"Sec. 414. (a) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Secretary of Health, Education, and Welfare, and in cooperation with other Federal Health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

(b) The center shall be authorized to be appropriated to carry out this section, subject to the availability of appropriations, for the fiscal year ending June 30, 1977, and for the fiscal year ending June 30, 1978.

"NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES"

"Sec. 415. (a) (1) The Director of the Institute may provide for the development of—

(A) fifteen new centers for basic and clinical research into training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for chronic lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children);

(B) fifteen new centers for basic and clinical research into training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart, blood vessel, and blood diseases.

(2) The center authorized under paragraph (1) (A) shall, in addition to the center authorized for research, training, and demonstration, be utilized for the following prevention programs for cardiovascular diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular disease.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such disease.

(C) Programs to develop health professions and allied health professionals personnel highly skilled in the prevention of such disease.

(D) Programs to develop improved methods of providing emergency medical services for persons with such disease.

Reason

The title of the Assistant Director for Health Information Programs should be changed to more accurately reflect the scope of his office. Many have noted the need to improve the transmission of research findings to the public and the professions. This important educational effort is the responsibility of this Office.

The prevention and control of cardiovascular and cerebrovascular disease may depend upon changes in life style and clinical standards. To do this, funds are needed for basic research in behavior modification and behavior development. New public and professional education programs will then have to be designed based on these findings. Unfortunately no programs have been funded pursuant to this section to date.

The Center concept has exciting possibilities. Because of possible geographical differences, it is desirable that there be at least one heart Center in each HEW region.

Assistant Director,
Prevention, Education
and Control,

\$20,000,000 for the fiscal year ending June 30, 1976, \$30,000,000 for the fiscal year ending June 30, 1977, and \$40,000,000 for the fiscal year ending June 30, 1978.

heart and blood vessel diseases
(1) and (2) for blood diseases and for research in the use of blood and blood products.

86 STAT. 882
86 STAT. 883
Appropriations.

86 STAT. 882
86 STAT. 883

"(3) Centers developed under this subsection may be supported under section (b) or under any other applicable provision of law. The research and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

"(b) The Director of the National Institutes of Health and after consultation with the Council, may enter into cooperative agreements with public or nonprofit private agencies or institutions to pay all or part of the cost of carrying out the following activities: (1) providing centers established under subsection (a) for basic or clinical research; (2) training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases. Funds use of funds.

paid to centers under cooperative agreements under this subsection may be used for—

"(1) construction, notwithstanding section 406, 58 Stat. 708, and other basic operating costs, including such as 42 USC 285.

"(2) patient care services, including such as 42 USC 285.

"(3) training, including training for allied health professions 58 STAT. 683

personnel, and

"(4) demonstration purposes.

The aggregate of payments (other than payments for construction) made to any center under such an agreement may not exceed \$10,000,000 in any year. Support of a center under this subsection may be for a period of not more than five years and may be extended by the Director of the Institute for additional periods of not more than one year each, after review of the operations of such center by an appropriate scientific review group established by the Director. As used in this section, the term 'construction' does not include the acquisition of land.

"INTERAGENCY TECHNICAL COMMITTEE

"Sec. 416. (a) The Secretary shall establish an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources which shall be responsible for coordinating those aspects of all Federal health programs and activities relating to heart, blood vessel, lung, and blood diseases and to blood resources to assure the adequacy and technical soundness of such programs and activities and to coordinate the dissemination and exchange of information necessary to maintain adequate coordination of such programs and activities.

"(b) The Director of the Institute shall serve as Chairman of the Committee and the Committee shall include representation from all Federal departments and agencies whose programs involve health functions or responsibilities as determined by the Secretary.

"NATIONAL HEART AND LUNG ADVISORY COUNCIL

"Sec. 417. (a) There is established in the Institute a National Heart and Lung Advisory Council to be composed of twenty-three members as follows:

"(1) The Secretary, the Director of the National Institutes of Health, the Director of the Office of Science and Technology, and the chief medical officer of the Veterans Administration (or their designees), and a medical officer designated by the Secretary of Defense, shall be ex officio members of the Council.

"(2) Eighteen members appointed by the Secretary. Eleven of the appointed members shall be selected from among the leading medical or scientific authorities who are skilled in the sciences

relating to diseases of the heart, blood vessels, lungs, and blood; two of the appointed members shall be selected from persons enrolled in residency programs providing training in heart, blood vessel, lung, or blood diseases; and five of the appointed members shall be selected from members of the general public who are leaders in the fields of fundamental or medical sciences or in public affairs.

(b) (1) Any appointed member of the Council shall be appointed for a term of four years.

"(A) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

"(B) of the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and five shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

"(2) A vacancy in the Council shall not affect its activities, and twelve members of the Council shall constitute a quorum.

"(3) The Council shall supervise the National Advisory Heart Council, which shall consist of the members of the National Advisory Heart Council serving on the effective date of this section shall serve as additional members of the National Heart and Lung Advisory Council for the duration of their terms then existing, or for such shorter time as the Secretary may prescribe.

"(4) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of their duties a per diem allowance of \$100, which shall not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem, in lieu of subsistence, in the same manner as such expenses are authorized by section 5705 of title 5, United States Code, for persons in the Government service employed intermittently.

"(5) The Secretary (or his designee) shall be the Chairman of the Council.

"(d) The Director of the Institute shall (1) designate a member of the staff of the Institute to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

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

AUTHORIZATION OF APPROPRIATIONS FOR PART B OF TITLE IV OF THE PUBLIC HEALTH SERVICE ACT

Sec. 4, Part B of title IV of the Public Health Service Act is amended by adding at the end thereof the following new section:

"AUTHORIZATION OF APPROPRIATIONS

"Sec. 410B. For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated for the fiscal year ending June 30, 1976, \$500,000,000 for the fiscal year ending June 30, 1977, and \$600,000,000 for the fiscal year ending June 30, 1978. Of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums shall be reserved

Terms.

86 STAT. 684
86 STAT. 685

Extension.

National Advisory Heart Council, placement provisions. 449, 54 STAT. 449, 42 USC 218.

5 USC 5332 note.

80 Stat. 499;
83 Stat. 150.

Executive Secretary.

Amis, p. 680.

Amis, p. 682.

\$410,000,000 for the fiscal year ending June 30, 1976, \$500,000,000 for the fiscal year ending June 30, 1977, and \$600,000,000 for the fiscal year ending June 30, 1978.

for programs under this part respecting diseases of the lung and not under this part for programs respecting disease of the blood.

-7-

Change

Reason

AUTHORITY OF THE DIRECTOR OF THE NATIONAL HEART AND LUNG INSTITUTE TO APPROVE GRANTS

Sec. 5. Section 410A of the Public Health Service Act (as so re-designated by section 3 of this Act) is amended by striking out "grants-in-aid" in subsection (4) and inserting in lieu thereof "except as provided in subsection (c), grants-in-aid"; and

(2) by adding after subsection (b) the following new subsection:

(c) under procedures approved by the Director of the National Institute of Health, the Director of the National Heart and Lung Institute may approve grants-in-aid for research and training in heart, blood vessel, lung, and blood diseases:

(1) in amounts not to exceed \$50,000 after appropriate review for scientific merit but without review and recommendation by the Council; and

(2) in amounts exceeding \$5,000 after appropriate review for scientific merit and recommendation for approval by the Council."

CONFORMING AMENDMENTS TO PART B OF TITLE IV OF THE PUBLIC HEALTH SERVICE ACT

Sec. 6. (a) Section 411 of the Public Health Service Act is amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart and Lung Institute"; and

(b) Section 412 of such Act is amended—

(1) by striking out "heart" each place it occurs (except in the heading) and inserting in lieu thereof "heart, blood vessel, lung, and blood";

(2) by striking out "Surgeon General" and inserting in lieu thereof "Director";

(3) by striking out "National Advisory Heart Council" and inserting in lieu thereof "National Heart and Lung Advisory Council";

(4) by redesignating paragraphs (a), (b), (c), (d), (e), (f), and (g) as paragraphs (1), (2), (3), (4), (5), (6), and (7), respectively; and

(5) by amending the section heading to read as follows:

"RESEARCH AND TRAINING IN DISEASES OF THE HEART, BLOOD VESSEL, LUNG, AND BLOOD"

(c) Section 418 of such Act (as so redesignated by section 3 of this Act) is amended—

(1) by inserting "(a)" immediately after "Sec. 418," and by adding the following: "(a) The Council shall advise and assist the Director of the Institute with respect to the Program established under section 413, and at such times and places, as the Council deems advisable to investigate programs and activities of the Program.

(2) The Council shall submit a report to the President for transmittal to the Congress not later than January 31 of each year on the progress of the Program and the amount of the appropriation available therefor."

Report to President to be submitted to Congress not later than January 31 of each year on the progress of the Program and the amount of the appropriation available therefor."

add: "excluding indirect costs"

Add new section 418(d):

"Approve areas of research in heart, blood vessel, lung and blood diseases to be supported by the contract mechanism, including the percentage of the NHLI budget to be expended on contract research."

Renumber sections 418 (d) (e) and (f) as sections 418 (e) (f) and (g).

add: "The President shall

transmit said Report to Congress within 30 days after he receives it."

The Director has not used his authority to approve grants without the action of the Advisory Council This is so because inflation has minimized the number of awards of the indicated size. This authority, however, might be more useful if indirect costs are excluded.

Contract research is becoming increasingly important at the National Heart and Lung Institute. Despite its magnitude there is some question of the authority of the Advisory Council with respect to contract research. Although full disclosure of contemplated contract authority might result in conflict of interest, limited jurisdiction is in the public interest.

See discussion above Re: Director's Report.

74-6218

after he receives it."

Report to President to be submitted to Congress not later than January 31 of each year on the progress of the Program and the amount of the appropriation available therefor."

42 USC 287a. 42 USC 287a.

42 USC 287a.

Reason

Change

66 STAT. 687

(2) by striking out "Surgeon General" each place it occurs (except paragraph (f)) and inserting in lieu thereof "Secretary";

(3) by striking out "heart" each place it occurs and inserting in lieu thereof "heart, blood vessel, lung, and blood";

(4) by striking out "Surgeon General" in paragraph (f) and inserting in lieu thereof "Secretary, the Director of the National Institute of Health, and the Director of the National Heart and Lung Institute"; and

(5) by redesignating paragraphs (a), (b), (c), (d), (e), and (f) as paragraphs (1), (2), (3), (4), (5), and (6), respectively.

(d) Section 410A of such Act (as so redesignated by section 8 of this Act) is amended—

(1) in subsection (a), by (A) striking out "Surgeon General" and inserting in lieu thereof "Secretary"; and (B) striking out "heart" and inserting in lieu thereof "heart, blood vessel, lung, and blood"; and

(2) in subsection (b), by (A) striking out "The Surgeon General shall recommend to the Secretary acceptance of conditional gifts, pursuant to section 501," and inserting in lieu thereof "The Secretary may, in accordance with section 501, accept conditional gifts"; and (B) striking out "heart, and inserting in lieu thereof "heart, blood vessel, lung, and blood";

(e) The heading for part B of such Act is amended to read as follows: "PART B—NATIONAL HEART AND LUNG INSTITUTE".

ADD NEW SECTION:

CONFIDENTIALITY OF GRANT APPLICATIONS

The recent decision of the U. S. Court of Appeals for the District of Columbia in Washington Research Project Inc V. H.E.W. could impair the process of generating new ideas about the fundamental biomedical mechanisms and processes which affect heart disease. This decision makes approved grant applications subject to public scrutiny, whether or not funded. Thus an excellent but unfunded research design could be pirated and this in turn could discourage the initiation of new projects.

"Section (b) of the Public Information Act, 5 U.S.C. 552, [This section does not apply to matters that are:] is amended by adding a new section (10):

"contained in biomedical research grant applications submitted to HEW."

56 Stat. 709.
42 USC 219.

64 Stat. 445.
42 USC 218.

56 Stat. 623
62 Stat. 601
42 USC 445.
42 USC 241.

Revised.

Pub. P. 680.

CONFORMING AMENDMENTS TO OTHER PROVISIONS OF THE PUBLIC HEALTH SERVICE ACT

Sec. 7. (a) Section 217 of such Act is amended—

(1) by striking out "the National Advisory Heart Council," each place it occurs in subsection (a);

(2) by striking out "heart diseases," in subsection (a) and by striking out "heart;" in subsection (b).

(b) Sections 301(c) and 301(f) of such Act are each amended by striking out "National Advisory Heart Council" and inserting in lieu thereof "National Heart and Lung Advisory Council".

REPORT TO CONGRESS

Sec. 8. The Secretary of Health, Education, and Welfare shall carry out a review of all administrative processes under the National Heart and Lung Institute, established by which the National Heart and Lung Institute, under the Public Health Service Act, will operate, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of the Program. Within one year of the date of enactment of this Act, the Secretary shall submit a report to the Congress of the findings of such review and the actions taken to facilitate the conduct of the Program, together with recommendations for any needed legislative changes.

September 19, 1972 - 9 - Pub. Law 92-423

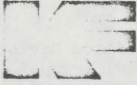
86 STAT. 687

EFFECTIVE DATE

Sec. 9. This Act and the amendments made by this Act shall take effect on the date of enactment of this Act or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register. Approved September 19, 1972.

LEGISLATIVE HISTORY

HOUSE REPORTS: No. 92-1108 accompanying H.R. 15081 (Comm. on Interstate and Foreign Commerce) and No. 92-1249 (Comm. of Conference).
SENATE REPORTS: No. 92-1249 (Comm. on Labor and Public Welfare) and No. 92-1288 (Comm. of Conference).
CONGRESSIONAL RECORD, Vol. 118 (1972):
Apr. 7, considered and passed Senate.
July 18, considered and passed House, amended in lieu of conferees report.
Aug. 19, House agreed to conferees report.
Sept. 5, Senate agreed to conferees report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 8, No. 39: Sept. 20, Presidential statement.



NATIONAL KIDNEY FOUNDATION

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MEMORANDUM

TESTIMONY

OF

JAMES C. HUNT, M.D.

PRESIDENT, NATIONAL KIDNEY FOUNDATION

BEFORE

THE COMMITTEE ON LABOR AND PUBLIC WELFARE

SUBCOMMITTEE ON HEALTH

UNITED STATES SENATE

MARCH 17, 1975

Chairman Kennedy and members of the Subcommittee:

On behalf of the National Kidney Foundation and its Affiliated Divisions it is my privilege to present comments and suggestions concerning the National Heart, Blood Vessel, Lung and Blood Act, Public Law 92-432, as outlined in detail in this document which I wish to submit.

I am James C. Hunt, M.D., President of the National Kidney Foundation and Professor and Chairman of Medicine, Mayo Clinic and Mayo Medical School. My concern is to express to you, and to the members of the Subcommittee, some of the observations and recommendations of the lay and professional volunteers of the National Kidney Foundation with respect to the National Heart, Blood Vessel, Lung and Blood Act as described in Public Law 92-432. My comments here today are intended to support the more detailed recommendations of my colleagues and friends, Elliot Rapaport, M.D., President of the American Heart Association and Charles Fisch, M.D., President of the American College of Cardiology.

The Committee on Health and Scientific Affairs of the National Kidney Foundation has carefully reviewed the provisions of Public Law 92-432, the National Heart, Blood Vessel, Lung and Blood Act of 1972. We have studied and are well familiar with the recommendations of the American Heart Association as presented by Dr. Elliot Rapaport, President, which urges the extension of the National Heart, Blood Vessel, Lung and Blood Act through June 30, 1978. In our judgment, the specific authorizations levels and suggested funding levels are responsible and realistic. With due consideration to the state of the economy in the United States we feel that there is an ideal opportunity to make authorization and appropriation levels more in keeping with the realities of program development. In the past, all too often the gap between expectations of authorization and the actual funding has created uncertainties and skepticism in the mind of providers and consumers. Hypertension, atherosclerosis, diseases

of the blood vessels, heart, lung, kidney and cerebral circulation are realities which must be recognized, acknowledged and addressed by the health care profession, the public and the Congress. You, the members of the Subcommittee, the public at large and I must consider ourselves "at risk". Heart attack, stroke, kidney failure and a variety of lung and blood diseases account for more than 70 percent of deaths in the United States each year. The financial cost and hardships to those citizens surviving the immediate crisis manifestations of the described disease processes are beyond reasonable description but amount to several billions of dollars in lost wages alone each year. We cannot ignore the effect of these diseases on the productivity of the citizens and on the economy of this country.

Mr. Chairman, you are aware that there is a close relationship between diseases of the heart and circulation and the kidney. The single most common cause of heart attack, stroke and kidney failure is high blood pressure (hypertension). Sustained hypertension almost invariably results in atherosclerosis with impaired circulation to the heart, brain, kidney and other vital functioning organs. The Congress has authorized significant funding for the National Heart and Lung Institute, the National Institute of Arthritis, Metabolism and Digestive Diseases and the other Institutes and Federal Agencies for the support of research and health care program development in these vital problem areas. The Congress has been responsive to needs of the public with respect to medical care and health care. For example, a considerable amount of the total Federal commitment in kidney related basic research and demonstration programs has been funded under the provisions of The National Heart, Blood Vessel, Lung and Blood Act of 1972 (Public Law 92-432). Section 299I of Public Law 92-603 has provided for the establishment of an end-stage renal disease program (ESRD) which allows Medicare coverage for dialysis and renal transplantation for individuals with permanent kidney failure.

Mr. Chairman, the Congress and the public are aware that the single most common cause of ESRD is arterial hypertension. During the past decade great advancements have been made in the treatment and care of individuals with end-stage renal disease through hemodialysis and renal transplantation; however, the hard fact remains that we do not have a cure for many of the diseases which cause kidney failure. We do have available sufficient know-how, technology and chemotherapeutic agents to control hypertension and to prevent kidney failure resultant therefrom. Prevalence data indicate that at least one out of every eight, more than 25 million adult Americans, has hypertension. Tragically, not more than 25 percent of this enormously large hypertensive population is receiving what most of us consider to be minimally satisfactory medical treatment. Probably less than 15 percent of individuals with hypertension have good blood pressure control.

The National Heart, Blood Vessel, Lung and Blood Act of 1972 provides for a major commitment of effort and resources for the establishment of research and demonstration programs in high blood pressure and other related problems. The National Heart and Lung Institute has been responsive to the directives of the Congress. Fully cognizant of the importance of research contributions by the professional community, it is the judgment of the Committee on Health and Scientific Affairs of the National Kidney Foundation that one of the most important contributions of the National Heart and Lung Institute has been its development of a National High Blood Pressure Education Program. As a result of the charge by former Secretary of Health, Education and Welfare, Elliot Richardson, the NHLI instituted a public information and education program to acquaint the citizens of this country of the dangers of high blood pressure. Under the able leadership of Dr. Theodore Cooper, a national campaign was inaugurated two years ago. Secretary Weinberger and Former Assistant Secretary for Health, Charles C. Edwards have afforded strong support for this program.

The American Heart Association, the National Kidney Foundation and a number of other volunteer and professional groups have strongly supported and contributed to the effort. Financial support has in part come from industry. Public education to date seems more productive than professional education. Much has been accomplished, but much remains to be done. For if we can accomplish effective public and professional campaigns, the control of high blood pressure will probably do more to prevent disability or early death from heart attack, stroke and end-stage renal disease than any other accomplishment by the National Heart and Lung Institute. Indeed, the relationship between hypertension and the ravages of blood vessel and kidney disease ^{is} ~~is~~ very real. The Federal fiscal support for the National High Blood Pressure Education Program ^{and support} for Centers of Excellence in Research and Demonstration is unreal. Therefore, we urge that the Subcommittee carefully consider and approve the American Heart Association's recommendations for funding of research grants and intramural and extramural research and demonstration programs of the National Heart and Lung Institute.

The National Health Planning and Resources Development Act of 1974 (Public Law 93-641) defines a number of most important "National Health Priorities". Included is a charge with respect to "the promotion of activities for the prevention of disease, including the studies of nutritional and environmental factors affecting health and the provision of preventive health care services; and the development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services". Heart, blood vessel and kidney diseases, especially as caused and aggravated by hypertension, are profoundly influenced by nutrition and environment. Previous investigations clearly have demonstrated nutrition and environment to be significant factors in heart and kidney disease management and control, especially for the person with hypertension.

It is probable that more than 50 percent of drug treatment failures in the management of hypertension result from inadequate provision for control of sodium, saturated fats, cholesterol, and calories in the diet or consideration of the patient's work environment, or both, when developing a management program. We are of the judgment that the National Health Planning and Resource Development Act will provide great benefit to the public at large. Public Law 93-641 does not, of course, provide for the training of investigators nor research and demonstration programs in heart and kidney diseases. However, the intent of Public Law 93-641 would be effected through the expansion of existing programs of the National Heart and Lung Institute which provides for research, research training, early detection and appropriate management of high blood pressure and other common diseases ~~which can effectively be accomplished~~ through the renewal of the National Heart, Blood Vessel, Lung and Blood Act of 1972. We believe that the Congress is committed to the concept of conjoint program development and integration as might be effected in the above instances and that you will provide adequate authorization and appropriations to the National Heart and Lung Institute so that its multiple programs might be continued and expanded.

It is difficult for us to suggest what might have happened in the reduction of heart, blood vessel and kidney diseases had the Congress appropriated the suggested monies which would have allowed the National Heart and Lung Institute to move ahead with its funding of centers for Research and Demonstration as originally visualized. Indeed, only one Heart Center has been funded. Many thousands of dollars have been expended by the Health Science Centers in preparing requests for funds to support research and demonstration projects. Heart Center monies simply have not been available and the requests for proposals under the circumstances were probably ill advised if not detrimental to the

overall health mission. We urge the Committee to consider carefully the concept of mandating at least one National Research and Demonstration Center for Heart and Blood Vessel Diseases in each Health, Education and Welfare region. How else might the benefits of medical science be transmitted to the public?

Mr. Chairman, the lay and professional volunteers of the National Kidney Foundation are fully aware of your commitment to the development of health care and medical care programs desperately needed by the American public. We stand available to add our counsel and assistance to the Congress in its deliberations on behalf of public need.

Again, we deeply appreciate this opportunity to make available to you and to the members of the Committee our recommendations in support of the renewal of the National Heart, Blood Vessel, Lung and Blood Act of 1972.

Senator KENNEDY. Our next witnesses will present the views of the Association of American Medical Colleges, Dr. Sherman, vice president of the association, and also Dr. Morgan, who is the director of the division of biomedical research.

We are happy to welcome you back to the committee.

STATEMENT OF JOHN F. SHERMAN, Ph. D., VICE PRESIDENT OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ACCOMPANIED BY THOMAS E. MORGAN, M.D., DIRECTOR, DIVISION OF BIOMEDICAL RESEARCH

Dr. SHERMAN. Thank you, Senator. It is my particular pleasure this morning to introduce to the subcommittee my associate, Dr. Thomas Morgan, who left Seattle, Wash., recently to become head of our division of biomedical research. Dr. Morgan is a former professor of medicine at the medical school at the University of Washington and also, by chance, a former member of the council concerned with the legislation which you have before you today.

If agreeable, perhaps it would be best to conserve time and spend a little more time on some of the other subjects that have come up this morning if I were to excerpt from our prepared statement and let the rest—

Senator KENNEDY. The statement will appear in the record in whole at the conclusion of your testimony.

Dr. SHERMAN. Mr. Chairman, the Association of American Medical Colleges welcomes this opportunity to appear before the subcommittee during its consideration of the extension of legislation supporting heart and related research, and biomedical research training.

The association is anxious to comment on the legislative proposals because of the important role of the Nation's medical schools in the Nation's attack upon diseases of the heart, blood vessels, lungs, and blood and in biomedical research training.

We also wish to comment on two closely related issues, the tender of the directorship of the National Institutes of Health and the confidentiality of research grant application documents.

When the National Heart, Blood Vessel, Lung and Blood Act of 1972 was under consideration, the association strongly supported the legislation and urged its enactment. Now, in considering the first extension of those authorities, the association remains a strong advocate for them and recommends enactment of legislation to continue the programs. A few relatively minor substantive modifications are being proposed by the association.

Following is a summary of the association's recommended changes in the 1972 or existing legislation, and our statement expands on those recommendations. We recommend:

One: A 3-year extension of the present authorities at levels recommended by the National Heart and Lung Advisory Council. We understand, however, the logic of the proposal in the subcommittee bill to establish a 2-year term so as to make certain authorities coterminous in their dates.

Two: We suggest a modification of the present earmarking of appropriations for diseases of the lung and blood so as to preserve the categorical thrust of these pieces of legislation, but to improve pro-

grammatic flexibility in order that the programs will be most effective and the funds will be most efficiently spent, and we have language available which will include a requirement for prior notification to Congress of any deviations from the present earmarking.

Three: We propose exemption of authorized experts or consultants from departmental personnel ceilings presently in the legislation so as to make this language similar to that in the National Cancer Act and, therefore, except from the ceiling imposed by higher headquarters on that particular institute.

We would also suggest that the committee look carefully at the need for improvement of regular staffing levels for that particular institute and others in NIH.

Four: We recommend modification of the timing and availability of the annual report on the programs so as to make it more useful to the Congress in its legislative and oversight activity.

Five: We propose a provision for National Heart and Lung Institute administration of support for clinical and research training in connection with its programs to be certain that the manpower necessary for the carrying out of those programs successfully will indeed be available; and,

Six: A series of modifications which reflect the Institute's increasing involvement in the management of blood resources.

We have given recommendations for authorization for the Institute's program as mentioned and as recommended by the National Heart and Lung Advisory Council after their extensive study of the fiscal needs of these various programs, including the control activities.

The recommended research authorizations represent a professional judgment of the appropriate Federal participation in heart and lung research, given present and reasonably expected research opportunities. These levels are concurred in by the National Heart and Lung Advisory Council.

In particular, the staffing problems, as you, I think, are well aware, Mr. Chairman, have plagued not only the National Heart and Lung Institute, but others at NIH, and we suggest or reiterate our previous mentioned concern that these staffing levels are inadequate for the carrying out of the programs for which legislation has been passed.

In particular, we suggest that the same language used in the National Cancer Act providing for that exemption be also applied to this legislation.

The association's comments on the general issue of biomedical research training appear elsewhere in this statement. In connection with heart and lung research, the association is concerned that the NHLI have authority to administer research training support in fields related to the national plan. This is because it is not clear that such authority presently exists.

Turning to the subject of research training, the association has several comments for the subcommittee's consideration on the extension of the National Research Service Awards Act. These comments are based on the association's firm belief that a strong, viable program of research training is absolutely essential in producing the numbers and quality of skilled biomedical scientists needed to carry out the Nation's future biomedical investigations.

Without these programs of training in the most sophisticated research methodologies, our scientific efforts and advances will be retarded seriously, since our knowledge and understanding are necessarily limited by the quality and flexibility of our methodology.

And we have the following recommendations for your consideration :

First of all : The clarification of the term predoctoral training. Since there appears to be some doubt, particularly in the minds of some in the administration, as to the meaning of that particular phrase, we are also particularly concerned about the apparent position of the Office of Management and Budget restricting the availability of predoctoral training in their interpretation of the language in the planning of training programs.

Second : We would suggest a clarification of payback requirements for individuals not trained to provide health services, particularly those seeking the doctor of philosophy degree.

Three : We propose that the subcommittee consider strongly the need to reinstate eligibility for training at Federal institutions such as Public Health Service hospitals and Veterans Administration hospitals.

Four : We recommend modifications in authority of the study group, since it appears that perhaps too much authority has been given to groups outside the Federal structure.

Five : We suggest a later date for submission of the study in order to make its application much more effective.

And, similarly, six : A change in the effective date by which the National Institutes of Health must employ the results of that study in the implementation of their programs.

And, seven : A 2-year extension of the national research service award program as provided for in S. 988.

To elaborate very briefly, the association's first recommendation is that the legislative history of the extension clarify the original intent of the act to include in the term predoctoral those individuals seeking the Ph. D. as well as those seeking the M.D. degree. This clarification would foreclose attempts to deny eligibility to individuals in Ph. D. programs and would insure that individuals in both Ph. D. and M.D. degree programs are accorded equal opportunities for training.

The association suggests that there be clarification of the act's intent to permit individuals not trained to provide health services to pay back their obligation in accordance with normal patterns of academic employment. Under these patterns, researchers do not carry out a full year of pure research or pure teaching, but alternate research, teaching, and other related pursuits, and we have language to implement this suggestion.

The time frame for the report of the National Academy of Sciences does not provide sufficient time for NIH to complete its report, and the association, therefore, suggests that appropriate changes be made so as to make that more appropriate.

And, similarly, with respect to the effective date closely related to this, the time frame for the issuance of the training announcements based on the National Academy study is not sufficient for the NIH to issue subsequent training announcements based on the content and recommendations of the report. The association, therefore, recommends language to clarify and make more appropriate that relationship.

And, last, the association has prepared recommendations for legislative authorizations and recommends that the 2-year program suggested by the legislation be extended.

In addition to its comments on the heart and research training legislation, the association would like to alert the subcommittee to two basic issues which affect not only the heart and training programs, but virtually all programs sponsored by the National Institutes of Health. These issues are the tenure of the director of the NIH and the confidentiality of research grant documents.

With respect to the director of NIH, the association believes that the establishment of a statutory term of office for that official is essential to the continuity of the leadership in biomedical research. Federal support of this research is a nonpartisan activity and its leadership should be equally nonpartisan.

It is imperative that the director of the national biomedical research effort be a highly qualified individual, with a background and training in biomedical research and administration, who is selected without regard to political affiliation. The administration of the research effort will be best served by the nonpolitical transition from one director to the next, with careful congressional review of the scientific qualifications of proposed directors.

In order to meet these goals, the association strongly urges the subcommittee to provide a statutory term of 6 years for the director of NIH and to make appointment subject to Senate confirmation. Language is also suggested for this purpose.

I might add that the AAMC recognizes that this language does not guarantee stability in the position of the director of NIH, but there is a general feeling that this language would be helpful for two reasons.

First: It would stimulate careful consideration of the qualifications of individuals considered for appointment to the position.

Second: It would stress the importance of reasonable stability in that position.

The language we recommend is patterned on that which presently governs the appointment of the director of the National Science Foundation.

Last: The matter of confidentiality of research grant documents. Under a recent court ruling data in research grant applications is subject to public disclosure. Under the court's interpretation—this is both the district court and the appellate court—exemption 4 of the Freedom of Information Act, which is designed to protect commercial trade secrets, does not apply to the research protocols for funded research grants awarded by the National Institutes of Health and the National Institute of Mental Health.

The association believes that confidentiality of these documents is essential and that public disclosure will produce deleterious consequences.

The information provided in grant applications submitted to the NIH is treated as confidential. Because research scientists and academic clinicians owe their advancement and standing in the scientific community to their original research contributions, their creative ideas are of critical importance, and research scientists carefully protect their ideas.

Thus, to the scientist and to the research clinician, research designs and details of protocols are regarded and treated as proprietary information, just as trade secrets are protected by the commercial and industrial sector.

If vigorous competition in health research is to be encouraged, the NIH or any other Federal agency must respect applicants' ideas and protect them. If they cannot be assured of this confidentiality, the NIH peer review system and its encouragement of scientific competition and quality could not be sustained. Scientists would not supply the explicit details of their proposed research approach and methodology essential for competent review, and the NIH ability to obtain evaluation of scientific merit for further programmatic judgments would be markedly hampered.

We recognize that the Congress and the public have a fundamental right to know how Federal revenues are being spent. It suggests then that when awards are made the names of recipients of awards and a brief description of research design should be published and that details of research applications should be public information 1 year after an award is made. This procedure would allow the applicant a reasonable opportunity to develop and test the research design, while safeguarding the public's right to know.

And we have included in our statement, Mr. Chairman, a draft of the proposed language.

We believe this amendment would be an important and significant step in preserving the high quality of health research in this country. Thank you.

Senator KENNEDY. Thank you very much.

I suppose you are aware that last year the committee held rather extensive hearings on the issue of medical experimentation on humans and we found very unethical and unsafe experiments being conducted on children and prisoners and other helpless groups.

Now, if we allow the protocols to be withheld from the public, how can persons or groups who are interested in protecting these human subjects learn about what is going on?

Dr. SHERMAN. Mr. Chairman, I think there are two ways in which the public interest is protected, and I realize that this is a somewhat indirect answer to your questions.

In the first place, it is our feeling that the trend in the discussion being held by the ethics commission set up under title II of the Research Training Act will not only bring to public attention but also devise a series of approaches and guidelines, as well as the methodology, by which the public interest will be well served.

Senator KENNEDY. Do you think it would be worthwhile to ask them their view on this particular amendment?

Dr. SHERMAN. I should think so. The whole subject is such a complex one that obviously some compromises between protection of privacy, whether it be of the individual involved in an investigation or a scientist involved, both of whom have the right to be protected, deserves as much exploration of these complicated issues as possible.

I would suggest that the second consideration, which also would seem to serve the public interest well, is indeed the fact that in the preparation of an application, an individual scientist is required to submit, as was noted earlier by administration witnesses, a general

outline of the proposed investigation, and one can readily tell from the contents of that outline whether or not individual human subjects are involved in that investigation and the purpose and nature without disclosing the details of the individual protocol.

Additionally, the following up on some of these very complicated studies, information of the sort in these detailed protocols would be made available after a period of time. The sense is that these other matters would give adequate protection and, therefore, adequate information if a public interest group is seeking information.

Senator KENNEDY. What about limiting the amendment to those proposals or applications which do not involve human subjects?

Dr. SHERMAN. This is a matter which we have considered, but I must admit, Senator, not thoroughly, and I would like to ask Dr. Morgan to comment on that because of his recent involvement in studies of this nature and his service on advisory groups such as study section and the council.

Dr. MORGAN. Senator, I think the suggestion that Dr. Sherman made to wait for the results of the president's or the Ethics Commission for the protection of human subjects, that we ought to give serious consideration to both hearing from them and to wait for their results.

I think that you will be reassured, as I have been, having followed very closely, having been present at all those hearings recently and proceedings—you will be reassured to see the progress which is being made by this very distinguished group of ethicists, lawyers, and scientists, and I feel certain that many of the excesses which have occurred in the past will be corrected.

I would not like to see us impose another structure which would in some cases prejudice their recommendations and the mechanisms which they will set up. In other words, I would hope that the disclosure amendment which we are proposing would be accepted and that no attention be given to the human subject protection pending the results of this very active commission.

Senator KENNEDY. I do not follow your reasoning. It would seem to me best to wait until they make their report and then act, rather than act and then await their report.

Dr. MORGAN. My reasoning is principally administrative because we see at the council level a number of difficult situations arising in which we would have two sets of conflicting administrative regulations or procedures to follow, and that is my primary reason.

Senator KENNEDY. And you do not draw a distinction between whether it involves humans or not?

Dr. MORGAN. No. I think the majority of the 3- to 5-year grants which are proposed generally—and certainly two-thirds of them—will start at the laboratory bench and very soon, as soon as practicable, move into the application to human problems. Biomedical research is by nature that sort of process, so most of these proposals would, since they have a 3- to 5-year span—would involve human research or human trials or the implications would be there. So there would be very few grant applications which might be picked up which would not—which would be protected by this amendment.

Dr. SHERMAN. If I may add a word on that, Senator Kennedy, we would suggest that there are two risks here, one of which seems to

be to one system and its methodology, scientific investigation; the other, the protection of human beings.

In the first, a system which was built largely on faith, that is, the review of grant applications at NIH, which seems to substantiate that investment of faith for many years now, may be very well inadvertently threatened by this particular court action wherein even Judge Cassell, phonetic, himself when he handed down the decision indicated that he felt that he had no recourse but to find in interpreting that law in a very, very narrow fashion, that is, with respect to commercial trade secrets.

On the other hand, we feel that with the existence now of the Ethics Commission, with the regulations presently in force, certain temporary bans on particular types of research, and the possibility of that group coming out with recommendations in the relatively new future that the rights of human beings involved are adequately protected at this time.

The system which has served the country well in other respects is rather seriously threatened.

You, yourself, have expressed on numerous occasions, and properly so, your concern about the threats to the peer review system, and this one situation is a good example of such a threat.

Senator KENNEDY. Do you think that HEW will go along?

Dr. SHERMAN. I think there is no question that the NIH would support this. As far as I am aware, there is no opposition to this type of approach within HEW.

Senator KENNEDY. Finally, on research training, should that be limited to the postdoctoral training?

Dr. SHERMAN. No, sir. We feel very strongly that the intent of the Congress in that original legislation, borne out by the legislative history, was to include predoctoral training and very properly so, and we feel it would be most unfortunate to limit the authority in that bill just to postdoctoral training.

Senator KENNEDY. Thank you very much.

[The prepared statement of Dr. Sherman follows:]



ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

STATEMENT BY THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES
ON THE EXTENSION OF THE NATIONAL HEART, BLOOD VESSEL, LUNG AND BLOOD ACT
AND THE NATIONAL RESEARCH SERVICE AWARD ACT*

Mr. Chairman and members of the subcommittee:

The Association of American Medical Colleges welcomes this opportunity to appear before the subcommittee during its consideration of the extension of legislation supporting heart and related research, and biomedical research training.

Now in its 98th year, the Association represents the whole complex of persons and institutions charged with the undergraduate and graduate education of physicians. It serves as a national spokesman for all of the 115 operational U.S. medical schools and their students, 400 of the major teaching hospitals, and 52 learned academic societies whose members are engaged in medical education and research.

The Association is anxious to comment on these legislative proposals because of the important role of the nation's medical schools in the nation's attack upon diseases of the heart, blood vessels, lungs, and blood, and in biomedical research training. The Association is also anxious to comment on two closely related issues -- the directorship of the National Institutes of Health and the confidentiality of research grant application documents.

* Presented by John F. Sherman, Ph.D., Vice President of the Association of American Medical Colleges, before the Subcommittee on Health of the Senate Labor and Public Welfare Committee, March 17, 1975.

Heart and Lung Research

When the National Heart, Blood Vessel, Lung and Blood Act of 1972 was under consideration, the Association strongly supported the legislation, and urged its enactment. Now, in considering the first extension of those authorities, the Association remains a strong advocate for them, and recommends enactment of legislation to continue the programs. A few, relatively minor, substantive modifications are being proposed by the Association.

Association recommendations

Following is a summary of the Association's recommended changes in the 1972 legislation. Further explanation follows the recommendations. The Association recommends --

1. A three-year extension of the present authorities at levels recommended by the National Heart and Lung Advisory Council;
2. Modification of the present earmarking of appropriations for diseases of the lung and blood;
3. Exemption of authorized experts or consultants from departmental personnel ceilings;
4. Modification of the timing and availability of the annual report on the programs;
5. Provision for NHLI administration of support for clinical and research training in connection with its programs; and
6. A series of modifications which reflect the Institute's increasing involvement in the management of blood resources.

Authorization levels: The Association recommends authorizations for the Institute's various research activities of \$479 million in fiscal 1976, \$580 million in fiscal 1977, and \$600 million in fiscal 1978. These compare to a fiscal 1975 authorization of \$475 million and Congressional ap-

propriation of \$324 million. For the Institute's control programs, the Association recommends authorizations of \$15 million in fiscal 1976, \$32 million in fiscal 1977, and \$34 million in fiscal 1978. These compare to a fiscal 1975 authorization of \$45 million and Congressional appropriation of \$3 million. (Details of these figures are provided in the table on the following page.)

The recommended research authorizations represent a professional judgment of the appropriate federal participation in heart and lung research, given present and reasonably expected research opportunities. These levels are concurred in by the National Heart Lung Advisory Council.

The recommended authorizations for the control programs reflect deep professional concern with the present development and operation of these programs. They have been put in place by the Institute through the diversion of scarce funds and personnel from other underfinanced and understaffed programs. Appropriations for the control programs need to be substantially increased. Those increases could be provided under the Association's recommended authorization levels. The Association is concerned that unrealistically high authorization levels could unduly arouse public expectations.

Earmarking of appropriations: Perhaps no section of the 1972 legislation has received more attention within the field than the earmarking of at least 15 percent of appropriated funds for lung diseases and 15 percent of appropriated funds for blood diseases. The principal concern has been the administrative inflexibility that such earmarking imposes, leaving no place for professional judgment based on a deep knowledge and understanding of research opportunities. At the same time, earmarking, or similar techniques, are useful legislative devices for drawing administrative attention to important activities. The Association considers it desirable to avoid the present inflexibility without giving up the intent of

Association of American Medical Colleges' Recommended Annual Budgets for the National Heart and Lung Institute
for Fiscal Years 1976-78
(Dollars in Thousands)

Program Activities	FY 1974 (Actual)	FY 1975 (Appropriation)	FY 1976 (Recommended)	FY 1977 (Recommended)	FY 1978 (Recommended)
Research Projects and Program Projects	\$149,147	\$145,000	195,000	\$231,500	\$243,100
Special Projects Heart Co-op Drug Study	4,897	886	---	---	---
SCOR	24,444	36,563	40,000	42,000	45,000
Control Programs	1,065	3,000	15,000	31,800	33,700
Research Professorships	---	---	5,000	12,000	12,700
Professorial Research Groups	---	---	8,000	18,000	19,000
National R & D Centers	---	6,405	20,000	48,000	54,000
Construction	---	---	60,000	45,000	30,000
Manpower Development	19,394	20,000	32,000	33,000	34,600
Intramural Research	22,348	24,000	25,000	27,500	30,300
R & D Contracts	89,534	70,780	76,000	100,000	110,000
Management & Program Services	<u>15,371</u>	<u>17,396</u>	<u>18,000</u>	<u>19,000</u>	<u>20,000</u>
TOTAL, NHLI	\$326,200	\$324,130	\$494,000	\$607,800	\$632,400

the earmarking. To do this, it recommends that the second sentence of present section 419B be amended to read as follows:

"Of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums or such lesser amount as the Secretary may determine shall be reserved for programs under this part respecting diseases of the lung and not less than 15 per centum of such sums or such lesser amount as the Secretary may determine shall be reserved for programs under this part respecting blood diseases and blood resources, provided that the Secretary shall not make such a determination without prior notification to the Congress."

Staffing changes: A number of staffing problems have plagued the Institute and affected its various programs and activities. Two remedies seem to suggest themselves, and the Association recommends them both. One recommendation is for the Institute Director's rolling five-year plan, required by present section 413(b)(2), to include estimates of staff required to carry out the plan. The other recommendation is to exempt from Departmental personnel ceilings the experts or consultants the Institute Director may employ under present section 413(c)(1).

Reporting procedures: There is a growing concern that many of the administrative reports mandated by Congress fail to meet their principal objective of providing timely and useful information to the Congress. In terms of the Institute's programs, there seems to be a particular problem with the Director's annual update on the five-year plan. The Association recommends two changes in connection with this report, which the Congress may wish to consider for application to other reports as well. One change is to shift the timing of the report from the end of the calendar year to the end of the fiscal year; the other change is to provide for simultaneous submission of the report to Congress and the President.

Research training: The Association's comments on the general issue of biomedical research training appear elsewhere in this statement. In connection with heart and lung research, the Association is concerned that the NHLI have authority to administer research training support in fields related to the

national plan. It is not clear that such authority presently exists.

Blood resources: Since enactment of the 1972 legislation, the Institute has become increasingly active in the management of blood resources. The blood diseases and blood resources program is vitally important in its own right, and also is intimately related to the Institute's responsibilities in both cardiovascular and pulmonary diseases. At the end of this statement is a copy of the 1972 law modified to reflect the Institute's greater role in blood resource management. The Association recommends enactment of these modifications.

Research Training

The Association has several comments, for the subcommittee's consideration, on the extension of the National Research Service Awards Act. These comments are based on the Association's firm belief that a strong, viable program of research training is absolutely essential in producing the numbers and quality of skilled biomedical scientists needed to carry out the nation's future biomedical investigations. Without these programs of training in the most sophisticated research methodologies, our scientific efforts and advances will be retarded seriously, since our knowledge and understanding are necessarily limited by the quality and flexibility of our methodology.

Association recommendations

Following is a summary of the Association's recommended changes --

1. Clarification of the term "predoctoral" training.
2. Clarification of pay back requirements for individuals not trained to provide health service.
3. Reinstatement of training at federal institutions.
4. Modifications in authority of the study group.
5. Later date for submission of the study.
6. Change in the effective date.
7. Two-year extension of the National Research Service Award program.

Predoctoral training: The Association's first recommendation is that the legislative history of the extension clarify the original intent of the Act to include in the term "predoctoral" those individuals seeking the Ph.D. as well as those seeking the M.D. degree. This clarification would foreclose attempts to deny eligibility to individuals in Ph.D. programs and would insure that individuals in Ph.D. and M.D. degree programs are accorded equal opportunities for training.

Pay back: The Association suggests that there be clarification of the Act's intent to permit individuals not trained to provide health services to pay back their obligation in accordance with normal pat-terms of academic employment. Under these patterns, researchers do not carry out a full year of pure research or pure teaching, but alternate research, teaching, and other related pursuits.

To implement this suggestion, the Association recommends that Section 472(c)(1)(A)(i) and Section 472(c)(2)(A) of the Public Health Service Act be amended by adding the words "or any usual combination thereof" after the word "teaching".

Eligibility: The Association is concerned that research training at federal institutions (Veterans Administration hospitals, Public Health Service hospitals, etc) was inadvertently repealed by PL 93-348. To reinstate these programs, the Association recommends that Sections 472 (a)(1)(A)(iii) and 472 (a)(1)(B) be amended by deleting the term "non-Federal".

The Association would also like to make recommendations concerning the procedural aspects of the studies and reports mandated by the National Research Service Awards Act.

Study group: The present language of the Act places excessive authority over the direction of federal biomedical research programs in the hands of the study group. The Association believes that there should be greater Congressional and Administrative control over policies and priorities. To accomplish this objective, the Association recommends that Section 473(a) be amended by:

1. Inserting before the words, "The Secretary" the words, "in order to provide guidance for federal policies respecting the training of biomedical and behavioral research personnel,";
2. Deleting in subsection (1) the word "establish" and inserting in lieu thereof "estimate"; and

3. Deleting in subsection (5) the words "determine" and "established", and inserting in lieu thereof, "recommend" and "estimated", respectively.

NAS report: The time frame for the report by the National Academy of Sciences does not provide sufficient time for the National Academy to complete its report. The Association therefore recommends that Section 473(c) be amended by deleting "March 31" and inserting in lieu thereof "September 30".

Effective date: Closely related, the time frame for the issuance of training announcements based on the NAS study is not sufficient for the NIH to issue subsequent training announcements based on the contents of the report. The Association therefore recommends that Section 472(a)(3) be amended by deleting the words, "Effective July 1, 1975" and by inserting in lieu thereof, "Nine months after the final report of the study of the National Academy of Sciences is released".

Authorization: The Association has prepared recommendations for legislative authorizations. The Association recommends that the National Research Service Award Act be extended for two years, and that Section 472(d) be amended by deleting the period after "1975" and inserting in lieu thereof the following: ", and such sums as may be necessary for the fiscal periods ending June 30, 1976; September 30, 1976; and September 30, 1977." This language would provide funding for fiscal years 1976 and 1977, plus the three-month interim period established by the Congressional Budget and Impoundment Control Act (PL 93-344).

Additional Recommendations

In addition to its comments on the heart and research training legislation, the Association would like to alert the subcommittee to two basic issues which affect not only the heart and training programs, but virtually all programs sponsored by the National Institutes of Health. These issues are the tenure of the director of the NIH, and the confidentiality of research grant documents.

Statutory Term for NIH Director

The Association believes that the establishment of a statutory term of office for the Director of the National Institutes of Health is essential to the continuity of leadership in biomedical research. Federal support of this research is a nonpartisan activity, and its leadership should be equally nonpartisan. It is imperative that the director of the federal biomedical research effort be a highly qualified individual, with a background and training in biomedical research and administration, who is selected without regard to political affiliation. The administration of the research effort will be best served by the nonpolitical transition from one director to the next, with careful Congressional review of the scientific qualifications of proposed directors.

In order to meet these goals, the Association strongly urges the subcommittee to provide a statutory term of six years for the Director of the NIH and to make appointment subject to Senate confirmation. The Association recommends that S.988 be amended to include the following revision of Section 471 of the Public Health Service Act:

"The Director of the National Institutes of Health shall be appointed by the President, by and with the advice and consent of the Senate, and shall serve for a term of six years unless sooner removed by the President. The Director of the National Cancer Institute shall be appointed by the President. Except as provided in section 407 (b)

(9), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health."

The Association recognizes that this language does not guarantee stability in the position of Director, NIH, but there is a general feeling that this language would be helpful for two reasons. First, it would stimulate careful consideration of the qualifications of individuals considered for appointment to the position. Second, it would stress the importance of reasonable stability in that position. This language is patterned on that which presently governs the appointment of the Director, National Science Foundation.

Confidentiality of Research Grant Data

Under a recent court ruling, data in research grant applications is subject to public disclosure. Under the court's interpretation, Exemption 4 of the Freedom of Information Act (which protects commercial trade secrets) does not apply to the research protocols for funded research grants awarded by the National Institutes of Health and the National Institute of Mental Health. The Association believes that confidentiality of these documents is essential, and that public disclosure will produce deleterious consequences.

The information provided in grant applications submitted to the NIH is treated as confidential. Because research scientists and academic clinicians owe their advancement and standing in the scientific community to their original research contributions, their creative ideas are of critical importance, and research scientists carefully protect their ideas. Thus, to the scientist and to the research clinician, research designs and protocols are regarded and treated as proprietary information, just as trade secrets are protected by the commercial and industrial sector. If vigorous competition in health research is to be encouraged, the NIH must respect applicants' ideas and protect them. If they cannot be assured of this confidentiality, the NIH peer review system and its encouragement of scientific competition could not be sustained. Scientists would not supply the explicit details of their proposed research approach and methodology essential for competent review, and the NIH ability to obtain effective evaluation of scientific merit for further programmatic judgments would be markedly hampered.

The Association recognizes that the Congress and the public have a fundamental right to know how Federal revenues are being spent. It suggests that, when awards are made, the names of recipients of awards and a brief description of research design should be published,

and that details of research applications should be public information one year after an award is made. This procedure would allow the applicant a reasonable opportunity to begin to develop and test the research design, while safeguarding the public's right to know.

The Association therefore recommends that the Public Health Service Act be amended by adding the following new subsection:

"301(j): Disclose to the public information of a proprietary or confidential nature (including any detailed research protocol, research hypothesis, or research design) in the records or possession of the Public Health Service obtained in connection with an application or proposal for a grant, fellowship, or contract either with the consent of the applicant or proposer or on condition that at least one year has elapsed following acceptance by the applicant or proposer of a grant, fellowship, or contract award based upon said application or proposal."

This amendment would be an important and significant step in preserving the high quality of health research in this country.



Public Law 92-423
92-1 Congress, S. 3323
September 19, 1972

Bill Act

To amend the Public Health Service Act to enlarge the authority of the National Heart, Lung, and Blood Institute to conduct research to reduce the national attack against diseases of the heart and blood vessels, the lungs, and blood, and for other purposes.

As it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

National Heart,
Lung, and Blood
Act of 1972.

SHORT TITLE

SECTION 1. This Act may be cited as the "National Heart, Lung, and Blood Act of 1972."

PURPOSE AND DECLARATION OF PURPOSE

SEC. 2. (a) Congress finds and declares that—

- (1) diseases of the heart and blood vessels collectively cause more than half of all the deaths each year in the United States and the combined effect of the disabilities and deaths from such diseases is having a major social and economic impact on the Nation;
- (2) elimination of heart and blood vessel diseases as significant causes of disability and death would increase the average American's life expectancy by about eleven years and would provide for annual savings to the economy in lost wages, productivity, and costs of medical care of more than \$200,000,000,000 per year;
- (3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema alone being the fastest rising cause of death in the United States;
- (4) certain respiratory diseases affect an estimated ten million Americans, including an estimated one million, chronic bronchitis, an estimated four million, and asthma an estimated five million;
- (5) thrombosis (the formation of blood clots in the vessels) may cause, directly or in combination with other problems, many deaths and disabilities from heart disease and stroke which can now be prevented;
- (6) blood and blood products are essential human resources, the availability of which in saving life and promoting health cannot be assessed in terms of dollars;
- (7) the provision of prompt and effective emergency medical services utilizing the latest equipment and progressive advances in transportation and communications and the development of systems and specially trained professional and paraprofessional health care personnel can reduce substantially the number of fatalities and severe disabilities due to critical illnesses in connection with heart, blood vessel, lung, and blood diseases; and
- (8) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart and Lung Institute, but the progress against such diseases depends not only on the research programs that are conducted there, but also on the research programs of other research institutes of the National Institutes of Health.

(b) It is the purpose of this Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases,

86 STAT. 672
56 STAT. 680

and blood resources

Pub. Law 92-423 - 2 - September 19, 1972

II. HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES PROGRAMS

12 Stat. 464,
2 052 287-
2876.

Sec. 3, Part B of title IV of the Public Health Service Act, in redesignating section 413 as section 410A, (2) by redesignating section 414 as section 418, and (3) by adding after section 412 the following new sections:

Diseases and Blood Resources

"NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES PROGRAM

"Sec. 413. (a) The Director of the Institute, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung, and Blood Diseases Program (hereafter in this part referred to as the Program) to expand, intensify, and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases, including its activities under section 412) and shall carry out the program in accordance with such plan. The Program shall be coordinated with the other major programs of the Department Institutes of Health to the extent that they have responsibilities respecting such diseases and shall provide for--

and blood resources

and resources

(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and diseases involved in the epidemiology, etiology, and prevention of such diseases;

(2) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(3) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases; and the rehabilitation of patients suffering from such diseases;

(4) establishment of programs that will focus and apply scientific and technological efforts involving biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of those diseases;

(5) clinical studies, large-scale testing, and evaluation and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(6) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionation, and distribution of it and its products;

(7) the education and training of scientists, clinicians, and educators in fields and specialties (including epidemiology, pathology, lung, and blood diseases);

clinical (amended by P.L. 93-438).

and blood resources

(8) public and professional education relating to all aspects of such diseases and the use of blood and blood products and the management of blood resources;

(9) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, lysine membrane, and hemolytic and hemophilic

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16 STAT. 680
16 STAT. 681

diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to these diseases; and (10) establishment of programs for study, research, development, demonstration and evaluation of emergency medical services for the care of patients with acute myocardial infarction, blood vessel, lung, or blood diseases, which programs shall include programs for (A) the training of paraprofessionals in emergency treatment procedures, and (ii) utilization and operation of emergency medical equipment, (B) the development and operation of (i) mobile critical care units (including helicopters and other airborne units where appropriate), (ii) radio, telecommunications, and other means of communications, and (iii) emergency monitoring systems, and (C) the coordination with other community agencies, and the joint use of all forms of emergency vehicles, communications systems, and other appropriate services.

The Program shall give special emphasis to the continued development in the Institute of programs relating to atherosclerosis, hypertension, thrombosis, and congenital abnormalities of the blood vessels, as causes of stroke, and to effective coordination of such programs with related stroke programs in the National Institute of Neurological Disorders and Stroke.

(b) (1) The Plan required by subsection (a) of this section shall also be developed within one hundred and eighty days after the effective date of this section, (B) be transmitted to the Congress, and (C) Congress, recommendations for appropriations for the Program.

(2) The Director of the Institute shall, as soon as practicable after the end of each calendar year, prepare in consultation with the Committee on the part of the President for transmittal to the Congress a list to report the progress of the Program during the preceding calendar year and a plan for the Program during the next five years.

(c) In carrying out the Program, the Director of the Institute, Director of Health and after consultation with the Council and without regard to any other provision of this Act, may—

- (1) if authorized by the Council, obtain (in accordance with section 3102 of title 38, United States Code, but without regard to the limitations in such section) the services of any days or the period of such service) the services of not more than fifty consultants who have scientific or professional qualifications, or conduct research, in the following areas: (A) heart, blood vessel, lung, and blood; (B) laboratory, research, training, and other necessary facilities and equipment, and related accommodations as may be necessary; and such other real or personal property (including patents) as the Director deems necessary; and (C) without regard to the Act of March 3, 1877 (49 U.S.C. 331) by the Director of the National Institutes of Health, or communities, buildings or parts of buildings in the District of Columbia, or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years; and

- (3) enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3543 and 3709 of the Revised Statutes of the United States (31 U.S.C. 502-51 U.S.C. 5102) as may be necessary in the conduct of his functions, with any public agency, institution, individual person, firm, association, corporation, or educational institution.

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This plan shall also set out the Institute's staff requirements to carry out the Program and recommendations for appropriations for the Program.

alter, renovate diseases and blood resources

Assistant Director of Health Information Programs. The Director of Health Information Programs shall be appointed by the Director of the Institute.

and blood resources and blood

"HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

"Sec. 414. (a) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Secretary of Health, Education, and Welfare, shall enter into cooperative arrangements with the Secretary of Health, Education, and Welfare for cooperation with other Federal Health agencies, State, local, and regional public health agencies, and nonprofit private health services in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

(b) There is authorized to be appropriated for each fiscal year ending June 30, 1973, and for each fiscal year thereafter, for the fiscal year ending June 30, 1973, and for each fiscal year thereafter, \$15,000,000 for the fiscal year ending June 30, 1973, and \$15,000,000 for the fiscal year ending June 30, 1974.

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"NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES

"Sec. 415. (a) (1) The Director of the Institute may provide for the development of

(A) fifteen new centers for basic and clinical research into training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart, blood vessel, and blood diseases; and

(B) fifteen new centers for basic and clinical research into training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for chronic lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children).

(2) The centers developed under paragraph (1)(A) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, lung and blood diseases:

(A) Programs to develop improved methods of detecting individuals with high risk of developing cardiovascular disease; and

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such disease.

(C) Programs to develop health professions and allied health professionals personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such disease.

(2) for research in the use of blood and blood products and the management of blood resources;

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"(3) Centers developed under this subsection may be supported under subsection (b) or under any other provision of this Act. The research, training, and demonstration activities referred to in paragraph (1) of this subsection.

"(b) The Director of the Institute, under policies established by the Board or non-Federal Council, may enter into cooperative agreements with public or cooperative nonprofit organizations to pay all or part of the cost of planning, establishing, operating, and maintaining basic operating support for existing or new centers (including training in, and demonstration of, advanced diagnostic, preventive, and treatment methods for heart, blood vessel, lung, or blood disease. Funds use of funds, paid to centers under cooperative agreements under this subsection may be used for—

- "(1) construction, notwithstanding section 405, 58 Stat. 708, and other basic operating costs, including such patient care costs, as may be determined by the Director; 58 Stat. 693
- "(2) training, including training for allied health professions personnel; and 58 Stat. 694
- "(4) demonstration purposes.

The aggregate of payments (other than payments for construction) limitations made to any center under such an agreement may not exceed \$5,000,000 in any year. Support of a center under this subsection may be for a period to exceed 5 years and may be extended by the Director of the Institute at his discretion. The Director shall conduct a periodic review of the operations of such centers. In this section, the term "construction" does not include the acquisition of land.

"INTERAGENCY TECHNICAL COMMITTEE

"Sec. 416. (a) The Secretary shall establish an Interagency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources which shall be responsible for coordinating the aspects of all Federal health programs and activities relating to heart, blood vessel, lung, and blood diseases and to blood resources to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

"(b) The Director of the Institute shall serve as Chairman of the Committee and the Committee shall include representatives from all Federal departments and agencies whose programs involve health functions or responsibilities as determined by the Secretary.

"NATIONAL HEART AND BLOOD ADVISORY COUNCIL

"Sec. 417. (a) There is established in the Institute a National Heart Establishment and Lung Advisory Council to be composed of twenty-three members membership, as follows:

- "(1) The Secretary, the Director of the National Institutes of Health, the Director of the Office of Science and Technology, and the chief medical officer of the Veterans Administration (or their designees), and a medical officer designated by the Secretary of Defense; shall have ex officio membership of the Council.

"(2) Eighteen members appointed by the Secretary. Eleven of the members shall be selected from among the leading medical or scientific authorities who are skilled in the sciences

or the management of blood resources

(excluding indirect costs)

except that adjustments for the costs of living shall be allowed when the budget is at the \$5,000,000 ceiling

and the term "training" does not include research training for which fellowship support may be provided under Section 472 (amended by P.L. 93-438)

National Science Foundation

relating to matters of the heart, blood vessels, lungs, and blood; few of the appointed members of the Council shall be persons who have received training in heart, blood vessel, lung, or blood vessel, and five of the appointed members shall be selected from members of the general public who are leaders in the fields of fundamental or medical sciences in public affairs.

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

"(A) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

"(B) if the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and three shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

"(2) A majority of the Council shall constitute a quorum.

"(3) The Council shall supersede the existing National Advisory Heart Council appointed under section 217, and the appointed members of the National Advisory Heart Council serving on the effective date of this section shall serve as additional members of the National Heart and Lung Advisory Council for the duration of their terms then existing, or for such shorter period as the Secretary may specify.

"(4) Members of the Council who are not officers or employees of the Government shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in the Government service employed under that title.

"(5) The Secretary (or his designee) shall be the Chairman of the Council.

"(6) The Director of the Institute shall (1) designate a member of the staff of the Institute to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

"(7) The Council shall meet at the call of the Chairman, but not less often than four times a year."

AUTHORIZATION OF APPROPRIATIONS FOR PART D OF TITLE IV OF THE PUBLIC HEALTH SERVICE ACT

Sec. 4. Part D of title IV of the Public Health Service Act is amended by adding at the end thereof the following new section:

AUTHORIZATION OF APPROPRIATIONS

"Sec. 410B. For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated \$215,000,000 for the fiscal year ending June 30, 1973; \$230,000,000 for the fiscal year ending June 30, 1974; and \$245,000,000 for the fiscal year ending June 30, 1975. Of the sums appropriated under this section for any fiscal year, not less than 10 per centum of such sums shall be reserved

Terms.

86 STAT. 684
86 STAT. 685

Extension.

National Advisory Heart Council, Re-Placement Pro-gram, 64 Stat. 445, 446
42 USC 218.

5 USC 5332
m45.

60 Stat. 499;
83 Stat. 190.

Executive Secretary.

Act, p. 680.

Act, p. 682.

6
7
8

for programs under this part respecting diseases of the lung and not less than 15 per centum such sums shall be reserved for research under this part for, as respecting diseases of the blood, and blood resources

and blood resources

AUTHORITY OF THE DIRECTOR OF THE NATIONAL HEART AND LUNG INSTITUTE TO APPROVE GRANTS

Sec. 5. Section 419A of the Public Health Service Act (as so redesignated by section 3 of this Act) is amended—

(1) by striking out "grants-in-aid" in subsection (a) and inserting in lieu thereof "except as provided in subsection (c), grants-in-aid"; and

(2) by adding after subsection (b) the following new subsection:

"(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Heart and Lung Institute may approve grants under this Act for research and training in heart, blood vessel, lung, and blood diseases—

"(1) in amounts not to exceed \$10,000 after appropriate review for scientific merit but without review and recommendation by the Council; and

(2) in amounts exceeding \$5,000 after appropriate review for scientific merit and recommendation for approval by the Council."

, the use of blood and blood products and the management of blood resources (excluding indirect costs)

CONFORMING AMENDMENTS TO PART B OF TITLE IV OF THE PUBLIC HEALTH SERVICE ACT

Sec. 6. (a) Section 411 of the Public Health Service Act is amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart and Lung Institute"; and

(b) Section 412 of such Act is amended—

(1) by striking out "heart" each place it occurs (except in the heading) and inserting in lieu thereof "heart, blood vessel, lung, and blood";

(2) by striking out "Surgeon General" and inserting in lieu thereof "Secretary";

(3) by striking out "National Advisory Heart Council" and inserting in lieu thereof "National Heart and Lung Advisory Council";

(4) by redesignating paragraphs (a), (b), (c), (d), (e), (f), and (g) as paragraphs (1), (2), (3), (4), (5), (6), and (7), respectively; and

(5) by amending the section heading to read as follows:

"RESEARCH AND TRAINING IN DISEASES OF THE HEART, BLOOD VESSELS, LUNG, AND BLOOD"

(c) Section 418 of such Act (as so redesignated by section 3 of this Act) is amended—

(1) by inserting "(a)" immediately after "Sec. 418" and by adding at the end thereof the following new subsection:

"(b) (1) The Council shall advise and assist the Director of the Institute in respect to the Program established under section 413, and shall act at such times and places, as the Council deems advisable to investigate programs and activities of the Program.

"(2) The Council shall submit a report to the President for transmittal to the Congress not later than January 31 of each year on the progress of the Program toward the accomplishment of its objectives."

and the Management of Blood Resources

November 30 during the preceding fiscal year

86 STAT., 587

(c) by striking out "Surgeon General" each place it occurs

(3) by striking out "heart" and inserting in lieu thereof "heart, blood vessel, lung, and blood";

(4) by striking out "Surgeon General" in paragraph (1) and inserting in lieu thereof "Secretary, the Director of the National Institutes of Health, and the Director of the National Heart and Lung Institute"; and

(f) as paragraphs (1), (2), (3), (4), (5), and (6) of section 501 of this Act is amended—

(1) in subsection (a), by (A) striking out "Surgeon General" and inserting in lieu thereof "Secretary", and (B) striking out "heart" and inserting in lieu thereof "heart, blood vessel, lung, and blood"; and

(2) by striking out "The Surgeon General shall accept conditional gifts, pursuant to section 501, and inserting in lieu thereof "The Secretary may, in accordance with section 501, accept conditional gifts", and (B) striking out "heart, lung, and blood" and inserting in lieu thereof "heart, blood vessel, lung, and blood";

(c) The heading for part B of such Act is amended to read as follows: "PART B.—NATIONAL HEART AND LUNG INSTITUTE".

CORRECTIVE AMENDMENTS TO OTHER PROVISIONS OF THE PUBLIC HEALTH SERVICE ACT

Sec. 7. (a) Section 217 of such Act is amended— (1) by striking out "the National Advisory Heart Council," and inserting in lieu thereof "the National Heart, Lung, and Blood Institute"; (2) by striking out "heart," in subsection (a) and by striking out "heart," in subsection (b);

(b) Sections 201 (d) and 201 (f) of such Act are each amended by striking out "National Advisory Heart Council" and inserting in lieu thereof "National Heart and Lung Advisory Council";

REPORT TO CONGRESS

Sec. 8. The Secretary of Health, Education, and Welfare shall carry out a review of all administrative processes under which the National Heart, Blood Vessel, Lung, and Blood Disease Program, established under part B of title IV of the Public Health Service Act, will operate, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of the Program. Within one year of the date of enactment of this Act, the Secretary shall submit a report to the Congress of the findings of such review and the actions taken to facilitate the conduct of the Program, together with recommendations for any needed legislative changes.

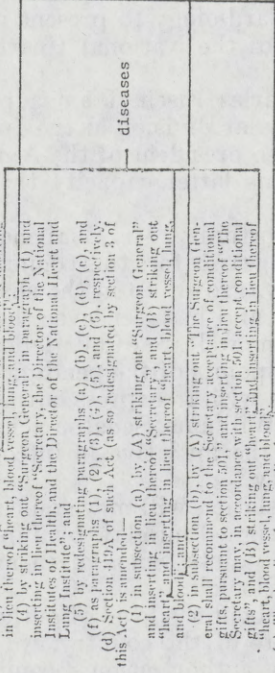
Revised.

Ames, p. 690.

59 Stat., 709.
42 USC 219.

64 Stat., 446.
42 USC 218.

58 Stat., 697.
62 Stat., 601.
79 Stat., 448.
42 USC 841.



diseases, the use of blood and blood products and the management of blood resources

, and by striking out "heart diseases" and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and blood resources"

Senator KENNEDY. The final panel will be Dr. Charles Fisch, who is president of the American College of Cardiology, and representing the American College of Chest Physicians, Dr. Beall, the association's president.

Dr. Fisch.

STATEMENT OF CHARLES FISCH, M.D., PRESIDENT, AMERICAN COLLEGE OF CARDIOLOGY; ACCOMPANIED BY ARTHUR C. BEALL, JR., M.D., PRESIDENT, AMERICAN COLLEGE OF CHEST PHYSICIANS, AND JOSEPH C. ROSS, M.D., CHAIRMAN, COMMITTEE ON GOVERNMENT LIAISON

Dr. FISCH. Mr. Chairman, I would like to thank you very much for inviting the American College of Cardiology to present its views on legislation to extend the authority of the National Heart and Lung Institute.

For the record, my name is Charles Fisch. I am a professor of medicine and director of cardiovascular division at the Indiana University School of Medicine. I am also president of the American College of Cardiology, and it is in this latter capacity that I appear before this committee.

I would also like to take this opportunity, Mr. Chairman, to thank you for the unique opportunity to appear before this committee simply as a physician who has, I might say, grown up in the shadow of the National Heart and Lung Institute and has seen over the years this organization, how it has advanced the welfare of our fellow man.

I would like to comment on a few points of the pending legislation. In the first place, Mr. Chairman, we wish to express our appreciation to you and Senator Javits, Senator Williams, Senator Schweiker, and Senator Stafford for having taken the initiative in introducing this legislation and to extend the authority.

We hope, moreover, that this legislation will move quickly through the processing in the Senate and be signed into law by June 30.

I would like to make only a few points. Some of them have been made before, and I hope you will overlook it.

There has been some controversy about the level of authorization in this bill. Given the economic climate of the country, we agree with you, Mr. Chairman, that the yearly authorization recommended for the fiscal years 1976 and 1977 is quite appropriate.

Cardiovascular research, as you well know, has reached a level of sophistication and has emphasized clinical large-scale trials which are expensive and, thus, they fully justify the recommended support.

We also believe firmly that the Institute has functioned effectively under the 1972 act. However, much important work remains to be done in an area which accounts for well over half of the deaths in the United States and presents a major health and economic problem.

On behalf of the American College of Cardiology, we wish very strongly to support section 109 of the bill which extends the authority of the National Heart and Lung Advisory Council. There has been some—one element in your bill about which, Mr. Chairman, we have some anxieties. As we understand, the bill calls for a 2-year extension of the authorization. We believe, respectfully, that this is too short a

timespan for the magnitude of the research that the NIH sponsors, directs, and otherwise engages in.

Our primary concern, Mr. Chairman, with the 2-year extension is that it may have an undesirable, negative effect on the stability of cardiovascular programs. Also, continuity tends to conserve expenditures and somewhat improves productivity.

Finally, in respect to the fellowship training, Mr. Chairman, we fully support postdoctoral and predoctoral training programs, and we would also like to urge that the training programs be extended not only to research and academic programs, but also support to some extent the clinical training programs.

Finally, we do hope that you will hold the record open for about 10 days in order to give us an opportunity to submit our comments in greater detail.

Finally, Mr. Chairman, on behalf of the American College of Cardiology and its 6,000 members, we again wish to thank you for inviting us to comment on this very important bill.

Thank you.

Senator KENNEDY. Very good. I am afraid we are going to have to close the record on the 21st. That will be the end of this week. We want the staff to work during the period of the break on the final recommendations so that we will be off and moving by the time we come back. If you think in those terms and get any other suggestions, I would welcome them, but we want to make sure that the time during the break is utilized by the staff.

Dr. Ross?

Dr. Ross. Mr. Chairman, my name is Dr. Joseph C. Ross, and I am a professor and chairman of the department of medicine at the Medical University of South Carolina. I also hold the position of chairman of the American College of Chest Physicians.

With me today is Dr. Arthur Beall, who is professor of surgery at Baylor College of Medicine and also president of the American College of Chest Physicians.

It is our pleasure to represent this organization which is composed of more than 9,500 heart and lung medical specialists. On behalf of the American College of Chest Physicians we wish to extend our deepest thanks for your having invited us to appear before you today in order to present our views on S. 988, the National Biomedical Heart, Lung, Blood, Blood Vessel, and Research Training Act of 1975.

Prior to the introduction of this bill, we sent you a letter dated January 23, 1975, which presented our views in general on the subject of renewal legislation for the National Heart and Lung Institute. We believe that your bill effectively deals with most of the concerns we raised in our letter of January 23.

With regard to the bill itself, we wish to commend the sponsors of this legislation for having taken the initiative at this time to move forward with legislation that not only extends the authority of the National Heart and Lung Institute but in many respects improves upon the 1972 act.

We hope, moreover, that the momentum created by the introduction of this legislation will insure its passage by the Congress before the deadline of June 30, 1975.

Since S. 988 does extend the NHLI operating and authorization authorities, we wish to support specifically your extension of section 419(b) which includes the 15 percent reservation of sums appropriated for lung diseases. We believe that this is a necessary element in the progress of biomedical research and training within the lung community.

With regard to section 106 of S. 988, we think that you were quite wise in including the clause permitting payments for research and demonstration centers to exceed the \$5 million limitation should the inflationary spiral which is now taking place within our economy continue.

Again, we are happy to support this provision of your bill.

We are also in agreement with the annual reports of the director of the institute and the National Heart and Lung Advisory Council be transmitted to the Congress and the President simultaneously. In our judgment, this will speed the dissemination of these documents, as well as ensure the public's right to have the best thinking of HEW prior to the surgery that is usually performed in the Office of Management and Budget.

We are particularly in agreement with section 109 of S. 988 which extends the authority of the National Heart and Lung Advisory Council to permit that body to balance the internal priorities of the institute.

In addition, as we understand that provision, the council will also have the authority to affect the proportion of moneys spent on contracts versus those funds which are spent in the form of grants. In our judgment, both elements are appropriate and necessary at this point in time.

There is one element of disagreement that we have, Mr. Chairman, with the sponsors of S. 988. It is our understanding that this bill extends the authorities and otherwise amends the basic NHLI legislation for the next 2 fiscal years. We believe that this is too short a timespan and we recommend that this legislation in itself be permitted to extend the authorities for the NHLI programs for a minimum of 3 years and, hopefully, even longer than that.

We urge you to consider carefully the negative psychological impact the short extension will have on the heart and lung biomedical research communities. Moreover, we believe that stability itself is a very important value in the conduct of all biomedical research and we, too, request since our staff only saw the printed S. 988 last Friday and I did not see it until last evening, that we might be permitted some time to study it and submit a formal written statement.

At any rate, Mr. Chairman, on behalf of more than 9,500 members of the American College of Chest Physicians who specialize in treating the diseases of the heart and lungs, I wish to express our deepest appreciation for your having invited us to present our views on the legislation that is now pending before your committee, and in a spirit of mutual cooperation and support, moreover, we hope that you will continue to call upon us for advice and consultation whenever you think we can be helpful to you and to this committee.

Thank you.

Senator KENNEDY. Thank you very much.

Is your position with regard to the training program that the Federal support should be limited to the postdoctoral or the predoctoral student? Do you have any view on that?

Dr. Ross. Well, we feel that postdoctoral support is certainly of prime importance and more postdoctoral support would benefit predoctoral education, but we certainly do not oppose predoctoral support.

Senator KENNEDY. Do you think it should be both?

Dr. Ross. Yes.

Senator KENNEDY. We will appreciate receiving your comments on the bill.

I want to thank you very much for your appearance. We, as you well understand, really depend upon the support and the help and the assistance of, the thousands of doctors that you represent, and it is extremely important that their interests are represented in the legislation. They are really on the firing line. They are the ones who see in a very practical sense the results of the work that is being done in the institute and their views, I think, are extremely helpful and valuable to us. So, we want to make sure that their views are represented in our legislation. We thank you for presenting them and we want to make sure that you have, the opportunity to look this over and make whatever additional comments you want. I hope you feel free to be in touch with the staff and with the members of the committee as well, to press any particular points of concern.

So we want to thank you very much for your appearance here. We appreciate it.

At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

[The material referred to follows:]

STATEMENT

OF

AMERICAN NURSES' ASSOCIATION

ON S.988

THE NATIONAL BIOMEDICAL HEART, LUNG, BLOOD, BLOOD VESSEL, AND
RESEARCH TRAINING ACT OF 1975

to the

SUBCOMMITTEE ON HEALTH

COMMITTEE ON LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

MONDAY, MARCH 31, 1975

The American Nurses' Association sincerely appreciates the opportunity to submit its views regarding the legislation extending the National Heart, and Lung Institute and the National Research Service Awards. S.988, the National Biomedical Heart, Lung, Blood, Blood Vessel and Research Training Act of 1975, is an important legislative proposal and merits continued Congressional support. The research conducted under the provisions of this Act has contributed greatly to the prevention, diagnosis, and treatment of heart, lung and blood diseases that kill and disable millions of Americans each year.

Over the past years, nursing research and research training have made a significant contribution to improved care of patients. It has been demonstrated many times that successful research leads to successful practice which dramatically increases the quality of patient care.

In recent years, and primarily due to the support of the Federal government, progress has been made in stabilizing or reducing the number of deaths due to heart and lung diseases. We are proud to say that nursing research has played a significant role in improving patient care.

For example, one recent study, sought to determine if intensive in-patient teaching programs for patients with congestive heart failure increases the patients' adherence to a medical regime after discharge from the hospital and reduces the number and length of subsequent hospitalizations. This study is particularly significant when one considers the high cost of in-patient care.

Another fine example of nursing research is a study done in Washington, D.C. A researcher is monitoring the circadian and ultradian rhythms in myocardial infarction patients. This research could provide a basis for the scheduling of events for patients geared to their individual requirements and thereby provide a more accurate preventive and therapeutic approach.

Another nurse researcher has studied the influence of a hospital environment on the presence of *Pseudomonas aeruginosa* in patients with interseptal and valvular defects requiring open heart surgery. This study is extremely important to a patient's recovery because health care providers must be made aware of the patient's environment and the influence it has on the patient's recovery.

Nursing research, made possible with the support of the Federal government, has done much to improve the care of patients with heart, blood and lung diseases. As dramatic and effective as past programs have been, there is an urgent need to continue necessary research.

In the United States there are only about 1,000 nurses with earned doctorate degrees. This means that there are not enough researchers with doctorate degrees to place one in each of the approximately 1400 schools of nursing throughout this country. Nor would this provide one doctorally-prepared researcher for all research centers, hospitals and other health care settings.

This clearly illustrates the need for continued support for nursing research and research training.

In 1955, Congress recognized the need for federal support for nursing research training programs as an adjunct to the program of nursing research grants. The Special Nurse Research Fellowship Program provided individual awards for qualified nurses to train for research at the university of their choice. Nurse Scientist Graduate Training Grants were begun in 1967 to assist both the institutions and the students to train in research. Under this program institutions can develop nursing research competence and nurse graduate students receive modest stipends to prepare for research. Grants are made to schools of nursing with graduate programs and include student support for full-time study in nursing and related biological and social sciences.

The Training Grant Program has supported research development in 12 universities and has assisted more than 260 graduate student trainees.

Like the research fellows, these prepared nurses are strengthening teaching and research activities. They are conducting research important to nursing practice and to health care delivery.

To date the Special Nurse Research Fellowship Program has supported 600 nurses in doctoral study. One third of all nurse researchers currently conducting research projects are past research fellows. Three quarters of the former fellows are engaged in teaching and research in academic settings, while others are conducting research or administering research programs in government and other health care settings.

From the beginning of the Fellowship Program in 1955 until 1963 the Division of Nursing and the Division of General Medical Services in the National Institutes of Health jointly administered the program. In 1963 the Division of Nursing assumed total responsibility for the nursing research grant and fellowship program. This change enabled the Division of Nursing to better coordinate and evaluate nursing research needs with other Division

programs and to be responsive to the nursing research needs, as demonstrated by the award of faculty research development grants in 1959 and nursing scientist training grants in 1967, and the conferences on doctoral preparation for nurses sponsored in 1971 and 1974.

However, nursing research programs are in serious jeopardy, and Congress must take action to reclarify its intention to provide funds for nursing research grants and fellowships.

The Congressional intent regarding nurse research training and fellowships is implicit in the Biomedical and Behavior Research Training Act. To date, there is much confusion as to the status of research grants and fellowships. One reason is that Congress has specified NIH and ADAMHA as the administrative agencies for the program. The Division of Nursing, formerly a part of NIH and now a part of the Health Resources Administration, has always administered nursing research programs. It was not the intention of Congress to move that program to NIH. The Division of Nursing has the staff experts and appropriate review committees to effectively administer the program. The nursing research program is unique and must be treated as such.

The ANA recommends an amendment to Sec. 472 of the Public Health Service Act as added by the National Research Service Awards Act to provide the authority for the continuation of the programs of training for nursing research administered by the Division of Nursing, HRA and as previously authorized by Sec. 301 (c) and (d) of the PHS Act.

It is the contention of the American Nurses' Association that this legislation is basically sound in its approach to health research and continued

federal assistance for qualified researchers.

Consistently, more applicants apply for the training and fellowship programs than can be accepted. Departmental requests for trainees have increased; more qualified individuals are seeking admissions, and the research components of graduate nursing education have developed into a full-fledged doctoral programs.

We are concerned about the Administration's recommendation that fellowships be limited to post doctoral research training. The number of registered nurses prepared at the doctoral level is very small. A great need in nursing is to increase this pool of highly qualified researchers. Therefore, limiting fellowships to post-doctoral research training seems very shortsighted. The demand for nurses with this specialized knowledge and expertise will become more acute in the years ahead.

In addition, we see a need for a three year extension so programs can be assured continuity. We also take strong exception to the authorization levels prepared by the Administration and recommend authorizations be at least at levels which are included in S.988.

Finally, we hope that the committee will reject the Administration's recommendation that no new categorical research programs be authorized under extension legislation. We urge that new research programs be encouraged and authorized funds be specifically mandated for that purpose.

We are somewhat astonished at the Administration's inability to recognize the strong national need for biomedical and behavioral research.

- 6 -

Health care and health care delivery is changing to meet the new demands required by a nation of 210 million people on the verge of establishing a national health insurance program. Research is essential to facilitate the process and insure continuing improvement in health care.

We note with considerable frustration the continued assertions by the Administration that training grants and fellowship programs serve to increase the number of specialists in disciplines which already have sufficient manpower to meet national research needs. In repeated attempts, the Administration is unable to provide the figures to substantiate this assertion.

Nursing care can be made even better and more efficient through nursing research and research training. We believe that this bill, with the modifications and clarifying amendment that we have suggested, can be instrumental in achieving that desirable objective.

We thank you again for the opportunity to present our views, and we look forward to working with this Committee in their efforts to provide quality health care for all Americans.

STATEMENT OF THE
CYSTIC FIBROSIS FOUNDATION
ON THE RENEWAL
OF THE

HEART, BLOOD VESSEL, LUNG AND BLOOD ACT OF 1972

AND S.988

THE NATIONAL BIOMEDICAL HEART, LUNG, BLOOD, BLOOD VESSEL,
AND RESEARCH TRAINING ACT OF 1975

BEFORE THE

SENATE SUBCOMMITTEE ON HEALTH

MARCH 17, 1975

(155)

Mr. Chairman and Members of the Subcommittee:

We deeply appreciate the opportunity to testify, in response to your subcommittee's request, on the renewal of the Heart, Blood Vessel, Lung, and Blood Act of 1972. Also, we will be pleased to make at least a partial statement on the bill you introduced several days ago, Mr. Chairman, S 988, The National Biomedical Heart, Lung, Blood, Blood Vessel, and Research Training Act of 1975.

About three years ago, almost exactly to this day, on March 24, 1972, you very graciously heard the statements of several prominent physicians on our concern about the proposed legislation which you and most of the members of the Subcommittee on Health co-authored, and which eventually became law. At that time, in the hearings, you indicate that there was some uncertainty whether the words "cystic fibrosis" should appear in the bill. Of course, this committee voted to include cystic fibrosis in the bill, and the eventual law contains the language that you included on this disease.

The three years since that hearing have been tumultuous ones for our country, and the political upheavals have extended to research on cystic fibrosis itself, in the form of severe budgetary "impoundments" and rescissions. We know of the work of many of the members of this committee to keep the research funding levels reasonable. (We should note that eight of the Institutes of Health fund research programs specifically in Cystic Fibrosis, and others support basic research programs vital to the understanding of the nature, control, and future cure of this disease of cystic fibrosis.)

In regard to those "impoundments" and "rescissions" we would say that our research teams have been as buffeted, and indeed harmed, as any other research teams--"impoundments" and "rescissions" have played no favorites. Now that the House of Representatives has voted against the proposed rescissions, we are hopeful

that the research dollars which have been held up will begin to flow again. We recognize the work of committee members to stop the "impoundments" and "rescissions" and are deeply grateful.

We are sure that in the forthcoming budget battle on the Fiscal Year 1976 budget, members of this committee will continue support for a reasonable level of funding to the NIH and other health programs. Our Pediatric Pulmonary Centers and the many other programs we help to fund, seriously need now a stable, generous level of support if we are to be able to continue our aim of developing still more the programs we have already begun. As you know, the proposed FY 1976 budget was pegged to the 1975 rescission proposal. We understand we will be asked to participate in the hearings in both the House and Senate, and will be pleased to do so.

Two points should be made here which we have not seen stressed in verbal testimony, though they may appear in statements of others sent to the committee:

- (1) The shortfall between NHLI authorizations and appropriations were great in 1973, when the Act was first enacted, and have grown more severe since then. In 1973, the authorization was \$345 million and the appropriation was \$290 million, or 77.5%. In 1974, the figures were \$425 million authorized, \$286.5 appropriated, or 61.4%. In 1975, the authorization was \$475 million, appropriations were \$286 million - only 60%. If one would estimate an average inflation rate of 12% over three years, it can only be understood that because of the almost flat level of appropriations in dollars, that research in NHLI programs has lost over 35% because of inflation.
- (2) Added to this severe strain is the problem of administrative personnel within the Institute. For example, fixed obligations of NHLI increased by 78% between FY 1970 and FY 1974, but personnel to deal with these programs increased only 23%, and administration has been severely hurt.

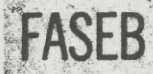
We have made these comments, because in an important sense they bear directly on the proposed legislation we are dealing with today, which, as we understand it, with a few relatively minor exceptions, is essentially a two-year renewal of the basic act. Your suggested legislation carries an authorization level of \$475 million, for each of the two years beyond the expiration date of the present legislation.

We direct our comments to that authorization level. We are aware that the Administration, in its testimony before you, proposed that any authorization the Congress establishes should be keyed to the President's proposed 1976 budget and should provide an authorization level which would permit "no new starts" for the duration of the legislation. We would prefer a higher authorization level, of course, but also recognize the serious limitations of our current economy to carry a higher load, so that we would support that level. We do expect, however, to testify for increased appropriations for this coming fiscal year, and will point out the serious shortcomings of the Administration's budget proposals.

We do not believe that we can offer, at this time, comments upon the proposal to extend for two years biomedical training programs at NIH. We received the bill much too late to offer meaningful comments on this section of the bill.

Mr. Chairman, three years ago you offered the Cystic Fibrosis Foundation the opportunity to testify at length, and a number of documents were included in the record. It is clear that the statements and documents were helpful to you in understanding the situation. As you remarked then, Mr. Chairman, "It is a heart-rendering situation". We will not burden the hearing record with further documentation at this time.

Thank you.



FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

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EUGENE L. HESS
Executive Director

JOHN R. RICE, C.P.A.
Comptroller

April 11, 1975

The Honorable J. Glen Beall,
United States Senate
Washington, D. C.

Dear Senator Beall:

As a member of the Senate Subcommittee on Health, I am sure you are aware of the Freedom of Information Act (P.L. 89-487) and its implications. Our Public Affairs Committee has considered some of the serious ethical issues raised by the Freedom Information Act. As a consequence of the discussion, the Committee passed a Resolution proposing an amendment to the Public Health Service Act under Exemption (3):

Notwithstanding Section 552 of Title 5, U.S. Code, relating to Freedom of Information, the Secretary of Health, Education, and Welfare shall proscribe such regulations as he may deem necessary to prohibit disclosures of any information obtained or developed in the conduct of research and development activities under this subsection if, in the opinion of the Secretary, the disclosure of such information--

would constitute an unwarranted invasion of personal privacy of information of a proprietary or confidential nature (including detailed research protocols, research hypotheses, research designs, and information that may qualify for a U.S. patent, in the records or possession of the Public Health Service, obtained in connection with an application for a grant or fellowship). Such information may be disclosed to the public only with the consent of the applicant or after a period of one year following acceptance by the applicant of a grant or fellowship awarded, based upon said application.

Nothing in this subsection shall be construed to authorize the withholding of information from the duly authorized committees of Congress.

The Honorable J. Glen Beall

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April 11, 1975

Representing the Federation of American Societies for Experimental Biology, I commend the Resolution to your attention. We would be pleased if you would bring the resolution to the attention of the Subcommittee on Health.

Sincerely yours,

Eugene L. Hess
Eugene L. Hess
Executive Director

Senator KENNEDY. The subcommittee will stand in recess.
[Thereupon, at 12:55 p.m., the subcommittee recessed, to reconvene
subject to the call of the Chair.]

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