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94TH CONGRESS }
1st Session }

HOUSE OF REPRESENTATIVES

{ REPORT
No. 94-498

HEART, LUNG AND BLOOD RESEARCH,
RESEARCH TRAINING, AND GENETIC
DISEASES AMENDMENTS OF 1975

REPORT

BY THE

COMMITTEE ON INTERSTATE AND
FOREIGN COMMERCE

[To accompany H.R. 7988]



SEPTEMBER 22, 1975.—Committed to the Committee of the Whole House
on the State of the Union and ordered to be printed

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(II)

HEART, LUNG, AND BLOOD RESEARCH, RESEARCH
TRAINING, AND GENETIC DISEASES AMENDMENTS
OF 1975

SEPTEMBER 22, 1975.—Committed to the Committee of the Whole House on the
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Mr. STAGGERS, from the Committee on Interstate and Foreign
Commerce, submitted the following

REPORT

[To accompany H.R. 7988]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment strikes out all after the enacting clause and inserts in lieu thereof a substitute text which appears in italic type in the reported bill.

SUMMARY OF LEGISLATION

H.R. 7988 would amend the Public Health Service Act to revise and extend for fiscal years 1976 and 1977 the program under the National Heart and Lung Institute; revise and extend for fiscal years 1976 and 1977 the program of National Research Service Awards; require the President's Biomedical Research Panel to conduct an investigation of the implications of disclosure of research information obtained by the Secretary of Health, Education, and Welfare in connection with an application for a research grant, fellowship or contract; and replace the existing authority for screening, counseling, treatment, research and information programs, and education programs for sickle cell anemia and Cooley's anemia with a new general authority authorizing a national program with respect to all genetic diseases, including, but not limited to, sickle cell anemia, Cooley's anemia and Tay-Sachs disease.

(1)

COST OF LEGISLATION

As reported by the Committee, H.R. 7988 provides for authorizations of appropriations for two fiscal years, 1976 and 1977, for programs under the National Heart and Lung Institute, for National Research Service Awards, and for a national program with respect to genetic diseases as shown in the following table.

NEW OBLIGATIONAL AUTHORITY FOR FISCAL YEARS 1976-77 UNDER H.R. 7988

[In millions of dollars]

Program	Fiscal year—		Total
	1976	1977	
Title I—Heart, lung and blood programs:			
Control program.....	20	30	50
Research program.....	340	375	715
Title II—National research service awards.....	175	200	375
Title IV—Genetic diseases.....	20	25	45
Total.....	555	630	1,185

This new obligational authority may be compared with a fiscal year 1975 obligational authority of \$781.647 million, a fiscal year 1975 appropriation of \$526.2 million, and a fiscal year 1976 budget request of \$447.5 million.

LEGISLATIVE BACKGROUND

The legislative authorities for the National Heart, Blood Vessel, Lung and Blood Act of 1972, the National Research Service Award Act, the National Sickle Cell Anemia Control Act, and the National Cooley's Anemia Control Act expired on June 30, 1975. The legislative authorities for these programs are presently being funded under Public Law 94-41, a continuing resolution making funding available for fiscal year 1976.

On May 15, 1975, most members of the Subcommittee on Health and the Environment introduced H.R. 7039, legislation which would revise and extend the program under the National Heart and Lung Institute, revise and extend the program of National Research Service Awards, control disclosure of research information, and establish a national program with respect to genetic diseases. Hearings were conducted on H.R. 7039 on May 20 through 22, 1975; H.R. 7039 was subsequently considered in open executive session by the Subcommittee on Health and the Environment, amended, reported, and reintroduced as a clean bill, H.R. 7988, on June 17, 1975. H.R. 7988 was subsequently considered and ordered reported with amendments by voice vote of the Committee on Interstate and Foreign Commerce on September 4, 1975.

PRINCIPAL PROVISIONS OF H.R. 7988

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

This title extends for fiscal years 1976 and 1977 the authority of the Department of Health, Education, and Welfare to conduct research, experiments and demonstration programs with respect to heart, lung, blood and blood vessel diseases. The only major substantive revisions to existing law are provisions that change the title

of the National Heart and Lung Institute to the National Heart, Lung and Blood Institute, provide explicit authority for the Institute to conduct programs with respect to the use of blood products and the management of blood resources, and authorize the Institute to hire an additional fifty experts and consultants.

The title would authorize \$20 million for fiscal year 1976 and \$30 million for fiscal year 1977 for prevention and control programs, and would authorize \$340 million for fiscal year 1976 and \$375 million for fiscal year 1977 for the National Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources Program.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

This title extends, with only technical modifications, for fiscal years 1976 and 1977, the explicit authority of the Secretary of Health, Education, and Welfare to provide awards to individuals and institutions for biomedical research training. It would authorize \$175 million for fiscal year 1976 and \$200 million for fiscal year 1977.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

This title would require the President's Biomedical Research Panel to conduct an investigation of the implications of disclosure of research information obtained by the Secretary of Health, Education, and Welfare in connection with applications or proposals for grants, fellowships or contracts submitted during calendar year 1975.

TITLE IV—GENETIC DISEASES

This title would substitute for the existing programs of research, services, and information relating to sickle cell anemia and Cooley's anemia a new Part A of title XI of the Public Health Service Act directing the Secretary of Health, Education, and Welfare to support research in genetic diseases and to establish an identifiable administrative unit charged with administering new, noncategorical authorities for testing, counseling, and information programs with respect to genetic diseases, primarily through existing health programs. The bill would authorize \$20 million for fiscal year 1976 and \$25 million for fiscal year 1977 for the testing, counseling and information programs. It would also direct HEW to establish within the Public Health Service, a program for the testing, diagnosis, counseling and treatment of individuals respecting genetic diseases.

TITLE V—MISCELLANEOUS

This title amends section 507 of the Public Health Service Act to expand the authority of the Secretary of Health, Education, and Welfare to award grants for research, training and demonstration projects to Federal institutions. Existing provisions of section 507 limit this authority to awards to hospitals of the Public Health Service, of the Veterans Administration and of the Bureau of Prisons, and to Saint Elizabeths Hospital. Title V would expand this authority to authorize the Secretary to make grants for research, training and demonstration projects under the Public Health Service Act and certain other grants under that Act and the Community Mental Health Centers Act to any Federal institution.

COMMITTEE PROPOSAL

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

Legislative Background

The National Heart Institute was established by Public Law 655 of June 16, 1948, in order "to improve the health of the people of the United States . . . [with respect to] diseases of the heart and circulation". Public Law 89-239 signed on October 6, 1965, provided funds for implementing the President's Commission on Heart Disease, Cancer, and Stroke; over \$5 million was provided for an expanded heart disease program. In November 1969, the Secretary of Health, Education, and Welfare designated the Institute as the National Heart and Lung Institute to reflect expansion of its functions in the lung disease area.

Specific authority for the development and implementation of a national program to combat heart, blood vessel, lung, and blood diseases with separate authorizations for the program was first enacted in 1972 (Public Law 92-423). The 1972 Act required the Director of the National Heart and Lung Institute, with the advice of the National Heart and Lung Advisory Council, to develop and carry out a ten-point plan for a National Heart, Blood Vessel, Lung and Blood Disease Program. The plan was required to cover a wide range of activities, including research into the epidemiology, etiology and prevention of all forms of heart, blood vessel, lung and blood diseases. In addition, the plan was to provide for the evaluation of methods of therapy, research into the effective use of the Nation's blood resources, education of the public and health professionals, training of scientists and clinicians, and establishment of programs for the study and evaluation of emergency medical services. The 1972 Act specifically provided for coordination of the program with the activities of other Institutes to the extent that they conducted research in these areas. Authorizations for the Program were established at \$1.38 billion to be appropriated over a three year period (fiscal years 1973-1975).

The Act provided the Director of the National Heart and Lung Institute, in accordance with policies established by the Director of NIH and after consultation with the National Heart and Lung Advisory Council, with authority to:

Obtain the services of not more than fifty experts or consultants who have scientific or professional qualifications without regard to the time limitations imposed by section 3109 of title 5, United States Code;

Acquire, construct, improve, repair, operate and maintain heart, blood vessel, lung and blood disease laboratories, research and other necessary facilities and equipment;

Enter into contracts, leases and cooperative agreements;

Establish, as necessary, Heart, Blood Vessel, Lung and Blood Disease Control Programs in cooperation with Federal, State and other health agencies;

Establish and participate in the support of thirty new research, training and demonstration centers and support existing centers (fifteen of the new centers were to be engaged in

programs dealing with heart, blood vessels and blood diseases, and fifteen in programs dealing with lung diseases, although the activities of any center could relate to more than one disorder);

Approve grants of under \$35,000 without review by the National Heart and Lung Advisory Council but with review and approval by the appropriate study section; and

Submit an annual report to the President for transmittal to Congress on the progress of the Program and plans for the next five years.

Public Law 92-423 also required the Director of the National Heart and Lung Institute to establish a program of education for the public and health professionals with respect to heart, blood vessel, lung and blood diseases. Special emphasis was placed on informing the public of the effect of reduction of known risk factors in preventing these disorders.

In order to coordinate all Federal programs dealing with cardiovascular, pulmonary and blood disorders, the 1972 law required that the Secretary of HEW establish an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources. Membership on the Committee includes representatives of all agencies so involved.

The law also established the National Heart and Lung Advisory Council and charged it with responsibility to oversee development and implementation of the Program and to approve grant requests in excess of \$35,000. The Council consists of five ex-officio members and eighteen members appointed by the Secretary of HEW. Eleven of the appointed members are scientific or medical authorities; two are enrolled in residency programs; and five are leaders in public affairs. The Council submits an annual report to the President for transmittal to Congress on the progress of the Program in accomplishing its objectives.

Implementation of the 1972 Act

The Committee is generally pleased with the accomplishments under the National Heart, Blood Vessel, Lung, and Blood Disease Program since the passage of Public Law 92-423 in 1972. In response to this legislation, the National Heart and Lung Institute was reorganized into five divisions: the Division of Heart and Vascular Diseases, the Division of Lung Diseases, the Division of Blood Diseases and Resources, the Division of Intramural Research (which conducts the laboratory and clinical research at the National Institutes of Health), and the Division of Extramural Affairs (which is responsible for the services associated with scientific and technical merit peer review of applications for grant and contact support and grant and contact management functions). In addition, an Office of Prevention, Control, and Education was established. This Office was charged with implementing the prevention, control, and education programs provided for in the Act.

Of the thirty research and development centers authorized in 1972, only three have been designated: one in each of the three disease areas emphasized in the legislation. The Cardiovascular Center is located in

Houston, Texas; the Pulmonary Center in Burlington, 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 educational projects designed to hasten the application of research findings.

Significant scientific and medical knowledge has been achieved through research fostered under the 1972 Act. For example, recent research has contributed greatly to the understanding of the roles of different risk factors for heart attacks, such as high blood pressure, cigarette smoking, high blood lipids, obesity, and diabetes, as well as those risk factors which act simultaneously. Of special significance is the development of methods for accurate and precise determination of blood lipids for effective risk factor detection and management.

New therapy for heart attacks has resulted from research sponsored by the Institute. Recent investigations have demonstrated that a heart attack victim's prognosis is directly related to the amount of dead heart muscle. 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 also be valuable in the treatment of acute heart attacks by reducing heart damage. New noninvasive methods have been developed which will be important in determining the benefits of various therapies in reducing heart muscle damage.

Considerable advances have been demonstrated in early detection of chronic bronchitis and emphysema, the major obstructive pulmonary diseases. A new and potentially more sensitive method has been developed to detect changes in lung function and structure, which appear to be the first sign of chronic obstructive lung disease.

Finally, important developments have occurred with respect to blood research and the use of blood. A procedure has been developed which will improve production of Factor VIII, 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. 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 new knowledge has been fostered under the authority of the 1972 Act. Examples of evaluation of new findings with respect to heart disease include a study being carried out in twelve Extramural Lipid Research Clinics to test whether or not lipid lowering can prevent or delay the onset of coronary heart disease; a large-scale clinical trial conducted in twenty clinics throughout the country which will determine the impact on cardiovascular disease of controlling, simultaneously, high levels of blood lipids, high blood pressure, and cigarette smoking; a Coronary Drug Project which has studied the effects of five lipid-lowering drug regimens in patients who have already had heart attacks; and initiation of 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.

Clinical trials of blood oxygenators for temporary support of the lung are underway, and two important trials in the blood area have just been completed. Trials to evaluate urea as an anti-sickling agent have demonstrated that it is not effective in the treatment of the sickle cell crisis. A clinical trial has been completed indicating 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 difficult to obtain.

Consistent with its statutory responsibilities, the National Heart and Lung Institute is promoting the dissemination of knowledge through prevention, control and education programs. The National High Blood Pressure Education Program is aimed at bringing individuals with hypertension under effective treatment programs. 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 the country. A primary goal of this Center will be to hasten the application of new research results. The Institute also supports twenty-six sickle cell disease screening and education clinics which are designed to evaluate new screening techniques and demonstrate counseling and education methodologies.

Thus, encouraging progress has been made over the last three years by the National Heart and Lung Institute, not only in obtaining research results with respect to diseases of the heart, blood vessel, lung, and blood but also in evaluating these results and in disseminating knowledge gained through research. It is clear that the Program needs to be continued to advance the Nation's efforts to combat the diseases that together are responsible for over half the deaths each year in the United States.

Proposed Legislation

The purpose of title I of H.R. 7988 is to extend the authority of the National Heart, Blood Vessel, Lung, and Blood Act of 1972 for two fiscal years, with substantive changes and revised authorization levels. The Committee is particularly concerned that the activities of the National Program—which appear to be developing well—continue without interruption. The two-year continuation is felt to be appropriate in this instance because this timing would cause the legislation to be reviewed again shortly after the President's Biomedical Research Panel has completed its work, and its recommendations on these and related program areas may then be taken into account.

The principal change made in the 1972 Act by the reported bill involves a series of amendments designed to provide increased emphasis on the need for a coordinated effort between programs in blood research and the use of blood resources. Thus, the reported bill contains provisions which would change the name of the National Heart and Lung Institute to the National Heart, Lung and Blood Institute, make a comparable change in the name of the Institute's advisory council, and make it clear that the authority of the Institute extends to the use of blood products and the management of blood resources.

The reported bill also expands the scope of prevention programs in the national research and demonstration centers to include all heart, lung, blood and related diseases in lieu of the existing, more limited requirement that centers be utilized for prevention programs relating to heart disease. Recent research advances have demonstrated that techniques are available to make prevention programs a worthwhile part of control for pulmonary and blood diseases as well as heart disease.

A minor change proposed in the reported bill has been made as a result of the dissolution of the Office of Science and Technology in 1973. Existing law designates the Director of the Office of Science and Technology, who at the time of enactment of P.L. 92-423 was the President's principal science advisor, as an ex-officio member of the National Heart and Lung Advisory Council. The legislation would substitute membership for the Director of the National Science Foundation, since the Director of the NSF now serves as the science advisor to the President. Should a new office, such as an Office of Science and Technology Policy, be established in the executive office of the President, the Committee intends to immediately consider substitution of the chief executive of that office for the Director of the National Science Foundation.

The Committee feels the duties of the National Heart, Lung, and Blood Advisory Council should include the making of recommendations concerning those portions of the National Program that are conducted under contract awards. Since the membership includes public representatives as well as scientists with diverse areas of expertise, the council has a wide perspective from which to provide advice regarding broad principles of program balance in extramural activities. Thus, the reported bill specifically includes as mandated functions of the advisory council the development of recommendations regarding general areas of research and development suitable for award under contracts, and suggestions as to portions of the Institute budget to be devoted to such research and development areas. It should be noted, however, that the council responsibility in the area of grants is to review and recommend approval or disapproval for funding of grant applications; in the area of contracts, the council is not authorized to review individual contract proposals.

The Committee has become concerned about the length of time that has been taken in the past for the annual report of the advisory council to become available to the Committee after its completion. For example, the report required to be submitted by the council to the President for submission to the Congress by January 31, 1975 did not reach the Congress until May 15, 1975, although it was submitted by the council to the President in December of 1974. This report, which describes the progress made by the National Heart and Lung Institute in accomplishing Program objectives, must be received by the Committee in a timely manner if effective oversight of the National Heart, Lung and Blood Institute is to be accomplished. The Committee is unaware of the reasons for the five month delay in the submission of the report to the President and his transmission of it to the Congress. For this reason, H.R. 7988 requires that the report be transmitted to the Secretary of Health, Education, and Welfare for simul-

taneous transmission to the President and the Congress not later than November 30 of each year.

Although the Committee is proposing authorization levels for the next two fiscal years which are lower than those in the 1972 Act, this does not indicate a desire to lower the operating levels of the National Heart, Lung and Blood Institute. The proposed authorization levels are consistent with the appropriations figures for the first three years of the National Program, with room for some growth. If it is determined that unexpected expenses cause the cost of continuation at current operating levels to exceed these authorizations, such information should be immediately transmitted to the Committee.

There are some additional aspects of the implementation of the 1972 Act and the amendments proposed in the reported bill that the Committee wishes to emphasize.

The Committee is disappointed that only three of the thirty research and development centers authorized by the 1972 Act have become operational, although it is pleased that the centers cover the three categories of diseases addressed by the Act—heart, lung and blood. While it is aware that monetary and personnel limitations have stalled center development, the Committee wishes to state again its support for a broader distribution of centers across the country. The centers are a most promising setting for research and the dissemination of the results of research into the health care delivery system. Underfunding this vital mechanism is false economy.

In adopting amendment providing increased emphasis on research on the use of blood and the management of blood resources, the Committee has demonstrated its belief that the National Heart, Lung and Blood Institute would be an appropriate locus of coordination for all blood resources activities of the Department, and recommends that necessary delegations of authority be given to the Institute for this purpose. It is intended, however, that HEW agencies with specific capabilities implement activities in their area of expertise. The National Heart, Lung and Blood Institute—in addition to its general coordinating role—should be the locus for studies and research into the science and management of the Nation's blood resources. Regulatory activity should remain with the Food and Drug Administration, and the new authority afforded the Institute regarding the use of blood and the management of blood resources is not intended to affect, prevent, or deter the Food and Drug Administration, through its Bureau of Biologics, from conducting similar research relevant to its regulatory programs. Implementation of new methodology and techniques, after they have been evaluated as effective, should be the responsibility of the health services arm of the Department of Health, Education, and Welfare—the Center for Disease Control, the Health Resources Administration, or the Health Services Administration.

The fivefold increase in support for research in lung disease between fiscal years 1970 and 1975 has been encouraging to the Committee. The achievements in the pulmonary disease area over the past few years have been significant, but many questions remain unanswered. The Committee wishes to be assured that this support continues so that the goal of understanding the basic processes that underlie pulmonary disease may be realized.

The Committee is generally pleased by the activities of the Interagency Technical Committee established by section 416 of the Act, and, thus, has proposed no amendments to that section. It does feel, however, that the coordination of Federal activities relating to heart, blood vessel, lung, and blood diseases and to blood resources would be better facilitated by the establishment of subcommittees to the Interagency Technical Committee in each of the subject areas, and would urge the Secretary to establish such subgroupings. The subcommittee on lung programs, for example, might include representatives from the Lung Program of the National Heart, Lung, and Blood Institute, the National Institute on Allergy and Infectious Diseases, the Maternal and Child Health program, the National Institute on Occupational Safety and Health, and the Center for Disease Control. In the Committee's view, such a reorganization would result in an improved coordination of programmatic activities and a valuable exchange of information in each of the subject areas.

As is true with all areas of NIH research, the Committee is concerned that the results of research be put into the health care system as rapidly as possible. It is of utmost importance that the knowledge obtained through the National Heart, Blood Vessel, Lung, and Blood Disease Program be effectively evaluated and demonstrated in the community.

The utilization of research results in community medical practice is dependent on health education of the public. Much of the current knowledge which increases man's ability to control diseases necessitates changes in human behavior to actually effect changes in morbidity and mortality. The Committee feels that effective health education is crucial to this effort. It is important to know what educational techniques will work in inducing beneficial changes in perspective and values—and thus ultimately in the behavior of the public. Therefore, the Committee is supportive of programs designed to measure the effectiveness of health education techniques and wishes to encourage the National Heart, Lung and Blood Institute to pursue these activities.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

Legislative Background

Since 1930, when authority for the training of biomedical researchers was first provided to the National Cancer Institute, the National Institutes of Health (and later the Alcohol, Drug Abuse, and Mental Health Administration) have supported significant and highly successful research training programs. The original research training authority has been reaffirmed and expanded by legislation on at least a dozen occasions, and programs for the support of training of biomedical and behavioral scientists have grown greatly both in size and scope—particularly since 1955. By 1971, NIH training grants and fellowships supported or assisted 37.5 percent of the Nation's full-time graduate students in the medical sciences and 21 percent in the life sciences. During the several decades these programs have existed, the United States has become the acknowledged world leader in biomedical and behavioral research.

In 1973, despite the tremendous success of the research training programs in preparing highly qualified biomedical scientists to meet the

needs of an ever-expanding national biomedical research effort, the Administration proposed phasing out the research training grant and fellowship programs of the NIH and ADAMHA. The Congress, while agreeing with the Administration's contention that certain modifications in the programs were in order, strongly disagreed with the decision to terminate the programs. The Congress then enacted, in July 1974, the National Research Service Award Act of 1974, Title I of Public Law 93-348.

This new authority abolished the previous broad research training authorities under the Public Health Service Act and consolidated them in a new mechanism called the National Research Service Award. Under this, the Secretary of Health, Education, and Welfare was directed to provide pre- and post-doctoral support to individuals, and additional support to institutions training such individuals. In addition, the National Research Service Award authority provided that recipients of support be required to fulfill a service obligation as a condition of receiving support; and further, that research training support be directed to and made available to persons in specific areas in which a need for additional researchers had been determined. Public Law 93-348 provided a one-year appropriation authorization.

Implementation of the 1974 Act

The Committee is concerned that the National Research Service Awards authority has been and continues to be misconstrued by the Administration and, further, that the Administration appears to be unwilling to commit the resources necessary to support the vigorous biomedical and behavioral research training programs mandated in the law. Indeed, many of the actions of the Administration during the first year of the authority appear to be consistent with its previous attempts to abandon the program.

Despite the clear intent of Congress in enacting the National Research Service Award Act of 1974, the Administration proposed, in its 1975 budget request to eliminate predoctoral and institutional support and to severely limit the number of new postdoctoral individual awards. The fiscal year 1976 budget request was based on a fiscal year 1975 rescission proposal and would have allocated only \$136 million for the funding of all research training for the NIH and ADAMHA. It was estimated that in fiscal year 1976 only 1,000 new postdoctoral individual awards could be granted by the National Institutes of Health and 100 by the Alcohol, Drug Abuse, and Mental Health Administration. The rationale for this decision was ostensibly to keep the number of new awardees in each year in proportion to the number of new research grants awarded each year. No facts or figures were cited to provide a basis for the rationale.

The Congress rejected the 1975 rescission proposal, which included the proposed cutback of research training activities, and the Committee notes with approval that in fiscal year 1975 the NIH and ADAMHA awarded an estimated \$177 million in individual and institutional research training awards. This figure included new starts under the National Research Service Awards authority as well as continuing commitments under previous research training authorities.

In order for the NIH and ADAMHA to honor their continuing research training commitments in fiscal year 1976 as well as to make new

awards, it is estimated that \$175 million will be required. Since the Administration, as reflected in its 1976 budget request of only \$136 million, persists in its attempts to underfund and thereby undermine research training activities, the Committee finds it necessary to state again certain fundamental premises with respect to biomedical and behavioral research training programs.

A National Research Service Award can take several forms—all of which the Committee intends should be used as appropriate. These forms or mechanisms consist of *both* individual and institutional awards for research training at *both* the predoctoral and postdoctoral levels.

The conference report accompanying H.R. 7724 which became Public Law 93-348 [H. Rept. 93-1148] stated that the conferees used the existing training grant programs of the National Institutes of Health as the basis for the provision of the Act authorizing grants to non-federal public and nonprofit private institutions in order for those institutions to select and support their own trainees. The Committee reiterates its intention that institutional support be given. Similarly, it was and still is the intent of the Committee that research training support be afforded to predoctoral students as well as individuals at the postdoctoral level.

The Committee disagrees with the position of the Administration that no institutional awards be granted. Institutional awards are a vital mechanism in the overall national biomedical and behavioral research training effort. It is through such awards that institutions are able to build up and maintain excellent environments in which to train future scientists. In addition, the institutional award is made to the training institution which selects the people to be trained and which is in the best position to weigh an applicant's merits and potential for a productive research career within the environment of that particular institution.

The individual award, on the other hand, is made on the basis of a national competition in which a selection committee makes awards after assessing the academic transcripts and potential of applicants who have not yet had the opportunity to establish research records on which to be judged. The recipient of an individual award then goes to an institution which he or she feels will provide the best training environment. Although the individual award carries with it some funds allotted to the institution selected by the awardee to cover costs of support services and other expenses, the individual award mechanism does not enable the institution to build up its training capacity in any significant or coherent manner. The institutional award does, and it is the Committee's intention that such awards provide sufficient support so as to allow institutions to plan training programs on a prospective basis. The Committee is aware of and opposes the arbitrary ceiling of 25 percent imposed by the Administration to cover institutional costs in each training grant and expects that each institutional award will include appropriate funding levels which adequately reflect institutional costs based on such factors as the nature of the training program and types of trainees in the particular program, and not an arbitrary percentage figure that may bear no relationship to costs.

No matter how great an individual's potential for becoming a research scientist might be, the quality of the training the individual receives remains a key determinant of his or her future productivity. For this reason, institutional awards are a vital adjunct to the individual award mechanism, and the Committee intends that the granting of institutional awards be continued as an integral part of the ADAMHA and NIH research training programs.

On a related matter, the Committee notes that the National Institutes of Health has revised its program of General Research Support grant awards to enable institutions which have not as yet established substantial research programs to develop research environments capable of supporting such programs. It is the Committee's understanding that, after interaction with Congressional Committees, the NIH has reserved 10 percent of its GRS award funding for institutions which receive less than \$200,000 in Federal biomedical research monies. While the Committee shares the concern reflected in the new proposed guidelines that new emerging institutions should participate in the GRS program and believes that this is an improvement over past policy which restricted GRS support to those institutions which had received more than \$200,000 in awards, the Committee plans to look into the entire concept of GRS support and the administration of the program in the near future.

The Administration's reluctance to support predoctoral-level research training has also caused the Committee great concern. It is from the predoctoral ranks that postdoctoral-level research scientists emerge. The Committee believes it is vitally important to support graduate students seeking the Ph. D. or a combined degree with a view to engaging in careers in biomedical or behavioral research. Not only should the supply of highly qualified Ph. D. candidates be maintained, but vigorous steps should be taken to attract bright young persons to careers as research scientists through programs of support for predoctoral training. In the case of the research training program of ADAMHA, 80 percent of the program is directed to providing assistance for research training to individuals pursuing doctoral degrees. At the National Institutes of Health, the figure is smaller, approximately 35 percent, but significant nonetheless. With the exception of the Administration, every witness questioned on this matter at the hearings stated that predoctoral training should be maintained.

The Committee never intended that predoctoral support nor institutional support be abandoned. Indeed, the continuation of such support was one of the primary reasons that research training legislation was enacted last year. The Committee believes strongly that a rational mix of pre- and post-doctoral individual awards *and* institutional awards is essential for the maintenance of the high quality training of our Nation's biomedical and behavioral research scientists.

The Committee notes with disappointment that nowhere in the Administration's statement on research training can it find an instance in which the word excellence is mentioned. The worldwide preeminence of this Nation's biomedical and behavioral research community was not attained by ignoring this essential element of our research training programs. The maintenance of scientific excellence is not only desir-

able, it is necessary with regard to research which is a vital part of our national health enterprise. The various research training support mechanisms authorized by the National Research Service Awards Act were designed to continue and to expand this tradition of excellence. It is the Committee's intent that this mandate be fully carried out according to the spirit as well as the letter of the law.

Proposed Legislation

The Committee remains firmly committed to Federal support for biomedical and behavioral research training programs. The Committee believes that successful research depends upon the availability of scientists and institutions capable of producing superior research and personnel. The amendments effected by H.R. 7988 are directed at extending programs and making some relatively small but important modifications to them.

H.R. 7988 would broaden the authority for research training authorized by section 472 to include biomedical and behavioral research training programs of entities other than the NIH and ADAMHA, such as the research training programs of the Health Resources Administration. The Committee did not intend to restrict authority for biomedical and behavioral research strictly to the NIH and ADAMHA, and this technical change should remove any doubt about that point.

The proposed legislation would also delete the words "non-Federal" in section 472(a)(1) which sets forth the kinds of institutions at which research training may take place under National Research Service Award support. Since many Federal institutions such as the Public Health Service and Veterans Administration hospitals can provide excellent environments for research training, the Committee does not wish to exclude individuals training at such Federal institutions from receiving awards.

A further amendment corrects an apparent misunderstanding with respect to the kinds of activities a National Research Services Award recipient might engage in as part of the service payback requirement under subsection 472(c). While the original legislation specified "health research or teaching" the Committee intended that this provision be interpreted broadly to include research or teaching or a combination of research and teaching. To make this intent clear, the Committee has added the phrase, "or any combination thereof which is in accordance with usual patterns of academic employment." The Committee intends that the regulations respecting this aspect of service payback be amended promptly to reflect this broader view.

In addition, the Committee intends that the teaching and research requirement be construed broadly so as to apply to a variety of settings and types of activities and not be limited solely to the university or academic setting. Particularly in the event an awardee is unable to secure employment in the areas of endeavor specified in the law, the Committee intends the Secretary have flexibility in setting forth reasonable standards for fulfillment of the service obligation.

Section 473 relates to the studies to be undertaken by either the National Academy of Sciences or another appropriate organization to determine the overall need for biomedical and behavioral research personnel and the subject areas in which such personnel are needed. H.R. 7988 would add a further specification to this provision to require that

the study be conducted in consultation with the Director of NIH. The Committee believes it is important that the National Institutes of Health be able to consult with those conducting the study and be afforded the opportunity to comment on any reports submitted pursuant to section 473 before these reports are transmitted. The Committee has a high degree of confidence in the ability of NIH program managers to contribute to the various facets of the study, and wishes those conducting the study to have the full benefit of such contributions in drawing their conclusions. The final recommendations should, of course, be the sole responsibility of those conducting the study.

A considerable amount of concern has been voiced about the feature of the Act which requires monetary payback in the case of an individual who has not completed the service payback requirement. The formula in the existing law specifies that the individual must reimburse the United States for all support funds received plus interest, and that, if there has been partial fulfillment of the service obligation, such time as has been served shall be given one half credit in the computation of the monetary debt. The present law states that interest shall accrue at the time the award is made to the individual. Originally, this provision was included to further encourage recipients of research training support to follow careers in research or teaching or both or provide some other health-related service. The Committee still intends that this be so. However, on reconsideration of the interest factor in the payback formula, the Committee has determined that to mandate interest accrual from the time the award is received results in inordinately high debt accumulation to the individual. Consequently, the Committee has modified the computation of the formula to specify that interest accrues only from the time the individual fails to complete the service obligation and the United States becomes entitled to receive repayment. Thus, for example, under the present law an individual who had received \$36,000 of support for three years of training would have been obligated to repay \$32,500 had he or she served two of the three years of the service obligation. Under the revised method of interest computation, the individual in the same circumstance would be obligated to repay only \$18,500.

Because of the undue harshness of the interest computation in the original law, the Committee has also provided that the effects of this amendment respecting interest be retroactively applied to fiscal year 1975 recipients of Awards.

Finally, the Committee has provided for authorizations of appropriations for fiscal years 1976 and 1977 of \$175 million and \$200 million, respectively. The Committee does not believe that the biomedical and behavioral research training programs of the NIH and ADAMHA can be maintained at monetary levels any lower than these. The fiscal year 1976 figure, in fact, provides for maintenance of the program at fiscal year 1975 levels.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

Background

Biomedical and behavioral research of the type sponsored by the Department of Health, Education, and Welfare is often highly sophisticated and specialized. In order to assure competent evaluation of

applications for biomedical and behavioral research awards, HEW has established a "peer review" system using panels of nongovernmental consultants to investigate and evaluate grant applications. These panels, called "initial review groups" (IRGs), are organized around particular specialized disciplines within the broader field of biomedicine and are comprised primarily of members of the public. One member of each IRG, the Executive Secretary, is a Federal employee.

Applications for research support are referred by the Executive Secretary to one member of the IRG as the "primary assignee", and to one or more other members who assume secondary responsibility. This subgroup undertakes a preliminary evaluation of the application and gathers such additional information as it feels is necessary. This may involve a "site visit" to the facility at which the applicant proposes to conduct his research in order to better evaluate the application by, for example, observing an experimental technique intended to be used in the proposed research, or determining the appropriateness of the facilities available to the applicant.

An evaluation of each application, and a site visit report, where appropriate, are written by the assignee group and circulated to the whole IRG, together with the application. The application is then discussed at length at a subsequent meeting of the full IRG, and a recommendation voted. If approval is recommended, the application is also given a priority rating since the cost of all proposals deemed worthy of funding usually exceeds available funding.

Following the IRG meeting, the Executive Secretary prepares a Summary Statement, called a "pink sheet", for each application considered by the group which describes the proposal and recounts the substantive considerations that led the IRG to recommend approval or disapproval. It contains an opinion of the professional qualifications of the sponsor and an evaluation of his competence and facilities. The IRG's evaluation of the risk to human subjects, if appropriate, is included, as well as the site visit report, if any. If there is a minority opinion of two or more, the minority's view is also summarized, without attribution.

Each application and the corresponding pink sheet is then submitted to an advisory council established within HEW for the purpose of making recommendations to the Secretary respecting approval or disapproval of the application.

The Freedom of Information Act requires disclosure, upon request, of the final decisions and records of each agency of the government unless they come within one of nine specific exemptions of the Act. Upon enactment of the Freedom of Information Act, the Department of Health, Education, and Welfare took the position that research grant applications, site visit reports and pink sheets fell under one or more of the following statutory exemptions from disclosure:

Section 552(b)(4), Trade secrets and commercial or financial information obtained from a person and privileged or confidential.

Section 552(b)(5), Inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency.

Section 552(b)(6), Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.

The bases for this determination by the Secretary were that the creative concepts embodied in research designs were analogous to trade secrets, that the applications contained financial information and that they were submitted to the Secretary of Health, Education, and Welfare as confidential material. Thus, research information was not released to the public and the portions of committee meetings in which such information was reviewed were closed to the public.

In 1973, a public interest group, the Washington Research Project, Inc., requested that the National Institute of Mental Health release records relating to eleven research grant awards studying the effects of drug therapy on children with learning difficulties or behavioral disorders. The NIMH released certain factual information with respect to the grant applications but refused to release most of the information contained in the associated summary sheets, site visit reports, and renewal applications. The Washington Research Project challenged this refusal in the United States District Court for the District of Columbia, invoking the Freedom of Information Act. HEW based its claim for confidential treatment of the documents on the three exemptions cited above. The District Court held that these exemptions were inapplicable and ordered that the requested documents be made available for inspection and copying, with provision for deletion of certain names and identifying marks. (*Washington Research Project Inc. v. Department of Health, Education, and Welfare*, 366 F. Supp. 929 (U.S.D.C. 1973).) On appeal, the United States Court of Appeals for the District of Columbia Circuit reversed the lower court on two counts, holding that site visit reports and summary opinions were not subject to disclosure, but upheld the lower court's findings concerning release of grant applications (504 F.2d 238 (D.C. Cir. 1974)).

The resultant requirement that research designs, hypotheses and protocols contained in grant applications be released to the public generated concern within the research community, which believes that a scientist's ideas are his or her "stock-in-trade" and deserve protection from disclosure in order to avoid plagiarism. While many members of the research community have urged that legislation exempting research information from disclosure be enacted, most public interest groups oppose legislation designed to withhold research data from disclosure, and are especially concerned that research protocols involving human subjects be disclosed upon request.

Proposed Legislation

The legislation on which hearings were conducted contained a provision which would provide the Secretary of HEW with a limited authority to withhold from public disclosure information contained in research protocols, hypotheses and designs submitted in connection with an application for a grant, fellowship or contract under the Public Health Service Act until twelve months after the application was approved, except in cases in which the information involves research on human subjects.

During hearings, representatives of the research community were unable to demonstrate that the court decision had resulted in plagiarism of scientists' ideas. Thus, in executive session the Subcommittee on Health and the Environment deleted the provisions in title III authorizing limited disclosure of research information and substituted a pro-

vision requiring the President's Biomedical Research Panel (which was established in 1974 by P.L. 93-352, and was charged with the responsibility of assessing policy issues concerning biomedical and behavioral research conducted and supported under programs of the National Institutes of Health and the National Institute of Mental Health) to conduct an investigation of the implications of public disclosure of information contained in research protocols, hypotheses and designs obtained by the Secretary of HEW in connection with applications for grants, fellowships and contracts submitted during the period January 1, 1975 through December 31, 1975. This provision requires that in making the study the panel is to determine the number of requests for disclosure of such information, the purposes for which the disclosed information was used, and the effect of disclosure on patent rights, on the protection of human subjects of such research, and on the adequacy of informed consent procedures.

The Committee does not intend that the Panel restrict itself to the determinations listed in the bill and would welcome consideration by the Panel of other matters relevant to disclosure of research information.

The findings of the Panel are to be reported to the Committee by April 30, 1976.

TITLE IV—GENETIC DISEASES

Background

The hereditary character of many of the most serious chronic and acute diseases has been known, if imperfectly understood, for many years. As more knowledge is made available each year, it is becoming increasingly obvious that the extent of genetic disease is far greater than has been estimated previously. The number of recognized genetic disorders approaches 2,000 and the list is growing at a rate of from 75 to 100 newly identified disorders each year.

There are four types of genetic disease. The first includes single-gene disorders that may be either transmitted from one parent or both or might result from a new mutation. These diseases can be dominant, in which one of the parents is affected and each child has a 50 percent chance of being affected (e.g. Huntington's chorea); recessive, in which both parents are normal and each child has a 25 percent chance of being affected (e.g. Cooley's anemia); or sex-linked, in which a gene that produces a certain trait is located on the X-chromosome therefore affects only males (e.g. hemophilia). The second type of genetic disease is exemplified by aberrations in the number and structure of chromosomes (e.g. Down's syndrome). It has been calculated that each year in the United States approximately 20,000 infants are born with a chromosome abnormality. Another category of genetic disease includes those caused by the interaction of multiple genes (e.g. diabetes). In these disorders, knowledge about the number of genes involved and how they interact is very limited. Finally, the fourth type of genetic disorder is caused by incompatibility between fetus and mother, such as Rh hemolytic disease of the newborn.

Extent of the Problem

When considered as a group, genetic disorders constitute a highly visible and growing problem, resulting in significant individual and social burdens. It has been estimated that 12 million Americans carry

true genetic diseases; 36 percent of all spontaneous abortions are caused by chromosomal defects; 40 percent of all infant mortality results from genetic factors; 80 percent of the incidence of mental retardation in this country is genetically related. These estimates do not take into account many of the conditions that have either recently been demonstrated to have genetic involvements or are strongly suspected to have such involvements. These conditions include heart diseases, certain forms of arthritis, diabetes, and cancer, and the most devastating and prevalent mental illnesses—schizophrenia and depressive illness.

The costs—both economic and social—of genetic disease are enormous. The cost to society of caring for those suffering from Down's Syndrome, for example, which results in mental retardation and has an estimated frequency of one in 600 births, is approximately \$1.7 billion annually. The estimated medical bill in the case of a child with Tay-Sachs disease ranges from \$20,000 to \$40,000 per year for the three to five year average life span of an affected child. Treatment for hemophilia can cost as much as \$12,000 per year. Regardless of the financial costs of treating genetic disease, the emotional pressure on the family of an affected individual is staggering.

Genetic Technology

Studies of the inheritance of metabolic diseases and physical defects are beginning to produce beneficial returns at a rapidly accelerating rate. Screening procedures have been developed which can identify and potentially reduce the incidence or severity of certain genetic diseases; new treatment modes have the capability of preventing or controlling many hereditary disorders which were considered incurable only a few years ago.

Recent advances in scientific and biomedical knowledge have resulted in the development of several large-scale screening programs for the detection of certain recessive disorders. Screening techniques have been developed to detect carriers of more than sixty recessive genetic diseases including sickle cell anemia, Cooley's anemia, and Tay-Sachs disease, thus enabling "at risk" potential parents to assess the possibility of having affected children and thus to choose to abstain from having children or assume the risks involved in pregnancy. Screening programs which permit prompt identification of an affected newborn can, in some cases, permit treatment which many prevent the serious consequences of genetic defects. The most frequently cited example is phenylketonuria (PKU), a disease of newborns caused by the absence of an enzyme which usually causes mental retardation. Identification of PKU through relatively simple testing procedures may result in the prevention of such retardation through use of a special diet.

The capacity to treat other genetic disorders is somewhat more limited. Common modes of treatment include surgery, diet, drug therapy, transplantation, blood transfusion, physical therapy, and enzyme induction. While there has been substantial progress in developing different modes of therapy, most genetic diseases do not respond to such treatment to the extent that affected individuals can lead "normal" lives. For instance, diabetics treated with insulin experience an increased incidence of vascular disorders compared to the normal population; transfusion therapy for Cooley's anemia can

lead to a life-threatening accumulation of iron in various organs of the body: the use of urea as a prophylactic remedy in sickle cell crises is accompanied by severe diuresis which can lead to dehydration and death.

Research efforts into identifying genetic defects, developing new screening techniques for at-risk populations, and better prophylactic therapy without attendant side effects, as well as into positive cures for genetic diseases continue to promise advances in the technology of genetic medicine. The rapid growth of various genetic technologies is providing an improved capability to diagnose, treat and eliminate numerous individual genetic defects. While this growing capability promises significant improvements in genetically-based health, it also raises complex questions regarding its application. The protection of human subjects of genetic research, the informed consent and voluntary participation of patients in genetic screening programs as well as the confidentiality of information gathered in connection with screening programs must be guaranteed by professionals in the genetic technology field.

Legislative Background

In 1972, Congress enacted two categorical disease programs—the National Sickle Cell Anemia Control Act (P.L. 92-294) and the National Cooley's Anemia Control Act (P.L. 92-414). Both laws authorized programs for research, screening and counseling, and information and education programs, and directed that treatment be made available through Public Health Service facilities. In both instances the National Institutes of Health was designated as the agency principally responsible for implementation of these programs. The NIH assumed responsibility for research; service programs were carried out by the Health Services Administration under a reimbursable agreement with the National Institutes of Health.

The sickle cell and Cooley's anemia legislation provided a valuable and needed spur to Federal efforts in those areas. Significant findings have been produced by research and service programs. For example, as noted in the report's discussion of the implementation of the 1972 heart, lung and blood legislation, it has been determined that trials have demonstrated that the use of urea as an anti-sickling agent is not effective in the treatment of the sickle cell crisis, and new approaches are being evaluated. The experience with twenty-six sickle cell anemia screening and education clinics has resulted in demonstrations of new types of screening procedures, an evaluation of counseling methods, and attempts to integrate these services into more comprehensive health centers.

On balance, the categorical approach embodied in the 1972 legislation appears to fall short of meeting the national need in the complex area of genetic diseases. Targeted research efforts in the area of sickle cell anemia and Cooley's anemia, while productive, can and should be expanded to include research on other genetic disorders. Experience with the service programs suggest that much remains to be learned about identifying populations at risk and providing information and services in a useful way. Finally, it has become increasingly obvious that the victims of many other inherited disorders have an equally

legitimate claim to a share of the Nation's health resources. H.R. 7988 as reported by the Committee seeks to maintain and enhance the Federal effort in genetic diseases and to provide a more appropriate setting for that effort.

The Committee is aware that the term "genetic diseases" defies precise definition. A number of diseases are clearly inherited; the causes of others are unknown; still others appear to be the result of a complex interaction between heredity and environment. Although some witnesses urged that an operational definition of genetic disease be included in the bill, no specific recommendations were offered and the Committee concluded that broad, general language would permit the greatest flexibility in exploiting opportunities for progress.

Proposed Legislation

Title IV of H.R. 7988 is designed to accomplish three major purposes. First, the categorical authorities for testing, counseling, information, and education programs for sickle cell anemia and Cooley's anemia are replaced by a broader authority which authorizes the Secretary to support projects for voluntary testing and counseling programs for all genetic diseases with the authorizations of \$20 million for fiscal year 1976, and \$25 million for fiscal year 1977 for such purposes. The Committee is persuaded that a flexible approach is most appropriate for the broad spectrum of disorders known as genetic diseases although it does not intend that this approach in any way vitiate the existing research or service programs respecting sickle cell anemia or Cooley's anemia. In addition, the Committee supports the principle of providing services relating to genetic diseases as part of an integrated health care setting wherever possible, and has therefore directed that these efforts primarily utilize existing programs supported under Title X of the Public Health Service Act (Family Planning Services) and Title V of the Social Security Act (Maternal and Child Health Services).

While recognizing the desirability of a noncategorical approach, the Committee has also directed that the service components of these programs be administered through an identifiable administrative unit within the Department of Health, Education, and Welfare, in order to assure efficient coordination and monitoring of programs. The Committee hopes that establishment of such a unit will provide sufficient visibility and impetus for the coordinated genetic disease programs envisaged by the legislation and that appropriate funding of the new program will be achieved. In this connection, it should be noted that the Committee expects the Department of Health, Education, and Welfare to utilize the new authorities provided for these purposes, and was pleased to hear from Department witnesses that in the future such specific directives would not be ignored without prior consultation with the Committee.

A second major component of title IV directs the Secretary to use the broad research authorities of section 301 of the Public Health Service Act for projects for research in diagnosis, treatment, and control (including prevention) of genetic diseases, training programs for genetic counseling and related professions, education programs for health care practitioners and the public, and development of counsel-

ing and testing programs and other programs for the diagnosis, prevention, control, and treatment of genetic diseases. The Committee recognizes that the best hope for long-term progress in this area rests in vigorous pursuit of research opportunities by the several NIH Institutes whose purview includes diseases of genetic origin. At the same time, the Committee expects the NIH and other components of the Department of Health, Education and Welfare to lend their full support to the educational and program development efforts essential to success of the service programs.

Finally, new section 1103 directs the Secretary to establish a program within the Public Health Service of voluntary genetic testing, diagnosis, counseling, and treatment, to be made available through facilities of the Public Health Service.

The reported bill further provides that participation in any program authorized by title IV shall be wholly voluntary; that information obtained about individuals shall be kept confidential; and that community representation in program development and operation shall be provided for, where appropriate. Data generated from such programs should be made available as appropriate to researchers in order to support further progress, consistent with the protection of individual privacy. The bill further stipulates that programs be based on the prevalence of diseases and presence of high-risk populations, and that testing and counseling be directed primarily to persons entering their child-producing years. While not set forth specifically in the legislation, the Committee would assume that programs directed at newborn screening and treatment would also receive a high priority in the administration of the Act. The Committee is also particularly concerned that screening programs include adequate counseling and follow-up of persons who have or who are likely to transmit a genetic disease, and that information programs include efforts to clarify any public misunderstandings in this area.

TITLE V—MISCELLANEOUS

Legislative Background

In 1967, at the request of the Administration, Congress enacted section 507 of the Public Health Service Act which authorized that appropriations for research, training or demonstration project grants be made available, for grants for the same purpose, to hospitals of the Public Health Service, of the Veterans' Administration, of the Bureau of Prisons and to Saint Elizabeths Hospital on the same terms and conditions that apply to non-Federal institutions. This authority had previously been permitted under provisions of annual appropriations acts. Section 507 was further amended in 1970 to expand the scope of grants which could be made to these institutions and to provide that grants to such institutions could be funded at up to 100 percent of the costs.

The Department of Health, Education, and Welfare has requested that this authority be expanded further to encompass all Federal institutions and facilities. The basis for this request is that other Federal institutions in addition to the hospitals now eligible to receive HEW support also provide unique research capabilities, spe-

cialized facilities, and diverse scientific and engineering talent, and are ideally suited and highly qualified to attack many problems in the biomedical, behavioral, and environmental areas. Examples of such Federal institutions and facilities are the NASA Jet Propulsion Laboratory and the Armed Forces Institute of Pathology, both of which conduct cardiovascular research. In addition, the Energy Research and Development Administration conducts research in a variety of areas including the study of radioisotopes, an area of major interest to the National Heart, Lung and Blood Institute. But for the limitations of section 507, the National Heart, Lung and Blood Institute and other NIH Institutes could be more directly engaged in the support of these important research activities and in improved collaborative efforts with other Federal research facilities.

Committee Proposal

Title V adopts the request of the Department of Health, Education, and Welfare. It would amend section 507 of the Public Health Service Act to expand the authority of the Secretary of Health, Education, and Welfare to award grants for research, training and demonstration projects and other programs to Federal institutions. As noted above, existing provisions of section 507 limit this authority to awards to hospitals of the Public Health Service, of the Veterans' Administration and of the Bureau of Prisons, and to Saint Elizabeths Hospital. Title V would expand this authority to authorize the Secretary to utilize appropriations for grants for research, training and demonstration projects under the Public Health Service Act and certain other grants under that Act and the Community Mental Health Centers Act to make grants for the same purpose to any Federal Institution.

AGENCY REPORT

The following letter from the Department of Health, Education, and Welfare, dated July 21, 1975, setting forth that agency's views on the bill, H.R. 7988, was received by the Committee.

SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., July 21, 1975.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is a report on H.R. 7988, a bill "To amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information."

Title I of the bill would provide several amendments to Title IV, part B, of the Public Health Service Act. It would change the yearly reporting requirement for the Director of the National Heart and Lung Institute from a calendar to a fiscal year basis, and require that such report set forth recommendations concerning staff and appropriations.

The bill would authorize extension of the Heart, Blood Vessel, Lung, and Blood Disease Control Program for two years at the level of \$20 million for fiscal year 1976 and \$30 million for fiscal year 1977. Other programs of the National Heart and Lung Institute would be extended for two years at authorization levels of \$340 million for fiscal year 1976 and \$375 million for fiscal year 1977. The bill would also amend the provision concerned with national research and demonstration centers so that prevention programs, as well as research programs, would deal with all heart, lung, and related diseases, not solely cardiovascular diseases; and would authorize the \$5 million maximum limit for single grants to research centers to be exceeded for cost of living increases. The bill would substitute the Director, National Science Foundation, for the abolished position of Director, Office of Science and Technology, as an ex officio member of the National Heart and Lung Advisory Council.

Provisions in the existing law would also be amended to clarify the fact that the authority of the National Heart and Lung Institute includes blood resources activities. The Director of the Institute would be authorized to obtain the services of not more than 100 experts or consultants, rather than not more than 50, as in present law. Finally, title I would modify the National Heart and Lung Advisory Council's functions to (1) require that the program progress report be submitted to the Secretary for transmittal to the President and the Congress by November 30 of each year; and (2) include making recommendations to the Secretary concerning areas of research to be supported by contracts and the percentage of the Institute's budget which should be expended for such contracts.

With respect to title I of H.R. 7988, the Department wishes to reaffirm its commitment to maintain the momentum of the heart, blood vessel, lung, blood research, and blood resources programs. In our view, these programs have a high health priority. We believe that extension of these authorities is unnecessary for the continuation of our efforts in this area. We do not object to the enactment of the title I provisions of H.R. 7988, as long as the authorization levels are consistent with the President's 1976 budget and no new programs are mandated.

We would also make the following technical suggestions:

1. Section 105 of the bill be modified to refer to the President's science advisor, rather than specifically to the Director of the National Science Foundation. This will ensure that whatever official in any particular period is acting as the President's science advisor will be the person who also sits on the National Heart and Lung Advisory Council.

2. Section 102(d) be deleted as unnecessary: "alter" and "renovate" connote the same idea as the present wording "improve" and "repair."

3. Sections 102(b)(1) and 106(3) be modified, as indicated in the enclosed technical attachment, to allow for the change-over to the new fiscal year period.

4. The provisions concerned with blood resources be modified and extended, as indicated in the enclosed technical attachment, so as to insure uniform interpretation throughout title IV, part B, of the Public Health Service Act.

5. The redundancy in lines 4 and 5, page 1, of the bill be corrected.

Title II of the bill would amend the provisions of the Public Health Service Act relating to research training programs of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration. It would make eligible for National Research Service Awards persons at all Federal institutions, rather than only those at the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration. The title would also eliminate interest charges for the period after an award was made but before the United States became entitled to recover the monetary payback required of individuals who failed to fulfill the service requirement. Title II would further amend present law to require the National Academy of Sciences to conduct its study of research personnel needs in consultation with the Director of the National Institutes of Health. It would extend appropriation authorizations for National Research Service Awards for two years at \$175 million for fiscal year 1976 and \$200 million for fiscal year 1977.

With regard to the proposed amendments to the National Research Service Awards authorities, we recommend Committee adoption of the Administration proposal, introduced as H.R. 7049. We particularly oppose the provision on extension of the authorizations. The appropriation authorizations are not consistent with the President's 1976 Budget, and we believe that a three-year rather than two-year extension is necessary to provide the stability necessary for the success of our research training efforts. We would therefore recommend that \$136 million be authorized for the fiscal year ending June 30, 1976, and for each of the two succeeding fiscal years.

In addition, the Administration's proposal includes a provision to ameliorate the harshness of the payback formula by allowing three-fourths credit for time served instead of one-half credit in the present law. Although H.R. 7988 does change the computation of interest of the present formula, the Administration's proposal in certain cases would ameliorate the payback burden to an even greater extent, and we urge that the Department's amendment be incorporated in H.R. 7988.

Similarly, while Title II of H.R. 7988 includes an amendment directing the National Academy of Sciences to conduct its manpower study in consultation with the Director of the National Institutes of Health, the Department's proposal would make several more substantive changes with regard to the National Academy of Sciences' study which, we feel, would provide additional clarification of the fact that the study is advisory in nature. Here, too, we strongly urge that the Department's amendments be incorporated in H.R. 7988. We would also note that for consistency and appropriateness the National Academy of Sciences manpower study should be conducted in consultation with the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration as well as the Director of the National Institutes of Health.

Finally, sections 201(b) and (c) should be deleted as unnecessary; "or" in this context in the Public Health Service Act is inclusive (and/or), not exclusive.

The Department looks forward to working with the Committee regarding modifications of the existing research training authority. We

would not oppose title II of H.R. 7988 if it is amended as we suggest, and if no new program activities are mandated.

Title III of H.R. 7988 is concerned with disclosure of research information. It would require the President's Biomedical Research Panel [which was established by Section 201(a) of P.L. 93-352, the National Cancer Act Amendments of 1974] to conduct an investigation and study of the implication of disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare in connection with a grant application or contract proposal submitted to the Secretary under the Public Health Service Act in the period beginning January 1, 1975, and ending December 31, 1975. [Note: The bill reads "December 31, 1976" which is clearly in error, as the bill also requires the entire study to be completed by March 15, 1976.]

The Panel would be required to complete its investigation and study not later than March 15, 1976, and submit a report on this study to the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare not later than April 30, 1976. The report would contain whatever legislative recommendations the Panel deemed appropriate.

While it is important that the issues associated with disclosure of research information be clarified, the Freedom of Information Act, enacted in 1966 and revised in 1967 and 1974, the Federal Advisory Committee Act of 1972, and the Privacy Act of 1976 contain general provisions pertaining to public access to information. We believe that the issue raised by this proposal (which would modify the impact of the Freedom of Information Act on the release of research information) requires additional study to determine its implications for other programs of the Executive Branch. Therefore we are unable to endorse enactment of this title.

Title IV of H.R. 7988 would establish a national program to provide research, training, testing, counseling, and information dissemination with respect to genetic diseases. Specifically, it would authorize the Secretary, through an identifiable administrative unit in the Department of Health, Education, and Welfare, to make grants and contracts for the operation of voluntary genetic testing and counseling programs and for the development and dissemination of information and materials on genetic diseases. It would also authorize the Secretary, in carrying out Section 301 of the Public Health Service Act, to make grants and contracts for research, training, education programs, and counseling and testing programs on the nature, diagnosis, treatment, and control of genetic diseases. Title IV of the bill would also direct the Secretary to establish within the Public Health Service a voluntary testing, diagnosis, counseling, and treatment program respecting genetic diseases. Title IV specifically includes, but is not limited to, sickle cell anemia, Cooley's anemia, and Tay-Sachs disease.

We are opposed to the categorical genetic diseases authority proposed in title IV. Such authority is duplicative, unnecessary, and would not enhance the administration of programs concerned with genetic diseases.

A major problem inherent in title IV is that it is difficult to identify which diseases should be included under the rubric "genetic diseases."

Our understanding of all diseases, including those which are currently called "genetic diseases," is constantly evolving. We are now inclined to believe that there is a genetic component in nearly every kind of disease. However, in some cases diseases which we have thought to be primarily genetic in origin, such as childhood diabetes, may in fact be caused by a virus. In short, the severe definitional problems posed by this title would not enhance and could potentially confound present research activities on genetic diseases.

Another issue is that title IV is unnecessary. Advances in genetics research to date suggest that the potential benefits of, for example, prenatal diagnosis, enzyme therapy, and therapeutic modification of genetic material, have been and will continue to be the result of improved understanding of the most basic hereditary processes. We have, under existing provisions of the Public Health Service Act, ample authority to continue such research whether it is called genetic research or not.

Moreover, past and current research efforts in the field of genetics are not insignificant. We estimate that at the present time some \$138 million is being expended by the National Institutes of Health in genetic disease research (though the definitions used to obtain these figures are somewhat arbitrary), and we estimate that an additional \$70 million is expended in research related to genetic diseases.

We believe that it would be unwise at this time to enact a law requiring establishment of an identifiable administrative unit for genetic testing and counseling programs and an identifiable unit for dissemination of information concerning genetic diseases. We see no need for a law to require what can and is being done by administrative action.

Therefore, because title IV(1) is plagued by definitional problems which would make it difficult to administer and (2) would duplicate authorities already contained in the Public Health Service Act for genetic disease counseling and education programs which already exist in the Department, we are opposed to enactment of this Title at this time.

There is one additional legislative change which the Department proposes to submit and which we believe could be appropriately included in H.R. 7988 under title V—Miscellaneous. This would be a modification of Section 507 of the Public Health Service Act to make all Federal institutions eligible under the same conditions (except for 100 percent funding) under which non-Federal institutions are eligible to receive research, training, and demonstration project grants under the Public Health Service Act, and certain other grants under that Act and the Community Mental Health Centers Act. Currently only hospitals of the Public Health Service, Veterans Administration, and Federal Bureau of Prisons, and St. Elizabeths Hospital are authorized to receive such support. Since other Federal institutions also provide unique research capabilities, specialized facilities and diverse scientific and engineering talent, they are ideally suited and highly qualified to attack many problems in the biomedical, behavioral, and environmental areas. Examples of such Federal institutions and facilities are the NASA Jet Propulsion Laboratory and the Armed Forces Institute of Pathology, both of which conduct cardiovascular research. In addition, the Energy Research and Development Administration conducts research in a variety of areas including the study of radio-

isotopes, a subject very relevant to the National Heart and Lung Institute. But for the limitations of Section 507, the National Heart and Lung Institute and other NIH Institutes could be more directly engaged in the support of these important research activities and in improved collaborative efforts with other Federal research facilities.

We therefore suggest that Section 507 be amended to delete mention of the specifically named institutions and to insert instead language which would encompass Federal research institutions and facilities generally. We urge the Committee to consider this amendment to the Public Health Service Act and would be happy to work with the Committee further on this matter.

Subject to the exceptions noted above, we do not oppose enactment of H.R. 7988.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

STEPHEN KURZMAN,
Acting Secretary.

INFLATION IMPACT STATEMENT

The Committee is unaware of any inflationary impact on the economy that would result from passage of the proposed legislation. The proposed authorization for fiscal year 1976 of \$555 million represents only .15 percent of the total estimated Federal outlay for fiscal year 1976, and less than 2 percent of the estimated Federal outlay for health programs for fiscal year 1976. Furthermore, the proposed authorization represents only a slight increase over the fiscal year 1975 appropriation of \$526.2 million for these programs, despite the expansion of the genetic diseases program to encompass all genetic disorders.

The programs supported by the provisions of this bill are of critical importance to the health and welfare of the more than 40 million Americans who are directly affected by genetic disorders and diseases of the heart, lung, and blood. The economic costs associated with diseases of the heart, lung, and blood and those which are genetically-related have been estimated at more than \$50 billion annually. The authorization levels in H.R. 7988, in the Committee's view, offer a significant opportunity to lower the economic and social costs as well as the incidence of these diseases, and, by supporting biomedical and behavioral research training programs, insure the future quality of this Nation's research effort.

PROGRAM OVERSIGHT

The Committee's principal oversight activities with respect to this program have been conducted by the Subcommittee on Health and the Environment in connection with its consideration of the legislative authorities for these programs. Legislative hearings on the programs were conducted on May 20, 21, and 22, 1975, and the findings are discussed in the report under Committee Proposal as the proposed legislation is designed to respond to the Subcommittee's findings. The Subcommittee on Health and the Environment also conducted oversight

hearings on the National Institutes of Health in April of 1975 at which time many of these programs were discussed.

The Committee has not received oversight reports from either its own Subcommittee on Investigations and Oversight or the Committee on Government Operations.

SECTION-BY-SECTION ANALYSIS

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

Section 101 amends section 411 of the Public Health Service Act (hereinafter, "the Act") to change the name of the National Heart and Lung Institute to the National Heart, Lung and Blood Institute.

Section 102 amends section 412 of the Act to (1) make a technical and conforming amendment to reflect the change in the name of the Institute's Advisory Council accomplished by amendments to section 417 of the Act; and (2) make it explicit that the responsibilities of the Director of the National Heart, Lung and Blood Institute include activities with respect to the use of blood and blood products and the management of blood resources.

Section 103 amends section 413 of the Act to (1) change the name of the National Heart, Blood Vessel, Lung and Blood Disease Program to the National Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources Program and make it explicit that the program encompasses blood resources; (2) change the existing requirement for submission of an annual report respecting the Program so that future reports will be concerned with the accomplishments of the Program on a fiscal, rather than calendar, year basis and to provide that future five-year plans submitted with such reports will include estimates of necessary personnel and recommendations for appropriations; (3) increase from 50 to 100 the number of experts and consultants authorized to be utilized by the National Heart, Lung and Blood Institute; (4) broaden the authority of the Institute with respect to construction to include authority to alter and renovate facilities and to make it explicit that the construction authority extends to blood resource facilities; (5) change the title of the Assistant Director for Health Information Programs to the Assistant Director for Prevention, Education and Control to more clearly reflect his responsibilities and expand the scope of the health information programs for which the Assistant Director is responsible to include programs with regard to blood diseases and blood resources; and (6) make a conforming amendment to the title of section 413.

Section 104 amends section 414(b) of the Act to extend the Heart, Blood Vessel, Lung and Blood Disease Prevention and Control Program for two years with authorizations of appropriations of \$20 million for fiscal year 1976 and \$30 million for fiscal year 1977 for the Program.

Section 105 amends section 415 of the Act to (1) make it explicit that the authority for the development of research and demonstration centers with respect to heart, blood vessel and blood diseases includes authority with respect to the management of blood resources;

(2) remove the stipulation that the authority for the development of research centers with respect to lung disease be limited to chronic diseases; (3) expand the scope of the prevention programs to be conducted by the research and demonstration centers to include programs for pulmonary and blood diseases; (4) expand the existing authority to support centers which provide research, training and demonstration methods with respect to heart, blood vessel, lung and blood diseases to include the authority to support centers which provide research, training and demonstrations with respect to the management of blood resources; (5) authorize that support of such centers may exceed the annual statutory maximum of \$5,000,000 by an amount attributable to increases reflected in the Consumer Price Index; and (6) make a conforming amendment to the title of section 415.

Section 106 amends section 417 of the Act to (1) substitute the Director of the National Science Foundation as an ex-officio member of the National Heart, Lung and Blood Advisory Council in place of the Director of the Office of Science and Technology since that office has been abolished; (2) change the name of the National Heart and Lung Advisory Council to the National Heart, Lung and Blood Advisory Council; and (3) make a conforming change in the title of section 417.

Section 107 amends section 418 of the Act to (1) expand the functions of the National Heart, Lung and Blood Advisory Council to include review and approval of research and training programs in the use of blood and blood products and the management of blood resources, and the collection of information with respect to the use of blood and blood products and the management of blood resources; (2) expand the Council's functions to include making recommendations to the Secretary on areas of research which should be supported by contracts and on the percentage of the Institute's budget which should be expended for such contracts; (3) change the timing and manner of submission of the report required to be submitted by the Council to the President to require that the report be transmitted by the Secretary to the President and the Congress simultaneously not later than November 30 of each year; and (4) to clarify that the focus of the report is to be on the progress of the National Heart, Blood Vessel, Lung and Blood Diseases and Resources Program during the preceding fiscal year.

Section 108 amends section 419A of the Act to (1) make its various administrative provisions apply to the use of blood and blood products and the management of blood resources and (2) change the authority of the Director of the Institute to approve research and training grants not exceeding \$35,000 without Council review to provide that the \$35,000 limitation apply only to the direct costs of research and training.

Section 109 amends section 419B of the Act to (1) extend the programs authorized by Part B of Title IV of the Act (except the Prevention and Control Programs authorized by section 414) for two years and authorize appropriations of \$340 million for fiscal year 1976 and \$375 million for fiscal year 1977 for such programs; and (2) specify that the requirement that not less than 15 percent of sums appropriated under section 419B be reserved for programs respecting blood diseases applies to programs in blood resources as well.

Section 110 amends section 301 of the Act to (1) make a technical and conforming amendment to reflect the change of the name of the Advisory Council accomplished by amendments to section 417 of the Act; and (2) make it explicit that the functions of the council authorized by section 301 apply to heart, blood vessel, lung and blood diseases and blood resources and not only to heart disease, as existing statutory language implies.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

Section 201(a) amends section 472(a)(1)(A)(iii) of the Act to authorize the award of National Research Service Awards to individuals engaged in biomedical and behavioral research at Federal institutions as well as nonfederal public and nonprofit private institutions.

Sections 201(b) and (c) amend sections 472(c)(1)(A)(i) and 472(c)(2)(A) of the Act to make it explicit that service requirements applicable to persons who receive National Research Service Awards may include a combination of health research or teaching and not either health research or teaching.

Section 201(d) amends section 472(d) of the Act to extend the National Research Service Award Act for two years with authorizations of appropriations of \$175 million for fiscal year 1976 and \$200 million for fiscal year 1977.

Section 202 amends sections 472(a)(i)(A)(i) and 472(b)(2) of the Act to authorize the award of National Research Service Awards for research within any of the divisions of the Department of Health, Education, and Welfare. Existing law limits such awards to research at the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration.

Section 203 amends section 472(c)(4) of the Act, which provides for the recovery by the Federal government of the monetary value, including interest, of a National Research Service Award in those instances in which a recipient fails to fulfill the applicable service requirement. Interest on the award would be computed from the time the United States becomes entitled to recover all or part of the award, rather than from the time the award is made, as is the case under present law. The new method of computing interest is made applicable to National Research Service Awards made from appropriations beginning in the fiscal year ending June 30, 1975.

Section 204 amends section 473(b) of the Act to direct that the National Academy of Sciences or other group or association conducting the continuing study of biomedical and behavioral research personnel required by section 473(a) to conduct such study in consultation with the Director of the National Institutes of Health.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

Section 301(a) directs the President's Biomedical Research Panel (established by Section 201(a) of the National Cancer Act Amendments of 1974) to conduct a study of the implication of public disclosure of information contained in research protocols, hypotheses, and designs submitted during the period from January 1, 1975 to Decem-

ber 31, 1975 to the Secretary of Health, Education, and Welfare in connection with an application or proposal for a grant, fellowship, or contract under the Act. The study is to include a determination of the number of requests for disclosure of such information, the interests represented by persons for whom the requests were made, and the purposes for which information disclosed was used. The study is also to address the effect of disclosure of such information on proprietary interests, patent rights, the ability of peer review systems to insure high-quality Federally funded research, the adequacy of protection of the public against research which presents an unreasonable risk to human subjects, and informed consent procedures. The Panel is directed to complete its study no later than March 15, 1976, and report thereon to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate no later than April 30, 1976. The report is to contain such recommendations for legislation as the Panel deems appropriate.

Section 301(b) changes from July 1, 1976 to January 1, 1977 the effective date on which the National Advisory Council for the Protection of Human Subjects of Biomedical and Behavioral Research is to be established.

TITLE IV—GENETIC DISEASES

Section 401 provides that title IV of the bill may be cited as the "National Genetic Diseases Act."

Section 402 states that purposes of title IV are to establish programs of basic research, applied research, research training, testing, counseling, information, and education with respect to genetic diseases including, but not limited to, sickle cell anemia, Cooley's anemia, and Tay-Sachs disease.

Section 403(a) provides that, effective July 1, 1975, Title XI of the Act is amended by striking out Parts A and B (relating to programs for sickle cell anemia and Cooley's anemia) and substituting for such programs a new Part A, entitled "Genetic Diseases" which adds the following new sections to the Act:

New section 1101 of the Act authorizes the Secretary, through an identifiable administrative unit within the Department of Health, Education, and Welfare, to make grants and enter into contracts for the establishment and operation of voluntary genetic counseling and testing programs. Such programs are to be conducted primarily in conjunction with existing health programs, including Federally supported family planning programs under title X of the Act and maternal and child health programs under title V of the Social Security Act. In addition, under new section 1101, the Secretary is directed to carry out, through an identifiable administrative unit within HEW, a program to develop and disseminate information and educational materials relating to genetic diseases in order to make available the latest advances in the testing, diagnosis, counseling and treatment respecting genetic diseases. The Secretary is authorized to make grants and enter into contracts as above for the development and dissemination of such materials. Appropriations of \$20 million for fiscal year 1975 and \$25 million for fiscal year 1977 are authorized for payments under grants and contracts under new section 1101.

New Section 1102 of the Act authorizes the Secretary, in implementing his general authority to foster research under section 301 of the Act, to make grants and enter into contracts for (1) basic or applied research leading to the understanding, diagnosis, treatment and control of genetic diseases; (2) special programs for the training of genetic counselors, social and behavioral scientists and other health professionals; (3) educational programs regarding the nature of genetic processes, inheritance patterns of genetic diseases and the available means, methods and facilities to diagnose, control and treat genetic diseases; and (4) the development of counseling, testing and other programs for the diagnosis, control and treatment of genetic diseases.

New Section 1103 of the Act requires that participation in genetic disease programs authorized by title IV of the bill be wholly voluntary and not a prerequisite to participation in any other program.

New Section 1104(a) of the Act requires that applications for grants and contracts shall contain such information as the Secretary may require and that each applicant for a grant or contract shall (1) administer or supervise the programs and activities for which assistance is sought; (2) provide for strict confidentiality of test results, medical records and other information regarding persons treated except for information which the patient or his guardian gives informal consent to be released and for statistical data compiled without reference to the identity of the patient; (3) provide for community representation in the development or operation of genetic counseling programs; (4) in cases of applications for programs involving delivery of services, provide assurances that genetic testing and counseling services will involve widely prevalent diseases and high risk population groups and be directed especially to persons entering child producing years, and that arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and (5) establish appropriate fiscal control and accounting procedures.

New Section 1104(b) of the Act provides that in making grants or entering into contracts for testing and counseling programs under section 1101 of the Act, the Secretary shall take into account the number of persons to be served and the extent to which rapid and effective use will be made of funds awarded, and give priority to programs in areas having the greatest number of persons who will benefit from and are in need of services.

Section 403(b) makes a technical change in Section 1121(b)(5) of the Act (relating to authorizations of appropriations for grants and contracts for sudden infant death syndrome programs) to reflect the change in the date on which fiscal years will terminate pursuant to the Congressional Budget and Impoundment Control Act of 1974; redesignates part C of title XI of the Act as Part B and makes a technical and conforming change in the heading of title XI.

TITLE V—MISCELLANEOUS

Section 501(a) redesignates the second paragraph (4) of section 472(c) of the Act as paragraph (5).

Section 501(b) amends section 507 of the Act (which authorizes the Secretary of Health, Education, and Welfare to utilize appropriations available for grants for research, training, and demonstration projects and other programs under this Act or the Community Mental Health Centers Act to make grants for the same purpose to hospitals of the Public Health Service, the Veterans' Administration, the Bureau of Prisons and to Saint Elizabeths Hospital at up to 100 percentum of costs) to authorize the Secretary to award grants authorized under such section to any Federal institution.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Surgeon General is authorized to—

(a) * * *

* * * * *

(c) Make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to [heart diseases] *heart, blood vessel, lung, and blood diseases and blood resources*, recommended by the National Heart [and Lung], *Lung, and Blood* Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council, and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals,

laboratories, and other institutions for the general support of their research: *Provided*, That such uniform percentage, not to exceed 15 per centum, as the Surgeon General may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year;

(h) Adopt, upon recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board or with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to [heart diseases] *heart, blood vessel, lung, and blood diseases and blood resources*, upon recommendation of the National Heart and Lung Advisory Council, or, with respect to dental diseases and conditions, upon recommendation of the National Advisory Dental Research Council, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

TITLE IV—NATIONAL RESEARCH
INSTITUTES

* * * * *

PART B—NATIONAL HEART AND LUNG INSTITUTE

ESTABLISHMENT OF INSTITUTE

SEC. 411. There is hereby established in the Public Health Service a National [Heart and Lung] *Heart, Lung, and Blood* Institute (hereafter in this part referred to as the "Institute").

RESEARCH AND TRAINING IN DISEASES OF THE HEART, BLOOD VESSELS, LUNG,
AND BLOOD AND IN THE MANAGEMENT OF BLOOD RESOURCES

SEC. 412. In carrying out the purposes of section 301 with respect to heart, blood vessel, lung, and blood diseases *and with respect to the use of blood and blood products and the management of blood resources* the Secretary through the Institute and in cooperation with the National Heart and Lung Advisory Council (hereinafter in this part referred to as the "Council"), shall—

(1) conduct, assist, and foster researches, investigations, experiments, and demonstrations relating to the cause, prevention, and methods of diagnosis and treatment of heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources*;

(2) promote the coordination of research and control programs conducted by the Institute, and similar programs conducted by other agencies, organizations, and individuals;

(3) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special studies related to the purposes of this part;

(4) make grants-in-aid to universities, hospitals, laboratories, and other public or private agencies and institutions, and to in-

dividuals for such research projects relating to heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources* as are recommended by the Council, including grants to such agencies and institutions for the construction, acquisition, leasing, equipment, and maintenance of such hospital, clinic, laboratory, and related facilities, and for the care of such patients therein, as are necessary for such research:

(5) establish an information center on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases *and on the use of blood and blood products and the management of blood resources*, and collect and make available, through publications and other appropriate means, information as to, and the practical application of, research and other activities carried on pursuant to this part;

(6) secure from time to time, and for such periods as he deems advisable, the assistance and advice of persons from the United States or abroad who are experts in the field of heart diseases;

(7) in accordance with regulations and from funds appropriated or donated for the purpose, provide clinical training and instruction and establish and maintain clinical traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources* with such stipends and allowances (including travel and subsistence expenses) for trainees as he may deem necessary, the number of persons receiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and, in addition, provide for such training, instruction, and traineeships through grants, upon recommendation of the Council, to public and other nonprofit institutions.

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD [DISEASE] DISEASES AND BLOOD RESOURCES 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] Diseases and Blood Resources 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 *and blood resources* (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 research institutes 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, behavioral, nutritional, 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 approaches to, the diagnosis, treatment (including emergency medical service), 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) 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 into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionalization, 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 clinical programs respecting heart, blood vessel, lung, and blood diseases *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, hyaline membrane, and hemolytic and hemophilic 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, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases, which programs shall include programs for (A) the training of paraprofessionals in (i) 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) electronic monitoring systems, and (C) the coordination with other community services and agencies in 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 Diseases and Stroke.

(b) (1) The plan required by subsection (a) of this section shall (A) be developed within one hundred and eighty days after the effective date of this section, (B) be transmitted to the Congress, and (C) set out the Institute's staff requirements to carry out the Program and recommendations for appropriations for the Program.

(2) The Director of the Institute shall, as soon as practicable after the end of each [calendar] fiscal year, prepare in consultation with the Council and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments under the Program during the preceding [calendar] fiscal year and a plan for the Program during the next five years. *Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the Program during such five years.*

(c) In carrying out the Program, the Director of the Institute, under policies established by the Director of the National Institutes 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 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than [fifty] one hundred experts or consultants who have scientific or professional qualifications;

(2) acquire, construct, improve, repair, operate, alter, renovate and maintain heart, blood vessel, lung, and blood disease and blood resource 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 acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, 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 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution.

(d) There shall be in the Institute an Assistant Director for [Health Information Programs] *Prevention Education, and Control* who shall be appointed by the Director of the Institute. The Director of the Institute, acting through the Assistant Director for [Health Informa-

tion Programs] *Prevention Education, and Control*, shall conduct a program to provide the public and the health professions with health information with regard to cardiovascular, blood, and pulmonary diseases and blood resources. 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 and blood diseases.

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 Council, shall establish programs as necessary for 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) There is authorized to be appropriated to carry out this section \$25,000,000 for the fiscal year ending June 30, 1973, \$35,000,000 for the fiscal year ending June 30, 1974, [and] \$45,000,000 for the fiscal year ending June 30, 1975, \$20,000,000 for fiscal year 1976, and \$30,000,000 for fiscal year 1977.

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

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 for research in the use of blood and blood products and in the management of blood resources; 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)] subparagraphs (A) and (B) of paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing [cardiovascular disease] cardiovascular, pulmonary, and blood diseases.

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

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

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

(3) Centers developed under this subsection may be supported under subsection (b) or under any other applicable provision of law. The research, training, 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 Institute, under policies established by 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 planning, establishing, or strengthening, and providing basic operating support for, existing or new centers (including centers established under subsection (a)) for basic or clinical research into, training in, and demonstration of, *the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases*. Funds paid to centers under cooperative agreements under this subsection may be used for—

- (1) construction, notwithstanding section 405,
- (2) staffing and other basic operating costs, including such patient care costs as are required for research,
- (3) training, including training for allied health professions 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 \$5,000,000 in any year.] *for its costs (other than indirect costs) described in the first sentence may not exceed \$5,000,000 in any year, except that the aggregate of such payments in any year may exceed such amount to the extent that the excess amount is attributable to increases in such year in appropriate costs as reflected in the Consumer Price Index published by the Bureau of Labor Statistics.* Support of a center under this subsection may be for a period of not to exceed five years and may be extended by the Director of the Institute for additional periods of not more than five years 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; and the term "training" does not include research training for which fellowship support may be provided under section 472.

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 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 representation from all Federal department and agencies whose programs involve health functions or responsibilities as determined by the Secretary.

NATIONAL HEART [AND LUNG], LUNG, AND BLOOD ADVISORY COUNCIL

SEC. 417. (a) There is established in the Institute a [National Heart and Lung Advisory Council] *National Heart, Lung, and Blood 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] *Director of the National Science Foundation* 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) 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) 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 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 vacancy in the Council shall not affect its activities, and twelve members 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] *National Heart, Lung, and Blood 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 the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-13 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 intermittently.

(c) 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.

FUNCTIONS OF THE COUNCIL

SEC. 418. (a) The Council is authorized to—

(1) review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources*, and certify approval to the Secretary, for prosecution under section 412, any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products in the management of blood resources*;

(2) review applications from any university, hospital, laboratory, or other institution or agency, whether public or private, or from individuals, for grants-in-aid for research projects relating to heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources*, and certify to the Secretary its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood disease;

(3) review applications from any public or other nonprofit institution for grants-in-aid for training, instruction, and traineeships in matters relating to the diagnosis, prevention, and treatment of heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources*, and certify to the Secretary its approval of such applications for grants-in-aid as it determines will best carry out the purposes of this act;

(4) *recommend to the Secretary (A) areas of research in heart, blood vessels, lung, and blood diseases and in the use of blood and blood products and the management of blood resources which it determines should be supported by the awarding of contracts in order to best carry out the purposes of this part, and (B) the percentage of the budget of the Institute which should be expended for such contracts;*

[(4)] (5) collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases *and to the use of blood and blood products and the management of blood resources*, by correspondence or by personal investigation of such studies, and with the approval of the Secretary make available such information through appropriate publications for the benefit of health and welfare agencies and organizations (public or private), physicians, or any other scientists, and for the information of the general public;

[(5)] (6) recommend to the Secretary for acceptance conditional gifts pursuant to section 501 for carrying out the purposes of this part; and

[(6)] (7) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health, and the Director of the National Heart and Lung Institute with respect to carrying out the provisions of this part.

(b) (1) The Council shall advise and assist the Director of the Institute with respect to the Program established under section 413. The Council may hold such hearings, take such testimony, and sit and 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 Secretary for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress on the progress of the Program toward the accomplishment of its objectives during the preceding fiscal year.*

ADMINISTRATION

SEC. 419A. (a) In carrying out the provisions of section 412 all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and except as provided in subsection (c), grants-in-aid for heart, blood vessel, lung, and blood disease research and training projects *and projects with respect to the use of blood and blood products and the management of blood resources* shall be made only after review and recommendation of the Council made pursuant to section 414.

(b) The Secretary may, in accordance with section 501, accept conditional gifts for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases *and into the use of blood and blood products and the management of blood resources*, or for the acquisition of grounds or for the erection, equipment, or maintenance of premises,

buildings, or equipment of the Institute. Donations of \$50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

(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 *and for research and training in the use of blood and blood products and the management of blood resources*—

(1) [in amounts not to exceed \$35,000] *if the direct costs of such research and training do not exceed \$35,000, but only after appropriate review for scientific merit but without review and recommendation by the Council, and*

(2) [in amounts exceeding \$35,000] *if the direct costs of such research and training exceed \$35,000, but only after appropriate review for scientific merit and recommendation for approval by the Council.*

AUTHORIZATION OF APPROPRIATIONS

SEC. 419B. For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated \$375,000,000 for the fiscal year ending June 30, 1973, \$425,000,000 for the fiscal year ending June 30, 1974, [and] \$475,000,000 for the fiscal year ending June 30, 1975. *\$340,000,000 for fiscal year 1976, and \$375,000,000 for fiscal year 1977.* Of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums shall be reserved for programs under this part respecting diseases of the lung and not less than 15 per centum of such sums shall be reserved for programs under this part for programs respecting [diseases of the blood] *blood diseases and blood resources.*

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PART I—GENERAL PROVISIONS

DIRECTORS OF INSTITUTES

SEC. 471. 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 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.

NATIONAL RESEARCH SERVICE AWARDS

SEC. 472. (a) (1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of [the disease (or diseases)

or other health problems to which the activities of the Institutes and Administration are directed] *diseases or other health problems.*

(ii) training at the Institutes and Administration of individuals to undertake such research,

(iii) biomedical and behavioral research at [non-Federal] public institutions and at nonprofit private institutions, and

(iv) pre- and post-doctoral training at such public and private institutions of individuals to undertake such research; and

(B) make grants to non-Federal public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake such research) in the matters described in subparagraph (A)(i).

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be.

(2) National Research Service Awards may not be used to support residencies.

(3) Effective July 1, 1975, National Research Service Awards may be made for research or research training in only those subject areas for which, as determined under section 473, there is a need for personnel.

(b) (1) No National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c) (1); and

(C) in the case of a National Research Service Award for a purpose described in subsection (a) (1) (A) (iii) or (a) (1) (A) (iv), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the Award will be conducted.

An application for an Award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The award of National Research Service Awards by the Secretary under subsection (a) and the making of grants for such Awards shall be subject to review and approval by the appropriate advisory councils [to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration] *within the Department of Health, Education, and Welfare* (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted.

(3) No grant may be made under subsection (a) (1) (B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such man-

ner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section other than paragraph (1) of this subsection, National Research Service Awards made under a grant under subsection (a) (1) (B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed three years in the aggregate unless the Secretary for good cause shown waives the application of the three-year limit to such individual.

(5) National Research Service Awards shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the Awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(c) (1) (A) Each individual who receives a National Research Service Award shall, in accordance with paragraph (3), engage in—

(i) health research or teaching *or any combination thereof which is in accordance with usual patterns of academic employment,*

(ii) if authorized under subparagraph (B), serve as a member of the National Health Service Corps or serve in his specialty, or

(iii) if authorized under subparagraph (C), serve in a health related activity approved under that subparagraph.

for a period computed in accordance with paragraph (2).

(B) Any individual who received a National Research Service Award and who is a physician, dentist, nurse, or other individual trained to provide health care directly to individual patients may, upon application to the Secretary, be authorized by the Secretary to—

(i) serve as a member of the National Health Service Corps,

(ii) serve in his specialty in private practice in a geographic area designed by the Secretary as requiring that specialty, or

(iii) provides services in his specialty for a health maintenance organization to which payments may be made under section 1876 of title XVIII of the Social Security Act and which serves a medically underserved population (as defined in section 1302(7) of this Act),

in lieu of engaging in health research or teaching if the Secretary determines that there are no suitable health research or teaching positions available to such individual.

(C) Where appropriate the Secretary may, upon application, authorize a recipient of a National Research Service Award, who is not trained to provide health care directly to individual patients, to engage in a health-related activity in lieu of engaging in health research

or teaching if the Secretary determines that there are no suitable health research or teaching positions available to such individual.

(2) For each year for which an individual receives a National Research Service Award he shall—

(A) for twelve months engage in health research or teaching *or any combination thereof which is in accordance with the usual patterns of academic employment* or, if so authorized, serve as a member of the National Health Services Corps, or

(B) if authorized under paragraph (1) (B) or (1) (C), for twenty months serve in his specialty or engage in a health-related activity.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall (A) by regulation prescribe (i) the type of research and teaching which an individual may engage in to comply with such requirement, and (ii) such other requirements respecting such research and teaching and alternative service authorized under paragraphs (1) (B) and (1) (C) as he deems necessary; and (B) to the extent feasible, provide that the members of the National Health Service Corps who are serving in the Corps to meet the requirement of paragraph (1) shall be assigned to patient care and to positions which utilize the clinical training and experience of the members.

(4) (A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirement, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi \left(\frac{t - \frac{1}{2}s}{t} \right)$$

in which "A" is the amount the United States is entitled to recover; " ϕ " is the sum of the total amount paid under one or more National Research Service Awards to such individual [and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing at the time each Award to such individual was made]; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by him in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount [at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States] *at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.*

[(4)](5) (A) Any obligation of any individual under paragraph (3) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve extreme hardship to such individual and if enforcement of such obligation with respect to any individual would be against equity and good conscience.

(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such Awards \$207,947,000 for the fiscal year ending June 30, 1975, \$175,000,000 for fiscal year 1976, and \$200,000,000 for fiscal year 1977. Of the sums appropriated under this subsection, not less than 25 per centum shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a) (1) (A).

STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

SEC. 473. (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) 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;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act at or through institutes under the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b) (1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will

conduct such study and prepare and submit the reports thereon as provided in subsection (c).

(3) *The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health.*

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TITLE V—MISCELLANEOUS

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GRANTS TO FEDERAL INSTITUTIONS

SEC. 507. Appropriations to the Public Health Service available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence, and appropriations available under the Community Mental Health Centers Act for construction and staffing of community mental health centers and alcoholism and narcotic addiction, drug abuse, and drug dependence facilities shall also be available, on the same terms and conditions as apply to non-Federal institutions, for grants for the same purpose to [hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except that grants to such] *Federal institutions, except that grants to Federal institutions may be funded at 100 per centum of the costs.*

TITLE XI—GENETIC [BLOOD DISORDERS] DISEASES AND SUDDEN INFANT DEATH SYNDROME

[PART A—SICKLE CELL ANEMIA PROGRAMS

[SICKLE CELL ANEMIA SCREENING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

[SEC. 1101. (a) (1) The Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects for the establishment and operation of voluntary sickle cell anemia screening and counseling programs, primarily through other existing health programs.

[(2) The Secretary shall carry out a program to develop information and educational materials relating to sickle cell anemia and to disseminate such information and materials to persons providing health care and to the public generally. The Secretary may carry out such program through grants to public and nonprofit private entities or contracts with public and private entities and individuals.

[(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$20,000,000 for the fiscal year ending June 30, 1973, \$30,000,000 for

the fiscal year ending June 30, 1974, and \$35,000,000 for the fiscal year ending June 30, 1975.

【PROJECT GRANTS AND CONTRACTS

【SEC. 1102. (a) The Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) research and research training in the diagnosis, treatment, and control of sickle cell anemia, (2) the development of programs to educate the public regarding the nature and inheritance of the sickle cell trait and sickle cell anemia, and (3) the development of sickle cell anemia counseling and testing programs and other programs for diagnosis, control, and treatment of sickle cell anemia.

【(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$5,000,000 for the fiscal year ending June 30, 1973, \$10,000,000 for the fiscal year ending June 30, 1974, and \$15,000,000 for the fiscal year ending June 30, 1975.

【VOLUNTARY PARTICIPATION

【SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

【APPLICATIONS; ADMINISTRATION OF GRANT AND CONTRACT PROGRAMS

【SEC. 1104. (a) A grant under this part may be made upon application to the Secretary at such time, in such manner, containing and accompanied by such information, as the Secretary deems necessary. Each applicant shall—

【(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

【(2) provide for strict confidentiality of all test results, medical records, and other information regarding screening, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) consents to be released; or (B) statistical data compiled without reference to the identity of any such patient;

【(3) provide for appropriate community representation in the development and operation of any program funded by a grant under this part;

【(4) in the case of an application for a grant under section 1101(a) (1), provide assurances satisfactory to the Secretary that (A) the screening and counseling services to be provided under the program for which the application is made will be directed first to those persons who are entering their child-producing years, and secondly to children under the age of 7, and (B) appropriate arrangements have been made to provide counseling to persons found to have sickle cell anemia or the sickle cell trait;

【(5) set forth such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant under this part; and

【(6) provide for making such reports in such form and containing such information as the Secretary may reasonably require.

【(b) In making any grant or contract under this part, the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the greatest number of persons in need of the services provided under such programs.

【PUBLIC HEALTH SERVICE FACILITIES

【SEC. 1105. The Secretary shall establish a program within the Public Health Service to provide for voluntary sickle cell anemia screening, counseling, and treatment. Such program shall be made available through facilities of the Public Health Service to any person requesting screening, counseling, or treatment, and shall include appropriate publicity of the availability and voluntary nature of such programs.

【REPORTS

【SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

【(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary.

【PART B—COOLEY'S ANEMIA PROGRAMS

【COOLEY'S ANEMIA SCREENING, TREATMENT, AND COUNSELING, RESEARCH, AND INFORMATION AND EDUCATION PROGRAMS

【SEC. 1111. (a) (1) The Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects for the establishment and operation, primarily through other existing health programs, of Cooley's anemia screening, treatment, and counseling programs.

【(2) The Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for research in the diagnosis, treatment, and prevention of Cooley's anemia, including projects for the development of effective and inexpensive tests which will identify those who have the disease or carry the trait.

【(3) The Secretary shall carry out a program to develop information and educational materials relating to Cooley's anemia and to disseminate such information and materials to persons providing health care and to the public generally. The Secretary may carry out such program through grants to public and nonprofit private entities or contracts with public and private entities and individuals.

[(b) (1) For the purpose of making payments pursuant to grants and contracts under subsection (a) (1), there are authorized to be appropriated \$1,000,000 for the fiscal year ending June 30, 1973, and for each of the next two fiscal years.

[(2) For the purpose of making payments pursuant to grants and contracts under subsection (a) (2), there are authorized to be appropriated \$1,700,000 for the fiscal year ending June 30, 1973, and for each of the next two fiscal years.

[(3) For the purpose of carrying out subsection (a) (3), there are authorized to be appropriated \$1,000,000 for the fiscal year ending June 30, 1973, and for each of the next two fiscal years.

[VOLUNTARY PARTICIPATION

[SEC. 1112. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

[APPLICATIONS; ADMINISTRATION OF GRANT AND CONTRACT PROGRAMS

[SEC. 1113. (a) A grant under this part may be made upon application to the Secretary at such time, in such manner, containing and accompanied by such information, as the Secretary deems necessary. Each application shall—

[(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

[(2) provide for strict confidentiality of all test results, medical records, and other information regarding screening, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) consents to be released, or (B) statistical data compiled without reference to the identity of any such patient;

[(3) provide for appropriate community representation in the development and operation of any program funded by a grant under this part;

[(4) set forth such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant under this part; and

[(5) provide for making such reports in such form and containing such information as the Secretary may reasonably require.

[(b) (1) In making any grant or contract under this title, the Secretary shall (A) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (B) give priority to programs operating in areas which the Secretary determines have the greatest number of persons in need of the services provided under such programs.

[(2) The Secretary may make a grant under section 1111(a) (1) for a screening, treatment, and counseling program when he determines that the screening provided by such program will be done through an effective and inexpensive Cooley's anemia screening test.

[PUBLIC HEALTH SERVICE FACILITIES

[SEC. 1114. The Secretary shall establish a program within the Public Health Service to provide for voluntary Cooley's anemia screening, counseling, and treatment. Such program shall utilize effective and inexpensive Cooley's anemia screening tests, shall be made available through facilities of the Public Health Service to any person requesting screening, counseling, or treatment, and shall include appropriate publicity of the availability and voluntary nature of such programs.

[REPORTS

[SEC. 1115. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

[(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary.]

PART A—GENETIC DISEASES

TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

SEC. 1101. (a) (1) The Secretary through an identifiable administrative unit within the Department of Health, Education, and Welfare may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects to establish and operate voluntary genetic testing and counseling programs primarily in conjunction with other existing health programs, including programs assisted under title X of this Act and title V of the Social Security Act.

(2) The Secretary shall carry out, through an identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. The Secretary may, under such program, make grants to public and nonprofit private entities and enter into contracts with public and private entities and individuals for the development and dissemination of such materials.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$20,000,000 for the fiscal year 1976, and \$25,000,000 for the fiscal year 1977.

RESEARCH PROJECT GRANTS AND CONTRACTS

SEC. 1102. In carrying out section 301, the Secretary may make grants to public and nonprofit entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases.

VOLUNTARY PARTICIPATION

SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, in any other program.

APPLICATIONS; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

SEC. 1104. (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require necessary. Each applicant shall—

(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) satisfied data compiled without reference to the identity of any such patient;

(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant under this part;

(4) in the case of an applicant for a grant or contract for the delivery of services under section 1101 (a) (1), provide assurances satisfactory to the Secretary that (A) the services for community-wide testing and counseling to be provided under the program for which the application is made (i) will take into consideration widely prevalent diseases with a genetic component and high-risk population groups in which certain genetic diseases occur, and (ii) where appropriate will be directed especially but not exclusively to persons who are entering their child-producing

years, and (B) appropriate arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and

(5) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

(b) In making any grant or entering into any testing and counseling programs under section 1101, contract for the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the greatest number of persons who will benefit from and are in need of the services provided under such programs.

PUBLIC HEALTH SERVICE FACILITIES

SEC. 1105. The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

REPORTS

SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary.

PART [C] B—SUDDEN INFANT DEATH SYNDROME

SUDDEN INFANT DEATH SYNDROME COUNSELING, INFORMATION, EDUCATIONAL, AND STATISTICAL PROGRAMS

SEC. 1121. (a) The Secretary, through the Assistant Secretary for Health, shall carry out a program to develop public information and professional educational materials relating to sudden infant death syndrome and to disseminate such information and materials to persons providing health care, to public safety officials, and to the public generally.

(b) (1) The Secretary may make grants to public and nonprofit private entities, and enter into contracts with public and private entities, for projects which include both—

(A) the collection, analysis, and furnishing of information (derived from post mortem examinations and other means) relating to the causes of sudden infant death syndrome; and

(B) the provision of information and counseling to families affected by sudden infant death syndrome.

(2) No grant may be made or contract entered into under this subsection unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information as the Secretary shall by regulation prescribe. Each application shall—

(A) provide that the project for which assistance under this subsection is sought will be administered by or under supervision of the applicant;

(B) provide for appropriate community representation in the development and operation of such project;

(C) set forth such fiscal controls and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant under this subsection; and

(D) provide for making such reports in such form and containing such information as the Secretary may reasonably require.

(3) Payments under grants under this subsection may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

(4) Contracts under this subsection may be entered into without regard to sections 3648 through 3709 of the Revised Statutes (31 U.S.C. 529; 44 U.S.C. 5).

(5) For the purpose of making payments pursuant to grants and contracts under this subsection, there are authorized to be appropriated \$2,000,000 for the fiscal year [ending June 30,] 1975, \$3,000,000 for the fiscal year [ending June 30,] 1976, and \$4,000,000 for the fiscal year [ending June 30,] 1977.

(c) The Secretary shall submit, not later than January 1, 1976, a comprehensive report to the Committee on Labor and Public Welfare of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives respecting the administration of this section and the results obtained from the programs authorized by it.

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TITLE XVI—HEALTH RESOURCES DEVELOPMENT

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PART B—ALLOTMENTS

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AUTHORIZATION OF APPROPRIATION

Sec. 1613. Except as provided in section 1625(d), there are authorized to be appropriated for allotments under section [1510] 1610 \$125,000,000 for the fiscal year ending June 30, 1975, \$130,000,000 for the fiscal year ending June 30, 1976, and \$135,000,000 for the fiscal year ending June 30, 1977.

* * * * *

SECTION 211 OF THE NATIONAL RESEARCH ACT

* * * * *

TITLE II—PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

* * * * *

PART B—MISCELLANEOUS

NATIONAL ADVISORY COUNCIL FOR THE PROTECTION OF SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 211. (a) Section 217 of the Public Health Service Act is amended by adding at the end the following new subsection:

“(f) (1) There shall be established a National Advisory Council for the Protection of Subjects of Biomedical and Behavior Research (hereinafter in this subsection referred to as the ‘Council’) which shall consist of the Secretary who shall be Chairman and not less than seven nor more than fifteen other members who shall be appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. The Secretary shall select members of the Council from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but three (and not more than three) of the members of the Council shall be individuals who are or who have been engaged in biomedical or behavioral research involving human subjects. No individual who was appointed to be a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established under title II of the National Research Act) may be appointed to be a member of the Council. The appointed members of the Council shall have terms of office of four years, except that for the purpose of staggering the expiration of the terms of office of the Council members, the Secretary shall, at the time of appointment, designate a term of office of less than four years for members first appointed to the Council.

“(2) The Council shall—

“(A) advise, consult with, and make recommendations to, the Secretary concerning all matters pertaining to the protection of human subjects of biomedical and behavioral research;

“(B) review policies, regulations, and other requirements of the Secretary governing such research to determine the extent to which such policies, regulations, and requirements require and are effective in requiring observance in such research of the basic ethical principles which should underlie the conduct of such research and, to the extent such policies, regulations, or requirements do not require or are not effective in requiring observance of such principles, make recommendations to the Secretary respecting appropriate revision of such policies, regulations, or requirements; and

“(C) review periodically changes in the scope, purpose, and types of biomedical and behavioral research being conducted and the impact such changes have on the policies, regulations, and other requirements of the Secretary for the protection of human subjects of such research.

“(3) The Council may disseminate to the public such information, recommendations, and other matters relating to its functions as it deems appropriate.

“(4) Section 14 of the Federal Advisory Committee Act shall not apply with respect to the Council.”

(b) The amendment made by subsection (a) shall take effect **July 1, 1976** *January 1, 1977*.

○

CONSIDERATION OF H.R. 7988

SEPTEMBER 30, 1975.—Referred to the House Calendar and ordered to be printed

Mr. PEPPER, from the Committee on Rules,
submitted the following

REPORT

[To accompany H. Res. 757]

The Committee on Rules, having had under consideration House Resolution 757, by a nonrecord vote, report the same to the House with the recommendation that the resolution do pass.

○

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

DECEMBER 5 (legislative day, DECEMBER 2), 1975.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Public Welfare,
submitted the following

REPORT

[To accompany S. 988]

The Committee on Labor and Public Welfare, to which was referred the bill (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, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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I. INTRODUCTION

The National Heart, Lung, Blood, and Blood Vessel Act, P.L. 92-243 was initially enacted September 19, 1972. The Act expired June 30, 1975.

Title I of the National Research Act, P.L. 93-348, Biomedical and Behavioral Research Training was initially enacted July 12, 1974. It also expired June 30, 1975.

S. 988, the National Biomedical, Heart, Blood Vessel, Lung, Blood, and Research Training Act of 1975, is the Committee's bill to improve

and extend these authorities for two additional fiscal years through June 30, 1977 and for other purposes.

II. SUMMARY OF THE BILL

Title I of the bill extends for 2 fiscal years the authority of HEW to conduct research, experiments and demonstration programs with respect to heart, lung, blood and blood vessel diseases. The major substantive revisions are provisions that change the title of the National Heart and Lung Institute to the National Heart, Lung and Blood Institute and provide explicit authority for the Institute to conduct programs with respect to the use of blood products and the management of blood resources.

There are authorized \$10 million for fiscal year 1976 and \$25 million for fiscal year 1977 for prevention and control programs, and there are authorized \$338 million for fiscal year 1976 and \$372 million for fiscal year 1977 for the national heart, blood vessel, lung and blood diseases and blood resources program.

Title II would extend, with only technical modifications, for fiscal years 1976 and 1977, the explicit authority of the Secretary of Health, Education, and Welfare to provide awards to individuals and institutions for biomedical and behavioral research training. It would authorize \$160 million for fiscal year 1976 and \$176 million for fiscal year 1977.

The total authorization for such programs is \$59 million below the comparable House passed provisions.

Title III of the bill includes miscellaneous provisions respecting:

1. Deletion of the prohibition of the Secretary of HEW's authority to waive a right of recovery under section 1631(b) of the PHS Act.

2. Rights and benefits equality for PHS officers of the commissioned corps to the Armed Forces under the Soldiers and Sailors Civil Relief Act.

3. Broadens the scope of Federal institutions eligible for funding as requested by the Department, respecting its authority under section 507 of the PHS Act.

4. A one year extension, at a reduced level of authorizations of \$2 million for fiscal year 1976, for physician area shortage scholarships.

5. A one year extension of health profession student loan programs for fiscal year 1976, at their current authorization level, \$60 million and \$35 million.

6. Authorizes a stipend up to \$25,000 to be paid visiting scientists who agree to teach at minority schools and authorizes the Minority Access to Research Careers (MARC) Program in HEW, to initiate programs at the undergraduate level.

Title IV of the bill amends the Federal Food, Drug and Cosmetic Act to prohibit regulation of vitamin and mineral supplements solely on the basis of potency; permit sale of any combination of vitamins and minerals and other foods; define foods "for special dietary use" using the current definition; provide FDA authority to seize a manufacturer's product if his advertising is false and misleading in a material respect; permit seizure in retail outlets under certain, limited

conditions; and provide FDA authority to regulate vitamin and mineral products marketed for pregnant and lactating women and children to age 12.

Title V of the bill are technical and conforming amendments to the National Arthritis Act.

III. NEED FOR THE LEGISLATION

A. HEART AND LUNG¹

Cardiovascular diseases (heart and blood vessel diseases) continue to be the primary health problem in the United States. It is estimated that 28,000,000 Americans are afflicted with some form of heart or blood vessel disease: 23,000,000 of them have hypertension, 3,900,000 suffer from coronary heart disease and 1,700,000 from rheumatic heart disease, while 1,650,000 have had one or more strokes. In 1972, an estimated 1,060,000 Americans died from heart and blood vessel diseases; this represented more than 54 percent of deaths from all causes.

Arteriosclerosis

Arteriosclerosis, or "hardening of the arteries," is by far the most common of the serious diseases affecting man in Western society. It represents a chronic progressive pathologic change in which the inner lining of the arteries becomes rough, thick, hard, and covered with lipid-rich plaques. Eventually, the inner diameter of the vessels decreases and blood flow in the diseased arteries diminishes or stops completely. Arteriosclerosis begins early in life and generally becomes manifest in middle age or later. Until it does become manifest as heart attacks, stroke, or other illness, it is often without symptoms and is therefore undetected. Its first clinical manifestation may be an abrupt catastrophic illness.

Virtually all adult American males and post-menopausal women are afflicted to some degree. The economic impact of arteriosclerotic disease in the United States has been estimated at \$26 billion per year in lost productivity and expenses for medical care. If arteriosclerosis could be prevented, hundred of thousands of lives might be prolonged. International statistics reveal a great variation in death rates for atherosclerotic coronary heart disease. For instance, in Denmark and Sweden, the death rate for men under the age 55 is less than half that for the same age group in the United States; in many countries it is far lower and in some, for example Japan, atherosclerotic coronary disease is a rare condition. This difference indicates that the high death rates due to arteriosclerosis in the United States are neither necessary nor inevitable. Although attempts to learn why the United States fares so poorly in these comparisons have not been conclusive, studies have suggested that differences in diet, lifestyle, and personal habits may be important. Risk factors associated with an increased rate of development and progression of arteriosclerosis are age, sex, high levels of cholesterol in the blood, high blood pressure, and smoking. Of these, the latter three can potentially be controlled, and considerable effort is currently being expended in the National Program

¹ Excerpted from the "Second Annual Report of the Director of the National Heart and Lung Act," March 10, 1975 as required by section 413(b) of the Public Health Service Act.

to learn more about these as well as other factors which may play a role in the development of atherosclerosis.

Hypertension

Hypertension, or high blood pressure, is a common and often serious condition. An estimated 23 million adult Americans, or about 15 percent of the adult population, have some degree of hypertension. It is more common in the black population than in the white population. It predisposes to arteriosclerosis and is a risk factor for heart attack and heart failure, and it is the major predisposing factor for stroke.

Hypertension can be treated, and treatment reduces the incidence of stroke, kidney failure, and heart failure. However, it is uncertain at present whether treatment will also reduce the incidence of heart attacks. It is also uncertain whether slight or mild degrees of hypertension require treatment. Current treatment, while effective, is unsatisfactory in that it requires lifelong adherence to medication, is expensive, has some side effects, and must be individualized. In more than nine out of ten cases of hypertension, the cause of the disorder is unknown and hence we still lack the means to prevent or cure it even though treatment and control are possible.

High blood pressure is easily detected, but may exist for many years without symptoms. While it can be controlled with available therapy, of the millions of Americans with this disease, half are probably unaware that they have it, and of those who are aware, less than half are receiving adequate therapy. The National Program is expending efforts both on research to discover the causes of hypertension and on programs to educate the public about the dangers of hypertension and the benefits of treatment.

Cerebrovascular Disease

Cerebrovascular disease occurs when an artery supplying blood to the brain is blocked, ruptured, or injured. Cerebrovascular disease due primarily to arteriosclerosis and hypertension is the basis for the great majority of strokes. The individual and public health burden of death, paralysis, and brain damage from cerebrovascular disease is large. Of the 1.7 million adults who have this disease, 800,000 are partially or completely disabled and 200,000 reside in nursing homes. Stroke kills about 200,000 persons a year particularly at older ages. The death rate is greater among men than women, and greater among blacks than whites. Each year, nearly 600,000 patients are discharged from our hospitals with a diagnosis of stroke, and each year about 250,000 individuals between the ages of 25 and 64 are crippled mentally or physically by a stroke. Many more lives could be saved and disabilities prevented if we had effective methods for prevention and treatment of arteriosclerosis and hypertension, and if available treatment were more widely applied. There has been an appreciable decrease in deaths from stroke, and some of this decrease may be attributable to recent advances in therapy for high blood pressure.

Coronary Heart Disease

Coronary heart disease refers to the consequences of atherosclerosis in the arteries that supply the heart muscle. A heart attack is a manifestation of coronary heart disease and occurs when a coronary artery is blocked, preventing the blood from reaching the heart muscle nor-

mally nourished by the artery. This produces death of the heart muscle, technically called myocardial infarction. Depending upon the site of the coronary blockage, a small or a large fraction of the total heart may be involved.

Heart disease associated with arteriosclerosis of the coronary arteries remains the predominant form of heart disease in the adult American population. It is responsible for chronic illness in 4 million Americans, 2.5 million below the age of 65. In 1972, coronary heart disease accounted for about 685,000 deaths in this country. It is the largest single cause of death from cardiovascular disease and is the leading cause of death in men after age 40 and in women after age 60. Each year, approximately 170,000 persons below age 65 die of coronary heart disease.

Coronary heart disease may also result in angina pectoris (a temporary pain usually located in the center and left arm that is brought on by exercise, exposure to cold, and other factors and relieved by rest), heart failure (impaired pumping performance of the heart leading to accumulation of fluid in the body and congestion in the lungs), disturbances of heart rhythm, and sudden death.

The coronary artery bypass operation has been perfected surgically and can bring increased blood supply to endangered heart muscle. This technique uses a blood vessel graft to bypass narrowed or occluded segments of coronary arteries. Over 25,000 such operations are being done annually in the United States, with hospitalization costs in excess of \$5,000 for each operation. Although such surgery generally provides substantial decrease of symptoms in patients with severe angina pectoris, the long-term effects upon mortality and the clinical circumstances in which it is preferable to medical therapy are not adequately defined.

Peripheral Vascular Diseases

Peripheral vascular diseases are the cause of considerable suffering and disability. They are abnormalities that occur within arteries or veins. Atherosclerotic narrowing may result in inadequate blood flow through the arteries. The veins may become dilated (varicosities) or inflamed and obstructed by blood clots (thrombophlebitis). These diseases may be painful and result in organ damage, skin ulcerations, and gangrene. Peripheral vascular disease in the legs may affect the ability to walk or run. Thrombosis in the veins may produce pulmonary embolism, i.e., clot fragments may be carried in the blood from their site of origin to the lungs. This in turn may result in shock and death. About 265,000 patients are discharged from hospitals each year with a primary diagnosis of peripheral vascular disease.

Arrhythmias

Arrhythmias, or abnormal heart rhythms, are one of the most common manifestations of various types of heart disease and they are frequently the immediate cause of heart failure and death. Arrhythmias result from an alteration in the normal generation and transmission of electrical impulses within the heart.

They may also occur without recognizable disease. Many rhythm disturbances have minor influence upon life expectancy and cause little disability, while others cause serious symptoms, and some are almost instantaneously fatal. For example, arrhythmias kill more

than half of the patients with coronary heart disease and are a major problem in patients with rheumatic heart disease. The National Program is concerned with the development of improved methods for prevention, diagnosis, and management of arrhythmias.

Heart Failure and Shock

Heart failure and shock represent major causes of death and may be the consequence of various disorders ranging from inadequate pumping by a severely damaged heart (cardiogenic shock), loss of blood (hemorrhagic shock), and impairment in the control of arterial tone. Heart failure occurs when the heart has been damaged so extensively that its ability to pump blood is impaired and it can no longer meet the needs of the body. In its chronic form, it is often associated with shortness of breath, accumulation of fluid, and swelling of the legs. Shock is also a secondary phenomenon characterized by an inability of the heart and peripheral arterial tone to maintain adequate blood pressure and blood perfusion. Left untreated, it rapidly leads to irreversible damage to such critical organs as the brain and the kidney, and ultimately to death.

Heart failure and shock are the most common causes of in-hospital deaths from heart attack and most other types of heart disease, thus accounting for about a quarter of a million deaths annually. In addition, chronic heart failure may follow a heart attack or result from high blood pressure or other cardiovascular diseases. About two million Americans have chronic heart failure. In the majority of chronic heart failure patients, symptoms can be relieved by drugs.

In the absence of valvular lesions or intracardiac defects, insufficient surviving or poorly functioning heart muscle is the immediate cause of heart failure and shock in most instances. An improved understanding of energy utilization in heart muscle is essential for adequate control or prevention of heart failure and shock in these cases.

Congenital and Rheumatic Heart Diseases

Congenital heart disease occurs when the heart or major blood vessels near the heart fail to mature normally before birth. About half of the children born with this disease do not survive until their first birthday. The causes of congenital heart disease are generally unknown. Less than three percent are known to be related to a particular event or disorder occurring during pregnancy, such as rubella (German measles), infection, or the use of certain drugs, such as thalidomide.

At present there are 35 recognizable types of congenital or inborn heart defects and about 25,000 babies are born each year with heart defects. The postnatal mortality from heart defects is about 7,500 per year. In addition, there are 100,000 children and 1,600,000 adults with known rheumatic heart disease with an annual mortality rate of about 15,000.

The earliest surgical successes in the treatment of heart diseases were in the correction or palliation of congenital heart disease. These successes are being exploited in the development of diagnostic and surgical techniques applicable to the newborn. Important insights have also been gained into the development of the cardiovascular system. However, in most cases, it is still not known what makes the heart develop abnormally before a baby is born.

Rheumatic fever and rheumatic heart disease were once considered leading causes of serious childhood illnesses. They can now be prevented. Rheumatic fever is almost always preceded by a streptococcal infection and may be prevented by prompt treatment of such infections. Rheumatic heart disease is an immunological disturbance that frequently occurs years after initial rheumatic fever and prior streptococcal infection. This type of heart disease may lead to serious damage of the heart valves. This, in turn, may not only shorten life, but also seriously impair the quality of the patient's life. Improved understanding and control of immunological problems is thus important in the identification of susceptibility and the prevention of rheumatic heart disease, as well as in the success of cardiac transplants and in the prevention of cardiomyopathies and possibly other forms of heart disease.

Cardiomyopathies and Infections of the Heart

Cardiomyopathies and infections of the heart are diseases of the heart muscle and its lining. These diseases cause enlargement of the heart, heart failure, irregularities of the heart rhythm, and occasionally sudden death. The prevalence of these diseases, caused by a variety of factors, is unknown. Known factors producing cardiomyopathies include toxic substances, viral infections, alcohol, immunological phenomena, nutritional deficiencies, muscular dystrophy, and a number of rare diseases. The condition may be acute or chronic and progressive. Rapidly fatal disease may be associated with heart failure, disturbances of rhythm, and sudden death. Infections may affect the heart muscle (myocarditis), its interior wall (endocarditis), or its exterior surface (pericarditis). They may be caused by certain viruses, bacteria, or fungi. Cardiomyopathies and myocarditis are being recognized with increasing frequency.

Circulatory Assistance

Circulatory assistance to the failing heart may be provided by many types of devices currently under development. Some are applied externally to the lower extremities in synchrony with the heart beat. In others, the pumping action of the heart is enhanced by synchronously expanding and collapsing a "balloon" positioned in the aorta, the artery leading from the heart. On a very limited scale, a few devices have been employed which require substantial surgery and the actual positioning of a pumping device within the chest. While circulatory assist devices are designed to improve the mechanical function of the heart, the apparatus also generally involves important electronic, pneumatic, hydraulic, and mechanical systems.

Diseases of the lung constitute a major national health problem of increasing dimensions. In the United States, lung diseases covered by the Program account for an estimated 150,000 deaths each year, cause 45 million days lost from work, 40 million days of bed-restricted activity, and cost the economy approximately \$6 billion a year in lost productivity and wages and medical care costs.

Respiratory diseases that represent national health problems include chronic obstructive pulmonary diseases (COPD), acute respiratory distress syndromes (ARDS), and fibrotic and immunologic lung diseases. The economic cost of these diseases has been estimated at \$6.3 billion per year.

Lung diseases afflict both the young and the old. In the newborn, the most common cause of death is the neonatal respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases as well. Fibrotic and immunologic lung diseases are a major cause of lung problems in the young adult, and may cause COPD. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death. An estimated 10 million Americans are currently affected by these diseases. Together with asthma, emphysema and chronic bronchitis represent a particularly pressing health problem since the death rate and prevalence of these conditions have been increasing at an alarming rate over the past 15 years. As a disabling disease, emphysema is the third leading cause of worker retirement on social security disability payments. Seven major problem areas are defined below:

Pediatric Pulmonary Diseases

Pediatric pulmonary diseases present health problems of national dimensions. Hyaline membrane disease (neonatal respiratory distress syndrome), cystic fibrosis (an inherited disease of abnormal mucus secretion), and bronchiolitis (acute airway obstruction in young children) are among the most important disorders of childhood that involve the lung and the airways. About 40,000 babies are born each year with hyaline membrane disease. Many of these will die unless given prompt treatment, presently unavailable except in a few specialized facilities.

Cystic fibrosis occurs in about one of every 2,000 live births and approximately 5 percent of the general population in the United States carries the gene for this disorder. Cystic fibrosis is one of the main causes of chronic illness in children and young adults and accounts for most of the deaths from pulmonary disease in the pediatric age group. Bronchiolitis is a common pediatric disorder, but data are not available on its incidence.

Emphysema and Chronic Bronchitis

Emphysema and chronic bronchitis are among the major causes of mortality and illness from pulmonary diseases. Emphysema is a disease in which the thin walls in the alveoli (air sacs) lose their elasticity and tear. Chronic bronchitis refers to a persistent inflammation of the lungs characterized by recurrent coughing and excess mucus in the airways. These diseases may be associated with certain risk factors, such as cigarette smoking, and in some cases with genetic determinants (e.g., deficiency of alpha₁-antitrypsin enzyme). Emphysema is a leading cause of death in this country and an even greater cause of disability. Data from 1967 indicate that chronic bronchitis and emphysema account for half of the total 181,000 man-years lost due to lung diseases. The crude death rate for chronic bronchitis doubled between 1950 and 1967. The death rate for emphysema increased thirteen-fold in the same period to a level of 10.6 per 100,000 population. Since 1968, the rate decreased 10 percent for chronic bronchitis and 12 percent for emphysema.

Fibrotic and Immunologic Lung Disease

Fibrotic and immunologic lung diseases are induced by many factors. Fibrotic responses (proliferation of connective tissue or scar forma-

tion) and immunologic responses are characteristic of a variety of lung diseases. Among the factors that may induce these responses are exposure to substances such as coal dust, silica, and asbestos in the environment; viral and bacterial infections; diseases of the connective tissue such as rheumatoid arthritis, lupus, and scleroderma; radiation damage; and exposure to substances like molds and dust that initiate hypersensitivity reactions. Diseases characterized by pulmonary fibrosis and/or immunologic reactions include pneumoconiosis, sarcoidosis, diffuse hypersensitivity pneumonitis, farmer's lung, and bronchial asthma. This group of lung diseases is a major national health problem, second in magnitude among lung diseases only to emphysema and chronic bronchitis.

Statistical data on fibrotic lung diseases are inadequate because these diseases are difficult to diagnose and poorly reported. However, their national health impact is far greater than is generally appreciated. For example, sarcoidosis is about 12 to 15 times more common among blacks than among whites in this country, and now outranks tuberculosis as a cause of disability from pulmonary insufficiency in black populations. It is also more common in women.

Among immunologic lung diseases, asthma is the most common, affecting about 6 million persons in this country (approximately 3 percent of the population). It is responsible for 5 percent of all chronic disabilities and causes an annual loss of about 4 million workdays. Other immunologic lung diseases are associated with specific occupations where exposure to organic dusts or molds is high; for example, farmer's lung in the north central states, bagassosis among sugar cane workers in the south, and hypersensitivity pneumonitis from organisms growing in humidifiers and air conditioners. While none of these diseases is very common in the general population, their importance stems from their high incidence in particular environments.

Respiratory Failure

Respiratory failure is a complication of many nonpulmonary diseases. Acute respiratory distress syndromes have been recognized as such only recently. For these two reasons, data on incidence are not available. A conservative estimate is that 150,000 adult cases of acute respiratory distress syndrome occur each year in the United States with a mortality rate of 40 percent. These figures do not include failure due to chronic pulmonary disease (see italics section on Emphysema and Chronic Bronchitis), nor do they adequately reflect the true incidence because so many cases are unreported.

Pulmonary Vascular Diseases

Pulmonary vascular diseases include cor pulmonale, pulmonary hypertension, and pulmonary edema. Cor pulmonale refers to enlargement of the heart due to an increased workload of the right ventricle resulting from conditions which affect the pulmonary circulation. Pulmonary hypertension is characterized by elevation of pulmonary arterial pressure above normal levels. The condition is considered primary when found in the absence of cardiac or pulmonary diseases and secondary when associated with these diseases. Primary hypertension may be caused by factors such as high altitude and low oxygen, or ingestion of certain drugs and chemicals; secondary hypertension may result from destruction of the pulmonary vascular bed, congenital

heart disease, pulmonary vasoconstriction, or congestive heart failure. Pulmonary edema, difficult to detect early, is a pathologic state in which there is abnormal extravascular storage of fluid in the lung. Reliable data on the incidence and prevalence of these diseases are not available. However, it has been estimated that cor pulmonale alone occurs in 40 percent of cases of emphysema and chronic bronchitis, both of which are chronic respiratory diseases of national impact.

Inhalation Diseases

Inhalation diseases are becoming more prevalent in the United States as industrialization and the technological age progress. Of all occupational illnesses, dust inhalation diseases, or pneumoconioses, are the most serious health problem. The dusts inhaled are so fine that they escape the natural cleaning mechanism of the upper respiratory tract and lodge permanently in the lungs. If exposure is sufficiently high and prolonged, the accumulated particles may cause fibrosis or scarring of the lung tissue and in many cases lead to serious disability and even death. One of the most serious problems in our country today comes from the direct handling of asbestos by some 200,000 workers and by another 3 to 5 million persons who are secondarily exposed to the dust. Asbestos is believed to be a leading factor in the deaths of over 2,000 persons each year in the U.S. The breathing of quartz dust, or silica, is another hazard which gradually causes irreversible damage to the lungs. Of the more than 125,000 workers now engaged in coal mining in the United States, an estimated 10 to 20 percent have coal worker's pneumoconiosis, or "black lung." Beryllium, iron, tin, and barium dusts are also hazardous to the lung tissue. Pneumoconioses are also caused by organic dusts from plants such as cotton (byssinosis), sugar cane (bagassosis), and moldy hay (farmer's lung).

Respiratory Assistance

Respiratory assistance can be provided by mechanical devices (ventilators or membrane oxygenators) that support the gas transfer functions of the lung when, as a consequence of the disease, the lungs are unable to maintain proper levels of oxygen and carbon dioxide. Ventilators are devices that mechanically inflate the lungs and can deliver increased amounts of oxygen. Membrane oxygenators are externally placed "artificial lungs" which are connected with the patient's circulatory system. Blood from the patient enters the oxygenator, carbon dioxide is removed, the blood is oxygenated, and then returned to the patient's circulatory system. At present, oxygenators can only be used safely for several days. Recent experience suggests that this method of respiratory assistance holds promise for treatment of some patients in acute respiratory failure.

The following summarizes the four major problem areas in blood diseases and blood resources.

Bleeding and Clotting Disorders

Before describing the major bleeding and clotting disorders addressed in the National Program, the general principles involved in the arrest of bleeding (hemostasis) are outlined below. The hemostatic mechanism is designed to repair breaks in the wall of small blood vessels, namely the components of the microcirculation. The micro-

circulation is an important part of the circulatory system. It carries to the cells of the body the materials needed for their metabolism and function and removes their waste products so that the internal environment is maintained in a manner which allows the cells to survive and perform their interrelated tasks. Bleeding and clotting in the microcirculation contribute to the adverse effects of many diseases and disorders such as hypertension, stroke, diabetes, infectious and inflammatory disease, autoimmune disease, host-graft rejection, cancer, sickle cell anemia, drug toxicity, mismatched blood transfusion, liver disease, nephritis and hemophilia. The impact of the bleeding and clotting diseases is vast even if it cannot be expressed statistically.

Biomaterials

Biomaterials are synthetic materials which can be implanted in the body and used in a variety of medical devices. To be "blood compatible", such materials must not cause damage to the various components of blood and must not induce blood to clot. In addition, biomaterials must possess specific properties suitable for specialized functions (for example, gas permeability for oxygenation devices) and have minimal risk of causing chemical toxicity, allergic reactions, and tumors. Several approaches are being pursued in the development of suitable biomaterials. Properties of the vessel wall have been imitated by "hydrogels," a network structure of long polymer chains and water. Blood compatible surfaces can be grafted or bonded to a variety of materials which have otherwise promising physical properties. Another approach involves the use of human cells which can be grown in culture and attached to certain man-made materials to make them compatible with blood. Materials can be synthesized which contain anticoagulants, clot-dissolving enzymes, and surface-active agents. Composite materials can be produced which are based on a variety of components mentioned above.

Sickle Cell Disease and Other Disorders of the Red Blood Cell

The three groups of disorders considered here include sickle cell anemia and sickle cell trait, conditions closely related to sickle cell disease such as Cooley's anemia, and defects affecting the red blood cell membrane and its metabolic machinery.

Sickle Cell Anemia and Sickle Cell Trait.—Sickle cell trait, the most common inherited blood abnormality in the United States, is believed to be carried by more than 2 million U.S. citizens, primarily blacks. However, most of these "carriers" are healthy. If two carriers marry, each of their children has a one in four chance of having sickle cell anemia, a painful and debilitating disorder affecting nearly 50,000 individuals (see Figure 11). About one in 500 black babies in this country is born with sickle cell anemia.

Sickle cell anemia is a disorder characterized by the presence of painful "crises" which may last for hours or days, a chronic anemia related to accelerated destruction of red blood cells and acute and chronic damage to various body organs. These clinical manifestations are caused by the presence of an abnormal hemoglobin (Hb S) leading to crescent shaped "sickled" red cells. Sickled red cells have difficulty traversing the small blood vessels and tend to occlude them. This in turn results in impaired circulation, tissue damage, and painful crises.

Sickle cell anemia, the homozygous state for the gene for Hb S

(S/S disease), often causes severe and disabling symptoms and may markedly shorten life. Milder symptoms and greater longevity are encountered in certain genetic variants of sickle cell disease (Hb S-C disease, Hb S-thalassemia).

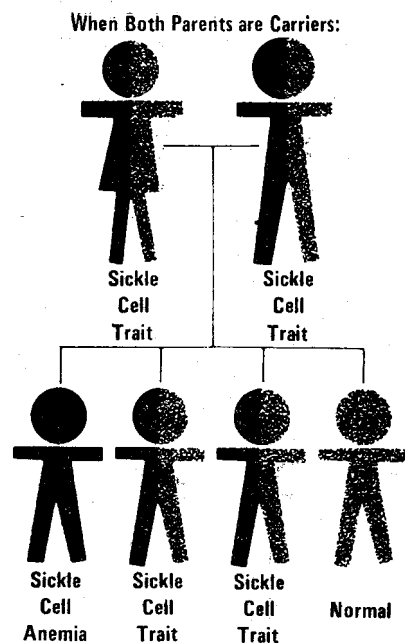


FIGURE 1. Hereditary Impact of Sickle Cell Trait.

If sickling of the red cells could be altered or prevented, perhaps by a suitably designed pharmacologic agent, both the quality and duration of life for patients with sickle cell disease would be greatly improved. While we know the primary defect in sickle cell disease (a mutation which leads to the substitution of a single amino acid in one of the two kinds of polypeptide chains in hemoglobin), much remains to be learned about the formation and structure of the aggregates of deoxygenated Hb S and the interactions of these polymers of Hb S with other red cell components. In a sense, the molecular and cellular manifestations can be considered "causes" of sickle cell disease, since the clinical manifestations are based upon the molecular and cellular phenomena.

The cost of caring for a patient with sickle cell disease may approach \$2,500 to \$5,000 a year. The loss of time from school and jobs, and the resultant psychological and educational problems, make this disorder one of high social and economic impact.

Cooley's Anemia.—Cooley's anemia (thalassemia) results from defective production of one of the sub-units of the hemoglobin molecule, leading to rapid destruction of the red cells. It occurs in perhaps 5,000 Americans, largely of Mediterranean ancestry. Its victims suffer profound anemia and require repeated blood transfusions for survival. As with the sickle cell trait, most carriers do not have symptoms, but one in four offspring may be affected if two carriers marry.

Membrane and Enzyme Defects.—Defects in red cell membranes and red cell enzymes also produce anemia by causing premature destruction of the red blood cells. Such defects are relatively rare, except one, called glucose-6-phosphate dehydrogenase (G6PD) deficiency, which occurs in about 10 percent of black males and less frequently in males of Mediterranean ancestry and other populations. Most of these individuals are healthy, but may develop anemia with certain illnesses or if they take a variety of commonly used drugs.

Blood Resources

Safe and adequate supplies of blood must be available for the nation. Most whole blood is collected by an assemblage of organizations which might be referred to as the blood service complex. As stated earlier, whole blood contains red blood cells, white blood cells, and platelets suspended in plasma. About 9 million units of whole blood and another 8.5 million unit equivalents of blood plasma are collected and used for therapy in the United States each year. The optimal management and utilization of this national resource is vital to the improved health care of the nation.

Transfusion of red blood cells is important in restoring the normal oxygen-carrying capacity of the blood in patients acutely anemic as a result of hemorrhage or chronically anemic because of diseases interfering with normal red cell production. Of all the blood components used in transfusion therapy, red cells are needed in the greatest quantity. White blood cells are vital to the body's defense against infection. In cancer, leukemia, and certain allergic states, circulating leukocytes (a type of white blood cell) are frequently diminished in quantity or impaired in functional quality. As a result, the patient is susceptible to serious infections that may not respond to antibiotic treatment. Transfusions of white blood cells may be beneficial in such cases. Platelets play a prominent role in the initiation of coagulation and in the maintenance of the blood vessel integrity. Leukemia patients often have low circulating platelet levels, either as a result of the disease itself or as a toxic reaction to the drugs used in treating their disease. Drug treatment of solid tumors also frequently reduces platelet levels. Such platelet deficiencies can result in serious, often fatal hemorrhage. Platelet transfusions are vital for these patients.

Approximately 1.7 million liters of plasma are collected each year, mainly for the preparation of plasma protein fractions such as serum albumin used to treat shock; blood grouping protein needed for blood typing; gamma globulin for antibodies to fight disease; and anti-hemophilic globulin to allay bleeding in hemophiliacs.

B. NATIONAL RESEARCH SERVICE AWARDS²

NATIONAL ACADEMY OF SCIENCES.

Washington, D.C., June 16, 1975.

HON. CASPAR W. WEINBERGER,
Secretary of Health, Education, and Welfare,
Washington, D.C.

MY DEAR MR. SECRETARY: I am pleased to present to the Department of Health, Education, and Welfare the 1975 report of the Committee

² Excerpted from "Personnel Needs and Training for Biomedical and Behavioral Research," Commission on Human Resources—National Research Council.

on a Study of National Needs for Biomedical and Behavioral Research Personnel. This continuing study has been undertaken by the National Research Council pursuant to Title I of the National Research Act of 1974 (Public Law 93-348). It responds to your request of September 16, 1974 that the National Academy of Sciences make such a study and follows my letter of March 6, 1975 indicating that the Academy would accept this task. The work has been supported under Contract NO1 OD 5 2109 with the National Institutes of Health.

The Act states (Section 473 (a)) that the purposes of the study are to: "(1) 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 of and extent of training which should be provided such personnel; (2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act at or through institutes under the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel; (3) identify the kinds of research positions available to and held by individuals completing such programs; (4) determine, to the extent feasible, whether the programs referred to in clause (b) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and (5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1)."

The present document, submitted in order to meet the requirement for a report in fiscal year 1975, was prepared little more than three months after commencement of the study, hence, it cannot respond fully to the broad and difficult requirements set by the Act. But a beginning has been made. I trust that our reports in 1976 and thereafter will deal in a more detailed and meaningful way with the significant problem you have brought to us.

We shall be glad to discuss this report for 1975 with you and your staff.

Sincerely yours,

PHILIP HANDLER, *President.*

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

Chairman: Robert J. Glaser, M.D., President, The Henry J. Kaiser Family Foundation.

Vice Chairman: Henry W. Riecken, Ph.D., Professor of Behavioral Sciences, University of Pennsylvania.

John J. Burns, Ph.D., Vice President of Research, Hoffmann-La Roche, Inc., Nutley, New Jersey.

Allan M. Cartter, Ph.D., Professor of Higher Education, Director, Laboratory of Research in Higher Education, University of California, Los Angeles.

Julius H. Comroe, Jr., M.D., Professor of Physiology, University of California, San Francisco.

John E. Jacobs, Ph.D., Walter P. Murphy Professor of Electrical Engineering and Engineering Sciences, Director, Biomedical Engineering Center, Northwestern University.

David Mechanic, Ph.D., Professor of Sociology, University of Wisconsin.

Lincoln E. Moses, Ph.D., Dean of Graduate Studies, Stanford University.

Carl Pfaffmann, Ph.D., Vice President, Rockefeller University.
Mitchell W. Spellman, M.D., Executive Dean, Charles R. Drew Postgraduate Medical School, Los Angeles, California.

P. Roy Vagelos, M.D., Professor and Chairman, Department of Biological Chemistry, Director, Division of Biology and Biomedical Sciences, Washington University.

James B. Wyngaarden, M.D., Chairman, Department of Medicine, Duke University Medical Center.

SUMMARY

We recapitulate some points of the earlier discussion:

1. Federal support of research training contributes to the continuing vitality of biomedical and behavioral research, and, thus, contributes a vital buttress to health care in the United States. The federal presence brings with it national standards. The peer-review system ensures that the standards will be uniformly applied to recognize excellence. Biomedical research training itself (a) aids in selecting the next generation of research leaders, (b) accelerates their graduate education, (c) gives M.D.'s essential research tools and Ph.D.'s essential contact with medical problems, (d) makes it possible for postdoctoral scientists to move into undersupplied fields of specialization, (e) stimulates the development of new fields of research, and (f) provides opportunity for the most able students to have access to biomedical and behavioral graduate education, independent of their private resources.

2. The competitively awarded research training grant is a unique and versatile mechanism that offers advantages beyond those of supplying trained personnel. Among them are: (a) maintenance of a complete training environment, (b) encouragement of existing interdisciplinary linkages and of new interaction of disciplines, and (c) recognition of excellence of training environments in the same way that fellowships recognize excellence of individual performance.

3. Largely due to training efforts of the last decade, a cadre of about 47,000 biomedical and behavioral researchers exists in the United States. About 70 percent of them conduct research in the basic biomedical sciences, 14 percent in the behavioral sciences, 14 percent in the clinical sciences, and 2 percent in health services studies. Seventeen percent hold M.D. degrees, and 83 percent hold Ph.D.'s.

4. Essentially full employment currently exists for doctoral scientists in these fields of research. Unemployment in 1973 was at the "frictional" level of about 1.2 percent for all fields and age groups combined, but may be higher now—perhaps 2 percent overall with somewhat higher rates for some fields and for the most recent recipients of the Ph.D. In a few fields—health services research is an example—personnel shortages exist. The commonly used market indi-

cators, such as trends in relative salaries, suggest that, overall, no serious disequilibrium exists at the moment.

5. There is reason, however, to be concerned about future oversupply in some of the fields and about the costs thereof. Graduate enrollments have been growing strongly, indicating a plentiful supply of graduating Ph.D.'s over the next five years. The cadre of established research workers is relatively young, and attrition will be relatively low. Research and development funds are stabilizing, and demand for personnel will stabilize accordingly. Although M.D. researchers can turn to private practice for alternative careers, similar opportunities will be more limited for Ph.D.'s. The demographic facts suggest there will be relatively few new appointments to faculties in the 1980's. Some caution is needed, and the Committee is not prepared on the basis of its limited studies to urge significant further growth of research training.

6. The training "pipeline" is long—seven years on the average from baccalaureate to Ph.D., 10 years from the baccalaureate to the M.D. researcher. The flow cannot be rapidly turned on or off. Time is required to set up high-quality training programs, and stability is necessary for an efficient and high-quality system. In this regard, the federal-budget decision not to include *any* funds for new starts in training at the predoctoral level in FY 1976 causes the Committee great concern.

7. Certain structural and administrative problems connected with research training have emerged. In the past, some two thirds of postdoctoral M.D. trainees and fellows in these programs entered medical practice soon after completion of training. This result was expected in an earlier period of the training programs when program goals included the training of clinical specialists in shortage fields. Now, however, this goal has essentially been met, and there seems to be little reason to maintain training for clinical practice in the future. A second issue, almost as old as the training programs themselves, concerns the percentage of training-grant funds allotted to various forms of institutional support—faculty salaries, salaries of supporting staffs, equipment purchases, library and computer costs, purchase of supplies, and so on. The Committee believes there should be a limit on the percentage of training funds used for these purposes, but notes that the matter is complex. The strength of the training-grant mechanism resides in large part in its ability to create a strong and vital total environment for training. Stipends for trainees are an essential requirement for training, but so are a strong faculty, adequate equipment and supplies, and other training elements.

8. The difficult problem of proliferation of programs that results in excess training capacity cannot easily be disposed of. The decade of the 1960's witnessed a rapid growth of training programs in response to perceptions of national needs. Now that some of those needs have been met, the situation is changing. The Committee urges upon agencies of government and training institutions a readiness for change in both the character and the magnitudes of the training programs. Legitimate aspirations of institutions and departments can best be accommodated within an adaptive mechanism that recognizes new needs, establishes excellence as the governing criterion, and sets a high priority on flexible response.

9. We have found existing data and field taxonomies insufficient for our task of forecasting personnel needs and the adequacy of the supply. The recommendations in this report are limited by that consideration to statements about immediate training requirements in broad fields. In the course of the year ahead, we expect to acquire more satisfactory data about the training pipeline, the research-personnel pool and the mobility of persons in it, and the components of demand. We also expect to develop a more adequate list of the training and research specialties in these areas.

IV. PUBLIC HEARINGS—S. 988

The Subcommittee on Health conducted hearings on S. 988 on March 17, 1975. At that time testimony was received from:

A. The Administration:

Theodore Cooper, M.D., Acting Assistant Secretary for Health.
Ronald Lamont-Havers, M.D., Acting Director, National Institutes of Health.

Robert Ringler, M.D., Acting Director, National Heart and Lung Institute.

B. The American Lung Institute: Gareth M. Green, President, American Thoracic Society.

C. The American Heart Association: Elliott Rapaport, President.

D. The National Kidney Association: James C. Hunt, M.D., President.

E. The Association of American Medical Colleges:

John F. Sherman, Ph.D., Vice President.

Thomas E. Morgan, M.D., Director, Division of Biomedical Research.

F. The American College of Cardiology: Charles Fisch, M.D., President.

G. The American College of Chest Physicians:

Arthur C. Beall, Jr., M.D., President.

Joseph C. Ross, M.D., Chairman, Committee on Government Liaison.

All of the witnesses testified to the need to reauthorize and improve the expired authorities contained in S. 988, as introduced.

V. PROGRAM ACCOMPLISHMENTS

The Act.—Section 413(a). The Director, NHLI, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung and Blood Program.

Response.—In 1972, NHLI undertook a review of programs at NIH and at other Federal Agencies, and also, with the aid of approximately 300 consultants, reviewed the state of knowledge in the four areas specified in the 1972 Act, namely, Heart and Blood Vessel Diseases, Lung Diseases, Blood Diseases and Blood Resources. The review resulted in an assessment of the ongoing programs, and the opportunities for additional efforts. With the advice of the National Heart and Lung Advisory Council, the Interagency Technical Committee (IATC) and representatives of nonfederal and voluntary organizations with related programs, NHLI organized the results of

this review into a National Program Plan (DHEW Publication No. (NIH) 73-515) supported by extensive resource material from the Council, Panels and IATC.

The National Program Plan was forwarded by the Director of the Institute in May 1972 for transmittal to the Congress and was transmitted to the Congress on July 24, 1973.

As forwarded, the total report is contained in the following publications:

Volume I: National Heart and Lung Institute Summary. (This included the actual 5 year plan as required by the Act and the Institute's projections on the appropriation necessary to carry it out.)

Volume II: Report of the National Heart and Lung Advisory Council. (This contains the Council's recommendations, after having reviewed the scientific inputs of the Panel Reports (Volume IV) and the analysis of current program activities (Volume V).)

Volume III: Report of the Panel Chairmen.

Volume IV: Panel Reports:

Part I—Report of the Heart and Blood Vessel Diseases Panel.

Part II—Report of the Lung Diseases Panel.

Part III—Report of the Blood Diseases Panel.

Part IV—Report of the Blood Resources Panel.

Volume V: Program Analysis:

Part I—National Heart and Lung Institute.

Part II—National Institutes of Health (Exclusive of NHLI).

Part III—Other Federal Agencies.

The Act.—Section 413(a) . . . and (The Director, NHLI) . . . shall carry out the Program in accordance with the plan.

Response.—Within the constraints of available resources the program is carried out as detailed in the report, described above.

The Act.—Section 413(b)(2). The Director of the NHLI shall prepare annually a report on activities, progress and accomplishments during the preceding calendar year and a plan for the Program for the next five years.

Response.—During the latter part of 1973 and the early part of 1974, an update of the National Program Plan was prepared, which presented the Institute's revised plan for FY 1976-1980. This updated plan (The First Annual Report of the Director of the NHLI, DHEW Publication No. (NIH) 75-514), was forwarded to the President who transmitted it to the Congress on September 24, 1974. The updated plan for FY 1977-1981 (The Second Annual Report of the Director of the NHLI, DHEW Publication No. (NIH) 75-748) was forwarded to the President who transmitted it to the Congress on June 27, 1975.

The Act.—Section 413(c)(1). If authorized by Council, obtain services of not more than 50 experts or consultants.

Response.—The Institute currently has on board 3 full-time and 1 part-time experts/consultants under these provisions. The Institute did not make fuller use of these provisions because these special NHLI experts/consultants were not exempted from the Institute's regular personnel ceiling. During FY 1975, this ruling was changed, and the Institute is actively recruiting experts/consultants with the expectation that the number will increase substantially during the next year.

The Act.—Section 413(d). There shall be in NHLI an Assistant Director for Health Information Programs appointed by Director,

NHLI . . . shall conduct a program to provide public and health professionals with health information.

Response.—The Institute has established and filled the position of Assistant Director for Health Information Programs. An analysis of public and professional inquiries has resulted in several workshops, and new publications for broad distribution are being developed. New approaches to communication involving multi-media approaches are being developed. The distribution of health related information is steadily increasing; last year in the area of hypertension alone, approximately 30,000 articles appeared in magazines and newspapers (or the print media).

The Act.—Section 414(a)(1). Director of NHLI shall establish control programs as necessary for cooperation with other federal health agencies, state, local, and regional . . . and non-profit private health agencies.

Response.—The National High Blood Pressure Education Program is the major effort currently involving active cooperation and participation of other federal, state, local and regional public health agencies. There are currently about 100 such agencies actively involved in this program. This activity is of high priority to the Institute and will continue. The Sickle Cell Disease Program is another major program involving the coordination by NHLI of the National Institutes of Health, Health Services Administration, Center for Disease Control, Veterans' Administration, Department of Defense and the Labor Department. Major emphasis is on decreasing morbidity and mortality in sickle cell disease through a program of research and development and demonstration activities in public education, testing, rehabilitation and follow-up. Other cooperative efforts are in the planning stages to deal with cardiac rehabilitation, hemophilia and diet modification.

The Act.—Section 415(a)(1). Director, NHLI may provide for development of: (A) 15 new centers for research and demonstration in heart and blood diseases, (B) 15 new centers for research and demonstration in lung diseases.

Response.—(A) During FY 1975 one National Research and Demonstration Center was established for heart diseases (Baylor College of Medicine, Houston, Texas) and one for blood resources (King County Central Blood Bank, Inc., Seattle, Washington). Each of these deals with a broad spectrum of issues including basic and clinical investigation, community demonstrations of diagnostic and preventive techniques and public and health professional education dealing with current knowledge and new approaches to disease control.

(B) One National Research and Demonstration Center for lung diseases (University of Vermont, Burlington, Vermont) has been established. It focuses primarily on occupational safety and health as related to lung diseases. The program of this center covers the spectrum as in (A) above.

The Act.—Section 416(a). The Secretary shall establish an Interagency Technical Committee responsible for coordinating all related Federal programs and providing for full communication and exchange of information.

Response.—The Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources was established

by the Secretary, DHEW, on November 3, 1972. Departments and agencies represented on this committee are:

Constituent Agencies of HEW:

Alcohol, Drug Abuse and Mental Health Administration.
Center for Disease Control.
Food and Drug Administration.
Health Resources Administration.
Health Services Administration.
National Institutes of Health.
Social and Rehabilitation Services.
Social Security Administration.

Other Departments and Agencies:

Department of Agriculture.
Department of Defense.
Department of Transportation.
Atomic Energy Commission.
Environmental Protection Agency.
National Science Foundation.
National Aeronautics and Space Administration.
Veterans Administration.

This Committee has assisted in the preparation of an annual report which summarizes the Federally-supported research programs in Heart, Blood Vessel, Lung and Blood Diseases and Resources. It has also provided a vehicle for exchange of information on current operating programs and the development of new programs.

The Act.—Section 417(a). There is established a Heart and Lung Advisory Council of 23 members.

*Response.—*The Council was revised to 23 members following enactment of the legislation.

The Act.—Section 417(d). The Director, NHLI, shall designate a member of the staff . . . to act as Executive Secretary to the Council.

*Response.—*Following the enactment of P.L. 92-423, the Director appointed a senior member of the Institute staff to serve as Executive Secretary to the Council. One of the major duties of the Executive Secretary is to assist the Council in preparation of the annual Council report required by P.L. 92-423.

The Act.—Section 417(e). The Council shall meet not less often than 4 times per year.

*Response.—*The Council as a whole meets regularly four times per year; in addition, subcommittees or working groups meet between Council meetings as necessary.

The Act.—Section 418(b)(2). The Council shall submit a report to the President for transmittal to the Congress not later than January 31 of each year.

*Response.—*The First Annual Report of the National Heart and Lung Advisory Council, DHEW Publication No. (NIH) 74-508, was forwarded to the President who transmitted it to the Congress on July 29, 1974. The Second Annual Report of the National Heart and Lung Advisory Council, DHEW Publication No. (NIH) 75-747, was forwarded to the President who transmitted it to the Congress on May 15, 1975.

The Act.—Section 5, Section 419A(2)(c). The Director, NHLI, may approve grants not to exceed \$35,000 without review and recommendation by Council.

*Response.—*The Institute has not taken advantage of this provision because of administrative difficulties and the necessity for clarification whether the stipulated sum refers to direct cost or total cost. The Institute has submitted a legislative recommendation that the \$35,000 be identified as direct costs in a similar manner to the provision in the National Cancer Act Amendment of 1974 (P.L. 93-352, July 23, 1974).

The Act.—Section 419B. Appropriations for any fiscal year shall be not less than 15% lung and 15% blood.

*Response.—*This requirement has been met. For FY 1974 this allocation for Lung Diseases was 15%; for Blood Diseases and Resources, 17%.

The Act.—Section 8. The Secretary, HEW, shall carry out a review of all administrative processes and submit a report to Congress within one year of the findings.

*Response.—*The Secretary, HEW, forwarded the required report on administrative processes to the Congress on September 27, 1973. The report concluded that the authorities made available by the 1972 Act generally have provided the administrative tools necessary to implement the National Heart, Blood Vessel, Lung and Blood Act efficiently.

VI. ADMINISTRATION POSITION—S. 988

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
JUNE 6, 1975.

HON. HARRISON A. WILLIAMS, JR.,
Chairman, Committee on Labor and Public Welfare,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 13, 1975, for a report on S. 988, 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."

Title I of the bill would provide several amendments to title IV, part B, of the Public Health Service Act. It would change the yearly reporting requirement for the Director of the National Heart and Lung Institute from a calendar to a fiscal-year basis and require the Director to submit his annual report to the Secretary for transmittal to the President and the Congress simultaneously; and require that such report set forth staff and appropriations recommendations. It would also change the title of the Assistant Director for Health Information to Assistant Director for Prevention and Education.

The bill would extend the Heart, Blood Vessel, Lung, and Blood Control Program for two years at \$45 million, the current level of authorizations, and extend the other programs of the National Heart and Lung Institute for two years at the current authorization levels of \$475 million annually. The bill would also amend the provision concerned with national research and demonstration centers so that prevention programs, as well as research programs, would deal with all heart, lung, and related diseases, not solely cardiovascular diseases;

authorize the \$5 million maximum limit for single grants to research centers to be exceeded for "cost of living" increases; and substitute the Director, National Science Foundation, for the abolished position of Director, Office of Science and Technology, as a member of the National Heart and Lung Advisory Council.

Finally, title I would amend the National Heart and Lung Advisory Council's functions to include the submission of a program progress report to the Secretary for transmittal to the President and Congress by November 30 of each year; amend Council functions to include the approval of areas of research supported by contracts and approval of the percentage of the National Heart and Lung Institute's budget expended for such contracts; and allow the Director of the National Heart and Lung Institute to approve grants not exceeding \$35,000 in direct costs without Council review.

Title II of the bill would amend the section of the PHS Act concerned with the National Research Service Awards. It would make eligible for National Research Service Awards persons at all Federal institutions, rather than those only at the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration. The bill would also change the date by which the Secretary must submit a report to Congress on the results of the research manpower study from March 31 to September 30 of each year. Finally, this title would extend appropriation authorization levels for two years at the present level of \$207.9 million annually.

Addressing first the provisions of title I of S. 988, the Department wishes to reaffirm its commitment to maintain the momentum of the heart, blood vessel, lung, and blood research programs. In our view, these efforts have a high health priority. Although we believe that extension of the authorities is unnecessary for 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 that no new activities are mandated.

We disagree with the authorization level for heart and lung activities proposed by S. 988 because of our need to consider these programs against the background of the total resources available for other health research efforts and for other Federal programs as well.

We are opposed to the amendment specified in section 109 of the bill, which would modify the Advisory Council's duties to include approval of research areas to be supported by contracts and approval of the percentage of the Institute budget which may be expended for such contracts. These provisions would change the role of the Council from its advisory role as established in the 1972 Act to administrative role, which is properly reserved to Department officials who can be held accountable for their decisions. This accountability is characteristic not only of the Department of Health, Education, and Welfare officials but also of officials in all other Government agencies.

In addition, the Institute's planned expenditures for contracts and grants are approved by Congress in the appropriation process, and the Institute must obtain approval from Congress for any major shifts in planned expenditures. Given time and other constraints, the Council would be unable to function effectively in the appropriation process. Therefore, the Department feels that the Council's efforts regarding contracts can best be directed towards providing advice

regarding broad principles of program balance in extramural activities and by performing periodic overviews of the objectives and accomplishments of Institute programs. The Council, composed of public representatives and scientists with diverse areas of expertise, is better qualified to serve in a general advisory function than to make specific decisions concerning the percentage of Institute funds to be utilized in the contract program. Institute scientific program advisory groups now provide the kinds of detailed advice needed to identify more specific priorities in technical areas and more definitive guidelines are being developed at Department and NIH levels to standardize appropriate uses of the grant and contract award instruments.

The choice of funding mechanism should remain the Institute's within broad agency and departmental guidelines.

Finally, we would make the following technical suggestions:

(1) The order of words in the bill's short title be changed to read, "National Biomedical Heart, Blood Vessel, Lung, Blood, and Research Training Act of 1975," to coincide with the title of the 1972 Act.

(2) We recommend against changing current law to require the Director of the National Heart and Lung Institute to recommend staffing and appropriation levels in his annual report. Such recommendations would not reflect the needs for that one institute in the context of the needs in NIH elsewhere in light of the overall availability of resources. We also oppose the title change in the bill for the Assistant Director for Health Information as unnecessary.

(3) Sections 101 and 108 of the bill be modified, as indicated in the enclosed technical attachment, to allow for the change-over to the new fiscal year period.

(4) "such disease" in section 105(c) be changed to "such diseases".

(5) Section 102 be deleted as unnecessary: "alter" and "renovate" connote the same idea as the present wording "improve" and "repair".

Turning to the amendments concerned with the National Research Service Awards, we recommend Committee adoption of the Administration proposal which has been introduced as H.R. 7049. We particularly oppose the provision on extension of the authorizations. The appropriation authorizations are not consistent with the President's 1976 Budget and we believe that a three-year rather than two-year extension is necessary to provide the stability necessary for the success of our research training efforts. We would therefore recommend that \$136 million be authorized for the fiscal year ending June 30, 1976, and for each of the two succeeding fiscal years.

The Department has submitted legislation to the Congress which embodies our proposed changes concerning the National Research Service Awards. Two specific changes included in this bill are proposals to ameliorate the harshness of the pay-back formula by allowing three-fourths credit for time served instead of one-half credit in the present law and to clarify that the NAS study is advisory in nature. We strongly urge that these amendments be incorporated in S. 988.

The Department looks forward to working with the Committee regarding modifications of the existing research training authority. We

would not oppose S. 988 if it is amended to incorporate our comments and proposals.

We would also suggest the following technical changes for title II:

(1) References to section 472 of the PHS Act refer also to the specific section heading "National Research Service Awards", as there is presently another section 472 dealing with peer review.

(2) Section 202 of the bill be deleted as unnecessary; "or" in this context in the PHS Act is inclusive (and/or), not exclusive.

Although not addressed in S. 988, several additional legislative issues were raised at the hearings on S. 988 before the Subcommittee on Health on March 17. We would like to comment on two of them at this time.

The Department urges that amendments be made to the current law to clarify the fact that the authority of the National Heart and Lung Institute includes blood resources activities. Although the 1972 amendments included blood resources in its provision relating to studies of blood diseases, it omits reference to blood resources in several relevant sections. We recommend that section 414 and 415 be amended by inserting references to blood resources where appropriate. Suggested wording may be found in the enclosed technical attachment.

There is a provision in the Department's proposed legislation which we believe could be appropriately included in S. 988. This would modify section 507 of the PHS Act to make all Federal institutions eligible, under the same conditions under which non-Federal institutions are eligible (except that 100 percent funding may be provided), for research, training, and demonstration project grants under the PHS Act, and certain other grants under that Act and the Community Mental Health Centers Act. Currently only Public Health Service Veterans Administration, and Federal Bureau of Prisons hospitals and St. Elizabeths Hospital are authorized to receive such support. Since other Federal institutions also provide unique research capabilities such as specialized facilities and diverse scientific and engineering talent, they are ideally suited and highly qualified to attack many problems in the biomedical, behavioral, and environmental areas. Examples of such Federal institutions and facilities are the NASA Jet Propulsion Laboratory and the Armed Forces Institute of Pathology, both of which conduct cardiovascular research.

Subject to the exceptions noted above, we do not oppose enactment of S. 988.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

CASPAR W. WEINBERGER,
Secretary.

Enclosure.

TECHNICAL ATTACHMENT

I. SUGGESTED CHANGES IN SECTION 101 OF THE BILL

A. Add a subsection designation "(a)" after "Sec. 101."

B. Add a new subsection (b), as follows:

"(b) For purposes of paragraph (2) of subsection (b) of section 413 of the Public Health Service Act (as amended by this Act), the

period beginning January 1, 1975, and ending December 31, 1975, and the period beginning January 1, 1976, and ending September 30, 1976, shall each be considered a fiscal year."

II. SUGGESTED CHANGES IN SECTION 108 OF THE BILL

A. Add a subsection designation "(a)" after "Sec. 108."

B. Add new subsections (b) and (c), as follows:

"(b) For purposes of paragraph (2) of subsection (b) of section 418 of the Public Health Service Act, the period beginning July 1, 1975, and ending September 30, 1976, shall be considered a fiscal year.

"(c) This section shall take effect on January 1, 1976."

III. SUGGESTED NEW SECTION 112

"References to Blood Resources

"SEC. 112. (a) Section 414 of such Act is amended by—

"(1) In subsection (a), inserting ', and in blood resources activities' after 'children', and

"(2) in the heading, inserting 'and blood resources' after 'control'.

"(b) Section 415 is amended by—

"(1) In paragraph (a) (1) (A), (A) striking out 'demonstration of,' and inserting instead 'demonstration concerning, (i)', and (B) inserting ', and (ii) blood resources' after 'blood diseases',

"(2) In paragraph (a) (3), inserting 'and to blood resources' immediately before the last period,

"(3) In paragraph (b), (A) striking out 'demonstration of,' and inserting instead 'demonstration concerning, (1)', and (B) inserting ', or (2) blood resources' after 'or blood diseases', and

"(4) Adding at the end of the heading ', and blood resources'."

VII. COMMITTEE AMENDMENTS AND VIEWS

A. TITLE I—HEART, LUNG, AND BLOOD RESEARCH

1. The principal change made respecting the authority of Public Law 92-423, the 1972 Act, by the reported bill involves a series of amendments designed to provide increased emphasis on the need for a coordinated effort between programs in blood research and the use of blood resources. Thus, the reported bill contains provisions which would change the name of the National Heart and Lung Institute to the National Heart Lung and Blood Institute, make a comparable change in the name of the Institute's advisory council, and make it clear that the authority of the Institute extends to the use of blood products and the management of blood resources.

The Committee, however, wishes to emphasize strongly that these amendments respecting blood, blood products and blood resources in no way are intended set in motion a series of actions by HEW with regard to an overall national blood policy centered in the National Heart, Lung and Blood Institute. The committee has, as yet, held no hearings and made no legislative record with regard to the creation

of a coherent national blood policy in general, including the role of the Federal Government in the implementation of that policy.

The committee intends to turn its attention to this vital public policy issue in the context of its overall review of the Nation's biomedical research policy over the period of the next two years.

2. The Committee's bill authorizes \$10 million for the fiscal year ending June 30, 1976, and \$25 million for fiscal year ending June 30, 1977, for the continuation of the programs to prevent and control heart, blood vessel, lung, and blood diseases. These programs are, in the Committee's judgment, of vital importance to the nation. The Administration's lack of performance in implementing this authority concerns the Committee. The Committee wishes to point out that it considers authority like this to be one of the crucial aspects of a well-functioning NIH. It is the Committee's belief that the NIH, its sister research institutions throughout the nation, and research scientists and clinicians are in the best position to assure that research advances are rapidly translated into improved patient care. The Committee urges HEW, NIH, and the National Heart, Lung, and Blood Institute to effectively implement this authority.

3. With the Committee's amendments to increase emphasis on blood, blood products, and blood resources, the Committee has amended Section 415 of the Act so as to permit the creation of ten new centers for basic and clinical research respecting heart disease, ten new centers for basic and clinical research in lung disease, and ten new centers for basic and clinical research for blood and blood vessel diseases.

The Committee urges the Administration to implement this authority effectively and expeditiously.

4. The Committee also is concerned about the implementation of Section 416 of the Act respecting the Interagency Technical Committee. The Committee wishes to reaffirm its support for such a Committee. The Committee is concerned that there has not been effective coordination of the federal effort respecting heart, lung, and blood research, which spans many federal departments. In addition, the Committee is concerned that there has not been effective coordination of these functions within HEW. Therefore, given the breadth of the authority regarding these diseases and the scope of federal departments involved, the Committee urges the Interagency Committee to seriously consider the creation of working sub-groups for each of the major disease areas with special emphasis upon intra-HEW coordination.

5. The Committee feels the duties of the National Heart, Lung, and Blood Advisory Council should include the making of recommendations concerning those portions of the National Program that are conducted under contract awards. Since the membership includes public representatives as well as scientists with diverse areas of expertise, the council has a wide perspective from which to provide advice regarding broad principles of program balance in extramural activities. Thus, the reported bill specifically includes as mandated functions of the advisory council the development of recommendations regarding general areas of research and development suitable for award under contracts, and suggestions as to portions of the Institute budget to be devoted to such research and development areas.

Nonhuman primates have proven to be excellent experimental models for investigations in a variety of biomedical research areas, including cardiovascular, cancer, infectious diseases, drug development, vaccine testing, and behavioral studies. Because of their close phylogenetic relationship to the human, primates are widely considered to be the model of choice for investigations in several areas of cardiovascular (CV) research, including atherosclerosis. The effects of dietary constituents and modifying drugs on, for example, cholesterol levels is currently being studied in a number of laboratories. Extensive use has also been made of the nonhuman primate model to further the understanding of physiological mechanisms involved in the CV system.

The Committee believes an adequate supply of such animals is vitally important. Because the normal overseas supply is diminishing, the Committee would recommend that NIH establish the necessary arrangements to provide for domestic sources.

6. In the course of hearings on S. 988 the Association of American Medical Colleges raised the concern it has respecting the confidentiality of research grant data. The Association proposed an amendment to remedy the problem it perceived.

The Association testified: 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 applicant's 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.

Subsequent to its testimony the Association modified its proposed amendment in a letter to the Committee dated April 1, 1975, as follows:

ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
Washington, D.C., April 1, 1975.

HON. EDWARD M. KENNEDY,
Chairman, Health Subcommittee, Committee on Labor and Public Welfare, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: During the course of hearings on S. 988, the extension of heart and research training legislation, you expressed your concerns about the relationship between the protection of human research subjects and the confidentiality of information contained in research grant protocols.

In response to your concerns, the Association would like to propose language which it believes will provide both protection and confidentiality until the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research sets forth its recommendations. A copy of this language is attached for your consideration.

The major feature of this proposal is the authority given to the Secretary to disclose upon request all research protocols, research hypotheses, and research designs of investigations which involve human subjects but which have not been exempted by the Congress from the Freedom of Information Act. This provision acknowledges that, where human rights are at issue, public disclosure may contribute to the assurance of adequate protection for human subjects and promote confidence in the nation's biomedical research efforts.

In those cases where human subjects are not involved and where Freedom of Information Act exemptions are not applicable, the Secretary may disclose these documents one year after the award of the grant, contract, or fellowship. This one-year period will give the researcher an opportunity to begin to test his or her hypothesis, and it is absolutely essential for three important reasons:

First, it prevents the possibility that the investigator's ideas will be appropriated by another scientist before the investigator has an opportunity to implement the research design. The research scientist's principal stock-in-trade is the ability to generate creative ideas. These

ideas are the primary determinant in establishing the investigator's scientific reputation and career opportunities. Therefore, these ideas are of a proprietary nature and should be afforded some measure of protection.

Second, the one-year period acknowledges the importance of the integrity and the internationally acclaimed success of the current system of scientific peer review sponsored by the National Institutes of Health. Under this system researchers' ideas are protected, but at the same time are subjected to intense scrutiny for scientific merit by experts in the investigator's field. These experts on the peer review panels represent the public interest by helping to assure that only the highest caliber of scientific research will be supported by Federal funds. In addition, current and proposed Federal regulations will ensure that research protocols will also be closely examined for ethical considerations.

The Association would like to point out that a researcher's findings are subjected to a second, unofficial, form of peer review, through publication in journals which use the referee system. This dual system of review is, the Association believes, in the best public interest.

Unlike investigators participating in the NIH peer review and the academic referee systems, many competing scientists (for example, those in the private sector,) are not subject to intense scrutiny for scientific merit. If the traditional confidentiality of Federally funded basic science research projects is removed, these scientists may gain immediate access to the new ideas of young investigators. While they might be able to develop or expand these ideas, the public will not be able to scrutinize the methods, the ethics, or the financial interest in marketing a given product. The Association believes that such a situation would not be in the best interests of the public.

Third, and of crucial importance, the one-year interval will help prevent premature—and potentially hazardous—disclosure of scientific discoveries and hypotheses before they can be tested and proved. Premature publication of such hypotheses may create intense public pressure upon practicing physicians to apply research advances before they have undergone sufficient investigation by research scientists. In the long run, the public interest will be served best by thorough scientific investigation. Therefore, the public's understandable desire to hasten the application of research findings must not be allowed to outweigh the need for responsible and adequate scientific evaluation and control.

In summary, Mr. Chairman, the Association believes that the proposed language provides for protection of human subjects and the protection of nascent scientific ideas. This combination will not only fulfill the best public interest, but will help ensure that the system of scientific peer review developed by the National Institutes of Health will not be compromised.

The Association of American Medical Colleges appreciates this opportunity to express its views on this subject. If I or other members of the Association staff may be of assistance to you in this or other matters, please do not hesitate to call upon us.

Sincerely yours,

JOHN F. SHERMAN, Ph. D.,
Vice President.

Attachment.

AAMC PROPOSED LANGUAGE TO AMEND THE PUBLIC HEALTH SERVICE ACT
TO PROVIDE FOR THE PROTECTION OF HUMAN SUBJECTS AND CONFIDENTIALITY OF RESEARCH PROTOCOLS

Section 301 of the Public Health Service Act is amended by adding the following:

(j) Disclose to members of the public, upon request, research protocols, research hypotheses, and research designs in the records or possessions of the Public Health Service obtained in connection with any application or proposal for a grant, fellowship, or contract only on condition that: (1) the protocol, hypothesis, or design is not exempt from disclosure under 5 U.S.C. 552(b); and (2) at least 12 months have elapsed following award of a grant, fellowship, or contract based upon said application or proposal, provided that the Secretary, upon request of any member of the public, may waive the 12 month time period before disclosure in the case of research protocols, hypotheses or designs which propose to involve human subjects. The Secretary may deny requests for waiver of the time period only after consultation with the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research established by Section 217(f) of this Act. Until such time as such Advisory Council is established, the Secretary may deny such requests only after consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research established by P.L. 93-348.

Because of its concern about the justification of the need for such an amendment, in early May, 1975, Senators Kennedy, Javits, and Schweiker solicited the views of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the President's Cancer Panel, and the President's Biomedical Research Panel.

The responses follow:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D. C., May 26 1975.

HON. EDWARD M. KENNEDY,
U.S. Senate, Committee on Labor and Public Welfare,
Washington, D.C.

DEAR SENATOR KENNEDY: On behalf of the President's Biomedical Research Panel, I am responding to the letter from you and Senators Javits and Schweiker of May 14 concerning the material contained in Title III of HR 7039.

The Panel discussed this matter at its meeting on May 26 and is deeply aware of the sensitive issues involved. Clearly, there is a need to provide relief from the decision of Judge Gesell, as well as that of the Appellate Court, interpreting the Freedom of Information Act in such a way as to permit immediate public scrutiny of all research protocols funded at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration. This area is most

complex, particularly with regard to those biomedical and behavioral research projects that deal with human subjects.

As you know, the Panel is addressing a number of critical issues among which is that of peer review. We do not feel that we have adequate information at the present time to deal with all the nuances embodied in the proposed legislation. While we are in support of providing the relief it seeks, we feel unable to endorse any specific legislation at this time.

Therefore, the Panel would prefer to develop this issue in the context of its own investigation and to maintain close contact with you and your colleagues as this progresses.

Sincerely yours,

FRANKLIN D. MURPHY, M.D.,
Chairman, President's Biomedical Research Panel.

HARVARD MEDICAL SCHOOL,
BOSTON HOSPITAL FOR WOMEN,
Boston, Mass., May 27, 1975.

Senator EDWARD M. KENNEDY,
Chairman, Senate Health Subcommittee, Committee on Labor and
Public Welfare, Washington, D.C.

DEAR SENATOR KENNEDY: I should like to acknowledge receipt on May 21, 1975 of the letter from Senators Javits, Schweiker and yourself relating to the AAMC amendment to the National Heart and Lung Act. This will be distributed to all Commission members and be on the agenda of our next meeting on June 20, 21. As soon as possible a reply will be forthcoming. Should an earlier response be required, it would be possible to poll the Commission members, and I will await your advice on this matter.

Sincerely,

KENNETH J. RYAN, M.D.

J. H. WHITNEY & Co.,
New York, N.Y., June 3, 1975.

Senator EDWARD M. KENNEDY,
Senator JACOB K. JAVITS,
Senator RICHARD S. SCHWEIKER,
Senate Health Subcommittee,
Washington, D.C.

GENTLEMEN: I am pleased to respond to your letter of May 14, 1975, requesting the opinion of the President's Cancer Panel regarding the necessity and appropriateness of an amendment proposed by the Association of American Medical Colleges which proposes to restrict public access to biomedical research protocols.

In general, the Panel favors openness and full disclosure wherever possible. However, peer review as it has operated up to this time is fundamental to the excellence that has characterized the research programs of the N.I.H. We would be seriously concerned about any change in peer review procedures that would be likely to lessen their effective-

ness. We have grave doubts that peer review would work with anything approaching today's effectiveness in a climate of nonconfidentiality.

Our concern has two aspects. First, we believe it is desirable that grant applications remain confidential. Originality and creativity of ideas are the scientist's life blood and he will be reluctant to make the detailed disclosures which now characterize grant applications unless he can rely on their confidentiality. Hence, we believe that nonconfidentiality will lead to a new pattern of grant applications which will make them far less descriptive. This could be particularly damaging to the chances of the young scientist whose reputation is not yet established. The second aspect of the problem relates to the deliberations and the processes of evaluation. Scientists will be far less likely to state their opinions candidly if what they say and write is on the record. Frankness in assessing the scientific merit of applications and the quality of work of individual scientists has been the essence of the effectiveness of peer review. Nothing should be done that will impinge even slightly on this frankness.

We have not been aware of legitimate complaints in this area of sufficient magnitude or importance to justify a change in procedures that have served the public interest so well. Therefore, we would favor legislation that would protect the confidentiality of peer review as it has heretofore existed notwithstanding the provisions of the Freedom of Information Act. However, if some change is needed, we believe that a review procedure can be created for the purpose of reviewing specific complaints which would preserve the essential confidentiality and at the same time provide even further assurance against the possibility of inequity.

We have checked with a large number of scientists who have been personally involved in the peer review system and, without exception, they are of the view that the confidentiality of applications and study section proceedings is a critical aspect of peer review as it now operates. Therefore, while we feel that the proposed AAMC amendment would be preferable to permitting interpretations of the Freedom of Information Act to eliminate confidentiality entirely, we prefer legislation as above suggested.

Sincerely yours,

BENNO C. SCHMIDT.

NATIONAL COMMISSION FOR PROTECTION
OF HUMAN SUBJECTS OF BIOMEDICAL
AND BEHAVIORAL RESEARCH,
Bethesda, Md., July 26, 1975.

HON. EDWARD M. KENNEDY,
*Chairman, Senate Health Subcommittee, U.S. Senate,
Washington, D.C.*

DEAR MR. CHAIRMAN: The letter from Senators Javits, Schweiker and yourself relating to the AAMC amendment to the National Heart and Lung Act was extensively discussed by the members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research at their meeting on June 28, 1975. The members determined that preparation and adoption of a formal

opinion regarding the necessity and appropriateness of the amendment would not be possible at the present time. Although the Commission will be conducting comprehensive studies and investigations regarding the protection of human subjects, it does not now have materials at hand on which to base conclusions regarding the specific issues raised by the AAMC amendment.

Sincerely yours,

KENNETH J. RYAN, M.D.,
Chairman.

On May 19, 1975, the Association of American Medical Colleges wrote to the Subcommittee on Health and urged prompt action on S. 988, as follows:

ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
Washington, D.C., May 19, 1975.

HON. EDWARD M. KENNEDY,
*Chairman, Subcommittee on Health, Committee on Labor and Public
Welfare, U.S. Senate, Washington, D.C.*

DEAR SENATOR KENNEDY: As you will recall in the testimony presented on behalf of our Association during your hearings on S. 988, we suggested consideration of an amendment to the Public Health Service Act to protect the confidentiality of biomedical scientists' ideas as included in research grant applications. The substance of our proposal was to permit a scientist, particularly the younger investigator attempting to establish his scientific reputation, sufficient lead time to initiate his research before his ideas are subject to public disclosure. An equally important component of the proposal would provide for disclosure upon funding of applications in which human subjects were involved. We did not explicitly recommend the inclusion of such an amendment in S. 988; nonetheless, the simultaneous consideration of renewal of the heart/lung and research training authorities seemed to offer a reasonable vehicle for such an amendment.

It has come to our attention that our introduction of this subject for consideration at that time may have served inadvertently to delay the mark-up of S. 988 by your Subcommittee. While we feel very strongly about the principle involved in our proposition as a matter of deep concern for the public interest and desire that its purpose be satisfied with appropriate legislation, we have no desire to impede prompt passage by the Senate of S. 988.

We note that the recently introduced House Bill renewing the heart/lung and research training authorities, H.R. 7039, does contain a provision similar to that which we have suggested. This will permit consideration during the forthcoming hearings scheduled by the House and subsequent action as deemed suitable by the Congress. Because of this circumstance and as no amendment has been introduced in the Senate, there would seem to be no basis for delay on this account.

Thank you for your continued interest in and concern for the Nation's biomedical research program.

Sincerely yours,

JOHN F. SHERMAN, Ph. D.,
Vice President.

The Committee continues in its commitment to the spirit and letter of the Freedom of Information Act, as well as to support of a quality peer review system and excellence in biomedical research. The Committee is not yet convinced that there is at this point in time sufficient justification for an amendment to the Freedom of Information Act or the Public Health Service Act which would in effect exempt research grant data from public scrutiny.

Accordingly, no such amendment is included in the Committee's bill.

The Committee will hold whatever hearings are necessary, and stands ready to take whatever action it believes appropriate, including joint hearings with the Senate Judiciary Committee, which has jurisdiction respecting the Freedom of Information Act, in the event the Committee is presented with substantial and persuasive evidence that, in fact, material damage is being done to continued excellence in biomedical research as a consequence of the provisions in the Freedom of Information Act.

The Committee solicits further views from the President's Biomedical Research Panel concerning this important matter, as the Panel's letter of May 26, 1975 indicates will be forthcoming. In addition, the Committee urges all of the interested parties in this complicated public policy issue to present to the Committee whatever data they may have and whatever recommendations they may wish to make. In particular, the Committee urges the Administration, the scientific community, the Commission for the Protection of Human Subjects, the President's Cancer and Biomedical Research Panels, and public interest law firms to continue to monitor and assess the extent to which there are, in fact, real problems in this area requiring legislative remedy.

B. TITLE II—RESEARCH TRAINING

1. The Committee is concerned that the National Research Service Awards authority has been and continues to be misconstrued by the Administration and, further, that the Administration appears to be unwilling to commit the resources necessary to support the vigorous biomedical and behavioral research training programs mandated in the law. Indeed, many of the actions of the Administration during the first year of the authority appear to be consistent with its previous attempts to abandon the program.

The Administration's reluctance to support predoctoral-level research training has also caused the Committee great concern. It is from the predoctoral ranks that postdoctoral-level research scientists emerge. The Committee believes it is vitally important to support graduate students seeking the Ph. D. or a combined degree with a view to engaging in careers in biomedical or behavioral research. Not only should the supply of highly qualified Ph. D. candidates be maintained, but vigorous steps should be taken to attract bright young persons to careers as research scientists through programs of support for predoctoral training.

C. TITLE III.—MISCELLANEOUS

1. The Committee's bill amends Section 1631 of the Public Health Service Act respecting the rights of the United States to cover funds

appropriated for the construction or modernization of health facilities. The Committee's amendment permits the Secretary of HEW to waive the right of recovery, which heretofore has been partially limited.

2. The Committee's bill amends section 212 of the PHS Act by adding a new section respecting the Soldiers and Sailors Civil Relief Act of 1940.

The PHS Commissioned Corps is governed by a personnel system—including appointment, promotion, pay, leave, and retirement—which is similar or identical to the personnel system of the Army, Navy and Air Force. Like officers of the other services, PHS commissioned officers are subject to assignment to any location in the world to which the Public Health Service orders them. To this extent, the Congress has recognized the similarity between service in the Public Health Service and service in the Armed Forces, and PHS officers enjoy many of the rights, benefits, and privileges provided members of the Armed Forces under Federal law. In addition, a male officer serving in the PHS Commissioned Corps could fulfill his selective service obligation when the draft was operative.

Unfortunately, the Commissioned Corps of the U.S. Public Health Service does not have available to it the provisions of the Soldiers and Sailors Civil Relief Act. As a matter of fact, on December 31, 1970, President Nixon signed into law a bill—Public Law 91-621—which extended to commissioned officers of the National Oceanic and Atmospheric Administration—NOAA—the provisions of the act, leaving the PHS Commissioned Corps as the only uniformed service not covered under this act.

A provision of the Soldiers and Sailors Civil Act of 1940—title 50, United States Code—war, appendix, section 574—provides, in effect, that for the purposes of State income tax liability a member of the military service shall not be regarded as having lost his residence or domicile in his "home" State solely because he is absent under military or naval orders; nor shall he be regarded as having acquired a residence or domicile in any other State solely because of such absence. It also provides that a State—other than "home" State—cannot tax the income of a member of a military service merely because he resides and/or performs his duties there. The act further provides that a member of a military service may continue to register and license his solely owned automobile in his State of legal residence provided that the license, fee or exercise required by that State has been duly paid.

One of the basic elements of the Public Health Service Commissioned Corps is mobility. Commissioned officers spend many years of their careers at stations which are located in a State other than the home State. In many instances, this results in the officer's having to pay a State income tax in two or more jurisdictions. To this extent the officers involved receive a reduction in pay as compared to their fellow officers in the other uniformed services who are only required to pay an income tax in the State of their domicile, and then only if such State imposes an income tax.

In view of these circumstances, PHS officers should be provided this long overdue benefit and that is what this bill achieves. It would not entail the expenditure of any Federal funds and correct an inequity in existing law.

3. The Committee's bill, as proposed by the Administration in their views on the legislation, set forth in section VI of the report, amends section 507 of the Public Health Service Act to expand the authority of the Secretary of Health, Education, and Welfare to award grants for research, training and demonstration projects to Federal institutions. Existing provisions of section 507 limit this authority to awards to hospitals of the Public Health Service, of the Veterans Administration and of the Bureau of Prisons, and to Saint Elizabeths Hospital. The bill expands this authority to authorize the Secretary to make grants for research, training and demonstration projects under the Public Health Service Act and certain other grants under that Act and the Community Mental Health Centers Act to any Federal institution.

4. In order to provide continuity for funding the Committee's bill amends Section 786 of the Public Health Service Act to provide \$2 million for the fiscal year ending June 30, 1976, for the physician area shortage scholarship program.

5. The Committee added Section 305 respecting health professors student assistance to ensure that the student loan program for health professions is not interrupted. The Committee is aware that action has not been taken on the extension of most programs under Title VII of the Public Health Service Act, including the authorization contained in part C, section 742(a) (3), for student loans. Without extension of that section, the student loan program goes into statutory phase out, meaning that any funds distributed to the health professions schools through the continuing appropriations resolution authority for FY 1976 cannot be used by the school to award loans to new students. Only students who have been *previous recipients* of federal health professions loans can be supported.

The loan program legislative authority for first year students lapsed with the Health Manpower Act in 1974. Congress intended for the program to continue, however, as is evidenced by clearly stated authority for nurse training loans in the Health Services and Nurse Training Act. Moreover, loan authority for other health profession will be a critical factor in health manpower legislation soon to be considered by the Committee.

In the interim, the Committee believes that a simple one year extension of the student loan authority will place the Department of Health, Education and Welfare on notice—as was achieved under P.L. 93-385—that Congress intends for the program to continue and to let institutions and needy potential students make their plans sufficiently in advance to take advantage of the loan program.

When the Senate considered the resolution continuing appropriations for certain departments and agencies for Fiscal Year 1976, authority was allowed to lapse for beginning students. Such action occurred because members of the Appropriations Committee provided assurances from the DHEW that certain programs, including the loan program for new students, would not need funding during the first two quarters of the fiscal year.

In the Senate debate on the continuing appropriations resolution for fiscal year 1976, Senators were assured that the Department of Health, Education, and Welfare had a way to support new students.

The committee understands that the methods alluded to are the following:

1. Schools participating in the federal student loan program can use any balance in the schools' federal capital contribution account as of June 30, 1975, to support new student loans.

2. Amounts repaid by former students to the schools during the period July 1, 1975-June 30, 1976, can be loaned to new students. However, a school cannot award loans in anticipation of such repayments. Also, any school that participates in the Health Professions Training Fund (revolving fund) would not have those repayments available because they go to the federal government.

The committee views the first of the two methods as unrealistic because most schools award all possible loan funds, retaining only extremely small balances in their capital contribution accounts. The second is almost equally unrealistic because the loan program has been in operation for such a limited time that only negligible amounts are likely to be repaid during fiscal year 1976. In short, neither method provides a realistic means to meet in any way the financial needs of new students.

Thus, while this may have been technically correct—since the funds for loans financing students beginning in the Fall of 1976 would not normally be committed until the Spring of 1976—in fact, the result would have been vastly different.

Moreover, the Committee notes with concern that a number of institutions were being told informally by DHEW that no first-year student loans could be granted for the coming academic year, because no authority existed in the summer of 1975.

The Committee is distressed by the conduct displayed by DHEW in trying to abolish this program contrary to the wishes of Congress—particularly with its relating information, which while within the letter of the law, violates the spirit of the law.

6. These new sections have been included because of the Committee's concern that the National Research Service Awards program was interpreted in such a way as to deny authority for the NIH and ADAMHA programs designed to assist colleges, universities, and health professional schools with large enrollments of minority group students. The Committee is firmly convinced that minority group persons are under-represented in the biomedical and behavioral research community and that they are, as a group, a largely untapped resource with great potential to contribute to the health programs of the Nation. A 1974 study conducted by the National Academy of Sciences¹ indicates that, of the 208,000 science and engineering Ph.D.'s in the United States, only 0.8 percent are blacks, 0.6 percent are Latins, and less than 0.1 percent are American Indians.

The Committee realizes that, to help improve these dismal statistics, sound undergraduate programs in science and other related disciplines are necessary to provide the foundation for the successful training of minority group students for later careers in biomedical and behavior research. Completely adequate backgrounds are not now being pro-

¹ *Minority Groups among United States Doctoral-Level Scientists, Engineers, and Scholars, 1973*, National Academy of Sciences, Washington, D.C., 1974.

vided at institutions with large enrollments of minority group students in many instances, and the Committee believes it is vital that there be unambiguous authority providing support at the undergraduate level for such institutions.

Furthermore, the Committee has added Section 475 as a separate authority because it believes that, given the special situation and the special needs of such institutions and their undergraduate students, applying the service obligations of the National Research Service Award would tend to discourage their participation in the very programs designed to assist them. The Committee feels it is not practical or reasonable to require such undergraduate students, who are working toward careers in biomedical research through the Minority Access to Research Careers of the National Institutes of Health and similar training programs, to incur an added service obligation beyond that currently required for the graduate and postgraduate-level training under the National Research Service Awards authority. New Section 475 therefore is to relieve this category of student from the payback requirement and to enable the institution with large enrollments of minority group students to receive grants to improve the quality of its undergraduate-level programs without requiring payback agreements from its students.

Awards to visiting scientists authorized in new Section 474 are designed to draw on the special talents of scientists-teachers from other institutions by bringing them to colleges, universities, and health professional schools with large enrollments of minority group students, and by supporting their participation in research, teaching, and curriculum development. These individuals are mature, established, biomedical and behavioral scientists and academicians. New Section 474 provides that such scientists of high accomplishment in the field of biomedical science who are willing to assist minority schools in developing programs in biomedical sciences are given stipends more in keeping with salaries which they would be earning at their home institutions. Moreover, Section 474 is intended to insure that the visiting scientists not be subject to the payback provision of the National Research Service Act authority. These persons are not receiving training in any sense but rather are giving service through assisting institutions with large enrollments of minority group students.

By the term "enter into agreements" with the Secretary is meant the submission of a competitive application detailing the activities such a "visiting scientist" will undertake in providing assistance for a specified period of time to a minority institution to develop a program of biomedical sciences. Such applications shall be reviewed by the appropriate review groups. If a scientist who receives a visiting scientist award is unable to serve the entire term of his award according to his agreement, Section 474 would require that he forfeit no more than that portion of the stipend which he has not as yet earned by serving in this capacity.

National Research Service Awards may, of course, be available to minority group students, faculty, and institutions with high enrollments of minority group students in the same manner and under the same conditions as they are available to all others with respect to graduate and postgraduate training. The National Research Service Award authorities are, however, separate from those contained in new Sections 474 and 475.

D. TITLE IV.—FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

The Committee's amendment respecting vitamins is designed to clarify Congress' position on the vitamin controversy which has existed for the past decade. On August 2, 1973, the Food and Drug Administration (FDA), after lengthy deliberations, promulgated regulations which would have placed most vitamins and minerals exceeding 150 percent of the U.S. RDA (United States Recommended Daily Allowance) under the jurisdiction of Chapter V of the Federal Food, Drug, and Cosmetic Act. Where the potency of vitamin or mineral products exceeded 150 percent of the RDA, those products would generally have become over-the-counter drugs. The regulations would have restricted combinations of vitamins and minerals that did not contain all FDA approved vitamins and minerals.

In a concurrent action, the FDA limited high dosages of vitamins A and D (dosages exceeding 100 percent of the U.S. RDA of vitamin D or 200 percent of the U.S. RDA of Vitamin A) to sale by prescription because of evidence that high levels of these fat soluble vitamins could cause serious harm.

On August 15, 1974, the U.S. Court of Appeals for the Second Circuit issued a decision upholding most of FDA's requirements but ordering reconsideration of others (*National Nutritional Foods Association v. FDA*, 504 F.2d 761 (2d Cir., 1974), cert. denied, 95 S. Ct. 1326 (1975)). The Court decided that FDA could properly restrict the variety of combinations of vitamins and minerals offered to consumers, but should consider permitting the marketing of certain additional combination products. The Court also held that FDA could not deem vitamin or mineral products to be drugs solely on the basis of their potency, but had to consider as well the use for which they are marketed.

Title IV of S. 988 reaffirms and positively states the position of the Senate in this matter. This section prohibits the FDA from regulating the composition of oral preparations of vitamins and minerals and combinations thereof, unless they are toxic, habit forming, or must be administered by the direction of a physician or where they are marketed for drug use. Last year, the Senate accepted an amendment, of similar purpose, offered by Senator Proxmire, by the vote 81-10 to the Health Manpower Bill. Subsequently, this bill died with the adjournment of the 93rd Congress.

Title IV does contain one major, new provision, not contained in last year's bill. It gives, for the first time, the FDA authority to regulate advertising for vitamin and mineral products. When advertising is found to be deceptive or misleading in a material respect, the FDA can seize the offending advertiser's product, at the manufacturing, distributional, or retail levels. In exercising his authority with respect to seizures, the Committee calls to the attention of the Secretary section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 336. The Committee believes that seizure need not be instituted for minor violations of the Act whenever the Secretary believes that the public interest will be adequately served by a suitable written notice or warning.

On May 8, 1975, Senators Proxmire and Schweiker introduced S. 1692, which is identical in many respects to Title IV. The original

version of the bill (S. 1692) included several specific references to the Secretary's obligation or authority to act by regulation. It is not intended that the omission of these repetitive references should be understood as in any way restricting the Food and Drug Administration's present authority to adopt regulations refining and enforcing the provisions of the Federal Food, Drug and Cosmetic Act, as amended. The FDA in recent years has relied increasingly on administrative rule-making to enforce the requirements of the law. Rulemaking affords opportunity for broader participation in the formulation of agency policy, promotes clarity of legal requirements, and assures equitable application of the law, while at the same time reduces the cost to the taxpayer of case-by-case enforcement. The FDA's legal authority, under section 701(a) of the Act, 21 U.S.C. 371(a), to adopt binding regulations has been recognized by the Supreme Court, see *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. (1973); *Abbott Laboratories, Inc. v. Gardner*, 387 U.S. 136 (1967), and has recently been upheld by the United States Court of Appeals for the Second Circuit. *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688 (2d Cir. 1975.).

Furthermore, as originally introduced, S. 1692 stated specifically that the restrictions imposed by section 411(a)(1) did not limit the authority of the Food and Drug Administration to regulate vitamins and minerals, or other food ingredients, under section 402 (the food adulteration provision), 406 (the emergency permit provision), and 409 (the food additives provision) of the present Act. The deletion of these references to specific provisions of the statute does not imply any limitation on the FDA's present authority to assure that such food constituents are safe for consumption. It is recognized that consumers must be protected against potentially toxic food ingredients, as well as constituents that are acknowledged to be hazardous. It is intended that the FDA should retain its present authority to deal with these matters of public health.

Because of suggestions that the Food and Drug Administration, having failed to regulate safe vitamins as dangerous drugs, might attempt to regulate them as food additives, the authors of the vitamin amendment considered language to prohibit the Food and Drug Administration from regulating safe vitamins, minerals, and associated ingredients of foods as food additives.

This was not done for two reasons. First of all, it is unnecessary. It would be inappropriate and contrary to the intention of this Title for the FDA to treat vitamins, minerals, and their associated ingredients about whose safety there currently is no doubt, as food additives. There are those who considered vitamins and minerals essentially foods with a long history of safe use. The authors rejected that course of action on grounds that there was insufficient evidence to support such a course of action at this time.

Second, there are some nutrients and ingredients or natural chemicals which are tangentially a part of vitamins or minerals which currently may be considered food additives because of their potential toxicity. We did not wish to prevent the FDA from acting in these circumstances. For the agency to do so based on the policies on potency

and combinations which this amendment endorses, however, would be inappropriate.

Section 411 (b) (2) (A) of the bill requires the listing of ingredients which are not vitamins or minerals in the labeling of the food product in a list of all ingredients of the product and in accordance with applicable regulations promulgated under section 403 (j). This provision should not be construed as allowing the Secretary, by action or inaction, to prevent or render impracticable the Committee's intent to permit the listing of all ingredients which are not vitamins or minerals. When applicable regulations under section 403 (j) of the Food, Drug, and Cosmetics Act are in effect, ingredients which are not vitamins or minerals must be listed in accordance with these regulations.

Considerable and continuing concern has been expressed by consumers and by various members of the food supplement industry and related publishers about the impact of the advertising provisions in this bill upon freedom of the press under the First Amendment. Obviously, nothing in this bill is intended to contravene such rights in any way.

It is intended that the term "advertising", whenever used in this bill, should be so interpreted as to be confined to overt advertising, as that term is generally understood in the advertising industry.

Furthermore, the Committee wishes to make clear that the conferring of regulatory authority over vitamin and mineral supplement advertising, being in the nature of a *quid pro quo* to counterbalance the limitations placed upon FDA's authority over these products, is in no sense a precedent for extending the agency's regulatory power over other types of advertising.

In any action initiated or prosecuted under these advertising provisions, with respect to, or against, any food supplement because of, or based upon, the allegedly deceptive advertising thereof, the editorial content or policy of any independently owned and circulated publication or periodical (or of any particular or single issue thereof) in which such advertising appears, should not be considered as part of, or contributing or auxiliary to, the content, substance, meaning or interpretation of the advertising which is the basis of such action.

However, it is recognized that at some point a publication supported by advertising can become a cloak for deceptive advertisements of a product if its editorial content is prepared, controlled, or financed by the advertiser of such product or if there is a commercial scheme to sell and position advertising in exchange for editorial comment on the product of the advertiser. The publication, sale, and distribution of false or misleading matter concerning an article of trade by a person engaged or financially interested in commerce in that trade could be treated as false or misleading advertising under certain circumstances, see *Scientific Mfg. Co. v. FTC*, 124 F. 2d 640, 644 (3d Cir. 1941) and *Perma-Maid Co. v. FTC*, 121 2d 282 (6th Cir. 1941). In such cases the editorial content or policy of the publication might be considered as a basis for an action by the FDA. Certainly, for example, the dressing up of an advertisement in the format and style of a news

article or editorial in the publication (commonly referred to as a "reader ad") could be, in certain circumstances, a deceptive advertisement rather than speech protected by the First Amendment. In cases of this category, only the courts can ultimately articulate the difficult distinction between commercial advertising masquerading as protected speech and protected speech bearing a superficial resemblance to commercial advertising.

We recognize that it is a well-accepted marketplace fact that manufacturers of particular types of products will normally place their advertising in publications or periodicals, the editorial content of which normally deals with the categories of products being advertised, and which are addressed to a readership which is interested in such subjects and products. Thus, a manufacturer of motorboats or marine accessories or products could be expected to place advertising in magazines or other publications which deal with motorboating and related subjects.

This bill does not contemplate that any nexus should be implied from the fact that an otherwise acceptable advertisement for a particular food supplement appears in a magazine, the editorial content of which may deal with that specific type of product and which contains matter which, if contained in the paid advertising in question, might be deemed to make such paid advertising unacceptable under this bill.

The simple existence of any publication which has not been singled out by the owner or operator of a retail establishment to advertise a particular product within the establishment does not constitute advertising for that product. What does constitute advertising of a product is the specific use of prominent display of the publication to encourage or convince consumers that they should purchase the product. The owner or operator of the establishment must affirmatively link the publication to the product.

This bill does not take away the regulatory authority of FDA with regard to vitamin and mineral preparations intended for use by pregnant or lactating women and children under 12. However, the Committee is concerned that attention must also be given to those vitamin and mineral products not intended for use by this special group but inadvertently taken by or administered to them. Just as the fetus may be affected by excessive doses of some food supplements, excessive doses of vitamins and minerals taken by children during the period of growth and hormonal development (up to 18 years of age) can interfere with their normal development. Because of the possibility of unrecognized or unanticipated harm which might come from the administration of large doses of vitamins and minerals, the Committee recommends that FDA consider promulgating regulations with respect to vitamin and mineral products designed to assure that such preparations are not inadvertently administered to children.

E. TITLE V. NATIONAL ARTHRITIS ACT AMENDMENTS

The amendments to the National Arthritis Act (with slight modifications as noted below) were originally introduced as S. Con. Res. 127 and adopted by the Senate during the last days of the 93rd Con-

gress on December 19, 1974, as modifications to the House Amendments to the Senate-passed National Arthritis Act (now P.L. 93-640).

The House was unable to take action on the amendments due to the press of other legislative matters under consideration that day and the next. The 93rd Congress adjourned on December 20, 1974.

The amendments are primarily of a technical, clarifying, and perfecting nature. Two are of a more substantive nature.

1. (a) The first substantive amendment would add the phrase "(hereinafter in this Act collectively referred to as 'arthritis')" in the Findings and Declaration of Purpose section of the Act. Inclusion of this phrase is necessary to make it clear that the mandate by the Public Law given the National Commission on Arthritis covers arthritis and related musculoskeletal diseases.

(b) A conforming change has been made in amendments to Part D of title IV of the Public Health Service Act so that it is clear that the term "arthritis" includes "arthritis and related musculoskeletal diseases" wherever it is referred to in that Part of the Public Health Service Act.

2. The second substantive amendment would reallocate the total amounts of appropriations authorized so that the authorizations for fiscal year 1975 would be slightly reduced and the authorization for fiscal years 1976 and 1977 would be commensurately increased. The Senate bill had authorized a total of \$75.5 million over a three-year period. The House reduced this to \$50 million, and, in doing so, did not retain the proportionate relationship among the funding authorizations and among the years in the Senate bill. The Senate bill had a comparatively low amount authorized for fiscal year 1975 in the belief that by the time of enactment, there would be insufficient time remaining in fiscal year 1975 to obligate funds effectively. This, of course, has been borne out.

One modification from the original amendments has been made in the allocation of the funds. In S. Con. Res. 127 in the 93rd Congress, it was proposed to reallocate the appropriations authorizations under section 439(h) which authorizes funding for the development, modernization, and operation of Comprehensive Arthritis Centers, by deducting \$6 million from fiscal year 1975 and dividing that amount equally between fiscal years 1976 and 1977, authorizing \$16 and \$18 million, respectively.

Public Law 93-640 states that these centers are to be supported consistent with the Arthritis Plan developed by the National Commission on Arthritis, established by that Public Law. It now appears that the Commission will not complete its studies until December and that firm recommendations on the development and allocation of resource support will not be completed until January. That time schedule will permit the inclusion in a supplemental appropriation bill for fiscal year 1976 of an appropriation for support of the Centers, but will not permit the effective obligation of the \$16 million originally suggested. The amendment included in S. 988 reflects the practicalities of the appropriations time schedule and provides for the addition of the full \$6 million to the fiscal year 1977 authorization of appropriations, for a total authorization of \$21 million for Center support for that year and makes no change in the amount authorized to be appropriated for fiscal year 1976 (\$13 million).

The reallocation of authorizations are explained on the following chart:

AUTHORIZATIONS OF APPROPRIATIONS UNDER THE NATIONAL ARTHRITIS ACT OF 1974

[In millions of dollars]

Authorization	Fiscal year—		
	1975	1976	1977
1. Commission on Arthritis and Musculoskeletal Diseases (sec. 3(k)):			
Existing law.....	2.0	(1)	(1)
Original Senate bill.....	.5	0.5	
Proposed amendment.....	1.5	(1)	(1)
2. Screening projects and data bank (see 438(d) of PHS Act):			
Existing law.....	2.0	3.0	4
Original Senate bill.....	5.0	10.0	15
Proposed amendment.....	1.5	4.0	4
3. Comprehensive Arthritis Centers (sec. 459(h) of PHS Act):			
Existing law.....	11.0	13.0	15
Original Senate bill.....	10.0	15.0	20
Proposed amendment.....	5.0	13.0	21
Note: 3-yr grant total:			
Existing law.....			\$50.0
Original Senate bill.....			75.5
Proposed amendment.....			50.0

¹ To remain until expended.

3. A third substantive amendment included in the original Concurrent Resolution has been dropped in the amendments offered to S. 988. That amendment would have provided that the Commission must submit the Arthritis Plan within two hundred and ten days after the date on which the Commission holds its first meeting, rather than 210 days after funds were first appropriated for the Commission. This amendment was offered originally to avoid any undue delay in the submission of the plan which might result from appropriations acts being out of sequence with the Commission's calendar or work pace. However, initial funds were appropriated for the Commission in the Second Supplemental Appropriations Act for FY 1975. This appropriation makes the original amendment unnecessary.

4. The technical amendments:

(a) Specify in the Findings and Declaration of Purpose section that the annual cost of arthritis includes \$2,500,000,000 in medical expenses.

(b) Insert a purpose clause, dropped by the House, in the Findings and Declarations of Purpose section.

(c) Make a number of purely technical and perfecting amendments.

VIII. COST ESTIMATES PURSUANT TO SECTION 252 OF THE LEGISLATIVE REORGANIZATION ACT OF 1970 *

In accordance with Section 252 (a.) of the Legislative Reorganization Act of 1970 (Public Law 91-510, 91st Congress) the Committee estimates that the cost which would be incurred in carrying out this bill is as follows:

*The reallocation of costs representing the committee's amendment to Public Law 93-640, the National Arthritis Act are contained in the chart included in sec. VII of this report.

[In millions of dollars]

	Fiscal year—		Total
	1976	1977	
Heart, lung, and blood prevention and control.....	10	25	35
Heart, lung, and blood research.....	338	372	710
Research training.....	160	176	336
Physician area shortage scholarships.....	2		2
Health manpower, loans.....	60		60
Nursing loans.....	35		35
Total.....	605	573	1,178

IX. VOTES IN COMMITTEE

Pursuant to section 133(b) of the Legislative Reorganization Act of 1949, as amended, the following is a tabulation of votes in Committee:

Motion by Senator Schweiker to amend the Federal Food, Drug, and Cosmetic Act respecting vitamins adopted 7 to 4 as follows:

AYE	NAY
Javits	Beall
Loxalt	Hathaway
Pell	Kennedy
Randolph	Mondale
Schweiker	
Stafford	
Williams	

Motion to favorably report S. 988, as amended, to the Senate carried unanimously by voice vote.

X. SECTION-BY-SECTION ANALYSIS

PREAMBLE

The preamble to S. 988, as reported by the Senate Committee on Labor and Public Welfare remains "A bill to amend the Public Health Service Act to revise and extend programs of the National Heart and Lung Institute and the National Research Service Awards."

SHORT TITLE

S. 988, as reported, provides that the Act may be cited as the "National Biomedical Heart, Blood Vessel, Lung, Blood, and Research Training Act of 1975."

TITLE I—NATIONAL HEART AND LUNG INSTITUTE

FINDINGS AND DECLARATION OF PURPOSE

Section 101. (a) Repeats the eight major findings originally declared in The National Heart, Blood Vessel, Lung, and Blood Act of 1972 [subsections (1)–(7), (9)]. Inserts an additional major finding [subsection (8)] relating to the devastating impact of blood diseases, espe-

cially nutritional anemias, sickle cell anemia, Cooley's anemia, hemorrhagic defects, and malignancies of the lymph nodes and bone marrow; notes that these diseases require major attention.

Section 101. (b) Declares that it is the purpose of this Act to enlarge the authority of the National Heart, Lung, and Blood Institute in order to advance the attack upon heart, blood vessel, lung, and blood diseases and resources.

REPORT AND PLAN OF THE DIRECTOR OF THE INSTITUTE

Section 102. (a) Amends Chapter IV, Part B, Section 413(b)(2) of the Public Health Service Act (relating to the National Heart and Lung Institute) to require that the Director of the National Heart, Lung, and Blood Institute prepare in consultation with the Institute's Advisory Council and submit to the Secretary of the Department of Health, Education, and Welfare as soon as possible after the end of each fiscal year, an annual report on the activities, progress, and accomplishments under the program during the preceding fiscal year and a plan for the program during the next five years. Reiterates that the plan should also project the staff and recommend appropriations for the program. Requires that the annual report be transmitted by the Secretary DHEW to the President and the Congress simultaneously.

Section 102. (b) Redefines the fiscal year for the purposes of submitting annual reports. The fiscal years are defined as the period beginning January 1, 1975 and ending December 31, 1975, and the period beginning January 1, 1976 and ending September 30, 1976.

CONFORMING AMENDMENTS

Section 103. Amends the heading of Title IV, Part B, National Heart and Lung Institute, of the Public Health Service Act to read "National Heart, Lung, and Blood Institute."

Section 104. Amends Section 411, Establishment of Institute, of the same Act to read "There is hereby established in the Public Health Service a National Heart, Lung, and Blood Institute."

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

Section 105. (a) Amends Section 413(a) of the same Act to require that the Director of the Institute specifically include blood diseases and blood resources as part of the plan for the National Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources Program. Amends Section 413(a) generally to include blood diseases and resources in the National Program administered by the Institute and coordinated with other research institutes of the National Institutes of Health.

Section 105. (b) Amends Section 413(a)(7) to explicitly include the education and training of scientists, clinicians, and educators in the fields and specialties requisite to the conduct of programs in blood resources, as well as in blood, heart, blood vessel, and lung diseases.

Section 105. (c) Amends Section 413(c)(2) to require that the Director of the Institute operate, alter, and renovate, in addition to

acquiring, constructing, improving, repairing, and maintaining, facilities and equipment necessary to administer the National Program respecting blood diseases and blood resources as well as heart, blood vessel, and lung diseases.

Section 105. (d) Amends the title of the Assistant Director for Health Information Programs every time it appears in Section 413(d) of the same Act to read "Assistant Director for Prevention and Education". Requires that this Assistant Director provide information on blood diseases and blood resources, as well as on cardiovascular and pulmonary diseases, to the public and health professions as part of the Institute's health information program.

Section 105. (e) Amends the heading of Section 413 to read "National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program".

AUTHORIZATION OF APPROPRIATIONS

Section 106. Amends Section 414(b) of the same Act to authorize appropriations for heart, blood vessel, lung, and blood disease prevention and control programs in the following amounts: \$10,000,000 for fiscal year 1976, and \$25,000,000 for fiscal year 1977.

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

Section 107. (a) Amends Section 415(a)(1)(A) of the same Act by specifying the number of Research and Demonstration Centers for heart diseases as ten.

Section 107. (b) Amends Section 415(a)(1)(B) to limit the number of Research and Demonstration Centers for lung diseases to ten, instead of the present fifteen.

Section 107. (c) Inserts into Section 415(a)(1) a new subsection (C) to provide for the development of ten new Research and Demonstration Centers for basic and clinical research, training, and demonstration of advanced diagnostic, prevention, and treatment methods (including emergency medical services) for blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.

Section 107. (d) Amends Section 415(a)(2) to include prevention programs for lung and blood diseases, in addition to those prevention programs for cardiovascular diseases, in the research, demonstration, and training programs of the Research and Demonstration Centers.

Section 107. (e) Amends Section 415(a)(2)(A) to include preventive programs for the development of improved detection methods regarding lung and blood diseases, as well as cardiovascular diseases, in high risk individuals.

Section 107. (f) Amends Section 415(a)(2)(B) to include preventive programs for the development of improved intervention methods against those factors which cause individuals to have a high risk of developing lung, blood, and/or cardiovascular diseases.

Section 107. (g) Amends Section 415(a)(2)(C) to include programs for the development of health professions and allied health professions personnel highly skilled in the prevention of lung, blood, and/or cardiovascular diseases.

Section 107. (h) Amends Section 415(a)(2)(D) to include preventive programs to develop improved methods of providing emergency medical services for persons with lung, blood, and/or cardiovascular diseases.

Section 107. (i) Amends Section 415(b) to provide that the purposes for which Federal support of new or existing Research and Demonstration Centers include research in the management of blood resources. Provides that Federal payments for the operation of these Centers may only exceed \$5,000,000 per year if the annual excess can be attributed to increased costs as reflected in the cost of living index published by the Department of Labor for that year.

NATIONAL HEART AND LUNG ADVISORY COUNCIL

Section 108. Amends Section 417(a)(1) of the same Act to remove the Director of the Office of Science and Technology, and to include the Director of the National Science Foundation among the ex officio members of the National Heart and Lung Advisory Council.

FUNCTIONS OF THE COUNCIL

Section 109. (a) Amends Section 418(b)(2) to require that the Advisory Council submit to the Secretary DHEW an annual report on the progress of the national program toward accomplishment of its objectives during the preceding fiscal year. Requires that the Secretary DHEW must transmit this report simultaneously to the President and to the Congress not later than November 30 of each year.

Section 109. (b) Provides that the period beginning July 1, 1975 and ending September 30, 1976 be considered a fiscal year for the purpose of submitting Advisory Council reports.

Section 109. (c) Provides that the effective date of Section 109 is January 1, 1976.

Section 110. (a) Amends Section 418(a) of the same Act by redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7) respectively.

Section 110. (b) Amends Section 418(a) by inserting a new paragraph (4) which authorizes the National Heart and Lung Advisory Council to approve contract-supported areas or research in heart, blood vessel, lung, blood diseases, and the use of blood and blood products and research in the management of blood resources. Authorizes the Council to approve the percentage of the Institute's budget to be expended for these contracts.

Section 110. (c) Amends Section 418(a) to insert the phrase "heart diseases" instead of "heart" each time it appears.

Section 110. (d) Amends Section 418(a) to insert "the use of blood and blood products and research in the management of blood resources" after "blood diseases" each time it appears.

ADMINISTRATION

Section 111. (a) Amends Section 419A(c) of the same Act to authorize the Director of the Institute to approve grants for research and training in amounts not to exceed \$35,000 (excluding indirect costs).

Section 111. (b) Amends Section 419A(c) to authorize the Director of the Institute to approve grants for research and training in the use of blood and blood products and in the management of blood resources as well as in heart, blood vessel, lung, and blood diseases.

AUTHORIZATION OF APPROPRIATIONS

Section 112. (a) Amends Section 419B to authorize appropriations for programs and activities (other than those authorized in Section 414) of the National Heart Lung and Blood Institute in the following amounts: \$338,000,000 for fiscal year 1976, and \$372,000,000 for fiscal year 1977.

Section 112. (b) Amends Section 419B to provide that not less than 15% of the Institute's appropriations be reserved for programs respecting blood diseases.

Section 112. (c) Amends Section 419B to provide that blood resources be considered with blood diseases in the minimum allocation of 15% of the Institute's total appropriation.

RESEARCH AND INVESTIGATION IN GENERAL

Section 113. Amends Section 301(d) and 301(i) of the same Act to authorize grants-in-aid, and any other necessary actions, for research and investigations in heart, blood vessel, lung, and blood diseases and resources.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

NATIONAL RESEARCH SERVICE AWARDS PUBLIC LAW 93-348—NATIONAL RESEARCH ACT

Section 201. Amends Section 472(a)(1)(A)(iii) of the Public Health Service Act to permit the Secretary DHEW to provide National Research Service Awards for biomedical and behavioral research at Federal as well as non-Federal public institutions.

Section 202. (a) Amends Section 412(a)(1)(B) of the same Act to permit the Secretary DHEW to make grants to Federal as well as non-Federal public institutions to enable these institutions to administer National Research Service Awards.

Section 202. (b) Amends Section 412(a)(1)(B) to include the related programs administered by the National Advisory Council on Nurse Training among those institutes, divisions, and bureaus in the National Institutes of Health, and the Alcohol, Drug Abuse, and Mental Health Administration for reference purposes in Section 412(a).

Section 203. Amends Section 472(b)(2) to require that awards and grants under National Research Service Awards be subject to review and approval by the National Advisory Council on Nurse Training, as well as by other appropriate advisory councils of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

Section 204. (a) Amends Section 472(c)(1)(A)(i) of the same Act to permit any combination of health research or teaching which is in accordance with usual patterns of academic employment as legitimate

activities required to be performed by the individual recipient of a National Research Service Award.

Section 204. (b) Amends Section 472(c)(2)(A) of the same Act to require that the individual recipient of a National Research Service Award engage in any combination of health research or teaching which reflects the usual patterns of academic employment for a period of twelve months.

AUTHORIZATION OF APPROPRIATIONS

Section 205. Amends Section 472(d) of the same Act to authorize payments and grants under National Research Service Awards in the following amounts: \$160,000,000 for fiscal year 1976, and \$176,000,000 for fiscal year 1977.

STUDIES RESPECTING BIOMEDIC AND BEHAVIORAL RESEARCH PERSONNEL

Section 206. Amends Section 473(c) of the same Act to require that studies on biomedical and behavioral research personnel be submitted by the Secretary DHEW to the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare not later than September 30 of each year.

REFERENCES

Section 207. Provides that all references to Section 472, National Research Service Awards, of the National Research Act shall be followed by "Public Law 93-348—National Research Act".

TITLE III—MISCELLANEOUS PROVISIONS

HEALTH RESOURCES DEVELOPMENT—GENERAL PROVISIONS

Section 301. Amends Section 1631(b), Recovery, of the Public Health Service Act to permit the Secretary DHEW to waive a right of recovery which arose one year before January 4, 1975.

MILITARY BENEFITS

Section 302. Amends Section 212 of the Public Health Service Act to include a new subsection (e) which provides that active service of commissioned officers of the Public Health Service shall be deemed to be active military service in the Nation's armed forces for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940, as amended.

GRANTS TO FEDERAL INSTITUTIONS

Section 303. Amends Section 507 of the Public Health Service Act to provide that grants may be made to any Federal institution, on the same terms and conditions that apply to non-Federal institutions, except that grants to Federal institutions may be funded at 100% of the costs.

AUTHORIZATION OF APPROPRIATIONS

Section 304. Amends Section 786 of the Public Health Service Act to authorize appropriations for the Physician Shortage Area Scholarship Program as follows: \$3,500,000 for fiscal year 1975, and \$2,000,000 for fiscal year 1976.

Section 305. (a) Amends Section 742(a) of the same Act to authorize appropriations for Federal loans to certain schools as follows: \$60,000,000 for fiscal year 1976.

Section 305. (b) Amends Section 740(b)(4) of the same Act to provide that no student who has attended certain schools before July 1, 1975 may receive a loan from a fund established by Section 204 of the National Defense Education Act of 1958.

Section 305. (c) Amends Section 824 of the same Act to authorize appropriations for loans as follows: \$35,000,000 for fiscal year 1976.

Section 305. (d) Amends Section 822(b)(4) of the same Act to provide that no student who has attended nursing schools before July 1, 1975 may receive a loan from a fund established by Section 204 of the National Defense Education Act of 1958.

STIPENDS

Section 306. Amends Title IV, National Research Institutes, of the Public Health Service Act by adding two new sections, Section 474, Stipends, and Section 475, Undergraduate Training In Biomedical Sciences in Minority Schools:

STIPENDS

(a) Permits the Secretary DHEW to grant a maximum stipend of \$25,000 per year to visiting scientists who agree formally with the Secretary to assist minority schools in developing programs in biomedical sciences. Permits the United States to recover an amount, set forth by the recovery formula in Section 472(c)(4) of the National Research Act—Public Law 93-348, if the recipient of a stipend does not complete the requirements of his agreement with the Secretary DHEW.

(b) *Definitions.*—Defines "visiting scientist" to mean an accomplished, reputable scientist in the fields of biomedical sciences who has entered into an agreement with the Secretary DHEW. Defines "minority school" to mean an institution of postsecondary education which has enrolled a substantial number of minority students as determined in regulations established by the Secretary DHEW. Defines "biomedical sciences" to mean all health related sciences and requisite related courses.

(c) *Authorization of Appropriations.*—Authorizes such sums as may be necessary to carry out this program of stipends for visiting scientists.

UNDERGRADUATE TRAINING IN BIOMEDICAL SCIENCES IN MINORITY SCHOOLS

(a) Permits the Secretary DHEW to make grants to minority schools to initiate the development of undergraduate programs in biomedical sciences.

(b) Stipulates that each minority school which establishes grant-supported programs in biomedical sciences must do so in accordance with regulations promulgated by the Secretary DHEW.

(c) *Definitions.*—Defines “minority school to be an institution of post secondary education which has enrolled a substantial number of minority students as determined in regulations established by the Secretary DHEW. Defines “biomedical sciences to mean all health related sciences and requisite related courses.

(d) *Authorization of Appropriations.*—Authorizes such sums as may be necessary to carry out this Federally supported grant program for undergraduate training in biomedical sciences in minority schools.

TITLE IV—FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

Section 401. Amends Chapter IV, Food, of the Food, Drug, and Cosmetic Act, after Section 410, Bottled Drinking Water, by inserting a new Section 411:

VITAMINS AND MINERALS

(a) Prohibits the Secretary DHEW from: limiting the potency of any vitamin or mineral within a food; classifying any single or combination vitamin/mineral product as a drug on the basis of high potency which the Secretary determines to be in excess of nutritional usefulness; limiting the combination or number of vitamins or minerals or other ingredients in foods to which Section 411 applies. Permits the Secretary DHEW to exercise his authority regarding Chapter IV, Food, Chapter V, Drugs and Devices, or any other provision of the Food, Drug, and Cosmetic Act except as is prohibited above regarding vitamins, minerals, or other food ingredients. Permits the Secretary DHEW to regulate vitamins, minerals, or other food ingredients which the Secretary determines by regulation to be represented for use by pregnant or lactating women or children under the age of twelve years.

MISBRANDED FOODS

(b) Clarifies Section 403, Misbranded Food, of the same Act so that foods labeled to include all ingredients or advertised to refer to all ingredients beside vitamins and/or minerals cannot be deemed misbranded. Permits the labeling of non-vitamin/non-mineral constituents of foods only in the list of ingredients and only in accordance with, and by exemptions to, regulations promulgated by the Secretary DHEW. Prohibits the labeling or advertising of any food from emphasizing ingredients which are not vitamins, minerals, or sources of vitamins/minerals.

DEFINITIONS

(c) Defines “food to which this section applies” as food for humans which is a food for special dietary use; which is or contains any vitamin or mineral; which is intended for ingestion in tablet, capsule, or liquid form; and which does not simulate or is not represented to be conventional food if it is not in the specified form. Defines a food in liquid form to be formulated in a fluid carrier and be intended for ingestion in daily, small units of measure.

DEFINITIONS

Section 402. (a) Amends Section 201(f) of the Food, Drug, and Cosmetic Act by redesignating Section 201 to redefine the term “special dietary use” as applied to food. “Special dietary use” is defined to mean a particular use for which a food is represented to be used, included but not limited to: supplying a special dietary need that exists by reason of any health condition; supplementing the diet to increase the total intake of vitamins, minerals, or other food ingredients; supplying a special dietary need because a food is the sole item in the diet.

REGULATIONS

Section 402. (b) Directs the Secretary DHEW to amend existing regulations and promulgate these amendments to make all regulations consistent with the new Section 411.

ADVERTISING

Section 403. (a) Amends Section 403 (a), Misbranded Food, of the Food, Drug, and Cosmetic Act, by redesignating this subsection to include a new paragraph (2) which provides that a food as defined by new Section 411 is defined to be misbranded if its advertising is false or misleading in a material respect or if its labeling is in violation of the new Section 411. Amends Section 201 (n), Definitions, of the same Act, so that the specifications employed to determine misleading labeling would be employed to determine misleading advertising. Amends Section 303, Penalties, of the same Act by adding a new subsection (d) which exempts a person from prison penalties and fines when a food has been deemed to be misbranded due to its advertising, unless the violation is committed with the intent to defraud or mislead. Amends Section 304 (a), Seizure, of the same Act, by adding a new subparagraph (3) which prohibits the institution of a libel for condemnation against any food misbranded because of its advertising and being held for sale to the consumer in an establishment not owned or operated by the manufacturer, packer, or distributor of the food; and which permits such a condemnation if the food's advertising was disseminated in the selling establishment, was disseminated by the owner or operator of such establishment, was paid for by the owner or operator, or was used to promote the sale of the food.

GENERAL ADMINISTRATIVE PROVISIONS

Section 403. (b) Amends Chapter VII, General Administrative Provisions, of the Food, Drug, and Cosmetic Act by adding a new Section 707, “Advertising of Certain Foods”, which requires that the Secretary DHEW must consult and coordinate with the Federal Trade Commission any action to be taken against food deemed to be misbranded because of its advertising.

EFFECTIVE DATE

Section 403. (c) Provides that the amendments made by Section 403 (a), Misbranded Food, of this Act take effect 180 days after enactment of this Act.

TITLE V—ARTHRITIS ACT AMENDMENTS

SHORT TITLE

Section 501. Provides that this title may be cited as the "National Arthritis Act Technical Amendments of 1975".

FINDINGS AND DECLARATIONS OF PURPOSE

Section 502. (a) Amends Public Law 93-640 by inserting "(a)" after "Sec. 2.", and by inserting a clause to permit references to the term "arthritis" in the National Arthritis Act of 1974 to collectively mean arthritis and related musculoskeletal diseases. Inserts a phrase to designate that the annual cost to the Nation's economy due to arthritis, \$9,200,000,000, includes \$2,500,000,000 in medical expenses. Adds a new subsection (b) which states that the purpose of the National Arthritis Act of 1974 is to provide for a long-range plan to expand and coordinate the national research, treatment and control effort against arthritis; to advance educational activities to alert the Nation's citizens to the early indications of arthritis; to emphasize early detection, proper control, and possible complications of these diseases; to establish and support the development of improved methods for arthritis screening, prevention and referral; to establish a central arthritis screening and detection data bank; to develop, modernize and operate centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, research and training programs.

NATIONAL COMMISSION ON ARTHRITIS; ARTHRITIS PLAN

Section 502. (b) Amends Section 3(b)(4) of Public Law 93-640 to correct the reference to the Chief Medical Director of the Veterans Administration as a member of the National Commission on Arthritis and Related Musculoskeletal Diseases. That section currently incorrectly identifies the "Chief Medical Director" as the "chief medical officer" of the Veterans Administration.

Amends Section 3(k) of the same Public Law to authorize, without fiscal year limitation, an appropriation of \$1,500,000 to support the Commission's specified activities.

CHANGE OF HEADING

Section 502. (c) Amends the heading above Section 4 of Public Law 93-640 to read "Arthritis Coordinating Committee, Projects, and Comprehensive Arthritis Centers".

CONFORMING AMENDMENTS

Section 503. (a) Amends Section 431(c), Research Funding, of the Public Health Service Act to remove "and related musculoskeletal diseases" to make this subsection consistent with the language as clarified in Section 502(a) of this Act.

Section 503. (b) Amends Section 434(b), Advisory Council, of the Public Health Service Act to remove "and related musculoskeletal

diseases" to make this subsection consistent with the language as clarified in Section 502(a) of this Act.

Section 503. (c) Amends Section 434(e) of the Public Health Service Act to make this subsection consistent with the language as clarified in Section 502(a) of this Act.

Section 503. (d) Amends Section 438(a) of the Same Act to correct existing grammatical errors. Amends Section 438(d) to change authorized appropriations for arthritis screening, detection, prevention, and referral demonstration projects, and data bank to the following amounts: \$1,500,000 for fiscal year 1975, and \$4,000,000 for fiscal year 1976.

Section 503. (e) Amends Section 439(a) of the same Act to permit the Secretary DHEW to provide for the development, modernization, and operation of new and existing comprehensive arthritis centers. Amends Section 439(c) of the same Act to correct existing grammatical errors. Amends Section 439(h) to change authorized appropriations for comprehensive arthritis centers to the following amounts: \$5,000,000 for fiscal year 1975, and \$21,000,000 for fiscal year 1977.

XI. CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by titles I through V of the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets; new matter printed in italic) :

PUBLIC HEALTH SERVICE ACT, AS AMENDED

* * * * *

TITLE II—ADMINISTRATION

* * * * *

MILITARY BENEFITS

SEC. 212. * * *

(e) *Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940, as amended (50 App. U.S.C. 501 et seq.).*

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION IN GENERAL

SEC. 301. The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases

and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Surgeon General is authorized to—

* * * * *

(d) Make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research or research training projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to [heart diseases] heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart and Lung Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council, and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research and research training programs: *Provided*, That such uniform percentage, not to exceed 15 per centum, as the Surgeon General may determine, of the amounts provided for grants for research or research training projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research and research training program grants-in-aid for such fiscal year;

* * * * *

(i) Adopt, upon recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board or with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to [heart diseases] heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart and Lung Advisory Council, or, with respect to dental diseases and conditions, upon recommendation of the National Advisory Dental Research Council, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

* * * * *

PART B—NATIONAL HEART [AND] LUNG AND BLOOD INSTITUTE

ESTABLISHMENT OF INSTITUTE

Sec. 411. There is hereby established in the Public Health Service a National Heart [and] Lung and Blood Institute (hereinafter in this part referred to as the "Institute").

* * * * *

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD [DISEASE] DISEASES AND BLOOD RESOURCES 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] Diseases and Blood Resources 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 and blood resources (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 research institutes of the National Institutes of Health to the extent that they have responsibilities respecting such diseases and resources and shall provide for—

* * * * *

(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 and resources;

* * * * *

(b) * * *

[(2) The Director of the Institute shall, as soon as practicable after the end of each calendar year, prepare in consultation with the Council and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments under the Program during the preceding calendar year and a plan for the program during the next five years.]

(2) The Director of the Institute shall, as soon as possible after the end of each fiscal year, prepare in consultation with the Council and submit to the Secretary of Health, Education, and Welfare for transmittal to the President and the Congress simultaneously a report on the activities, progress, and accomplishments under the program during the next five years. The plan shall also project the staff required by the Institute to carry out the program and recommendations for appropriations for the program.

(c) In carrying out the Program, the Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council and without regard to any other provision of this Act, may — * * *

(2) acquire, construct, improve, repair, [operate] operate, alter, renovate, and maintain heart, blood vessel, lung, and blood [disease] diseases and blood resources 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 acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, 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

* * * * *

(d) There shall be in the Institute an [Assistant Director for Health Information Programs] *Assistant Director for Prevention and Education* who shall be appointed by the Director of the Institute. The Director of the Institute, acting through the [Assistant Director for Health Information Programs] *Assistant Director for Prevention and Education*, shall conduct a program to provide the public and the health professions with health information with regard to cardiovascular and pulmonary and blood diseases and blood resources. 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 diseases.

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

SEC. 414. * * *

(b) There is authorized to be appropriated to carry out this section \$25,000,000 for the fiscal year ending June 30, 1973, \$35,000,000 for the fiscal year ending June 30, 1974, [and \$45,000,000 for the fiscal year ending June 30, 1975] and \$10,000,000 for the fiscal year ending June 30, 1976, and \$25,000,000 for the fiscal year ending June 30, 1977.

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] *ten* 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] *diseases*; and

(B) [fifteen] *ten* 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).

(C) *Ten 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 blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.*

(2) The centers developed under paragraph (1) (A) (B) and (C) 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 a high risk of developing [cardiovascular disease] *these diseases*.

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

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

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

* * * * *

(b) The Director of the Institute, under policies established by 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 planning, establishing, or strengthening, and providing basic operating support for, existing or new centers (including centers established under subsection (a)) for basic or clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases or research in the management of blood resources. Funds paid to centers under cooperative agreements under this subsection may be used for—

- (1) construction, notwithstanding section 405,
- (2) staffing and other basic operating costs, including such patient care costs as are required for research,
- (3) training, including training for allied health profession 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 \$5,000,000 in any year.] *The aggregate of payments (other than payments for construction) made to any center under such an agreement may not exceed \$5,000,000 (excluding indirect costs) in any year, except that such aggregate may exceed such sum in any year to the extent that any excess amount is attributable to increases in appropriate costs as reflected in the cost of living index published by the Department of Labor for such year.* Support of a center under this subsection may be for a period of not to exceed five years and may be extended by the Director of the Institute for additional periods of not more than five years 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.

* * * * *

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] *Director of the*

National Science Foundation, 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.

* * * * *

FUNCTIONS OF THE COUNCIL

SEC. 418. (a) The Council is authorized to—

(1) review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis or treatment of heart *diseases*, blood vessel, lung, and blood diseases, *the use of blood and blood products and research in the management of blood resources*, and certify approval to the Secretary, for prosecution under section 412, any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of heart *diseases*, blood vessel, lung, and blood diseases, *the use of blood and blood products and research in the management of blood resources*;

(2) review applications from any university, hospital, laboratory, or other institution or agency, whether public or private, or from individuals, for grants-in-aid for research projects relating to heart *diseases*, blood vessel, lung, and blood diseases, *the use of blood and blood products and research in the management of blood resources*, and certify to the Secretary its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of heart *diseases*, blood vessels, lung, and blood disease;

(3) review applications from any public or other nonprofit institution for grants-in-aid for training, instruction, and traineeships in matters relating to the diagnosis, prevention, and treatment of heart *diseases*, blood vessel, lung, and blood diseases, *the use of blood and blood products and research in the management of blood resources*, and certify to the Secretary its approval of such applications for grants-in-aid as it determines will best carry out the purpose of this act;

(4) approve areas of research in heart, blood vessel, lung, blood diseases, and the use of blood and blood products and research in the management of blood resources to be supported by the awarding of contracts and approve the percentage of the budget of the Institute which may be expended for such contracts;

(5) collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of heart *diseases*, blood vessel, lung, and blood diseases, *the use of blood and blood products and research in the management of blood resources*, by correspondence or by personal investigation of such studies, and with the approval of the Secretary make available such information through appropriate publications for the benefit of health and welfare agencies and organizations (public or private), physicians, or any other scientists, and for the information of the general public;

(6) recommend to the Secretary for acceptance conditional gifts pursuant to section 501 for carrying out the purposes of this part; and

(7) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health, and the Director of the National Heart *Diseases* and Lung Institute with respect to carrying out the provisions of this part.

(b) * * *

[(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.]

(2) *The Council shall submit a report to the Secretary of Health, Education, and Welfare for transmittal to the President and to the Congress simultaneously not later than November 30 of each year on the progress of the program toward the accomplishment of its objectives during the preceding fiscal year.*

* * * * *

SEC. 419A. * * *

(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, *the use of blood and blood products and research in the management of blood resources*—

(1) in amounts not to exceed ~~[\$35,000]~~ \$35,000 (excluding indirect costs) after appropriate review for scientific merit but without review and recommendation by the Council, and

(2) in amounts exceeding ~~[\$35,000]~~ \$35,000 (excluding indirect costs) after appropriate review for scientific merit and recommendation for approval by the Council.

AUTHORIZATION OF APPROPRIATIONS

SEC. 419B. For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated \$375,000,000 for the fiscal year ending June 30, 1973, \$425,000,000 for the fiscal year ending June 30, 1974, ~~[and \$475,000,000 for the fiscal year ending June 30, 1975]~~ and \$475,000,000 for the fiscal year ending June 30, 1976 and \$372,000,000 for the fiscal year ending June 30, 1977; of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums shall be reserved for programs under this part respecting diseases of the lung and not less than 15 per centum of such sums shall be reserved for programs under this part for programs respecting *blood diseases* ~~[of the blood]~~ and *blood resources*.

* * * * *

PART D—NATIONAL INSTITUTE ON ARTHRITIS, RHEUMATISM, AND METABOLIC DISEASES, NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE, AND OTHER INSTITUTES—ESTABLISHMENT OF INSTITUTES

SEC. 431. * * *

(c) Of the sums appropriated for any fiscal year under this Act for the National Institutes of Health, not less than \$500,000 shall be

obligated for basic and clinical orthopedic research conducted within the National Institute of Arthritis, Metabolism, and Digestive Diseases which relates to the methods of preventing, controlling, and treating arthritis [and related musculoskeletal diseases], including research in implantable biomaterials and biomechanical and other orthopedic procedures and research in the development of new and improved orthopedic treatment methods.

* * * * *

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE
DISEASES

SEC. 434. * * *

(b) There is established in the National Arthritis, Metabolism, and Digestive Diseases Advisory Council a committee to advise the Director of the Institute respecting the activities of the Institute concerning digestive diseases. The committee shall be composed of those members of the Advisory Council who are outstanding in the diagnosis, prevention, and treatment of digestive diseases. The committee shall review applications made to the Director for grants for research projects relating to the diagnosis, prevention, and treatment of digestive diseases and shall recommend to the Director for approval those applications and contracts which the committee determines will best carry out the purposes of this part. The Advisory Council shall review applications made to the Director for grants for research projects related to arthritis [and related musculoskeletal diseases] and shall recommend to the Director for approval those applications and contracts which the Council determines will best carry out the purposes of this part. The Advisory Council shall also review and evaluate the arthritis programs under this part and shall recommend to the Director such changes in the administration of such programs as it determines are necessary.

* * * * *

(e) There is established within the Institute the position of Associate Director for Arthritis and Related Musculoskeletal Disease ([hereinafter] in this part referred to as the "Associate Director") who shall report directly to the Director of such Institute and who, under the supervision of the Director of such Institute, shall be responsible for programs regarding arthritis and related musculoskeletal diseases ([hereinafter in] in this part collectively referred to as "arthritis") within such Institute.

* * * * *

ARTHRITIS SCREENING, DETECTION, PREVENTION, AND REFERRAL
DEMONSTRATION PROJECTS; AND DATA BANK

SEC. 438. (a) The Secretary, acting through the Assistant Secretary for Health, may make grants to public and nonprofit entities to establish and support projects for the development and demonstration of methods for arthritis, screening, detection, prevention, and referral, and for the dissemination of these methods to the health and allied health professions. Activities under such projects shall be coordinated with (1) Federal, State, local, and regional health agencies, (2) centers assisted under section 439, and (3) the data bank established under subsection (c).

* * * * *

(d) There are authorized to be appropriated to carry out this section [\$2,000,000] \$1,500,000 for fiscal year ending June 30, 1975, [\$3,000,000] \$4,000,000 for fiscal year ending June 30, 1976, and \$4,000,000 for fiscal year ending June 30, 1977.

COMPREHENSIVE ARTHRITIS CENTERS

SEC. 439. (a) The Secretary, acting through the Assistant Secretary for Health may, after consultation with the National Advisory Council established under section 434(a) and consistent with the Arthritis Plan developed pursuant to the National Arthritis Act of 1974, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of *new and existing* centers for arthritis research, screening, detection, diagnosis, prevention, control, and treatment, for education related to arthritis, and for rehabilitation of individuals who suffer from arthritis. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers describing in the preceding sentence.

* * * * *

(c) Each center assisted under this section may conduct programs to—

(1) develop new and improved methods of screening and early detection, referral, and diagnosis of individuals with a risk of developing arthritis, asymptomatic arthritis, or symptomatic arthritis[.];

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping[.];

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

* * * * *

(h) For purposes of this section, there are authorized to be appropriated [\$11,000,000] \$5,000,000 for fiscal year ending June 30, 1975, \$13,000,000 for fiscal year ending June 30, 1976, and [\$15,000,000] \$21,000,000 for fiscal year ending June 30, 1977. Not less than 20 per centum of the funds appropriated for each fiscal year under this subsection shall be used for the purposes of establishing new centers.

* * * * *

PART I—GENERAL PROVISIONS

* * * * *

NATIONAL RESEARCH SERVICE AWARDS

SEC. 472. (a) (1) The Secretary shall—
(A) provide National Research Service Awards for— * * *
(iii) biomedical and behavioral research at [non-Federal] public institutions and at nonprofit private institutions, and

* * * * *

(B) make grants to [non-Federal] public institutions and to non-profit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake such research) in the matters described in subparagraph (A) (i).

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be, and also to include the related programs administered by the Division of Nursing, Health Resources Administration.

* * * * *

(b) * * *

(2) The award of National Research Service Awards by the Secretary under subsection (a) and the making of grants for such Awards shall be subject to review and approval by the appropriate advisory councils to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration and the National Advisory Council on Nurse Training (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted. * * *

* * * * *

(c) (1) (A) Each individual who receives a National Research Service Award shall, in accordance with paragraph (3), engage in—

(i) [health research or teaching] *health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment.* * * *

* * * * *

(c) (2) For each year for which an individual receives a National Research Service Award he shall—

(A) for twelve months engage in [health research or teaching] *health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment,* or, if so authorized, serve as a member of the National Health Service Corps, or * * *

* * * * *

(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such Awards [\$207,947,000 for the fiscal year ending June 30, 1975] \$160,000,000 for the fiscal year ending June 30, 1976, and \$176,000,000 for the fiscal year ending June 30, 1977. Of the sums appropriated under this subsection, not less than 25 per centum shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a) (1) (A).

SEC. 473. * * *

(c) A report on the results of such study shall be submitted by the Secretary to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate not later than [March 31] *September 30* of each year.

STIPENDS

SEC. 474. (a) *The Secretary is authorized to grant stipends, in amounts not to exceed \$25,000 per annum, to visiting scientists (as defined in subsection (b)) who enter into agreements with the Secretary to assist minority schools in developing programs in biomedical sciences. In the event a recipient of a stipend under this section does not complete the requirements of his agreement with the Secretary, the United States shall be entitled to recover an amount determined under section 472 (c) (4).*

(b) *For the purposes of this section the term—*

(1) *“visiting scientist” means a person who by his accomplishments and reputation has distinguished himself in the fields of biomedical science and has entered into an agreement with the Secretary under subsection (a);*

(2) *“minority school” means a school of postsecondary education which has enrolled a substantial number of minority students, as determined in accordance with regulations of the Secretary; and*

(3) *“biomedical sciences” means all the health related sciences and requisite related courses.*

(c) *There are authorized to be appropriated to carry out the purposes of this section, such sums as may be necessary.*

UNDERGRADUATE TRAINING IN BIOMEDICAL SCIENCES IN MINORITY SCHOOLS

SEC. 475. (a) *The Secretary may make grants to minority schools to initiate the development of undergraduate programs relating to biomedical sciences.*

(b) *Each minority school (as defined in subsection (c) (1)) may apply for a grant under subsection (a) to establish an undergraduate program in the biomedical sciences (as defined in subsection (c) (2)) in accordance with regulations established by the Secretary.*

(c) *For the purposes of this section the term—*

(1) *“minority school” means a school of postsecondary education which has enrolled a substantial number of minority students, as determined in accordance with regulations of the Secretary; and*

(2) *“biomedical sciences” means all the health related sciences and requisite related courses.*

(d) *There are authorized to be appropriated to carry out the purposes of this section, such sums as may be necessary.*

* * * * *

TITLE V—MISCELLANEOUS

GRANTS TO FEDERAL INSTITUTIONS

SEC. 507. Appropriations to the Public Health Service available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence, and appropriations available under the Community Men-

tal Health Centers Act for construction and staffing of community mental health centers and alcoholism and narcotic addiction, drug abuse, and drug dependence facilities shall also be available, on the same terms and conditions as apply to non-Federal institutions, for grants for the same purpose to [hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeth's Hospital, except that grants to such] Federal institutions, except that grants to Federal institutions may be funded at 100 per centum of the costs.

* * * * *

TITLE VII—HEALTH RESEARCH AND TEACHING FACILITIES AND TRAINING OF PROFESSIONAL HEALTH PERSONNEL

* * * * *

PART C—STUDENT LOANS

SUBPART I—LOANS TO STUDENTS STUDYING IN THE UNITED STATES

LOAN AGREEMENTS

SEC. 740. * * *

(b) Each agreement entered into under this section shall * * *

(4) provide that loans may be made from such funds only to students pursuing a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry, or an equivalent degree, doctor of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of podiatry or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree, and that while the agreement remains in effect no such student who has attended such school before July 1, [1975] 1976 shall receive a loan from a loan fund established under section 204 of the National Defense Education Act of 1958; and * * *

* * * * *

AUTHORIZATION OF APPROPRIATIONS

SEC. 742. (a) For the purpose of—

(1) making Federal capital contributions into the loan funds of schools which have established loan funds under this part,

(2) making payments into the fund established by section 744(d), and

(3) making transfers under section 746, there are authorized to be appropriated \$50,000,000 for the fiscal year ending June 30, 1972, \$55,000,000 for the fiscal year ending June 30, 1973, \$60,000,000 for the fiscal year ending June 30, 1974, [and] \$60,000,000 for the fiscal year ending June 30, 1975, and \$60,000,000 for the fiscal year ending June 30, 1976.

* * * * *

AUTHORIZATION OF APPROPRIATIONS

SEC. 786. For the purpose of making scholarship grants under this subpart, there are authorized to be appropriated \$2,500,000 for the

fiscal year ending June 30, 1972, \$3,000,000 for the fiscal year ending June 30, 1973, and \$3,500,000 for the fiscal year ending June 30, 1974, and \$3,500,000 for the fiscal year ending June 30, 1975 and \$2,000,000 for the fiscal year ending June 30, 1976. For the fiscal year ending June 30, 1975, and for each succeeding fiscal year, there are authorized to be appropriated such sums as may be necessary to continue to be appropriated such sums as may be necessary to continue to make such grants to students who (prior to July 1, 1974) have received such a grant and who are eligible for such a grant under this part during such succeeding fiscal year.

* * * * *

TITLE VIII—NURSE TRAINING

* * * * *

PART B—ASSISTANCE TO NURSING STUDENTS

* * * * *

LOAN AGREEMENTS

SEC. 822. * * *

(b) Each agreement entered into under this section shall—* * *

(4) provide that loans may be made from such fund only to students pursuing a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree or a diploma in nursing, or to a graduate degree in nursing, and that while the agreement remains in effect no such student who has attended such school before July 1, [1975] 1976, shall receive a loan from a loan fund established under section 204 of the National Defense Education Act of 1958; and * * *

* * * * *

AUTHORIZATION OF APPROPRIATIONS FOR LOANS

SEC. 824. There are authorized to be appropriated to the Secretary of Health, Education, and Welfare for Federal capital contributions to student loan funds pursuant to section 822(b)(2)(A) \$3,100,000 for the fiscal year ending June 30, 1965, \$8,900,000 for the fiscal year ending June 30, 1966, \$16,800,000 for the fiscal year ending June 30, 1967, \$25,300,000 for the fiscal year ending June 30, 1968, \$30,900,000 for the fiscal year ending June 30, 1969, \$20,000,000 for the fiscal year ending June 30, 1970, \$21,000,000 for the fiscal year ending June 30, 1971, \$25,000,000 for the fiscal year ending June 30, 1972, \$30,000,000 for the fiscal year ending June 30, 1973, and \$35,000,000 for the fiscal year ending June 30, 1974, [and] such sums for the fiscal year ending June 30, 1975, and \$35,000,000 for the fiscal year ending June 30, 1976, and each of the two succeeding fiscal years as may be necessary to enable students who have received a loan for any academic year ending before July 1, 1974, to continue or complete their education. Sums appropriated pursuant to this section for the fiscal year ending June 30, 1967, or any subsequent fiscal year shall be available to the Secretary (1) for payments into the fund established by section 827(d), and (2) in accordance with agreements under this part, for Federal capital contributions to schools with which such agreements have been made, to be used, together with deposits in such funds pursuant to section

822(b) (2) (B), for establishment and maintenance of student loan funds, and (3) for transfers pursuant to section 829.

* * * * *

TITLE XVI—HEALTH RESOURCES DEVELOPMENT

* * * * *

PART E—GENERAL PROVISIONS

* * * * *

RECOVERY

SEC. 1631. * * *

(b) The Secretary may waive the recovery rights of the United States under subsection (a) with respect to a facility in any State—

(1) if (as determined under regulations prescribed by the Secretary) the amount which could be recovered under subsection (a) with respect to such facility is applied to the development, expansion, or support of another medical facility located in such State which has been approved by the Statewide Health Coordinating Council for such State as consistent with the State health plan established pursuant to section 1524(c); or

(2) if the Secretary determines, in accordance with regulations, that there is good cause for waiving such requirement with respect to such facility. If the amount which the United States is entitled to recover under subsection (a) exceeds 90 per centum of the total cost of the construction or modernization project for a facility, a waiver under this subsection shall only apply with respect to an amount which is not more than 90 per centum of such total cost. [The Secretary may not waive a right of recovery which arose one year before the date of the enactment of this title.]

* * * * *

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * * * *

(f) (1) The term "food" means [(1)] (A) articles used for food or drink for many or other animals, [(2)] (B) chewing gum, and [(3)] (C) articles used for components of any such article.

(2) The term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

* * * * *

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, work, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

* * * * *

PENALTIES

SEC. 303. * * *

(d) No person shall be subject to the penalties of subsection (a) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a) (2) because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead.

SEIZURE

SEC. 304. (a) * * *

(3) (A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph 1 or (2) against any food which—

(i) is misbranded under section 403(a) (2) because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i) (I) the food's advertising which resulted in the food being misbranded under section 403(a) (2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the

direction of, the owner or operator of such establishment, or (III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

* * * * *

CHAPTER IV—FOOD

* * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411 (b) (2).

* * * * *

VITAMINS AND MINERALS

SEC. 411. (a) (1) Except as provided in paragraph (2)—

(A) the Secretary may not establish maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful.

(C) the Secretary may not limit the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food, within a food to which this section applies.

(2) (A) Paragraph (1) does not limit the Secretary in the exercise of his authority under and in accordance with—

(i) this chapter (other than this section) or chapter V, or

(ii) any other provision of this Act except to the extent that the authority under such other provision is to be exercised to take an action specifically prohibited by subparagraph (A), (B), or

(C) or such paragraph.

(B) Paragraph (1) shall not apply in the case of a vitamin, mineral, or other ingredient of food which the Secretary determines by regulation is represented for use by children or pregnant or lactating women. For purposes of this subparagraph, the term "children" means individuals who are under the age of twelve years.

(b) (1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403 (i) (2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) (A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except

as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with an applicable regulation promulgated under section 403 (j). To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(B) Notwithstanding the provisions of subparagraph (b) (2) (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

(i) vitamins,

(ii) minerals, or

(iii) represented as a source of vitamins or minerals.

(c) (1) For purposes of subsections (a) and (b) of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, or liquid form, or

(ii) if not intended for ingestion in such a form, does not simulate or is not represented as conventional food.

(2) For purposes of paragraph (1) (B) (i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

* * * * *

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

* * * * *

ADVERTISING OF CERTAIN FOODS

SEC. 707. Before initiating any action under chapter III with respect to any food to which section 411 applies and which is deemed to be misbranded under section 403 (a) (2) because of its advertising, the Secretary shall consult with the Federal Trade Commission and, for the purpose of avoiding unnecessary duplication, coordinate such action with any action taken or proposed to be taken by the Commission under the Federal Trade Commission Act.

* * * * *

PUBLIC LAW 93-640 NATIONAL ARTHRITIS ACT OF 1974

FINDINGS AND DECLARATION OF PURPOSE

SEC. 2. (a) The Congress makes the following findings—

(1) Arthritis and related musculoskeletal diseases (hereinafter in this Act collectively referred to as "arthritis") constitute major health problems in the United States in that they afflict more than twenty million Americans and are the greatest single cause of chronic pain and disability.

* * * * *

(3) The annual cost of arthritis to the national economy in 1970, from medical care expenses and lost wages, was \$9,200,000,000, including \$2,500,000,000 in medical expenses, and number of workdays lost in that year totaled over 14,500,000.

* * * * *

(b) *It is therefore the purpose of this Act to provide for—*

(1) *the formulation of a long-range plan—*

(A) *to expand and coordinate the national research, treatment, and control effort against arthritis;*

(B) *to advance educational activities for patients, professional and allied health personnel, and the public which will alert the citizens of the United States to the early indications of arthritis; and*

(C) *to emphasize the significance of early detection and proper control of these diseases and of the complications which may evolve from them;*

(2) *the establishment and support of programs to develop new and improved methods of arthritis screening, detection, prevention, and referral;*

(3) *the establishment of a central arthritis screening and detection data bank; and*

(4) *the development, modernization, and operation of centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, and research and training programs.*

NATIONAL COMMISSION ON ARTHRITIS; ARTHRITIS PLAN

SEC. 3. * * *

b) The Commission shall be composed of eighteen members as follows: * * *

(4) The Director of the National Institutes of Health or his designee, the Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases or his designee, the Directors, or their designees, of the National Institute of Allergy and Infectious Diseases and the National Institute of General Medical Science, the Associate Director for Arthritis and Related Musculoskeletal Diseases of such Institute, and the [chief medical officer] *Chief Medical Director* of the Veterans' Administration and the Secretary of Defense or their designees, each of whom shall serve as ex officio, nonvoting members.

* * * * *

(k) There are authorized to be appropriated, without fiscal year limitation, to carry out the purposes of this section, [\$2,000,000] \$1,500,000.

ARTHRITIS COORDINATING COMMITTEE, [DEMONSTRATION] PROJECTS, AND COMPREHENSIVE ARTHRITIS CENTERS

SEC. 4. Part D. of title IV of the Public Health Service Act is amended by adding at the end thereof the following new sections: * * *

* * * * *

HEALTH RESEARCH AND HEALTH SERVICES
AMENDMENTS OF 1976

APRIL 2, 1976.—Ordered to be printed

Mr. STAGGERS, from the committee of conference,
submitted the following

CONFERENCE REPORT

[To accompany H.R. 7988]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

SECTION 1. (a) This Act may be cited as the "Health Research and Health Services Amendments of 1976".

(b) Whenever in this Act (other than in titles III, V, VI, VII, and XI) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

TITLE I—REVISION OF NATIONAL HEART AND LUNG
INSTITUTE PROGRAMS

SEC. 101. (a) Congress finds and declares that—

(1) diseases of the heart, blood, 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 cost of medical care of more than \$40,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema being among the fastest rising causes of death in the United States;

(4) chronic respiratory diseases affect an estimated ten million Americans, emphysema 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 whose value in saving life and promoting health cannot be assessed in terms of dollars;

(7) 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 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;

(8) blood diseases, including nutritional anemia, anemia due to inherited abnormalities (such as sickle cell anemia and Cooley's anemia (thalassemia), anemias resulting from failure of the bone marrow, hemorrhagic defects (a common cause of death in patients with leukemia and other malignancies, and of disability from inherited diseases such as hemophilia), and malignancies of the lymph nodes and bone marrow, such as leukemia, have a devastating impact in spite of recent advances, and constitute an important category of illness that requires major attention; and

(9) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart, Lung, and Blood Institute, but advancement against such diseases depends not only on the research programs of that Institute but also on the research programs of other research institutes of the National Institutes of Health.

(b) It is the purpose of this title to enlarge the authority of the National Heart, Lung, and Blood Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases and to enlarge its authority with respect to blood resources.

SEC. 102. Sections 411, 418(a)(6), and 419A(c) are each amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart, Lung, and Blood Institute".

SEC. 103. (a) Section 412 is amended—

(1) by inserting "and with respect to the use of blood and blood products and the management of blood resources" after "diseases" in the matter preceding paragraph (1);

(2) by inserting "and to the use of blood and blood products and the management of blood resources" before the semicolon at the end of paragraph (1);

(3) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (4);

(4) by inserting "and on the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (5);

(5) by striking out "heart diseases" in paragraph (6) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and the management of blood resources";

(6) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (7); and

(7) by inserting at the end of the section heading "AND IN THE MANAGEMENT OF BLOOD RESOURCES".

(b) Section 412 is amended by striking out "National Heart and Lung Advisory Council" and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 104. (a) Section 413(a) is amended—

(1) by striking out "Disease" in the first sentence and inserting in lieu thereof "Diseases and Blood Resources"; and

(2) by inserting "and blood resources" after "diseases" in such sentence and in paragraph (7).

(b) Section 413(b) is amended—

(1) by striking out "calendar" each place it occurs in paragraph (2) and inserting in lieu thereof "fiscal"; and

(2) by adding at the end of such paragraph the following: "Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations for appropriations to carry out the program during such five years".

(c) Section 413(c)(1) is amended by striking out "fifty" and inserting in lieu thereof "one hundred".

(d) Section 413(c)(2) is amended—

(1) by striking out "operate" and inserting in lieu thereof "operate, alter, renovate"; and

(2) by inserting "and blood resource" after "disease".

(e) Section 413(d) is amended—

(1) by striking out "Assistant Director for Health Information Programs" each place it occurs and inserting in lieu thereof "Assistant Director for Prevention Education, and Control";

(2) by striking out "and pulmonary" in the second sentence and inserting in lieu thereof "blood, and pulmonary" and by inserting "and blood" after "pulmonary" in the third sentence; and

(3) by inserting "and blood resources" after "diseases" in the second sentence.

(f) The section heading of section 413 is amended by striking out "DISEASE" and inserting in lieu thereof "DISEASES AND BLOOD RESOURCES".

SEC. 105. Section 414(b) is amended (1) by striking out "and" after "1974," and (2) by inserting before the period a comma and the following: "\$10,000,000 for fiscal year 1976, and \$30,000,000 for fiscal year 1977".

SEC. 106. (a)(1) Subsection (a)(1)(A) of section 415 is amended by—
 (A) striking out “fifteen” and inserting in lieu thereof “ten”, and
 (B) striking out “, blood vessel, and blood diseases” and inserting in lieu thereof “diseases”.

(2) Subsection (a)(1)(B) of such section is amended by striking out “fifteen” and inserting in lieu thereof “ten”.

(3) Subsection (a)(1) of such section is amended—

(A) by striking out “and” at the end of subparagraph (A),

(B) by striking out the period at the end of subparagraph (B) and inserting in lieu thereof “; and”, and

(C) by inserting after subparagraph (B) the following new subparagraph:

“(C) ten 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 blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.”

(b) Section 415(a) is further amended—

(1) by inserting “and for research in the use of blood and blood products and in the management of blood resources” after “diseases” in paragraph (1) (A);

(2) by striking out “chronic” in paragraph (1)(B);

(3) by striking out “paragraph (1)(A)” in paragraph (2) and inserting in lieu thereof “paragraph (1)”;

(4) by inserting “, pulmonary, and blood” before “diseases” in paragraph (2);

(5) by striking out “cardiovascular disease” in paragraph (2)(A) and inserting in lieu thereof “cardiovascular, pulmonary, and blood diseases”; and

(6) by striking out “such disease” in subparagraphs (B), (C), and (D) of paragraph (2) and inserting in lieu thereof “such diseases”.

(c) Section 415(b) is amended—

(1) by inserting “the management of blood resources and” before “advanced”; and

(2) by amending the first sentence after paragraph (4) to read as follows: “The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed \$5,000,000 in any year, except that the aggregate of such payments in any year may exceed such amount to the extent that the excess amount is attributable to increases in such year in appropriate costs as reflected in the Consumer Price Index published by the Bureau of Labor Statistics.”

(d) The section heading of section 415 is amended by inserting “AND BLOOD RESOURCES” after “DISEASES”.

SEC. 107. (a) Section 417(a)(1) is amended by striking out “Director of the Office of Science and Technology” and inserting in lieu thereof “Director of the National Science Foundation”.

(b) Section 417 is amended by striking out “National Heart and Lung Advisory Council” in subsection (a) and in subsection (b)(3) and inserting in lieu thereof “National Heart, Lung, and Blood Advisory Council”.

(c) The section heading of section 417 is amended by striking out “AND LUNG” and inserting in lieu thereof “, LUNG, AND BLOOD”.

SEC. 108. Section 418 is amended—

(1) by inserting “and to the use of blood and blood products and the management of blood resources” after “diseases” in paragraphs (1), (2), (3), and (4) of subsection (a);

(2) by redesignating paragraphs (4), (5), and (6) of subsection (a) as paragraphs (5), (6), and (7), respectively, and by adding after paragraph (3) the following new paragraph:

“(4) recommend to the Secretary (A) areas of research in heart, blood vessels, lung, and blood diseases and in the use of blood and blood products and the management of blood resources which it determines should be supported by the awarding of contracts in order to best carry out the purposes of this part, and (B) the percentage of the budget of the Institute which should be expended for such contracts;”; and

(3)(A) by amending paragraph (2) of subsection (b) to read as follows:

“(2) The Council shall submit a report to the Secretary for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress on the progress of the Program toward the accomplishment of its objectives during the preceding fiscal year.”

(B) For purposes of section 418(b)(2) of the Public Health Service Act (as amended by subparagraph (A)), the period beginning July 1, 1975, and ending September 30, 1976, shall be considered a fiscal year.

(C) The amendment made by subparagraph (A) shall take effect as of January 1, 1976.

SEC. 109. Section 419A is amended—

(1) by inserting “and projects with respect to the use of blood and blood products and the management of blood resources” after “training projects” in subsection (a);

(2) by inserting “and into the use of blood and blood products and the management of blood resources” after “diseases” in subsection (b);

(3) by inserting “and for research and training in the use of blood and blood products and the management of blood resources” after “diseases” in subsection (c);

(4) by striking out “in amounts not to exceed \$35,000” in paragraph (1) of subsection (c) and inserting in lieu thereof “if the direct costs of such research and training do not exceed \$35,000, but only”; and

(5) by striking out “in amounts exceeding \$35,000” in paragraph (2) of subsection (c) and inserting in lieu thereof “if the direct costs of such research and training exceed \$35,000, but only”.

SEC. 110. Section 419B is amended—

(1) by striking out “and” after “1974,” and by inserting before the period at the end of the first sentence a comma and the following: “\$339,000,000 for fiscal year 1976, and \$373,000,000 for fiscal year 1977”; and

(2) by striking out “diseases of the blood” and inserting in lieu thereof “blood diseases and blood resources”.

SEC. 111. (a) Section 301 is amended by striking out "heart diseases" in paragraphs (c) and (h) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and blood resources".

(b) Section 301 is amended by striking out "National Heart and Lung Advisory Council" in paragraphs (c) and (h) and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 112. The title of Part B of title IV is amended to read as follows:

"PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE".

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

SEC. 201. (a)(1) Subsection (a)(1)(A)(i) of section 472 is amended (A) by striking out "in matters" and inserting in lieu thereof "or under programs administered by the Division of Nursing of the Health Resources Administration, in matters", and (ii) by inserting before "are directed" the following: "or Division of Nursing".

(2) Subsections (a)(1)(A)(iii) and (a)(1)(B) of such section are each amended by striking out "non-Federal".

(b) Subsection (c)(1)(A)(i) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment".

(c) Subsection (c)(2)(A) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment".

(d) The first sentence of subsection (d) of such section is amended by inserting a comma before the period and the following: "\$165,000,000 for fiscal year 1976, and \$185,000,000 for fiscal year 1977".

SEC. 202. (a) Subsection (a)(1)(A)(i) of section 472 is amended by striking out "the disease or (diseases) or other health problems to which the activities of the Institutes and Administration are directed" and inserting in lieu thereof "diseases or other health problems".

(b) Subsection (b)(2) of section 472 is amended by striking out "to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration" and inserting in lieu thereof "within the Department of Health, Education, and Welfare".

SEC. 203. (a)(1) Subparagraph (A) of the first paragraph (4) of subsection (c) of section 472 is amended by striking out "and the interest on such amount" down through and including "was made".

(2) The last sentence of subparagraph (B) of such paragraph is amended by striking out "at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States" and inserting in lieu thereof "at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount".

(b) The amendments made by subsection (a) shall apply with respect to National Research Awards under section 472 which are made from appropriations for fiscal years ending on or after June 30, 1975.

SEC. 204. Section 473(b) is amended by adding after paragraph (2) the following new paragraph:

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health."

SEC. 205. Subsection (c) of section 473 is amended by striking out "March 31" and inserting in lieu thereof "September 30".

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

SEC. 301. (a)(1) The President's Biomedical Research Panel (established by section 201(a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

(A) The number of requests made to the Secretary for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such requests were made.

(B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.

(C) The effect of the disclosure of such information on—

(i) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on patent rights;

(ii) the ability of peer review systems to insure high quality federally funded research; and

(iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

(2)(A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Panel deems appropriate.

(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission deems appropriate.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof "January 1, 1977".

TITLE IV—GENETIC DISEASES

SEC. 401. This title may be cited as the "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act".

SEC. 402. In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

SEC. 403. (a) Title XI is amended by striking out parts A and B and inserting in lieu thereof the following:

"PART A—GENETIC DISEASES

"TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

"SEC. 1101. (a)(1) The Secretary, through an identifiable administrative unit within the Department of Health, Education, and Welfare, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects to establish and operate voluntary genetic testing and counseling programs primarily in conjunction with other existing health programs, including programs assisted under title V of the Social Security Act.

"(2) The Secretary shall carry out, through an identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. The Secretary may, under such program, make grants to public and nonprofit private entities and enter into contracts with public and private entities and individuals for the development and dissemination of such materials.

"(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for fiscal year 1976, \$30,000,000 for fiscal year 1977, and \$30,000,000 or fiscal year 1978.

"RESEARCH PROJECT GRANTS AND CONTRACTS

"SEC. 1102. In carrying out section 301, the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases,

and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

"VOLUNTARY PARTICIPATION

"SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

"APPLICATIONS; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

"SEC. 1104. (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require. Each applicant shall—

"(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

"(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

"(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part;

"(4) in the case of an applicant for a grant or contract under section 1101(a)(1) for the delivery of services, provide assurances satisfactory to the Secretary that (A) the services for community-wide testing and counseling to be provided under the program for which the application is made (i) will take into consideration widely prevalent diseases with a genetic component and high-risk population groups in which certain genetic diseases occur, and (ii) where appropriate will be directed especially but not exclusively to persons who are entering their child-producing years, and (B) appropriate arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and

"(5) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

"(b) In making any grant or entering into any contract for testing and counseling programs under section 1101, the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the

greatest number of persons who will benefit from and are in need of the services provided under such programs.

"(c) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 or under section 1101 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

"PUBLIC HEALTH SERVICE FACILITIES

"SEC. 1105. The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

"REPORTS

"SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

"(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary."

(b)(1) Section 1121(b)(5) is amended by striking out "ending June 30," each place it occurs.

(2) Parts C and D are redesignated as parts B and C, respectively.

(3) The heading of such title is amended to read as follows:

"TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME."

(c) The amendments made by subsections (a) and (b) shall take effect July 1, 1976.

TITLE V—FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

SEC. 501 (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 410 (21 U.S.C. 349) the following new section:

"VITAMINS AND MINERALS

"SEC. 411. (a)(1) Except as provided in paragraph (2)—

"(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

"(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

"(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

"(i) vitamin,

"(ii) mineral, or

"(iii) other ingredient of food,

within a food to which this section applies.

"(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years.

"(b)(1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i)(2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

"(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

"(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

"(i) vitamins,

"(ii) minerals, or

"(iii) represented as a source of vitamins or minerals.

"(c)(1) For purposes of this section, the term 'food to which this section applies' means a food for humans which is a food for special dietary use—

"(A) which is or contains any natural or synthetic vitamin or mineral, and

"(B) which—

"(i) is intended for ingestion in tablet, capsule, or liquid form, or

"(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

"(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

"(3) For purposes of paragraph (1) and of section 403 (j) insofar as that section is applicable to food to which this section applies, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

"(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

"(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

"(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet."

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

SEC. 502. (a)(1) Section 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(a)) is amended (A) by inserting "(1)" after "If", and (B) by inserting before the period at the end a comma and the following: "or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2)".

(2) (A) Section 201(n) of such Act is amended by inserting "or advertising" after "labeling" each time it occurs.

(B) Section 303 of such Act is amended by adding at the end the following new subsection:

"(d) No person shall be subject to the penalties of subsection (a) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead."

(C) Section 304(a) of such Act (21 U.S.C. 334(a)) is amended by adding after paragraph (2) the following new paragraph:

"(3) (A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

"(i) is misbranded under section 403(a)(2) because of its advertising, and

"(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

"(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

"(i) (I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

"(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

"(III) all or part of the cost of such advertising was paid by such owner or operator; and

"(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food."

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

"ADVERTISING OF CERTAIN FOODS

"SEC. 707. (a)(1) Except as provided in subsection (c), before the Secretary may initiate any action under chapter III—

"(A) with respect to any food which the Secretary determines is misbranded under section 403(a)(2) because of its advertising, or

"(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded, the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

"(2) The notice required by paragraph (1) shall—

"(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

"(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

"(b)(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter III with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

"(A) it has initiated under the Federal Trade Commission Act an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

"(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 with respect to such advertising,

"(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act respecting such advertising, or

"(D) pursuant to section 16(b) of such Act it has made a certification to the Attorney General respecting such advertising, the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

"(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a)—

"(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

"(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

"(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a). The Commission shall promptly notify the Secretary of the commencement by

the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

“(c) The requirements of subsections (a) and (b) do not apply with respect to action under chapter III with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

“(d) For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter III because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act with respect to such advertising.”

(c) The amendments made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

TITLE VI—ARTHRITIS ACT AMENDMENTS

SEC. 601. This title may be cited as the “National Arthritis Act Technical Amendments of 1976”.

SEC. 602. (a) Section 2 of the National Arthritis Act of 1974 (Public Law 93-640) (hereinafter in this section referred to as the “Act”) is amended by—

(1) inserting “(a)” after “SEC. 2.”;

(2) inserting a comma and “including \$2,500,000,000 in medical expenses,” after “\$9,200,000,000” in paragraph (3); and

(3) inserting a new subsection (b) at the end thereof as follows:

“(b) It is therefore the purpose of this Act to provide for—

“(1) the formulation of a long-range plan—

“(A) to expand and coordinate the national research, treatment, and control effort against arthritis;

“(B) to advance educational activities for patients, professional and allied health personnel, and the public which will alert the citizens of the United States to the early indications of arthritis; and

“(C) to emphasize the significance of early detection and proper control of these diseases and of the complications which may evolve from them;

“(2) the establishment and support of programs to develop new and improved methods of arthritis screening, detection, prevention, and referral;

“(3) the establishment of a central arthritis screening and detection data bank; and

“(4) the development, modernization, and operation of centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, and research and training programs.”

(b) Section 3 of the Act is amended by striking out “chief medical officer” and inserting in lieu thereof “Chief Medical Director” in subsection (b)(4).

(c) The section heading for section 4 of the Act is amended by striking out “DEMONSTRATION” after “COMMITTEE.”

SEC. 603. (a)(1) Section 431(c) of the Public Health Service Act is amended by inserting “(hereinafter in this part collectively referred to as ‘arthritis’)” after “musculoskeletal diseases”.

(2) The fourth sentence of section 434(b) of such Act is amended by striking out “and related musculoskeletal diseases”.

(3) Section 434(e) of such Act is amended by striking out “and related musculoskeletal diseases (hereinafter in this part collectively referred to as ‘arthritis’)”.

(b) Section 438 of such Act is amended by—

(1) inserting “the” before “health” the first time it appears in the first sentence of subsection (a); and

(2) inserting “established” after “bank” in the second sentence of subsection (a).

(c) Section 439 of such Act is amended by—

(1) inserting “new and existing” before “centers” in the first sentence of subsection (a);

(2) striking out “\$13,000,000” and inserting in lieu thereof “\$8,000,000”, and striking out “\$15,000,000” and inserting in lieu thereof “\$20,000,000” in subsection (h); and

(3) redesignating subsections (e), (f), (g), and (h) as subsections (d), (e), (f), and (g), respectively.

TITLE VII—DIABETES PLAN

SEC. 701. Section 3(i)(2) of the National Diabetes Mellitus Research and Education Act (42 U.S.C. 289c-2) is amended to read as follows:

“(2) The Commission shall cease to exist after September 30, 1976.”

TITLE VIII—HEALTH SERVICES

AMBULATORY SURGICAL SERVICES

SEC. 801. (a) Section 319(a)(7) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

“(L) ambulatory surgical services;” and

(2) redesignating subparagraphs (L) and (M) as subparagraph (M) and (N), respectively.

(b) Section 330(b)(2) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

“(L) ambulatory surgical services;” and

(2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

TITLE IX—INDIAN HEALTH SERVICE

SEC. 901. Section 225 is amended by adding at the end thereof the following new subsection—

“(j) Notwithstanding any other provision of law, the Secretary may, where he deems advisable, allow the Indian Health Service to utilize non-profit recruitment agencies to assist in obtaining personnel for the Public Health Service.”

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation

Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation.

TITLE XI—MISCELLANEOUS PROVISIONS

SEC. 1101. Section 212 of the Public Health Service Act is amended by adding after subsection (d) the following new subsection:

"(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940 (50 App. U.S.C. 501 et seq.)."

SEC. 1102. (a) The second paragraph (4) of subsection (c) of section 472 of the Public Health Service Act is redesignated as paragraph (5).

(b) Section 507 of the Public Health Service Act is amended by striking out "hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except that grants to such" and insert in lieu thereof "Federal institutions, except that grants to".

SEC. 1103. Title IV of the Public Health Service Act is amended by adding after section 475 the following new section:

"VISITING SCIENTIST AWARDS

"SEC. 476. (a) The Secretary may make awards (referred to as 'Visiting Scientist Awards') to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe."

SEC. 1104. Section 786 of the Public Health Service Act is amended by inserting before the period at the end of the first sentence "and \$3,500,000 for the fiscal year ending June 30, 1975 and \$2,000,000 for the fiscal year ending June 30, 1976".

SEC. 1105. (a) Section 742(a) of the Public Health Service Act is amended by striking out "and" after "1974," and by inserting after "1975" the following: ", and \$60,000,000 for the fiscal year ending June 30, 1976".

(b) Section 740(b)(4) of such Act is amended by striking out "1975" and inserting in lieu thereof "1976".

SEC. 1106. Section 1511(b)(5) of the Public Health Service Act is amended by striking out "1535" and inserting in lieu thereof "1536".

(b) Section 1613 of such Act is amended by striking out "1510" and inserting in lieu thereof "1610".

(c) The last sentence of section 1631 of such Act is repealed.

SEC. 1107. (a) Section 132(a)(1)(A) of the Developmental Disabilities Services and Facilities Construction Act (42 U.S.C. 6062) (hereinafter in this section referred to as the "Act") is amended by striking out "134" and inserting in lieu thereof "133".

(b) Section 134(b)(1) of the Act is amended by striking out "134" and inserting in lieu thereof "133".

(c) Section 134(b)(1) of the Act is amended by striking out "136" and inserting in lieu thereof "135".

(d) Section 301(a) of the Developmentally Disabled Assistance and Bill of Rights Act is amended by striking out "101(7)" and inserting in lieu thereof "102(7)".

And the Senate agree to the same.

HARLEY O. STAGGERS,
PAUL G. ROGERS,
DAVID E. SATTERFIELD,
JAMES W. SYMINGTON,
JAMES H. SCHEUER,
TIM LEE CARTER,
JAMES T. BROYHILL,
Managers on the Part of the House.
HARRISON A. WILLIAMS, JR.,
CLAIBORNE PELL,
EDWARD M. KENNEDY,
WALTER F. MONDALE,
ALAN CRANSTON,
WILLIAM D. HATHAWAY,
JOHN A. DURKIN,
THOMAS F. EAGLETON,
GAYLORD NELSON,
JACOB K. JAVITS,
RICHARD S. SCHWEIKER,
ROBERT TAFT,
J. GLENN BEALL, JR.,
ROBERT T. STAFFORD,
PAUL LAXALT,
Managers on the Part of the Senate.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study on the release of research information, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The Senate amendment struck out all of the House bill after the enacting clause and inserted a substitute text.

The House recedes from its disagreement to the amendment of the Senate with an amendment which is a substitute for the House bill and the Senate amendment. The differences between the House bill, the Senate amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

FINDINGS

The Senate amendment, in a provision not in the House bill, specified Congressional findings, with respect to the impact of diseases of the heart, lung and blood vessels and blood disease and the need for the proposed legislation.

The conference substitute conforms to the Senate amendment, with technical changes.

ADVISORY COUNCIL

The House bill changed the name of the National Heart Lung Advisory Council to the National Heart, Lung and Blood Advisory Council.

The Senate amendment contained no comparable provision.

The conference substitute conforms to the House bill.

EXPERTS AND CONSULTANTS

Existing law authorizes the Director of the National Heart and Lung Institute to obtain the services of not more than 50 experts and consultants.

The House amendment increased this number to 100.
The Senate amendment contained no comparable provision.
The conference substitute conforms to the House bill.

ASSISTANT DIRECTOR

Existing law establishes within the National Heart and Lung Institute (redesignated as the National Heart, Lung and Blood Institute under provisions of both the House bill and the Senate amendment) an Assistant Director for Health Information Programs.

The House bill changed the name to Assistant Director for Prevention, Education, and Control.

The Senate amendment changed the name to Assistant Director for Prevention and Information.

The conference substitute conforms to the House bill.

AUTHORIZATION FOR PREVENTION AND CONTROL PROGRAMS

The House bill authorized appropriations of \$20 million for fiscal year 1976 and \$30 million for fiscal year 1977 for heart, blood vessel, lung, and blood disease control programs.

The Senate amendment authorized appropriations of \$10 million for fiscal year 1976 and \$25 million for fiscal year 1977 for such programs.

The conference substitute authorizes \$10 million for fiscal year 1976 and \$30 million for fiscal year 1977 for such programs.

CENTERS

Existing law authorizes the development of fifteen centers for research, training, and demonstrations respecting heart, blood vessel, and blood diseases, and fifteen such centers for chronic lung diseases.

The House bill increased the responsibilities of the heart, blood vessel, and blood disease centers to include research in the use of blood and blood products and in the management of blood resources. Further, the House bill expanded the responsibilities of the lung disease centers by deleting the word "chronic."

The Senate amendment authorized the development of ten centers for research, training, and demonstrations respecting heart diseases; ten such centers for chronic lung diseases; and ten such centers for blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.

The conference substitute conforms to the Senate amendment, except that it authorizes the development of ten centers for lung diseases, as opposed to chronic lung diseases.

FUNCTIONS OF THE ADVISORY COUNCIL

The House bill added to the existing authority of the National Heart, Lung, and Blood Advisory Council the prerogative to recommend to the Secretary of Health, Education, and Welfare areas of research conducted or supported by the newly designated National Heart, Lung, and Blood Institute which the Council determines should be supported by the awarding of contracts and the percentage of the budget of the Institute which should be expended for such contracts.

The Senate amendment contained no comparable provision.

The conference substitute conforms to the House bill.

REPORT OF THE ADVISORY COUNCIL

Both the House bill and the Senate amendment required that the Advisory Council submit by November 30 of each year a report to the Secretary for simultaneous transmittal to the President and to the Congress on the progress of the National Heart, Blood Vessel, Lung, and Blood Disease Program during the preceding fiscal year. However, the Senate amendment stipulates that for purposes of this requirement, the period beginning July 1, 1975 and ending September 30, 1976 shall be considered a fiscal year and the House amendment contains no comparable provision.

The conference substitute conforms to the Senate amendment.

AUTHORIZATIONS FOR RESEARCH

The House bill authorized appropriations of \$340 million for fiscal year 1976 and \$375 million for fiscal year 1977 for carrying out the programs of the redesignated National Heart, Lung, and Blood Institute (except prevention and control programs).

The Senate amendment authorized \$338 million for fiscal year 1976 and \$372 million for fiscal year 1977 for such purposes.

The conference substitute authorized \$339 million for fiscal year 1976 and \$373 million for fiscal year 1977 for such purposes.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

AUTHORIZATIONS

The House bill authorized appropriations of \$175 million for fiscal year 1976 and \$200 million for fiscal year 1977 for payments for National Research Services Awards.

The Senate amendment authorized \$160 million for fiscal year 1976 and \$176 million for fiscal year 1977 for such purposes.

The conference substitute authorizes \$165 million for fiscal year 1976 and \$185 million for fiscal year 1977 for such purposes.

ACCUAL OF INTEREST

Under existing law, interest accrues on National Research Service Awards from the time the award is made in instances in which recipients fail to fulfill applicable service requirements.

The House bill changed existing law to make interest on the award computed from the time the United States becomes entitled to recover all or part of the award.

The Senate bill contained no comparable provision.

The conference substitute conforms to the House bill.

STUDY RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

Under existing law, the Secretary is to annually submit a study respecting biomedical and behavioral research personnel.

The Senate amendment changed the date for submission of the report to September 30, and the House bill contained no comparable

provision. The House bill required that the entity conducting the study conduct such study in consultation with the Director of the National Institutes of Health.

The conference substitute conforms to the changes made in existing law by both the House bill and the Senate amendment.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

The House bill contained a provision which required the President's Biomedical Research Panel to conduct an investigation and study of the implication of disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary in conjunction with an application or proposal for a grant, fellowship, or contract under the Public Health Service Act and to submit a report on the investigation and study to the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare. The House bill also included a provision which deferred, from July 1, 1976 to January 1, 1977, the establishment of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

The Senate amendment contained no comparable provisions.

The conference substitute conforms to the House bill, except that the National Commission for the Protection of Human Subjects is also required to conduct the investigation and study, and technical changes are made with respect to the dates on which the Panel is to complete its investigation and submit its report.

The Conferees express their concern that inadequate attention is being paid to the problems of transfer of research progress, technology, and information from the "bench to the bed", an area frequently referred to as the interface between research and the health care delivery system. This includes such areas as extensive clinical trials, demonstration projects, specific disease control programs, the assessment of new health technologies, health education, and the fields of preventive medicine and public health. The Conferees have received assurance that the report of the President's Biomedical Research Panel will address these important issues.

TITLE IV—GENETIC DISEASES

SHORT TITLE AND STATEMENT OF PURPOSE

The House bill provided for the following short title: "National Genetic Diseases Act." Under the Senate amendment the short title was "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs and Genetic Diseases Act."

The House bill stated a purpose of establishing a national program for genetic diseases, including sickle cell anemia, Cooley's anemia and Tay-Sachs disease. The Senate amendment, in its statement of purpose, stipulated that genetic diseases are to include but not be limited to sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

The conference substitute conforms to the Senate amendment.

TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

The house bill required that testing and counseling programs be established and operated primarily in conjunction with other existing health programs, including programs established under title X of the Public Health Service Act (family planning programs) and under title V of the Social Security Act (maternal and child health programs). The Senate amendment contained comparable requirements, except that it did not specify programs under title X of the Public Health Service Act or under title V of the Social Security Act.

The conference substitute conforms to the House bill, except that only programs assisted under title V of the Social Security Act are specified.

The Senate amendment further provided that a priority in the awarding of grants and contracts for genetic disease counseling and testing programs was to be given to projects which are recipients of awards for sickle cell anemia testing and counseling programs on the date of enactment. There was no similar provision in the House bill.

The conference substitute conforms to the Senate amendment with technical amendments.

The House bill authorized \$20 million for each of fiscal years 1976 and 1977 to support genetic disease testing and counseling programs and information and education programs. The Senate amendment authorized \$20 million for fiscal year 1976, \$25 million for fiscal year 1977, and \$30 million for fiscal year 1978 for such programs; and an additional \$15 million for each of fiscal years 1976, 1977, and 1978 to support sickle cell anemia testing and counseling programs.

The conference substitute authorizes \$30 million for each of fiscal years 1976, 1977, and 1978 to support genetic diseases testing and counseling programs and information and education programs, and provides that the Secretary shall give special consideration in the awarding of grants and contracts to sickle cell anemia testing and counseling project applications.

RESEARCH PROJECT GRANTS AND CONTRACTS

Both the House bill and the Senate amendment authorized the Secretary to award grants and contracts for research projects with respect to genetic diseases.

Both the House bill and the Senate amendment set forth four purposes for which the Secretary could award research grants and contracts. They are identical except that as the first purpose the House bill provided that projects for basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases would be eligible for funding. The Senate amendment included projects for basic research, including lower organisms, applied research, and research training.

The conference substitute conforms to the House bill.

The House bill instructed the Secretary to undertake genetic disease research under the general authority of section 301 of the Public Health Service Act. The Senate amendment provided for a specific authority and authorized \$80 million for fiscal year 1976, \$100 million for fiscal year 1977, and \$120 million for fiscal year 1978; and ear-

marked 10 percent of the sums appropriated each year under the authority for research projects with respect to Cooley's anemia. The Senate amendment further provided for a separate authorization for sickle cell anemia research of \$15 million for each of fiscal years 1976, 1977, and 1978.

The conference substitute conforms to the House bill, except that the Secretary is directed, in making grants and entering into contracts for research projects, to give priority to applications which are submitted for research on sickle cell anemia or for research on Cooley's anemia.

TITLE V.—VITAMINS AND MINERALS

The Senate amendment contained provisions not included in the House bill relating to regulation of vitamin and mineral products under the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as "the Act").

Under the Senate amendment, the Secretary of Health, Education and Welfare would generally have been prohibited from establishing maximum limits on the potency of vitamins or minerals in dietary supplements or classifying vitamins or minerals as drugs solely because they exceeded the level of potency determined by him to be nutritionally rational or useful. In addition, the Secretary would have been prohibited from limiting the combination of vitamins, minerals or other ingredients in dietary supplements. However, under the Senate amendment, the Secretary would have retained full authority to limit the potencies and combinations of vitamins, minerals and other ingredients in foods in the exercise of his authority under chapter V of the Act (relating to drugs) and under provisions of the Act respecting unsafe foods which are not generally recognized as safe. In addition, the Senate amendment contained provisions rendering the amendment's limitations on the authority of the Secretary inapplicable to vitamin and mineral products for use by children or by pregnant or lactating women.

The Senate amendment also contained provisions with respect to the labeling and advertising of vitamin and mineral products. It prohibited a product containing vitamins or minerals from being deemed misbranded solely because its label lists all ingredients of such a product. However, the amendment required that the labeling of such products could not list ingredients which are not vitamins or minerals except as a part of a list of all ingredients of the product and unless such ingredients are listed in accordance with applicable regulations. Moreover, the Senate amendment prohibited the labeling of or advertising for any such product to give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals.

In addition, the Senate amendment afforded the Secretary significant new authority with respect to the advertising of certain products containing vitamins or minerals. (Under existing law, the Federal Trade Commission has exclusive authority with respect to the advertising of such products.) Under the Senate amendment, such products would be deemed misbranded if their advertising were false or misleading in a material respect. However, criminal penalties could not be imposed against persons who were in violation of the prohibitions against false or misleading advertising unless such a violation

was committed with the intent to defraud or mislead. Further, such products which are misbranded because their advertising is false or misleading in a material respect and are held for sale to the ultimate consumer in an establishment not owned by a manufacturer, packer or distributor, could not be seized unless (1) the advertising was disseminated in the establishment in which the product was held for sale to the ultimate consumer, the advertising was disseminated by or under the direction of the owner or operator of such establishment, or all or part of the cost of such advertising was paid for by the owner or operator, and (2) the owner or operator used the advertising to promote the sale of the product. Finally, the Senate amendment required the Secretary to consult with the Federal Trade Commission prior to initiating action with respect to such products deemed misbranded because of their advertising.

The Conference substitute conforms to the Senate amendment except that:

(1) It adds two technical amendments (clarifying the intention of the Senate amendment) to provide specifically that foods represented for use by individuals in the treatment or management of specific diseases or disorders and foods represented for use as the sole item of a meal or of the diet are excluded from the limitations on the Secretary's authority.

(2) Except in instances in which immediate action is necessary to eliminate an imminent hazard to health, it requires the Secretary to provide notification to the Federal Trade Commission of his intention to initiate an action with respect to false or misleading advertising, and it affords the Federal Trade Commission the opportunity to take specific enforcement action against false or misleading advertising for a period of up to 90 days before the Secretary may take comparable action.

Since the House has taken no action during this Congress with respect to this matter, it is important to provide more legislative history concerning these complex new provisions. Thus, presented below is a detailed description of the new provisions, as well as statements of the intentions of the managers with respect to their implementation.

PRODUCTS SUBJECT TO THE CONFERENCE SUBSTITUTE

Under the conference substitute, products subject to its provisions are defined as safe human foods for special dietary use which are or contain any natural or synthetic vitamin or mineral and which are intended for ingestion in tablet or capsule form or in small units of liquid measure. In addition, such foods not intended for ingestion in tablet, capsule, or liquid form are subject to the provisions of the substitute only if they do not simulate conventional foods, if they are not represented to be conventional foods, and if they are not represented for use as the sole item of a meal or of the diet.

The definition of "special dietary use" in the conference substitute applies only to the foods to which the substitute is applicable and not to other foods, such as foods represented for use by infants or foods represented for use as the sole item of a meal or of the diet, that may be subject to 403(j) of the Act.

Thus, vitamins and minerals in tablet, capsule, or liquid form as well as those products which are represented for special dietary use in humans and which do not simulate and are not represented as conventional foods or substitutes for conventional foods and which are not represented for use as the sole item of a meal or of the diet, are products subject to the provisions of the substitutes.

Except with respect to products defined above, the conference substitute does not alter existing provisions of the Federal Food, Drug, and Cosmetic Act with respect to foods and drugs.

The Secretary retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in conventional foods such as milk, enriched bread and enriched rice, as well as in products which simulate conventional foods such as soybased protein substitutes for meats and poultry. The Secretary also retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in foods represented by labeling, advertising, or other promotional materials for use as the sole item of a meal or of the diet. Because consumers purchase these foods as nutritional equivalents of a well-balanced meal or diet, the conferees believe it is essential that the consumer of such products can be confident that a meal or diet based upon such products is nutritionally adequate and balanced and provides for the proper maintenance of the user's health for the duration of his use of these products.

LIMITATIONS ON THE SECRETARY'S AUTHORITY

Under the conference report, three significant restrictions would be imposed on the Secretary with regard to the regulation of products subject to the conference substitute. First, new section 411(a)(1)(A) of the Act prohibits the Secretary from using his existing authority under sections 201(n) or 403 of the Act (relating to misbranding) or under section 401 of the Act (relating to standards of identity) to impose maximum limits on the potency of safe vitamins and minerals contained in products subject to the conference substitute. This provision would not restrict the Secretary from prescribing minimum potency levels for vitamins or minerals in such products in order to prevent the addition of insignificant or useless amounts.

Second, new section 411(a)(1)(B) of the Act prohibits the Secretary from classifying as a drug a natural or synthetic vitamin or mineral, offered by itself or in combination, solely because it exceeds the level of potency that the Secretary determines is nutritionally rational or useful.

Third, new section 411(a)(1)(C) of the Act prohibits the Secretary from using his authority with respect to misbranding or establishment of standards of identity to limit the combination or number of any safe vitamin, mineral or other ingredient of food in products subject to the conference substitute.

EXCEPTIONS TO LIMITATIONS ON THE SECRETARY

Under the conference substitute (proposed new section 411(a)(2) of the Act), the limitations on the Secretary, described above, do not apply with respect to a product otherwise subject to the provisions

of the conference substitute where such product is represented for use by (1) individuals in the treatment or management of specific diseases or disorders, (2) children, or (3) pregnant or lactating women.

The provision with respect to foods intended for use in the treatment or management of specific diseases or disorders was adopted in conference in order to make clear that the proposed new section 411(a) of the Act does not override the Secretary's authority under sections 401, 403, or 201(n) of the Act to limit the potency and combination of vitamins, minerals, other ingredients in foods, or foods, represented for use in the dietary treatment or management of individuals with specific diseases or disorders, or of post-operative or convalescing medical patients. Since each of these foods must be precisely formulated to meet the needs of individuals with specific diseases and disorders, the conferees believe it to be important that the language in the conference substitute clearly preserve the authority of the Secretary to regulate as foods the nutritional formulation, composition, and potency of each product represented for such uses. Inclusion of this language is not, however, intended to permit the Secretary to limit (under sections 401, 403, or 201(n) of the Act) the potency or combination of a safe vitamin, mineral, food ingredient, or food represented in its labeling and advertising to be solely for use by adults, other than pregnant or lactating women, as a nutritional supplement to general human dietary intake.

Dietary management with these products is not only of major clinical value to the individual, but can be lifesaving in many instances. In the case of a number of inborn abnormalities of metabolism, such as phenylketonuria and maple syrup urine disease, these foods provide the only means for prevention of mental retardation, particularly in infants and young children, or for the partial restoration of mental capacity in older children. Special formula feedings are essential to long-term maintenance of severely debilitated individuals. Low sodium foods are useful in dietary management of individuals with severe forms of hypertension, acute heart failure, acute nephritis, toxemias of pregnancy and similar disorders when the degree of sodium restriction must be greater than that achievable with conventional foods. Chemically defined formula diets are extremely useful for nutritional management of patients prior to and subsequent to gastrointestinal surgery.

The Senate amendment included, in proposed new section 411(a)(2) of the Act, a specific reference to the Secretary's authority to act by regulation. This reference was deleted by the conferees as unnecessary. It is not intended that the omission of this reference should be understood as in any way restricting the Food and Drug Administration's present authority to adopt regulations defining and enforcing the provisions of the Act. The Secretary in recent years has relied increasingly on administrative rulemaking to enforce the requirements of the law. Rulemaking affords opportunity for broader participation in the formulation of agency policy, promotes clarity of legal requirements, and assures equitable application of the law, while at the same time it reduces the cost to the taxpayer of case-by-case enforcement. The Secretary's legal authority, under section 701(a) of the Act, to adopt binding regulations has been recognized by the Supreme Court. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973); *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). This

authority has recently been upheld by the United States Court of Appeals for the Second Circuit. *National Nutritional Foods Assn. v. Weinberger*, 512 F. 2d 688 (C.A. 2, 1975).

For the purposes of the conference substitute, the term "children" is defined to mean individuals under the age of 12 years. The conferees are also concerned that attention should be given to those vitamin and mineral preparations that are not intended for use by infants, children or pregnant or lactating women, but may be taken by or administered to them inadvertently. Just as the fetus may be affected by excessive doses of some food supplements, excessive doses of vitamins and minerals taken by children during the period of rapid growth and maturation can interfere with their normal development. Because of such possibilities of unrecognized or unanticipated harm, it is intended that the Secretary retain full authority to promulgate regulations designed to assure that unsuitable or inappropriate vitamin and mineral preparations are not inadvertently administered to individuals in these vulnerable groups.

Except as specifically provided, the conference substitute does not alter the drug or food provisions of the Federal Food, Drug, and Cosmetic Act. If a product containing vitamins, minerals or other ingredients is a drug within the meaning of section 201 (g) of the Act, the Secretary may, with respect to such product, exercise his authority under Chapter V of the Act. For example, the Secretary may bring an action for misbranding of a product which purports to be or is represented as a drug (within the meaning of section 201 (g) of the Act) if its labeling fails to bear adequate directions for its purported use or for the use for which it is represented (within the meaning of section 502 (f) (1) of the Act). See *V. E. Irons, Inc. v. United States*, 244 F. 2d 34 (C.A. 1, 1957); *Alberty Food Products v. United States*, 194 F. 2d 463 (C.A. 9, 1952); *United States v. Vitasafe Co.*, 345 F. 2d 864 (C.A. 3, 1965); *United States v. Article of Drug . . . B-Complex Cholinol Capsules*, 362 F. 2d 923 (C.A. 3, 1966).

The Secretary also has the authority to regulate the composition and potency of a product subject to the provisions of the conference substitute on the basis of safety. If a high potency preparation of a vitamin or mineral is a drug as defined by section 201 (g) of the Act and the Secretary determines that within the meaning of section 503 (b) of the Act, it is not safe for use except under the supervision of a physician, such a high potency preparation is subject to regulation as a prescription drug under the Act.

Similarly, if any vitamin, mineral or other food ingredient is not generally recognized as safe by qualified experts and meets the other criteria of the definition of a "food additive" under section 201 (s) of the Act, it would be subject to regulation under section 409 of the Act. If such a vitamin, mineral or other ingredient is intentionally added to a food, such food is adulterated (within the meaning of section 402 (a)(2)(C) of the Act) unless its use is in conformity with a regulation issued by the Secretary which prescribes the conditions under which it may be safely used or exempts it for investigational use by qualified experts. It is on precisely this basis that the Secretary has, by regulation, restricted the potency of the vitamin folic acid that may be added to a food.

PROVISIONS WITH RESPECT TO LABELING AND ADVERTISING

Under the conference substitute, the Secretary retains the authority to initiate enforcement actions against a product to which the conference substitute is applicable if its labeling is false or misleading in any particular. In addition, the conference substitute contains special provisions respecting the labeling and advertising of these products.

The conference substitute provides that a food to which the conference substitute is applicable shall not be deemed misbranded under section 403 of the Act solely because its label bears a listing of all of the ingredients in the food, or solely because its advertising contains references to ingredients in the food that are not vitamins or minerals. Thus, for example, if a tablet or capsule of vitamin C contains rutin, a substance that the Secretary has concluded has no dietary usefulness, the list of ingredients as well as the advertising for the product may refer to rutin without causing the food to be deemed misbranded. However, because of the conferees' concern that consumers not be misled into a belief that such substances have nutritional value, the conference substitute provides that the labeling so such a product may not list ingredients that are not vitamins or minerals except as a part of a list of all the ingredients of the food, in accordance with applicable regulations promulgated by the Secretary pursuant to section 403 of the Act. The Secretary is directed that in circumstances where compliance with this provision is impracticable or results in deception or unfair competition, exceptions shall be established by regulation. Further, the conference substitute provides that the labeling or advertising of a food to which the conference substitute is applicable may not give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals.

The conference substitute also provides the Secretary new authority over the advertising of foods subject to the conference substitute. Seizure and injunction actions are authorized in instances in which the advertising of a food to which the conference substitute is applicable is false or misleading in a material respect. However, in order to protect an innocent retailer from seizures based upon deceptive advertising claims made by a manufacturer, the conference substitute provides that libel for condemnation may not be instituted against such products which are misbranded because of their advertising unless (1) the advertising was disseminated in the establishment in which the product was held for sale to the ultimate consumer, the advertising was disseminated by or under the direction of the owner or operator of such establishment, or all or part of the cost of such advertising was paid for by the owner or operator, and (2) the owner or operator used the advertising in the establishment to promote the sale of the food.

The conference substitute would also add a new section 707 to the Federal Food, Drug, and Cosmetic Act which would require that the Federal Trade Commission be afforded the opportunity to take certain specific enforcement actions under the Federal Trade Commission Act for a period of up to 90 days before the Secretary could initiate an enforcement action under Chapter III of the Act with respect to the advertising of a product subject to the provisions of the conference substitute. It would prohibit the Secretary, except under limited

circumstances, from initiating such an enforcement action before, during, or after the expiration of the 90 day period, if the Federal Trade Commission takes action in accordance with the conference substitute.

These provisions are intended to provide the Secretary with authority to protect the public from consumer fraud perpetrated by the false advertising of these products. They are intended to serve as a partial substitute for the authority denied to the Secretary under other provisions of the conference substitute.

Proposed new section 707 of the Act would require the Secretary to notify the Federal Trade Commission before he initiates any action, under Chapter III of the Federal Food, Drug, and Cosmetic Act, with respect to any food which the Secretary determines is misbranded under proposed new section 403(a)(2) of the Act because of its advertising or a food's advertising which the Secretary determines causes the food to be so misbranded. The notice by the Secretary must contain (1) a description of the Secretary's proposed action, (2) a description of the advertising which the Secretary has determined causes the food to be misbranded under section 403(a)(2) of the Act, and (3) a statement of the reasons for the Secretary's determination that the advertising has caused the food to be so misbranded. In addition, the notice from the Secretary must be accompanied by records, documents, and other written materials which the Secretary determines support his determination that the food is so misbranded because of its advertising.

If, within a 30 day period beginning on the date of receipt of the notice and accompanying written materials from the Secretary, the Federal Trade Commission notifies the Secretary in writing that—

(1) it has initiated an investigation of the advertising (referred to in the Secretary's notice) to determine if it is prohibited by the Federal Trade Commission Act or a rule or order promulgated thereunder;

(2) it has commenced or intends to commence a civil action in the courts under section 5, 13, or 19 of such Act with respect to such advertising or the Attorney General has commenced or intends to commence a civil action under section 5 of such Act with respect to such advertising;

(3) it has issued and served or intends to issue and serve a complaint under section 5(b) of such Act with respect to such advertising; or

(4) it had made certification to the Attorney General under section 16(b) of such Act with respect to such advertising, the Secretary is prohibited from initiating his proposed action for an additional period of time, which is not to exceed 60 days. If the Commission notifies the Secretary that neither the Attorney General nor the Commission intends to take any of these actions or fails to respond to the Secretary in writing within the 30 day period, the Secretary may initiate his proposed action.

If, before the expiration of the 60 day period beginning on the date the Secretary receives the notice from the Commission that the Attorney General or the Commission intends to take one of the actions described above, the Commission or the Attorney General has not commenced a civil action, the Commission has not issued and served a complaint or made certification to the Attorney General

which has caused appropriate criminal proceedings to be brought against the advertising, the Secretary may act under Chapter III of the Federal Food, Drug, and Cosmetic Act.

The Commission is required to notify the Secretary promptly of the commencement of a civil action, the issuance and service of a complaint, or the causing by the Attorney General of criminal proceedings to be brought against the advertising described in the Secretary's notice.

The conferees intend that the Commission or the Attorney General, where practical, take appropriate regulatory action under the Federal Trade Commission Act pursuant to a notice from the Secretary. The conferees believe that the period of 90 days provided in the conference substitute is sufficient time within which to take such action. However, in instances in which the Secretary determines that, although action has not been taken by the Commission or the Attorney General within the 90 day period, such action is imminent, he may defer taking his proposed action to permit the Commission or the Attorney General to take action.

Under the conference substitute the notification and other procedural requirements in subsections (a) and (b) of proposed new section 707 of the Act do not apply with respect to any action under Chapter III of the Act with respect to any food or food advertising to which the conference substitute is otherwise applicable, if the Secretary determines that such action is required to eliminate an imminent hazard to health. Under these circumstances the Secretary would neither be required to provide formal notification to the Commission nor delay his proposed enforcement action. However, under the conference substitute, if the Secretary takes any action under Chapter III of the Act with respect to a food because of its advertising or with respect to a food's advertising under proposed section 403(a)(2) of the Act, proposed section 707(d) of the Act requires the Secretary to coordinate the action with any action of the Federal Trade Commission with respect to the advertising of such food.

The conferees recognize that for many years the Food and Drug Administration and the Federal Trade Commission have operated in overlapping areas of jurisdiction in the regulation of false claims and that both agencies have been functioning under written memoranda of understanding concerning jurisdiction and liaison since 1954. The conferees expect both agencies to continue to coordinate their regulatory actions in a manner to avoid unnecessary duplication and waste. The conferees also emphasize that the conference substitute is not intended to modify the primary role of the Federal Trade Commission in exercising its regulatory authority over the false or misleading advertising of food products.

Although the substitute gives the Secretary substantial new authority with respect to the advertising of vitamin and mineral products, the conferees intend that the Secretary use his authority under existing section 306 of the Federal Food, Drug, and Cosmetic Act which provides for written notice or warning in lieu of judicial action where the Secretary believes that such notification or warning adequately protects the public interest.

TITLE VI—ARTHRITIS ACT AMENDMENT

The Senate amendment contained a title, not included in the House bill, which amended the National Arthritis Act (Public Law 93-640). The Senate amendment (1) made it clear that arthritis and related musculoskeletal diseases are to be collectively referred to as arthritis for the purposes of the Act; (2) added a statement of purposes of the Act; (3) corrected the reference to the Chief Medical Director of the Veterans Administration as an ex-officio member of the National Commission on Arthritis; (4) lowered the authorization of appropriations under that Act for the Arthritis Commission from \$2 million to \$1.5 million; (5) revised the authorizations of appropriations under the Public Health Service Act for arthritis screening, detection, prevention, and referral demonstration projects and the Arthritis Screening and Detection Data Bank from \$2 million for fiscal year 1975, \$3 million for fiscal year 1976 and \$4 million for fiscal year 1977 to \$1.5 million for fiscal year 1975, \$4 million for fiscal year 1976, and \$4 million for fiscal year 1977; and (6) amended section 439 of the Public Health Service Act to provide that the Secretary may assist in the development, modernization, and operation of *new and existing* comprehensive arthritis centers and to revise the authorizations from \$11 million for fiscal year 1975, \$13 million for fiscal year 1976, and \$15 million for fiscal year 1977 to \$5 million for fiscal year 1975, \$13 million for fiscal year 1976, and \$21 million for fiscal year 1977.

The conference substitute conforms to the Senate amendment, except that it would authorize under the Public Health Service Act \$11 million for fiscal year 1975, \$8 million for fiscal year 1976 and \$20 million for fiscal year 1977 for the development, modernization and operation of new and existing comprehensive arthritis centers, and would not change existing law with respect to authorizations for demonstration projects and the Arthritis Screening and Detection Data Bank.

TITLE VII—DIABETES PLAN

The Senate amendment contained a title, not included in the House bill, which extended the expiration date of the National Diabetes Commission (established under Public Law 93-354) to September 30, 1976.

The conference substitute conforms to the Senate amendment.

TITLE VIII—HEALTH SERVICES

The Senate amendment contained a title, not included in the House bill, which amended sections 319 (migrant health centers) and 330 (community health centers) of the Public Health Service Act to add ambulatory surgical services as a supplemental health service which could be offered by such centers.

The conference substitute conforms to the Senate amendment.

TITLE IX—INDIAN HEALTH SERVICE

The Senate amendment contained a title, not included in the House bill, which amended section 225 of the Public Health Service

Act to permit the Indian Health Service to utilize non-profit recruitment agencies to assist in obtaining personnel for the Public Health Service.

The conference substitute conforms to the Senate amendment.

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

The Senate amendment contained a title, not included in the House bill, which prohibited consideration of political affiliation in making appointments to advisory committees established to assist the Secretary in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.

The conference substitute conforms to the Senate amendment.

TITLE XI—MISCELLANEOUS PROVISIONS SOLDIERS' AND SAILORS' CIVIL RELIEF ACT

The Senate amendment contained a provision, not included in the House bill, which equated active service of commissioned officers of the Public Health Service with active military service in the Armed Forces for the purposes of all rights, privileges, immunities, and benefits provided under the Soldiers' and Sailors' Civil Relief Act of 1940.

The conference substitute conforms to the Senate amendment.

VISITING SCIENTIST AWARDS

The Senate amendment contained provisions, not included in the House bill, which (1) authorized the Secretary to grant stipends, in amounts not to exceed \$25,000 per annum, to visiting scientists who enter into agreements with the Secretary to assist minority schools in developing programs in biomedical sciences, and (2) authorized the Secretary to make grants to minority schools to initiate the development of undergraduate programs relating to biomedical sciences.

The conference substitute authorizes the Secretary to make awards (referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. The amount of each such award shall include such sum as is commensurate with the salary or remuneration which the individual had received from the institution with which he has, or had, a permanent or immediately prior affiliation.

HEALTH PROFESSIONS STUDENT ASSISTANCE

The Senate amendment contained provisions, not included in the House bill, which extended the authorizations of appropriations for physician shortage area scholarships at \$3.5 million for fiscal year 1975 and \$2 million for fiscal year 1976, and for health professions student loans at \$60 million for fiscal year 1976.

The conference substitute conforms to the Senate amendment.

HARLEY O. STAGGERS,
PAUL G. ROGERS,
DAVID E. SATTERFIELD,
JAMES W. SYMINGTON,
JAMES H. SCHEUER,
TIM LEE CARTER,
JAMES T. BROYHILL,
Managers on the Part of the House.
HARRISON A. WILLIAMS, JR.,
CLAIBORNE PELL,
EDWARD M. KENNEDY,
WALTER F. MONDALE,
ALAN CRANSTON,
WILLIAM D. HATHAWAY,
JOHN A. DURKIN,
THOMAS F. EAGLETON,
GAYLORD NELSON,
JACOB K. JAVITS,
RICHARD S. SCHWEIKER,
ROBERT TAFT,
J. GLENN BEALL, JR.,
ROBERT T. STAFFORD,
PAUL LAXALT,
Managers on the Part of the Senate.

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HEALTH RESEARCH AND HEALTH SERVICES
AMENDMENTS OF 1976

APRIL 8, 1976.—Ordered to be printed

Mr. KENNEDY, from the committee of conference,
submitted the following

CONFERENCE REPORT

[To accompany H.R. 7988]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

SECTION 1. (a) This Act may be cited as the "Health Research and Health Services Amendments of 1976".

(b) Whenever in this Act (other than in titles III, V, VI, VII, and XI) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

**TITLE I—REVISION OF NATIONAL HEART AND LUNG
INSTITUTE PROGRAMS**

Sec. 101. (a) Congress finds and declares that—

(1) diseases of the heart, blood, 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 cost of medical care of more than \$40,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema being among the fastest rising causes of death in the United States;

(4) chronic respiratory diseases affect an estimated ten million Americans, emphysema 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 whose value in saving life and promoting health cannot be assessed in terms of dollars;

(7) 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 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;

(8) blood diseases, including nutritional anemia, anemia due to inherited abnormalities (such as sickle cell anemia and Cooley's anemia (thalassemia), anemias resulting from failure of the bone marrow, hemorrhagic defects (a common cause of death in patients with leukemia and other malignancies, and of disability from inherited diseases such as hemophilia), and malignancies of the lymph nodes and bone marrow, such as leukemia, have a devastating impact in spite of recent advances, and constitute an important category of illness that requires major attention; and

(9) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart, Lung, and Blood Institute, but advancement against such diseases depends not only on the research programs of that Institute but also on the research programs of other research institutes of the National Institutes of Health.

(b) It is the purpose of this title to enlarge the authority of the National Heart, Lung, and Blood Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases and to enlarge its authority with respect to blood resources.

SEC. 102. Sections 411, 418(a)(6), and 419A(c) are each amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart, Lung, and Blood Institute".

SEC. 103. (a) Section 412 is amended—

(1) by inserting "and with respect to the use of blood and blood products and the management of blood resources" after "diseases" in the matter preceding paragraph (1);

(2) by inserting "and to the use of blood and blood products and the management of blood resources" before the semicolon at the end of paragraph (1);

(3) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (4);

(4) by inserting "and on the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (5);

(5) by striking out "heart diseases" in paragraph (6) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and the management of blood resources";

(6) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (7); and

(7) by inserting at the end of the section heading "AND IN THE MANAGEMENT OF BLOOD RESOURCES".

(b) Section 412 is amended by striking out "National Heart and Lung Advisory Council" and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 104. (a) Section 413(a) is amended—

(1) by striking out "Disease" in the first sentence and inserting in lieu thereof "Diseases and Blood Resources"; and

(2) by inserting "and blood resources" after "diseases" in such sentence and in paragraph (7).

(b) Section 413(b) is amended—

(1) by striking out "calendar" each place it occurs in paragraph (2) and inserting in lieu thereof "fiscal"; and

(2) by adding at the end of such paragraph the following: "Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the program during such five years".

(c) Section 413(c)(1) is amended by striking out "fifty" and inserting in lieu thereof "one hundred".

(d) Section 413(c)(2) is amended—

(1) by striking out "operate" and inserting in lieu thereof "operate, alter, renovate"; and

(2) by inserting "and blood resource" after "disease".

(e) Section 413(d) is amended—

(1) by striking out "Assistant Director for Health Information Programs" each place it occurs and inserting in lieu thereof "Assistant Director for Prevention Education, and Control";

(2) by striking out "and pulmonary" in the second sentence and inserting in lieu thereof ", blood, and pulmonary" and by inserting "and blood" after "pulmonary" in the third sentence; and

(3) by inserting "and blood resources" after "diseases" in the second sentence.

(f) The section heading of section 413 is amended by striking out "DISEASE" and inserting in lieu thereof "DISEASES AND BLOOD RESOURCES".

SEC. 105. Section 414(b) is amended (1) by striking out "and" after "1974," and (2) by inserting before the period a comma and the following: "\$10,000,000 for fiscal year 1976, and \$30,000,000 for fiscal year 1977".

SEC. 106. (a)(1) Subsection (a)(1)(A) of section 415 is amended by—
 (A) striking out “fifteen” and inserting in lieu thereof “ten”, and
 (B) striking out “, blood vessel, and blood diseases” and inserting
 in lieu thereof “diseases”.

(2) Subsection (a)(1)(B) of such section is amended by striking out
 “fifteen” and inserting in lieu thereof “ten”.

(3) Subsection (a)(1) of such section is amended—

(A) by striking out “and” at the end of subparagraph (A),

(B) by striking out the period at the end of subparagraph (B)
 and inserting in lieu thereof “; and”, and

(C) by inserting after subparagraph (B) the following new sub-
 paragraph:

“(C) ten 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 blood, blood vessel diseases, research in the use
 of blood products, and research in the management of blood re-
 sources.”

(b) Section 415(a) is further amended—

(1) by inserting “and for research in the use of blood and blood
 products and in the management of blood resources” after “diseases”
 in paragraph (1) (A);

(2) by striking out “chronic” in paragraph (1)(B);

(3) by striking out “paragraph (1)(A)” in paragraph (2) and
 inserting in lieu thereof “paragraph (1)”;

(4) by inserting “, pulmonary, and blood” before “diseases” in
 paragraph (2);

(5) by striking out “cardiovascular disease” in paragraph (2)(A)
 and inserting in lieu thereof “cardiovascular, pulmonary, and blood
 diseases”; and

(6) by striking out “such disease” in subparagraphs (B), (C),
 and (D) of paragraph (2) and inserting in lieu thereof “such
 diseases”.

(c) Section 415(b) is amended—

(1) by inserting “the management of blood resources and” before
 “advanced”; and

(2) by amending the first sentence after paragraph (4) to read as
 follows: “The aggregate of payments (other than payments for con-
 struction) made to any center under such an agreement for its costs
 (other than indirect costs) described in the first sentence may not
 exceed \$5,000,000 in any year, except that the aggregate of such
 payments in any year may exceed such amount to the extent that the
 excess amount is attributable to increases in such year in appropriate
 costs as reflected in the Consumer Price Index published by the
 Bureau of Labor Statistics.”

(d) The section heading of section 415 is amended by inserting “AND
 BLOOD RESOURCES” after “DISEASES”.

SEC. 107. (a) Section 417(a)(1) is amended by striking out “Director
 of the Office of Science and Technology” and inserting in lieu thereof
 “Director of the National Science Foundation”.

(b) Section 417 is amended by striking out “National Heart and Lung
 Advisory Council” in subsection (a) and in subsection (b)(3) and insert-
 ing in lieu thereof “National Heart, Lung, and Blood Advisory Council”.

(c) The section heading of section 417 is amended by striking out
 “AND LUNG” and inserting in lieu thereof “, LUNG, AND BLOOD”.

SEC. 108. Section 418 is amended—

(1) by inserting “and to the use of blood and blood products and
 the management of blood resources” after “diseases” in paragraphs
 (1), (2), (3), and (4) of subsection (a);

(2) by redesignating paragraphs (4), (5), and (6) of subsection (a)
 as paragraphs (5), (6), and (7), respectively, and by adding after para-
 graph (3) the following new paragraph:

“(4) recommend to the Secretary (A) areas of research in heart,
 blood vessels, lung, and blood diseases and in the use of blood and
 blood products and the management of blood resources which it de-
 termines should be supported by the awarding of contracts in order to
 best carry out the purposes of this part, and (B) the percentage of the
 budget of the Institute which should be expended for such contracts;”;
 and

(3)(A) by amending paragraph (2) of subsection (b) to read as
 follows:

“(2) The Council shall submit a report to the Secretary for simultaneous
 transmittal, not later than November 30 of each year, to the President and
 to the Congress on the progress of the Program toward the accomplishment
 of its objectives during the preceding fiscal year.”

(B) For purposes of section 418(b)(2) of the Public Health
 Service Act (as amended by subparagraph (A)), the period beginning
 July 1, 1975, and ending September 30, 1976, shall be considered
 a fiscal year.

(C) The amendment made by subparagraph (A) shall take effect
 as of January 1, 1976.

SEC. 109. Section 419A is amended—

(1) by inserting “and projects with respect to the use of blood and
 blood products and the management of blood resources” after “train-
 ing projects” in subsection (a);

(2) by inserting “and into the use of blood and blood products and
 the management of blood resources” after “diseases” in subsection
 (b);

(3) by inserting “and for research and training in the use of blood
 and blood products and the management of blood resources” after
 “diseases” in subsection (c);

(4) by striking out “in amounts not to exceed \$35,000” in para-
 graph (1) of subsection (c) and inserting in lieu thereof “if the
 direct costs of such research and training do not exceed \$35,000,
 but only”; and

(5) by striking out “in amounts exceeding \$35,000” in paragraph
 (2) of subsection (c) and inserting in lieu thereof “if the direct costs
 of such research and training exceed \$35,000, but only”.

SEC. 110. Section 419B is amended—

(1) by striking out “and” after “1974,” and by inserting before
 the period at the end of the first sentence a comma and the following:
 “\$339,000,000 for fiscal year 1976, and \$373,000,000 for fiscal year
 1977”; and

(2) by striking out “diseases of the blood” and inserting in lieu
 thereof “blood diseases and blood resources”.

Sec. 111. (a) Section 301 is amended by striking out "heart diseases" in paragraphs (c) and (h) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and blood resources".

(b) Section 301 is amended by striking out "National Heart and Lung Advisory Council" in paragraphs (c) and (h) and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

Sec. 112. The title of Part B of title IV is amended to read as follows:

"PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE".

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

Sec. 201. (a)(1) Subsection (a)(1)(A)(i) of section 472 is amended (A) by striking out "in matters" and inserting in lieu thereof "or under programs administered by the Division of Nursing of the Health Resources Administration, in matters", and (ii) by inserting before "are directed" the following: "or Division of Nursing".

(2) Subsections (a)(1)(A)(iii) and (a)(1)(B) of such section are each amended by striking out "non-Federal".

(b) Subsection (c)(1)(A)(i) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment".

(c) Subsection (c)(2)(A) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment".

(d) The first sentence of subsection (d) of such section is amended by inserting a comma before the period and the following: "\$165,000,000 for fiscal year 1976, and \$185,000,000 for fiscal year 1977".

Sec. 202. (a) Subsection (a)(1)(A)(i) of section 472 is amended by striking out "the disease or (diseases) or other health problems to which the activities of the Institutes and Administration are directed" and inserting in lieu thereof "diseases or other health problems".

(b) Subsection (b)(2) of section 472 is amended by striking out "to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration" and inserting in lieu thereof "within the Department of Health, Education, and Welfare".

Sec. 203. (a)(1) Subparagraph (A) of the first paragraph (4) of subsection (c) of section 472 is amended by striking out "and the interest on such amount" down through and including "was made".

(2) The last sentence of subparagraph (B) of such paragraph is amended by striking out "at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States" and inserting in lieu thereof "at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount".

(b) The amendments made by subsection (a) shall apply with respect to National Research Awards under section 472 which are made from appropriations for fiscal years ending on or after June 30, 1975.

Sec. 204. Section 473(b) is amended by adding after paragraph (2) the following new paragraph:

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health."

Sec. 205. Subsection (c) of section 473 is amended by striking out "March 31" and inserting in lieu thereof "September 30".

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

Sec. 301. (a)(1) The President's Biomedical Research Panel (established by section 201(a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

(A) The number of requests made to the Secretary for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such requests were made.

(B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.

(C) The effect of the disclosure of such information on—

(i) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on patent rights;

(ii) the ability of peer review systems to insure high quality federally funded research; and

(iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

(2)(A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Panel deems appropriate.

(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission deems appropriate.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof "January 1, 1977".

TITLE IV—GENETIC DISEASES

SEC. 401. This title may be cited as the "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act".

SEC. 402. In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

SEC. 403. (a) Title XI is amended by striking out parts A and B and inserting in lieu thereof the following:

"PART A—GENETIC DISEASES

"TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

"SEC. 1101. (a)(1) The Secretary, through an identifiable administrative unit within the Department of Health, Education, and Welfare, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects to establish and operate voluntary genetic testing and counseling programs primarily in conjunction with other existing health programs, including programs assisted under title V of the Social Security Act.

"(2) The Secretary shall carry out, through an identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. The Secretary may, under such program, make grants to public and nonprofit private entities and enter into contracts with public and private entities and individuals for the development and dissemination of such materials.

"(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for fiscal year 1976, \$30,000,000 for fiscal year 1977, and \$30,000,000 or fiscal year 1978.

"RESEARCH PROJECT GRANTS AND CONTRACTS

"SEC. 1102. In carrying out section 301, the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases,

and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

"VOLUNTARY PARTICIPATION

"SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

"APPLICATIONS; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

"SEC. 1104. (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require. Each applicant shall—

"(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

"(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

"(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part;

"(4) in the case of an applicant for a grant or contract under section 1101(a)(1) for the delivery of services, provide assurances satisfactory to the Secretary that (A) the services for community-wide testing and counseling to be provided under the program for which the application is made (i) will take into consideration widely prevalent diseases with a genetic component and high-risk population groups in which certain genetic diseases occur, and (ii) where appropriate will be directed especially but not exclusively to persons who are entering their child-producing years, and (B) appropriate arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and

"(5) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

"(b) In making any grant or entering into any contract for testing and counseling programs under section 1101, the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the

greatest number of persons who will benefit from and are in need of the services provided under such programs.

"(c) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 or under section 1101 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

"PUBLIC HEALTH SERVICE FACILITIES

"SEC. 1105. The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

"REPORTS

"SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

"(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary."

(b)(1) Section 1121(b)(5) is amended by striking out "ending June 30," each place it occurs.

(2) Parts C and D are redesignated as parts B and C, respectively.

(3) The heading of such title is amended to read as follows:

"TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME."

(c) The amendments made by subsections (a) and (b) shall take effect July 1, 1976.

TITLE V—FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

SEC. 501 (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 410 (21 U.S.C. 349) the following new section:

"VITAMINS AND MINERALS

"SEC. 411. (a)(1) Except as provided in paragraph (2)—

"(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

"(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

"(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

"(i) vitamin,

"(ii) mineral, or

"(iii) other ingredient of food,

within a food to which this section applies.

"(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years.

"(b)(1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i)(2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

"(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

"(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

"(i) vitamins,

"(ii) minerals, or

"(iii) represented as a source of vitamins or minerals.

"(c)(1) For purposes of this section, the term 'food to which this section applies' means a food for humans which is a food for special dietary use—

"(A) which is or contains any natural or synthetic vitamin or mineral, and

"(B) which—

"(i) is intended for ingestion in tablet, capsule, or liquid form, or

"(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

"(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

"(3) For purposes of paragraph (1) and of section 403 (j) insofar as that section is applicable to food to which this section applies, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

"(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

"(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

"(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet."

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

SEC. 502. (a)(1) Section 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(a)) is amended (A) by inserting "(1)" after "If", and (B) by inserting before the period at the end a comma and the following: "or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2)".

(2)(A) Section 201(n) of such Act is amended by inserting "or advertising" after "labeling" each time it occurs.

(B) Section 303 of such Act is amended by adding at the end the following new subsection:

"(d) No person shall be subject to the penalties of subsection (a) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead."

(C) Section 304(a) of such Act (21 U.S.C. 334(a)) is amended by adding after paragraph (2) the following new paragraph:

"(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

"(i) is misbranded under section 403(a)(2) because of its advertising, and

"(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

"(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

"(i)(I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

"(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

"(III) all or part of the cost of such advertising was paid by such owner or operator; and

"(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food."

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

"ADVERTISING OF CERTAIN FOODS

"SEC. 707. (a)(1) Except as provided in subsection (c), before the Secretary may initiate any action under chapter III—

"(A) with respect to any food which the Secretary determines is misbranded under section 403(a)(2) because of its advertising, or

"(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded, the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

"(2) The notice required by paragraph (1) shall—

"(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

"(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

"(b)(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter III with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

"(A) it has initiated under the Federal Trade Commission Act an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

"(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 with respect to such advertising,

"(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act respecting such advertising, or

"(D) pursuant to section 16(b) of such Act it has made a certification to the Attorney General respecting such advertising, the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

"(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a)—

"(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

"(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

"(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a). The Commission shall promptly notify the Secretary of the commencement by

the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

"(c) The requirements of subsections (a) and (b) do not apply with respect to action under chapter III with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

"(d) For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter III because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act with respect to such advertising."

(c) The amendments made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

TITLE VI—ARTHRITIS ACT AMENDMENTS

SEC. 601. This title may be cited as the "National Arthritis Act Technical Amendments of 1976".

SEC. 602. (a) Section 2 of the National Arthritis Act of 1974 (Public Law 93-640) (hereinafter in this section referred to as the "Act") is amended by—

(1) inserting "(a)" after "SEC. 2.";

(2) inserting a comma and "including \$2,500,000,000 in medical expenses," after "\$9,200,000,000" in paragraph (3); and

(3) inserting a new subsection (b) at the end thereof as follows:

"(b) It is therefore the purpose of this Act to provide for—

"(1) the formulation of a long-range plan—

"(A) to expand and coordinate the national research, treatment, and control effort against arthritis;

"(B) to advance educational activities for patients, professional and allied health personnel, and the public which will alert the citizens of the United States to the early indications of arthritis; and

"(C) to emphasize the significance of early detection and proper control of these diseases and of the complications which may evolve from them;

"(2) the establishment and support of programs to develop new and improved methods of arthritis screening, detection, prevention, and referral;

"(3) the establishment of a central arthritis screening and detection data bank; and

"(4) the development, modernization, and operation of centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, and research and training programs."

(b) Section 3 of the Act is amended by striking out "chief medical officer" and inserting in lieu thereof "Chief Medical Director" in subsection (b)(4).

(c) The section heading for section 4 of the Act is amended by striking out "DEMONSTRATION" after "COMMITTEE,".

SEC. 603. (a)(1) Section 431(c) of the Public Health Service Act is amended by inserting "(hereinafter in this part collectively referred to as 'arthritis')" after "musculoskeletal diseases".

(2) The fourth sentence of section 434(b) of such Act is amended by striking out "and related musculoskeletal diseases".

(3) Section 434(e) of such Act is amended by striking out "and related musculoskeletal diseases (hereinafter in this part collectively referred to as 'arthritis')".

(b) Section 438 of such Act is amended by—

(1) inserting "the" before "health" the first time it appears in the first sentence of subsection (a); and

(2) inserting "established" after "bank" in the second sentence of subsection (a).

(c) Section 439 of such Act is amended by—

(1) inserting "new and existing" before "centers" in the first sentence of subsection (a);

(2) striking out "\$13,000,000" and inserting in lieu thereof "\$8,000,000", and striking out "\$15,000,000" and inserting in lieu thereof "\$20,000,000" in subsection (h); and

(3) redesignating subsections (e), (f), (g), and (h) as subsections (d), (e), (f), and (g), respectively.

TITLE VII—DIABETES PLAN

SEC. 701. Section 3(i)(2) of the National Diabetes Mellitus Research and Education Act (42 U.S.C. 289c-2) is amended to read as follows:

"(2) The Commission shall cease to exist after September 30, 1976."

TITLE VIII—HEALTH SERVICES

AMBULATORY SURGICAL SERVICES

SEC. 801. (a) Section 319(a)(7) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

"(L) ambulatory surgical services;" and

(2) redesignating subparagraphs (L) and (M) as subparagraph (M) and (N), respectively.

(b) Section 330(b)(2) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

"(L) ambulatory surgical services;" and

(2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

TITLE IX—INDIAN HEALTH SERVICE

SEC. 901. Section 225 is amended by adding at the end thereof the following new subsection—

"(j) Notwithstanding any other provision of law, the Secretary may, where he deems advisable, allow the Indian Health Service to utilize non-profit recruitment agencies to assist in obtaining personnel for the Public Health Service."

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation

Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation.

TITLE XI—MISCELLANEOUS PROVISIONS

SEC. 1101. Section 212 of the Public Health Service Act is amended by adding after subsection (d) the following new subsection:

“(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers’ and Sailors’ Civil Relief Act of 1940 (50 App. U.S.C. 501 et seq.).”

SEC. 1102. (a) The second paragraph (4) of subsection (c) of section 472 of the Public Health Service Act is redesignated as paragraph (5).

(b) Section 507 of the Public Health Service Act is amended by striking out “hospitals of the Service, of the Veterans’ Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except that grants to such” and insert in lieu thereof “Federal institutions, except that grants to”.

SEC. 1103. Title IV of the Public Health Service Act is amended by adding after section 475 the following new section:

“VISITING SCIENTIST AWARDS

“SEC. 476. (a) The Secretary may make awards (referred to as ‘Visiting Scientist Awards’) to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

“(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.”

SEC. 1104. Section 786 of the Public Health Service Act is amended by inserting before the period at the end of the first sentence “and \$3,500,000 for the fiscal year ending June 30, 1975 and \$2,000,000 for the fiscal year ending June 30, 1976”.

SEC. 1105. (a) Section 742(a) of the Public Health Service Act is amended by striking out “and” after “1974,” and by inserting after “1975” the following: “, and \$60,000,000 for the fiscal year ending June 30, 1976”.

(b) Section 740(b)(4) of such Act is amended by striking out “1975” and inserting in lieu thereof “1976”.

SEC. 1106. Section 1511(b)(5) of the Public Health Service Act is amended by striking out “1535” and inserting in lieu thereof “1536”.

(b) Section 1613 of such Act is amended by striking out “1510” and inserting in lieu thereof “1610”.

(c) The last sentence of section 1631 of such Act is repealed.

SEC. 1107. (a) Section 132(a)(1)(A) of the Developmental Disabilities Services and Facilities Construction Act (42 U.S.C. 6062) (hereinafter in this section referred to as the “Act”) is amended by striking out “134” and inserting in lieu thereof “133”.

(b) Section 134(b)(1) of the Act is amended by striking out “134” and inserting in lieu thereof “133”.

(c) Section 134(b)(1) of the Act is amended by striking out “136” and inserting in lieu thereof “135”.

(d) Section 301(a) of the Developmentally Disabled Assistance and Bill of Rights Act is amended by striking out “101(7)” and inserting in lieu thereof “102(7)”.

And the Senate agree to the same.

HARRISON A. WILLIAMS, JR.,
 CLAIBORNE PELL,
 EDWARD M. KENNEDY,
 WALTER F. MONDALE,
 ALAN CRANSTON,
 WILLIAM D. HATHAWAY,
 JOHN A. DURKIN,
 THOMAS F. EAGLETON,
 GAYLORD NELSON,
 JACOB K. JAVITS,
 RICHARD S. SCHWEIKER,
 ROBERT TAFT,
 J. GLENN BEALL, JR.,
 ROBERT T. STAFFORD,
 PAUL LAXALT,
Managers on the Part of the Senate.
 HARLEY O. STAGGERS,
 PAUL G. ROGERS,
 DAVID E. SATTERFIELD,
 JAMES W. SYMINGTON,
 JAMES H. SCHEUER,
 TIM LEE CARTER,
 JAMES T. BROYHILL,
Managers on the Part of the House.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 7988) to amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study on the release of research information, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The Senate amendment struck out all of the House bill after the enacting clause and inserted a substitute text.

The House recedes from its disagreement to the amendment of the Senate with an amendment which is a substitute for the House bill and the Senate amendment. The differences between the House bill, the Senate amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

FINDINGS

The Senate amendment, in a provision not in the House bill, specified Congressional findings, with respect to the impact of diseases of the heart, lung and blood vessels and blood disease and the need for the proposed legislation.

The conference substitute conforms to the Senate amendment, with technical changes.

ADVISORY COUNCIL

The House bill changed the name of the National Heart Lung Advisory Council to the National Heart, Lung and Blood Advisory Council.

The Senate amendment contained no comparable provision.

The conference substitute conforms to the House bill.

EXPERTS AND CONSULTANTS

Existing law authorizes the Director of the National Heart and Lung Institute to obtain the services of not more than 50 experts and consultants.

The House amendment increased this number to 100.
The Senate amendment contained no comparable provision.
The conference substitute conforms to the House bill.

ASSISTANT DIRECTOR

Existing law establishes within the National Heart and Lung Institute (redesignated as the National Heart, Lung and Blood Institute under provisions of both the House bill and the Senate amendment) an Assistant Director for Health Information Programs.

The House bill changed the name to Assistant Director for Prevention, Education, and Control.

The Senate amendment changed the name to Assistant Director for Prevention and Information.

The conference substitute conforms to the House bill.

AUTHORIZATION FOR PREVENTION AND CONTROL PROGRAMS

The House bill authorized appropriations of \$20 million for fiscal year 1976 and \$30 million for fiscal year 1977 for heart, blood vessel, lung, and blood disease control programs.

The Senate amendment authorized appropriations of \$10 million for fiscal year 1976 and \$25 million for fiscal year 1977 for such programs.

The conference substitute authorizes \$10 million for fiscal year 1976 and \$30 million for fiscal year 1977 for such programs.

CENTERS

Existing law authorizes the development of fifteen centers for research, training, and demonstrations respecting heart, blood vessel, and blood diseases, and fifteen such centers for chronic lung diseases.

The House bill increased the responsibilities of the heart, blood vessel, and blood disease centers to include research in the use of blood and blood products and in the management of blood resources. Further, the House bill expanded the responsibilities of the lung disease centers by deleting the word "chronic."

The Senate amendment authorized the development of ten centers for research, training, and demonstrations respecting heart diseases; ten such centers for chronic lung diseases; and ten such centers for blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.

The conference substitute conforms to the Senate amendment, except that it authorizes the development of ten centers for lung diseases, as opposed to chronic lung diseases.

FUNCTIONS OF THE ADVISORY COUNCIL

The House bill added to the existing authority of the National Heart, Lung, and Blood Advisory Council the prerogative to recommend to the Secretary of Health, Education, and Welfare areas of research conducted or supported by the newly designated National Heart, Lung, and Blood Institute which the Council determines should be supported by the awarding of contracts and the percentage of the budget of the Institute which should be expended for such contracts.

The Senate amendment contained no comparable provision.

The conference substitute conforms to the House bill.

REPORT OF THE ADVISORY COUNCIL

Both the House bill and the Senate amendment required that the Advisory Council submit by November 30 of each year a report to the Secretary for simultaneous transmittal to the President and to the Congress on the progress of the National Heart, Blood Vessel, Lung, and Blood Disease Program during the preceding fiscal year. However, the Senate amendment stipulates that for purposes of this requirement, the period beginning July 1, 1975 and ending September 30, 1976 shall be considered a fiscal year and the House amendment contains no comparable provision.

The conference substitute conforms to the Senate amendment.

AUTHORIZATIONS FOR RESEARCH

The House bill authorized appropriations of \$340 million for fiscal year 1976 and \$375 million for fiscal year 1977 for carrying out the programs of the redesignated National Heart, Lung, and Blood Institute (except prevention and control programs).

The Senate amendment authorized \$338 million for fiscal year 1976 and \$372 million for fiscal year 1977 for such purposes.

The conference substitute authorized \$339 million for fiscal year 1976 and \$373 million for fiscal year 1977 for such purposes.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

AUTHORIZATIONS

The House bill authorized appropriations of \$175 million for fiscal year 1976 and \$200 million for fiscal year 1977 for payments for National Research Services Awards.

The Senate amendment authorized \$160 million for fiscal year 1976 and \$176 million for fiscal year 1977 for such purposes.

The conference substitute authorizes \$165 million for fiscal year 1976 and \$185 million for fiscal year 1977 for such purposes.

ACCRUAL OF INTEREST

Under existing law, interest accrues on National Research Service Awards from the time the award is made in instances in which recipients fail to fulfill applicable service requirements.

The House bill changed existing law to make interest on the award computed from the time the United States becomes entitled to recover all or part of the award.

The Senate bill contained no comparable provision.

The conference substitute conforms to the House bill.

STUDY RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

Under existing law, the Secretary is to annually submit a study respecting biomedical and behavioral research personnel.

The Senate amendment changed the date for submission of the report to September 30, and the House bill contained no comparable

provision. The House bill required that the entity conducting the study conduct such study in consultation with the Director of the National Institutes of Health.

The conference substitute conforms to the changes made in existing law by both the House bill and the Senate amendment.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

The House bill contained a provision which required the President's Biomedical Research Panel to conduct an investigation and study of the implication of disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary in conjunction with an application or proposal for a grant, fellowship, or contract under the Public Health Service Act and to submit a report on the investigation and study to the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare. The House bill also included a provision which deferred, from July 1, 1976 to January 1, 1977, the establishment of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

The Senate amendment contained no comparable provisions.

The conference substitute conforms to the House bill, except that the National Commission for the Protection of Human Subjects is also required to conduct the investigation and study, and technical changes are made with respect to the dates on which the Panel is to complete its investigation and submit its report.

The Conferees express their concern that inadequate attention is being paid to the problems of transfer of research progress, technology, and information from the "bench to the bed", an area frequently referred to as the interface between research and the health care delivery system. This includes such areas as extensive clinical trials, demonstration projects, specific disease control programs, the assessment of new health technologies, health education, and the fields of preventive medicine and public health. The Conferees have received assurance that the report of the President's Biomedical Research Panel will address these important issues.

TITLE IV—GENETIC DISEASES

SHORT TITLE AND STATEMENT OF PURPOSE

The House bill provided for the following short title: "National Genetic Diseases Act." Under the Senate amendment the short title was "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs and Genetic Diseases Act."

The House bill stated a purpose of establishing a national program for genetic diseases, including sickle cell anemia, Cooley's anemia and Tay-Sachs disease. The Senate amendment, in its statement of purpose, stipulated that genetic diseases are to include but not be limited to sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

The conference substitute conforms to the Senate amendment.

TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

The house bill required that testing and counseling programs be established and operated primarily in conjunction with other existing health programs, including programs established under title X of the Public Health Service Act (family planning programs) and under title V of the Social Security Act (maternal and child health programs). The Senate amendment contained comparable requirements, except that it did not specify programs under title X of the Public Health Service Act or under title V of the Social Security Act.

The conference substitute conforms to the House bill, except that only programs assisted under title V of the Social Security Act are specified.

The Senate amendment further provided that a priority in the awarding of grants and contracts for genetic disease counseling and testing programs was to be given to projects which are recipients of awards for sickle cell anemia testing and counseling programs on the date of enactment. There was no similar provision in the House bill.

The conference substitute conforms to the Senate amendment with technical amendments.

The House bill authorized \$20 million for each of fiscal years 1976 and 1977 to support genetic disease testing and counseling programs and information and education programs. The Senate amendment authorized \$20 million for fiscal year 1976, \$25 million for fiscal year 1977, and \$30 million for fiscal year 1978 for such programs; and an additional \$15 million for each of fiscal years 1976, 1977, and 1978 to support sickle cell anemia testing and counseling programs.

The conference substitute authorizes \$30 million for each of fiscal years 1976, 1977, and 1978 to support genetic diseases testing and counseling programs and information and education programs, and provides that the Secretary shall give special consideration in the awarding of grants and contracts to sickle cell anemia testing and counseling project applications.

RESEARCH PROJECT GRANTS AND CONTRACTS

Both the House bill and the Senate amendment authorized the Secretary to award grants and contracts for research projects with respect to genetic diseases.

Both the House bill and the Senate amendment set forth four purposes for which the Secretary could award research grants and contracts. They are identical except that as the first purpose the House bill provided that projects for basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases would be eligible for funding. The Senate amendment included projects for basic research, including lower organisms, applied research, and research training.

The conference substitute conforms to the House bill.

The House bill instructed the Secretary to undertake genetic disease research under the general authority of section 301 of the Public Health Service Act. The Senate amendment provided for a specific authority and authorized \$80 million for fiscal year 1976, \$100 million for fiscal year 1977, and \$120 million for fiscal year 1978; and ear-

marked 10 percent of the sums appropriated each year under the authority for research projects with respect to Cooley's anemia. The Senate amendment further provided for a separate authorization for sickle cell anemia research of \$15 million for each of fiscal years 1976, 1977, and 1978.

The conference substitute conforms to the House bill, except that the Secretary is directed, in making grants and entering into contracts for research projects, to give priority to applications which are submitted for research on sickle cell anemia or for research on Cooley's anemia.

TITLE V.—VITAMINS AND MINERALS

The Senate amendment contained provisions not included in the House bill relating to regulation of vitamin and mineral products under the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as "the Act").

Under the Senate amendment, the Secretary of Health, Education and Welfare would generally have been prohibited from establishing maximum limits on the potency of vitamins or minerals in dietary supplements or classifying vitamins or minerals as drugs solely because they exceeded the level of potency determined by him to be nutritionally rational or useful. In addition, the Secretary would have been prohibited from limiting the combination of vitamins, minerals or other ingredients in dietary supplements. However, under the Senate amendment, the Secretary would have retained full authority to limit the potencies and combinations of vitamins, minerals and other ingredients in foods in the exercise of his authority under chapter V of the Act (relating to drugs) and under provisions of the Act respecting unsafe foods which are not generally recognized as safe. In addition, the Senate amendment contained provisions rendering the amendment's limitations on the authority of the Secretary inapplicable to vitamin and mineral products for use by children or by pregnant or lactating women.

The Senate amendment also contained provisions with respect to the labeling and advertising of vitamin and mineral products. It prohibited a product containing vitamins or minerals from being deemed misbranded solely because its label lists all ingredients of such a product. However, the amendment required that the labeling of such products could not list ingredients which are not vitamins or minerals except as a part of a list of all ingredients of the product and unless such ingredients are listed in accordance with applicable regulations. Moreover, the Senate amendment prohibited the labeling of or advertising for any such product to give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals.

In addition, the Senate amendment afforded the Secretary significant new authority with respect to the advertising of certain products containing vitamins or minerals. (Under existing law, the Federal Trade Commission has exclusive authority with respect to the advertising of such products.) Under the Senate amendment, such products would be deemed misbranded if their advertising were false or misleading in a material respect. However, criminal penalties could not be imposed against persons who were in violation of the prohibitions against false or misleading advertising unless such a violation

was committed with the intent to defraud or mislead. Further, such products which are misbranded because their advertising is false or misleading in a material respect and are held for sale to the ultimate consumer in an establishment not owned by a manufacturer, packer or distributor, could not be seized unless (1) the advertising was disseminated in the establishment in which the product was held for sale to the ultimate consumer, the advertising was disseminated by or under the direction of the owner or operator of such establishment, or all or part of the cost of such advertising was paid for by the owner or operator, and (2) the owner or operator used the advertising to promote the sale of the product. Finally, the Senate amendment required the Secretary to consult with the Federal Trade Commission prior to initiating action with respect to such products deemed misbranded because of their advertising.

The Conference substitute conforms to the Senate amendment except that:

(1) It adds two technical amendments (clarifying the intention of the Senate amendment) to provide specifically that foods represented for use by individuals in the treatment or management of specific diseases or disorders and foods represented for use as the sole item of a meal or of the diet are excluded from the limitations on the Secretary's authority.

(2) Except in instances in which immediate action is necessary to eliminate an imminent hazard to health, it requires the Secretary to provide notification to the Federal Trade Commission of his intention to initiate an action with respect to false or misleading advertising, and it affords the Federal Trade Commission the opportunity to take specific enforcement action against false or misleading advertising for a period of up to 90 days before the Secretary may take comparable action.

Since the House has taken no action during this Congress with respect to this matter, it is important to provide more legislative history concerning these complex new provisions. Thus, presented below is a detailed description of the new provisions, as well as statements of the intentions of the managers with respect to their implementation.

PRODUCTS SUBJECT TO THE CONFERENCE SUBSTITUTE

Under the conference substitute, products subject to its provisions are defined as safe human foods for special dietary use which are or contain any natural or synthetic vitamin or mineral and which are intended for ingestion in tablet or capsule form or in small units of liquid measure. In addition, such foods not intended for ingestion in tablet, capsule, or liquid form are subject to the provisions of the substitute only if they do not simulate conventional foods, if they are not represented to be conventional foods, and if they are not represented for use as the sole item of a meal or of the diet.

The definition of "special dietary use" in the conference substitute applies only to the foods to which the substitute is applicable and not to other foods, such as foods represented for use by infants or foods represented for use as the sole item of a meal or of the diet, that may be subject to 403(j) of the Act.

Thus, vitamins and minerals in tablet, capsule, or liquid form as well as those products which are represented for special dietary use in humans and which do not simulate and are not represented as conventional foods or substitutes for conventional foods and which are not represented for use as the sole item of a meal or of the diet, are products subject to the provisions of the substitutes.

Except with respect to products defined above, the conference substitute does not alter existing provisions of the Federal Food, Drug, and Cosmetic Act with respect to foods and drugs.

The Secretary retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in conventional foods such as milk, enriched bread and enriched rice, as well as in products which simulate conventional foods such as soybased protein substitutes for meats and poultry. The Secretary also retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in foods represented by labeling, advertising, or other promotional materials for use as the sole item of a meal or of the diet. Because consumers purchase these foods as nutritional equivalents of a well-balanced meal or diet, the conferees believe it is essential that the consumer of such products can be confident that a meal or diet based upon such products is nutritionally adequate and balanced and provides for the proper maintenance of the user's health for the duration of his use of these products.

LIMITATIONS ON THE SECRETARY'S AUTHORITY

Under the conference report, three significant restrictions would be imposed on the Secretary with regard to the regulation of products subject to the conference substitute. First, new section 411(a)(1)(A) of the Act prohibits the Secretary from using his existing authority under sections 201(n) or 403 of the Act (relating to misbranding) or under section 401 of the Act (relating to standards of identity) to impose maximum limits on the potency of safe vitamins and minerals contained in products subject to the conference substitute. This provision would not restrict the Secretary from prescribing minimum potency levels for vitamins or minerals in such products in order to prevent the addition of insignificant or useless amounts.

Second, new section 411(a)(1)(B) of the Act prohibits the Secretary from classifying as a drug a natural or synthetic vitamin or mineral, offered by itself or in combination, solely because it exceeds the level of potency that the Secretary determines is nutritionally rational or useful.

Third, new section 411(a)(1)(C) of the Act prohibits the Secretary from using his authority with respect to misbranding or establishment of standards of identity to limit the combination or number of any safe vitamin, mineral or other ingredient of food in products subject to the conference substitute.

EXCEPTIONS TO LIMITATIONS ON THE SECRETARY

Under the conference substitute (proposed new section 411(a)(2) of the Act), the limitations on the Secretary, described above, do not apply with respect to a product otherwise subject to the provisions

of the conference substitute where such product is represented for use by (1) individuals in the treatment or management of specific diseases or disorders, (2) children, or (3) pregnant or lactating women.

The provision with respect to foods intended for use in the treatment or management of specific diseases or disorders was adopted in conference in order to make clear that the proposed new section 411(a) of the Act does not override the Secretary's authority under sections 401, 403, or 201(n) of the Act to limit the potency and combination of vitamins, minerals, other ingredients in foods, or foods, represented for use in the dietary treatment or management of individuals with specific diseases or disorders, or of post-operative or convalescing medical patients. Since each of these foods must be precisely formulated to meet the needs of individuals with specific diseases and disorders, the conferees believe it to be important that the language in the conference substitute clearly preserve the authority of the Secretary to regulate as foods the nutritional formulation, composition, and potency of each product represented for such uses. Inclusion of this language is not, however, intended to permit the Secretary to limit (under sections 401, 403, or 201(n) of the Act) the potency or combination of a safe vitamin, mineral, food ingredient, or food represented in its labeling and advertising to be solely for use by adults, other than pregnant or lactating women, as a nutritional supplement to general human dietary intake.

Dietary management with these products is not only of major clinical value to the individual, but can be lifesaving in many instances. In the case of a number of inborn abnormalities of metabolism, such as phenylketonuria and maple syrup urine disease, these foods provide the only means for prevention of mental retardation, particularly in infants and young children, or for the partial restoration of mental capacity in older children. Special formula feedings are essential to long-term maintenance of severely debilitated individuals. Low sodium foods are useful in dietary management of individuals with severe forms of hypertension, acute heart failure, acute nephritis, toxemias of pregnancy and similar disorders when the degree of sodium restriction must be greater than that achievable with conventional foods. Chemically defined formula diets are extremely useful for nutritional management of patients prior to and subsequent to gastrointestinal surgery.

The Senate amendment included, in proposed new section 411(a)(2) of the Act, a specific reference to the Secretary's authority to act by regulation. This reference was deleted by the conferees as unnecessary. It is not intended that the omission of this reference should be understood as in any way restricting the Food and Drug Administration's present authority to adopt regulations defining and enforcing the provisions of the Act. The Secretary in recent years has relied increasingly on administrative rulemaking to enforce the requirements of the law. Rulemaking affords opportunity for broader participation in the formulation of agency policy, promotes clarity of legal requirements, and assures equitable application of the law, while at the same time it reduces the cost to the taxpayer of case-by-case enforcement. The Secretary's legal authority, under section 701(a) of the Act, to adopt binding regulations has been recognized by the Supreme Court. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973); *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). This

authority has recently been upheld by the United States Court of Appeals for the Second Circuit. *National Nutritional Foods Assn. v. Weinberger*, 512 F. 2d 688 (C.A. 2, 1975).

For the purposes of the conference substitute, the term "children" is defined to mean individuals under the age of 12 years. The conferees are also concerned that attention should be given to those vitamin and mineral preparations that are not intended for use by infants, children or pregnant or lactating women, but may be taken by or administered to them inadvertently. Just as the fetus may be affected by excessive doses of some food supplements, excessive doses of vitamins and minerals taken by children during the period of rapid growth and maturation can interfere with their normal development. Because of such possibilities of unrecognized or unanticipated harm, it is intended that the Secretary retain full authority to promulgate regulations designed to assure that unsuitable or inappropriate vitamin and mineral preparations are not inadvertently administered to individuals in these vulnerable groups.

Except as specifically provided, the conference substitute does not alter the drug or food provisions of the Federal Food, Drug, and Cosmetic Act. If a product containing vitamins, minerals or other ingredients is a drug within the meaning of section 201 (g) of the Act, the Secretary may, with respect to such product, exercise his authority under Chapter V of the Act. For example, the Secretary may bring an action for misbranding of a product which purports to be or is represented as a drug (within the meaning of section 201 (g) of the Act) if its labeling fails to bear adequate directions for its purported use or for the use for which it is represented (within the meaning of section 502 (f)(1) of the Act). See *V. E. Irons, Inc. v. United States*, 244 F. 2d 34 (C.A. 1, 1957); *Alberty Food Products v. United States*, 194 F. 2d 463 (C.A. 9, 1952); *United States v. Vitasafe Co.*, 345 F. 2d 864 (C.A. 3, 1965); *United States v. Article of Drug . . . B-Complex Cholinol Capsules*, 362 F. 2d 923 (C.A. 3, 1966).

The Secretary also has the authority to regulate the composition and potency of a product subject to the provisions of the conference substitute on the basis of safety. If a high potency preparation of a vitamin or mineral is a drug as defined by section 201 (g) of the Act and the Secretary determines that within the meaning of section 503 (b) of the Act, it is not safe for use except under the supervision of a physician, such a high potency preparation is subject to regulation as a prescription drug under the Act.

Similarly, if any vitamin, mineral or other food ingredient is not generally recognized as safe by qualified experts and meets the other criteria of the definition of a "food additive" under section 201 (s) of the Act, it would be subject to regulation under section 409 of the Act. If such a vitamin, mineral or other ingredient is intentionally added to a food, such food is adulterated (within the meaning of section 402 (a)(2)(C) of the Act) unless its use is in conformity with a regulation issued by the Secretary which prescribes the conditions under which it may be safely used or exempts it for investigational use by qualified experts. It is on precisely this basis that the Secretary has, by regulation, restricted the potency of the vitamin folic acid that may be added to a food.

PROVISIONS WITH RESPECT TO LABELING AND ADVERTISING

Under the conference substitute, the Secretary retains the authority to initiate enforcement actions against a product to which the conference substitute is applicable if its labeling is false or misleading in any particular. In addition, the conference substitute contains special provisions respecting the labeling and advertising of these products.

The conference substitute provides that a food to which the conference substitute is applicable shall not be deemed misbranded under section 403 of the Act solely because its label bears a listing of all of the ingredients in the food, or solely because its advertising contains references to ingredients in the food that are not vitamins or minerals. Thus, for example, if a tablet or capsule of vitamin C contains rutin, a substance that the Secretary has concluded has no dietary usefulness, the list of ingredients as well as the advertising for the product may refer to rutin without causing the food to be deemed misbranded. However, because of the conferees' concern that consumers not be misled into a belief that such substances have nutritional value, the conference substitute provides that the labeling so such a product may not list ingredients that are not vitamins or minerals except as a part of a list of all the ingredients of the food, in accordance with applicable regulations promulgated by the Secretary pursuant to section 403 of the Act. The Secretary is directed that in circumstances where compliance with this provision is impracticable or results in deception or unfair competition, exceptions shall be established by regulation. Further, the conference substitute provides that the labeling or advertising of a food to which the conference substitute is applicable may not give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals.

The conference substitute also provides the Secretary new authority over the advertising of foods subject to the conference substitute. Seizure and injunction actions are authorized in instances in which the advertising of a food to which the conference substitute is applicable is false or misleading in a material respect. However, in order to protect an innocent retailer from seizures based upon deceptive advertising claims made by a manufacturer, the conference substitute provides that libel for condemnation may not be instituted against such products which are misbranded because of their advertising unless (1) the advertising was disseminated in the establishment in which the product was held for sale to the ultimate consumer, the advertising was disseminated by or under the direction of the owner or operator of such establishment, or all or part of the cost of such advertising was paid for by the owner or operator, and (2) the owner or operator used the advertising in the establishment to promote the sale of the food.

The conference substitute would also add a new section 707 to the Federal Food, Drug, and Cosmetic Act which would require that the Federal Trade Commission be afforded the opportunity to take certain specific enforcement actions under the Federal Trade Commission Act for a period of up to 90 days before the Secretary could initiate an enforcement action under Chapter III of the Act with respect to the advertising of a product subject to the provisions of the conference substitute. It would prohibit the Secretary, except under limited

circumstances, from initiating such an enforcement action before, during, or after the expiration of the 90 day period, if the Federal Trade Commission takes action in accordance with the conference substitute.

These provisions are intended to provide the Secretary with authority to protect the public from consumer fraud perpetrated by the false advertising of these products. They are intended to serve as a partial substitute for the authority denied to the Secretary under other provisions of the conference substitute.

Proposed new section 707 of the Act would require the Secretary to notify the Federal Trade Commission before he initiates any action, under Chapter III of the Federal Food, Drug, and Cosmetic Act, with respect to any food which the Secretary determines is misbranded under proposed new section 403(a)(2) of the Act because of its advertising or a food's advertising which the Secretary determines causes the food to be so misbranded. The notice by the Secretary must contain (1) a description of the Secretary's proposed action, (2) a description of the advertising which the Secretary has determined causes the food to be misbranded under section 403(a)(2) of the Act, and (3) a statement of the reasons for the Secretary's determination that the advertising has caused the food to be so misbranded. In addition, the notice from the Secretary must be accompanied by records, documents, and other written materials which the Secretary determines support his determination that the food is so misbranded because of its advertising.

If, within a 30 day period beginning on the date of receipt of the notice and accompanying written materials from the Secretary, the Federal Trade Commission notifies the Secretary in writing that—

(1) it has initiated an investigation of the advertising (referred to in the Secretary's notice) to determine if it is prohibited by the Federal Trade Commission Act or a rule or order promulgated thereunder;

(2) it has commenced or intends to commence a civil action in the courts under section 5, 13, or 19 of such Act with respect to such advertising or the Attorney General has commenced or intends to commence a civil action under section 5 of such Act with respect to such advertising;

(3) it has issued and served or intends to issue and serve a complaint under section 5(b) of such Act with respect to such advertising; or

(4) it had made certification to the Attorney General under section 16(b) of such Act with respect to such advertising,

the Secretary is prohibited from initiating his proposed action for an additional period of time, which is not to exceed 60 days. If the Commission notifies the Secretary that neither the Attorney General nor the Commission intends to take any of these actions or fails to respond to the Secretary in writing within the 30 day period, the Secretary may initiate his proposed action.

If, before the expiration of the 60 day period beginning on the date the Secretary receives the notice from the Commission that the Attorney General or the Commission intends to take one of the actions described above, the Commission or the Attorney General has not commenced a civil action, the Commission has not issued and served a complaint or made certification to the Attorney General

which has caused appropriate criminal proceedings to be brought against the advertising, the Secretary may act under Chapter III of the Federal Food, Drug, and Cosmetic Act.

The Commission is required to notify the Secretary promptly of the commencement of a civil action, the issuance and service of a complaint, or the causing by the Attorney General of criminal proceedings to be brought against the advertising described in the Secretary's notice.

The conferees intend that the Commission or the Attorney General, where practical, take appropriate regulatory action under the Federal Trade Commission Act pursuant to a notice from the Secretary. The conferees believe that the period of 90 days provided in the conference substitute is sufficient time within which to take such action. However, in instances in which the Secretary determines that, although action has not been taken by the Commission or the Attorney General within the 90 day period, such action is imminent, he may defer taking his proposed action to permit the Commission or the Attorney General to take action.

Under the conference substitute the notification and other procedural requirements in subsections (a) and (b) of proposed new section 707 of the Act do not apply with respect to any action under Chapter III of the Act with respect to any food or food advertising to which the conference substitute is otherwise applicable, if the Secretary determines that such action is required to eliminate an imminent hazard to health. Under these circumstances the Secretary would neither be required to provide formal notification to the Commission nor delay his proposed enforcement action. However, under the conference substitute, if the Secretary takes any action under Chapter III of the Act with respect to a food because of its advertising or with respect to a food's advertising under proposed section 403(a)(2) of the Act, proposed section 707(d) of the Act requires the Secretary to coordinate the action with any action of the Federal Trade Commission with respect to the advertising of such food.

The conferees recognize that for many years the Food and Drug Administration and the Federal Trade Commission have operated in overlapping areas of jurisdiction in the regulation of false claims and that both agencies have been functioning under written memoranda of understanding concerning jurisdiction and liaison since 1954. The conferees expect both agencies to continue to coordinate their regulatory actions in a manner to avoid unnecessary duplication and waste. The conferees also emphasize that the conference substitute is not intended to modify the primary role of the Federal Trade Commission in exercising its regulatory authority over the false or misleading advertising of food products.

Although the substitute gives the Secretary substantial new authority with respect to the advertising of vitamin and mineral products, the conferees intend that the Secretary use his authority under existing section 306 of the Federal Food, Drug, and Cosmetic Act which provides for written notice or warning in lieu of judicial action where the Secretary believes that such notification or warning adequately protects the public interest.

TITLE VI—ARTHRITIS ACT AMENDMENT

The Senate amendment contained a title, not included in the House bill, which amended the National Arthritis Act (Public Law 93-640). The Senate amendment (1) made it clear that arthritis and related musculoskeletal diseases are to be collectively referred to as arthritis for the purposes of the Act; (2) added a statement of purposes of the Act; (3) corrected the reference to the Chief Medical Director of the Veterans Administration as an ex-officio member of the National Commission on Arthritis; (4) lowered the authorization of appropriations under that Act for the Arthritis Commission from \$2 million to \$1.5 million; (5) revised the authorizations of appropriations under the Public Health Service Act for arthritis screening, detection, prevention, and referral demonstration projects and the Arthritis Screening and Detection Data Bank from \$2 million for fiscal year 1975, \$3 million for fiscal year 1976 and \$4 million for fiscal year 1977 to \$1.5 million for fiscal year 1975, \$4 million for fiscal year 1976, and \$4 million for fiscal year 1977; and (6) amended section 439 of the Public Health Service Act to provide that the Secretary may assist in the development, modernization, and operation of *new and existing* comprehensive arthritis centers and to revise the authorizations from \$11 million for fiscal year 1975, \$13 million for fiscal year 1976, and \$15 million for fiscal year 1977 to \$5 million for fiscal year 1975, \$13 million for fiscal year 1976, and \$21 million for fiscal year 1977.

The conference substitute conforms to the Senate amendment, except that it would authorize under the Public Health Service Act \$11 million for fiscal year 1975, \$8 million for fiscal year 1976 and \$20 million for fiscal year 1977 for the development, modernization and operation of new and existing comprehensive arthritis centers, and would not change existing law with respect to authorizations for demonstration projects and the Arthritis Screening and Detection Data Bank.

TITLE VII—DIABETES PLAN

The Senate amendment contained a title, not included in the House bill, which extended the expiration date of the National Diabetes Commission (established under Public Law 93-354) to September 30, 1976.

The conference substitute conforms to the Senate amendment.

TITLE VIII—HEALTH SERVICES

The Senate amendment contained a title, not included in the House bill, which amended sections 319 (migrant health centers) and 330 (community health centers) of the Public Health Service Act to add ambulatory surgical services as a supplemental health service which could be offered by such centers.

The conference substitute conforms to the Senate amendment.

TITLE IX—INDIAN HEALTH SERVICE

The Senate amendment contained a title, not included in the House bill, which amended section 225 of the Public Health Service

Act to permit the Indian Health Service to utilize non-profit recruitment agencies to assist in obtaining personnel for the Public Health Service.

The conference substitute conforms to the Senate amendment.

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

The Senate amendment contained a title, not included in the House bill, which prohibited consideration of political affiliation in making appointments to advisory committees established to assist the Secretary in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.

The conference substitute conforms to the Senate amendment.

TITLE XI—MISCELLANEOUS PROVISIONS SOLDIERS' AND SAILORS' CIVIL RELIEF ACT

The Senate amendment contained a provision, not included in the House bill, which equated active service of commissioned officers of the Public Health Service with active military service in the Armed Forces for the purposes of all rights, privileges, immunities, and benefits provided under the Soldiers' and Sailors' Civil Relief Act of 1940.

The conference substitute conforms to the Senate amendment.

VISITING SCIENTIST AWARDS

The Senate amendment contained provisions, not included in the House bill, which (1) authorized the Secretary to grant stipends, in amounts not to exceed \$25,000 per annum, to visiting scientists who enter into agreements with the Secretary to assist minority schools in developing programs in biomedical sciences, and (2) authorized the Secretary to make grants to minority schools to initiate the development of undergraduate programs relating to biomedical sciences.

The conference substitute authorizes the Secretary to make awards (referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. The amount of each such award shall include such sum as is commensurate with the salary or remuneration which the individual had received from the institution with which he has, or had, a permanent or immediately prior affiliation.

HEALTH PROFESSIONS STUDENT ASSISTANCE

The Senate amendment contained provisions, not included in the House bill, which extended the authorizations of appropriations for physician shortage area scholarships at \$3.5 million for fiscal year 1975 and \$2 million for fiscal year 1976, and for health professions student loans at \$60 million for fiscal year 1976.

The conference substitute conforms to the Senate amendment.

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CLAIBORNE PELL,
EDWARD M. KENNEDY,
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ALAN CRANSTON,
WILLIAM D. HATHAWAY,
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THOMAS F. EAGLETON,
GAYLORD NELSON,
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RICHARD S. SCHWEIKER,
ROBERT TAFT,
J. GLENN BEALL, JR.,
ROBERT T. STAFFORD,
PAUL LAXALT,
Managers on the Part of the Senate.

HARLEY O. STAGGERS,
PAUL G. ROGERS,
DAVID E. SATTERFIELD,
JAMES W. SYMINGTON,
JAMES H. SCHEUER,
TIM LEE CARTER,
JAMES T. BROYHILL,
Managers on the Part of the House.

○

Ninety-fourth Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the nineteenth day of January,
one thousand nine hundred and seventy-six*

An Act

To amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. (a) This Act may be cited as the "Health Research and Health Services Amendments of 1976".

(b) Whenever in this Act (other than in titles III, V, VI, VII, and XI) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

SEC. 101. (a) Congress finds and declares that—

(1) diseases of the heart, blood, 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 cost of medical care of more than \$40,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema being among the fastest rising causes of death in the United States;

(4) chronic respiratory diseases affect an estimated ten million Americans, emphysema 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 whose value in saving life and promoting health cannot be assessed in terms of dollars;

(7) 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 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;

(8) blood diseases, including nutritional anemia, anemia due to inherited abnormalities (such as sickle cell anemia and Cooley's anemia (thalassemia), anemias resulting from failure of the bone marrow, hemorrhagic defects (a common cause of death in patients with leukemia and other malignancies, and of disability from inherited diseases such as hemophilia)), and malignancies of the lymph nodes and bone marrow, such as leukemia, have a devastating impact in spite of recent advances, and constitute an important category of illness that requires major attention; and

(9) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart, Lung, and Blood Institute, but advancement against such diseases depends not only on the research programs of that Institute but also on the research programs of other research institutes of the National Institutes of Health.

(b) It is the purpose of this title to enlarge the authority of the National Heart, Lung, and Blood Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases and to enlarge its authority with respect to blood resources.

SEC. 102. Sections 411, 418(a) (6), and 419A(c) are each amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart, Lung, and Blood Institute".

SEC. 103. (a) Section 412 is amended—

(1) by inserting "and with respect to the use of blood and blood products and the management of blood resources" after "diseases" in the matter preceding paragraph (1);

(2) by inserting "and to the use of blood and blood products and the management of blood resources" before the semicolon at the end of paragraph (1);

(3) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (4);

(4) by inserting "and on the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (5);

(5) by striking out "heart diseases" in paragraph (6) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and the management of blood resources";

(6) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (7); and

(7) by inserting at the end of the section heading "AND IN THE MANAGEMENT OF BLOOD RESOURCES".

(b) Section 412 is amended by striking out "National Heart and Lung Advisory Council" and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 104 (a) Section 413(a) is amended—

(1) by striking out "Disease" in the first sentence and inserting in lieu thereof "Diseases and Blood Resources"; and

(2) by inserting "and blood resources" after "diseases" in such sentence and in paragraph (7).

(b) Section 413(b) is amended—

(1) by striking out "calendar" each place it occurs in paragraph (2) and inserting in lieu thereof "fiscal"; and

(2) by adding at the end of such paragraph the following: "Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the program during such five years".

(c) Section 413(c)(1) is amended by striking out "fifty" and inserting in lieu thereof "one hundred".

(d) Section 413(c)(2) is amended—

(1) by striking out "operate" and inserting in lieu thereof "operate, alter, renovate"; and

(2) by inserting "and blood resource" after "disease".

(e) Section 413(d) is amended—

(1) by striking out "Assistant Director for Health Information Programs" each place it occurs and inserting in lieu thereof "Assistant Director for Prevention Education, and Control";

(2) by striking out "and pulmonary" in the second sentence and inserting in lieu thereof "blood, and pulmonary" and by inserting "and blood" after "pulmonary" in the third sentence; and

(3) by inserting "and blood resources" after "diseases" in the second sentence.

(f) The section heading of section 413 is amended by striking out "DISEASE" and inserting in lieu thereof "DISEASES AND BLOOD RESOURCES".

SEC. 105. Section 414(b) is amended (1) by striking out "and" after "1974," and (2) by inserting before the period a comma and the following: "\$10,000,000 for fiscal year 1976, and \$30,000,000 for fiscal year 1977".

SEC. 106. (a)(1) Subsection (a)(1)(A) of section 415 is amended by—

(A) striking out "fifteen" and inserting in lieu thereof "ten", and

(B) striking out "blood vessel, and blood diseases" and inserting in lieu thereof "diseases".

(2) Subsection (a)(1)(B) of such section is amended by striking out "fifteen" and inserting in lieu thereof "ten".

(3) Subsection (a)(1) of such section is amended—

(A) by striking out "and" at the end of subparagraph (A),

(B) by striking out the period at the end of subparagraph (B) and inserting in lieu thereof "and", and

(C) by inserting after subparagraph (B) the following new subparagraph:

"(C) ten 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 blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources."

(b) Section 415(a) is further amended—

(1) by inserting "and for research in the use of blood and blood products and in the management of blood resources" after "diseases" in paragraph (1)(A);

(2) by striking out "chronic" in paragraph (1)(B);

(3) by striking out "paragraph (1)(A)" in paragraph (2) and inserting in lieu thereof "paragraph (1)";

(4) by inserting “, pulmonary, and blood” before “diseases” in paragraph (2);

(5) by striking out “cardiovascular disease” in paragraph (2) (A) and inserting in lieu thereof “cardiovascular, pulmonary, and blood diseases”; and

(6) by striking out “such disease” in subparagraphs (B), (C), and (D) of paragraph (2) and inserting in lieu thereof “such diseases”.

(c) Section 415 (b) is amended—

(1) by inserting “the management of blood resources and” before “advanced”; and

(2) by amending the first sentence after paragraph (4) to read as follows: “The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed \$5,000,000 in any year, except that the aggregate of such payments in any year may exceed such amount to the extent that the excess amount is attributable to increases in such year in appropriate costs as reflected in the Consumer Price Index published by the Bureau of Labor Statistics.”

(d) The section heading of section 415 is amended by inserting “AND BLOOD RESOURCES” after “DISEASES”.

SEC. 107. (a) Section 417 (a) (1) is amended by striking out “Director of the Office of Science and Technology” and inserting in lieu thereof “Director of the National Science Foundation”.

(b) Section 417 is amended by striking out “National Heart and Lung Advisory Council” in subsection (a) and in subsection (b) (3) and inserting in lieu thereof “National Heart, Lung, and Blood Advisory Council”.

(c) The section heading of section 417 is amended by striking out “AND LUNG” and inserting in lieu thereof “, LUNG, AND BLOOD”.

SEC. 108. Section 418 is amended—

(1) by inserting “and to the use of blood and blood products and the management of blood resources” after “diseases” in paragraphs (1), (2), (3), and (4) of subsection (a);

(2) by redesignating paragraphs (4), (5), and (6) of subsection (a) as paragraphs (5), (6), and (7), respectively, and by adding after paragraph (3) the following new paragraph:

“(4) recommend to the Secretary (A) areas of research in heart, blood vessels, lung, and blood diseases and in the use of blood and blood products and the management of blood resources which it determines should be supported by the awarding of contracts in order to best carry out the purposes of this part, and (B) the percentage of the budget of the Institute which should be expended for such contracts;” and

(3) (A) by amending paragraph (2) of subsection (b) to read as follows:

“(2) The Council shall submit a report to the Secretary for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress on the progress of the Program toward the accomplishment of its objectives during the preceding fiscal year.”

(B) For purposes of section 418 (b) (2) of the Public Health Service Act (as amended by subparagraph (A)), the period beginning July 1, 1975, and ending September 30, 1976, shall be considered a fiscal year.

(C) The amendment made by subparagraph (A) shall take effect as of January 1, 1976.

SEC. 109. Section 419A is amended—

(1) by inserting “and projects with respect to the use of blood and blood products and the management of blood resources” after “training projects” in subsection (a);

(2) by inserting “and into the use of blood and blood products and the management of blood resources” after “diseases” in subsection (b);

(3) by inserting “and for research and training in the use of blood and blood products and the management of blood resources” after “diseases” in subsection (c);

(4) by striking out “in amounts not to exceed \$35,000” in paragraph (1) of subsection (c) and inserting in lieu thereof “if the direct costs of such research and training do not exceed \$35,000, but only”; and

(5) by striking out “in amounts exceeding \$35,000” in paragraph (2) of subsection (c) and inserting in lieu thereof “if the direct costs of such research and training exceed \$35,000, but only”.

SEC. 110. Section 419B is amended—

(1) by striking out “and” after “1974,” and by inserting before the period at the end of the first sentence a comma and the following: “\$339,000,000 for fiscal year 1976, and \$373,000,000 for fiscal year 1977”; and

(2) by striking out “diseases of the blood” and inserting in lieu thereof “blood diseases and blood resources”.

SEC. 111. (a) Section 301 is amended by striking out “heart diseases” in paragraphs (c) and (h) and inserting in lieu thereof “heart, blood vessel, lung, and blood diseases and blood resources”.

(b) Section 301 is amended by striking out “National Heart and Lung Advisory Council” in paragraphs (c) and (h) and inserting in lieu thereof “National Heart, Lung, and Blood Advisory Council”.

SEC. 112. The title of Part B of title IV is amended to read as follows:

“PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE”.

TITLE II—NATIONAL RESEARCH SERVICE AWARDS

SEC. 201. (a) (1) Subsection (a) (1) (A) (i) of section 472 is amended (A) by striking out “in matters” and inserting in lieu thereof “or under programs administered by the Division of Nursing of the Health Resources Administration, in matters”, and (ii) by inserting before “are directed” the following: “or Division of Nursing”.

(2) Subsections (a) (1) (A) (iii) and (a) (1) (B) of such section are each amended by striking out “non-Federal”.

(b) Subsection (c) (1) (A) (i) of such section is amended by striking out “health research or teaching” and inserting in lieu thereof “health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment”.

(c) Subsection (c) (2) (A) of such section is amended by striking out “health research or teaching” and inserting in lieu thereof “health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment”.

(d) The first sentence of subsection (d) of such section is amended by inserting a comma before the period and the following: “\$165,000,000 for fiscal year 1976, and \$185,000,000 for fiscal year 1977”.

SEC. 202. (a) Subsection (a) (1) (A) (i) of section 472 is amended by striking out "the disease or (diseases) or other health problems to which the activities of the Institutes and Administration are directed" and inserting in lieu thereof "diseases or other health problems".

(b) Subsection (b) (2) of section 472 is amended by striking out "to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration" and inserting in lieu thereof "within the Department of Health, Education, and Welfare".

SEC. 203. (a) (1) Subparagraph (A) of the first paragraph (4) of subsection (c) of section 472 is amended by striking out "and the interest on such amount" down through and including "was made".

(2) The last sentence of subparagraph (B) of such paragraph is amended by striking out "at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States" and inserting in lieu thereof "at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount".

(b) The amendments made by subsection (a) shall apply with respect to National Research Awards under section 472 which are made from appropriations for fiscal years ending on or after June 30, 1975.

SEC. 204. Section 473 (b) is amended by adding after paragraph (2) the following new paragraph:

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health."

SEC. 205. Subsection (c) of section 473 is amended by striking out "March 31" and inserting in lieu thereof "September 30".

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

SEC. 301. (a) (1) The President's Biomedical Research Panel (established by section 201 (a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

(A) The number of requests made to the Secretary for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such requests were made.

(B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.

(C) The effect of the disclosure of such information on—

(i) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on patent rights;

(ii) the ability of peer review systems to insure high quality federally funded research; and

(iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

(2) (A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Panel deems appropriate.

(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission deems appropriate.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof "January 1, 1977".

TITLE IV—GENETIC DISEASES

SEC. 401. This title may be cited as the "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act".

SEC. 402. In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

SEC. 403. (a) Title XI is amended by striking out parts A and B and inserting in lieu thereof the following:

"PART A—GENETIC DISEASES

"TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

"SEC. 1101. (a) (1) The Secretary, through an identifiable administrative unit within the Department of Health, Education, and Welfare, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects to establish and operate voluntary genetic testing and counseling programs primarily in conjunction with other existing health programs, including programs assisted under title V of the Social Security Act.

"(2) The Secretary shall carry out, through an identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials

relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. The Secretary may, under such program, make grants to public and nonprofit private entities and enter into contracts with public and private entities and individuals for the development and dissemination of such materials.

“(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for fiscal year 1976, \$30,000,000 for fiscal year 1977, and \$30,000,000 for fiscal year 1978.

“RESEARCH PROJECT GRANTS AND CONTRACTS

“SEC. 1102. In carrying out section 301, the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

“VOLUNTARY PARTICIPATION

“SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

“APPLICATIONS; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

“SEC. 1104. (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require. Each applicant shall—

“(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

“(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

“(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part;

“(4) in the case of an applicant for a grant or contract under section 1101(a)(1) for the delivery of services, provide assurances satisfactory to the Secretary that (A) the services for community-wide testing and counseling to be provided under the program for which the application is made (i) will take into consideration widely prevalent diseases with a genetic component and high-risk population groups in which certain genetic diseases occur, and (ii) where appropriate will be directed especially but not exclusively to persons who are entering their child-producing years, and (B) appropriate arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and

“(5) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

“(b) In making any grant or entering into any contract for testing and counseling programs under section 1101, the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the greatest number of persons who will benefit from and are in need of the services provided under such programs.

“(c) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 or under section 1101 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

“PUBLIC HEALTH SERVICE FACILITIES

“SEC. 1105. The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

“REPORTS

“SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part.

“(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary.”

(b)(1) Section 1121(b)(5) is amended by striking out “ending June 30,” each place it occurs.

(2) Parts C and D are redesignated as parts B and C, respectively.

(3) The heading of such title is amended to read as follows:

"TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME."

(c) The amendments made by subsections (a) and (b) shall take effect July 1, 1976.

TITLE V—FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

SEC. 501 (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 410 (21 U.S.C. 349) the following new section:

"VITAMINS AND MINERALS

"SEC. 411. (a) (1) Except as provided in paragraph (2)—

"(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

"(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

"(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

"(i) vitamin,

"(ii) mineral, or

"(iii) other ingredient of food,

within a food to which this section applies.

"(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years.

"(b) (1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i) (2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

"(2) (A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

"(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

"(i) vitamins,

"(ii) minerals, or

"(iii) represented as a source of vitamins or minerals.

"(c) (1) For purposes of this section, the term 'food to which this section applies' means a food for humans which is a food for special dietary use—

"(A) which is or contains any natural or synthetic vitamin or mineral, and

“(B) which—

“(i) is intended for ingestion in tablet, capsule, or liquid form, or

“(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

“(2) For purposes of paragraph (1) (B) (i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

“(3) For purposes of paragraph (1) and of section 403(j) insofar as that section is applicable to food to which this section applies, the term ‘special dietary use’ as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

“(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

“(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

“(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.”

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

Sec. 502. (a) (1) Section 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(a)) is amended (A) by inserting “(1)” after “If”, and (B) by inserting before the period at the end a comma and the following: “or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b) (2)”.

(2) (A) Section 201(n) of such Act is amended by inserting “or advertising” after “labeling” each time it occurs.

(B) Section 303 of such Act is amended by adding at the end the following new subsection:

“(d) No person shall be subject to the penalties of subsection (a) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a) (2) because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead.”

(C) Section 304(a) of such Act (21 U.S.C. 334(a)) is amended by adding after paragraph (2) the following new paragraph:

“(3) (A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

“(i) is misbranded under section 403(a) (2) because of its advertising, and

“(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

“(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

“(i) (I) the food’s advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

“(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

“(III) all or part of the cost of such advertising was paid by such owner or operator; and

“(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.”.

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

“ADVERTISING OF CERTAIN FOODS

“SEC. 707. (a) (1) Except as provided in subsection (c), before the Secretary may initiate any action under chapter III—

“(A) with respect to any food which the Secretary determines is misbranded under section 403(a)(2) because of its advertising,

or

“(B) with respect to a food’s advertising which the Secretary determines causes the food to be so misbranded, the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

“(2) The notice required by paragraph (1) shall—

“(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary’s determination that such advertising has caused such food to be misbranded, and

“(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

“(b) (1) If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter III with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

“(A) it has initiated under the Federal Trade Commission Act an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

“(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 with respect to such advertising,

“(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act respecting such advertising, or

“(D) pursuant to section 16(b) of such Act it has made a certification to the Attorney General respecting such advertising, the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary’s notice to the Federal Trade Commission.

“(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a)—

“(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary’s notice,

“(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

“(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a). The Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

“(c) The requirements of subsections (a) and (b) do not apply with respect to action under chapter III with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

“(d) For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter III because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act with respect to such advertising.”

(c) The amendments made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

TITLE VI—ARTHRITIS ACT AMENDMENTS

SEC. 601. This title may be cited as the “National Arthritis Act Technical Amendments of 1976”.

SEC. 602. (a) Section 2 of the National Arthritis Act of 1974 (Public Law 93-640) (hereinafter in this section referred to as the “Act”) is amended by—

(1) inserting “(a)” after “SEC. 2.”;

(2) inserting a comma and “including \$2,500,000,000 in medical expenses,” after “\$9,200,000,000” in paragraph (3); and

(3) inserting a new subsection (b) at the end thereof as follows:

“(b) It is therefore the purpose of this Act to provide for—

“(1) the formulation of a long-range plan—

“(A) to expand and coordinate the national research, treatment, and control effort against arthritis;

“(B) to advance educational activities for patients, professional and allied health personnel, and the public which will alert the citizens of the United States to the early indications of arthritis; and

“(C) to emphasize the significance of early detection and proper control of these diseases and of the complications which may evolve from them;

“(2) the establishment and support of programs to develop new and improved methods of arthritis screening, detection, prevention, and referral;

“(3) the establishment of a central arthritis screening and detection data bank; and

“(4) the development, modernization, and operation of centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, and research and training programs.”

(b) Section 3 of the Act is amended by striking out “chief medical officer” and inserting in lieu thereof “Chief Medical Director” in subsection (b) (4).

(c) The section heading for section 4 of the Act is amended by striking out “DEMONSTRATION” after “COMMITTEE.”

SEC. 603. (a) (1) Section 431(c) of the Public Health Service Act is amended by inserting “(hereinafter in this part collectively referred to as ‘arthritis’)” after “musculoskeletal diseases”.

(2) The fourth sentence of section 434(b) of such Act is amended by striking out “and related musculoskeletal diseases”.

(3) Section 434(e) of such Act is amended by striking out “and related musculoskeletal diseases (hereinafter in this part collectively referred to as ‘arthritis’)”.

(b) Section 438 of such Act is amended by—

(1) inserting “the” before “health” the first time it appears in the first sentence of subsection (a); and

(2) inserting “established” after “bank” in the second sentence of subsection (a).

(c) Section 439 of such Act is amended by—

(1) inserting “new and existing” before “centers” in the first sentence of subsection (a);

(2) striking out “\$13,000,000” and inserting in lieu thereof “\$8,000,000”, and striking out “\$15,000,000” and inserting in lieu thereof “\$20,000,000” in subsection (h); and

(3) redesignating subsections (e), (f), (g), and (h) as subsections (d), (e), (f), and (g), respectively.

TITLE VII—DIABETES PLAN

SEC. 701. Section 3(i) (2) of the National Diabetes Mellitus Research and Education Act (42 U.S.C. 289c-2) is amended to read as follows:

“(2) The Commission shall cease to exist after September 30, 1976.”

TITLE VIII—HEALTH SERVICES

AMBULATORY SURGICAL SERVICES

SEC. 801. (a) Section 319(a) (7) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

“(L) ambulatory surgical services;” and

(2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

- (b) Section 330(b) (2) is amended by—
- (1) inserting after subparagraph (K) the following new subparagraph:
“(L) ambulatory surgical services;” and
 - (2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

TITLE IX—INDIAN HEALTH SERVICE

SEC. 901. Section 225 is amended by adding at the end thereof the following new subsection—

“(j) Notwithstanding any other provision of law, the Secretary may, where he deems advisable, allow the Indian Health Service to utilize nonprofit recruitment agencies to assist in obtaining personnel for the Public Health Service.”.

TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation.

TITLE XI—MISCELLANEOUS PROVISIONS

SEC. 1101. Section 212 of the Public Health Service Act is amended by adding after subsection (d) the following new subsection:

“(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940 (50 App. U.S.C. 501 et seq.).”.

SEC. 1102. (a) The second paragraph (4) of subsection (c) of section 472 of the Public Health Service Act is redesignated as paragraph (5).

(b) Section 507 of the Public Health Service Act is amended by striking out “hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except that grants to such” and insert in lieu thereof “Federal institutions, except that grants to”.

SEC. 1103. Title IV of the Public Health Service Act is amended by adding after section 475 the following new section:

“VISITING SCIENTIST AWARDS

“SEC. 476. (a) The Secretary may make awards (referred to as ‘Visiting Scientist Awards’) to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

“(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.”

SEC. 1104. Section 786 of the Public Health Service Act is amended by inserting before the period at the end of the first sentence “and \$3,500,000 for the fiscal year ending June 30, 1975 and \$2,000,000 for the fiscal year ending June 30, 1976”.

SEC. 1105. (a) Section 742(a) of the Public Health Service Act is amended by striking out “and” after “1974,” and by inserting after “1975” the following: “, and \$60,000,000 for the fiscal year ending June 30, 1976”.

(b) Section 740(b)(4) of such Act is amended by striking out “1975” and inserting in lieu thereof “1976”.

SEC. 1106. Section 1511(b)(5) of the Public Health Service Act is amended by striking out “1535” and inserting in lieu thereof “1536”.

(b) Section 1613 of such Act is amended by striking out “1510” and inserting in lieu thereof “1610”.

(c) The last sentence of section 1631 of such Act is repealed.

SEC. 1107. (a) Section 132(a)(1)(A) of the Developmental Disabilities Services and Facilities Construction Act (42 U.S.C. 6062) (hereinafter in this section referred to as the “Act”) is amended by striking out “134” and inserting in lieu thereof “133”.

(b) Section 134(b)(1) of the Act is amended by striking out “134” and inserting in lieu thereof “133”.

(c) Section 134(b)(1) of the Act is amended by striking out “136” and inserting in lieu thereof “135”.

(d) Section 301(a) of the Developmentally Disabled Assistance and Bill of Rights Act is amended by striking out “101(7)” and inserting in lieu thereof “102(7)”.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*

April 13, 1976

Dear Mr. Director:

The following bills were received at the White House on April 13th:

- ✓ H.J. Res. 890
- ✓ H.R. 7988

Please let the President have reports and recommendations as to the approval of these bills as soon as possible.

Sincerely,

Robert D. Linder
Chief Executive Clerk

The Honorable James T. Lynn
Director
Office of Management and Budget
Washington, D.C.