NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD ACT OF 1972

HEARINGS

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

NINETY-SECOND CONGRESS

SECOND SESSION

ON

H.R. 12571, H.R. 13715, H.R. 12460, H.R. 13500, S. 3323 (and identical bills)

TO AMEND THE PUBLIC HEALTH SERVICE ACT SO AS TO ADVANCE THE NATIONAL EFFORT AGAINST HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND AGAINST NEUROLOGICAL DISEASES AND STROKE, AND FOR OTHER PURPOSES

APRIL 25 AND 26, 1972

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NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD ACT OF 1972

TUESDAY, APRIL 25, 1972

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers (chairman) presiding.

Mr. ROGERS. The subcommittee will come to order, please.

The hearings today are on H.R. 12571, introduced by Chairman Staggers, and H.R. 13715 which I introduced along with most of the members of the Health Subcommittee, and S. 3323, bills designed to more effectively carry out the national effort against diseases of the heart, blood vessels, lungs, and blood.

Diseases of the heart, lungs, blood vessels, and blood are the major killers in the United States today. Cardiovascular diseases account for approximately 55 percent of all deaths in the United States killing more than 1 million people each year. Approximately 1¼ million Americans suffer heart attacks annually. If this rate continues, more than 12 million Americans will experience heart attacks within the next 10 years.

Strokes kill more than 200,000 Americans annually. Asthma, chronic bronchitis, and emphysema were responsible for over 30,000 deaths in 1970 and were a contributing factor to 60,000 other deaths, and the incidence of these diseases is increasing, particularly in the case of emphysema.

Asthma afflicts 5 million Americans; chronic bronchitis 4 million, and emphysema, 1 million.

Both cardiovascular and pulmonary diseases are a serious drain on our national resources Arteriosclerotic and hypertensive diseases cost their victims over $4 billion annually for medical care. It has been estimated that the average American life expectancy could be increased by 10.5 years if cardiovascular diseases were eliminated as a major cause of disability and death. If this were to happen, the annual savings to the economy in terms of medical care costs, lost wages, and productivity and earnings eliminated by premature death could exceed $30 billion per year.

The bills pending before the subcommittee today are designed to strengthen the national attack upon these diseases by improving the organization and structure of the National Heart and Lung Institute. Last year the Congress enacted legislation strengthening the national attack on cancer, and the time is now right for a similar approach on cardiovascular disease and lung disorders.

At this point in the record there will be included the text of the bills and the agency reports thereon.

(The text of H.R. 12571, H.R. 13715, H.R. 12460, H.R. 13500, H.R. 14493, H.R. 14682, H.R. 14686, and S. 3323, together with departmental reports thereon, follow:)

92D CONGRESS
2D SESSION

H. R. 12571

IN THE HOUSE OF REPRESENTATIVES

JANUARY 24, 1972

Mr. STAGGERS introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Public Health Service Act so as to strengthen the National Heart and Lung Institute, the National Institute of Neurological Diseases and Stroke, and the National Institutes of Health in order more effectively to carry out the national effort against heart, lung, and neurological diseases and stroke.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Heart, Lung, and Neurological Diseases and Stroke Amendments of 1972".

PROGRAMS OF THE NATIONAL HEART AND LUNG INSTITUTE

SEC. 2. (a) Part B of title IV of the Public Health Service Act is amended by adding after section 414 the following new sections:

"AUTHORITY OF DIRECTOR

"SEC. 415. In carrying out the programs of the National Heart and Lung Institute, the Director of the Institute, after consultation with the National Advisory Heart and Lung Council and without regard to any other provision of this Act, may—

"(1) if authorized by the National Advisory Heart and Lung 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 experts or consultants who have scientific or professional qualifications;

"(2) acquire, construct, improve, repair, operate, and maintain heart and lung centers, laboratories, research, 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 Gen-

eral 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;

"(3) appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

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

"(5) accept voluntary and uncompensated services;

"(6) accept unconditional gifts, or donations of services, money, or property (real, personal, or mixed, tangible or intangible);

"(7) 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; and

"(8) take necessary action to insure that all channels for the dissemination and exchange of scientific

knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations, nationally and internationally.

"SCIENTIFIC REVIEW; REPORTS

"SEC. 416. (a) The Director of the National Heart and Lung Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Advisory Heart and Lung Council and the Director of the National Institutes of Health, other formal peer review groups as may be required.

"(b) The Director of the National Heart and Lung Institute shall, as soon as practicable after the end of each calendar year, prepare in consultation with the National Advisory Heart and Lung Council and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments of the Institute during the preceding calendar year and a plan for the Institute during the next five years.

"NATIONAL HEART AND LUNG DISEASES RESEARCH AND DEMONSTRATION CENTERS

"SEC. 417. (a) The Director of the National Heart and Lung Institute is authorized to provide for the establishment of centers for clinical research, training and demonstration of advanced diagnostic and treatment methods relating to heart and lung diseases. Such centers may be supported under subsection (b) or under any other applicable provision of law.

"(b) The Director of the National Heart and Lung Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Advisory Heart and Lung Council, is authorized to enter into cooperative agreements with public or private nonprofit 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, but not limited to, centers established under subsection (a)) for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to heart and lung diseases. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under 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; but support under this subsection (other than support for construction) shall not exceed $5,000,000 per year per center. Support of a center under this section may be for a period of not to exceed three years and may be extended by the Director of the National Heart and Lung Institute for additional periods of not more than three years each, after review of the operations of such center by an appropriate scientific review group established by the Director.

"(c) No center may be established or supported under this section before the Director has consulted with the regional medical program for the area in which the center is or will be located.

"HEART AND LUNG DISEASES CONTROL PROGRAMS

"SEC. 418. (a) The Director of the National Heart and Lung Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of heart and lung diseases.

"(b) There are authorized to be appropriated to carry out this section $20,000,000 for the fiscal year ending June 30, 1973, $30,000,000 for the fiscal year ending June 30, 1974, and $40,000,000 for the fiscal year ending June 30, 1975.

"BUDGET REQUESTS; AUTHORIZATION OF APPROPRIATIONS

"SEC. 419. (a) The Director of the National Heart and Lung Institute shall prepare and submit, directly to the

President for review and transmittal to Congress, an annual budget estimate for the programs of the Institute, after reasonable opportunity for comment (but without change), by the Secretary, the Director of the National Institutes of Health, and the National Advisory Heart and Lung Council. The Director shall receive directly from the President and the Office of Management and Budget all funds appropriated by Congress for obligation and expenditure by the National Heart and Lung Institute.

"(b) For purposes of carrying out this part (other than section 418), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1973, $500,000,000 for the fiscal year ending June 30, 1974, and $600,000,000 for the fiscal year ending June 30, 1975."

(b) (1) Section 412 of the Public Health Service Act is amended by adding at the end thereof the following:

"(b) 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 heart or lung diseases research or training—

"(1) in amounts not to exceed $35,000 after appropriate review for scientific merit but without review and recommendation by the National Advisory Heart and Lung Council, and

"(2) in amounts exceeding $35,000 after appro-

priate review for scientific merit and review and recommendation for approval by such Council."

(2) Section 412 of such Act is further amended—

(A) by inserting "(a)" immediately after "SEC. 412."; and

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

(3) Section 413 (a) of such Act is amended by striking out "grants-in-aid" and inserting in lieu thereof "except as provided in section 412 (b), grants-in-aid".

(c) The President shall carry out a review of all administrative processes applicable to programs of the National Heart and Lung Institute, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of such programs. Within one year of the date of enactment of this Act the President shall submit a report to Congress of the findings of such review and the actions taken to facilitate the conduct of such programs, together with recommendations for any needed legislative changes.

(d) The President shall request of the Congress without delay such additional appropriations (including increased authorizations) as are required to pursue immediately any development under a program of the National Heart and

Lung Institute requiring prompt and expeditious support and for which regularly appropriated funds are not available.

(e) (1) Section 414 of the Public Health Service Act is amended by adding at the end thereof the following:

"(b) The Council shall meet at the call of the Director of the National Heart and Lung Institute or the Chairman of the Council, but not less often than four times a year, and shall advise and assist the Director with respect to the programs of the Institute. 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 Institute."

(2) Section 414 of such Act is further amended—

(A) by inserting "(a)" immediately after "SEC. 414.", and

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

(f) (1) Section 217 of the Public Health Service Act is amended—

(A) by striking out "National Advisory Heart Council" each place it occurs in subsection (a) and inserting in lieu thereof "National Advisory Heart and Lung Council",

(B) by striking out "heart diseases" in subsection (a) and inserting in lieu thereof "heart and lung diseases", and

(C) by inserting "lung," immediately after "heart," in subsection (b).

(2) Sections 301(d), 301(i), and 412 of such Act are each amended by striking out "National Advisory Heart Council" and inserting in lieu thereof "National Advisory Heart and Lung Council".

(3) Part B of such Act is further amended—

(A) by striking out "National Heart Institute" in section 411 and inserting in lieu thereof "National Heart and Lung Institute";

(B) by striking out "heart diseases" each place it occurs in sections 412, 413(b), and 414(a) and inserting in lieu thereof "heart and lung diseases";

(C) by striking out "heart disease" in sections 413(a) and 414(a)(2) and inserting in lieu thereof "heart and lung diseases";

(D) by striking out "HEART DISEASE" in the section heading of section 412 and inserting in lieu thereof "HEART AND LUNG DISEASES"; and

(E) by striking out "NATIONAL HEART INSTITUTE" in the heading of such part and inserting in lieu thereof "NATIONAL HEART AND LUNG INSTITUTE".

PROGRAMS OF THE NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE

SEC. 3. (a) Part D of title IV of the Public Health Service Act is amended by adding after section 433 the following new sections:

"DESIGNATION OF INSTITUTE AND ADVISORY COUNCIL; AUTHORITY OF DIRECTOR

"SEC. 434. (a) The research institute on neurological diseases established under section 431 is designated the 'National Institute of Neurological Diseases and Stroke', and the advisory council established under section 432 to advise the Secretary with respect to activities of the Institute is designated the 'National Neurological Diseases and Stroke Advisory Council'. The Director of the Institute shall be appointed as provided in section 454.

"(b) In carrying out the programs of the Institute, the Director, after consultation with the National Neurological Diseases and Stroke Advisory Council and without regard to any other provision of this Act, may—

"(1) if authorized by the Advisory 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 experts or

consultants who have scientific or professional qualifications;

"(2) acquire, construct, improve, repair, operate, and maintain neurological diseases and stroke centers, laboratories, research, 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;

"(3) appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

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

"(5) accept voluntary and uncompensated services;

"(6) accept unconditional gifts, or donations of services, money, or property (real, personal, or mixed, tangible or intangible);

"(7) 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; and

"(8) take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

"(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Institute of Neurological Diseases and Stroke may approve grants under this Act for research or training involving neurological diseases or stroke—

"(1) in amounts not to exceed $35,000 after appropriate review for scientific merit but without review and recommendation by the National Neurological Diseases and Stroke Advisory Council, and

"(2) in amounts exceeding $35,000 after appropriate review for scientific merit and review and recommendation by the Advisory Council.

"(d) The Director of the National Institute of Neurological Diseases and Stroke shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Neurological Diseases and Stroke Council and the Director of the National Institutes of Health, other formal peer review groups as may be required.

"(e) The Director of the National Institute of Neurological Diseases and Stroke shall, as soon as practicable after the end of each calendar year, prepare in consultation with the National Neurological Diseases and Stroke Council and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments of the Institute during the preceding calendar year and a plan for the Institute during the next five years.

"NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR NEUROLOGICAL DISEASES AND STROKE

"SEC. 435. (a) The Director of the National Institute of Neurological Diseases and Stroke is authorized to provide for the establishment of centers for clinical research, training,

and demonstration of advanced diagnostic and treatment methods relating to neurological diseases and stroke. Such centers may be supported under subsection (b) or under any other applicable provision of law.

"(b) The Director, under policies established by the Director of the National Institutes of Health and after consultation with the National Neurological Diseases and Stroke Advisory Council, is authorized to enter into cooperative agreements with public or private nonprofit 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, but not limited to, centers established under subsection (a)) for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to neurological diseases and stroke. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under 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; but support under this subsection (other than support for construction) shall not exceed $5,000,000 per year per center. Support of a center under this section may be for a period of not to exceed three

years and may be extended by the Director for additional periods of not more than three years each, after review of the operations of such center by an appropriate scientific review group established by the Director.

"(c) No center may be established or supported under this section before the Director has consulted with the regional medical program for the area in which the center is or will be located.

"NEUROLOGICAL DISEASES AND STROKE CONTROL PROGRAMS

"SEC. 436. (a) The Director of the National Institute of Neurological Diseases and Stroke shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of neurological diseases and stroke.

"(b) There are authorized to be appropriated to carry out this section $20,000,000 for the fiscal year ending June 30, 1973, $30,000,000 for the fiscal year ending June 30, 1974, and $40,000,000 for the fiscal year ending June 30, 1975.

"NATIONAL NEUROLOGICAL DISEASES AND STROKE ADVISORY COUNCIL

"SEC. 437. The National Neurological Diseases and Stroke Advisory Council shall meet at the call of the Director of the National Institute of Neurological Diseases and

Stroke or the Chairman of the Council, but not less often than four times a year, and shall advise and assist the Director with respect to the programs of the Institute. 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 Institute.

"BUDGET REQUESTS; AUTHORIZATION OF APPROPRIATIONS

"SEC. 438. (a) The Director of the National Institute of Neurological Diseases and Stroke shall prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the programs of the Institute, after reasonable opportunity for comment (but without change), by the Secretary, the Director of the National Institutes of Health, and the National Advisory Neurological Diseases and Stroke Council. The Director shall receive directly from the President and the Office of Management and Budget all funds appropriated by Congress for obligation and expenditure by the National Institute of Neurological Diseases and Stroke.

"(b) For purposes of carrying out the program of the National Institute of Neurological Diseases and Stroke (other than the program authorized by section 436), there are authorized to be appropriated $300,000,000 for the fiscal year ending June 30, 1973, $400,000,000 for the fiscal year

ending June 30, 1974, and $500,000,000 for the fiscal year ending June 30, 1975."

(b) The President shall carry out a review of all administrative processes applicable to programs of the National Institute of Neurological Diseases and Stroke, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of such programs. Within one year of the date of enactment of this Act the President shall submit a report to Congress of the findings of such review and the actions taken to facilitate the conduct of such programs, together with recommendations for any needed legislative changes.

(c) The President shall request of the Congress without delay such additional appropriations (including increased authorizations) as are required to pursue immediately any development under a program of the Institute requiring prompt and expeditious support and for which regularly appropriated funds are not available.

APPOINTMENTS OF DIRECTORS OF THE INSTITUTES

SEC. 4. Section 454 of the Public Health Service Act is amended—

(1) by striking out "Director of the National Cancer Institute" in the first sentence and inserting in lieu thereof "Directors of the National Cancer Institute, the

National Heart and Lung Institute, and the National Institute of Neurological Diseases and Stroke"; and

(2) by amending the second sentence to read as follows: "Except as provided in sections 407(b)(9), 419(a), and 438(a), the Directors of the National Cancer Institute, the National Heart and Lung Institute, and the National Institute of Neurological Diseases and Stroke shall report directly to the Director of the National Institutes of Health.".

EFFECTIVE DATE

SEC. 5. (a) This Act and the amendments made by this Act shall take effect sixty days after the date of enactment of this Act or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register.

(b) The first sentence of section 454 of the Public Health Service Act (as amended by section 4 of this Act) shall apply only with respect to appointments of Directors of the National Heart and Lung Institute and the National Institute of Neurological Diseases and Stroke made after the effective date of this Act (as prescribed by subsection (a)).

92D CONGRESS
2D SESSION

H. R. 13715

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 1972

Mr. ROGERS (for himself, Mr. SATTERFIELD, Mr. KYROS, Mr. PREYER of North Carolina, Mr. SYMINGTON, Mr. ROY, Mr. NELSEN, Mr. CARTER, and Mr. HASTINGS) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Public Health Service Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack against diseases of the heart and blood vessels, the lungs, and blood; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

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

FINDINGS AND DECLARATION OF PURPOSE

SEC. 2. (a) Congress finds and declares that—

(1) diseases of the heart and blood vessels collectively cause more than half of all the deaths each year in

the United States and the combined effect of the disabilities and deaths from such diseases is having a major social and economic impact on the Nation;

(2) elimination of such cardiovascular diseases as significant causes of disability and death could increase the average American's life expectancy by about eleven years and could provide for annual savings to the economy in lost wages, productivity, and costs of medical care of more than $30,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema alone being the fastest rising cause of death in the United States;

(4) 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; and

(7) the greatest potential for advancement against

diseases of the heart and blood vessels, the lungs, and blood lies in the National Heart and Lung Institute of the National Institutes of Health whose research institutes have brought into being the most productive scientific community centered upon health and disease that the world has ever known.

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

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PROGRAMS

SEC. 3. Part B of title IV of the Public Health Service Act is amended (1) by redesignating section 413 as section 419A, (2) by redesignating section 414 as section 418, and (3) by adding after section 412 the following new sections:

"NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PROGRAM

"SEC. 413. (a) The Director of the Institute, with the advice of the Council, shall within one hundred and eighty days after the effective date of this section, develop a plan for a National Heart, Blood Vessel, Lung, and Blood Disease Program (hereafter in this part referred to as the 'Program') to expand, intensify, and coordinate the activities of the In-

stitute respecting such diseases (including its activities under section 412). The Program shall provide for—

"(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of cardiovascular, 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 cardiovascular, pulmonary, and blood phenomena;

"(3) research into the development, trial, and evaluation of techniques, drugs, and devices used in, and approaches to, the diagnosis, treatment, and prevention of cardiovascular and pulmonary diseases and the rehabilitation of patients suffering from such diseases;

"(4) establishment of programs and centers for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive diagnostic, therapeutic, and rehabilitative approaches to cardiovascular and pulmonary diseases;

"(5) studies and research into blood diseases (such as sickle cell anemia and hemophilia) and blood, its

uses 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;

"(6) the education and training of scientists and clinicians in fields and specialties requisite to the conduct of programs respecting cardiovascular, pulmonary, and blood diseases;

"(7) public and professional education relating to all aspects of cardiovascular, pulmonary, and blood diseases and the use of blood and blood products and the management of blood resources; and

"(8) establishment of programs and centers for study and research into cardiovascular, pulmonary, 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.

"(b) (1) The plan required by subsection (a) of this section shall be transmitted to the Congress and shall 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 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.

"(c) In carrying out the Program, the Director of the Institute, after consultation with the Council and without regard to any other provisions 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 experts or consultants who have scientific or professional qualifications;

"(2) acquire, construct, improve, repair, operate, and maintain cardiovascular and pulmonary disease centers, laboratories, research, 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 adja-

cent 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.

"HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE 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 of heart, blood vessel, lung, and blood diseases.

"(b) There are authorized to be appropriated to carry out this section $20,000,000 for the fiscal year ending June 30, 1973, $30,000,000 for the fiscal year ending June 30, 1974, and $40,000,000 for the fiscal year ending June 30, 1975.

"NATIONAL CLINICAL RESEARCH AND DEMONSTRATION CENTERS FOR CARDIOVASCULAR AND PULMONARY DISEASES

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

"(1) fifteen new centers for clinical research into, training in, and demonstration of, advanced diagnostic and treatment methods for cardiovascular diseases; and

"(2) fifteen new centers for clinical research into, training in, and demonstration of, advanced diagnostic and treatment methods for chronic pulmonary diseases (including bronchitis, emphysema, asthma, and cystic fibrosis and other pulmonary diseases of children).

Centers developed under this subsection may be supported under subsection (b) or under any other applicable provision of law.

"(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 clinical research into, training in, and demonstration of, advanced

diagnostic and treatment methods for cardiovascular and chronic pulmonary 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. 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.

"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 diseases of the heart, blood vessels, the lung, and blood 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 departments and agencies whose programs involve health functions or responsibilities as determined by the Secretary.

"NATIONAL HEART AND LUNG ADVISORY COUNCIL

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

"(1) The Secretary, the Director of the National Institutes of Health, the chief medical officer of the Veterans' Administration (or his designee), 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.

Each of the appointed members of the Council shall be a leader in a field of fundamental science, medical science,

or public affairs. Nine 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 full-time students enrolled in health professions schools; and seven of the appointed members shall be selected from the general public.

"(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 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–18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for persons in the Government service employed intermittently.

"(c) The Chairman of the Council shall be appointed by the Secretary from among the members of the Council and shall serve as Chairman for a term of two years.

"(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 Director of the Institute or of the Chairman, but not less often than four times a year."

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

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

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 419B. For the purpose of carrying out this part (other than section 414), there are authorized to be appropriated $350,000,000 for the fiscal year ending June 30, 1973, $400,000,000 for the fiscal year ending June 30, 1974, and $450,000,000 for the fiscal year ending June 30, 1975."

DIRECTOR'S AUTHORITY TO APPROVE GRANTS

SEC. 5. Section 419A of the Public Health Service Act (as so redesignated by section 3 of this Act) is amended—

(1) by striking out "grants-in-aid" in subsection (a) and inserting in lieu thereof "except as provided in subsection (c), grants-in-aid"; and

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

"(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Heart and Lung Institute may approve grants under this Act for research and training in heart, blood vessel, lung, and blood diseases—

"(1) in amounts not to exceed $35,000 after appropriate review for scientific merit but without review and recommendation by the Council, and

"(2) in amounts exceeding $35,000 after appropriate review for scientific merit and recommendation for approval by the Council."

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

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

(b) Section 412 of such Act is amended—

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

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

(3) by striking out "National Advisory Heart

Council" and inserting in lieu thereof "National Heart and Lung Advisory Council";

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

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

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

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

(1) by inserting "(a)" immediately after "SEC. 418." and by adding at the end thereof the following new subsection:

"(b) (1) The Council shall advise and assist the Director of the Institute 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 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) by striking out "Surgeon General" each place it occurs (except paragraph (f)) and inserting in lieu thereof "Secretary";

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

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

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

(d) Section 419A of such Act (as so redesignated by section 3 of this Act) is amended—

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

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

and (B) striking out "heart" and inserting in lieu thereof "heart, blood vessel, lung, and blood".

(e) The heading for part B of such Act is amended to read as follows:

"PART B—NATIONAL HEART AND LUNG INSTITUTE".

CONFORMING AMENDMENTS TO OTHER PROVISIONS OF THE PUBLIC HEALTH SERVICE ACT

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

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

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

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

REPORT TO CONGRESS

SEC. 8. The Secretary of Health, Education, and Welfare shall carry out a review of all administrative processes under which the National Heart, Blood Vessel, Lung, and Blood Disease Program, established under part B of title IV of the Public Health Service Act, will operate, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the

objectives of the Program. Within one year of the date of enactment of this Act, the Secretary shall submit a report to the Congress of the findings of such review and the actions taken to facilitate the conduct of the Program, together with recommendations for any needed legislative changes.

EFFECTIVE DATE

SEC. 9. This Act and the amendments made by this Act shall take effect sixty days after the date of enactment of this Act or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register.

92D CONGRESS
2D SESSION

H. R. 12460

IN THE HOUSE OF REPRESENTATIVES

JANUARY 18, 1972

Mr. PEPPER introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Public Health Service Act to strengthen the National Heart and Lung Institute and the National Institutes of Health in order more effectively to carry out the national effort against heart and lung diseases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as "The National Heart and Lung Diseases Act of 1972".

FINDINGS AND DECLARATION OF PURPOSE

SEC. 2. (a) The Congress finds and declares—

(1) that the incidence of heart and lung diseases is increasing and they are a major health concern of Americans today;

(2) that new scientific leads, if comprehensively and energetically exploited, may significantly advance the time when more adequate preventive and therapeutic capabilities are available to cope with those diseases;

(3) that those diseases are a leading cause of death in the United States;

(4) that the present state of our understanding of those diseases is a consequence of broad advances across the full scope of the biomedical sciences;

(5) that a great opportunity is offered as a result of recent advances in the knowledge of those diseases to conduct energetically a national program against them; and

(6) that in order to provide for the most effective attack on those diseases it is important to use all of the biomedical resources of the National Institutes of Health.

(b) It is the purpose of this Act to enlarge the authorities of the National Heart and Lung Institute and the National Institutes of Health in order to advance the national effort against heart and lung diseases.

NATIONAL HEART AND LUNG DISEASES PROGRAM

SEC. 3. (a) Part B of title IV of the Public Health Service Act is amended by adding after section 414 the following new sections:

"NATIONAL HEART AND LUNG DISEASES PROGRAM

"SEC. 415. (a) The Director of the National Heart and Lung Institute shall coordinate all of the activities of the National Institutes of Health relating to heart and lung diseases with the National Heart and Lung Diseases Program.

"(b) In carrying out the National Heart and Lung Diseases Program, the Director of the National Heart and Lung Institute shall:

"(1) With the advice of the National Heart and Lung Advisory Board, plan and develop an expanded, intensified, and coordinated heart and lung diseases research program encompassing the programs of the National Heart and Lung Institute, related programs of the other research institutes, and other Federal and non-Federal programs.

"(2) Expeditiously utilize existing research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise.

"(3) Encourage and coordinate heart and lung diseases research by industrial concerns where such concerns evidence a particular capability for such research.

"(4) Collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of

heart and lung diseases, including the establishment of an international heart and lung diseases research data bank to collect, catalog, store, and disseminate insofar as feasible the results of heart and lung diseases research undertaken in any country for the use of any person involved in heart and lung diseases research in any country.

"(5) Establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials.

"(6) Support research in the field of heart and lung diseases outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States.

"(7) Support appropriate manpower programs of training in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base from which to select investigators, physicians, and allied health professions personnel, for participation in clinical and basic research and treatment programs relating to

heart and lung diseases, including where appropriate the use of training stipends, fellowships, and career awards.

"(8) Call special meetings of the National Heart and Lung Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other actions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

"(9) (A) Prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the National Heart and Lung Diseases Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Heart and Lung Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the National Heart and Lung Institute.

"(c) (1) There is established the President's Heart and Lung Panel (hereinafter in this section referred to as the 'Panel') which shall be composed of three persons appointed by the President, who by virtue of their training, experience, and background are exceptionally qualified to

appraise the National Heart and Lung Diseases Program. At least two of the members of the Panel shall be distinguished scientists or physicians.

"(2) (A) Members of the Panel shall be appointed for three-year terms, except that (i) in the case of two of the members first appointed, one shall be appointed for a term of one year and one shall be appointed for a term of two years, as designated by the President at the time of appointment, and (ii) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

"(B) The President shall designate one of the members to serve as Chairman for a term of one year.

"(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel, and shall be allowed travel expenses (including a per diem allowance) under section 5703 (b) of title 5, United States Code.

"(3) The Panel shall meet at the call of the Chairman, but not less often than twelve times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and

the Chairman shall make such transcript available to the public.

"(4) The Panel shall monitor the development and execution of the National Heart and Lung Diseases Program under this section, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and annually an evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct. At the request of the President, it shall submit for his consideration a list of names of persons for consideration for appointment as Director of the National Heart and Lung Institute.

"NATIONAL HEART AND LUNG DISEASES RESEARCH AND DEMONSTRATION CENTERS

"SEC. 408. (a) The Director of the National Heart and Lung Institute is authorized to provide for the establishment of fifteen new centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to heart and lung diseases. Such centers may be supported under subsection (b) or under any other applicable provision of law.

"(b) The Director of the National Heart and Lung

Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Heart and Lung Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit 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, but not limited to, centers established under subsection (a)) for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to heart and lung diseases. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under 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; but support under this subsection (other than support for construction) shall not exceed $5,000,000 per year per center. Support of a center under this section may be for a period of not to exceed three years and may be extended by the Director of the National Heart and Lung Institute for additional periods of not more than three years each, after review of the operations of such center by an appro-

priate scientific review group established by the Director of the National Heart and Lung Institute.

"HEART AND LUNG DISEASES CONTROL PROGRAMS

"SEC. 416. (a) The Director of the National Heart and Lung Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of heart and lung diseases.

"(b) There are authorized to be appropriated to carry out this section $20,000,000 for the fiscal year ending June 30, 1973, $30,000,000 for the fiscal year ending June 30, 1974, and $40,000,000 for the fiscal year ending June 30, 1975.

"AUTHORITY OF DIRECTOR

"SEC. 417. The Director of the National Heart and Lung Institute (after consultation with the National Heart and Lung Advisory Board), in carrying out his functions in administering the National Heart and Lung Diseases Program and without regard to any other provision of this Act, is authorized—

"(1) if authorized by the National Heart and Lung Advisory Board, to 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 experts or consultants who have scientific or professional qualifications;

"(2) to acquire, construct, improve, repair, operate, and maintain heart and lung centers, laboratories, research, 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; to 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 National Heart and Lung Institute for a period not to exceed ten years;

"(3) to appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

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

"(5) to accept voluntary and uncompensated services;

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

"(7) to 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; and

"(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the National Heart and Lung Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

"SCIENTIFIC REVIEW; REPORTS

"SEC. 418. (a) The Director of the National Heart and Lung Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established

within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Heart and Lung Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

"(b) The Director of the National Heart and Lung Institute shall, as soon as practicable after the end of each calendar year, prepare in consultation with the National Heart and Lung Advisory Board and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments under the National Heart and Lung Diseases Program during the preceding calendar year and a plan for the Program during the next five years.

"NATIONAL HEART AND LUNG ADVISORY BOARD

"SEC. 419. (a) There is established in the National Heart and Lung Institute a National Heart and Lung Advisory Board (hereinafter in this section referred to as the 'Board') to be composed of twenty-three members as follows:

"(1) The Secretary, the Director of the Office of Science and Technology, the Director of the National Institutes of Health, the chief medical officer of the

Veterans' Administration (or his designee), and a medical officer designated by the Secretary of Defense shall be ex officio members of the Board.

"(2) Eighteen members appointed by the President.

Not more than twelve of the appointed members of the Board shall be scientists or physicians and not more than eight of the appointed members shall be representatives from the general public. The scientists and physicians appointed to the Board shall be appointed from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of heart and lung diseases or in fields related thereto. Each appointed member of the Board shall be appointed from among persons who by virtue of their training, experience, and background are especially qualified to appraise the programs of the National Heart and Lung Institute.

"(b) (1) Appointed members shall be appointed for six-year terms, except that of the members first appointed six shall be appointed for a term of two years, and six shall be appointed for a term of four years, as designated by the President at the time of appointment.

"(2) Any member appointed to fill a vacancy occurring prior to expiration of the term for which his predecessor was appointed shall serve only for the remainder of such

term. Appointed members shall be eligible for reappointment and may serve after the expiration of their terms until their successors have taken office.

"(3) A vacancy in the Board shall not affect its activities, and twelve members thereof shall constitute a quorum.

"(4) The Board shall supersede the existing National Advisory Heart Council, and the appointed members of the Council serving on the effective date of this section shall serve as additional members of the Board for the duration of their terms then existing, or for such shorter time as the President may prescribe.

"(c) The President shall designate one of the appointed members to serve as Chairman for a term of two years.

"(d) The Board shall meet at the call of the Director of the National Heart and Lung Institute or the Chairman, but not less often than four times a year and shall advise and assist the Director of the National Heart and Lung Institute with respect to the National Heart and Lung Diseases Program.

"(e) The Director of the National Heart and Lung Institute shall designate a member of the staff of the Institute to act as Executive Secretary of the Board.

"(f) The Board may hold such hearings, take such testimony, and sit and act at such times and places as the

Board deems advisable to investigate programs and activities of the Program.

"(g) The Board 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.

"(h) Members of the Board who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the duties of the Board compensation at rates not to exceed the daily equivalent of the annual rate in effect for GS–18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for persons in the Government service employed intermittently.

"(i) The Director of the National Heart and Lung Institute shall make available to the Board such staff, information, and other assistance as it may require to carry out its activities.

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 419A. For the purpose of carrying out this part (other than section 416), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30,

1973; $500,000,000 for the fiscal year ending June 30, 1974; and $600,000,000 for the fiscal year ending June 30, 1975."

(b) (1) Section 412 of the Public Health Service Act is amended by adding at the end thereof the following:

"(b) 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 heart and lung diseases research or training—

"(1) in amounts not to exceed $35,000 after appropriate review for scientific merit but without the review and recommendation by the National Heart and Lung Advisory Board prescribed by section 413 (a), and

"(2) in amounts exceeding $35,000 after appropriate review for scientific merit and recommendation for approval by such Board as prescribed by section 413 (a)."

(2) Section 412 of such Act is further amended—

(A) by inserting "(a)" immediately after "SEC. 412."; and

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

(3) Section 413 (a) of such Act is amended by striking

out "grants-in-aid" and inserting in lieu thereof "except as provided in section 412 (b), grants-in-aid".

REPORT TO CONGRESS

SEC. 4. (a) The President shall carry out a review of all administrative processes under which the National Heart and Lung Diseases Program, established under part B of title IV of the Public Health Service Act, will operate, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of the program. Within one year of the date of enactment of this Act the President shall submit a report to Congress of the findings of such review and the actions taken to facilitate the conduct of the Program, together with recommendations for any needed legislative changes.

(b) The President shall request of the Congress without delay such additional appropriations (including increased authorizations) as are required to pursue immediately any development in the National Heart and Lung Diseases Program requiring prompt and expeditious support and for which regularly appropriated funds are not available.

PRESIDENTIAL APPOINTMENTS

SEC. 5. Section 454 of the Public Health Service Act is amended—

(1) by striking out "Director of the National Can-

cer Institute" in the first sentence and inserting in lieu thereof "Directors of the National Cancer Institute and the National Heart and Lung Institute"; and

(2) by inserting immediately before the period at the end of the second sentence "; and except as provided in section 415(b)(9), the Director of the National Heart and Lung Institute shall report directly to the Director of the National Institutes of Health".

CONFORMING AMENDMENTS

SEC. 6. (a) Section 217 of the Public Health Service Act is amended (A) by striking out "National Advisory Heart Council," each place it occurs in subsection (a), (B) by striking out "heart diseases," in subsection (a) of such section, and (C) by striking out "heart," in subsection (b) of such section.

(b) Sections 301(d), 301(i), and 412 of such Act are each amended by striking out "National Advisory Heart Council" and inserting in lieu thereof "National Heart and Lung Advisory Board".

(c) Section 414 of such Act is amended—

(A) by striking out "Council" in the matter preceding paragraph (a) and inserting in lieu thereof "National Heart and Lung Advisory Board", and

(B) by striking out "COUNCIL" in the section heading and inserting in lieu thereof "BOARD".

(d) Part B of such Act is further amended—

(A) by striking out "National Heart Institute" in section 411 and inserting in lieu thereof "National Heart and Lung Institute";

(B) by striking out "heart diseases" each place it occurs in sections 412, 413 (b), and 414 and inserting in lieu thereof "heart and lung diseases";

(C) by striking out "heart disease" in sections 413 (a) and 414 (b) and inserting in lieu thereof "heart and lung diseases";

(D) by striking out "HEART DISEASE" in the section heading of section 412 and inserting in lieu thereof "HEART AND LUNG DISEASES"; and

(E) by striking out "NATIONAL HEART INSTITUTE" in the heading of such part and inserting in lieu thereof "NATIONAL HEART AND LUNG INSTITUTE".

EFFECTIVE DATE

SEC. 7. (a) This Act and the amendments made by this Act shall take effect sixty days after the date of enactment of this Act or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register.

(b) The first sentence of section 454 of the Public Health Service Act (as amended by section 5 of this Act) shall apply only with respect to appointments of Directors

of the National Heart and Lung Institute made after the effective date of this Act (as prescribed by subsection (a)).

(c) Notwithstanding the provisions of subsection (a), members of the National Heart and Lung Advisory Board (authorized under section 419 of the Public Health Service Act, as added by this Act) may be appointed, in the manner provided for in such section, at any time after the date of enactment of this Act. Such officers shall be compensated from the date they first take office, at the rates provided for in such section 419.

92D CONGRESS
2D SESSION

H. R. 13500

IN THE HOUSE OF REPRESENTATIVES

MARCH 1, 1972

Mr. DUNCAN introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To expand the scope of the National Heart and Lung Institute, to provide for special emphasis on the prevention of arteriosclerosis and the creation of cardiovascular disease prevention centers, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act shall be known as the "Heart Disease Prevention Act of 1972".

STATEMENT OF PURPOSE

SEC. 2. It is the purpose of this Act to—

(1) provide for the creation of centers concerned with the study and research of arteriosclerosis;

78-994 O—72——5

(2) provide for the establishment of model cardiovascular disease prevention centers within the framework of the existing programs; and

(3) provide for a clearinghouse for information concerning arteriosclerosis and cardiovascular disease within the National Heart and Lung Institute.

AMENDMENT TO PUBLIC HEALTH SERVICE ACT

SEC. 3. Part B of title IV of the Public Health Service Act is amended by adding at the end thereof the following new sections:

"NATIONAL CENTERS FOR THE PREVENTION OF ARTERIOSCLEROSIS

"SEC. 415. (a) The Director of the National Heart and Lung Institute is authorized to provide for the establishment of new multidisciplinary centers for the study of arteriosclerosis including its prevention, epidemiology, genesis, clinical manifestations and treatment, and the screening of individuals to determine those who are high risk in relation to arteriosclerosis. Such centers are to be located at major medical centers.

"(b) Payments under this section may be used for—

"(1) construction;

"(2) staffing and other basic operational costs, including such patient care costs as are required for research;

"(3) training, including training for allied health professions personnel; and

"(4) demonstration purposes.

"(c) Support under this section shall not exceed $10,000,000 per year per center. Support of a center may be for a period of not to exceed three years and may be extended by the Director for additional periods of not more than three years each, after the review of the operation of such center by an appropriate scientific review group.

"CARDIOVASCULAR DISEASE PREVENTION CLINICS

"SEC. 416. (a) The Director of the Heart and Lung Institute is authorized to establish ten model cardiovascular disease prevention clinics throughout the United States within the framework of existing programs. The purpose of such clinics shall be—

"(1) to develop improved methods of detecting high risk individuals;

"(2) to develop improved methods of intervention against high risk factors; and

"(3) to develop highly skilled manpower in cardiovascular disease prevention.

"(b) Such clinics shall be served by a central coordinating unit that shall be responsible for the development of standardized procedures for diagnosis, treatment, and data collection in relation to cardiovascular disease.

"OFFICE OF HEART HEALTH EDUCATION

"SEC. 417. There is hereby established within the National Heart and Lung Institute an Office of Education which shall provide a program of heart health education for public, medical, and allied health professions. Special emphasis shall be placed upon dissemination of information regarding diet, hypertension, cigarette smoking, weight control, and other factors in the prevention of arteriosclerosis and cardiovascular disease.

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 418. There are authorized to be appropriated for the purposes of sections 415, 416, and 417, $50,000,000 for the fiscal year ending June 30, 1973; $75,000,000 for the fiscal year ending June 30, 1974; $100,000,000 for the fiscal year ending June 30, 1975; $100,000,000 for the fiscal year ending June 30, 1976; and $100,000,000 for fiscal year ending June 30, 1977."

[H.R. 14493, 92d Cong., 2d sess., introduced by Mr. Patten on April 19, 1972;
H.R. 14682, 92d Cong., 2d sess., introduced by Mr. Minish on April 27, 1972;
H.R. 14686, 92d Cong., 2d sess., introduced by Mr. Rodino on April 27, 1972; and
S. 3323, 92d Cong., 2d sess., passed the Senate April 7, 1972, and referred to the Committee on Interstate and Foreign Commerce on April 10, 1972,

are identical as follows:]

A BILL

To amend the Public Health Service Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack against diseases of the heart and blood vessels, the lungs, and blood, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

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

FINDINGS AND DECLARATION OF PURPOSE

SEC. 2. (a) Congress finds and declares that—

(1) diseases of the heart and blood vessels collectively cause more than half of all the deaths each year in

the United States and the combined effect of the disabilities and deaths from such diseases is having a major social and economic impact on the Nation;

(2) elimination of such cardiovascular diseases as significant causes of disability and death could increase the average American's life expectancy by about eleven years and could provide for annual savings to the economy in lost wages, productivity, and costs of medical care of more than $30,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema alone being the fastest rising cause of death in the United States;

(4) 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 emer-

gency 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; and

(8) the greatest potential for advancement against diseases of the heart and blood vessels, the lungs, and blood lies in the National Heart and Lung Institute of the National Institutes of Health whose research institutes have brought into being the most productive scientific community centered upon health and disease that the world has ever known.

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

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES PROGRAMS

SEC. 3. Part B of title IV of the Public Health Service Act is amended (1) by redesignating section 413 as section 419A, (2) by redesignating section 414 as section 418, and (3) by adding after section 412 the following new sections:

"NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PROGRAM

"SEC. 413. (a) The Director of the Institute, with the advice of the Council, shall within one hundred and eighty days after the effective date of this section, develop a plan for a heart, blood vessel, lung, and blood disease program (hereafter in this part referred to as the 'program') to expand, intensify, and coordinate the activities of the Institute respecting such diseases (including its activities under section 412). The program shall provide for—

"(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of cardiovascular, 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 cardiovascular, pulmonary, and blood phenomena;

"(3) research into the development, trial, and evaluation of techniques, drugs, and devices used in, and approaches to, the diagnosis, prevention, and treatment (including emergency medical service) of cardiovascular

and pulmonary 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 cardiovascular, pulmonary, and other related 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 these diseases;

"(5) establishment of programs and centers for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches (including emergency medical services) to cardiovascular and pulmonary diseases;

"(6) studies and research into blood diseases (such as sickle cell anemia and hemophilia) and blood, its uses 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 requisite to

the conduct of programs respecting cardiovascular, pulmonary, and blood diseases;

"(8) public and professional education relating to all aspects of cardiovascular, pulmonary, and blood diseases and the use of blood and blood products and the management of blood resources;

"(9) establishment of programs and centers for study and research into cardiovascular, pulmonary, 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 sustain critical illnesses in connection with heart, blood vessel, lung or blood diseases which programs shall include the training of paraprofessionals in emergency treatment procedures, and in the utilization and operation of emergency medical equipment, the development and operation of mobile critical care units (including helicopters and other airborne units where appropriate), and radio and telecommunications, other communications and electronic monitoring systems, the coordination with other

community services and agencies in the joint use of all forms of emergency vehicles, communications systems, and other appropriate services.

"(b) (1) The plan required by subsection (a) of this section shall be transmitted to the Congress and shall 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 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.

"(c) In carrying out the program, the Director of the Institute, after consultation with the Council and without regard to any other provisions 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 experts or consultants who have scientific or professional qualifications;

"(2) acquire, construct, improve, repair, operate, and maintain cardiovascular and pulmonary disease cen-

ters, laboratories, 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.

"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 emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases of children.

"(b) (1) The Director of the Heart and Lung Institute is authorized to establish ten model cardiovascular disease prevention clinics throughout the United States within the framework of existing programs. The purpose of such clinics shall be—

"(A) to develop improved methods of detecting high risk individuals;

"(B) to develop improved methods of intervention against high risk factors;

"(C) to develop highly skilled manpower in cardiovascular disease prevention; and

"(D) to develop improved methods of providing emergency medical services."

"(2) Such clinics shall be served by a central coordinating unit that shall be responsible for the development of standardized procedures for diagnosis, treatment, and data collection in relation to cardiovascular disease.

"(c) There are authorized to be appropriated to carry out this section $30,000,000 for the fiscal year ending June 30, 1973, $40,000,000 for the fiscal year ending

June 30, 1974, and $50,000,000 for the fiscal year ending June 30, 1975.

"NATIONAL BASIC AND CLINICAL RESEARCH AND DEMONSTRATION CENTERS FOR CARDIOVASCULAR AND PULMONARY DISEASES

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

"(1) fifteen new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic and treatment methods (including emergency medical services) for cardiovascular diseases; and

"(2) fifteen new centers for basic and clinical research into, training in, and demonstration of advanced diagnostic and treatment methods (including emergency medical services) for chronic pulmonary diseases of adults and children (including but not limited to bronchitis, emphysema, asthma, and cystic fibrosis and other pulmonary diseases of children).

Centers developed under this subsection may be supported under subsection (b) or under any other applicable provision of law.

"(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 clinical research into, training in, and demonstration of advanced diagnostic and treatment methods for cardiovascular and chronic pulmonary 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. 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.

"INTERAGENCY TECHNICAL COMMITTEE AND OFFICE OF HEART AND LUNG HEALTH EDUCATION

"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 diseases of the heart, blood vessels, the lung, and blood 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 departments and agencies whose programs involve health functions or responsibilities as determined by the Secretary.

"(c) There is hereby established within the Department of Health, Education, and Welfare an Office of Heart and Lung Health Education which shall provide a program of heart and lung health education for public, medical, and allied health professions. Special emphasis shall be placed upon dissemination of information regarding diet, hypertension, cigarette smoking, weight control, and other factors in

the prevention of arteriosclerosis, cardiovascular disease, and lung disease.

"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, the chief medical officer of the Veterans' Administration (or his designee), 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.

Each of the appointed members of the Council shall be leaders in the fields of fundamental sciences, medical sciences, or public affairs. Not more than twelve of the appointed members of the Council shall be leading medical or scientific authorities who are skilled in the sciences relating to disease of the heart, blood vessels, lungs, and blood, and not more than eight of the appointed members shall be representatives of the general public.

"(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 oc-

curring 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 appointment 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 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–18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for persons in the Government service employed intermittently.

"(c) The Chairman of the Council shall be appointed by the Secretary from among the members of the Council and shall serve as Chairman for a term of two years.

"(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 Director of the Institute or the Chairman, but not less often than four times a year."

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

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

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 419B. For the purpose of carrying out this part (other than section 414), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1973, $450,000,000 for the fiscal year ending June 30, 1974, and $500,000,000 for the fiscal year ending June 30, 1975, of which not less than 20 per centum of the funds appropriated under this section in each such year shall be reserved for programs in connection with diseases of the lung and not less than 20 per centum of the funds appropriated under this section in each fiscal year shall be reserved for programs in connection with diseases of blood.

"SEC. 419C. Notwithstanding any limitation on appropriations for any program or activity under section 419B of this Act or any Act authorizing appropriations for such program or activity, not to exceed 10 per centum of the amount appropriated or allocated for each fiscal year from any appropriation for the purpose of allowing the Secretary to carry out any such program or activity under section 419B of this Act may be transferred and used by the Secretary for the purpose of carrying out any other such program or activity under this part."

DIRECTOR'S AUTHORITY TO APPROVE GRANTS

SEC. 5. Section 419A of the Public Health Service Act (as so redesignated by section 3 of this Act) is amended—

(1) by striking out "grants-in-aid" in subsection (a) and inserting in lieu thereof "except as provided in subsection (c), grants-in-aid"; and

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

"(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Heart and Lung Institute may approve grants under this Act for research and training in heart, blood vessel, lung, and blood diseases—

"(1) in amounts not to exceed $35,000 after appropriate review for scientific merit but without review and recommendation by the Council, and

"(2) in amounts exceeding $35,000 after appropriate review for scientific merit and recommendation for approval by the Council."

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

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

(b) Section 412 of such Act is amended—

(1) by striking out "heart" each place it occurs

(except in the headings) and inserting in lieu thereof "heart, blood vessel, lung, and blood";

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

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

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

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

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

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

(1) by inserting "(a)" immediately after "SEC. 418." and by adding at the end thereof the following new subsection:

"(b) (1) The Council shall advise and assist the Director of the Institute 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 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) by striking out "Surgeon General" each place it occurs (except paragraph (f)) and inserting in lieu thereof "Secretary";

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

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

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

(d) Section 419A of such Act (as so redesignated by section 3 of this Act) is amended—

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

(2) in subsection (b), by (A) striking out "The Surgeon General shall recommend to the Secretary ac-

ceptance of conditional gifts, pursuant to section 501," and inserting in lieu thereof "The Secretary may, in accordance with section 501, accept conditional gifts", and

(B) striking out "heart" and inserting in lieu thereof "heart, blood vessel, lung, and blood".

(e) The heading for part B of such Act is amended to read as follows:

"PART B—NATIONAL HEART AND LUNG INSTITUTE"

CONFORMING AMENDMENTS TO OTHER PROVISIONS OF THE PUBLIC HEALTH SERVICE ACT

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

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

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

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

REPORT TO CONGRESS

SEC. 8. The Secretary of Health, Education, and Welfare shall carry out a review of all administrative processes under which the national heart, blood vessel, lung, and blood disease program, established under part B of title IV of the Public Health Service Act, will operate, including the proc-

esses of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of the program. Within one year of the date of enactment of this Act, the Secretary shall submit a report to the Congress of the findings of such review and the actions taken to facilitate the conduct of the program, together with recommendations for any needed legislative changes.

EFFECTIVE DATE

SEC. 9. This Act and the amendments made by this Act shall take effect sixty days after the date of enactment of this Act or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register.

DEPARTMENT OF DEFENSE,
DEPARTMENT OF THE ARMY,
Washington, D.C., April 26, 1972

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

DEAR MR. CHAIRMAN: Reference is made to your request to the Secretary of Defense for the views of the Department of Defense on H.R. 12460, 92d Congress, a bill "To amend the Public Health Service Act to strengthen the National Heart and Lung Institute and the National Institues of Health in order more effectively to carry out the national effort against heart and lung diseases;" and H.R. 12571, 92d Congress, a bill "To amend the Public Health Service Act so as to strengthen the National Heart and Lung Institute of Neurological Diseases and Stroke, and the National Institutes of Health in order more effectively to carry out the national effort against heart, lung, and neurological diseases and stroke." The Department of the Army has been assigned responsibility for expressing the views of the Department of Defense on these bills.

The purpose of the bills is to enlarge the authorities of the National Heart and Lung Institute, the National Institutes of Health, and other national institutes in appropriate instances in order to advance the national effort against heart and lung diseases and, in the case of H.R. 12571, neurological diseases and strokes through research projects advisory committees, demonstration centers, and control programs.

Inasmuch as enactment of the bills would not affect the operations of the the Department of Defense, the Department of the Army on behalf of the Department of Defense defers to the views of the Department of Health, Education, and Welfare as the agency having primary interest in this matter.

The enactment of these bills will cause no apparent increase in budgetary requirements of the Department of Defense.

This report has been coordinated within the Department of Defense in acordance with procedures prescribed by the Secretary of Defense.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there is no objection to the presentation of this report for the consideration of the Committee.

Sincerely,

KENNETH E. BELIEU,
Acting Secretary of the Army.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., June 1, 1972.

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

DEAR MR. CHAIRMAN: This letter is in response to your requests of January 20, January 28, March 6, March 16, and April 14, for a report on H.R. 12460, H.R. 12571, H.R. 13500, H.R. 13715, and S. 3323 as passed by the Senate, respectively. All of these bills deal with expansion of the national effort in heart and lung disease.

The Department's views on H.R. 13500, H.R. 13715, S. 3323, and similar legislation were presented to the Subcommittee on Public Health and Environment by Dr. Merlin K. DuVal, Assistant Secretary of Health and Scientific Affairs, on April 25, 1972.

Dr. Duval's statement, enclosed, raises objection to certain provisions of these bills, but indicates our preference for H.R. 13715, rather than S. 3323, if the suggestions outlined in regard to H.R. 13715 are incorporated. We would have no objection to enactment of H.R. 13715, if so amended.

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,

ELLIOT L. RICHARDSON,
Secretary.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., May 4, 1972.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, 2125 Rayburn House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your requests of March 16, 1972 and April 13, 1972, respectively, for our views on H.R. 13715 and S. 3323 as passed by the Senate, bills "To amend the Public Health Service Act to enlarge the authority of the National Heart and Lung Institute in order to advance the national attack against diseases of the heart and blood vessels, the lungs, and blood, and for other purposes."

The Department of Health, Education, and Welfare, in testimony before your Committee on April 25, 1972, identified a significant number of objectionable provisions in S. 3323. The Department stated that it would prefer enactment of H.R. 13715 subject to certain revisions, rather than S. 3323, as it passed the Senate. In addition, the Office of Science and Technology in its report on S. 3323, indicates its concerns from a scientific viewpoint about several provisions in the bill, and has also recommended that the Committee adopt the provisions of H.R. 13715 with the changes recommended by HEW, rather than S. 3323.

We concur in the views expressed by the Department of Health, Education, and Welfare and the Office of Science and Technology. Accordingly, we would prefer the enactment of H.R. 13715 with the changes recommended by the Department, rather than the Senate-passed version of S. 3323.

This will also serve as our report on H.R. 13500, H.R. 12571, and H.R. 12460, related bills concerning research on heart and lung diseases on which your Committee has requested our views.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

Mr. ROGERS. This morning our first witnesses will be from the Department of Health, Education, and Welfare. We are pleased to welcome to the committee Dr. Merlin DuVal, the Assistant Secretary for Health and Scientific Affairs; Dr. John Zapp, Deputy Assistant Secretary for Legislation (Health); Dr. Robert Marston, Director of the National Institutes of Health; and Dr. Theodore Cooper, Director of the National Heart and Lung Institute. We welcome all of you gentlemen here. We appreciate your presence today and we will be glad to receive your testimony.

It is the Chair's understanding that Dr. DuVal has a slight case of laryngitis, so he has a spokesman with him to give some of his viewpoints. We certainly understand, and we appreciate your presence here.

STATEMENT OF DR. MERLIN K. DuVAL, ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DR. JOHN S. ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DHEW; DR. ROBERT Q. MARSTON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, DHEW; AND DR. THEODORE COOPER, DIRECTOR, NATIONAL HEART AND LUNG INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DHEW

Dr. DUVAL. Mr. Chairman, thank you very much, I am sorry to be indisposed at the present time. I have a keen interest in this legislation and wish to be present. However, wth your permission, I will ask Dr. Marston to read my statement.

Mr. ROGERS. We understand, and appreciate your being here. Dr. Marston?

Dr. MARSTON. Mr. Chairman and members of the subcommittee, I am pleased to be speaking here today to present the views of the administration on several legislative proposals before your committee. The high incidence and prevalence of diseases of the heart, blood vessels, lungs, and blood constitutes a major national health problem which the President himself has characterized as deeply disturbing. The continued interest in this problem and in the health of the American people which has been demonstrated by this committee is to be commended, and we appreciate the opportunity to share with you our plans for dealing with this health problem.

As you know, the President, in his state of the Union address of this year said:

> * * * we will be giving increased attention to the fight against diseases of the heart, blood vessels and lungs, which presently account for more than half of all the deaths in this country. It is deeply disturbing to realize that, largely because of heart disease, the mortality rate for men under the age of 55 is about twice as great in the United States as it is, for example, in some Scandinavian countries.

The President also stated his intention, which he reaffirmed in his health message of March 2, to assign a panel of distinguished professional experts to guide us in determining why heart disease is so prevalent and what we should be doing to combat it. I am pleased to report to you that the President has named Dr. John Millis, president of the National Fund for Medical Education as chairman of the panel. He has also appointed 18 distinguished physicians to serve on the panel along with Dr. Millis.

Mr. ROGERS. May I interrupt to say that I think it would be helpful if you could furnish the names of the panel for us and their qualifications.

(The following information was received for the record:)

HEART DISEASE STUDY PANEL

ANNOUNCEMENT OF APPOINTMENT OF 18 MEMBERS OF THE PANEL
APRIL 4, 1972

The President today announced that he has asked a panel of experts to determine why heart disease is so prevalent and so menacing and what can be done about it.

Previously, on March 24, 1972, the President announced that he had asked Dr. John S. Millis, president and director of the National Fund for Medical Education, to head the panel. The 18 panel members are:

Arthur C. Beall, Jr., professor of surgery, Baylor College of Medicine, Houston, Tex. Born in Atlanta, Ga., in 1929, he holds the B.S. and M.D. degrees from Emory University. A noted thoracic surgeon, he is the author of more than 200 scientific papers.

S. Gilbert Blount, Jr., professor of medicine and head, division of cardiology, University of Colorado Medical Center, Denver, Colo. Born in Providence, R.I., in 1917, he received the B.S. degree from Rhode Island State College and the M.D. degree from Cornell University Medical College. He won the American Heart Association Research Achievement Award in 1962 and the American College of Cardiology Cummings Humanitarian Award in 1966. He and his wife, Jean, have five daughters, Randa, Ann, Donna, Sarah, and Lauren.

Morton D. Bogdonoff, department of medicine, University of Illinois Medical Center, Chicago, Ill., specialist in internal medicine. Born in 1925, he received his M.D. from Cornell University Medical College in 1948. He completed his residency at the New York Hospital, New York City, and Duke University Affiliated Hospitals in Durham, N.C.

Eugene Braunwald, Hersey Professor of Medicine at the Harvard Medical School in Boston, Mass. Dr. Braunwald, a native of Austria, received his A.B. and

M.D. from New York University. From 1949 to 1952 he was a Schepp Foundation Scholar.

C. Joan Coggin, assistant professor of medicine, Loma Linda University, Loma Linda, Calif. Dr. Coggin was born in Washington, D.C., in 1928 and educated at Columbia Union College, Maryland, and Loma Linda University, California, where she received her M.D. She served as cardiologist with the Loma Linda Heart Surgery Mission to Pakistan and Southern Asia sponsored by the Department of State in 1963 and was cardiologist and codirector of the Loma Linda University Heart Surgery Team in Athens, Greece, 1967–71. She has won awards from the City of Karachi, Pakistan, and Evangelismos Hospital, Athens, for service to the people of those countries.

Julius H. Comroe, Jr., professor of physiology and director, Cardiovascular Research Institute, University of California Medical Center, San Francisco, Calif. Born in York, Pa., in 1911, he received his M.D. from the University of Pennsylvania in 1934.

Eliot Corday, clinical professor of medicine at the University of California at Los Angeles, Calif. Dr. Corday, a native of British Columbia, received his M.D. from the University of Alberta in 1940.

Joyce Wilson Craddick, associate cardiologist at Children's Hospital Medical Center, Oakland, Calif. Born in Laconia, N.H., in 1932, she received the B.S. degree from Wheaton College, Wheaton, Ill., and the M.D. from the University of Pennsylvania School of Medicine. She has also served as teaching coordinator of pediatrics at the Highland-Alameda County Hospital in Oakland and as Norman Leet Fellow and AHA Research Fellow in pediatric cardiology at Children's Hospital Medical Center, Oakland.

Salvadore J. DeVito, chairman of the cardiovascular unit, Laughlin Hospital and Clinic, and clinical professor of cardiology, Kirksville College of Osteopathic Medicine, Kirksville, Mo. A diplomate of the American Osteopathic Board of Internal Medicine and a fellow of the American College of Osteopathic Surgeons, Dr. DeVito received his B.A. from the University of Buffalo and the D.O. degree from Kirksville College of Osteopathy and Surgery. He held a fellowship in cardiopulmonary disease at the Detroit Osteopathic Hospital during 1970–71.

Mary Allen Engle, director of pediatric cardiology and attending pediatrician, the New York Hospital, and professor of pediatrics, Cornell University Medical College, New York, N.Y. She received her A.B. degree from Baylor University and the M.D. from the Johns Hopkins University School of Medicine. She is a diplomate of the American Board of Pediatrics and sub-Board of Pediatric Cardiology. In 1958 she won the Spence-Chapin Award for "Outstanding Contribution to Pediatrics."

Nancy C. Flowers, professor of medicine. Department of Medicine, Medical College of Georgia, Augusta, Ga. Born in McComb, Miss., in 1928, she received the B.S. degree from the Mississippi State College for Women and the M.D. from the University of Tennessee College of Medicine, Memphis. She also attended the Medical College of Virginia School of Physical Therapy.

Mario R. Garcia-Palmieri, professor and head, department of medicine, and chief, section of cardiology, University of Puerto Rico School of Medicine, San Juan, P.R. Born in 1927, Dr. Garcia-Palmieri received his B.S. from the University of Puerto Rico and his M.D. from the University of Maryland. He is a former Secretary of Health of Puerto Rico and president of the board of directors of the Puerto Rico Medical Center. He has published 63 scientific papers and a book on electrocardiography and vectorcardiology in congenital heart disease.

Ronald Martin Lauer, professor of pediatrics and director, section of pediatric cardiology, University Hospital, University of Iowa, Iowa City. Born in Winnipeg, Manitoba, in 1930, Dr. Lauer received his B.S. and M.D. degrees at the University of Manitoba. He is a former associate professor of pediatrics at the University of Kansas Medical Center and assistant professor of pediatrics at the University of Pittsburgh. He and his wife, Eileen, have a son, Geoffrey, 11, and a daughter, Judith, 5.

William H. Muller, Jr., thoracic surgeon, University of Virginia Hospital, Charlottesville, Va., and professor, University of Virginia School of Medicine. Dr. Muller was born in Dillon, S.C., in 1919, and received his M.D. from the Duke University School of Medicine, Durham, N.C. He is a diplomate of the American Board of Thoracic Surgery. His internship and residency were served at the Johns Hopkins Hospital in Baltimore.

John C. Norman, thoracic surgeon, Harvard Medical School, member of staff of Boston City Hospital, Boston, Mass. Born in Charlestown, W. Va., in 1930, Dr. Norman received his B.A. from Harvard College and M.D. from Harvard

Medical School. He is the author of more than 200 scientific papers and in 1971 was named by the Charlestown Gazette-Mail as the "West Virginian of the Year."

Raymond Donald Pruitt, director of the Mayo Graduate School of Medicine, University of Minnesota, dean of the Mayo Medical School, and director for education of the Mayo Foundation, Rochester, Minn. He is former vice president for medical affairs and chief executive officer of the Baylor University College of Medicine. Born in Wheaton, Minn., in 1912, he won his B.S. at Baker University, B.A. and M.A. at Oxford University while a Rhodes Scholar, and M.D. at Kansas University. He has won distinguished service awards from the University of Minnesota, the University of Kansas, and University of Kansas Medical School.

Joseph C. Ross, professor and chairman of the department of medicine at the Medical University of South Carolina, Charleston, S.C. Dr. Ross, a native of Kentucky, received his B.S. from the University of Kentucky and his M.D. from Vanderbilt University. He resides in Charleston, S.C.

Roger J. Williams, director of the Clayton Foundation Biochemical Insitute at the University of Texas in Austin, Tex. Born in Ootacumund, India, Dr. Williams received his Ph. D. from the University of Chicago.

Dr. MARSTON. Mr. Chairman, I would propose to submit the entire statement of Dr. DuVal for the record, but if it is all right with the committee, I would like to move to the middle of page 6 and speak directly to the administration's position on these bills.

Mr. ROGERS. Without objection, the statement will be made a part of the record at the end of your testimony.

Dr. MARSTON. In summary, Mr. Chairman, this administration is in agreement with many of the goals expressed by H.R. 13500, H.R. 13715, and S. 3323 as amended and passed by the Senate. The President has repeatedly stressed his intention to foster an augmented attack on the problems of heart, vascular, and lung diseases. In honoring this commitment, he has made a budget request of more than $250 million for 1973, and he has appointed the panel I described earlier. Any further fiscal requests should await the recommendations of the President's panel as to the appropriate areas for scientific investigation.

In our review of H.R. 13715 we have identified some changes that would, we believe, result in improvement and eliminate some issues that might be troublesome. Excerpts from our Senate testimony concerning S. 3323, as introduced, a bill identical to H.R. 13715, are offered for the record.

Mr. Chairman, I would be pleased to make these available.

Mr. ROGERS. Without objection, they will be made a part of the record at this point.

(The following material was received for the record:)

EXCERPT—TESTIMONY OF DR. MERLIN K. DUVAL BEFORE THE SUBCOMMITTEE ON HEALTH, SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE, MARCH 24, 1972

Mr. Chairman, as reflected in the request for over $250 million for 1973, the Administration agrees with the essential goals contained in a number of the bills before the Committee. The President, in both his State of the Union Message and Message to Congress on Health this year, has stressed his commitment. One of the bills you have before you, S. 3323, captures the concerns we have and, as we understand them, the concerns of the scientific community outside the Government. This Committee has highlighted most of the important matters that need resolution.

In our review of S. 3323, we have identified a few changes that would, we believe, result in some improvement and eliminate some issues that might be troublesome. I would like to list these for your consideration:

AUTHORIZATION LEVELS

The bill would establish specific authorization levels for the conduct of heart and lung disease research for Fiscal Years 1973 through 1975. We have traditionally favored "such sums as may be necessary" in authorizing legislation.

BLOOD DISEASES

Research in blood diseases takes place in several places in the National Institutes of Health. These programs are operating effectively and are more related to the other work of the Institutes in which they now are than to the programs of the National Heart and Lung Institute. The National Heart and Lung Institute concentrates on blood resources, on thrombosis (blood clotting), and on embolic phenomena (the blocking of blood vessels), and on uses of blood as a therapeutic agent. The National Institute of Allergy and Metabolic Diseases performs research on hematological diseases, and has long had an intramural program and laboratory. The National Cancer Institute performs and supports research on blood malignancies, and the National Institute of Allergy and Infectious diseases research on infectious diseases of the blood. If it is understood these programs will continue to be administered where they are, we have no objections.

CYSTIC FIBROSIS

This is a more difficult problem. Research on cystic fibrosis is now being performed and supported by the National Institute of Arthritis and Metabolis Diseases because the disease is a metabolic disorder and the biochemical disturbance which is responsible for the clinical manifestations are not confined to the lungs.

Solutions and control of the disease will not be found in the lungs, but in fundamental and pervading areas involving aberrant metabolism throughout the body. We therefore suggest that cystic fibrosis not be included here.

CONTROL PROGRAMS

S. 3323 would authorize what we interpret as a program of services for heart and related diseases. While we recognize an important aspect of health programs is bridging the gap between the laboratory and the day-to-day use of knowledge in the practice of medicine, we believe that the National Heart and Lung Institute should concentrate its efforts on research activities. Moreover, the Regional Medical Programs of the Health Services and Mental Health Administration are already authorized to conduct programs along the lines proposed in the bill, but in a more comprehensive framework. The delivery of services should only be included in a research institute where essential to the achievement of the research and demonstration functions and this authority is already implicit in the conduct of research.

CONCLUSION

In summary, Mr. Chairman, subject to the preceding comments, we have no objection to the enactment of S. 3323.

I appreciate the opportunity to be here and discuss with the Committee this common concern. My associates and I will be pleased to answer questions.

Dr. MARSTON. S. 3323 as amended and passed by the Senate includes a number of additional provisions which we consider objectionable.

The first area of concern is a matter of general policy. These bills would establish specific authorization levels for fiscal years 1973 through 1975. We favor provision for "such sums as may be necessary" in authorizing legislation for research programs. Specified amounts tend to limit the flexibility desirable for exploiting new developments, and earmarking tends to discourage discontinuance of programs that have outlived their usefulness. Also to specify a fixed percentage of the NHLI appropriation as proposed by S. 3323 for research on diseases of the lungs and blood would further limit the flexibility and professional discretion to set the funding for research at levels commensurate with the scientific opportunities in the field.

The second area of concern has to do with three of the categorical research programs contained in the bill: (1) blood diseases, (2) cystic fibrosis, and (3) asthma. There is a sound basis for the distribution of programs and they should be maintained in their current organizational frameworks. Leaving them undisturbed will in no way compromise the goals of the legislation. For example:

One, because the National Heart and Lung Institute must deal with problems of shock and hemorrhage, it concentrates on resources for blood replacement and transfusion and on thrombosis. The National Institute of Arthritis and Metabolic Diseases studies red blood cell formation and metabolism. The National Cancer Institute conducts and supports research on white blood cells because an understanding of these cells is necessary for studying malignancies of the blood like leukemia. The National Institute of Child Health and Human Development conducts a program on hemolytic disease of the newborn; this is a critical problem that cannot be studied out of the context of pregnancy and total human development. The inclusion of blood diseases in the NHLI authority would be acceptable only if it is understood that these other programs will remain in the Institutes where they are presently located.

Two, cystic fibrosis is a disorder which involves many tissues besides the lungs. The basic biology of this condition is appropriately studied in association with other biochemical and metabolic disorders. Research on cystic fibrosis is now being performed and supported by the National Institute of Arthritis and Metabolic Diseases. Pulmonary facets of the problem are and will continue to be studied by the National Heart and Lung Institute; however, control of the disease will not be found in the lungs alone. Therefore, we recommend that the cystic fibrosis program remain under the aegis of the National Institute of Arthritis and Metabolic Diseases.

Three, asthma is an allergy. Therefore, the key to solving this important problem is an understanding of the basic biology of allergy. The National Institute of Allergy and Infectious Diseases has an extensive program in allergy and has established seven allergic disease centers most of which are studying asthma. The response of the lung to this process is also studied by the NHLI where the primary concerns are the derangement in pulmonary function and metabolism. The present wording of these bills could cause difficulty in program development between the National Institute of Allergy and Infectious Diseases and the National Heart and Lung Institute and could eventually cause a major shift in emphasis which we would consider undesirable and unprofitable from a research standpoint. Deletion of all reference to asthma in the bill will solve this problem.

Unless provisions in the bills for programs dealing with blood diseases, cystic fibrosis, and asthma are altered in such a way as to allow for continuation and growth of these programs as outlined within the Institutes where their program content dictates the greatest research relevance, a number of the Institutes of the National Institutes of Health will experience disruptive blurring of research, unnecessary multiplication of administrative procedures, and perhaps even a dilution of support for essential basic research efforts.

S. 3323 would also mandate the creation of an Office of Heart and Lung Health Education in the Department of Health, Education, and

Welfare. We strongly oppose this provision. It will serve as a dangerous precedent for creating an office to discharge a similar public information function for each major category of disease on which the National Institutes of Health conducts research. Moreover, the statutory creation of such an office restricts the flexibility of the Secretary in organizing the Department and would simply add another organizational layer on top of ongoing activities. Also, section 412(e) of the Public Service Act currently provides that the National Heart and Lung Institute shall—

> Establish an information center on research, prevention, diagnosis, and treatment of heart diseases, and collect and make available . . . information as to, and the practical application of, research and other activities carried on pursuant to this part.

Since the NHLI currently has an ongoing heart and lung public information program, we believe that the proposal to establish a statutory office is unnecessary.

A further cause for concern arises from the inclusion in the Senate-passed bill of an emergency medical services program for victims of heart, blood vessel, lung, and blood diseases. As you know, the President has recently directed the Department of Health, Education, and Welfare to "develop new ways of organizing emergency medical services (EMS)." Accordingly, we are now implementing an "EMS Initiative" to meet this directive under existing legislative authorities in the agency in the Department responsible for health service delivery demonstrations, the Health Services and Mental Health Administration. Under this initiative, we will be supporting the planning, development, initial operation, and evaluation of several areawide comprehensive emergency medical service systems through which the resources of communities will be coordinated for the provision of a full range of emergency medical services regardless of the medical diagnosis. Also under this initiative, we will be establishing and maintaining effective communications and coordination among those Federal departments and agencies, including NHLI, with responsibilities and activities in EMS. The addition of separate and duplicating responsibilities within the NHLI could, in our opinion, be disruptive to the effort underway and would lead to unnecessary duplicating costs and responsibilities.

H.R. 13715, and S. 3323 as amended and passed by the Senate, would authorize what we interpret as a program of services for heart and related diseases. While we recognize an important aspect of health programs is bridging the gap between the laboratory and day-to-day use of knowledge in the practice of medicine, we believe that the National Heart and Lung Institute should concentrate its efforts on research activities. Moreover, the regional medical programs of the Health Services and Mental Health Administration are already authorized to conduct programs along the lines proposed in the bill, but in a more comprehensive framework. The delivery of services should only be included in a research institute where essential to the achievement of the research and demonstration functions and this authority is already implicit in the conduct of research.

In summary, we believe that because of the objectionable provisions we have outlined above, S. 3323 as passed by the Senate, would inhibit the development of a balanced and productive research program. Ac-

cordingly, we would prefer H.R. 13715 to S. 3323, as passed by the Senate, subject to acceptance of our recommendations for changes cited in the excerpts from our Senate testimony on S. 3323, as introduced, which was identical to your bill, Mr. Chairman, H.R. 13715.

My colleagues and I would be pleased to answer any questions you or other members of the subcommittee may have.

(Dr. DuVal's prepared statement follows:)

STATEMENT OF DR. MERLIN K. DUVAL, ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman and members of the subcommittee, it is a pleasure for me to be here today to present the views of the Administration on several legislative proposals before your Committee. The high incidence and prevalence of diseases of the heart, blood vessels, lungs, and blood constitutes a major national health problem which the President himself has characterized as "deeply disturbing." The continued interest in this problem and in the health of the American people which has been demonstrated by this Committee is to be commended, and we appreciate the opportunity to share with you our plans for dealing with this health problem.

As you know, the President, in his State of the Union Address of this year said:

> . . . we will be giving increased attention to the fight against diseases of the heart, blood vessels and lungs, which presently account for more than half of all the deaths in this country. It is deeply disturbing to realize that, largely because of heart disease, the mortality rate for men under the age of 55 is about twice as great in the United States as it is, for example, in some Scandinavian countries.

The President also stated his intention, which he reaffirmed in his Health Message of March 2, "to assign a panel of distinguished professional experts to guide us in determining why heart disease is so prevalent and what we should be doing to combat it." I am pleased to report to you that the President has named Dr. John Millis, President of the National Fund for Medical Education as Chairman of the Panel. He has also appointed 18 distinguished physicians to serve on the panel along with Dr. Millis.

Now, Mr. Chairman, I should like to describe briefly for you the scope of the problem of heart disease and some of our current programs to combat it.

CARDIOVASCULAR DISEASE

Statistics do not reflect the cost of disease in terms of human suffering, but they do illustrate the extent and seriousness of the problem. Each year about one and one quarter million Americans suffer heart attacks; of these, more than half a million die of the attack, and of them one half die too suddenly to receive medical attention. Cardiovascular diseases account for at least 40 per cent of all deaths among Americans in their most productive years, ages 35 to 64, and two-thirds of all deaths among Americans over age 65. The death rate from heart attacks is twice as high for American men as for men in Denmark, Norway, and Sweden, and six times as high as for men in Japan. No age group or economic class is exempt from heart disease, which takes many forms and which often is well advanced before its presence is discovered.

Death from heart disease ranked fourth among causes of death in 1900, at which time the death rate from heart diseases was about 150 per 100,000 population. By 1968 heart disease had not only become the number one killer disease in the country but the death rate had climbed to 373 per 100,000.

The most common form of heart and blood vessel disease is arteriosclerosis, a hardening and thickening of the artery walls. This disease starts early in life and progresses continuously for many years before the patient becomes aware of it. It is probable that in the United States most men and women beyond 50 years of age have moderately advanced arteriosclerosis even though they have not yet manifested any symptoms.

Not only is heart disease the number one killer disease in this country, it is also a major cause of disability. The combined economic and social impact of this morbidity and mortality is enormous. Direct costs of medical care for patients with heart disease and related complications are estimated to cost

billions of dollars per year. Indirect costs as a result of lost work and lost income add to the total.

LUNG DISEASES

Lung diseases also constitute an extremely serious health problem. Some 36,000 people die each year from chronic respiratory conditions, and more than 13,000 of these are under the age of 65 years. These figures do not include the victims of cancer of the lung or of respiratory infections such as tuberculosis, nor do they include the 20,000 infants who die each year with respiratory distress syndrome or hyaline membrane disease. Present therapeutic regimens do not, in most cases, significantly alter the course of these diseases. This means that, with present treatment methods, many Americans will be obliged to submit to what has characteristically been a long and debilitating illness with heavy financial burdens.

BLOOD AND BLOOD DISEASES

Blood diseases and the management of blood resources are health problems worthy of national attention. This Committee has already held extensive hearings on sickle cell disease. You are well aware that an estimated two million black Americans carry sickle cell trait and 25,000 to 50,000 black Americans suffer a painful, debilitating, and life-shortening form of the disease called sickle cell anemia.

Another important blood disease problem involves the clotting of blood. The formation of blood clots within blood vessels—thrombosis—is thought to be implicated in stroke, gangrene of the limbs, blindness of sudden onset, and heart attacks. On the other hand, there are some 10 to 15 thousand severe hemophiliacs in this country who must exercise extraordinary caution because their blood will *not* clot properly. Research to investigate the basic mechanisms of clot-dissolution and blood coagulation and to evaluate drugs permitting manipulation of these mechanisms for preventive or therapeutic purposes is important.

The management of blood resources must be improved. Human blood is an essential health resource. Currently, our society fails to realize all of the potential health benefits from the use of blood because existing arrangements are deficient in meeting blood demand. We need to improve the efficiency of procurement, processing, distribution, and usage methods. The President, in recognition of the problem of blood resources, stated in his recent message on health:

> Blood is a unique national resource. An adequate system for collecting and delivering blood at its time and place of need can save many lives. Yet we do not have a nationwide system to meet this need and we need to draw upon the skills of modern management and technology to develop one. I have therefore directed the Department of Health, Education, and Welfare to make an intensive study and to recommend to me as soon as possible a plan for developing a safe, fast, and efficient nationwide blood collection and distribution system.

Of particular importance are efforts to improve our capability for detecting the presence of hepatitis in blood prior to its use in transfusions. The occurrence of hepatitis induced by transfusion should be preventable. While some progress has been made in the development of a test for hepatitis-associated antigen, a completely effective test remains to be discovered.

CURRENT PROGRAMS

Public and private programs to combat diseases of the heart, blood vessels, lungs, and blood have been serving the American people for many years. The more widely publicized accomplishments of these programs include development of open-heart surgery, pacemakers, the use of cardiac assistance devices, and progress toward an artificial heart. Even more importantly, deaths from hypertension have been reduced by at least 50 percent over the last 15 years, rheumatic heart disease by at least 80 percent over the last two decades, and the primary risk factors in heart attacks—high blood pressure, cigarette smoking, and cholesterol (high blood fats)—have been identified over the last two decades, improving our ability to prevent heart attacks.

The Federal Government has been the principal supporter of research and development of methods to combat and control these diseases, although private efforts have also been extremely important.

THE ROLE OF THE NATIONAL HEART AND LUNG INSTITUTE

The National Heart and Lung Institute conducts direct, categorical programing for diseases of he heart, blood vessels, lung, and blood, and is the primary focus within the Federal Government for research on these diseases.

In 1950 the Institute operated on a budget of less than $11 million. In 1973, in recognition of its important mission, the President's budget contains more than a quarter billion dollars for heart and lung research alone. This reflects the President's firm commitment to support research in these diseases and includes an increase of $22 million in fiscal year 1973.

SUMMARY OF THE ADMINISTRATION'S POSITION

Mr. Chairman, this Administration is in agreement with many of the goals expressed by H.R. 13500, H.R. 13715, and S. 3323 as amended and passed by the Senate. The President has repeatedly stressed his intention to foster an augmented attack on the problems of heart, vascular, and lung diseases. In honoring this commitment, he has made a budget request of more than $250 million for 1973, and he has appointed the panel I described earlier. Any further fiscal requests should await the recommendations of the President's panel as to the appropriate areas for scientific investigation.

In our review of H.R. 13715 we have identified some changes that would, we believe, result in improvement and eliminate some issues that might be troublesome. Excerpts from our Senate testimony concerning S. 3323, as introduced, a bill identical to H.R. 13715, are offered for the record. S. 3323 as amended and passed by the Senate includes a number of additional provisions which we consider objectionable.

The first area of concern is a matter of general policy. These bills would establish specific authorization levels for fiscal years 1973 through 1975. We favor provision for "such sums as may be necessary" in authorizing legislation for research programs. Specified amounts tend to limit the flexibility desirable for exploiting new developments. Earmarking tends to discourage discontinuance of programs that have outlived their usefulness. Also to specify a fixed percentage of the NHLI appropriation as proposed by S. 3323 for research on diseases of the lungs and blood would further limit the flexibility and professional discretion to set the funding for research at levels commensurate with the scientific opportunities in the field.

The second area of concern has to do with three of the categorical research programs contained in the bill: (1) blood diseases, (2) cystic fibrosis, and (3) asthma. There is a sound basis for the distribution of programs and they should be maintained in their current organizational frameworks. Leaving them undisturbed will in no way compromise the goals of the legislation. For example:

1. Because the National Heart and Lung Institute must deal with problems of shock and hemorrhage, it concentrates on resources for blood replacement and transfusion and on thrombosis. The National Institute of Metabolic Diseases studies red blood cell formation and metabolism. The National Cancer Institute conducts and supports research on white blood cells because an understanding of these cells is necessary for studying malignancies of the blood like leukemia. The National Institute of Child Health and Human Development conducts a program on hemolytic disease of the newborn; this is a critical problem that cannot be studied out of context of pregnancy and total human development. The inclusion of blood diseases in the NHLI authority would be acceptable only if it is understood that these other programs will remain in the Institutes where they are presently located.

2. Cystic fibrosis is a disorder which involves many tissues besides the lungs. The basic biology of this condition is appropriately studied in association with other biochemical and metabolic disorders. Research on cystic fibrosis is now being performed and supported by the National Institute of Arthritis and Metabolic Diseases. Pulmonary facets of the problem are and will continue to be studied by the National Heart and Lung Institute, however, control of the disease will not be found in the lungs alone. Therefore, we recommend that the cystic fibrosis program remain under the aegis of the National Institute of Arthritis and Metabolic Diseases.

3. Asthma is an allergy. Therefore, the key to solving this important problem is an understanding of the basic biology of allergy. The National Institute of Allergy and Infectious Diseases has an extensive program in allergy and has established seven allergic disease centers most of which are studying asthma.

The response of the lung to this process is also studied by the NHLI where the primary concerns are the derangement in pulmonary function and metabolism. The present wording of these bills could cause difficulty in program development between the National Institute of Allergy and Infectious Diseases and the National Heart and Lung Institute and could eventually cause a major shift in emphasis which we would consider undesirable and unprofitable from a research standpoint. Deletion of all references to asthma in the bill will solve this problem.

Unless provisions in the bills for programs dealing with blood diseases, cystic fibrosis and asthma are altered in such a way as to allow for continuation and growth of these programs as outlined within the Institutes where their program content dictates the greatest research relevance, a number of the Institutes of the National Institutes of Health will experience disruptive blurring of research, unnecessary multiplication of administrative procedures, and perhaps even a dilution of support for essential basic research efforts.

S. 3323 would also mandate the creation of an Office of Heart and Lung Health Education in the Department of Health, Education, and Welfare. We strongly opposed this provision. It will serve as a dangerous precedent for creating an office to discharge a similar public information function for each major category of disease on which the National Institutes of Health conducts research. Moreover, the statutory creation of such an office restricts the flexibility of the Secretary in organizing the Department and would simply add another organizational layer on top of ongoing activities. Also, Section 412(e) of the Public Health Service Act currently provides that the National Heart and Lung Institute shall: . . . establish an information center on research, prevention, diagnosis, and treatment of heart diseases, and collect and make available . . . information as to, and the practical application of research and other activities carried on pursuant to this part.

Since the NHLI currently has an ongoing heart and lung public information program, we believe that the proposal to establish a statutory office is unnecessary.

A further cause for concern arises from the inclusion in the Senate-passed bill of an emergency medical services program for victims of heart, blood vessel, lung, and blood diseases. As you know, the President has recently directed the Department of Health, Education, and Welfare to "develop new ways of organizing emergency medical services (EMS)." Accordingly, we are now implementing an "EMS Initiative" to meet this directive under existing legislative authorities in the agency in the Department responsible for health service delivery demonstrations, the Health Services and Mental Health Administration. Under this initiative, we will be supporting the planning, development, initial operation, and evaluation of several area-wide comprehensive emergency medical service systems through which the resources of communities will be coordinated for the provision of a full-range of emergency medical services regardless of the medical diagnosis. Also under this initiative, we will be establishing and maintaining effective communications and coordination among those Federal departments and agencies, including NHLI, with responsibilities and activities in EMS. The addition of separate and duplicating responsibilities within the NHLI could, in our opinion, be disruptive to the effort underway and would lead to unnecessary duplicating costs and responsibilities.

H.R. 13715 and S. 3323, as amended and passed by the Senate, would authorize what we interpret as a program of services for heart and related diseases. While we recognize an important aspect of health programs is bridging the gap between the laboratory and day-to-day use of knowledge in the practice of medicine, we believe that the National Heart and Lung Institute should concentrate its efforts on research activities. Moreover, the Regional Medical Programs of the Health Services and Mental Health Administration are already authorized to conduct programs along the lines proposed in the bill, but in a more comprehensive framework. The delivery of services should only be included in a research institute where essential to the achievement of the research and demonstration functions and this authority is already implicit in the conduct of research.

CONCLUSION

In summary, we believe that because of the objectionable provisions we have outlined above, S. 3323 as passed by the Senate, would inhibit the development of a balanced and productive research program. Accordingly, we would prefer H.R. 13715 to S. 3323, as passed by the Senate, subject to acceptance of our rec-

ommendations for changes cited in the excerpts from our Senate testimony on S. 3323, as introduced, which was identical to your bill, Mr. Chairman, H.R. 13715. My colleagues and I would be pleased to answer any questions you or other members of the Subcommittee may have.

Mr. ROGERS. I might say I presume you know most of the subcommittee members have introduced separate legislation for emergency health care. We will probably be taking this up this year to deal with this problem rather than separating it into various pieces of legislation.

Mr. SATTERFIELD. Thank you, Mr. Chairman. I think this statement is a very lucid one. It certainly points up your views. I don't think there is much question about what it is you are saying. I will study it very carefully as we get into this bill. I appreciate your coming here his morning and delivering it.

Mr. ROGERS. Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman. I think the statement has been very good and I find many of the suggestions about the Senate bill to be, in my opinion, correct. I think your position is correct in that, except that that bill might be adding to overlaying the work of different agencies, and I think it should be simplified as you suggest.

I was interested in some of the things you said about heart diseases, some of the causes. What do you think is the most prevalent cause of heart disease?

Dr. COOPER. Arteriosclerosis of the coronary arteries is the most common cause of heart disease in this country today.

Mr. CARTER. Why is the rate in Denmark so much less than the United States?

Dr. COOPER. I don't know the answer to that question. It is an important one we must pursue to find what we can do in order to further our own interest. The important thing to keep in mind, in addition, is that Denmark and these other Scandinavian countries are beginning to catch up with us. What we may be seeing is a lag as they reach the peak of disease incidence.

Mr. CARTER. What is the cause of arteriosclerosis? Large amounts of cholesterol would cause this, arteriosclerosis, and so forth.

Dr. COOPER. What we have been able to identify so far are several factors called risk factors which seem to be associated with the development of arteriosclerosis. But no single one can be said to be the cause of arteriosclerosis. The most serious of these risk factors are cholesterol, high blood pressure, cigarette smoking, overweight, diabetes, inactivity, and stress.

Mr. CARTER. So far as cholesterol is concerned, I think the diet of the Danes should be as heavy as it is in the United States.

Dr. COOPER. That is correct.

Mr. CARTER. To get the basic cause of this, don't you think that stress has more to do with heart attacks than almost any other one thing?

Dr. COOPER. Stress is an important cause that has been identified in several studies thus far. It may be that stress expresses itself through some common metabolic path perhaps related to the liquid hypothesis.

Mr. CARTER. We know that stress does express itself in different actions within the body, internal secretions and so on?

Dr. COOPER. Yes, indeed.

Mr. CARTER. I would suggest to you that certainly I believe it is probably the most comon cause of deaths from heart conditions. Many people think this is true.

Dr. COOPER. Yes.

Mr. CARTER. I notice in your paper you mention sickle cell anemia. We did pass a bill on that in which 25,000 to 50,000 of our black people suffer. Do you have any evidence of the number of people in the United States that have pernicious anemia.

Dr. MARSTON. We would submit that for the record.

(The following information was received for the record:)

NUMBER OF PEOPLE IN THE UNITED STATES HAVING PERNICIOUS ANEMIA

An estimated range of 13,000 to 20,000 people in the U.S. are found to have pernicious anemia.

Mr. CARTER. Do you think it is as large a problem as sickle cell anemia?

Dr. MARSTON. It certainly is a large problem at present. In terms of control of the disease, I think we do a better job of controlling pernicious anemia than we do sickle cell anemia.

Mr. CARTER. There is no question about that, because we do have and have had medicines which would permit a pernicious anemia patient to live longer and more comfortably. I noticed you don't want this particular part in the Heart and Lung Institute; is that correct?

Dr. MARSTON. I think I would point out, as far as the sickle cell anemia program is concerned, while the Heart and Lung Institute is carying the lead role there, it is a coordinating role not only with the other institutes in NIH, but with the community-based programs and family planning services of the Health Services and Mental Health Administration. So I think we have made it very clear in the sickle cell anemia cause that this is not a Heart and Lung Institute program. It is a joint program involving a number of agencies.

Mr. CARTER. You would include that in which institute instead of the Heart and Lung Institute—the study of the different blood diseases, pernicious anemia, leukemia, and so on?

Dr. MARSTON. There are different parts of it. Leukemia, of course, is primarily the responsibility of the Cancer Institute, and there are other problems and blood-related things such as hepatitis. This covers four institutes. I have set up a formal coordinating activity to be sure that maximal use of the competence and facilities of these various institutes is used. I don't think you can take an area like hematology and say it belongs to just one categorical disease institute. You have to go further down the line and do as you have done, pick out something like leukemia, or sickle cell, or pernicious anemia.

Mr. CARTER. You would fragment it among different institutes; is that correct?

Dr. MARSTON. I think there is no way in medicine one can have an organizational arrangement that doesn't lend to some overlaps. I don't consider this a fragmentation.

Mr. CARTER. I believe the concentration on hematological diseases should be made. I believe you can coordinate them. Don't you think you should have a group that does work on hematology particularly?

Dr. MARSTON. Yes; and if I had one institute on it, this would be the Arthritis and Metabolic Disease Institute—that would have that

focus. On the other hand, it is important for the Heart and Lung Institute to be concerned about blood resources.

Mr. CARTER. Thank you, Mr. Chairman.

Mr. ROGERS. Dr. Roy?

Mr. ROY. I have no questions at this time, Mr. Chairman. Thank you.

Mr. ROGERS. Maybe you could tell us right new what your present setup is in the National Heart Institute. How many people do you have working for you, your budget, how many working on lung, how many on heart, and so forth?

Dr. COOPER. Yes, sir. At the current time we are staffed at approximately 600 positions. We expect to complete the year at approximately 625 positions, and our plan for next year calls for an additional 38 positions.

Mr. ROGERS. How many of those are Ph. D.'s or M.D.'s, and so forth?

Dr. COOPER. Approximately 75 full-time people in the intramural program are full-time professionals out of a total cadre of 358. An additional 150 are young sicentists and physicians who will be with us for a short period of time.

In the nonintramural portion of the Institute, we have approximately another 50 professionals. The remaining staff of the Institute is made up of technical support and clerical support. The majority of our people are concerned with programs that are related to the cardiovascular mission of the Institute.

In the pulmonary segment, we began our program in late 1969, and at the present time we have nine people at the professional level spending their time on the study of the lung. In addition, a good deal of the clerical and program staff, obviously, perform functions for all segments of the Institute's program. So we would have to fractionate out the rest of the nonintramural staff for their role in the management and administration of the pulmonary programs.

Mr. ROGERS. In other words, you have no specific separate section handling the extramural programs for lung?

Dr. COOPER. That is right. We combine them to make it a more efficient operation. The pulmonary section is as yet a small portion of the total Institute's expenditures; approximately 10 percent. Therefore, we have not duplicated services by maintaining a separate pulmonary line.

Mr. ROGERS. What expertise do those handling the extramural program have in the lung and pulmonary disease section?

Dr. COOPER. The way we have arranged this is that we have recruited a director for our lung program who is an associate director of the Institute, Dr. Claude Lenfant, from the University of Washington. He has recruited during this past year two people in the extramural program to begin the core of the pulmonary extramural branch. They are supported by clerical staff. One is basically metabolic oriented toward the metabolics of the lung and the second is related to the physiologic functions of lung.

In the collaborative division Dr. Lenfant has recruited two people to begin the operations directing a contract program in that area. In addition, he has initiated the centers program and utilizes himself and the extramural staff to begin this program.

Mr. ROGERS. What is the center's program?

Dr. COOPER. During this past year the Institute initiated what we call the SCOR program, which are specialized centers of research. There are 11 in pulmonary disease, 34 altogether and these are divided between arteriosclerosis, thrombosis, lung disease, and hypertension. These are multidisciplinary efforts located mainly in medical schools which focus on special portions of the pulmonary disease program where they have the competence and the interest and the resources to develop a multidisciplinary approach.

For example, three are devoted largely to the study of pulmonary problems in children. There are epidemiologic approaches in others. There are others focusing mainly on emphysema and chronic bronchitis and so on.

We are also trying to develop a devices program, a respiratory assistance devices program, and one professional in the medical devices program is devoting his attention to this.

In the intramural program we have now two people working on this. We have initiated a pulmonary function laboratory which will be able to service the hospital as well as the research program, and we have recruited a basic protein chemist who will be beginning the studies on the basic properties and functions of the lung. At the present time Dr. Lenfant coordinates this and interdigitates it with the rest of the programs of the Institute.

Mr. ROGERS. So you have three people doing research in your intramural program?

Dr. COOPER. Yes, sir. This is a program which we plan to expand during this next year. We have developed the space. The initial part of the problem in recruiting the staff was the unavailability of space until this spring. New modules have been freed up by the transfer and the closing of other older laboratories, and we expect that a fully functioning pulmonary program on the intramural program should have at least 36 people, the average in our other major applied laboratories.

We also expect that many of the scientists in the basic biochemical pharmacology, and genetic laboratories will begin to devote some of their time and convert their interest to the pulmonary mission. We expect to accomplish this next year.

Mr. ROGER. You expect to have 36 people abroad?

Dr. COOPER. I doubt whether we can recruit 36 professionals all at one time, but the goal would be to reach a standard operating laboratory program in the intramural program. This averages in our institute to about 36 people. This would probably take us a couple of years to accomplish.

Mr. ROGERS. You started getting into this in 1969?

Dr. COOPER. Yes, sir.

Mr. ROGERS. How many people were hired in 1969?

Dr. COOPER. None in 1969.

Mr. ROGERS. How many in 1970?

Dr. COOPER. In 1970 we hired Dr. Lenfant and then we recruited one extramural chief at that time. The remaining people were acquired during this past 1971.

Mr. ROGERS. So, basically, at this moment you have no real intramural research program?

Dr. COOPER. That is right: Only the core pulmonary function laboratory and the initial implementation of the chemical program.

Mr. ROGERS. Now in heart you say you have 75 in the intramural program?

Dr. COOPER. Seventy-five at the professional level, plus the 150 young scientists that are there for short periods of time.

Mr. ROGERS. What periods of time?

Dr. COOPER. They generally serve 2 years to 3 years in their tour with the Institute.

Mr. ROGERS. Now, are all these 75 in intramural research actually doing active research?

Dr. COOPER. Yes.

Mr. ROGERS. Could you set forth in the record for us all of the various programs you are researching and how many people are devoted to it and their qualifications?

Dr. COOPER. Yes.

(The following information was supplied for the record:)

INTRAMURAL RESEARCH PROGRAMS, WITH PEOPLE ENGAGED AND THEIR QUALIFICATIONS

The Institute's intramural clinical research programs include twenty-one senior investigators in cardiovascular diseases, three in blood diseases, and five in pulmonary diseases. In addition, there are thirty-six younger or temporary scientists in the cardiovascular area, four in blood diseases, and two in the pulmonary field.

Mr. ROGERS. What has been your budget beginning in 1969 for the whole institute and then a breakdown of intramural and extramural.

Dr. COOPER. The budget in 1969 was approximately $161 million. I can provide the specific figures. In 1970 we increased the budget by $35 million.

Mr. ROGERS. So that would make it how much?

Dr. COOPER. We went to $196 million approximately. Then we went on to another $37 million and that brought it to the current $232 million.

Mr. ROGERS. 1973?

Dr. COOPER. 1973 is planned for $254 million.

Mr. ROGERS. If you would give us a breakdown of intramural and extramural. What are the percentages?

Dr. COOPER. The percentage is approximately 10 percent.

Mr. ROGERS. Intramural?

Dr. COOPER. Intramural.

Mr. ROGERS. That is in the heart field?

Dr. COOPER. It has largely been in the heart field and the basic laboratory undergirding the applied cardiac laboratories.

Mr. ROGERS. Should it be more?

Dr. COOPER. Should which be more?

Mr. ROGERS. The intramural programs.

Dr. COOPER. For us to accomplish our pulmonary mission we should be doing more in the lung and in certain blood areas particularly applicable to our Institute's mission. We hould be doing more, and that is in our forward plan.

Mr. ROGERS. You say nine people in lung have been recruited. Are they actually on board?

Dr. COOPER. Yes.

Mr. ROGERS. What is your current breakdown between lung and heart?

Dr. COOPER. We haven't finished our current year's allocations and reviews yet, but our current obligations on the lung program this year will be between $22 million and $25 million.

Mr. ROGERS. How much is intramural, 10 percent of that?

Dr. COOPER. I doubt whether it is 10 percent of that at the present time. The support of those people and the implementation of the pulmonary laboratory would be less than 10 percent.

Mr. ROGERS. So you are doing less than 10 percent in lung intramurally?

Dr. COOPER. Yes, sir.

Mr. ROGERS. What about heart? That would leave what for heart, projecting $25 million.

Dr. COOPER. I think if we consider our blood program separately, we will be spending approximately $35 million on blood and about $25 million on lung. This will leave roughly between $185 and $194 million on the cardiovascular program.

Mr. ROGERS. Could you tell use the difference between a stroke, a heart attack, and heart failure? Can you differentiate these for the committee?

Dr. COOPER. What we call a stroke is a cerebral stroke and this is an occlusion or disruption of the blood supply to the brain which results in difficulties in speech, paralysis, or unconsciousness.

A heart attack is a lack of blood supply to the heart muscle itself which occurs by occlusion of the blood vessels to the heart or within the heart. It causes disturbances in function, disturbances in rhythm, or death of heart tissue in the area that is deprived of blood supply. This is associated with a great deal of pain, along with anxiety on the part of the patient. This is what is known as a heart attack.

Heart failure, on the other hand, is a weakness of the pumping function of the heart which can be caused by arteriosclerotic disease, deficient blood supply for a long period of time, toxic effects, other types of disease, such as rheumatic diseases, valvular disease consequent to rheumatic fever, weakening of the heart, and a weak heart cannot pump well. It results in a fluid backup of the lungs, shortness of breath, accumulation of fluid in the legs, anemia, poor exercise tolerance, and so on.

Mr. CARTER. If the distinguished gentleman would yield.

Mr. ROGERS. Certainly.

Mr. CARTER. I believe you stated a heart attack was caused by an interruption of the blood supply to the heart, which in many cases I know is true. However, what would you say is paroxysmal tachycardia?

Dr. COOPER. A sudden attack of altered rhythm of the heart is often called, in common parlance, a heart attack.

Mr. CARTER. It has nothing to do with the blood supply.

Dr. COOPER. It may not. Often it does not.

Mr. CARTER. Most of the time it doesn't.

Dr. COOPER. It is an alteration in the electrical matrix of the atrium, which could be modified by hormonal influences, ingestion of large amounts of coffee, and so on.

Mr. CARTER. Or stress.

Dr. COOPER. Or stress; yes, sir.

Mr. ROGERS. What is the area that offers most hope, do you feel, in the attack on heart disease?

Dr. COOPER. I think the area that offers the most hope at the present time in the large problem of arteriosclerotic disease or the heart attack problem would be the control of the risk factors or an attempt to intervene on the risk factors in order to minimize what effect they may have on the development or initiation of the disease; that is, the early detection of hypertension and particularly treating those hypertensions that are known to be moderate or severe.

Secondly, would be the elimination of the lipid abnormality if it exists, trying to keep the lipid abnormality down, and the elimination of cigarette smoking.

Mr. ROGERS. What do you mean by "lipid"?

Dr. COOPER. The fatty substances in the blood that are associated with the increased risk of arteriosclerosis, specifically cholesterol and triglyceride.

Mr. ROGERS. The third was what?

Dr. COOPER. Cigarette smoking.

Mr. ROGERS. What about diet other than the fat? Is there any problem there?

Dr. COOPER. Yes, in two ways. The most important way that you can manage elevated cholesterol when elevation is not due principally to the inheritance is by regulation of total caloric intake. That is another way of saying you should seek your lean weight. This will help a great deal in minimizing the effects or propensity toward elevation of serum cholesterol.

Other types of cholesterol abnormalities are related to the ingestion of other food substances, such as carbohydrates and sugars. It is a problem of what you eat, not just how much, but both are important. It is both the total calories and the composition.

So weight control, activity control, the control of stress, the elimination of stress, and personality factors, ought to influence the progress of the disease.

Mr. CARTER. Mr. Chairman, would you yield?

Mr. ROGERS. Certainly.

Mr. CARTER. I would like to ask you if decreased ingestion of cholesterol is always paralleled by a decrease in blood cholesterol.

Dr. COOPER. No, it is not.

Mr. CARTER. It is not? Do you mean the less fat you eat doesn't always mean you also have less cholesterol and triglycerides in the blood; is that correct?

Dr. COOPER. If it is associated with eating less cholesterol or less fat when you take in fewer total calories, the answer would be yes. But very often people have been advised to stop eating cholesterol and went on their way eating a lot of other substances and their cholesterol did not lessen. We have to adjust the total caloric composition. Then I think most people will lower their cholesterol.

Mr. CARTER. Is it true there is a genetic factor in this?

Dr. COOPER. Yes.

Mr. CARTER. What do you do in a case like that? Will ingestion of cholesterol influence the blood cholesterol if there is a genetic factor?

Dr. COOPER. Very often the cholesterol lipid factor will be influenced by the amount taken in.

Mr. CARTER. In some cases I have had, I am sure that people who rigidly adhered to their diets and the blood cholesterol remained high. I think no doubt the cause was a genetic factor. I regret to say I doubt if diet would have much effect in those cases.

Mr. ROGERS. Is it a genetic cause?

Mr. CARTER. Yes, sir.

Dr. COOPER. We feel, also, in the genetically susceptible persons—diet will not be helpful in reducing the cholesterol level itself. We think other factors would be required.

Mr. ROGERS. What are we doing for early detection in the Nation? Do we have any programs? Do you have any programs? Are you funding any such programs, or are there any centers carrying out such programs now?

Dr. COOPER. We are initiating this current year two programs.

Mr. ROGERS. Do you mean we are doing nothing at the present?

Dr. COOPER. This Institute is not supporting a program of detection. We are initiating in the present year a community program in hypertension, a program in lipid research clinics and a multifactor program in order to accumulate the scientific evidence that we need. To acquire this, we will indeed have to begin in the community, establish quality controlled laboratories, standard setups and screening of large numbers of people in the free-living population in order to select out the high susceptibles. But it is not a program of detection for detection's sake in the treatment-service sense.

Mr. ROGERS. Let me ask you this: If you can detect hypertension early, does that help? Can you then treat it?

Dr. COOPER. If there is followthrough on therapy, it will help, yes, sir.

Mr. ROGERS. I am saying do we know how to treat it if we can detect it?

Dr. COOPER. In the moderate and severe forms we could, indeed, do that.

Mr. ROGERS. Should that be done to prevent heart attacks?

Dr. COOPER. In the moderate to severe case I feel this is a program that should be done by somebody.

Mr. ROGERS. I know the Department takes the position they don't want anything done like that in NIH. I understand that.

Dr. COOPER. I want to qualify what I am saying. The very excellent studies of the Veterans' Administration by Dr. deVries has demonstrated in the moderate and severe hypertensives that aggressive treatment with medications currently available will reduce deaths from stroke and heart failure. We still haven't proven it will eliminate the risk factor for heart attack. This is an important thing that must continue to be studied. But there is no question that an important influence on cardiovascular disease mortality would be obtained by detecting the millions of hypertensives that are not known at the present time and getting the ones that are in the moderate and severe categories to undergo proper treatment.

Mr. SATTERFIELD. Would the gentleman yield?

Mr. ROGERS. Certainly.

Mr. SATTERFIELD. In connection with a person working in a "proper field," would this involve a change in working environment, working conditions? Or can the objective be achieved without that type of change?

Dr. COOPER. In many cases I think so. In hypertension of the moderate and severe degree there are current drugs and understandings of salt and water metabolism and salt-free diets that could affect significant improvement in the lives of those people.

Mr. ROGERS. Now, what about the elimination of the lipids? That is a question of diet?

Dr. COOPER. Diet is a factor, in our opinion, in the management of all abnormal lipids. We think that the diet alone will be ineffective in many types of lipid abnormalities. We feel the important thing here is weight control and that is based on diet and a balance between activity and diet; weight control, selective identification of the genetic and other abnormal lipid types. Then there are other pharmacologic and research approaches that may be used in special cases to treat these people. But weight control, activity control, will be an important factor in almost every case to help reduce the risk based on the elevated cholesterol.

Mr. CARTER. Mr. Chairman?

Mr. ROGERS. Yes.

Mr. CARTER. What really has been the basic reason for control in hypertensive cases in the past few years?

Dr. COOPER. I think there are probably three categories of influences, Dr. Carter. One is the recognition that all hypertension is not idiopathic. There are many cases that can now be diagnosed and treated specifically, whether it be secondary to renal disease or other forms of vascular disease. Second, is the availability of potent pharmacologic agents, such as guanethidine and reserpine.

Mr. CARTER. As I see it, other drugs you have mentioned are quite effective, but thiazides have done more to control hypertension than almost any other drug?

Dr. COOPER. Yes, I think they have a wider applicability with wider margin of safety in influencing the background that salt and water plays on the response of neural hormones and other factors.

Mr. ROGERS. Now, let me ask you, if diet is a factor—evidently it is for weight, cholesterol, and nutrition, I presume—the foods that we eat have a definite effect on all of this. What have you done to work with Food and Drug and the National Academy of Sciences and their diet committee, Food Standards, to get any action to change the American diet? Have you taken any action as a department?

Dr. COOPER. We in the Institute have worked with the Food and Drug Administration in the efforts to improve food labeling. One of the important things is, if I say it to a housewife, you should feed your husband and family a 30- to 35-percent fat diet, that she be able to select foods to provide this. With the nutritional background of the physicians in many cases, much less the public, they are unable to easily translate into a workable and economically feasible program of food planning or a diet in meal planning the requirements to lower fat.

So we do think that a program of labeling of foods will not only insure some information about what a calorie count means and how

to become facile in doing it, but in trying to determine the composition of what you take in. We have been active with the Food Committee of the Academy since 1966 in the discussions of what are appropriate criteria, and have recently worked with the Food and Drug Administration in their plans on fat labeling.

Mr. ROGERS. Now, what action has been taken? Has the Academy recommended any changes? Have they come out with any change of standard?

Dr. COOPER. I have not seen a recent position.

Mr. ROGERS. It is all study, study, study but no action.

Dr. DUVAL. Mr. Chairman, the FDA has been meeting with National Academy of Sciences representatives of the consumer groups, to collate information from the consumer groups as to how best they would like to have the information displayed. We are tremendously encouraged by this. It is not easy labeling foods, but progress is being made.

Mr. ROGERS. Even in the classification of milk, do you work with Agriculture on that? They have gotten the American people believing it is better to have butterfat in the milk. It is a great appeal. Is this good?

Dr. DUVAL. In some instances it is good and in some it isn't. Obviously, that doesn't fall within our jurisdiction, so it is a little more difficult to control.

Mr. ROGERS. Why not? If you can influence diet and labeling, why shouldn't it be? If it is related to health, it is a health factor.

Dr. DUVAL. It is a dairy product and it falls under the Agriculture Department.

Mr. ROGERS. That is why we need a separate Department of Health.

Dr. DUVAL. The President's Department of Consumer Resources would do the same thing.

Mr. ROGERS. I can't see why you can't take action now. That is what I don't understand. If milk products have fat in them, why don't we have a different categorization? Have you had discussions with Agriculture on that?

Dr. COOPER. Yes.

Mr. ROGER. What do they say?

Dr. COOPER. They indicated it was possible to modify many of the food products that are currently impugned to be dangerous. They seek from us the evidence that it is definitely dangerous, which we really do not have as definitive evidence. We have the risk factor approach. They are working on the sort of programs in which you could reduce the saturated fat content of beef and make it more polyunsaturated or leaner. So I think the discussions have gone on and they regularly are appraised by us of what our current findings in the lipid metabolism field are.

Mr. ROGERS. It is my understanding that this can be done. We know how to do it, but until there is positive proof it will affect every person the same way, they don't want to do anything?

Dr. COOPER. They want proof that lowering the blood lipids and eliminating the other risk factors will in fact prevent heart attacks or prevent the progress of the disease.

Mr. ROGERS. Doesn't the fat also put on weight? When you eat fat, doesn't it have a tendency to increase your weight?

Dr. COOPER. Fat is a high caloric food. If a lot of it is in your total diet you will gain weight, but the problem is not fat alone.

Mr. ROGERS. But I think that would be one of the factors we want to eliminate.

Dr. COOPER. Yes, sir.

Mr. CARTER. Mr. Chairman, we brought out just a few minutes ago that in Denmark, where the production and consumption of milk products is probably twice as high as it is in the United States, heart attacks are half as numerous as they are here. You see, there are factors other than the ingestion of fats involved. I think a lot of this is a matter of exercise on the part of the people of this country. If they exercise enough they will metabolize the ingested food.

Mr. ROGERS. I understand that, but I don't know how we can get the American people to exercise. I think we can change the diet, and if you cut the fat out that ought to help. I know in Norway during the war—and this can be documented—when they cut out milk and dairy products—and I am not advising that; I am just saying get some fat out of it—Ancher says take it easy—but when they cut it out of the diet, heart disease and heart attacks dramatically fell. When it was put back in the diet after the war, it went up again.

Now, I am not going to press that too far, Ancher, but I am sure, as Dr. Carter says, if you get people to exercise properly, to bring about a metabolism, it would use it up. I can understand that. But I think it is going to be easier to change the diet than to get people to exercise.

Mr. NELSEN. Mr. Chairman, Dr. Carter referred to Denmark. I have recently been there. They ride bicycles in Denmark. I am going to contribute to your bicycle if you will exercise a little more.

But don't be too tough on my dairy cows, because they claim you can drop a dime to the bottom of a pail of Holstein milk and see it on the bottom. So I think we move in the direction of less fat.

Mr. ROGERS. I think this is what we should do, but we are not doing enough of it.

Mr. CARTER. There is one question I would like to ask the heart specialist here. What is colostrum?

Dr. COOPER. Colostrum is the early phase of lactation products that comes in mothers' milk just before the mothers' milk.

Mr. CARTER. What is the chemical composition?

Dr. COOPER. I can't cite for you the exact composition, but I know it does have substantial amounts of lipid in it, as well as protein.

Mr. CARTER. It is heavy in lipid and cholesterol and triglycerides and so forth?

Dr. COOPER. Yes, sir.

Mr. CARTER. My question is: What are we going to do to lessen this in order to provide our youngsters——

Dr. COOPER. I don't think the chairman wanted to imply that at all stages of life all fats should be eliminated. Many fats in the diet are essential for good health. It is again here a proper prescription in balance for the situation at hand.

Mr. CARTER. Then you would advise mastectomies; is that correct?

Dr. COOPER. No, sir.

Dr. DUVAL. Mr. Chairman, I would remind Dr. Carter, as he well knows, that the urgent need for calories at that stage of the game is precisely why the fat level is so high.

Mr. CARTER. It is unusual that youngsters when they come are provided with higher levels of cholesterol.

Dr. MARSTON. Mr. Chairman, it seems to me that the discussion on this problem is important and the questions have looked into the current state of the art in the lipid areas. Would it be helpful to the committee to provide you with a short statement at this time of our assessment of the present state of the art on which these discussions are based?

Mr. ROGERS. I think we should have for the record what you are doing, what discussions there have been, any action if any—and I haven't seen much—what the chances are for any action.

Dr. MARSTON. I think the very fact that we have talked this morning as if there were one type of lipid problem, whereas there are discrete types with different implications, as far as the diagnosis and treatment is concerned, indicates different implications in terms of additional information that we need, different implications in terms of very broad policy issues facing the country. If you would like that statement, we can provide it. (See pp. 176–178, this hearing.)

Dr. COOPER. May I add one thing? In the context of what we are doing, understanding these five or six different types of lipid abnormalities, the Institute has now distributed about 2 million specific booklets which are designed for the physicians' guidance in how to determine the abnormalities and then how to set up a dietary regimen for each one of these. These are in high demand by physicians around the country.

Mr. ROGERS. Aren't we at the point where we know enough risk factors that we ought to be able to take some action? We often have to do this in many areas.

Dr. DUVAL. That would be premature. I think we are making very good headway and it is very attractive and appealing, but it is not quite there. The most we know today, for example, in the incidence of strokes, we have epidemiologic evidence that says if you have high blood pressure and high blood fats in a person who is a smoker and those three things occur together, you then have very markedly changed the incidence of stroke.

Beyond that finding, which is relatively contemporaneous, we don't have much. The confusion has been well illustrated by Dr. Carter's point. We don't know whether it is exercise. We don't know whether it is high fats. We are not quite there yet. So while we are moving in the area where this may prove to be important, I think it would be equally wrong to move precipitously without firm answers.

Mr. ROGERS. I don't know whether it is precipitous to move when you know those three factors combined will bring it about. With anyone who has that combination we ought to be able to take some action.

Dr. DUVAL. We are just now starting.

Mr. ROGERS. You are slow starting. How long has the Heart Institute been in being?

Dr. COOPER. Since June of 1948.

Mr. ROGERS. I have quite a number of questions but there are other witnesses, too, and I haven't even yet given Dr. Carter or Mr. Nelsen an opportunity to ask questions.

Mr. NELSEN. Very briefly, Mr. Chairman, I received a call from the University of Minnesota Medical School concerning the possibility of

our current legislation on heart, including research on stroke. They feel it should continue to be separated and not included in this bill. Because of the neurology angle and the relationship of the nerve centers of the body, they feel a totally different study should be made.

Dr. MARSTON. I think we would agree that the situation that we have at present indicates clearly the Heart and Lung Institute has an interest in stroke, but the primary responsibility with the Neurological Disease and Stroke Institute should be continued. We have on an ongoing basis, and have had now for 4 years, a committee with representation from both of these Institutes that meets on a regular basis for these programs.

Mr. NELSEN. One other question. You referred to heart attacks and severe pain. It seems to me there are many deaths by heart attack that are almost painless.

Dr. COOPER. There are probably many different manifestations of a heart attack, depending on which portion of the heart is injured and which portion of the blood supply is injured. On a statistical basis, about 80 percent of the heart attacks are associated with clear signals, the most important of which is pain. Probably about 15 to 20 percent occur either when you are sleeping or without any associated pain.

Very often what is called really instantaneous death can occur from an arrhythmia of a serious nature, from ventricular fibrillation with no serious pain at all.

Mr. ROGERS. Dr. Roy?

Mr. ROY. Do you support or not support the interagency technical committee idea?

Dr. DUVAL. We have one in operation now with regard to the certain aspects of heart disease. In principle we do.

Mr. ROY. Do you think there is any labeling at the present time that would be worth while, labeling of cholesterol contents in foods?

Dr. DUVAL. I am reluctant to answer that affirmatively. We do think that labeling of foods, from the viewpoint of calories and general nutritional value, is keenly desirable. We are a little reluctant to move too far into the area of labeling in the area of cholesterol because we are not certain of its meaning.

Each time you take that step you further, as it were, excite the public. We are cautiously looking at that one. We are moving more vigorously in the area of labeling of nutritional value.

Mr. ROY. If foods were labeled, those who chose not to eat a great deal of cholesterol would have a choice; is that correct?

Dr. DUVAL. That is correct.

Mr. ROY. You say that RMP has the duty of bringing some information you have to the practicing physician. Could you submit for the record what program RMP has and in fact what is being done?

Dr. DUVAL. Yes.

(The following material was received for the record:)

UPDATING THE KNOWLEDGE OF HEALTH PROFESSIONALS—
REGIONAL MEDICAL PROGRAMS

Continuing education activities must deal increasingly with health care system improvement. Regardless of how well continuing education is now provided or will be provided in the future, the public benefits will depend upon the extent to which continuing education efforts give attention to the management and utilization of health services. The goal of continuing education is improving the per-

formance of the provider of the services so that the maximum benefits of science are provided to the consumer through effective health care delivery.

Regional Medical Programs are supporting sixty (60) projects which are designed to update the knowledge and improve the skills of health professions in the area of heart disease. These efforts constitute a significant thrust in Regional Medical Programs throughout the country—the expenditure in this fiscal year amounts to over four million dollars.

The New Jersey RMP, in an effort to improve manpower utilization, is supporting a program to standardize coronary care unit training programs for licensed practical nurses, so that they can function with the same protection and legal sanctions as registered nurses. Given a high turnover rate among coronary care unit trained registered nurses, their use as supervisors and teachers of licensed practical nurses may represent better utilization of professional nursing personnel.

Other manpower and training activities, although basically designed to provide continuing education for professional and allied health personnel, have important spin-off benefits. A recently completed program to upgrade the quality of continuing education at a community medical center in Columbus, Georgia, for example, has contributed to substantial growth in the city's physician population and the establishment of the medical center as an areawide continuing education resource for smaller neighboring hospitals.

As the basis for the program, the medical center in Columbus established a regular university-affiliated teaching program with the Emory University School of Medicine. Local physicians were sent to the University for a newly organized clinical training program, and then, on return to the medical center in Columbus, set up similar clinical and didactic training for their associates. As part of its upgrading, the medical center at Columbus was selected by the Georgia RMP as one of five community hospitals across the State which would become areawide continuing education facilities. In addition, approximately 28 new physicians have been attracted to the town during two years of the project, while there had been no increase in the previous eight years.

The Michigan RMP supported a pilot study in Grand Rapids—a major medical referral center. This watershed includes 10 counties outside of Grand Rapids with a total of 315,000 people with a per capita income 35% below the state average, and served by less than 70 active primary physicians. In 1970 a systematized approach to education in coronary care was applied to the entire rural area. In the first 1½ years of full-scale operation, funded by MRMP, 400 hours of consultant teaching were delivered to the staffs of 9 outlying hospitals within 110 miles of Grand Rapids.

To conserve time for patient care, physicians were taught on their home ground on a regular basis by the same group of consulting cardiologists from Grand Rapids. Teaching methods were adjusted for major impact on patient care. Practicality and self-sufficiency were emphasized.

By chart review and PAS analysis, the mortality rate from myocardial infarction dropped from 34% (pre-course) to 18% (post-course). Such a statistically significant change has been rare in other types of post-graduate or "refresher" programs. At the end of the project period, 8 of the 9 hospitals had voted self-sustaining funds for the education visits.

Many of the current continuing education and training activities of RMP such as those highlighted above, are being expanded and extended, are being given a new focus in the form of community-based education programs. Nearly 50 such proposals from some 20 Regions are presently pending; and it is fully anticipated that funds will be awarded for a number of these programs before the end of the present fiscal year.

These community-based education programs are viewed as a "more systematic" and "more scientific" approach for linking continuing education for physicians, nurses, and other health professions with the actual service needs and utilization of health manpower in given areas. It also is expected that this new approach will be able to more effectively use the increasing "feedback" from quality of care monitoring mechanisms, targeting continuing education efforts on problem areas where remedial action is indicated.

Mr. ROY. How much money are you spending and what programs do you have in the areas of research into cardiovascular and pulmonary diseases in children?

Dr. COOPER. I cannot break that out all at one time.

Dr. MARSTON. I think probably, Dr. Roy, we have a page and a half summary.

Mr. ROY. Is there a total there to give us some idea of what percentage of the grants is being spent?

Dr. COOPER. I will have to break that out and we will submit it.

Could you define what should be included in programs for children?

Mr. ROY. You can do that better than I.

Dr. COOPER. There will be some overlapping. As I mentioned previously, in the pulmonary program we have areas where we can identify amounts spent on children. We can do that in the new arteriosclerosis centers as well. We will make an estimate of the amount of effort in that area and submit it.

(The following material was received for the record:)

NATIONAL HEART AND LUNG INSTITUTE PROGRAMS OF PEDIATRIC RELEVANCE

The National Heart and Lung Institute has programs with major emphasis or impct on the pediatric population in each of three areas: cardiovascular, lung, and blood programs.

A. *Cardiovascular Programs.* The principal programs of pediatric relevance in this disease category are three: congenital heart disease, rheumatic fever and rheumatic heart disease, and pediatric aspects of arteriosclerosis.

The Institute's total budget in FY 1971 for these programs was:

Extramural regular research grants	$2,882,383
Training grants and awards	1,485,162
Specialized Center of Research	533,691
Lipid Research Clinics	750,465

In addition, the following intramural and extramural cardiovascular programs have pediatric relevance or pediatric program components: Biochemical Genetics, Endocrinology, Surgery and Technical Development; and the collaborative contract program in Medical Devices. The amount of funding of the pediatric portion of these programs is not available as a separate budget item.

B. *Pulmonary Program.* The principal programs of pediatric relevance in this disease category are three: acute respiratory distress syndrome in the newborn or hyaline membrane disease; cystic fibrosis; and the pediatric aspects of chronic pulmonary disease.

The Institute's total budget in FY 1971 for programs with major emphasis on pediatric pulmonary disease was:

Extramural regular research grants	$194,220
Training grants and awards	159,043
Specialized Centers of Research (2)	949,044

In addition, the intramural laboratory of Technical Development and the collaborative contract program in Medical Devices supported research of pediatric relevance. The amount of funding of the pediatric portion of these programs is not available as a separate budget item.

C. *Blood Program.* The principal programs of pediatric relevance in this category are: Blood Diseases, i.e., Sickle Cells Disease and Hemophilia; and Blood Management.

The Institute's total budget in FY 1971 for programs with major emphasis on pediatric blood disease and blood management was:

Extramural regular research grants	$96,913

In addition, the following extramural programs have pediatric relevance or pediatric program components: Sickle Cell Disease Program and the National Blood Resource Program which includes studies of Hemophilia. The amount of funding of the pediatric portion of these programs is not available as a separate budget item.

Mr. ROY. The types of hyperlipemia in children can be diagnosed earlier.

Dr. COOPER. There are some projects currently being carried on assessing the use of the technology as early as from the core blood

itself. We feel this is technically possible, and we are initiating some programs of very early assessment of how early we can detect the types or propensity toward the type.

Mr. ROY. So you see the time we may be doing screening on newborns routinely in this area?

Dr. COOPER. I think it would depend on what our experience will be with the screening in the adult population first as to what might need to be done with the children. But it is technically feasible.

Mr. ROY. May I ask what mechanisms you have of coordination with State health departments with regard to not only your research but with regard to information?

Dr. COOPER. We are not directly involved with coordinating the programs in any formal way with State departments. We do provide written information on requests. We have no formal program through the Institute.

Mr. ROY. Is there anything to be gained in this area? Is there something that might be done in this area?

Dr. DUVAL. I wouldn't have thought so, but maybe I am missing the point of your question. Dr. Cooper is describing, of course, purely research projects. At this point in time when material is made available which is useful, then it goes out, as it were, to the State health departments either through RMP or through projects on the HSMHA side. We have treated these two differently.

Mr. ROY. I just wondered if there were something to be gained in this respect. I am aware of the variability of State health departments. I am aware, also, of the fact that they seem to be stunted somewhat in many States. I wondered, again, if there was a mechanism that could be established with regard to dissemination of information.

Dr. DUVAL. Yes, sir. We do better, at least our experience indicates we do better, under the children and youth projects than we do through the State health departments. But we try to do both.

Mr. ROY. I have no further questions.

Mr. ROGERS. How many centers are there now that are devoting their main effort to heart that we are sponsoring or funding?

Dr. COOPER. The specialized centers of research in heart disease are the 13 devoted largely to arteriosclerosis and five devoted principally to hypertension.

Mr. ROGERS. The bill provides for additional centers. I understand you felt they should not have a clinical setting?

Dr. DUVAL. I think the point of our testimony, Mr. Chairman, is to illustrate that the concept of a control program, if it is to fall back on clinical experience in order to determine whether or not taking this, that or the other step is useful, as clearly a part of and performed by the NIH. After having found that a particular screening process or methodologic tool is useful, it is easier to put it into the field through a service organization such as one of the units of HSMHA or some other device, rather than to have the research arm of the Department become the service arm. We don't want to inhibit their capacity to be R. & D. forward oriented.

Mr. ROGERS. I know we went through this in the cancer hearings, but your service arm let the cancer control programs die. That was not a very effective program. What has RMP done for heart control programs? I don't know of any, do you?

Dr. DuVAL. I think, depending on how you use the term "control" ——

Mr. ROGERS. I am talking about early detection, for instance.

Dr. DuVAL. We do have opportunities for early detection that are being displayed by RMP. I do think RMP's have focused more on treatment of conditions than are recognized, and they do have an outstanding track record here.

Mr. ROGERS. I think it would be well to give us for the record what RMP's have done to try to control heart disease in this Nation.

(The following material was received for the record:)

ROLE OF REGIONAL MEDICAL PROGRAMS IN SCREENING AND EARLY DIAGNOSIS

Regional Medical Programs seek to improve personal health care through the regionalization of health resources and enhancement of the capabilities of providers of care at the community level. As such, they are concerned with the entire range of health care, including prevention and early intervention in the disease process, as well as diagnosis, treatment, and rehabilitation.

The Regional Medical Programs are currently supporting some 53 projects dealing with screening and/or early detection, funded at a level of $4.4 million. Sixteen of these projects, funded at a level of approximately $1 million, are directly related to heart disease. Many of the others involve multiphasic screening which includes heart disease.

The 56 individual Regional Medical Programs are involved with screening and early diagnosis in a variety of ways. One line of emphasis is the development of new diagnostic and predictive techniques, and means of automating existing tests. The Ohio Valley RMP, for example, is initiating an automated multiphasic screening project which envisions extensive use of automated techniques and paramedical manpower. The Memphis RMP is experimenting with a mobile multiphasic health screening unit in Northeastern Mississippi. A mobile health trailer will first serve the medical trade areas of two applicant hospitals, after which it will serve a five-country area. It is expected that up to 20,000 will be screened annually.

Another are of emphasis is demonstration projects involving particular population groups. Among the types of activities being carried on are:

Screening of Children for Heart Disease, Southeast Tennessee—Through cooperative efforts of Tennessee/Mid-South RMP and the Chattanooga Heart Association, school children in Appalachian counties are being screened by Cardio-scan for heart disease. Follow-up is also provided for positive cases. Begun in 1970 for a three-year period, the project had screened 17,194 children in 14 counties by the end of 1971. In 1972, two other counties and between 12,000 and 22,475 children will be screened.

North Carolina Adult Screening and Referral Program—Another screening project was initiated in July, 1971, in Winston-Salem, North Carolina, under the sponsorship of the local Heart Association, which has begun testing 100 adults per day for hypertension, diabetes, anmesia, and elevated cholesterol. Local vounteers work as technicians and aides. Initial testing covered an industrial setting, a low-income area, and a rural area. The project is designed to develop screening procedures which can be used on a State-wide basis in future years. Areas selected for screening over the three-year period will include a minimum total adult (age 21+) population of 500,000 covering a cross-section of urban, rural, economic, and white/non-white factors.

School Heart Sounds Screening Program—This project has tested 38,402 school children in 12 Missouri communities for previously unsuspected heart disease. Of these, 1,524 were referred for further examination to their physicians, with a resultant 600 children found positive. The Missouri Heart Association plans to continue this program on a State-wide basis when Missouri RMP funding terminates in late 1972.

In addition to the variety of screening programs currently being carried out by the Regional Medical Programs, the authority was added in the 1970 legislative extension and is now available in Section 910(a)(2) of the Public Health Service Act for the "development, trial, or demonstration of methods for control of heart disease, cancer, stroke, kidney disease, or other related diseases."

This authority may be used to fund such disease control programs either through the 56 individual Regional Medical Programs, through two or more RMPs for an interregional program, or through individual public or nonprofit private agencies. Thus the authority provides a high degree of flexibility as to the types of disease control programs which may be carried out, and as to the types of institutions and agencies selected to run them. With the additional grant funds projected as being available in fiscal year 1973, this authority for heart and other disease control programs could be used to a greater extent, allowing for initiation of an expanded variety of control activities.

Mr. CARTER. Mr. Chairman?

Mr. ROGERS. Yes.

Mr. CARTER. On that very thing we do have some programs that are oriented mostly toward diagnosis and treatment. I know that Vanderbilt and western Kentucky, which is associated with it, and western Tennessee have a very good program in which physicians in rural communities can get almost instant readings of electrocardiograms and so on, which is very helpful. They also have relations with the professors at Vanderbilt in which they come out to the rural communities and teach or tell the physicians the newer methods. I think this is good.

I regret that these programs are not being carried out in other parts of our country. For instance, in eastern Kentucky, they have not been implemented as well as they should be. This network should be used by the university or with very knowledgeable specialists and the physicians that are giving primary aid.

Thank you for yielding.

Mr. ROGERS. Now, let me ask you this, Dr. Cooper: Does the National Heart and Lung Institute have any input as to what kinds of programs are being run by regional medical? Do you design it?

Dr. COOPER. We do not design their programs, nor do we specify what the concept of their programs should be. We are available for consultation and cooperation.

Mr. ROGERS. You are there if they want to ask you, but you find all of the research out and then somebody down there starts getting out regional medical programs and, hopefully, as Dr. Carter says, maybe they will be implemented and maybe they won't.

Mr. CARTER. I think we need more direction and leadership in this to see that these programs are implemented. I have watched it and seen in many areas it has not been done.

Mr. ROGERS. What would we need to actually implement this bill as we now envision it in its current status? Could you give us this for the record? Give us this as far as personnel, funding and so forth. You may not be able to give us an offhand estimate.

(The following information was received for the record:)

ESTIMATES FOR FIRST THREE YEARS' FUNDING OF H.R. 13715

It is difficult to give an entirely satisfactory answer to the question of the cost of full funding of the bill as it now stands. As you know, one of the provisions of the bill calls for the development of a complete spending plan. Assuming enactment of H.R. 13715 and subject to adjustment when the detailed program plan required is developed in Year I, the following are professional estimates for the first three years of operation. It should be noted that these estimates merely represent some professional judgments. It should be noted that they are not intended to predict future economic conditions or changes in the scope or quality of the program which might result from experience gained in actual practice. Moreover, they do not represent Agency, Department, or Administration estimates or budget requests.

[In millions of dollars]

Program component	Year I	Year II	Year III
1. Development of program plan	1	(1)	(1)
2. Control programs	30	40	50
3. Centers programs, including construction	100	117	148
4. Interagency Technical Committee	(1)	(1)	(1)
5. National Heart and Lung Advisory Council	(1)	(1)	(1)
6. Research grants and training	167	176	180
7. Collaborative programs	70	80	82
8. Intramural program, including construction	20	22	24
9. Research and management services	12	15	16
Total	400	450	500

1 Funding requirements would be small.

Mr. ROGERS. Are we having any important developments in artificial hearts or parts?

Dr. COOPER. As you may recall, in March we did announce some new developments in engine technology and control systems technology which demonstrate the feasibility of having an implantable engine. There have also been improvements in material design and in pump design.

Mr. ROGERS. Do any of these have to be approved by you or by anyone else before they are used?

Dr. COOPER. For the ones that are currently being directly supported by our coordinated program we do make it a requirement to be approved for clinical use by us before allowing it even to be used experimentally. In other words, we undertake a technical review and make sure at the place proposed for implantation that the proposers have subjected it to a local peer review in association with arrangements currently available for human research review.

Mr. ROGERS. But this just goes to any project funded by you?

Dr. COOPER. This is true of any project funded by us, but in this particular program we undertake an additional technical review of the adequacy of the scientific base before we concur in the decision for them to use it. We do not select out the patient nor enter into any particular clinical decision at the bedside. We do make a special review of the adequacy of the scientific base for its general use.

Mr. ROGERS. Did you approve the devices of heart implant, the pacemakers?

Dr. COOPER. No, sir, we did not. These were not developed under our supervision nor our contract programs. These were independently developed by the community in association with medical centers and industry. The decisions for applying these were made in the community itself.

Mr. ROGERS. I was wondering how you let it get out if that were so without the protective shield to prevent the radiation that is stopping it.

Dr. COOPER. In the radar shield.

Mr. ROGERS. Yes.

Dr. COOPER. We cannot review that material.

Mr. ROGERS. We hope to get to a medical devices bill this year.

Mr. Schmitz?

Mr. SCHMITZ. I will have to apologize for having been unavoidably absent to attend a previous meeting during part of the witness' testi-

mony. I would like to ask one question here. Is the basic thrust of the bills before us to find a cure for these illnesses or to find some way of getting people to act on the already known causes?

Dr. COOPER. Both.

Mr. ROGERS. I think both.

Mr. SCHMITZ. Don't we know, for example, with regard to heart diseases, that if people exercised we could cut it down three-fourths?

Dr. COOPER. Not with exercise alone, but appropriate planning would help in the management of the problem. But exercise alone will not account for a three-fourths reduction.

Mr. SCHMITZ. If everyone exercised the way their bodies were intended to exercise, how much would this cut down on heart and lung disease?

Dr. COOPER. This would be a very difficult estimate to make. But as a single risk factor, I would put it in the perhaps 10 to 20 percent category. That is just a guess.

Mr. SCHMITZ. I would guess a lot higher than that. I am not a doctor, though.

Mr. CARTER. Mr. Chairman, on that very thing, not long ago there was an interesting study by, I believe, Boston University in connection with the University of Dublin.

Dr. COOPER. Was it Belfast?

Mr. CARTER. It could have been Belfast; I am not sure. I don't believe it was. This study showed that although those Irishmen ate twice or three times as much as Americans in the Boston area, again the incidence of heart disease was approximately one-half or even less.

Dr. COOPER. My memory doesn't serve me too well here, Dr. Carter, but I have the impression that in Ireland, and in the British Isles as well, the attack rate very closely approximates ours.

Mr. CARTER. I hate to tell you that what you say is directly in conflict with this study, and I would commend this study to you.

Mr. SCHMITZ. Would the gentleman yield?

Mr. CARTER. Yes, sir.

Mr. SCHMITZ. I am also aware of that study, along with other studies, which support my comments. Although I am not a doctor, most of the things I have read in this field are from doctors. Other doctors make an excellent case for the proposition that our primary problem with regard to all of these diseases before us here is simply the nature of our society, which is quite abnormal.

Mr. ROGERS. In the lung area, what have you done in areas where pollution is quite high?

Dr. COOPER. We have not worked with EPA, but have been coordinating our program with the National Institute of Environmental Health Sciences. They are establishing a facility down in North Carolina which will offer a laboratory in which we can work with them on the study of this problem. We do feel that substances in the environment are injurious to certain pulmonary functions and a good deal of work on this system needs to be done in this area.

Mr. ROGERS. In other words, you have not done any work in this but you are planning it?

Dr. COOPER. Yes, sir.

Mr. ROGERS. You haven't had any people and no funding to go into it? You have two people to work on lung. It is unbelievable.

I understand you have advised or somebody advised about not doing X-ray examinations for TB because of the potential harm of examination. Was that Food and Drug? Do you concur in that or were you asked to give your opinion?

Dr. COOPER. I was not asked to give my opinion on that question.

Mr. ROGERS. Let us know if anybody asked Heart and Lung to concur in that action. I think it would be helpful to the committee to judge coordination.

(The following material was received for the record:)

DISCONTINUANCE OF MOBILE X-RAY UNITS

So far as can be ascertained, this question refers to discontinuance of mobile X-ray units for detection and early diagnosis of tuberculosis. No consultation on the matter was made with the National Heart and Lung Institute in this instance, since the decision was apparently made on the basis of the high cost for a low yield program. While no mechanism of formal coordination between research and service programs exists it is customary for consultation to take place on substantive issues.

Mr. ROGERS. What about your manpower situation for your work in blood as such? What do you have there?

Dr. COOPER. We have a very small staff in blood, Mr. Chairman.

Mr. ROGERS. Whom do you have? How many?

Dr. COOPER. The chief of our national blood resource program is Dr. Stengel, and he has four young associates with him. In the extramural program we have Dr. Fann Harding. We will have Dr. Therriault coming on board in June. In the intramural program we have a laboratory section under the supervision of Drs. French and Anderson which will be proposed for branch level within the coming year.

Mr. ROGERS. So you have three senior people?

Dr. COOPER. Three senior people at the present time.

Mr. ROGERS. And four students?

Dr. COOPER. There are more in the extramural program. There are probably on the order of eight or nine students.

Mr. ROGERS. That is the Government's effort in research on blood.

Dr. COOPER. It is not the total Government effort. The National Institute of Arthritis and Metabolic Diseases has a major laboratory.

Mr. ROGERS. What are they doing?

Dr. COOPER. I am not competent to speak on that.

Mr. ROGERS. Maybe Dr. Marston can speak quickly and supplement it for the record.

Dr. MARSTON. We have a program in the Arthritis and Metabolic Diseases Institute and another in the Allergy and Infectious Diseases Institute, where we have a major program for hepatitis, and then in the Division of Biologic Standards we have the control functions for blood and blood products. I would be glad to expand each of these for the record.

(The following information was received for the record:)

SCOPE OF GOVERNMENT RESEARCH ON BLOOD

NATIONAL INSTITUTE OF ARTHRITIS AND METABOLIC DISEASES

The area of Institute responsibility is defined by reference to (1) certain disease areas and corresponding fields of inquiry, (2) certain training and

developmental experience in preparation of these areas, and (3) institutional setting. The hematology program of the NIAMD includes investigations into blood-cell formation, its disturbance in deficiency states, e.g., iron lack, folate deficiency, intrinsic factor deficiency, the control of hemoglobin production and associated inborn metabolic errors, e.g., sickling disease, thalassemia; immune disturbance, e.g., hemolytic anemia. To these examples taken from the red cell area may be added a comparable range for the white cell.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Areas of Institute responsibility include: (1) immunology, particularly those aspects involving host reactions to infections and parasitic organisms, auto-immunity, immune deficiency states, and homotransplantation; (2) infectious diseases and diseases of undetermined etiology in which microorganisms may be important pathogenic factors.

Among these diseases can be found rheumatic fever and infectious hepatitis. Research includes broad areas of cell biology, including cellular components of blood as they play a role in immunological phenomena *in vitro* or *in vivo*.

NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE

The Institute's area of responsibility includes research where the target entity under study is either the nervous system, the neuromuscular and muscular apparatus, hearing, equilibrium, the other senses and special senses, or neural-based symbolic processes such as language, thinking, model making, etc.

The cerebrovascular disease program includes research on stroke, including the mechanism of damage to nervous tissue, secondary to pathology of blood vessels (e.g., the pathogenesis of cerebral infarction).

NATIONAL CANCER INSTITUTE

The area of Institute responsibility includes basic and clinical research related to cancer in man and animal species.

Within this responsibility, programs relating to cardiovascular, broncho-pulmonary, and hematopoietic system abnormalities secondary to the development of tumors; development of collateral lymphatic and vascular channels and lymphatic-venous anastomoses.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The area of Institute responsibility includes projects in basic and clinical research relating to maternal health, child health, human development, reproduction, perinatal biology, infant mortality, mental retardation, and aging.

Included in this responsibility are programs for normal and abnormal development of blood vessels and heart, rheumatic fever, renal development of function, and certain hematologic disorders, respiratory distress syndrome, and related respiratory difficulties.

Mr. ROGERS. What is the scope of the hepatitis problem? Is it increasing or decreasing or what?

Dr. DUVAL. Related to transfusion?

Mr. ROGERS. I guess it is not just related to transfusion? They don't just get it from transfusions, do they?

Dr. MARSTON. The progress, the real breakthrough in posttransfusion hepatitis as opposed to the infectious hepatitis has occurred in recent years with the ability to determine the presence of the Australian antigen, and within the last year the ability thereby to sort out in nonhuman primates susceptible hosts. So we have been able to transmit in an animal model for the first time in history the agent for transfusion hepatatis.

This has had other implications. The ability to detect, in portions of the blood for transfusion, whether or not they contain the Australian antigen should give us not only a better opportunity to protect against infectious hepatitis but also is allowing us to have more in-

formation on conditions under which one collects blood, that is, the relative dangers of commercial versus noncommercial donors.

Mr. ROGERS. We plan to get into the blood bank business.

Dr. MARSTON. In the infectious hepatitis there are some reports of progress of the possibility to transmit in experimental animals—these need to be confirmed now—the antigens for that disease.

So I would say the field is very active at present, having had a major, almost crash, program in World War II, because of special problems at that time, to learn more about hepatitis. Those efforts, for the most part, failed, but in recent years we have made, I think, very significant progress.

Mr. ROGERS. I think if you could outline the details for the record this would be helpful.

(The following information was supplied for the record:)

BLOOD RESOURCES PROGRAM

The question of infectious diseases transmitted by transfusion of blood is one with which the National Blood Resources Program is properly concerned. This problem includes infections such as cytomegalovirus, toxoplasmosis, malaria, as well as the most important problem, hepatitis. The Blood Resources Program is supporting projects on ways to prevent infections associated with blood transfusion, especially the improvements in techniques to identify bloods which contain the hepatitis agent, and to some extent to prevent the development of hepatitis in blood recipients by specific immune globulin.

While the National Heart and Lung Institute is engaged in these activities, the National Institute of Allergy and Infectious Diseases is concerned with viral hepatitis as an infectious disease, the characterization of the agent(s), the development of active immunization, and the usefulness of passive immunization for prophylaxis against accidental parenteral exposure, etc. The Division of Biologics Standards is also involved in its relationship to the regulation of blood and blood products. The National Institute of Arthritis and Metabolic Diseases, because of its program in hematology, is also involved in hepatitis diagnosis and prophylaxis, and in the treatment of hepatitis. The Clinical Center blood bank is also engaged in hepatitis research. The multiplicity of Institutes interested in research on viral hepatitis led Dr. Marston to establish a Task Force on Viral Hepatitis to maintain communication among the interested Institutes and Divisions and to coordinate programs by assignment of responsibilities among them. After considerable trial and tribulation, the coordination of programs is now going on well.

1972 RESEARCH HEPATITIS GRANTS AND CONTRACTS

PRIMARY HEPATITIS PROJECTS

Name and institution	Amount	Title and number
A. National Institute of Allergy and Infectious Diseases:		
Contracts: Riopelle, Arthur J., Tulane University	[1] $48,565	Study of hepatitis in chimpanzees, NO1AI12197.
Grants:		
Gordon, Irving, University of Southern California.	62,059	Measles virus or other virus infections (human, mice, rabbits), RO1AI03874.
Starzl, Thomas E., University of Colorado Medical Center.	26,850	Transplantation and applied immunology, PO2AI08898.
Prince, Alfred M., New York Blood Center	58,939	Serum hepatitis virus related antigen (human, primates), RO1AI09516.
Horstmann, Dorothy M., Yale University	78,062	Etiology of viral hepatitis (human, rodents), RO1AI09937.
Aziz, M. A., University of Maryland	42,329	Viral hepatitis sequelae in Pakistani soldiers (human), RO7AI10049.
Gocke, David J., Columbia University		Viral hepatitis—Role of Australia antigen and other agents (human), RO1AI10165.
Kohler, Peter F., University of Colorado Medical Center.	31,142	Immunologic response to hepatitis-associated antigen (human, rodents, ungulates), RO1AI10176.
Mosley, James W., University of Southern California.	37,200	Epidemiology of HAA-positive viral hepatitis (human), RO1AI10586.
Carver, David H., Johns Hopkins University	23,191	Intrinsic interference assay for hepatitis viruses (human, chimpanzees), RO1AI10711.
Wright, Harry T., Jr., Children's Hospital (Los Angeles).	[2]	Etiologic agents of viral hepatitis (human), RO1AI09042.

[1] 18 months.
[2] Unfunded.

1972 RESEARCH HEPATITIS GRANTS AND CONTRACTS—Continued

PRIMARY HEPATITIS PROJECTS—Continued

Name and institution	Amount	Title and number
B. National Institute of Arthritis and Metabolic Diseases:		
Grants:		
Leaf, Alexander, Massachusetts General Hospital.	$52,900	Mechanism of viral injury to liver (mice, human), PO2AM04501.
Schoenfeld, Leslie, Mayo Foundation	52,250	Digestive and hepato-biliary function. Hepatitis (human mice), PO2AM06908.
Saravis, Calvin, Harvard University	26,000	Diseases of liver and portal circulation. Serum hepatitis associated antigens (human), PO1AM08681.
C. Division of Biologics Standards:		
Contracts:		
Goldfield, Martin:		
N.J. State Dept. of Health	226,800	Epidemiological study of transfusion-associated hepatitis, NO1BS02026.
TRW Inc. (Hazelton Labs, Inc.)	76,500	Susceptibility of subhuman primates to human hepatitis, NO1BS22050.
D. National Cancer Institute:		
Grants:		
Blumberg, Baruch S., Institute for Cancer Research	32,820	Australia antigen—Transmission to primates, PO2CA06551.
Do	32,280	Chemical composition of Australia antigens, PO2CA06551.
Do	55,380	Australian antigen, hepatitis virus and its relation to leukemia, PO1CA06927.
Vaughn, Clarence B., Michigan Cancer Foundation.	74,280	Clinical cancer research center immunological program (human) PO2CA07177.
E. Center for Disease Control:		
Grants:		
Carver, David H., Johns Hopkins University	45,785	Viral studies of infectious hepatitis (human), RO1CC00499.
Vyas, Girish N., University of California (San Francisco).	48,157	Serologic specificity of the Australia antigen (human), RO1CC00578.
F. National Heart and Lung Institute:		
Contracts:		
Melnick, Joseph, Baylor College of Medicine		Develop tests to detect the HAA (human, mammals nonhuman), NO1HL02231.
Halbert, Seymour P., Cordis Corp		Hepatitis associated antigen (human, sheep, horses), NO1HL02232.
Blumberg, Baruch S., Institute for Cancer Research.		Australian antigen (human), NO1HL02234.
Prince, Alfred M., New York Blood Center		Produce antibodies to the Australian antigen in animals (human, monkeys), NO1HL02236.
Pert, James H., N.Y. State Department of Health		Antibodies to the Australia antigen (guinea pigs, goats, sheep, rabbits), NO1HL02240.
Grady, George:		
Harvard University		
Aerojet-General Corp	42,905	Hepatitis-associated antibody (human), NO1HL12064.
Gitnick, Gary L., University of California (Los Angeles).		Develop test protoool to detect HAA (mammals nonhuman), NO1HL12350.
Smith, James E., Syracuse University	9,856	Detection of hepatitis in blood (human), NO1HL12351.
Aach, Richard D., Washington University		Detection of hepatitis in blood (human, mammals nonhuman), NO1HL12352.
Melnick, Joseph L., Baylor College of Medicine.		Detection of hepatitis in blood (human, mammals nonhuman), NO1HL12353.
Vyas, Girish N., University of California (San Francisco).		Remove agent of hepatitis from blood (human, mammals nonhuman), NO1HL12354.
Hinman, John, Blood Research Institute	15,100	Detection of hepatitis in blood (mammals nonhuman), NO1HL12355.
Prince, Alfred M., New York Blood Center	1,991	Transmembrane washing of red blood cells (human), NO1HL12356.
Johnson, Allan, Jr., New York University		Bioassay for serum hepatitis virus (human), NO1HL12358.
Grants:		Removal of infectious agent of hepatitis from blood (human), NO1HL12359.
Kuhns, William J., New York University		Prevention of hepatitis after cardiovascular surgery, RO1HL12732.
Johnson, Allan, New York University		Removal of hepatitis-associated antigen from plasma (human), RO1HL13984.
Prince, Alfred M., New York Blood Center	155,790	A research and resource program in blood virology (human, rats, chimps), PO1HL09011.
G. Office of the Director: Contracts: National Academy of Sciences.		Establish a committee on viral hepatitis, NO10D40044.

1972 RESEARCH HEPATITIS GRANTS AND CONTRACTS—Continued

PRIMARY HEPATITIS PROJECTS—Continued

Name and institution	Amount	Title and number
H. Research Resources:		
Grants:		
Abbruzzese, Americo, Peter Bent Brigham Hospital.	$23,547	Detection of occult liver disease in blood donors (human), MO1RR00031.
Senior, J., University of Pennsylvania	17,750	Anicteric hepatitis after administration of frozen washed red blood cells (human), MO1RR00040.
Jeffries, Graham H., Cornell University Medical College.	11,450	P liver disorders, hepatitis viral (human) MO1RR00047.
Kohler, Peter F., University of Colorado Medical Center.	16,800	Antibody effect on HAA carrier (human), MO1RR00051.
Marin, G. A., Philadelphia General Hospital	17,000	Post-transfusional hepatitis (human), MO1RR00107.
Hersh, Theodore, Baylor College of Medicine.	10,340	Malabsorption and hepatitis (human), MO1RR00134.
Gocke, David J., Columbia University	12,625	Role of Australia antigen in pathogenesis of hepatitis, MO1RR00645.
Do	12,625	Treatment of fulminant viral hepatitis with hepatitis immune globulin (human), MO1RR00645.

SECONDARY HEPATITIS PROJECTS

A. National Institute of Allergy and Infectious Diseases:		
Grants:		
Weller, Thomas H., Harvard University		Pathogenic agents using in vitro technique (rats), RO1AI01023.
Morgan, Councilman, Columbia University	$49,678	Electron microscopy of virus-host interactivity, RO1AI06814.
Enders, John F., Children's Hospital (Boston).	74,447	Viral cytopathogenicity—Mechanisms and applications (human, hamsters), RO1AI01992.
Douglas, Steven D., Mount Sinai School of Medicine.	37,995	Cellular and subcellular studies in immunogenetics (human), RO1AI09338.
Bang, Frederick B., Johns Hopkins University.		International center for research and training, RO7AI10048.
Buckley, Rebecca H., Duke University	44,061	Bone marrow transplantation in immunologic deficiency (human), RO1AI10157.
Fields, Bernard N., Yeshiva University		Genetic and biochemical studies of Reovirus RO-1AI10326.
B. National Institute of Arthritis and Metabolic Diseases:		
Grants:		
Popper, Hans, Mount Sinai School of Medicine.	110,409	Structure and function in liver injury (human, rats), RO1AM03846.
Schur, Peter H., Robert B. Brigham Hospital.		Antigen-antibody complexes in human disease PO2AM05577.
Klatskin, Gerald, Yale University		Hepatic injury (human, rats), RO1AM05966.
Iber, Frank L., Tufts University	37,923	Interhospital cooperative studies of cirrhosis (human) RO1AM09128.
Matelson, Samuel, Michael Reese Hospital and Medical Center.	27,153	Guanidino compounds in health and disease (human, swine), RO1AM09958.
Sturgeon, Phillip, University of California (Los Angeles).	81,142	Automation of hematological methods (human animals), RO1AM10722.
Combes, Burton, University of Texas Southwest Medical School.	85,888	Splanchnic hemodynamics and splanchnic metabolism (human, rats, guinea pigs), RO1AM137
B. Division of Biologics Standards:		
Contracts:		
Dalgard, Dan W., Thompson Ramo Wooldridge.	23,100	Provide housing and special care of chimpanzees, NO1BS12040.
Sharp, D. Gordon, University of North Carolina.		Zonal centrifugation in identifying biological samples, NO1BS92197.
C. National Cancer Institute:		
Grants:		
Blumberg, Baruch S., Institute for Cancer Research.		Immunologic basis for susceptibility to cancer in man, PO2CA06551.
Do		Relation of inherited antigens to cancer susceptibility in man, PO2CA06551.
Do		Human and animal antisera to detect leukemia-related antigens (rabbits), PO2CA0655.
Do		Factors in the development of malignant hepatoma. PO2CA06551.
D. National Institute of General Medical Sciences:		
Grants:		
Brunner, Edward A., Northwestern University.		Anesthesia research center (human, monkeys, mammals non-human), PO1GM15420.
Van Oss, Carel J., State University of New York (Buffalo).	44,882	Separation of blood proteins by ultrafiltration, RO1GM16256.
E. National Heart and Lung Institute: Grants: Johnson, Alan J., New York University.	103,943	Blood coagulation components—Structure and function (human, baboons, dogs), RO1HL05003.
F. National Institute of Neurological Diseases and Stroke: Grants: Herndon, Robert M., Johns Hopkins University.		Fine structural alterations in CNS viral disease (human, mice, rats, cats), RO1NS08997.
G. Research Resources: Grants: Hendrix, Thomas R., Johns Hopkins University.		Intestinal disaccharidases (human), MO1RR00035.

Mr. ROGERS. What is your budget for blood?

Dr. COOPER. About $30 million.

Mr. ROGERS. What are the major areas you are looking into?

Dr. COOPER. We do have a program segment on hepatitis associated with blood transfusion, blood fractionation, and storage.

We have a program on methods to improve the coordination of methods of typing bloods, providing a central focus for minimizing the loss in that category.

We have a thrombolic therapy program which is aimed at detecting substances that will aid in the dissolution rate of blood clots.

We have a program aimed at increasing the ability to prevent platelet aggregation and we have a program on the pulmonary embolization.

Mr. ROGERS. What has been your budget for blood since 1969, 1970, 1971?

Dr. COOPER. There is one large segment I missed. Let me insert that. Sickle cell anemia, which is a large segment. So, in our $30 million at the present time, $10 million will be involved with the new sickle cell initiative.

The remainder of the program has been relatively stable at about the $12 million level. This past year we increased our activities in the blood fractionation-hepatitis areas by about $12 million.

Mr. ROGERS. Should stroke be transferred to the Heart Institute? Do you feel it should not?

Dr. DUVAL. Absolutely not.

Mr. ROGERS. Stroke then doesn't have anything to do with the blood valves?

Dr. DUVAL. Sure it does. The same thing as the fever has something to do with measles.

Mr. Chairman, the point is one made earlier by Mr. Nelsen, that neurological diseases experts are going to do a better job in managing stroke. That does not mean that work going on in the Heart-Lung Institute is not germane and should not be reinforced.

Mr. ROGERS. There are many who are asking this committee to consider transferring stroke to the Heart Institute. This is a decision, I think, we should have your thinking on. If you would let use have that, and perhaps if you could come back this afternoon, because we have some other witnesses I want to get to now. I understand you cannot, nor can Dr. Marston, but that Dr. Zapp and Dr. Cooper could.

Dr. MARSTON. I could come back.

Mr. ROGERS. I think it might be helpful so we can continue some questioning we need to go into. I think this would be one matter the committee would like to look into, as well as some specifics of what we could do to get on top of this problem.

For instance, who coordinates heart information? I understand one will put out something on diet and one on something else. We really need some coordination on information to the public on heart. I think this might be a proper function of the Institute. If you would give that some thought so we can go into that this afternoon I think that would be very helpful.

Are there any other questions? If not, thank you very much.

Our next witness is Dr. John A. D. Cooper, who is the president of the Association of American Medical Colleges.

Dr. Cooper, we welcome you to the committee, and we will be pleased to receive your testimony.

STATEMENT OF DR. JOHN A. D. COOPER, PRESIDENT, ASSOCIATION OF AMERICAN MEDICAL COLLEGES; ACCOMPANIED BY PRENTICE BOWSHER, STAFF MEMBER

Dr. COOPER. Mr. Chairman, I have with me Mr. Prentice Bowsher, who is a member of the association staff.

The association welcomes this opportunity to appear before the subcommittee on this very important legislation which it is considering to expand and extend the National Heart and Lung Institute and the national attack against cardiovascular and pulmonary diseases.

I do have a statement which has been written, and I hope can be inserted in the record.

Mr. ROGERS. Without objection, it will be placed in the record.

Dr. COOPER. I would like to highlight some points we have made in the written statement, and add a few additional comments.

The legislation which this subcommittee is dealing with at this time, concerned with the diseases of the heart, lungs, blood, and blood vessels, is very important to the Nation, because these diseases are reaching epidemic proportions and we haven't devoted adequate attention to them. They are the major causes of death in the United States, killing more than a million people each year. Cardiovascular disease alone accounts for 54 percent of all of the deaths in the United States and it kills old and young alike. More than 12 million Americans will suffer from some form of heart attack in the next 10 years.

In addition, lung diseases are also deadly killers and debilitators. Approximately 20 million Americans are disabled with diseases of the lung. Death from emphysema is rising at a rate which is unparalleled by any other disease.

In addition, an enormous number of people are being killed or disabled by thrombosis. This is responsible for most of the suffering and death caused by the 200,000 strokes occurring annually in the United States.

We would like to point out, in response to your question to the Assistant Secretary and his staff, it is important that all of the information gained on arteriosclerosis and other studies of the blood vessels generally be applied to the area of stroke, because stroke is related to changes in the blood vessels and the central nervous system which are not dissimilar from those occurring in other parts of the body.

We are a little concerned that apparently only about $13 million a year is being expended in the National Institute of Neurological Diseases and Stroke against this very important and deadly disease.

We think the information that has already been provided to you by the administration, clearly establishes that it would be in the national interest to mount a real attack on cardiovascular and lung diseases which strike down people in their prime and most productive years.

We have considered the various bills which have been introduced into the House in relation to cardiovascular and pulmonary diseases, and we think that the bill that you have introduced, Mr. Rogers, is certainly preferable to all of the other bills. It is the broadest and

provides what we think is the best approach to an attack upon these problems. It is not restricted, as some of the other bills are, to specific and particular diseases.

We think that all diseases of the heart, lungs, and blood offer real opportunities for increased effort at this time, and the bill that you and your colleagues have introduced provides a basis for undertaking this effort.

One of the things I would like to point out, however, as we did when we testified last year on the cancer legislation, is the fact that the present scientific understanding which has led to our ability to mount an initiative in heart and lung diseases is the direct result of broad advances over the full scope of the biomedical sciences.

I think the colloquy between Dr. Carter and Dr. Cooper on the control of hypertension pointed out that advances which have been made in this important disease, have come from an understanding of the basic physiology of salt and water metabolism.

Advances in basic biomedical sciences provide us with the understanding of these major killer diseases and the opportunities for targeted research such as that which we are considering in this particular bill.

With regard to the other bills introduced, I might speak about them very briefly. The legislation which was introduced by Representative Pepper and the bill by Mr. Staggers include a number of very desirable approaches to overcome cardiovascular and pulmonary diseases. They include authority to establish control programs and demonstration centers and to simplify the approval of research and training grants. The legislation, however, also includes a number of organizational proposals which were developed in the 1971 debate on the legislation for an expanded national attack on cancer.

While many of those proposals might have seemed appropriate in that debate, we don't think they are as pertinent in this effort. We think we are confronting a different problem here, and we think this ought to be recognized in whatever legislation is recommended by this committee.

Mr. Duncan's bill encompasses many useful things, centered, however, almost entirely around arteriosclerosis. The other diseases do not seem to be covered by this legislation. We would like to point out that we are really dealing here with a family of diseases. There is little to be gained by singling out a single disease for legislative action. We think Mr. Duncan's bill is too limited in terms of the nature of the problem to be dealt with.

As I said, the bill you and your colleagues have introduced is broader, and, we believe, a very effective framework to deal with the problems of all of the cardiovascular and pulmonary diseases of the blood which the Heart and Lung Institute has under its jurisdiction. The bill does authorize the Director of the National Heart and Lung Advisory Council to develop a plan 180 days after the enactment of the legislation for a heart, blood vessel, lung, and blood program. We think the development of this plan is important so that we get the maximum and most effective program for intensifying and coordinating activities of the Institute concerning these diseases. It would provide for action in eight broad areas.

Among other things, the plan would confront the problem of research into the basic biological processes and mechanisms involved in the underlying normal and abnormal, cardiovascular and pulmonary, blood phenomena; studies into blood disease, such as sickle cell anemia and hemophilia; studies and research into the use of blood banks; and establishment of programs and centers for study and research into children's cardiovascular and pulmonary and blood diseases, and for the development and demonstration of diagnostic treatment and preventive approaches to these childhood diseases.

It is important that this plan, when it is submitted to the Congress, contain staff requirements to carry out the program, as well as recommendations for program appropriations. We prefer the determinations of allocation of effort within the program by the Institute Director and the Advisory Council through the development of this plan rather than through a predetermined distribution, such as has been added to the Senate bill.

We are also deeply concerned about the lack of an adequate staff within the Institute, not only to mount the expanded program which is envisioned under this legislation, but also to carry out properly the present program. We think this is a matter of great importance if we are to have an effective program in cardiovascular and lung disease, because it is an adequate staff within the Institute which will make it possible to coordinate this program with other agencies and to develop effective plans and approaches to these diseases. This Institute does not now have, in our view, an adequate staff.

We think that this requirement for the report of a plan within 180 days really makes unnecessary the Commission which the President has recently appointed. The plan will be developed by individuals with competence in the areas represented by their membership on the Council. They will then be a part not only of the development of the plan but of seeing that the plan is implemented in the years ahead.

We hope that in the development of the plan by the Director and Council that related lung and blood problems, such as cystic fibrosis and malignant diseases of the blood, constitute part of the whole effort.

We do think, however, that maybe some minor changes in the language in section 413 of the bill might be necessary to assure full coordination with the efforts of other institutes on these diseases.

We think the rolling plan which is envisioned in the bill will prevent us from developing a fixed approach, and changes can be incorporated as new opportunities are presented in the future. The Council and Director will present annually to the Congress their assessment of the new opportunities as they unfold from previous work.

The other important part of the legislation which we heartily endorse is the interagency technical committee. You have brought out in your questioning of the administration witnesses the fact that there has not been good coordination, not only within the Department itself, but with other Federal agencies. We think that this technical committee, established by the Department, will permit a much more unified and intensified attack upon cardiovascular and pulmonary diseases by all of the Federal agencies that have some interest and concern. We think this is a very important part of the legislation.

These remarks deal with the major areas we would like to discuss in our formal presentation here with the committee. Before I close, however, I would like to return to a very important underlying concern. We are fully supportive of the major new research efforts proposed here for heart and lung diseases and enacted recently for cancer. But we must again emphasize in the strongest possible way that useful progress in these categorical areas is completely and utterly dependent upon advances at fundamental scientific levels. Unfortunately, support for basic, fundamental research is not a separate program whose needs can be dealt with in primary and direct terms. Rather, such support is encompassed in what is called the regular research grant program of the National Institutes of Health and appears only as a secondary budget item within the overall appropriations estimates of the several NIH Institutes.

Thus, despite congressional establishment of appropriation authorizations and action on appropriation requests, there is no direct way for the Congress to insure that support for this area of basic research is sufficient to undergird the various categorical efforts. An example illustrates this point. In the President's budget request last year for fiscal 1972, a special additional sum of $100 million was included for an expanded national attack against cancer, which we were fully in support of. However, most of these additional funds were provided through a real but hard-to-perceive reduction in the regular research grant programs of the other Institutes.

I will give you some specific data here. For example, the President's fiscal 1972 budget request recommended the following levels of funding in relation to those appropriated by the Congress in 1971 for research and research training programs, as follows: NIH fellowships and research training programs, off $37.1 million; general research support programs, off $11.5 million; new and competing research grants—these are the investigator-initiated research grants which deal with the basic fundamental search for knowledge about the living process and the changes which occur in disease— off $10 million; categorical clinical research centers, off $4.2 million; cooperative heart drug study, off $1.3 million; scientific activities overseas through which we have a coordinated program with other countries in research, off $5.9 million; a total decrease of $70 million.

Even this year, despite the increases which are proposed in the President's budget for cancer and heart, support for new and competing research grants and for general research support grants has been cut back. Over $10 million in the case of new and competing research grants, and over a half million dollars for general research support.

We think, Mr. Chairman, this is tantamount to starving the goose that lays the golden egg. Without a vigorous and expanded body of fundamental scientific activity, there is little point in legislating new and massive categorical programs.

In closing, I would like to say there is much to suggest that the current NIH structure for support of investigator-initiated academic science in the face of nationally organized categorical research programs is becoming increasingly contradictory. It may be time for the Congress to review this structure in the context of current national objectives, the scope and nature of the scientific activity requisite to these objectives, and the most effective framework for its support.

Thank you, sir. We would be happy to answer any questions you may have.

(Dr. Cooper's prepared statement follows:)

STATEMENT OF DR. JOHN A. D. COOPER, PRESIDENT, ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Mr. Chairman and members of the subcommittee: The Association of American Medical Colleges welcomes this opportunity to appear before the subcommittee at its request during consideration of legislation to strengthen the National Heart and Lung Institute to advance the national attack against cardiovascular and pulmonary diseases.

Formed in 1876 to work for reforms in medical colleges, the Association has broadened its activities over the years, so that today it represents the whole complex of persons and institutions charged with the undergraduate and graduate education of physicians. It serves as a national spokesman for all of the 108 operational U.S. medical schools and their students, more than 400 of the major teaching hospitals, and 52 learned academic societies whose members are engaged in medical education and research.

Through its members, the concerns of the Association range far beyond medical education itself. They include the total health and well-being of all of the American people. The Association is concerned with the education and training of persons in other, related health professions and in allied health occupations. It is concerned with the conduct of a substantial portion of the nation's medical and health care research. It is concerned with the delivery of health care, directly through the facilities of teaching hospitals, and indirectly through the development of improved community health services. It is concerned with innovation and experimentation in all of these fields. The Association and its membership thus have a deep and direct involvement in the legislation the subcommittee is now reviewing.

THE PROBLEM

The legislation which the subcommittee asked the Association to comment on deals with the problems of diseases of the heart, lungs, blood and blood vessels. The Association is concerned about these diseases and the epidemic proportions they have assumed.

Heart and blood vessel diseases are among the major causes of death in the United States, killing more than one million people each year. Cardiovascular disease is responsible for 54.1 percent of all deaths in the United States, killing old and young alike. Heart attacks kill 600,000 people annually. More than 12 million Americans will suffer some kind of heart attack in the next 10 years.

Lung diseases are deadly killers and debilitators; approximately 20 million Americans are disabled with diseases of the lungs. In addition, death from emphysema is rising at a rate unparalled by any other disease.

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

The Association feels that these grim facts exemplify the need for action concerning these diseases. It is clearly in the national interest to act on these problems. These diseases strike down people in their prime, most productive years. Even when not fatal, these diseases seriously disable people so that they no longer can work. In addition to creating a life of nonproductive existence and suffering, these diseases also have a serious economic impact on the country.

PROPOSALS FOR ACTION

The Association has studied the various legislative proposals before the subcommittee which deal with diseases of the heart, lungs, blood and blood vessels.

HR 12460, the National Heart and Lung Diseases Act of 1972, was introduced by Representative Pepper. This bill enlarges the authorities of the National Heart and Lung Institute and the National Institutes of Health in order to advance the national effort against heart and lung diseases. The bill establishes a National Heart and Lung Diseases Program, headed by a Presidentially appointed Director of the National Heart and Lung Institute. The authorities of the Di-

rector are increased; he may submit the Institute's budget directly to the President and may approve after scientific review routine research and training grants of $35,000 and less. As part of the heart and lung program, the bill establishes 15 new heart and lung disease research and demonstration centers and authorizes heart and lung disease control programs. The bill also establishes a three-person President's Heart and Lung Panel to oversee the program and replaces the present National Advisory Heart Council with a new, 23-person National Heart and Lung Advisory Board. The bill authorizes appropriations of more than $1.5 billion through fiscal 1975, including $420 million in fiscal 1973.

HR 12571, the Heart, Lung and Neurological Diseases and Stroke Amendments of 1972, was introduced by the chairman of the Interstate and Foreign Commerce Committee, Representative Staggers. The bill deals in a parallel manner with strengthening the National Heart and Lung Institute and the National Institute of Neurological Diseases and Stroke. The bill provides for Presidentially appointed Institute Directors who may submit their Institutes' budgets directly to the President and may approve after scientific review routine research and training grants of $35,000 and less. In addition, the bill authorizes establishment of control programs and clinical research and demonstration centers in heart, lung and neurological diseases and stroke. To combat heart and lung diseases, the bill authorizes appropriations of more than $1.5 billion through fiscal 1975, including $420 million in fiscal 1973. To combat neurological diseases and stroke, the bill authorizes appropriations of more than $1.2 billion through fiscal 1975, including $320 million in fiscal 1973.

HR 13500, the Heart Disease Prevention Act of 1972, was introduced by Representative Duncan. This bill provides for the following: establishment of national multidisciplinary centers for the prevention of arteriosclerosis; establishment of 10 model cardiovascular disease prevention clinics; and creation of an Office of Heart Health Education within the National Heart and Lung Institute to provide for a program of heart health education. This bill authorizes $425 million to be appropriated for five years, beginning in fiscal 1973 with $50 million and rising to $100 million in fiscal 1977.

HR 13715, the National Heart, Blood Vessel, Lung, and Blood Act of 1972, was introduced by the chairman of this subcommittee, Representative Rogers, and others. This legislation is to enlarge the authority of the National Heart and Lung Institute to advance the national attack upon the diseases of the heart and blood vessels, the lungs and blood. To accomplish this purpose, HR 13715 provides the following: development of national heart, blood vessel, lung and blood disease program to expand, intensify and coordinate the activities of the National Heart and Lung Institute; re-establishment of heart, blood vessel, lung and blood disease control programs; establishment of thirty new national clinical research and demonstration centers for cardiovascular and pulmonary diseases; establishment of an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources to coordinate federal health programs in these areas; replacement of the National Advisory Heart Council with a new 22-member National Heart and Lung Advisory Council; and simplification of the review procedure for routine training and research grants of less than $35,000. For fiscal year 1973, $370,000,000 is authorized to be appropriated.

ASSOCIATION COMMENTS

The Association finds that cardiovascular and pulmonary diseases are a major drain on our national resources and looks with optimism to legislation that recognizes and deals with these problems. In discussing cardiovascular and pulmonary diseases, however, what cannot be overlooked is the fact that our present understanding of these diseases is a direct result of broad advances across the full scope of the biomedical sciences. Progress in basic fields related to heart, blood and lung diseases has advanced our state of knowledge to its present point. Further advances in these basic areas are essential to a clear understanding of these major killer diseases. While the Association agrees that there are greater opportunities in trageted research in some areas than have been possible to exploit with present NIH programs and levels of support, we urge that continued attention is vitally important to basic, investigator-initiated research.

In considering the legislative proposals before this subcommittee, the Association has reached certain conclusions.

We feel that the legislation introduced by Representative Pepper and Staggers includes a number of desirable approaches to overcome cardiovascular and

pulmonary diseases. Among them are the authority to establish control programs and clinical research and demonstration centers and to simplify the approval of routine research and training grants. The legislation also appears to include, however, a number of organizational proposals developed during the 1971 debate over legislation for an expanded national attack against cancer. While most of those proposals seemed to be apprpriate in that debate, the Association does not consider them appropriate to this effort. A different problem is to be confronted, and a different set of issues is involved. These differences should be recognized, in the Association's view, in whatever legislation is recommended by this subcommittee.

Representative Duncan's bill, the Heart Disease Prevention Act of 1972, encompasses many useful proposals centered, however, almost, exclusively around arteriosclerosis. Other cardiovascular and pulmonary diseases do not appear to be covered by the legislation. We would emphasize that we are dealing here with a family of related diseases affecting the vital role of breath and blood in sustaining the life process. There is little to be gained in singling out a single disease process for legislative action. Thus, we feel this bill is much too limited in terms of the problems to be dealt with.

Representative Rogers' bill, the National Heart, Blood Vessel, Lung and Blood Act of 1972, would provide considerably broader and. we believe, a more effective framework to deal with the problems of cardiovascular and plumonary diseases. This bill authorizes the Director of the National Heart and Lung Advisory Council, to develop a plan 180 days after enactment of the legislation for a heart, blood vesel, lung and blood program. The program would expand, intensify and coordinate the activities of the Institute concerning these diseases and would provide for action in eight broad areas. Among other things, these areas include research into the basic biological processes and mechanisms involved in the underlying normal and abnormal cardiovascular, pulmonary and blood phenomena; studies and research into blood diseases, such as sickle cell anemia and hemophilia; studies and research into the use of blood banks; and establishment of programs and centers for study and research into children's cardiovascular, pulmonary and blood diseases, and for the development and demonstration of diagnostic, treatment, and preventive approaches to these childhood diseases.

This basic plan is to be submitted to Congress and would contain staff requirements to carry out the program as well as recommendations for program appropriations. The Association believes this provision constitutes a rational approach to the problem of organizing the national attack against cardiovascular and pulmonary diseases. Such a plan would seem to provide a coherent plan for action and method of evaluation. Indeed, it is the provision of this plan in HR 13715 which, in the Association's view, makes this legislation distinctive and superior to the other bills considered.

The Association would hope, however, that the development of this plan would recognize and make provision for the work of other NIH institutes related to lung and blood problems which in the area of cystic fibrosis and the malignant and infectious diseases of the blood constitute an important part of the whole effort in these areas. Some minor change in the language of section 413 of the bill might be desirable to assure full coordination with these efforts in the overall plan.

Other essential elements of Representative Rogers' bill to help achieve the objectives of the program are provisions to establish control programs, clinical research and demonstration centers, and an Interagency Technical Committee. These provisions will enable the National Heart and Lung Institute to mount a unified, intensive attack upon cardiovascular pulmonary diseases. They will help establish effective and direct methods of disease prevention, diagnosis, and treatment.

As a consequence of this review of the legislation now before the subcommittee, the Association must conclude that Representative Rogers' bill provides a coherent, balanced program to deal with cardiovascular and pulmonary diseases. While it increases and strengthens the attack against a specific group of diseases, it simultaneously recognizes the necessity of full support for the broad base of scientific research.

Before closing, the Association must return to an important, underlying concern. It is fully supportive of the major new research efforts proposed here for heart and lung diseases and enacted recently for cancer. But the Association must again emphasize in the strongest possible way that useful progress in these categorical areas is completely and utterly dependent upon advances at more fundamental scientific levels. Unfortunately, support for this area of basic, funda-

mental research is not a separate program whose needs can be dealt with in primary and direct terms. Rather, such support is encompassed in what is called the regular research grant program of the National Institutes of Health and appears only as a secondary budget item within the overall appropriations estimates of the several NIH institutes.

Thus, despite Congressional establishment of appropriation authorizations and action on appropriation requests, there is no direct way for the Congress to insure that support for this area of basic research is sufficient to undergird the various categorical efforts. An example illustrates this point. In the President's budget request last year for fiscal 1972, a special additional sum of $100 million was included for an expanded national attack against cancer. However, the additional funds were provided through a real but hard-to-perceive reduction in the regular research grant programs of the other institutes. Similarly this year, despite the increases proposed in the President's budget for cancer and heart in fiscal 1973, support for new and competing research grants and for general research support have been cut back. In simpler terms, Mr. Chairman, this is tantamount to starving the goose that days the golden egg. Without a vigorous and expanding body of fundamental scientific activity, there is little point in legislating new and massive categorical programs.

There is, in fact, much to suggest that the current NIH structure for support of investigator-initiated academic science in the face of nationally organized categorical research programs is becoming increasingly contradictory. It may be time for the Congress to review this structure in the context of current national objectives, the scope and nature of the scientific activity requisite to these objectives, and the most framework for its support.

Mr. ROGERS. Thank you very much, Dr. Cooper. I know the committee shares your concern about reduction in the basic research support. In trying to design the bills the emphasis is also given to basic support.

Mr. Nelsen?

Mr. NELSEN. No questions. I thank the witness for this statement.

Mr. ROGERS. Mr. Kyros?

Mr. KYROS. Just one statement, Mr. Chairman. First of all, I welcome you here. I was enlightened by the testimony and I agree with everything you have said.

Let me say this question, as a layman. You have talked about the basic research in the chairman's bill. What about the fact that today we do not know how to rehabilitate the man who has sustained a myocardial infarction. We are all prone to it. How do rehabilitate him?

Dr. COOPER. If this relates to the difference between, let us say, investigator-initiated research and the more programmatic directed research, we would say we are fully in support of exploiting all of the opportunities that are available to us now in a concerted attack against many diseases. They are available, and we don't think we are spending an optimal amount of our resources to understand and to try to conquer these diseases.

The point we are trying to make, however, is that the very ability to mount this attack comes from the information that has flowed in from the basic biomedical investigator-initiated research.

In regard to the rehabilitation of individuals that have had, for instance, coronary occlusions or myocardial infarctions, we have a great number of studies going on, for example, to the changes that occur in the metabolism of cardiac tissue as a result of the reduction in the blood supply which comes from the infarction. From this has come a real understanding about, for instance, the passage of potassium out of the muscle, and this further complicates the metabolic activity of that muscle, which is not only denied its oxygen supply

but now has a complete disarrangement in its metabolic activities. This leads to further necrosis and death of tissue.

Understanding these kinds of things will permit us to try to do something to be more effective in preventing medical deaths from the infarction, in rehabilitation and in resupplying the heart with blood. There are many operations that are now being tried. Whether they are successful or not, I think, is open to speculation. Other techniques are certain to come out of the other directed programmatic research.

Mr. CARTER. Some of these transplants are successful, are they not?

Dr. COOPER. Yes, sir.

Mr. KYROS. Doctor, do I take it, then, that even in this field of rehabilitation of the patient, postcoronary occlusion requires still further basic research of all opportunities in other multidisciplinary fields to let us know what is going on?

Dr. COOPER. Not only to prevent the death, but to understand what we might do to this damaged organ, which is like a broken arm, but you can't put a splint on it. We need more knowledge of how to bring back the metabolism which it needs to produce the contractions.

Mr. KYROS. Do you induce myocardial infarction in animals?

Dr. COOPER. Yes, sir. You tie off a vessel.

Mr. KYROS. And you do research in how to save them afterwards?

Dr. COOPER. Yes, sir.

Mr. KYROS. Thank you very much, doctor.

Mr. ROGERS. Dr. Carter?

Mr. CARTER. I was particularly interested in what you said on page 9, that actually funds had been taken from other programs, as far as the cancer appropriation is concerned; is that correct?

Dr. COOPER. What we did here was just to compare—and I gave you the data—on what has happened to appropriations for other programs in other institutes. What we are concerned about is that these new initiatives be add-on programs. We don't think that the level of research support today for all of the institutes is excessive. We don't believe that we are going to move ahead on the front of all diseases if we rob Peter to pay Paul.

What has actually happened in fiscal 1972 is that although $100 million was added in the cancer area, which we fully supported, there were unfortunately corresponding reductions in the support of other institutes and programs. These support the basic investigator-initiated efforts.

In other words, the total increase which was given to the NIH did not amount to the $100 million.

Mr. CARTER. What was that total increase? There was an increase.

Dr. COOPER. I was talking about the administration request. The administration request was largely for an increase in the cancer budget with decreases in other institutes.

Mr. CARTER. Let me go over that appropriation again. The $100 million was appropriated for cancer; that is true, isn't it?

Dr. COOPER. Yes, sir.

Mr. CARTER. What about your other appropriations? Were they at the same level or increased?

Dr. COOPER. The President's initial budget request for fiscal 1972, for all of the research institutes was $79,663,000 above fiscal 1971. In that was the $100 million additional support requested for the cancer

program. That means there was a reduction in the other institutes of some $21 million.

For example, there was a reduction of $491,000 in Division of Biologics Standards.

Mr. CARTER. You are absolutely positive of what you are stating, that there was a reducation in what was appropriated for NIH outside of cancer?

Dr. COOPER. Yes, sir, what was requested.

Mr. CARTER. I want to be sure of that. And other programs have been deprived to the extent of $21.4 million?

Dr. COOPER. Yes, sir. That was in the President's request. The Congress appropriated more money. I am talking about the concerns we have about the kind of allocation of resources and effort that the administration has requested. $70 million came out of changes within the other programs. Now, there were increases in some other institutes. For example, child health and human development went up almost $7½ million; the Eye Institute $1.3 million; Environmental Health Sciences $4 million, and so on. There were some increases in some of the other institutes besides cancer.

If one examines now the programs within the institutes and the particular areas in which funds were to be expended, one sees that the research and training programs were down; general research support was down; new and competing research grants across all of the institutes were down.

Mr. CARTER. Your approach then, to the Institutes of Health was $20.6 million less, not counting the $100 million?

Dr. COOPER. That was the President's request.

Mr. CARTER. Now, let us see what you said here. "The additional funds were provided through the real but hard to perceive reduction in the regular research grant programs of the other institutes." That doesn't say one thing about the President's request.

Dr. COOPER. I think it comes in the first sentence: "In the President's budget request last year."

Mr. CARTER. You say the "requests." That doesn't mean a thing. It is actually the appropriation that counts, what gets to the people. Let us get down to the appropriations and make it so that it is really meaningful. Has there been any decrease in the appropriations to the National Institutes of Health outside the cancer program?

Dr. COOPER. No, sir.

Mr. CARTER. All right. That is good. Now you are telling us something. There has been no decrease, but you have inferred that which is not good to come before the committee in saying that somebody didn't want to give it but it was actually done.

Dr. COOPER. Dr. Carter, the reason we brought this up is because of our concern that the direction of the programs of the National Institutes of Health under the present organization in the legislation for those institutes is determined by the administration. The Congress is not able to direct how the funds for those particular institutes will be expended.

The reason we brought this up is evidence of our concern that the administration is reducing programs critical to the continued advance of basic biomedical knowledge.

Mr. CARTER. I don't deny in some areas they may have diminished the appropriations. But in others it more than accounts for that, according to what you have said. But in certain areas they were diminished.

Dr. COOPER. We think the Congress showed great wisdom in restoring some of these funds that had been cut in the administration's request.

Mr. BOWSHER. If I might amplify this a minute, I think what you two are discussing here is a case study of what Dr. Cooper mentioned at the bottom of page 9 of his prepared statement. We are talking about the possibility contradictory nature of categorical programs versus basic investigator-initiated research. What is happening is that the categorical program for cancer did in fact increase $100 million. The way they got a good deal of the $100 million increase was to reduce support for basic, fundamental research across the entire range of biomedical science. I think that you are illustrating what we pointed out.

Mr. CARTER. I have heard you say that. You and he have gone over that. Yet you admit the appropriation to NIH outside of the $100 million cancer bill was increased.

Dr. COOPER. Yes, sir; by the Congress.

Mr. ROGERS. I think you are saying that was done by the Congress.

Mr. CARTER. The administration doesn't appropriate the money anyway; the Congress has to do that.

Mr. ROGERS. Are there any other questions?

Thank you so much for being here. We appreciate the testimony. It is most helpful.

Our next witness is Dr. Samuel M. Fox, president of the American College of Cardiology.

We are delighted to welcome you, Dr. Fox, and we will be pleased to receive your statement.

STATEMENT OF DR. SAMUEL M. FOX III, PRESIDENT, AMERICAN COLLEGE OF CARDIOLOGY

Dr. FOX. Thank you, Mr. Chairman and other members of the subcommittee. It is a privilege and pleasure to appear before you and to join with you and your colleagues in seeking means to more effectively prevent and control diseases of the heart and circulation, diseases of the lungs, and disorders of the blood.

I have a fairly extensive statement which I will not take time to read in its full detail.

Mr. ROGERS. We will put it in the record and you may highlight the points you would like the committee to consider.

Dr. FOX. I would appreciate that. If I may request your attention to page 7, I have detailed some recommended areas of needed support for of the funds for control of these diseases. One of these areas is a new peripheral vascular disease program. This is not only important because people are disabled and uncomfortable with disorders of the circulation in their arms and legs, but because the peripheral circulation also represents a very fertile area in which to study the changes in the atherosclerotic process, to which other witnesses have testified.

Mr. KYROS. May I ask a question about nocturnal leg cramps in the

calf of a leg. I know people my age experience them now and then, and perhaps they go away and you may never have them again. Has this to do with circulatory problems?

Dr. Fox. Some of them are due to circulatory problems. As people relax in sleep and have a reduction of the circulation with the lower heart rate and stimulus to heart action, you may get a circulatory insufficiency and get a cramp from that cause. However, I would like to assure you in the case of many of us in the middle and very productive years that some of the cramps are not related to circulatory inadequacy and are not thereby suggestive of impending further difficulties of a more serious nature. Indeed, there are drugs available, as Dr. Carter and Dr. Roy, I am sure, have used in their practices, that help to, or at least tend to, eliminate the occurrence of such crampy pains.

The next item on page 7 is stroke research. We believe we must come out strongly for the return of the primary stroke preventive research effort to the National Heart and Lung Institute. Some years ago it was, indeed, largely in the National Heart Institute. Then at that time, and without much congressional discussion, the research program on blindness of that Institute was removed to become the new Eye Institute, perhaps a very well justifies thing, about which I cannot speak with expertise. At that time there was a movement to put stroke over in the neurological area.

As you well realize, the prime factor in the background of most strokes is either high blood pressure, which produces leakage or hemorrhage in the brain or brain stem areas or the occlusion of vessels. It is a vascular phenomenon. It lends itself to productive blood vessel research and, I believe, cure, through modification of those processes which produce vascular disease.

Therefore, we do make a strong plea that the prime focus for the vacular element be in the area of the National Heart and Lung Institute.

On page 8, stroke rehabilitation research is likewise included as needing more support. As we have stated in the prepared statement, there has been really very little research productivity in the 17 centers under the National Institute of Neurological Diseases and Stroke. The support of these centers, as I understand it from inquiry, has declined. There is only $1.3 million of other research in the stroke area being supported by grants. We believe there is a great need for more support and energy applied to stroke research.

I think that Dr. Theodore Cooper, for whom I have the greatest respect, as do my colleagues in all cardiovascular areas, realizes this need and would carry forward with it.

Next, we wish to emphasize the overwhelming need for more clinical trials in atherosclerosis prevention. This has been discussed by you and your colleagues earlier this morning.

In the area of diet therapy, the projected multifactor study has to do with diet modification and perhaps drug modification of elevated lipids, high blood pressure, and modification of the cigarette smoking habit.

Next there is acute heart attack treatment research. There is a need for more of the which is already started in looking at how we handle our patients when they shown signs suspicious of being in the heart attack area.

There are pharmacological and instrumental approaches that need to be developed. There is certainly a lot more than can be done as outlined in the very modest increment we put in our statement for this area.

Coronary care units, to which patients are now going with a rather striking improvement in their survival once admitted, have a need for further improvement, and the extension of these coronary care facilities out into the community through mobile services, such as picked up our former President Johnson, are in need of more evaluation. This is operational research. Dr. Crampton has a very exemplary model down in the Charlottesville area. We have one in Montgomery County. There is one in Miami which is very effective. Your Jacksonville group, Mr. Rogers, has demonstrated that nonphysicians can provide these very important—actually lifesaving—techniques.

I think there is much that can be done here, but we need a specific research and development program.

Next, surgical research. We certainly must have a very careful scientific evaluation of the new bypass surgery wherein you take a vein from the leg, which is easily spared, and you reverse it so the values don't obstruct, and by bridging from the aorta down into the distal parts of the coronary arteries beyond some of the major obstructions, a surgeon can provide a markedly increased blood flow to an area previously short of blood. This has to be evaluated, because the enthusiasm we see at the moment is perhaps unwarranted in part, although I personally share a real optimism from some of my own clinical experience.

Rehabilitation of coronary care patients. You asked about that Mr. Kyros. This is really a question of can our society afford to provide the services and facilities which—I think most of us are convinced—do a great deal to uplift the optimism, the feeling of well-being and the ability of most patients to get back to useful work and meaningful activity. Most patients are convinced of the benefits of a well-structured psychological and physical rehabilitation program.

We can do it. The question, I think, is a societal one: Can society, among its options, afford this? This means, in a sense, a definitive study, an operational "applications" study, with some basic elements in it, as to what really is worth doing and how much we can, therefore, recommend to communities and practitioners to include as frequent, if not routine, services.

I think this type of rehabilitation effort also has a great deal to do with our society in general. There are many people who are not victims of heart disease in the overt sense, who are less than optimally productive in their living because they have lost some of the vigor of life. I think for the benefit of the productivity and creativity in society we have to do this type of research, and there is a place for it tied into the cardiovascular component within the National Heart and Lung Institute.

I think this area of work also gets at Dr. Carter's comments about stress. Those who are physically able to get out and work off some of their anxieties sleep better. Dr. Howard Sprague of Boston said he "never knew a charwoman with insomnia." I think many of us have felt that this has a real application to the stressful living to which many of us expose ourselves.

New research centers: As covered in your bill, I think there is a very real place for them. They would include basic research, to which Dr. Cooper alluded, and I think many of the clinical applications-type research.

There is a need for construction of facilities, on which we have not had much emphasis. The resources in facilities and construction funds have been diminished, but if we are to get people to apply themselves to these areas, we must have the space. Many good academic institutions, with people both in the research area and in the service area, are not able to bid, in a sense, to the granting agencies or to respond to the requests for proposals for contracts under some of these programs in the Institute because they do not have the means to generate new space. We recommend that a major element of the appropriation be in this area.

Model Prevention Clinic evaluations is very important. I am emphasizing "evaluations," because some of our colleagues are concerned about putting service programs in the Heart Institute. But we don't know how to put these models in the field in their optimal form. So we have to do some modeling, if you will, and evaluate the models. It is very sophisticated community research.

We need training of personnel. We need education. You will see on page 13 we have tried to put out, not just the fact we need more money, but we have many and varied programs in which we could apply this money.

Mr. ROGERS. This is very helpful to the committee where you have broken this down in this way.

Dr. FOX. It took some restraint because I think you could put a lot more into these areas.

Returning, if I may, to some of the specific aspects of your bill, H.R. 13715 and the Senate bill as passed, S. 3323, I would like to make the following specific suggestions, and I would like, if I may, to go over this in some detail. I will not read it all.

I believe there is an emergency services opportunity. The statistics are that more than half of those 60,000 patients that Dr. Huntley said could be saved by an adequate emergency service system are in the cardiovascular area.

The 10 model clinics we definitely recommend be in, and we believe that if there is to be an authorization amount for control programs it should be pushed up by $10 million for each fiscal year.

Third, the technical committee we believe should not be in the Office of the Secretary but probably should be housed geographically and administratively in the National Heart and Lung Institute. We believe this is even more compelling in the area of the health education effort. Neutral ground is good for some of these, but I think the competence of the Institute staff persuades us that this is the best location.

Fourth, we believe the 18 members of the Council should include not more than 12 in the scientific area and not more than eight of the general public. We see no need for students, although we are most sympathetic to the input from youth.

Fifth, we believe that the chairman of the Council should be the director of the Institute for management purposes. But a cochairman should be a Council member and he should be chairman of a planning committee structure.

Sixth, we believe the authorization should be moved up if, indeed, it is to have any finite numbers, although I share with others the idea that appropriate as "necessary to do the job" would be more appropriate.

Seventh, there is a rather detailed enumeration why this should be the case. Time constraints do not permit a detailed review. I think the percentage formulas should be relaxed or eliminated.

Finally, I wish to make a personal plea of a somewhat different nature. I do this not as an officer of the American College of Cardiology, but as a private citizen, if I may.

I believe you are as aware, Mr. Chairman, as am I of the many dedicated men and women in our Government who are serving all our citizens at considerable personal, family, and financial sacrifice. I am concerned about how we will be able to maintain the interest of our present Government employees and to attract the extra talent we need to move forward with the programs I have just recommended.

Perhaps the most attractive increment that might be considered is the provision of a meaningful college tuition benefit package for Government workers. College tuition expenses are rising and, after the payment of taxes, represent a sizable family budget item. The loss of tuition benefits is one of those most frequently mentioned as being a reason for persons not leaving academic life for Government service. I hope some favorable consideration of this can be given by the appropriate committees of the Congress.

I would be glad to answer any questions, and I very much appreciate the opportunity to appear before you.

(Dr. Fox's prepared statement follows:)

STATEMENT OF DR. SAMUEL M. FOX, III, PRESIDENT, AMERICAN COLLEGE OF CARDIOLOGY

Mr. Chairman and Members of the Subcommittee: I am Samuel M. Fox, III, President of the five thousand member American College of Cardiology.

It is a privilege and pleasure to appear before you and to join with you and your colleagues in seeking means to more effectively prevent and control diseases of the heart and circulation, diseases of the lungs and disorders of the blood.

It is well established that heart disease is the cause of over half the deaths in the United States each year. It is also well established that many of these deaths occur prematurely in those in the prime of life—on whom families and society depend. Close to forty (40) percent of all deaths among persons under age sixty-five (65) are attributed to diseases of the heart. Much of the same background of high blood pressure and/or slowly accumulating fatty "atherosclerotic" material reducing the blood supply to the brain contributes to more than two hundred thousand (200,000) deaths each year classified as cerebrovascular disease—commonly called stroke. Heart disease and stroke are the first and third most frequent causes of death in this country.

The House of Representatives has had a distinguished history of providing generous support to the heart disease effort—for which we are most thankful. We are here today to give testimony in support of an even larger and accelerated effort appropriate to the expectations of our citizens and consonant with our belief that it will quickly repay the sizeably increased investment proposed.

Although we appreciate the hazards of planning a health strategy by assembling into a "patchwork whole" those individual efforts which command major attention, we believe special recognition for the needs of heart disease prevention and control is long overdue. Heart disease, cancer and stroke cause over seventy (70) percent of deaths in the United States.

We believe the best location for the planning and programming of the national heart disease prevention and control effort of the Federal Government is within the National Heart Disease and Lung Institute.

This is not only because of the widely recognized competence of its present Director, Dr. Theodore Cooper, but because the Institute has earned great respect for the manner in which it has enlisted the participation of non-Federal persons—both citizens and professional health workers—in its planning and review procedures. We therefore endorse the elevation of the National Heart and Lung Institute to status equivalent to that recently accorded the National Cancer Institute and support its designation as the coordination point for all Federal heart-related activities.

There are large numbers of conscientious and dedicated practioners and planners who have tried to implement the intent of Congress in applying, at the community level, what is known or thought promising through Regional Medical Programs. Lack of full support for their efforts and inadequate recognition of the importance of their work in the specific area of heart disease prevention and control has discouraged many and frustrated others. A focus of cardiovascular strategic and tactical planning and programming appears to be the needed ingredient for re-activating this valuable cadre of interested and dedicated workers. The Health Services and Medical Health Administration, Social and Rehabilitation need increased funding to move forward with their heart related programs, but we believe the administration of national planning and coordination will be done best by career professionals using the advice and review of non-Federal experts—a function with which the Heart and Lung Institute has demonstrated competence.

With the support of the House, past research has given us much understanding of the basic nature of many forms of heart, blood vessel, lung and blood diseases. The leads discovered make all the more important and persuasive the need to push forward further and faster. Further basic research into the energetics of the heart is necessary if we are to appropriately treat those with disease. The most powerful approaches to disease prevention and treatment will only become available with an understanding of the control mechanisms and how they become deranged.

There are also many unrealized opportunities to develop both fundamental and practical knowledge concerning the best forms of treatment. The collaborative efforts of the few Myocardial Infarction Research Units are developing meaningful data on the indications and contra-indications for specific heart attack therapies. Similar efforts in other areas, as well as more adequate support of these heart attack studies, would be productive.

A great need exists to evaluate scientifically both the long-term value of and contraindications relating to the exciting new techniques of coronary by-pass surgery. Optimistic reports abound and in my own practice I have seen impressive improvement provided my patients by my surgical colleague Dr. Paul Adkins. However, he, many others, and I are insecure as to when to apply this promising therapy. With the enthusiasm for this dramatic approach so great it will be difficult to undertake the appropriate evaluations. This very enthusiasm, however, makes it all the more imperative that such studies be done—done well and done promptly.

As we advance with fundamental and clinical research on heart diseases and their management, we must also move forward in applying the results of past research that suggest effective means for disease prevention.

After a review of research reports the Inter-Society Commission for Heart Disease Resources has identified numerous Coronary Risk Factors that appear to contribute to the multifactorial causation of coronary heart disease—the single most frequent diagnosis implicated in death in the United States.

Concerning none of these risk factors is there yet defined a clear-cut cause-and-effect relationship that will satisfy the appropriately skeptical scientific community. The necessary studies will require massive contributions of time, effort and resources but some of the studies' form and direction are clear. We have reason for optimism that appropriate studies regarding alterations of diet for the control of elevated serum lipid (or blood fat) levels, the administration of drugs for the reduction of high blood pressure and abstinence from cigarette smoking will give us some of the answers we seek. Dr. Cooper has initiated a small start on a "Multifactor Study" of this type—but he can provide only marginal support for getting the answers promptly. More extensive efforts are needed to do the job more securely.

Six blood lipid centers undertaking some vital new studies have been started recently and perhaps six more will soon start, but even twelve such units under present circumstances of short funding will have great difficulty developing the

information required. We need two or three dozen such centers, each expanding at a deliberate rate to become comprehensive atherosclerosis research and service centers of far broader scope. They should be specifically designed to support the translation of research results into community services as well as continue the further research. Likewise, there is a small but struggling high blood pressure research effort following up on the most encouraging work done in the Veteran's Administration. In the area of hypertension, we are trying to find answers to a condition involving over twenty million (20,000,000) individuals in the United States and threatening many more. We are trying to do this with grossly inadequate resources.

We must recognize that the work relating to both lipids and blood pressure is almost exclusively in adults yet it is widely accepted that the start of these disorders occurs in the teens or before.

Among other identified coronary risk factors, the contribution of diabetes, obesity, physical inactivity and psycho-social tension are all amenable to study, yet almost nothing is now being done to acquire the understanding we need of these factors for developing our total strategy.

Drs. Jean Mayer and Frederick Stare of Boston, Dr. Herman Hellerstein of Cleveland, Dr. Robert Bruce of Seattle and my colleague, Dr. John Naughton here at George Washington University have been leaders in exploring the role of the physically more active life in coronary disease prevention and control.

Preliminary data demonstrate that those persons who have had a heart attack return more rapidly to a more satisfying and productive life—of possibly longer duration—if provided with a carefully prescribed physical re-conditioning program. This is also applicable to many de-conditioned Americans without myocardial infarcts. Yet at this time there is no adequate study being mounted to define the place of increased habitual physical activity as either preventive or rehabilitative therapy. This is especially of concern because vigorous physical activity programs are now being widely endorsed and often pursued by our citizens without appropriate evaluation and advice and at intensities that can be catastrophic. In a larger view, such programs command the attention of all of us and require first-class scientific evaluation because of their great relevance to our concern with preserving and enhancing general health and stimulating a more creative, productive and happier society.

Diseases of the peripheral arteries—those to the hands and feet—cause severe disability and much pain. The use of present measurement techniques, and the application of bio-physical and engineering talent to develop new non-invasive techniques, will permit us to evaluate the effects of diet, drugs and changes in life-style on the atherosclerotic process in intact man without "invading" his body with those useful little catheter tubes which sometimes involve both discomfort and hazard. Almost no research in this area is now being supported, even in the lipid centers, due to stringent fiscal limitations. There is also grossly inadequate support for the development and validation of new measurement techniques needed for disease detection and evaluation.

The background of most cerebro-vascular accidents—or strokes—is considered by many to be similar to coronary heart disease—with high blood pressure and elevated serum cholesterol levels clearly implicated. Although the brain damage of a stroke produces a neurologic deficit, the great hope for the desired primary prevention is in the avoidance of vascular disease. We therefore believe that most elements of stroke research and demonstration should be supported and coordinated from within the strengthened National Heart and Lung Institute.

Earlier, we mentioned the needs for more community applications of our present knowledge to make available to all citizens that which is known or considered most promising. An example is the almost complete elimination of new cases of rheumatic heart disease in some communities in Wyoming through the prompt detection and treatment of streptococcal sore throats. Such efforts are just as applicable and important, if not more so, in our big cities as in our less populated areas. This is but one example of our having the knowledge but we are not applying it adequately due to the lack of a national prevention and control program.

In applying in our communities that which holds promise we must evaluate different approaches, their benefits and their costs. There is great need to evaluate various models of Prevention Clinics, Community Cardiovascular Control Centers and other such attractive concepts to provide valid data for wide implementation of the best activities.

There is great enthusiasm in many areas concerning early coronary care and other emergency services outside—before admission—to the hospital. Programs in Seattle, San Francisco, Columbus, Miami and our neighboring Montgomery County, Maryland demonstrate that an effective service can be provided-yet many of these programs are faltering or being discontinued because funds to train and support the personnel are lacking. It has been calculated that at least thirty-five thousand (35,000) premature cardiac deaths could be prevented each year if we only applied what we presently know in the way of good emergency care.

The training of personnel at all levels requires enhanced aid. Particularly, we need to train persons at all professional levels of expertise to operate the Prevention Clinics and other community programs. We also must have consistency in program planning or we will lose those we train for research or community service into other areas. Sporadic support of training will continue to impose damaging delays in program effectiveness unless corrected. New authority for the Heart and Lung Institute must also include enhanced training opportunities to permit the adequate translation of knowledge into service.

Likewise, along with a rejuvenated Control Program effort must be a parallel professional and public education and information program far above the restricted effort now in effect.

There are many other examples we could give of attractive or well proven programs and opportunities which need accelerated implementation and support. Part of this support must be in the area of facilities construction and maintenance in addition to the support of personnel and supplies. Laboratory and clinic space is often not available where men with bright ideas or a deep commitment to the provision of needed services are ready and eager to work.

There will also be the necessity to give the strengthened Heart and Lung Institute the ability to attract top level talent to join the staff in the new planning and programming efforts. Competition here is keen and appropriate inducements must be available.

We applaud the recognition by this Subcommittee of these needs for increased heart disease prevention and control. We support the Subcommittee's efforts to provide protection against and care for the disability and distress that plague our patients, friends and families in the form of diseases of the heart, blood vessels, lungs and blood.

Last week, on the 21st of April 1972, the College of Cardiology presented its recommendations for FY 73 appropriation increments above the President's Budget for the National Heart and Lung Institute. We made specific and, we believe, highly justified proposals for programs above the level that would be permitted by the FY 73 Administration Budget of 254 million dollars. Our programs would require approximately one hundred million dollars of additional support just to initiate programs of the highest priority. Clearly a major increase in the entire Heart and Lung Institute program and staff is in order.

We repeat the same list in our testimony today to demonstrate the specific nature of the opportunities and to make certain that no one carries away the impression that we are calling for authority and funding without a clear program that justifies our citizens' investment in it.

The opportunities are presented in the order of cardiovascular prevention, care and rehabilitation rather than in the order of their scientific importance or urgency.

PERIPHERAL VASCULAR DISEASE

One of the areas of greatest neglect is the study of the peripheral arteries in the arms and legs in which the atherosclerotic process can be evaluated by new techniques. This year there is less than three quarters of a million dollars worth of support available for this important research.

In the area of venous disease there is also a great need for stimulating research above the almost invisible effort now being supported. We recommend one half million dollars ($500,000) be made available specifically to develop instrumentation for the detection and more adequate management of thrombophlebitis—the abnormal clotting of venous blood which occurs far more frequently than is generally appreciated. The often lethal breaking loose of fragments from such clots requires major diagnostic and treatment program development. Encouraging reports of new instrumental applications require confirmation.

We therefore recommend a *new* peripheral vascular disease program for FY 73 with four parts.

	Millions
1. Three to five Peripheral Vascular Research and Development Centers with initial support of five hundred thousand dollars ($500,000) for each center	$2.5
2. Support for Special Academic Awards to stimulate research personnel and program design	0.3
3. Epidemiologic and research project activities	1.0
4. Thrombophlebitis detection and therapy	0.5
Total	4.3

STROKE RESEARCH

Closely related to peripheral vascular disease—and with exceedingly serious manifestations—is the area of cerebral vascular disease. Either hemorrhage or blockage of the vessels to the head and brain can produce blindness or a stroke with major resulting disability or death. Over two million victims of stroke are alive in the United States and over two hundred thousand (200,000) persons die of strokes each year.

Upon inquiry we find, however, that the National Institute of Neurological Disease and Stroke supports only seventeen (17) stroke research centers with only 3.7 million dollars and that the Institute has only 1.3 million dollars of other research being supported by grants. Five million dollars ($5,000,000) of research for a disease from which two million (2,000,000) Americans suffer! The causes of almost all strokes are vascular—not neurologic—even though brain and nerve damage are the dreaded results.

On March 24, 1972, we made a strong plea to the Senate Subcommittee on Health of the Committee on Labor and Public Welfare that the major research responsibilities relating to stroke prevention and control be returned to the National Heart and Lung Institute from which they were moved without much Congressional discussion some years ago. Today we repeat the request that the responsibilities for stroke be returned to the National Heart and Lung Institute and recommend an immediate increment of research support in the following areas:

	Millions
1. Clinical trials of platelet anti-aggregants	$0.6
2. Diagnostic instrumental research and development	1.0
3. Stroke rehabilitation research	2.0
Total increment for stroke	3.6

CLINICAL TRIALS OF ATHEROSCLEROSIS PREVENTION

Of paramount importance is the need to pursue at a more rapid and adequate level the many clinical trials having to do with the prevention of atherosclerosis—the process of fatty deposition that reduces the blood carrying capacity of arteries and predisposes to an acute occlusion, or total blockage, of the coronary or cerebral vessels producing a heart attack or stroke. In the search for the causes of atherosclerosis and its manifestations there has been major progress in the last twenty years—much of it made possible through Congressional support.

It is highly desirable that we evaluate the concept of risk reduction in relation to the prevention of coronary and other atherosclerotic manifestations. In the budget document we have reviewed, the fiscal increment requested by the administration will not suffice to support adequately even the early start we are happy to see being projected for community studies this year. It is most essential that these large and very demending community trials be done correctly for an inadequate trial would leave false impressions more damaging than having not attempted the research in the first place. We believe it is imperative to expand the support of these trials to help assure that the information derived is not of questionable statistical significance.

Three "Major Risk Factors" have been identified: High Blood Pressure, Elevated Blood Fat Levels and the Smoking of Cigarettes. Controlled clinical trials are mandatory because proof that risk factor reduction will prevent coronary disease has not been established.

1. *Hypertension detection and control in the community.*—We recommend an additional one and a half million dollars ($1,500,000) above the requested support which will permit the addition of six more research clinics each to be funded at

two hundred and fifty thousand dollars per year. These will provide the more rapid and secure accumulation of data than will be available with the nine clinics currently under development.

2. *Diet and drug therapy of high serum lipid levels.*—For the study of the type disorders producing elevated blood fats and for the recruitment of study subjects for specific dietary and drug trials, we recommend the addition of six more clinics to be funded at six hundred thousand dollars ($600,000) each—a total of 3.6 million dollars. This is in addition to twelve clinics already started or projected and budgeted at nine million dollars ($9,000,000).

3. *Multi-factor study.*—We are particularly persuaded that it will be necessary to create and support ten to fourteen additional clinics at a total cost of three and a half million dollars ($3,500,000) in the first year (FY 73) to screen, evaluate, select, and recruit the eleven thousand (11,000) participants in the multi-factor trials who will be randomly allocated into treatment and control groups. We believe it unrealistic to think the presently projected six clinics with only two and a half million dollars ($2,500,000) can undertake this formidable task of evaluating control of hypertension, elevated serum lipids and the cigarette habit.

Budget summary of additional support for clinical trials.

	Millions
Hypertension detection and control in the community	$1.5
Lipid centers	3.6
Multifactor trials	3.5
Total	8.6

These three studies are those recommended by the NHLI Task Force on Atherosclerosis as being urgently needed and promising of results that relate to the cause of eighty percent (80%) of all cardiovascular deaths under the age of sixty-five years.

ACUTE HEART ATTACK TREATMENT RESEARCH

In the therapy of those with acute heart attacks we have seen most encouraging results reported with the administration of thrombolytic agents—those that dissolve elements in blood clots. A three year trial of these agents is recommended with five to six thousand (5,000–6,000) patients under a randomized treatment and control allocation. A first year cost of three and a half million dollars ($3,500,000) is requested.

Two other acute care efforts command our support:

1. Pharmacologic and instrumental approaches to the support of the severely damaged heart show encouraging results. The administration of glucose, insulin, potassium and the enzyme hyaluronidase needs study as do the metabolic intermediary substances fumarate, malate and glutamate.

2. New and improved devices for work sparing circulatory "counterpulsation," both within the body and applied externally, need evaluation as do the instruments developed for observing and controlling their application.

A FY 73 increment of two million dollars ($2,000,000) is appropriate—and indeed will only just start the necessary further development.

Up to sixty percent (60%) of acute coronary deaths occur outside hospitals involving over one hundred and fifty thousand (150,000) United States' citizens under age sixty-five each year. Many of these catastrophies are thought to be the result of acute changes in the electrical stimulus to the heart from that which produces effective mechanical contraction to that which produces chaos. No adequate trial has been undertaken of some of the presently available drugs that appear to have application in these conditions—and new agents are being developed both here and abroad. Another one million dollar ($1,000,000) add-on is recommended for anti-dysrhythmic trials to be started.

CORONARY CARE INSTRUMENTATION IMPROVEMENT

Coronary Care Units have resulted in the reduction of in-hospital coronary mortality from around thirty percent to the mid-teens—almost half. Numerous attempts to operate mobile coronary care services have been started with some very encouraging results. The personnel involved in all these efforts need the type instrumental and computer support that our space technology has developed but not yet fully applied to acute medical care. There is a particular need for reasonably-priced systems of continuous surveillance and data analysis for the electrocardiogram from the time the patient can first be seen to a time when he has demonstrated he is in a status of acceptably low risk in his chosen life style

after rehabilitation. Other physiologic functions should be monitored if we can develop the appropriate sensor-transducer systems to pick up and relay the data in easily interpreted form.

Additional funding of three million dollars ($3,000,000) would stimulate a major improvement in monitoring techniques.

SURGICAL RESEARCH

A great need exists to evaluate scientifically both the long-term value of and contraindications relating to the exciting new techniques of coronary by-pass surgery. Optimistic reports abound and in my own practice I have seen impressive improvement provided my patients by my surgical colleague Dr. Paul Adkins. However, he, many others, and I are insecure as to when to apply this promising therapy. With the enthusiasm for this dramatic approach so great it will be difficult to undertake the appropriate evaluations. This very enthusiasm, however, makes it all the more imperative that such studies be done—done well and done promptly.

We recommend four million dollars ($4,000,000) for FY 73 to initiate a controlled trial of coronary by-pass surgery.

REHABILITATION OF CORONARY PATIENTS

Many encouraging reports of the benefits of physical and psychological rehabilitation after a heart attack have been reported but no well-controlled studies of sufficient size and duration have been started.

New instruments of measurement would enhance the scientific validity of such studies—instruments both physiologic and psychologic in application. Such studies should have major importance in our broad efforts to create a more productive, creative and happier society as well as one in which patients can recover their ability to work and live more actively with lesser hazard.

The American College of Cardiology supports the urgency of such studies in rehabilitation and requests that two million dollars ($2,000,000) be provided for this purpose in FY 73.

The Social and Rehabilitation Service and its system of Research and Training Centers has made plans for such research but without adequate funding being assured. We do not feel it is our place to specify the administrative base for such studies but we do welcome the opportunity to urge that they be done promptly and with the best of scientific talent and technique.

NEW CENTERS

In the new bills upgrading the National Heart and Lung Institute (S. 3323 supported by the administration, all citizen and organizational witnesses and already passed, and those of similar intent in the House) provision is made for " . . . fifteen new centers for basic and clinical research into, training in, and demonstration of advanced diagnostic and treatment methods (including emergency medical services) for cardiovascular diseases."

Each of these centers are projected at a level up to five million dollars ($5,000,000) and thus some significant part of seventy-five million dollars ($75,000,000) is needed—perhaps a first year (FY 73) funding level of thirty-six million dollars ($36,000,000) would be appropriate.

CONSTRUCTION OF FACILITIES

Construction funds are essential if we are to move ahead with these programs. Many well-qualified investigative or clinical service teams cannot expand their superior programs to become "centers" unless space is provided to conduct clinical trials or establish "centers for basic clinical research."

A new floor on many existing buildings costs around one million dollars ($1,000,000) or more. Even a small clinical research facility including a new building may cost five million dollars ($5,000,000).

We recommend an appropriation of twenty million dollars ($20,000,000) for construction of heart disease facilities for FY 73 to make possible the many needed research and demonstration programs previously described.

MODEL PREVENTION CLINIC EVALUATIONS

Much research is needed to delineate the control mechanisms that are disrupted as disease replaces health. While we learn how to help protect against the

development of disease at the level of basic mechanisms we must also learn how to develop systems for disease prevention, detection, therapy and rehabilitation that will attract and hold people's interest. The College recommends the establishment of ten (10) model clinics in various parts of the country with eight million dollars ($8,000,000) of FY 73 support. Careful evaluation of differing approaches tailored to local styles of life are an essential part of this effort.

TRAINING OF PERSONNEL

In the area of training we wish to emphasize our continuing concern about diminishing support for the creation of competent research and service personnel during a time of increased appreciation of the needs of heart disease prevention and control.

It is inconsistent with good sense to try to do an increased amount and more technically demanding types of research and community service without increasing training program support. We recommend two million dollars ($2,000,000) be provided in FY 73 to start new heart disease training programs involving nutritionists, health educators, physical educators and others as well as physicians.

PROFESSIONAL AND LAY EDUCATION

Finally, there is a tremendous need for an expanded program for professional and lay education concerning what is established fact or considered valuable information. There is no new money in the President's budget request and the present National Heart and Lung Institute expenditure in this area is only three hundred thousand dollars ($300,000). To expand present functions and support research into improved techniques for learning we recommend four million dollars ($4,000,000).

Recommended budget additions above the administration's request of $254 million for fiscal year 1973 for the National Heart and Lung Institute

	Millions
Peripheral vascular disease	$4.3
Stroke	3.6
Clinical trials of atherosclerosis prevention	8.6
Acute heart attack treatment	5.5
Anti-dysrhythmia trials	1.0
Coronary care instrumentation	3.0
Surgical research	4.0
Coronary rehabilitation	2.0
New centers	36.0
Construction of facilities	20.0
Model prevention clinics	8.0
Personnel training	2.0
Professional and lay education	2.0
Total	100,0

Returning, if we may, to some specific aspects of your bill H.R. 13715 and the Senate Bill S. 3323 I would like to make the following suggestions:

First, we are impressed with the statement of Dr. Huntley, Director of the Division of Emergency Health Services of the Health Services and Mental Health Administration at the Second Annual Meeting on Emergency Medical Services, December 12, 1971, concerning the unmet needs in ambulance and emergency care. He stated that thirty-five thousand (35,000) of the sixty thousand (60,000) American lives that could potentially be saved by a truly modern ambulance-emergency care system would be acute cardiac patients. We made a specific point of this opportunity in our testimony before the Senate Subcommittee on Health and are gratified that under Sec. 2, Item 7, of the S. 3323 there is a statement on "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. . . ." We believe this is worthy of inclusion and recommend it for Congressional action, perhaps as in S. 3323 under Section 413 (a) sections 5 and 10, Section 414 (a), (b), (d) and Section 415 (a) (2).

Second, we strongly recommend that ten Model Carviovascular Disease Prevention Clinics be established as part of the expanded control program function of the Heart and Lung Institute (Section 414) and that increased appropriations of thirty million dollars ($30,000,000) for the fiscal year ending June 30, 1973, forty million dollars ($40,000,000) for the fiscal year ending June 30, 1974, and fifty million dollars ($50,000,000) for the fiscal year ending June 30, 1975, be authorized—and at the appropriate time and place be appropriated—for these centers and other control program functions.

Third, we believe that it would be preferable to have the Interagency Technical Committee and Office of Heart and Lung Health Education located within the National Heart and Lung Institute rather than within the Office of the Secretary as implied in Section 416 (a) of S. 3323. As presented in our written statement I am so impressed with the competence, knowledge and dedication of Dr. Theodore Cooper and his staff to the larger national cause that I believe we would find more effective performance of this important function if such a coordination and stimulation role was geographically, physically and administratively within the Institute rather than within a loose and ever-expanding group of such Technical Committees within the Office of the Secretary.

That some "neutral" ground has some points of appeal is recognized—but in this specific case I believe other considerations are more persuasive. We are particularly desirous of seeing the Office of Heart and Lung Education (Section 416 (c)) established within the Institute so that the superb talent of the investigative and administrative staff are most conveniently available to insure the most valid presentation of educational communications.

Fourth, we believe that of the eighteen members to be appointed by the Secretary to the National Heart and Lung Advisory Council (Section 417 (a) (2)) not more than twelve of the appointed members of the Council shall be leading medical or scientific authorities who are skilled in the sciences relating to disease of the heart, blood vessels, lungs, and blood, and not more than eight of the appointed members shall be representatives of the general public. We see no need for students on this Council with its complex and demanding responsibilities.

Fifth, we believe that the Director of the National Heart and Lung Institute should be designated the Chairman of the Council (Section 417 (c)) rather than a member of the Council. We understand the importance of having the Council serve as an outside review group not only concerning the present and anticipated responsibilities of the National Heart and Lung Institute but also to consider future opportunities of all sorts. We believed, however that there is so much of importance that the Council must consider that even four (4) meetings a year, of perhaps three (3) days each, will require management demands and scheduling of a type that may place too heavy a burden on an outside Council member. We therefore propose that the Director be designated Chairman, that a Council member be designated Co-Chairman and that this same Council member be the Chairman of the National Heart and Lung Advisory Council Planning Committee—a well-established committee function that has worked well in Heart Institute functions of the past.

Sixth, we strongly recommend increasing the authorization of funds to four hundred and fifty million dollars ($450,000,000) for the fiscal year ending June 30, 1973, five hundred million dollars ($500,000,000) for the fiscal year ending June 30, 1974, and five hundred and fifty million dollars ($550,000,000) for the fiscal year ending June 30, 1975 (Section 419 B).

Seventh, under Section 419 B and C of Senate Bill 3323 there is a potential problem. If a maximum of only sixty percent (60%) of the Heart and Lung Institute appropriation can be allocated to cardiovascular disease program with a possible extra ten percent (10%) as authorized in Section 419 we might find ourselves limited in the ability to initiate new cardiovascular programs. Under these circumstances we would have but two hundred and forty million ($240,000,000) cardiovascular dollars (60% of $400,000,000) available for FY 73 under S. 3323 (possibly with 10% or $40,000,000 more using the 10%) or $210,000,000 of $350,000,000 if the same 60% formula was applied to HR 13715 for FY 1973. In the written statement presented we have proposed one hundred million dollars $100,000,000) worth of new—highly justified—programs that we believe would bring prompt returns. This hundred million added to a projected FY 73 President's Budget proposed program of one hundred and ninety-four million dollars for cardiovascular disease ($254,000,000 minus $30,000,000 each for lung and Blood Programs) would give two hundred and ninety-four million dollars ($294,000,000) of valuable cardiovascular program for FY 1973 yet at most we

may be authorized two hundred and eighty million dollars ($280,000,000) including the ten percent (10%).

We suggest that the percentage formulas be relaxed or eliminated and that the authorization figures be expanded above those of S. 3323. This would permit the Institute to take advantage of the best of all opportunities.

I will be glad to try to answer any questions you have and wish to again express my appreciation and that of the College of Cardiology for this opportunity to speak concerning this important and beneficial legislation. Thank you.

Mr. ROGERS. We appreciate your patience with the committee today. We had a lot of questions to go into with the administration. I think your testimony in such detail will be helpful.

Dr. FOX. Would you like me to try to get back at 2:30 for questions?

Mr. ROGERS. I think it would be better to go over in detail the questions and then get back to you.

The committee stands adjourned until 2:30 this afternoon.

(Whereupon, at 12:30 p.m. the subcommittee recessed, to reconvene at 2:30 the same day.)

AFTER RECESS

(The subcommittee reconvened at 2:30 p.m., Hon. Paul G. Rogers presiding.)

Mr. ROGERS. The subcommittee will come to order.

I was anxious to know what the regional medical program really is doing in the heart and lung field. Are they doing much in heart and lung?

STATEMENTS OF DR. JOHN S. ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, AND DR. THEODORE COOPER, DIRECTOR, NATIONAL HEART AND LUNG INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DHEW—Resumed

Dr. ZAPP. I would have to, as Dr. DuVal did this morning, submit for the record a list of these.

Mr. ROGERS. I think we need to know that.

(The following material was received for the record:)

REGIONAL MEDICAL PROGRAMS: ACTIVITIES IN HEART AND LUNG DISEASES

Listed below are some 130 operational projects that relate *directly* to heart and lung disease currently supported with RMP grant funds. These total over $9 million, and account for roughly 22 percent of the RMP funds specifically granted for operational projects.

This listing does not reflect either (1) operational projects of a multicategorical or comprehensive character or (2) those activities carried out by the program staffs of the 56 Regional Medical Programs. Many of these other RMP-supported projects and activities are also relevant for heart and lung disease. Thus, for example, an operational project designed to result in improved emergency medical services will benefit acute coronary attack victims as well as those injured in automobile accidents. Similarly, a survey and feasibility study conducted by the program staff of a RMP which seeks to improve rheumatic fever control programs for that Region's Indian population may lead to improved diagnosis and treatment of this ailment and yet never require or result in operational funding.

Therefore, the listing below very possibly understates the current RMP activity and grant investment in "the heart and lung fields" by as much as one-half. As a simple listing of projects it also fails to reflect any real details of what is actually being done.

A one-line entry, "Oklahoma—Coronary Care Monitoring Network for EKG Transmission—$174,000," cannot begin to relate that continual electronic heart

monitoring services comparable to those available in large urban hospitals are being introduced into Oklahoma's small community and rural hospitals as a result of a state-wide coronary care program initiated by the Oklahoma regional medical program. As a result, 43 monitor equipped beds for heart attack victims, or attack-threatened patients, in 29 small community hospitals have been linked by special telephone lines to 10 central monitoring hospitals (CMU's).

This program has been described by the University of Oklahoma cardiologist directing it as "a boon for small rural hospitals which cannot afford the services of the highly trained personnel required to operate an independent coronary care unit."

Specially trained nurses in the central monitoring units help monitor remote patients, and when an abnormally is detected confer with local staffs by telephone hotlines. The importance of immediate coronary care stems from the fact that most heart attack victims who die, do so within the first few hours.

The general hospital mortality rate from acute coronaries (myocardial infarction) is about 30 percent. With coronary care units, this is usually reduced 15 to 20 percent. An October 1970 survey of Oklahoma hospitals by the project staff showed that 46 percent of that State's hospitals with 50 beds or less had no facilities for coronary care, and 33 percent of hospitals with 51 to 150 beds had none. Besides training for nurses, the project also provides continuing education and training for physicians and paramedical personnel, including preparation of coronary care technicians.

Nor does this listing of present activities begin to convey the dimensions of the still unmet needs, which are staggering, or the real contribution RMP could make in this connection. Many of the individual projects listed below are reflections of need, the need for the major control programs and activities such as the early detection and management of hypertension, rheumatic fever screening and prevention, and the diagnosis and treatment of chronic respiratory and pulmonary diseases.

Major new control activities of this kind could be mounted both through regular grants to the 56 RMPs and by using the existing authority under Section 910(a)(2) to make grants to a wide range of public and private nonprofit agencies and institutions (e.g., health departments, hospitals) for the "development, trial, and demonstration of methods for control of heart disease * * *."

Current Heart Disease Projects in Regional Medical Programs

Region and project	*Funding*
I. Hypertension:	
Metropolitan Washington, D.C.: Establishment of selected hypertension clinics	$36,700
Intermountain: Curable hypertension identification	112,100
Mississippi: Hypertension control demonstration for aged, disabled, indigent	11,617
Missouri: High blood pressure control, early screening for stroke	160,200
Tennessee mid-south:	
Regional program for improved control of hypertension	113,559
Alton Park Health Center, demonstration hypertension	84,300
Category total	518,476
II. Rheumatic fever and/or congential heart disease:	
Maryland: Mass detection of heart disease	4,300
Missouri: School heart screening by phonocardioscan	18,000
North Carolina: Comprehensive rheumatic fever prevention program	38,827
Northeastern Ohio: Strep culture program	225,941
Category total	287,068
III. Heart disease:	
Alabama: Continuing nurses education, mobile coronary care unit	15,900
Albany: Coronary care training program	8,879
Arizona: Cardiopulmonary resuscitation training program	29,273
Arkansas:	
Coronary care training for nurses	32,522
Cardiac rehabilitation	28,917
Bi-State: Coronary care training program for nurses	67,116

Region and project	*Funding*
III. Heart disease—Continued	
California:	
Coronary care	$80, 149
Pacemaker registry	67, 841
Perinatal monitoring	89, 450
Rapid hospital myocardial infarction	55, 895
Metropolitan Washington, D.C.:	
Establish central peripheral vascular facility	4, 900
Coronary care nurses training. Freedmen's Hospital	7, 300
Regional exercise stress testing services	61, 600
Florida:	
Regional computerized EKG processing center	36, 900
Coronary care data collection	38, 400
Cardiovascular screening in four rural Florida counties	121, 600
Supervisory paramedical emergency teams	7, 100
Coronary care nurses training in 7 hospitals	87, 400
Georgia: Cardiovascular area facilities	100, 000
Greater Delaware Valley:	
Coronary care training, northeast Pennsylvania	50, 600
Coronary care training, east central Pennsylvania	48, 700
Coronary care training, Delaware	49, 100
Coronary care training	25, 000
Do	25, 000
Hawaii: Physiological data monitoring system	54, 246
Illinois: Multiphasic screen	203, 800
Indiana:	
Network of conorary care units throughout Indiana	149, 471
Nursing in coronary care units	31, 896
Intermountain:	
Physicians cardiovascular training project	101, 100
Nurses training in cardiac resuscitation	95, 200
Clinical cardiology training	64, 100
Community cardiovascular review	117, 000
Regional myocardial infarction data system	193, 700
Iowa:	
Coronary care training for physicians	3, 600
Clinical associate training in pediatric cardiology	60, 272
Mobile coronary care unit	34, 595
Cardiac ausculation cardio examination of children	15, 220
Kansas: Cardiac care	15, 460
Lake area: Coronary care training for nurses	50, 800
Louisiana: Cardiopulmonary resuscitation program	42, 154
Maine:	
Coronary care	39, 003
Coronary care	38, 408
Maryland:	
Early detection of heart disease in newborns	12, 100
Coronary care program	95, 300
Closed chest cardiopulmonary resuscitation	37, 300
Memphis:	
Intensive cardiopulmonary care training	93, 939
Strep center	38, 057
Electrocardiographic program	20, 195
Coronary care unit, St. Bernards Hospital	10, 833
North Mississippi cardiovascular clinics	29, 934
Michigan:	
Cardiovascular center	21, 324
Western Michigan medical education	39, 340
Mississippi:	
Cardiovascular clinics for indigents consultant continuing education	39, 176
Coordinated system in coronary care unit hospital training	71, 696

Region and project	*Funding*
III. Heart disease—Continued	
Missouri:	
Training unit for intensive care of cardiac patients	$25, 800
Intensive care unit pulmonary function laboratory	64, 400
Cardiovascular education evaluation, Springfield	65, 000
Cardiac care in Missouri	50, 000
Intensive care rehabilitation project	20, 000
Mountain States: Intensive care unit training in Southwest Idaho	20, 800
Nebraska: Coronary care training	141, 800
New Jersey:	
Statewide program for cardiopulmonary resuscitation in Community Hospital	25, 700
Evaluation status of Beth Israel Hospital pacemakers	69, 500
Decentralized RN–LPN cardiac care training	34, 300
New Mexico:	
Model cardiac care unit	22, 461
Coronary care nurses training program	6, 384
Monitoring remote coronary care unit project	22, 518
North Carolina:	
Coronary care training and development	42, 635
Close chest cardiopulmonary resuscitation	43, 954
Heart sounds screening program	16, 676
Comprehensive cardiac pacemaker education program	32, 819
Coronary care training course for nurses	8, 742
Northeastern Ohio: Coronary care unit training	150, 759
Northern New England: Progressive coronary care program	159, 339
Northlands:	
Multidisciplinary myocardial infarction medical care	158, 600
Pediatric cardiology education	20, 300
Ohio:	
Intensive cardiac care training	327, 623
Coronary care nurses training	78, 686
Sudden death mobile coronary care	138, 152
Oklahoma: Coronary care monitoring network EKG transmission	174, 900
Oregon:	
Coronary care training in Salem Memorial Hospital	54, 900
Coronary care training in Sacred Heart Nursing Academy	61, 400
Nurses education in rapid EKG consultation	27, 300
Coronary care teaching aids library, EKG tapes	900
Physicians in-residence course in techniques of cardiology	42, 400
Puerto Rico:	
Pediatric cardiovascular diseases	146, 600
Education and training program for physicians and nurses in intensive care unit for cardiac patients	88, 700
Rochester:	
Cardiovascular nursing	42, 508
Telephone EKG consultation	5, 029
South Carolina:	
Training coronary care nurses	61, 043
Comprehensive care of heart disease in children and infants	97, 009
Comprehensive coronary care unit	31, 493
South Dakota: Coronary care training	132, 300
Susquehanna Valley:	
Coronary care nurses training	19, 000
Nurses training coronary care unit program	14, 500
Tennessee mid-south: Cardiac screening of schoolchildren	22, 478
Training program in cardio pulmonary resuscitation	22, 639
Coronary care unit holding units	27, 124
Virginia:	
Myocardial infraction training program	96, 100
Coronary care evaluation	39, 200
Western Pennsylvania:	
Regional education program for nurses	137, 100
Regional training program for hospital emergency teams in cardio pulmonary resuscitation	33, 300
Category total	6, 083, 632

Region and project	*Funding*
IV. Pulmonary disease:	
Arizona: Chronic pulmonary disease program for Arizona	$116,230
California:	
Chronic respiratory disease	97,744
Comprehensive respiratory disease	91,635
Metropolitan Washington, D.C.: Comprehensive pulmonary training for physicians, nurses, and technicians	14,800
Greater Delaware Valley:	
Chronic pediatric pulmonary disease	161,600
Respiratory care centers	64,700
Renal disease patient support	33,700
Indiana: Chronic pulmonary disease	4,693
Intermountain: Chronic respiratory disease	92,200
Lakes Area: Chronic respiratory rehabilitation training	620,900
Mississippi: Training in diagnosis and treatment of Chronic pulmonary disease	137,988
Mountain States: Continuing education in inhalation therapy in respiratory care	15,800
North Carolina: North Carolina emphysema and lung disease program	60,000
Oklahoma: Regional emphysema	65,500
Puerto Rico: Pediatric pulmonary disease center	120,000
South Carolina: Comprehensive respiratory disease training statewide	17,597
Texas: Inhalation therapy	29,175
Western Pennsylvania: Emphysema and pulmonary disease	18,000
Category total	1,762,262

Mr. ROGERS. I think we need to know what the regional program that is developed in the line of heart research as well as services.

Dr. ZAPP. The regional medical program?

Mr. ROGERS. Yes.

Dr. ZAPP. I might say, Mr. Chairman, I think our position is, maybe not that it is effectively doing as we would like to see it, but what we would like to see is that once the National Institutes of Health have proven a particular method for application, the regional medical programs be used as a vehicle to transfer those methods into the field with their relationship between the academic centers and the practicing profession, and at that time that we use various existing or proposed third-party payment mechanisms to pay for the services.

But there is at many times a blurred line between the times when an institute has been working on a particular research application that it has to that particular proven point and such time as the methodology is defined enough so it can be transferred to the practicing profession.

Mr. ROGERS. How quickly do you think these centers can be established that we included in the legislation?

Dr. COOPER. We have centers program experience, Mr. Chairman. They are not centers quite as large as the ones envisioned in the legislation, but I think the time period that is required for this is about 9 months in order to get out an announcement, to allow a suitable time for competition and review.

Mr. ROGERS. I presume you would also try to spread them geographically.

Dr. COOPER. We have already in the present pattern tried to have excellence as the primary consideration. The program need is secondary, and then location for general availability as a resource is third.

Mr. ROGERS. I think it is important for us to get our centers of excellence spread as well as we can under limitation.

What is the ratio now of grants to contract?

Dr. COOPER. In 1972, we will be spending about 21 percent of our budget in contracts, about 10 percent, as I said this morning, on direct operations in the intramural program. The remaining, with the exception of the management requirements and overhead costs, are spent on grant mechanisms.

Mr. ROGERS. How long does it take to approve a grant and how long does it take to approve a contract as an average?

Dr. COOPER. The average time of submission depends, in part, upon the time of the year, but, in general, it takes between 6 and 9 months on a grant application in order to undergo submissions classifications, study, review, and referral to council and award.

In the contract area this, in some cases, is just as long. In other cases, depending on the nature of the request, it can be somewhat more rapid, because the nature of the proposals is more limited, the competition is more limited, and the review process, although it involves two levels, can be accomplished with greater rapidity.

Mr. ROGERS. Where does HEW have to approve in the process of grants and contracts?

Dr. COOPER. In the grant area, as I am sure has been established since the initial legislation, the primary responsibility for recommending grant approval is a statutory function of the Council. The responsibility of the Department, therefore, is limited to determining whether the awards are appropriate within the fiscal constraints that are currently available within the funding plan. They do not make a determination whether they are recommended for approval or not, but they do influence the procedure in determining the amounts of funds that are available for the total system.

In the contracting area, a similar surveillance is employed, and in some large contracts I believe it is the function of the Department from time to time to review particularly the large contracting activities prior to award.

Mr. ROGERS. In those contracts what is the time element, the ones that have to have departmental approval?

Dr. COOPER. It does not exceed 9 months if it involves that procedure.

Mr. ROGERS. I understand that sometimes it is very difficult to get departmental approval on equipment or a new facility where it is needed for new rooms to carry on research projects. What about that? Have you experienced that in your Institute, too?

Dr. COOPER. We have not had a large experience in the contracting for facilities construction, because we have largely limited our contracting operation to support of direct research operations and have not in our operations supported construction of facilities to any large extent. So we have not had that type of problem.

Mr. ROGERS. Do you think we can set up proper screening programs in the heart and lung areas?

Dr. COOPER. I think it is possible to set up appropriate screening programs, if there is a good program of followthrough to go beyond it.

Mr. ROGERS. Do you see this as a very accomplishable goal?

Dr. COOPER. Yes; for certain specific abnormalities.

Mr. ROGERS. Could you let us have those for the record?

Dr. COOPER. Certainly.

(The following information was supplied for the record:)

Feasibility of Screening and Detection Programs

Screening and detection programs for heart and lung diseases are presently entirely feasible and practicable. The information relating to heart disease is provided below. The question as it relates to lung screening is supplied separately.

A. Heart Screening and Detection Programs

Considerable experience has been gained in heart disease screening and detection programs in the past 15 years through epidemiological studies and screening programs in community populations, employee populations and among members of prepaid health insurance programs. Some of these screening programs have directed attention to heart disease detection alone whereas others have included efforts to detect diabetes, tuberculosis, lung cancer and obstructive lung disease. At the present time there are acceptable techniques for screening and detection programs for heart disease although further improvements in instrumentation, laboratory procedures and in automated data recording and of reporting are needed. Nevertheless a limited number of screening programs for heart disease are now being conducted by Heart Associations, private fee-for-service health screening organizations and other interested health groups.

Question. How long would it take to get such programs going?

Answer. Screening programs could be initiated reasonably quickly in employee populations with the cooperation of medical, labor and management groups which have interests in health care and prevention programs among employees.

Screening programs in community populations would require more time to organize and to enlist the cooperation of medical and community groups thereby encouraging participation of the public.

A minimum of 6 to 9 months would be needed for planning, organizing and training of personnel who would be conducting a screening and heart disease detection program. Equipment for the screening examinations would need to be rented or purchased depending on the expected duration of the screening program. All of this presupposes an interested and cooperative medical and community leadership which can obtain the participation of the persons for whom the screening would be intended.

Question. Which diseases and which symptoms would lend themselves to a screening program?

Answer. Hypertension, coronary heart disease, stroke and rheumatic heart disease and peripheral vascular disease lend themselves to screening programs in adults. Symptoms of chest pain characteristic of angina pectoris, shortness of breath and pain in the calf of the legs on walking could be included as part of the screening procedure.

Measurement of blood pressure, blood cholesterol, blood glucose and an electrocardiogram would provide more objective evidence of risk factor abnormalities which may warrant specific medical evaluation and possible measures for prevention.

Question. What follow-up would be needed for such programs?

Answer. A follow-up plan for persons found to have suspected abnormalities at screening would be an essential part of any screening program. Such a plan would have to be worked out in advance with the physicians to whom these persons with suspected abnormal findings would be referred for further evaluation and possible preventive management. Unless the personal physicians who will have the responsibility for diagnostic evaluation and management are convinced of the need for risk factor intervention and are knowledgeable of how to do this effectively, the screening participants will not be likely to benefit from having their abnormalities detected.

Special educational efforts with physicians in the recommended management for hypertensives and coronary patients would be desirable. The availability of trained nutrition consultation would also be desirable to assist with diet management for persons found to have hyperlipidemia.

It should be stressed that follow-up procedures and resources are essential to assure adequate diagnostic evaluation and long-term management for the individuals found to have evidence of hypertension, coronary heart disease or risk factors for these which require correction.

B. Lung Screening Programs

The feasibility of mass screening for lung diseases in the adult has been demonstrated in many occasions regarding the two most important categories: tuberculosis and chronic obstructive pulmonary disease (COPD). Among chil-

dren, a more specialized area, screening for cystic fibrosis has also been successful. Screening for other lung diseases on a mass-scale may be done also, but in this case its advisability is subject to special considerations such as relative frequency of the conditions in a given population, reliability and cost of screening methods, etc.

At the present time, chronic obstructive pulmonary diseases provide the best opportunity for lung screening programs because these are the most common pulmonary disorders and because they can be easily identified by means of a simple spirometric test and brief symptoms questionnaire. Before embarking on a chronic obstructive pulmonary diseases screening program, however, consideration should be given to the responsibility befalling the sponsoring agency for the follow-up and handling of newly detected cases since COPD is not particularly amenable to management even when good medical resources are available. A review of the indications and pitfalls of mass screening for COPD (i.e. chronic bronchitis and emphysema by the PHS–NTRDA "Task Force on Chronic Bronchitis and Emphysema," Princton, N.J., October 1966) led to the following conclusions:

"The Task Force discussed in detail the indications for mass surveys for chronic bronchitis and emphysema. It recognized that significant contributions to knowledge can be made by surveys, but only if the programs are properly planned and carried out. Before embarking on such a program a clear definition of the objectives of the study and a realistic appraisal of the community resources are essential. The cooperation of community physicians is needed and methods for the referral of cases to physicians should be systematized. Provision for periodic re-evaluation of cases should be made, and all results of the study should be validated.

The Task Force did not recommend large-scale surveys solely for the purpose of case finding. Unless the survey has broader objectives, or is part of a carefully planned demonstration or epidemiologic study, it may not be the best investment of manpower and resources.

Study of the respiratory system is an important aspect of all pre-employment and periodic health examinations, and of multiphasic screening health programs. The inclusion of pulmonary function tests, both in the initial evaluation and in subsequent follow-up examinations, was strongly endorsed by the Task Force."

On the basis of past experience, COPD screening could be organized readily in any community where TB detection programs by official and voluntary agencies exist. Depending on the scope of the new program the time necessary for getting it under way would be of the order of a few months to one year. Resources for follow-up discussed above would vary between communities. Acceptance of such programs by a given community, it should be kept in mind, can not always be taken for granted.

Mr. ROGERS. Also, I think it would be well to set forth for the record who has to give approval of those contract grants and specified by specific offices.

Dr. COOPER. Yes.

(The following material was received for the record:)

APPROVAL SYSTEM FOR GRANTS AND RESEARCH CONTRACTS

In fiscal year 1972, the Institute will fund approximately 1,470 regular research grants and 245 research contracts. Authority to approve grants and contracts has been delegated to the Institute and is exercised in accordance with NIH policy and procedure. A dual review system of approval is utilized to insure consideration of both technical merit and broader program relevance. Grant proposals require approximately four to five months between application deadline and final Advisory Council approval. Approved grants with high priorities are then awarded within thirty to sixty days of approval, depending on the requested start date. Grantee institutions request a start date in accordance with the scheduled meeting time of the Advisory Council, or to coincide with their academic year. Research contract proposals generally require between two to three months for review, negotiation and award. Additional clearance, after Institute approval, is required from the Department of State for grants to foreign institutions. Research contracts over $300,000 are reviewed by the NIH Office of Contracts and Grants.

Mr. ROGERS. What about people being treated, say, in the first 5 or 10 minutes in a heart situation? Is this a very critical time or not?

Dr. COOPER. This is a very critical time in the problem of heart attacks. Of the over 600,000 people who die each year from heart attacks, perhaps 300,000 or 350,000, by some estimates, die without the benefit of attention. If one applies the best information that we have at this point in time, a large number of those so-called sudden deaths occur in the early minutes and hours right after myocardial infarction. So this is a very vulnerable and very important period.

Mr. ROGERS. Now, what is the best way to get at this problem?

Dr. COOPER. I think there are two or three facets to this that are important. One is to try to find out what the risk factors for sudden death are as opposed to general arteriosclerosis to help you pick out those people who are at risk of sudden death.

The second is to try to educate the persons at risks as to what the warning signals are and to encourage them not to deny these signals and not to be overly concerned about seeking medical attention as promptly as possible.

The American Heart Association last year initiated a warning signals program which has proven in its initial attempts to be quite effective. This has been very helpful.

So I think this type of a program of education of the people at risk and the public at large is very important.

The third element is to have a system of responsiveness by the profession in the community in general that can deal with these emergency situations on a vigorous basis.

Mr. ROGERS. Now, what about an education program? Do you do anything on that from your Institution?

Mr. COOPER. We have an office of information in the Heart and Lung Institute currently at the present time in which we do some development of information and a limited distribution in certain areas. We do not have a special program on sudden death education at the present time.

Mr. ROGERS. Shouldn't we have?

Dr. COOPER. This would be an area where something could be accomplished, yes.

Mr. ROGERS. Would you let us know what you plan to do?

Dr. COOPER. Yes, sir.

(The following information was received for the record:)

PLANS FOR PROGRAM OF PUBLIC AND PROFESSIONAL EDUCATION IN THE PEOPLE-AT-RISK AND SUDDEN-DEATH AREAS

The National Heart and Lung Institute currently has underway plans for an augmented program of public and professional education, to be conducted by a separate organizational unit within the Institute. The responsibilities of this office would be numerous. It would stimulate greater use both of education and commercial television and radio time for discussion of heart and lung diseases and measures for their correction; it would also develop programs in cooperation with professional societies for continuing professional education in these areas. Heart, lung, and blood diseases would be included in the programing. In the area of sudden death, particular attention would be given to advising the public concerning relationship between smoking and heart disease; the seeming relationship between certain eating and physical activity habits and heart disease; the need to treat and control hypertension; and the need for persons at high risk of sudden death to know significant symptoms of impending heart attack and to act appropriately if premonitory signs appear.

Mr. ROGERS. Suppose we do put in the language saying you shall coordinate the heart information for the Government. Could you do it if we were to put it in the law?

Dr. COOPER. If the resources were forthcoming, besides the authorization and people to do it with, this ought to be possible.

Mr. ROGERS. Dr. Zapp, wouldn't it be a good idea? You said we didn't need this because they already had the authority. Suppose we want them to do it. Wouldn't it be possible for us to spell this out?

Dr. ZAPP. Where you are talking about governmentwide programs with interagency agreements and arangements, I would think the clear intent of Congress is always helpful.

Mr. ROGERS. So it would be good to spell out what the committee desires in that effect?

Dr. ZAPP. I think if that is the clear intent to cross agency lines.

Mr. ROGERS. And even within the Department?

Dr. ZAPP. I think that within the Department, certainly we have authority. I wouldn't by any means, say in all cases.

Mr. ROGERS. I understand. But it has not been used.

Dr. ZAPP. It has not been used. But, of course, as we discussed this morning, I would assume this may be one of the things that the new panel the President appointed on heart would be addressing.

Mr. ROGERS. We are going to address it ourselves. I am just saying it has not been used in the Department, and we want something done on it. I would agree with you that it is probably best for us to spell out our desires in legislation. I would hope the President's panel would address itself to that particular problem.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman. One of the bills provides for 15 research centers to be constructed and manned in our country, I believe. Is that correct?

Dr. COOPER. Yes; 15 in cardiovascular disease and 15 in pulmonary disease.

Mr. CARTER. Where do you plan to locate these?

Dr. COOPER. We have no plan at the present time of any specific locations for these centers.

Mr. CARTER. Where do you think would be a good place for them?

Dr. COOPER. I think the best determination of that should be determined on three criteria: The specific area of particular excellence and scientific merit that the team available to do the work has is one criterion.

The second criterion is the special interest and special resources local to the area to deal with the specialized problem. For example, in the area of lung, there are certain regions of the country where it is most appropriate to deal with the problem of pneumoconiosis—occupational lung disease.

The third is to determine a balance where this would provide the best resource for other reference and service to the profession and public at large.

I think those criteria would be the determining factors.

Mr. CARTER. What personnel would you use to man these centers?

Dr. COOPER. The personnel that should man these centers should be the personnel local to the operation that was available in each locale. I do not feature it to be a responsibility of the Institute to man them.

I would think it would be the responsibility of the applicant to demonstrate that they could man such an operation.

Mr. CARTER. You think, then, in areas where we have widespread pneumoconiosis, we would have the personnel to man such research centers?

Dr. COOPER. If that were the plan, and they would have the core resources, the clinical material, and the basic personnel to man it with additional resources, I think they could recruit and train the additional personnel they would need.

Mr. CARTER. You really didn't answer my question. Do you think these areas have the manpower and training and talented men for research centers?

Dr. COOPER. I think some areas do; not all of them.

Mr. CARTER. That is extremely doubtful. In areas where we have widespread pneumoconiosis, you have some trained men but not many of the caliber to do research in this area. Do you think these research centers should be arms of medical schools or be associated with them?

Dr. COOPER. I think traditionally the manpower pool is greater if it is in association with an academic center. It gives them some other resources and scientific base to operate with. But I don't think it is a sine qua non—that it is a necessary requirement.

Mr. CARTER. You are probably right on that. But certainly to conduct good research, you have to have people who are capable of doing it.

Dr. COOPER. Yes, sir.

Mr. CARTER. You can't just establish a center anywhere without the talent there.

Dr. COOPER. I agree with you. That is why I said the merit was the first criterion.

Mr. CARTER. As sadly as I hate to say it, areas which are high with pneumoconiosis, as in my own particular district, just don't have sufficient manpower for these centers. But with the assistance from the University of Kentucky, we might provide that.

I believe you have five research centers at the present time, is that correct?

Dr. COOPER. Thirty-four.

Mr. CARTER. Where are some of these?

Dr. COOPER. There are some in Florida, Texas, California, Missouri, Philadelphia, Pa., Tennessee.

Mr. CARTER. Where in Tennessee?

Dr. COOPER. At Memphis, hypertension. At Vanderbilt, pulmonary.

Mr. CARTER. The one at the University of Texas is in Houston?

Dr. COOPER. At Baylor University in Houston, arteriosclerosis; the University of Washington, Seattle, lung.

I could provide for the record the detailed list.

(The following material was supplied for the record:)

NATIONAL HEART AND LUNG INSTITUTE
ACTIVE SPECIALIZED CENTERS OF RESEARCH

Grant Number	Title / Investigator / Institution	Req.	Rec.	Awarded
HLR14136	CENTER FOR STUDY OF OBSTRUCTIVE LUNG DISEASE ARIZONA U COLL OF MEDICINE ARIZONA UNIVERSITY BURROWS, BENJAMIN	TUCSON TUCSON MD,	ARIZ 31 ARIZ 30 63-22-3398	
	01 671572	732208	287405	337985 71 A71 306
HLR14138	SPECIALIZED CENTER OF RESEARCH--ATHEROSCLEROSIS LOS ANGELES CO-USC MED CENTER SOUTHERN CALIFORNIA U. BLANKENHORN, DAVID H.	LOS ANGELES LOS ANGELES MD	CAL 54 CAL 50 314-26-9835	
	01 671572	697152	570906	697149 71 A71 230
HLR14141	SCOR FOR ATHEROSCLEROSIS IN CHILDHOOD MIAMI U SCHOOL OF MEDICINE MIAMI UNIVERSITY BLUMENTHAL SIDNEY	MIAMI CORAL GABLES MD	FLA 111 FLA 110 62-30-0321	
	01 671572	592904	410971	533691 71 A71 246
HLR14142	COAGULATION AND CELLS IN THROMBOSIS AND HEMOSTASIS WAYNE STATE U COLL OF MEDICINE WAYNE STATE UNIVERSITY SEEGERS WALTER H	DETROIT DETROIT PHD	MICH251 MICH250 382-20-7867	
	01 671572	390076	242356	326230 71 A71 258
HLR14147	SPECIALIZED CENTER OF RESEARCH IN THROMBOSIS WASHINGTON U ST LOUIS SCH MED WASHINGTON U ST LOUIS WESSLER STANFORD	ST LOUIS ST LOUIS MD	MO 281 MO 280 13-26-2537	
	01 671572	694576	392569	463133 71 A71 192
HLR14148	HYPERTENSION CENTER COLUMBIA U COLL OF PHYS & SURG COLUMBIA UNIVERSITY LARAGH JOHN H	NEW YORK NEW YORK MD	NY 361 NY 360 57-24-7762	
	01 671572	1356962	805287	992586 71 A71 180
HLR14150	SPECIALIZED CENTER OF RESEARCH IN HYPERTENSION HARVARD MEDICAL SCHOOL HARVARD UNIVERSITY BARGER A CLIFFORD	BOSTON CAMBRIDGE MD	MASS241 MASS240 23-12-4585	
	01 671572	433022	333168	418574 71 A71 236

HLR14152 PULMONARY SPECIALIZED CENTER OF RESEARCH
WASHINGTON U SEATTLE MED SCH SEATTLE WASH531
WASHINGTON U SEATTLE SEATTLE WASH530
BUTLER JOHN MD 203-32-2357
01 671572 626076 314333 370157 71 A71 200

HLR14153 JOHNS HOPKINS LUNG CENTER
JOHNS HOPKINS U SCH HYG & P H BALTIMORE MD 236
JOHNS HOPKINS UNIVERSITY BALTIMORE MD 230
PERMUTT SOLBERT MD 422-16-7976
01 671572 473753 205168 238754 71 A71 243

HLR14159 SPECIALIZED CENTER OF RESEARCH IN HYPERTENSION
INDIANA U PURDUE U SCH MED INDIANAPOLIS IND 161
INDIANA UNIVERSITY BLOOMINGTON IND 160
HIGGINS JAMES T JR MD 238-46-0948
01 671572 463870 360074 475961 71 A71 222

HLR14164 ARTERIOSCLEROSIS RESEARCH CENTER
BOWMAN GRAY SCHOOL OF MEDICINEWINSTON SALEM NC 371
BOWMAN GRAY SCHOOL OF MEDICINEWINSTON SALEM NC 371
CLARKSON THOMAS B DVM 411-58-3036
01 671572 617883 588667 604706 71 A71 193

HLR14169 PULMONARY DISEASE CENTER
CALIFORNIA U SAN DIEGO SCH MEDLA JOLLA CAL 51
CALIFORNIA U SAN DIEGO LA JOLLA CAL 50
MOSER KENNETH M MD 220-20-8585
01 671572 927237 449353 538757 71 A71 253

HLR14174 ATHEROSCLEROSIS--BEHAVIORAL & EPIDEMIOLOGICAL STUDIES
STANFORD U SCH OF MEDICINE PALO ALTO CAL 51
STANFORD UNIVERSITY STANFORD CAL 50
FARQUHAR JOHN W MD 561-26-6351
01 671572 585444 352590 363514 71 A71 230

HLR14177 CENTER FOR PREVENTION & TREATMENT OF ATHEROSCLEROSIS
ALBANY MEDICAL COLLEGE ALBANY NY 361
ALBANY MEDICAL COLLEGE ALBANY NY 361
THOMAS WILBUR A MD 427-14-7517
01 671572 692311 500540 641224 71 A71 210

HLR14179 CENTER FOR THE STUDY OF LUNG DISEASE
YALE U SCHOOL OF MEDICINE NEW HAVEN CONN 71
YALE UNIVERSITY NEW HAVEN CONN 70
BOUHUYS AREND MDPHD 256-72-1416
01 671572 566439 347317 465468 71 A71 243

HLR14182 SPECIAL CENTER OF RESEARCH IN THROMBOSIS
BETH ISRAEL HOSPITAL BOSTON BOSTON MASS244
BETH ISRAEL HOSPITAL BOSTON BOSTON MASS244
DEYKIN DANIEL MD 10-26-9936
01 671572 215071 173065 168012 71 A71 246

HLR14187 CENTER FOR LUNG RESEARCH
TEXAS U SOUTHWESTERN MED SCH DALLAS TEX 481
TEXAS U SOUTHWESTERN MED SCH DALLAS TEX 481
SAID SAMI I MD 65-30-1354
01 671572 659132 374969 479540 71 A71 260

HLR14192 SPECIALIZED CENTER OF RESEARCH IN HYPERTENSION
VANDERBILT U SCH OF MED NASHVILLE TENN471
VANDERBILT UNIVERSITY NASHVILLE TENN470
FOSTER JOHN H MD 452-22-9409
01 671572 423441 351864 413436 71 A71 193

HLR14194 PATHOPHYSIOLOGY OF ATHEROSCLEROSIS
BAYLOR COLL OF MEDICINE HOUSTON TEX 481
BAYLOR COLL OF MEDICINE HOUSTON TEX 481
GOTTO ANTONIO M JR MDPHD 509-58-3590
01 671572 702369 250004 356961 71 A71 285

HLR14196 LIPIDS THROMBOSIS & GENETICS IN ATHEROSCLEROSIS
MAYO FOUNDATION ROCHESTER MINN265
MAYO FOUNDATION ROCHESTER MINN265
KOTTKE BRUCE A MDDSC 473-38-7591
01 671572 543870 377200 483191 71 A71 170

HLR14197 SPECIALIZED CENTER OF RESEARCH ON ARTERIOSCLEROSIS
CALIFORNIA U SAN DIEGO SCH MEDLA JOLLA CAL 51
CALIFORNIA U SAN DIEGO LA JOLLA CAL 50
STEINBERG DANIEL MDPHD 371-12-5351
01 671572 635803 402523 480571 71 A71 220

HLR14201 PULMONARY DISEASE RESEARCH CENTER
CALIFORNIA U S F SCH OF MED SAN FRANCISCO CAL 51
CALIFORNIA U S F SCH OF MED SAN FRANCISCO CAL 51
COMROE JULIUS H JR MD 215-24-6034
101 671572 1300680 747472 873893
71 A71 126

HLR14207 EARLY DETECTION AND PREVENTION OF ARTERIOSCLEROSIS
JOHNS HOPKINS U SCHOOL OF MED BALTIMORE MD 231
JOHNS HOPKINS UNIVERSITY BALTIMORE MD 230
KROVETZ L JEROME MDPHD 115-20-7825
701 671572 334535 301081 221427
71 A71 283

HLR14209 M I T ARTERIOSCLEROSIS CENTER
MASS INSTITUTE OF TECHNOLOGY CAMBRIDGE MASS240
MASS INSTITUTE OF TECHNOLOGY CAMBRIDGE MASS240
LEES ROBERT S MD 129-28-7214
901 671572 476628 434258 561593
71 A71 183

HLR14212 CORRELATED STUDIES OF PULMONARY DISEASE
VERMONT U COLL OF MEDICINE BURLINGTON VT 511
VERMONT UNIVERSITY BURLINGTON VT 510
GREEN GARETH M MD 16-24-1550
201 671572 448921 205823 272303
71 A71 268

HLR14214 NEONATAL LUNG CENTER
VANDERBILT U SCH OF MED NASHVILLE TENN471
VANDERBILT UNIVERSITY NASHVILLE TENN470
STAHLMAN MILDRED THORNTONMD 358-26-0717
401 671572 449650 432251 512501
71 A71 140

HLR14217 SPECIALIZED CENTER OF RESEARCH--THROMBOSIS
TEMPLE U SCHOOL OF MEDICINE PHILADELPHIA PA 431
TEMPLE UNIVERSITY PHILADELPHIA PA 430
SHERRY SOL MD 89-26-4618
701 671572 666959 494695 630498
71 A71 173

HLR14218 NEWBORN LUNG CENTER
COLUMBIA U COLL OF PHYS & SURGNEW YORK NY 361
JAMES L STANLEY MD 74-30-4573
801 671572 881856 358390 436543
71 A71 226

HLR14228 SPECIALIZED CENTER OF RESEARCH IN THROMBOSIS
NORTH CAROLINA U SCH OF MED CHAPEL HILL NC 371
NORTH CAROLINA UNIVERSITY CHAPEL HILL NC 370
BRINKHOUS KENNETH M MD 478-30-6415
01 671572 365095 316384 370675 71 A71 215

HLR14230 LIPIDS ATHEROSCLEROSIS AND THROMBOSIS
IOWA U COLL OF MEDICINE IOWA CITY IOWA171
IOWA UNIVERSITY IOWA CITY IOWA170
CONNER WILLIAM E MD 485-05-7873
01 671572 670795 559045 709749 71 A71 163

HLR14236 CENTER FOR PREVENTION OF PREMATURE ARTERIOSCLEROSIS
ROCKEFELLER UNIVERSITY HOSP NEW YORK NY 364
ROCKEFELLER UNIVERSITY NEW YORK NY 360
AHRENS EDWARD H JR MD 71-28-6045
01 671572 1307331 1196339 939250 71 A71 240
60151 971572 300685 72

HLR14237 ARTERIOSCLEROSIS CENTER
CALIFORNIA U S F SCH OF MED SAN FRANCISCO CAL 51
CALIFORNIA U S F SCH OF MED SAN FRANCISCO CAL 51
HAVEL RICHARD J MD 537-03-1670
.01 671572 410686 410686 479649 71 A71 213

HLR14242 SPECIALIZED CENTER OF RESEARCH IN HYPERTENSION
TENNESSEE U COLL OF MEDICINE MEMPHIS TENN471
TENNESSEE U MEDICAL UNITS MEMPHIS TENN479
MUIRHEAD ERNEST ERIC MD 458-16-8764
01 671572 842525 388306 449694 71 A71 262

HLR14251 PHYSIOLOGY MANAGEMENT OF RESPIRATORY INSUFFICIENCY
MEDICAL COLL OF VIRGINIA VCU RICHMOND VA 521
VIRGINIA COMMONWEALTH U RICHMOND VA 520
PATTERSON JOHN L JR MD 254-50-2732
.01 671572 349305 111388 134625 71 A71 306

Mr. CARTER. Are most of these 34 associated with teaching institutions?

Dr. COOPER. At the present time, all of them are.

Mr. CARTER. Are they related to the regional medical program, integral parts of that?

Dr. COOPER. No.

Mr. CARTER. When I came in, Chairman Rogers was speaking to you about regional medical programs. How are they working at the present time?

Dr. ZAPP. I think, Dr. Carter, Mr. Rogers and I were discussing the fact that I would have to supply for the record the information I think both of you are most interested in. That is, currently, what the state of the art is with the RMP programs in transferring proven research into application in the professional community. I am sure without having a record to provide you today we could say it is uneven.

In some areas we would probably find this, particularly in the center where you would have one of the 15 centers of each type as the 34 Dr. Cooper was talking about. In a health science center, we have a strong relationship between the RMP and the science center. In cases such as that, you would see the transference of that applied research information into the profession. In other cases it may not be good.

I think we, ourselves, need to take a good look at that, because we are depending on them to be that transitional arm, so to speak, from the applied research into the applied professional mechanisms. I think we would be pleased to take a good look at that and provide it to the committee.

(The following material was supplied for the record:)

DISSEMINATION OF APPLIED RESEARCH, REGIONAL MEDICAL PROGRAMS

Adaptation of a curriculum, a technology, or a procedure to a specific situation usually involves some experimentation and evaluation of alternative modes of performance. In this sense, most regional medical programs demonstrations, training and information projects, in their own localities have some characteristics of applied research and development.

Generally, however, the Regional Medical Programs Service has classified as research and development those projects and other activities whose novel features are not in widespread standardized use, require technical (as distinguished from situational) experimentation, and may yield patterns of application that can be generalized for use in other situations.

To date, such activities have included projects ranging from development and demonstration of the physician assistant concept, adaptation of automatic equipment to patient care, organizational development and consumer-oriented research particularly related to problem-oriented medical records and various data systems.

RMPS has also had a variety of contracts, particularly in relation to fulfilling the requirements of Section 907 of the legislation dealing with maintaining information on the most advanced methods and techniques of diagnosis and treatment for heart disease, cancer, and stroke.

Probably the best example of this is the contracts with the Inter-Society Commission for Heart Disease Resources, an organization brought into being to implement a contract between RMPS and the American Heart Association. The purpose of the contract and the Commission is to establish guidelines for the prevention, treatment and rehabilitation of patients with cardiovascular diseases. These guidelines have been disseminated around the country and are being used in varying degrees for planning, evaluation, and quality of care standard setting and performance review mechanisms.

This is being followed up by a contract on evaluation of the heart guidelines, to see how and if those sections which have been completed are being implemented. This activity offers RMPS the opportunity to test the premise that the regional medical programs offer a unique mechanism to encourage broad adoption by individuals, institutions, and community groups of new methods for organizing and delivering comprehensive care.

The following illustrate the variety of operational projects involved with applied research:

Pacemaker Implant Evaluation.—The New Jersey RMP supported a project designed to evaluate 500 patients with implanted pacemakers in an effort to predict impeding failure. Eight satellite centers located in community hospitals with teletype link-up are presently operating. It is anticipated that the new method will reduce the number of deaths and emergency replacements. This new method, if successful, will be documented and guidelines will be published explaining in detail the equipment, procedures, methodology, and results for use by others throughout the Nation.

Communications Networks.—In Alabama, a Medical Information Service via Telephone (MIST) has been started. Physicians practicing in small towns and isolated rural areas of Alabama have instant access to specialists at the University of Alabama in Birmingham through the MIST. Calls can be placed free of charge from any point in Alabama, at any time of the day or night, on the MIST circuit. The systems switchboard operators are trained to locate specialists in all fields on split-second notice. This project was developed through the cooperative efforts of the Alabama Regional Medical Program, the University of Alabama in Birmingham, and the American Medical Association's Education and Research Fund. It has served as a prototype for similar programs in other regions.

Problem-Oriented Medical Information.—A contract with the Dartmouth Medical School, New Hampshire, is designed to establish a university-based center where health personnel can be trained in the philosophy and use of the problem-oriented medical information system. This system provides for restructuring of existing medical records according to a list or index of defined patient medical problems to allow for computerization of data. The format allows computerization of clinical data for: rapid audit of quality of care, analysis of personnel utilization, communication between health personnel, and a tool for physician continuing education. Ultimately, a regional medical information system will be developed based on this contract, linking medical centers at the University of Vermont, Dartmouth Medical School, and Augusta, Maine with rural practicing physicians in the three-state area. The training center will also provide for dissemination of the system to other states nationwide.

Computer-Assisted Instruction.—The Ohio State RMP has funded a Computer Assisted Instruction project, designed to establish and evaluate a computer-based information network having CAI capabilities aimed at both health professionals and allied health personnel. In its early stages, terminals were set up in 10 hospitals, linking them to the Ohio State University Medical Center. Eighteen new courses or course modules have been developed since August 1971.

Regional medical programs will be involving themselves to a greater extent as implementing arms for the products of the National Center for Health Services Research and Development, with its emphasis on advanced technology and systems innovations. Barriers to the transferability of new concepts of health delivery point to the need for clearly perceived mechanisms for testing and subsequent adoption by the private sector of valuable new ideas. The 56 regional medical programs, with their coverage of the entire Nation, provide at least one such mechanism.

In addition, there will be an increased emphasis on developing emergency medical service systems which promote both the use of advanced technology and the cooperative linkage of all involved elements for optimum effectiveness in performance. This involves coordination of the advanced technological aids available in terms of communications systems, transportation equipment and systems, and medical facilities and equipment.

Mr. CARTER. The way it was developed to begin with was for your heart and lung and stroke centers to have arms radiating into the communities throughout the country. Some of them have been developed that way and others have not. Why, I cannot understand.

Actually, in our research centers which we are discussing today,

do you think in many cases they should be separated from our universities, from our medical centers, or not?

Dr. ZAPP. I think for scientific judgment, Dr. Cooper would have to answer that. We were discussing before—and I think it is a very valid point—as to the strengths they would have to build on, they wouldn't necessarily have to be, I think, in the same physical plant but as an outreach they could build on what is existing in the health science center. But I think a satellite might be helpful.

Mr. CARTER. If we can tie all of these things into a good plan, if we could integrate our different institutions and get them on the same sort of plane, we would be much better off.

After we pass legislation we find separate institutions all over the country and we will realize we added another layer, a different agency, and that they are not coordinated and correlated as they should be, just as we in many cases have failed with our Hill-Burton legislation, which has been extremely helpful. We all know the value of it. Yet in some areas we have beds which are not utilized. In other areas we have a scarcity of hospital beds. We should plan and not complicate that plan too much.

Thank you, Mr. Chairman.

Dr. ZAPP. We couldn't agree more with you on that last point. We are in total agreement on that.

Dr COOPER. In our present centers program we are making a special feature of coordination and regulatory input from the Institute itself. So these programs do not go off all by themselves. There is an element of coordination and direction from the Institute so we can minimize duplication and yet facilitate the use of the strengths of the particular locales in a total national plan or strategy to attack all four of these areas. We couldn't agree more with you about this problem.

Mr. ROGERS. The Chair is very pleased to recognize the presence of Mrs. Albert Lasker, who has done so much in the health field for this Nation. I think you showed your endurance and real interest in health when you sat through all of those cancer hearings that you did so much for. We are pleased to recognize you today.

Mr. Symington?

Mr. SYMINGTON. I echo your sentiments, and I think Dr. Carter does, too, concerning Mrs. Lasker's devotion to American health.

I think some of these figures here will surprise and interest Americans, the fact that Scandinavian countries, as shown on page 2 of your statement, have a death rate from heart attacks half the level of ours. The Japanese is one-sixth. Has the Institute come to any conclusion as to why that is?

Dr. COOPER. We have made no firm determination as to the actual reason for this. I do not know the answer for this difference. There are several important things we are learning from this observation, however. For example, when the Japanese leave their own environment and come to America or Hawaii they begin to take on the American characteristics of the death rate. We have similar data from the Scandinavian countries and United Kingdom. As they have come to this country in specific occupational categories they have taken on the characteristics of our death rate for this disease.

This would suggest there is something in the American life style that is related to the current so-called epidemic of heart attacks in this country. But there is one other observation that, I think, is quite important. That is, in the Western European countries that have this lower death rate, as one follows their statistics that are available since World War II, one does find they are on the increase, whereas we are currently seeming to level off, although we have not turned the corner.

Mr. SYMINGTON. How long have you or the Institute been addressing itself to this kind of question? In other words, it seems to me if there is a different experience between civilized peoples, that this is a good place to look for answers. Have you been looking a long time?

Dr. COOPER. Yes, sir.

Mr. SYMINGTON. Then you must have studies considering the life styles.

Dr. COOPER. Yes, sir, we have studies that have been going on for some time.

Mr. SYMINGTON. Is it bicycle riding in the United Kingdom and Japan that ceases when people come here? Has the exercising something to do with it?

Dr. COOPER. There are some indicators that are important. One is the level of physical activity. Some is the nature, perhaps, of the climate or other geographical factors. As Dr. Carter pointed out this morning, I could not focus exclusively on the differences in diet, because he has overwhelming data to indicate that the diet, obviously, cannot be the only factor, particularly in the Scandinavian countries, if you were to try to implicate diet as a factor.

Mr. SYMINGTON. They are great butter and egg people.

Dr. COOPER. Obviously, there are some factors which we can try to determine and others that are still obscure at the present time.

Mr. SYMINGTON. Has there been some systematic approach to attempt to isolate factors and make comparisons that would lead to conclusions? What kind of studies have you engaged in?

Dr. COOPER. We have been trying to design clinical studies which would allow us to isolate single-factor analysis in a multifactorial situation. This is very difficult in a free-living population which is quite mobile, but we are trying to determine the effects of various elements in the life style which would address themselves to this difference.

Mr. SYMINGTON. I would hope this legislation would give you some fuel for that search.

I think one other point I would like to make, Mr. Chairman, is concerning the statistics that half of the heart patients who die, die before medical attention. I take it of that one-half, a great many, could be saved if they had prompt medical attention.

Dr. COOPER. Yes, we think so.

Mr. SYMINGTON. Is there some estimate of how many of the one-half?

Dr. COOPER. If we were to extrapolate from the experience in the coronary care unit where the management of electrical abnormalities of the heart could be dealt with promptly, the saving there has been on the order of 25 to 30 percent. So I think, as a minimum figure, we could anticipate that type of saving.

Mr. SYMINGTON. If 1 million die a year, 500,000 of them may die before medical attention and 150,000 of them could be saved.

Dr. COOPER. That is the rough estimate I have come to myself in various speeches, Mr. Symington.

Mr. SYMINGTON. What studies have you made concerning one or both of two things: One, self-administered injections provided by the family or individual himself, or the establishment of paramedical units so broadly and widely through a community that no man is more than 5 minutes away from the nearest unit?

Dr. COOPER. We have approached the problem of self-administration of antiarrhythmic agents. This is a difficult problem, because the drugs that are available for self-administration are quite potent drugs. If the patient or his family makes a misdiagnosis and applies the wrong drug at the wrong time it is conceivable he could precipitate a catastrophic event, as well as treat a catastrophic event.

Our efforts in this regard have been to develop techniques in which, by the use of modern communications media and availability of identification of high-risk susceptibles, education of the susceptible and his family in consultation with his physician, we think it is feasible to provide supplies of agents to the family and to the patient. That is like the astronauts have in the capsule at the present time.

Mr. CARTER. If the distinguished gentleman would yield.

Mr. SYMINGTON. Yes.

Mr. CARTER. There is an old adage about that. He who doctors himself has an unbalanced man, putting it politely, or woman, as a patient.

Mr. SYMINGTON. The corollary of which is: He who doesn't is dead.

Dr. COOPER. So I think there is a middle ground.

Mr. CARTER. He might certainly be dead when he doctors himself.

Mr. SYMINGTON. The old adage of the lawyer who represents himself has a fool for a client has great applicability, because certainly there are other lawyers in the neighborhood to consult. One doesn't generally have to have legal counsel in 5 minutes, although I am sure some of us need it that quickly.

I think it is different with doctors. I think if doctors are not there in 5 minutes, no matter how good they are, they are not much better, in the judgment of the gentleman in pain. If he has a device which has been approved for the reliability not only of the contents of it but for the likely usage of it, I would think it might prove to be a helpful adjunct to the overall effort to meet this problem.

Dr. COOPER. I think there is a ground here where, with advice from the physician and a good emergency care system a useful technique could be developed which would not depend on self-treatment but on administration of the drug with good advice on short notice.

The answer to your second question about what we are doing in development of paramedical personnel, this is not a responsibility at the present time of the National Heart and Lung Institute. We do not have specific programs in that area.

Mr. SYMINGTON. But you would certainly endorse the dissemination of the latest state of the art, equipment, and expertise, wouldn't you?

Dr. COOPER. Yes, indeed.

Mr. SYMINGTON. I would have in fact thought, although it is not within the direct purview of your Institute, that there would be nothing to prevent you from making the suggestion.

Dr. COOPER. We do make the suggestion; yes, sir.

Mr. SYMINGTON. To whom would you make such a suggestion?

Dr. COOPER. We would make the suggestion to the voluntary agencies and their plans and also to the Bureau of Health Manpower, which is responsible for the development and training of these people. And I think this would be a fertile ground for exploration.

Mr. SYMINGTON. I do, too, and I think you would want to make the suggestion, if you believe in it, very forcefully to other agencies of Government which have some jurisdiction, authority, and responsibility for assisting—let us say the Law Enforcement Assistance Agency, for example, with the police.

I am interested in getting help to these people quickly. I think we all are. I would hope you would turn your attention to good ways to do it.

Dr. COOPER. We shall.

Mr. CARTER. On that, many patients are given nitroglycerin tablets which they take if they have pain, such as anginal pain. Again, if they are faced with physical exertion, they could also take nitroglycerin prior to that.

Oxygen is routinely used by cardiac patients. Breathing apparatuses are often available, particularly in cases of emphysema, at fire departments as a usual thing and should be and perhaps more so.

There are many, many things that are helpful and could be helpful, and certainly we want to avail ourselves of that.

The use of the preventive medicines routinely would be extremely dangerous by one who doesn't know his medicines quite well.

Dr. COOPER. I would agree. I think the implementation of good advice is what would be sought, not the decision of what to use and when to use it.

Mr. SYMINGTON. I think, Mr. Chairman, when we passed the Health Manpower bill there was provision in that bill for what we call paramedical assistance. The term "para" perhaps is a much abused term. It creates false hope. I would have thought in this connection it would mean individuals capable of absorbing that degree of training that would enable them to use devices geared to their capabilities and make the right choice. I don't know. I would certainly defer to my distinguished colleague, Dr. Carter, and his judgment on these things.

Civilization is getting very complicated. We all have to be a little brighter in the manner in which we handle our difficulties, because help is not around the corner all of the time when we need it.

Mr. ROGERS. Should stroke be transferred from the Institute over to Heart, Dr. Zapp?

Dr. ZAPP. Not in our judgment, Mr. Chairman.

Mr. ROGERS. Why not? The president of the College on Cardiology just testified they felt strongly it should be because it results from a breakdown either in the blood vessel or a clotting and so forth.

Dr. ZAPP. In our judgment, it should remain in the Stroke and Neurological Disease Institute. I think Dr. Cooper could explain a little better as to how the blood related components can be coordinated with the National Heart and Lung Institute. We feel that it wouldn't necessarily be an additive to the program to simply uproot it, because as it has become a part of its present Institute it has built its own interrelationships and strengths. Simply to move it over would probably be more disruptive to the research program.

Mr. ROGERS. What is the current budget on stroke?

Dr. ZAPP. I am not sure I have the figures.

Mr. ROGERS. Is it about $13 million?

Dr. ZAPP. We would have to supply that for the record. I believe that is about accurate. The only figures I have are for the complete institution.

Mr. ROGERS. But it is my understanding it is approximately $13 million. If you would let us know for the record whether that is correct or not it would be helpful.

(The following information was supplied for the record:)

NATIONAL HEART AND LUNG INSTITUTE—BUDGET FOR CEREBROVASCULAR DISEASE AND STROKE-RELATED DISEASES, MAY 5, 1972

[Dollars in thousands]

	1968	1969	1970	1971	1972	1973 (estimated)
A. Cerebrovascular circulation	$1,602	$1,219	$976	$835	$464	$490
B. Thrombosis	2,553	2,702	2,859	3,720	4,169	5,725
C. Hypertension studies	3,031	3,165	3,307	4,747	5,179	5,376
D. Arteriosclerosis	4,652	3,873	3,558	5,500	6,391	7,045
E. Epidemiology	382	402	423	445	469	395
Total	12,220	11,361	11,123	15,247	16,762	19,031
Total obligations	162,134	161,834	160,433	194,826	232,000	255,000
Percent of total obligations	7	7	6	7	7	7

Mr. ROGERS. Now, $200,000 out of that doesn't seem to be a very high priority in that Institute. Is it?

Dr. ZAPP. I very honestly didn't come prepared well enough to discuss that.

Mr. ROGERS. You might let us have for the record what they have done and what progress has been made, what research projects they are funding and what the projection is for the coming year.

Dr. ZAPP. We would be pleased to give you a full status. (See p. 168.)

Mr. ROGERS. If we were to decide to put it in Heart could it be developed there? In other words, is there enough relationship that it would not be out of place in the Heart Institute? I don't want to put you on the spot here.

Dr. COOPER. I am not on the spot here. I think the nature of the disease explains the options which are available for choice in programing. I think here we have a disease which results from a disruption of the blood supply to the brain. The disease begins in the blood vessels or in the blood itself or is related to blood pressure. Obviously, the National Heart and Lung Institute activities and scope of research activities are related to the problem of stroke and will be continued to be related to it.

Mr. ROGERS. And you are doing something in this area now?

Dr. COOPER. Yes, sir.

Mr. ROGERS. About what is the budget allocated now?

Dr. COOPER. It depends on how you want to define the problem. If we are only talking about the cerebral circulation, it is somewhat less than a million dollars. But if you want to talk about the problem of hypertension as a primary factor in stroke, then we have a program close to $19 million.

Now, the great advances that have been made in the control of stroke over the past 20 years, a 20-percent reduction in the death rate,

although it is still 200,000, as you pointed out, is due largely to the control of the hypertension that has occurred during the past 20 years. I think that our programs, obviously, have an important impact and interrelationship to the problem of stroke.

As a clinical entity, a disease of the nervous system, as it expresses itself, it also requires a great deal of attention from neurological experts. I would say, in all candor, that the National Heart and Lung Institute does not have neurologists on its staff or expertise in this particular area.

We have tried to approach this joint problem, as we have in other areas, by attempting to coordinate our decisions and choices with the experts in the other areas. We feel on an ideological basis the problem of stroke will relate to our problems. On the problem of diagnosis of location of the lesion in the brain, the study of what its consequences are on brain function and on rehabilitation, will require other types of experts to participate in the total solution of the stroke problem.

So you have a problem here of where the appropriate leadership should be, where the appropriate emphasis should be at any time; and I don't think it is an either/or, black and white situation. It is a matter of judgment as to what to emphasize at what time.

Mr. CARTER. Mr. Chairman, if you will yield on this.

Mr. ROGERS. Certainly.

Mr. CARTER. You would admit that most of the causes of most of the cases originate in the cardiovascular system.

Dr. COOPER. That is right.

Mr. CARTER. If you want to treat the cause it should be in the Heart and Lung Institute; is that correct?

If you want to rehabilitate, or if you want to diagnose, it would belong in the other; is that correct?

Dr. COOPER. I think that is the spectrum of the problem.

Mr. CARTER. In some few instances we do have a few cases of stroke which are not necessarily related to the vascular system.

Dr. COOPER. Yes, sir. These are related to tumors or congenital malformations. There are infectious processes that cause a similar process which invades the bloodstream and causes a catastrophe but is not related primarily to a disease that originates in the blood vessel itself.

Mr. ROGERS. I think it might be well for the Department to give us some language which would be able to put the functions, as Dr. Carter and Dr. Cooper have discussed them, in the various areas where emphasis should be given. Could you give us that, Dr. Zapp?

Dr. ZAPP. Yes, sir.

(The following material was received for the record:)

NATIONAL HEART AND LUNG INSTITUTE—CEREBRAL VASCULAR DISEASE AND STROKE

MAGNITUDE OF THE PROBLEM

Stroke is the most common form of disease affecting the central nervous system and the second leading cause of death among the cardiovascular disorders. During 1970, strokes claimed the lives of 207,800 Americans, approximately 37,000 of them under age 65. A brain disease brought on by blood-vessel disease, stroke afflicts an estimated 1.7 million American adults and is a major cause of disability in the elderly. There are no reliable data on the total number partially or totally disabled by stroke, but data from the Framingham Study suggests that fully half of those who survive their first stroke may be left with some degree of permanent disability.

RISK FACTORS

A preventive approach to cerebrovascular disease seems imperative, since the damage done to the central nervous system by stroke is, within the current state of medical knowledge, irreversible. Fortunately, through epidemiological studies on human populations at Framingham and elsewhere, scientists have identified a number of factors in the person or in his environment that increase his susceptibility to cerebral vascular disease and his risk of stroke. The most serious factors aside from advancing age, are elevated blood pressure, elevated blood levels of certain fatty substances (in subjects under age 50), diabetes or other evidence of impaired carbohydrate metabolism, various heart disorders or electrocardiographic evidence of impaired heart function, cigarette smoking, and obesity. Combinations of these factors can sharply escalate risk.

CURRENT APPROACHES TO PREVENTION

The close similarity between factors increasing susceptibility to stroke and those increasing susceptibility to coronary heart disease make clear that stroke is an integral part of the larger problem of cardiovascular disease. A number of these risk factors are subject to correction or amelioration with the help of a physician. It is reasonable to suppose that many strokes might be postponed or averted by dietary measures or drugs to control hypertension, blood-lipid problems, diabetes, and other modifiable risk factors, particularly if the stroke-prone individual is identified early and preventive measures are initiated promptly. The value of blood-pressure control in reducing stroke risk has been well documented in a number of clinical studies, and many scientists believe that the widespread application of measures for the control of hypertension may be largely responsible for the 20 percent reduction in mortality rate from stroke that has been achieved since 1950. It is to be hoped that an aggressive approach to other risk factors can result in further reductions in death and disability from stroke, particularly among subjects under age 65.

CURRENT ACTIVITIES AND FUTURE PLANS

Current NHLI activities potentially relevant to the problems of stroke include research activities in thrombosis, atherogenesis, etc.; epidemological studies aimed at determining the underlying causes of stroke; primary prevention intervention trials, particularly on the risk factor of hypertension; research concerned with treatment of hypertension. These activities will be continued and intensified in the future.

NATIONAL HEART AND LUNG INSTITUTE—CEREBROVASCULAR DISEASE AND STROKE-RELATED DISEASES, MAY 5, 1972

[Dollars in thousands]

	1968	1969	1970	1971	1972	(Estimated) 1973
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C. Hypertension studies	3,031	3,165	3,307	4,747	5,179	5,376
D. Arteriosclerosis	4,652	3,873	3,558	5,500	6,391	7,045
E. Epidemiology	382	402	423	445	469	395
Total	12,220	11,361	11,123	15,247	16,672	19,031
Total obligations	162,134	161,834	160,433	194,826	232,000	255,000
Percent of total obligations	7	7	6	7	7	7

STROKE RESEARCH SUPPORTED BY THE NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE

The major emphasis programs in stroke in the NINDS began in 1961 with the initation of the Cerebrovascular Research Center Programs funded by research grants.

At present there are 17 centers having a total funding in 1972 of $3,900,000.

In addition, NINDS supports a number of ordinary research projects relating to stroke. Several cooperative studies of different methods of treating stroke are currently in progress.

The following table indicates the total level of research support by the NINDS since 1968, used specifically for stroke. Training support in various disciplines and research in related fields such as brain injury and basic neuroscience also contributes directly to stroke although they are not so identified.

	1968	1969	1970	1971	1972 estimate	1973 estimate
Total stroke research grants (in millions of dollars)	4.7	5.5	4.9	5.5	8.0	8.0
Research grant total obligation (in millions of dollars)	52.6	53.6	50.0	53.8	64.3	64.3
Percent of stroke grants to total grants	8.9	10.3	9.8	10.2	12.4	12.4

In 1972 an increase of $2 million was appropriated to establish several Stroke Acute Care Research Centers. A task force has been appointed to plan this program, and it is anticipated that applications will be ready for review by the NANDS Council in November 1972. Since funding will be in FY 1973, we have asked the Congress to permit us to spend the additional $2 million made available during FY 1972 for ordinary research project grants related to stroke.

With new funds that are available in FY 1972, the NINDS has initiated a contract program in stroke epidemiology, development of non-invasive, diagnostic methods, and other directed stroke research.

The Director of the NINDS has recently appointed a Commission on Stroke under the chairmanship of Dr. Clark Millikan, a distinguished neurologist with many years of experience in stroke. In addition to members in the required scientific disciplines, liaison members from NHLI, VA, and RMPS have been appointed. The first meeting will take place on May 10, 1972.

The Commission is charged with reviewing existing research programs in stroke, in formulating strategies, and identifying new opportunities for future research. In addition to this Commission, the NHLI/NINDS Joint Council Subcommittee on Cerebrovascular Disease will continue to advise both Institutes and to coordinate their activities in stroke.

During 1972 two conferences supported by the NINDS took place to discuss in detail current research in progress on stroke. These were the Princeton Conference on Cerebrovascular Disease and the Cerebrovascular Research Center Workshop.

NATIONAL INSTITUTE OF NEUROLOGICAL DISEASE AND STROKE—STROKE OBLIGATIONS

[In thousands of dollars]

	1968	1969	1970	1971	Estimate, 1972	Estimate, 1973
1. Total stroke obligations	4,987	5,899	5,109	5,784	8,628	8,633
2. Total Institute obligations	121,979	126,085	97,164	103,445	116,491	117,298
3. Percent of stroke to total	4.1	4.8	5.3	5.6	7.4	7.4
Included in line 2 above:						
Eye obligation	20,419	21,519	1,978			
GRSG	7,140	7,430	5,477	5,027	5,136	5,439
NIH management fund	4,888	6,358	5,226	6,500	5,507	5,588
Total	32,447	35,307	11,781	11,527	10,643	11,027
Total stroke obligation	4,987	5,899	5,109	5,784	8,628	8,633
Total Institute obligation minus eye, GRSG, and management fund	89,532	90,778	85,383	91,918	105,848	106,271
Percent of stroke to total	5.6	6.5	6.0	6.3	8.1	8.1

Stroke is a disease which causes severe damage to the brain. Its predominant underlying causes are atherosclerosis, hypertension, thrombosis, and congenital abnormalities of the blood vessels. Since these causative factors are the subject of major research programs of the National Heart and Lung Institute, the Committee expects that the Institute will give these programs high priority and that the new Advisory Council will give special emphasis to the continued development of these programs in the NHLI and to effective coordination with related stroke programs in the National Institute of Neurological Diseases and Stroke.

Mr. ROGERS. What is your feeling about including the pediatric pulmonary centers in the bill.

Dr. COOPER. I feel that to study lung function you don't set an age limit on it. It has been our approach to study the function of the lung where the problems lie. I think we have directed some initial intention to the study of the pediatric problem and would hope to be able to continue to do so.

Mr. ROGERS. In other words, you would have no objection to pediatric pulmonary programs being directed to this.

Mr. CARTER. If you would yield.

Mr. ROGERS. Certainly.

Mr. CARTER. You are referring to cystic fibrosis?

Mr. ROGERS. Part of it.

Dr. COOPER. I would agree with that. There is the problem of prematurity, of hyaline membrane disease. The problem of prematurity should be in the childrens' institute. The problem of pulmonary function in infants and children needs to be studied by lung specialists as well.

Mr. ROGERS. I think you could use a coordinating committee technique here, couldn't you?

Dr. COOPER. Yes, sir. I think a coordinating committee technique is a valuable one for this purpose.

Mr. ROGERS. I would like for the record to have what RMP has done in this pediatric pulmonary program, or any other such programs the Department has in being, and what the plans are for the future, along with proposed funding and what the funding has been, along with the numbers of people involved and any progress that has been made.

(The following information was supplied for the record:)

REGIONAL MEDICAL PROGRAMS SERVICE—PEDIATRIC RESPIRATORY DISEASE

Grants	1971	1972	
Colorado/Wyoming	$38,600		Terminated in 1971 after 3 years support.
Georgia	143,500	$73,887	
Greater Delaware Valley	16,,600	263,489	
Louisiana		445,198	Approved but unfunded to date.
Metropolitan District of Columbia		133,457	Do.
New Mexico	99,100	95,024	
New York Metropolitan	172,000		Support terminated after 3 years.
Puerto Rico	120,000	120,000	
Washington/Alaska (6 months)		58,000	
Total		1,189,055	

CENTERS NOW BEING FUNDED BY OUTSIDE SOURCES

California: $175,400; is now self-supporting.

Hawaii: $107,000; $15,000 granted to the Center by Wyeth Laboratories.

The approach of Regional Medical Programs has been one of Federal guidance and funding on the one hand and local planning and decisionmaking on the other. One basic tenet has always been that the Regional Advisory Group can best design the implementation and operation of programs which meet the needs of its region as defined by the community being served and its Comprehensive Health Planning agency. The role of the RMP and its Federal counterpart has been to assist in finding and demonstrating the best approach to meeting health needs.

Thus the pediatric pulmonary disease proposals must compete at the local level for program priority and funds, and it is basically the local Regional Advisory Group which has the responsibility to make those decisions.

As an example of the types of pediatric pulmonary activities being carried out by the Regional Medical Programs, the pediatric pulmonary disease program

sponsored by the Greater Delaware Valley RMP is working on the development of an acute diagnostic center, the development of satellite centers, and attempting to develop expertise among physicians and other health professionals in providing early diagnosis and treatment. With the leadership and assistance of the Philadelphia Pediatric Center, satellite centers have been developed to the point where they are beginning to provide needed services in their respective communities.

Funding for this program next year is planned to be at a level not less than that provided in 1972, which is consistent with the overall program budget requested for 1973. Further expansion is possible and dependent upon local program priorities in the same manner as are all other activities funded by regional medical programs.

Great emphasis to date has been placed upon providing physicians and other health professionals with the necessary, specialized training and, as a result of these efforts, significantly larger numbers of people may be expected to benefit because of earlier diagnosis and treatment.

Mr. ROGERS. How many people do you need for lung research?

Dr. COOPER. In the Institute or in the country?

Mr. ROGERS. Both, if you can give it to me. I realize these would be estimates.

Dr. COOPER. When the assessment of whether there needed to be a new focus program to the National Institute of Health for lung research, when these original studies were done, it became quite clear there was a great shortage of pulmonary experts and pulmonary scientists throughout the country. As Dr. Carter pointed out earlier, even in areas where there are special environmental problems, the experts for certain types of activities were just not available. Perhaps 48 or 50 percent of the major teaching institutions were deficient in having a staff that was adequate for doing lung research.

Now, to put an exact number of people on it is very difficult. The Institute is now conducting a survey in association with the specialty board in pulmonary diseases and the professional societies of pulmonary disease in order to try to determine what the national needs in these categories are.

We hope to have this study, which is being funded by a contract with the National Tuberculosis and Respiratory Disease Association, completed within the next several months. That, hopefully, will put a figure to shoot at on our projections.

But we, obviously, feel there is a great need. This would apply to the Institute as well.

Mr. ROGERS. Would you keep us advised of that report?

Dr. COOPER. Yes, sir.

(The following information was supplied for the record:)

As of this date, there are no results available from the survey of personnel needs in the pulmonary area. We have a contractor making the survey, and the final report will be available around the end of July, at which time further information can be supplied.

Mr. ROGERS. Obviously we are not producing enough young people to go into the area of lung, so this must be encouraged.

Dr. COOPER. Yes.

Mr. ROGERS. What about heart?

Dr. COOPER. The heart problem, in my opinion, is a selective one. Because of the long-term support of the Institute's program for the last 20 years, there has been significant development of cardiovascular and cardiological experts, and we have trained in excess of 15,000 people in this category to this point.

This has demonstrated that in some areas we probably are producing, in my opinion, enough experts for some categories. In other areas, even in the cardiological sphere we feel, now that we know what is necessary, we will need to do more.

In order to try to put some precise data on that, we are also conducting a survey in association with the American College of Cardiology, the Specialty Board of Cardiovascular Diseases, the Medical Board and with the American Heart Association in order to quantify that number. We should have that data available within the next 9 or 10 months as well.

I think this will be more selective. I don't think it is a case of needing more for everything all of the time.

Mr. ROGERS. What about researchers in the area of heart?

Dr. COOPER. This will also be in selective areas. In some specific disciplines, of people who direct their attention to the specialty of the cardiovascular system, we may have enough in some areas at this time. In other areas we probably do not have enough, like morphologists, in my opinion. I think we will need to identify where we need some of these areas bolstered.

We have finished the study of pediatric cardiological needs. We have an estimate of what we might need in this area over the next 10 years.

Mr. ROGERS. What is that estimate?

Dr. COOPER. It is about 225 experts in this field by 1980.

Mr. ROGERS. Is that within your Institutes?

Dr. COOPER. No, this would be a reflection of the national need for the certified specialists in this area.

Mr. ROGERS. I was not clear. I think I might ask you to comment on establishment of these centers and prevention control functions in the centers. How can we really get going on prevention control?

Dr. COOPER. I think in chronic disease the key to prevention is an awareness in the public and an awareness in the profession of what is really available in order to advise people who are basically nonsymptomatic to do something that will eliminate a disease which probably begins early in life and takes a large segment of time to develop. Therefore, it is important that people have available for themselves the ability to get their blood pressure checked and, if abnormal, properly treated; to get advice about their activity, about their rest, about their diet and so on.

Now, unfortunately we cannot approach prevention in this disease by, for example, a vaccination at the present time.

I think another area that needs to be investigated is the possibility of drug preventives. We probably need to explore what can be done on this. Obviously, the most potent agents that we have for the control of hypertension right now are the application of pharmacologic agents.

So I think the function of centers in this national problem is a focus on awareness, education, the resource available to the professional community as well, that will help in the overall adaptation of the American mind to the need for greater awareness of the problems of prevention in these diseases.

Mr. ROGERS. But we could establish screening programs. You feel this is feasible, as I recall.

Dr. COOPER. For the areas that should be identified, as you asked me to provide for the record, I think we should encourage the identification of these abnormalities.

Mr. ROGERS. I think it would be well if you could give us an example in your testimony for the record of the operation of a center, how you envision the center operating, personnel, what census population it could probably cover.

Dr. COOPER. All right.

(The following material was supplied for the record:)

OPERATION OF A CENTER

The centers to be established would be comprehensive in concept and in operation. They would be concerned with all the major aspects of disease prevention, epidemiology, genesis, clinical manifestations, and treatment. They would be located at or near major medical centers but, to a large extent, would be free-standing. These centers can best be viewed as national resources devoted to the alleviation of cardiovascular and pulmonary diseases. In virtually all circumstances, this would require new construction and the purchase and development of new and additional facilities; the recruitment of senior level personnel as well as technical and administrative staffs; and the development of suitable organizational frameworks.

The centers would, of course, have to be multidisciplinary in their approach and equipped with personnel and modern instrumentation to deal with the study, detection, prevention, arrest, and reversal of the particular diseases in question. They would be actively engaged in the screening of populations; they would provide an environment wherein new therapies could be promptly evaluated; although not primarily designed for training purposes, the environment would be especially suitable for such activities.

Mr. ROGERS. Is there any profile of activity or diet that is associated particularly with people who have a good set of lungs? Is there any profile of this? Is there any particular criteria that has been set forth to avoid lung diseases, other than smoking?

Dr. COOPER. Other than smoking and environmental pollution we are much further behind in the understanding of the risk factors in the genesis of lung disease than we are in cardiovascular disease. Just recently the suggestion has been made that there are also genetic factors that make individuals more susceptible to emphysema and this could be correlated with the specific enzyme in the blood. Whether this will prove to be a useful tool we are not sure, and we have a program designed to try to approach this evaluation.

We are fairly certain that infection plays a role in the long-term genesis of obstructive lung disease. We think allergy is a factor. We think environmental influences are.

One of the important deficiencies in our knowledge here is how to assess pulmonary function or what technique should be used early on in order to try to detect who is susceptible and what to do early enough. This is one of the objectives of our new program in lung research in order to try to develop methods to detect early compromise of the major airway systems.

I think when we have those techniques, we will be able to better answer your question. I am sorry I cannot be more specific scientifically in this area, but this is a great void of information that needs a great deal of research.

Mr. ROGERS. I think you might let us know what you are projecting in the way of research in this area, the funding, and the way you have been handling it.

Dr. COOPER. We will have a complete report available by the end of June, it is expected, on the various facets of the factors influencing pulmonary disease.

(The following information was supplied for the record:)

As of this date, there are no results available from the survey in the pulmonary area. We have a contractor making the survey, and the final report will be available around the end of July.

Mr. ROGERS. Also, I think the committee would like to see the various diseases that you are doing work on in your Institute, the amount of money, the pattern of that disease, say, over the last 20 years, whether it is going up or down in its rate, what significant advances have been made, and if those advances have been funded by our people or outside so we can have some concept of what has happened in this area.

(The testimony resumes at p. 192.)

(The following material was received for the record:)

NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

The National Heart and Lung Institute is the focal center of the Federal government responsible for research, development and education to control heart, blood, and lung diseases. This report briefly summarizes the Institute's programs and their historical development since the formation of the Institute in 1948. Tables I and II depict the funding and staffing history of the Institute.

Hundreds of threads are woven into the fabric of NHLI programs. This report does not include every one of them. But the sampling included is broad enough to give a comprehensive idea of the real issues faced by the NHLI and how the Institute is tackling these problems.

The federal involvement in programs related to heart, blood, and lung diseases is a public health issue commanding the attention of every American. As a taxpayer contributing funds for the solution of these problems or an individual who may directly benefit from new methods of prevention and therapy for these diseases, the American "consumer" has a great stake in the successful development of federal programs which will stem the tremedous economic and social drain resulting from the unchecked ravages of these diseases among our people. It is a costly problem running into billions of dollars a year, and it is exceedingly wasteful of human resources, amounting to the loss of more than one million lives per year and disabling many more of our citizens every year, year after year.

The stated mission of the Institute is as follows: conducts, fosters and supports research, investigations, and demonstrations relating to the cause, prevention, and methods of diagnosis and treatment of diseases of the heart, lungs, and circulation through: (1) research performed in its own laboratories and through contracts; (2) research grants to scientific institutions and to individuals; (3) training and instructions in the research and clinical aspects of cardiovascular and respiratory diseases; (4) promoting the coordination of all such research and activities and the useful application of their results, and (5) collection and dissemination of information on these diseases.

Over the years the Institute has developed a number of approaches to tackle these disease problems. These approaches include mechanisms for selection and development of people and research ideas throughout the national and international research communities; expansion of knowledge and expertise within the Institute itself; development of management tools and mechanisms to evaluate performance and efficiency of programs and guide future plans and developments; a continuous, aggressive search for new opportunities and powerful skills which could substantially contribute to solving or reducing the problems of heart, blood and lung diseases; and programs to ensure professional education in and public understanding and acceptance of these new public health developments.

As a result of these efforts National Heart and Lung Institute researchers have pioneered and developed many new ideas, techniques and skills which have significantly increased the options for dealing with these diseases in the United States population. It should be emphasized that many of these concepts and developments remain untapped as far as benefiting the American public as a whole. It is a paradox that almost by virtue of this relative neglect of application of available resources and solutions in cardiovascular and respiratory research, the potential opportunities for improved management of these diseases are now so much greater than would have been the case had applications kept pace with

new developments all along. The Institute has made plans for programs that will shorten the lead time for bringing these new developments to the people, and these plans are included in the five-year plan developed by the Institute. It is because of this substantial reservoir of knowledge and skills and the presence of these plans that one can predict with a high degree of confidence that increased funding of the Institute's programs at this point in time offers definite prospects of both immediate and long-term returns on the investment in terms of improving the quality of life for our people. Quite frankly, it is time to put these research findings to work for the American people by demonstrating their efficacy in actual field tests in community settings, and the Institute is ready and committed to proceed with this task.

I. Heart and Blood Vessel Diseases

ISSUES

Diseases of the heart and blood vessels account for more than 54 percent of all deaths in the United States, and the economic drain of heart disease alone has been estimated at more than $30 billion.[1] Among the major high-priority disease problems to be tackled by the Institute are: arteriosclerosis; hypertension and kidney diseases; and other cardiac and cardiovascular diseases.

DESCRIPTION OF PROGRAMS

A. Arteriosclerosis

Arteriosclerosis commonly referred to as hardening of the arteries is the greatest killer among the cardiovascular diseases. All ages are involved, with an increasing frequency in each decade of life. Over the years, the Institute has developed a number of approaches to the prevention, treatment, and rehabilitation of patients suffering from this serious disease including support for research grants, research contracts, training grants, and fellowships. A comprehensive review of the field, including conclusions and recommendations for further research and development may be found in the June, 1971 report by the NHLI Task Force on Arteriosclerosis.

In 1949, the Framingham Heart Disease Epidemiology Study was transferred to NHLI from the Bureau of State Services. This study has provided important data on factors, such as high blood pressure, smoking, overweight, and elevated blood lipids that increase susceptibility to coronary heart disease and stroke, two clinical disorders related to arteriosclerosis. This information is helping physicians to identify the highly susceptible patient early and to initiate measures calculated to reduce his risk.

In 1950, NIH launched the first undertaking in what was to become a long and distinguished series of cooperative studies, wherein investigators from numerous institutions pooled their efforts in attacking a common research or clinical problem. The first of these efforts was in arteriosclerosis, and explored the relationship between blood lipoprotein patterns and atherosclerosis. Subsequent cooperative studies related to arteriosclerosis include: The Joint U.S.-United Kingdom Study of Cardiopulmonary Disease initiated in 1959 to investigate factors in the person and his environment responsible for the differing patterns of mortality from coronary heart disease and chronic respiratory diseases, existing in the U.S.; the Cooperative Study of Extracranial Arterial Occlusion, initiated in 1959, to identify patients with strokes resulting from atherosclerotic or other obstructions to the brain's major feed lines in the chest and neck and with evaluation of the results of surgical procedures to remove or bypass operable obstructions; and plans were begun in 1960 for the current Cooperative Study of Drugs and Coronary Heart Disease. The objectives of this large-scale clinical trial involving 8,341 men with previous myocardial infarctions are to evaluate the effectiveness of several lipid-lowering drugs in the prevention of recurrences of premature death from heart attacks. The study involves 53 clinical groups, plus five supporting units.

In 1956, NHI participated for the first time in the U.S.-U.S.S.R. Scientific Exchange Missions. Dr. James Watt, NHI Director, was a member of the mission to visit centers for the study and treatment of heart disease in the Soviet Union. This was followed in 1957 by a reciprocal visit by leading Russian cardiologists to NHI and other U.S. heart research centers and by additional missions in subsequent years.

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[1] 1964 President's Commission on Heart Disease, Cancer, and Stroke.

Planning was begun in 1960 for a National Diet-Heart Feasibility Study to determine whether a large, long-term population study to assess the effects of cholesterol-lowering diets on morbidity and mortality from coronary heart disease should be undertaken by the NHI. The clinical phase of the feasibility study was begun in 1962 and completed in 1965. The final report and recommendations were completed in 1968.

In 1966, NHI established the Artificial Heart-Myocardial Infarction Program for the purpose of combining bioengineering and biomedical approaches toward the reduction of death and disability from acute heart attack. The Myocardial Infarction Branch of the program was established in 1966 for the purpose of setting up and administering a national program of research aimed at reducing death and disability from acute heart attacks. An important phase of this program is the establishment of a chain of Myocardial Infarction Research Units at major U.S. medical centers. These units combine unexcelled medical care for heart-attack patients with intensive clinical and laboratory research on acute heart attacks and their complications. The purposes of the MIRU's is to increase medical knowledge of the acute heart attack itself; to identify physiological, psychological, and other factors that critically affect the outcome; and to seek new or improved methods of diagnosis, patient monitoring, and treatment that will be widely applicable to the care of coronary patients. Considerable progress has been achieved along these lines, progress of direct benefit to patients with the disease.

In 1968, the Institute undertook a complete review and analysis of the research in arteriosclerosis. The scope of this study included a review of the grant program of the NHI with a view to determining the types of research being supported, a study of the apparent balance of the program in terms of kinds of research and their relation to each other, and identification of research inactivity and the causes thereof, as well as identification of technical and scientific areas where lack of appropriate interest appeared to be delaying the discovery or application of knowledge about arteriosclerosis. The study also extended beyond the NHI to the entire USPHS and to other agencies such as the Veterans Administration, the American Heart Association, the Life Insurance Medical Research Fund, and the Canadian Heart Foundation.

The NHI reorganization on August 12, 1969, provided for the formation of a branch for Arteriosclerotic Disease in the Extramural Program. The subject matter assigned to this branch includes research into the etiology and pathogenesis, prevention, diagnosis, and treatment of arteriosclerosis, coronary artery disease, peripheral vascular disease, cerebrovascular disease, aging and disorders of connective tissue of blood vessels. The variety of research supported through this branch continues to be very great. It ranges from the most basic studies in molecular structure and function to the evaluation of surgical procedures and the epidemiological description of disease. Recent progress includes animal models mimicking the human disease of arteriosclerosis and the new techniques in cardiovascular surgery, including revascularization of the heart. In FY 1971 the branch initiated a chain of thirteen Specialized Centers of Research in Arteriosclerosis throughout the United States. It is anticipated that these Centers will form a complimentary and supplementary network of sophisticated investigations that will appreciably shorten the timetable to attain common goals in the study of arteriosclerotic disease.

On June 12–13, 1970, the National Heart and Lung Institute convened a panel on Hyperlipidemia and Premature Atherosclerosis. Its mission was to evaluate the opportunities and requirements for a program which would apply the most sophisticated techniques available to the detection and management of premature atherosclerosis associated with hyperlipidemia. The panel concluded that further federal assistance is necessary to effect the optimal application of new knowledge acquired through many man-years of research. The panel recommended that the Institute fund a number of coordinated lipid laboratories where quality control of both methods and interpretation will be monitored, new diagnostic tests developed and evaluated, physicians will provide consultation on diagnosis and therapy, data on prevalence will be uniformly collected and forwarded for central collation, and important research questions relative to hyperlipoproteinemia will be studied by the most sophisticated techniques available. The prevention of premature atherosclerosis through the treatment of hyperlipidemia is a primary goal of the Institute. In order to capitalize on recent advances in the understanding of hyperlipidemia, the Institute established a Lipid Metabolim Branch in FY 1971 which will coordinate the work of the newly established Lipid Research Clinics in different parts of the country.

During FY 1971 the Institute convened a Task Force on Arteriosclerosis to develop plans designed to prevent and control the disease process and treat its complications, in order to reduce the number of victims and minimize the loss of health and of productive life. The report by the Task Force was submitted to the Institute on June 30, 1971 and is currently being considered by the Institute in future planning in arteriosclerosis.

B. Hypertension and kidney disease

Hypertension is one of the most commonly encountered forms of cardiovascular disease, affecting an estimated 17–22 million adult Americans. Of these, 10.5 million suffer from heart disease as a consequence of hypertension. Hypertension aggravates and accelerates the development of atherosclerosis, and is a major cause of strokes, heart failure, and kidney failure.

The great majority of patients with hypertension (perhaps 80–90 percent) must be labelled "essential" due to lack of identification of a specific cause. It appears that many variables contribute to this condition. However, identifiable causes of high blood pressure have been discovered in increasing numbers in recent years. Almost any form of kidney disease may be associated with an elevation of the blood pressure. Regrettably, curable causes of hypertension are identified in only a small fraction of patients.

However, the results of research show that there is considerable hope for these patients. Carefully controlled clinical trials have shown that treatment of hypertension is effective in decreasing the occurrence of some manifestations of arteriosclerosis, i.e., stroke and congestive failure. Despite the impressive evidence that treatment is effective, numerous studies indicate that the treatment of hypertension in the population is inadequate. For instance, in a county of Georgia, 70 percent of hypertensives were not receiving treatment at the time of the study. Of those found to be hypertensive, 41 percent did not even know that the condition was present. Only 47 percent of those receiving treatment had normal blood pressure readings; thus 53 percent of these taking medication were inadequately treated. It is apparent that improvements in the health delivery system must and can be made in order to identify patients with hypertension and provide them with effective treatment.

A Branch for Hypertension and Kidney Diseases was established within the Extramural Program on August 12, 1969, and in FY 1971 five Specialized Centers of Research in Hypertension were established in different parts of the United States. It is expected that the presence of these centers will quicken the pace of translating research results to bedside practice.

Recently, through its Clinical Applications Program, the NHLI initiated a program in nine communities throughout the United States to develop and evaluate methods of detecting and caring for hypertensive persons in the population at large. Initially, a population of about 3,000 hypertensives will be identified in their communities. These individuals will then be referred to various programs for medical care and periodic long-term follow-up. A major effort of the program will be the study of those patients who neglect taking adequate treatment. Procedures will be developed to improve participation both by helping to motivate the patients and by removing other barriers to compliance. Subsequently, the effects of treatment in terms of reduced death and disability will be studied in these patients.

C. Cardiac and other cardiovascular diseases

The research which falls within this category is concerned both with cardiovascular diseases, other than the above, and with normal cardiovascular function. Thus, there is little homogeneity of characteristics either within the subgroups or within the category as a whole.

The principal categories are: cardiac arrhythmias, studies of heart muscle, cardiovascular dynamics, congenital and rheumatic heart disease, heart failure and shock.

Studies by the Institute in the field of congenital heart diseases have included studies to identify potentially preventable causes of congenital heart defects, studies on the natural history of congenital heart defects, development of improved techniques for detecting and evaluating congenital heart defects, and more effective surgical procedures for palliating or correcting such defects and better life-support techniques (heart-lung machines, hyperbaric oxygenation, etc.) for sustaining patients during prolonged open-heart operations.

Long-term research continues on rheumatic heart disease. Studies conducted by the Institute over the years include: development and application of more rapid and sensitive means for early detection of strep infections, wider application of continuous antibiotic prophylaxis to protect susceptible individuals against recurrent attacks, more effective support measures for managing rheumatic carditis (inflammation of the heart), preventing or coping with congestive failure, a variety of artificial valves for replacing those hopelessly damaged by rheumatic fever, and improved methods of preserving, and installing valve homografts.

D. Multicategorical programs

In 1961, NHI embarked on a bold new program of research support with the awarding of the first of the program project grants. These are large grants, usually with long-term commitments, designed to stimulate broadly based, in-depth, multidisciplinary approaches to cardiovascular problems. The goal has been to encourage scientists skilled in such diversified fields as medicine, biochemistry, physiology, and engineering to work together in teams, each individual lending his particular expertise where needed in solving problems related to the team's research projects.

During FY 1972 the Institute started the largest single clinical trial it has ever undertaken to test the effects of multiple risk factors—smoking, high blood pressure, and elevated lipids together—and their relationship to heart attacks, strokes, and other events. This program is called the Multiple Risk Factor Trial and is scheduled to last for ten years. It is a very important study since it is expected to give a definite answer to the question whether it is possible to interfere with the process of arteriosclerosis once it has started. This study will be conducted in cooperation with a number of centers throughout the United States and will involve long-term, careful study of more than 10,000 people.

HISTORY

The National Heart Institute was created on June 16, 1948, when President Harry S. Truman signed the National Heart Act. The new Institute was charged with conducting research into the causes, prevention, diagnosis, and treatment of diseases of the heart and circulation; fostering, supporting, and coordinating cardiovascular research and related activities by public and private agencies, providing training in matters relating to heart diseases; developing more effective methods of prevention, diagnosis and, treatment; and assisting States and other agencies in the application of these methods.

On August 1, 1948 the Institute was formally established as one of the National Institutes of Health with headquarters at Bethesda, Maryland, and Dr. C. J. Van Slyke was appointed its first Director. During the fall of that first fiscal year (F.Y. 1949), the Institute was organized and staff recruiting begun. The first organization chart included the Office of the Director, the Co-operative Research Projects Section, the Statistical Analysis Branch, and the Heart Information Center. Later that fiscal year, an Associate Director for Research was added, a post initially occupied by Dr. James A. Shannon, later director of NIH. The Heart Disease Epidemiology Study at Framingham, Massachusetts, was transferred from the Bureau of State Services, PHS, to NHI on July 1, 1949. On July 6, 1953, the first patient was admitted to the Clinical Center for heart disease research.

The Institute received its first appropriation in 1950. It provided $10,725,000 for the support of current cardiovascular programs which had been transferred to NHI from elsewhere at NIH and $5,350,000 of contract authority, primarily for committing a second year of support for training grants and research construction. The Institute's intramural research budget that year was about $1.36 million. Some $3.9 million was allocated for research grants and $1.7 million for training grants to 45 medical schools and for clinical traineeships to 45 physicians. The appropriations for heart and blood vessel research during the remainder of the Institute's history are detailed in Table I.

By fiscal year 1950, the fundamental organization of the Institute was well outlined. Organizational changes have occurred over the years in response to the changing needs of cardiovascular research and training and the new opportunities for progress that have developed from earlier programs. Table II depicts the Institute's staffing history up to the present time in each of the major program areas of cardiovascular research, and Table III shows the current organizational components of the Institute.

Over the years groups of cardiovascular experts have met at periodic intervals to appraise developments and to determine needs and opportunities for continued and accelerated progress against heart and blood vessel diseases and to prepare reports. Some of these gatherings and their reports are: The first National Conference on Cardiovascular Diseases, sponsored by NHI and the American Heart Association, January 18–20, 1950; a report to the Nation on "A Decade of Progress Against Cardiovascular Disease," presented by the American Heart Association and NHI on February 19, 1959, at Department of Commerce Auditorium, Washington, D.C.; the report to President John F. Kennedy on April 21, 1961, by the President's Conference on Heart Disease and Cancer, to assist in charting the Government's further role in a National attack on these diseases; the second National Conference on Cardiovascular Diseases, sponsored by the American Heart Association, NHI, and Heart Disease Control programs of PHS, November 22–24, 1964; the report to President Lyndon B. Johnson on December 9, 1964, by the President's Commission on Heart Disease, Cancer, and Stroke, to recommend steps that can be taken to reduce the burden and incidence of these diseases; the 20th anniversary of NHI commemorated at the White House, with President Lyndon B. Johnson on November 14, 1968, and prominent figures associated with NHI, past and present, participating; a report was prepared for the occasion reviewing research progress; and finally during the last couple of years a number of consultant groups have carried out in-depth analysis of all the major program areas of the Institute and submitted reports to the Institute delineating recommendations for future plans for research and developments; the most recent group is the NHLI Task Force on Arteriosclerosis which submitted its report in June, 1971.

OPPORTUNITIES AND OPTIONS

The future opportunities and the options generated by recent Institute research in cardiovascular diseases are numerous and of great promise in terms of improved health of the nation. The 1971 Task Force on Arteriosclerosis prepared a two volume report containing detailed recommendations for programs to be implemented in the near future as a result of new research findings. Specific recommendations included a national, coordinated, comprehensive program for the prevention and control of arteriosclerosis; the development of new national resources such as centers for prevention, cardiovascular disease prevention clinics, and an office of health education within the Institute; clinical trials to test the "risk factor" hypothesis that modification of risk factors such as smoking, hypertension, and food intake can help prevent arteriosclerosis; expansion of lipid research clinics, a clinical trial to test the effect of interfering on several risk factors in one and the same person; studies to reduce death and disability from the acute events of arteriosclerosis, such as heart attacks and strokes; recommendations for research; manpower development and training; and managerial aspects of arteriosclerosis, such as the giving of incentives to the food and tobacco industries to make their products commensurate with optimal human health.

Research has given the physician of today a variety of drugs for treating hypertension of all degrees of severity, including milder forms of the disease, often left untreated before. The resulting decline in mortality has been striking in patients with severe or malignant hypertension. But none of these drugs is perfect, and some have unpleasant and sometimes serious side effects. Opportunities exist for new or improved therapeutic agents which will further increase the options available for the patient with hypertensive disease, so as to prevent the serious side effects of stroke and heat failure.

II. Blood Program

ISSUES

The Institute's programs in blood are intimately related to its responsibilities in cardiovascular and pulmonary diseases, and are sometimes so closely related that it becomes difficult to separate them from these areas of activity. Blood is a very vital part of the circulatory system since it is the vehicle in which oxygen, nutrients, and other body chemicals are carried through the blood vessels to every part of the body, to be exchanged for carbon dioxide, waste products and chemicals which in turn need to be transported away from the tissues to other body organs either for excretion from the body, or for use in their life processes.

Principally, the three areas addressed by the Institute's blood program are: Thrombosis, Hemorrhagic and other Blood Diseases, and Blood Management.

Thrombosis (clotting of the blood carried in the blood vessels) may be a serious circulatory complication in cardiovascular and pulmonary disorders. The Institute's current militancy in blood management programs is primarily a response to new needs created by successful new ventures in other NHLI programs, particularly in cardiovascular surgery. These new developments call for unusually large quantities of blood (e.g. 20 units) for a single surgical procedure, and the strong public demand for these new cardiovascular operations threaten to jeopardize the blood supply for other patients such as hemophilacs, patients with sickle cell crises, accident victims, etc., who also have legitimate claims to this limited vital resource.

DESCRIPTION OF PROGRAMS

A. Blood Management

The Institute's programs in blood management include studies to improve the quality of transfused blood by developing new preservatives and by eliminating contaminating disease agents such as hepatitis virus; studies aimed at multiplying the usefulness of a single unit of blood by fractionating it into its therapeutic component parts and giving each component to a different patient as his need dictates; and systematic studies of blood banking techniques and blood therapy to develop systems for more intelligent and efficient utilization of the limited national blood supply.

Early in the development of the Program, emphasis was on research in blood preservation and fricationation. Work on adenine as a blood preservative was successfully completed during FY 1969.

In 1967, a major project was undertaken with the American National Red Cross in the field of blood fractionation. Much of this work has been completed and the results disseminated to the blood banking community. Further refinements are possible, and work continues with current emphasis being on research in methods of platelet (one of the formed elements in the blood) preservation.

Beginning in fiscal year 1969 research was started to improve the effectiveness and detection of hepatitis virus in blood and blood products and techniques for removing it. This work was expanded in fiscal year 1970 and the Institute has undertaken a number of projects related to the control of hepatitis in blood, primarily in three areas: (1) refinement of testing procedures to detect the hepatitis associated antigen (HAA), (2) methods to produce the hepatitis associated antibody (HAAB) in large animals, and (3) distribution of the hepatitis associated antibody to blood banks throughout the United States. Research during the past past several years has shown that blood that is serologically positive for the HAA carries a very high risk of transmitting the hepatitis virus. If it were possible to remove all units of blood that contained the HAA, then the incidence of post-transfusion hepatitis in recipients would undoubtedly be significantly reduced. If these tests could be further developed and refined then many more units of potentially infectious blood could be identified and removed prior to transfusion. Significant progress has been achieved toward these goals. The Institute plans to continue support in this area to reduce the time necessary to complete the new tests and to make them simple enough for routine blood bank screening of blood. Both of these goals are feasible. Prior to February 1971 no HAAB was commercially available to blood banks in the United States to test for the HAA. The Institute anticipated this need and undertook a program together with the National Hemophilia Foundation and the Division of Biologics Standards to prepare and distribute the HAAB to all State Health Departments throughout the United States for use in their blood banks. This program was extremely successful. Commercially produced HAAB has since become available.

The Institute has initiated a number of studies aimed at improving the utilization of the national blood supply. In fiscal year 1968 studies were begun for the development of computerized automation of donor blood inventories and doner-recipient information. The purpose of these studies was to permit more complete utilization of available blood resources and to decrease the probability of human errors in blood handling, and hence reduce the risk to the patient receiving the blood. A systematic study of blood banking techniques and blood therapy in this country was initiated in fiscal year 1971. This study will cover both present and future resources and needs. Questions relating to the procurement, processing, and distribution of blood from donor to recipient will be examined. This study is extremely important since little comprehensive information is available on the various aspects of blood banking in the United States.

B. Thrombosis

The Institute's programs in thrombosis include investigations carried out in its intramural laboratories and extramural research through grants and contracts.

To provide additional thrust and emphasis in this area, a new initiative designated Specialized Centers of Research (SCOR) in Thrombosis was started in fiscal year 1971. The goal of this program is to achieve a solution to the problem of prevention, early diagnosis and improved treatment of thrombosis and hemorrhage. Five specialized centers of research in thrombosis are currently in operation. Projects underway include: investigations on the pathogenesis of thrombosis; diagnosis of clinical thrombosis by isotopic, radiologic and Doppler ultrasound techniques, and evaluation of measurements of certain blood factors influencing coagulation; studies of the degradation products of blood clots; and therapy, including the use of thrombolytic and antithrombolytic agents.

The National Blood Resources Program has conducted a series of clinical trials of urokinase and streptokinase, two agents which hold great promise against clotting complications so often responsible for the crippling or lethal manifestations of heart and blood vessel diseases. The first phase of these cooperative trials was successfully completed in August 1970. It was found that urokinase and subsequent heparin therapy sigificantly accelerated the resolution of clots in the lungs (pulmonary embolism). Upon the successful completion of the first trial, a second phase was entered in which the clot-dissolving capacity of urokinase will be compared with streptokinase, the other most common thrombolytic (clot-dissolving) agent. The limited supply of and hence the exorbitant cost of urokinase has prevented its extensive use in patients. Efforts by the Institute to produce large (and practically unlimited) quantities of urokinase from human cells grown in test tubes were recently successful and will make it possible to initiate further studies to evaluate this agent for the treatment of patients with heart attacks, certain strokes, and other thrombo-embolic (clots in the blood vessels or travelling through the blood vessels) complications of cardiovascular disorders, and studies in patients suffering from heart attacks are currently being initiated.

C. Bleeding disorders

Since 1965 when Dr. Judith Pool discovered a method (cryoprecipitate) to concentrate the antihemophilic factor (AHF) from blood, this material has been the main stay of treatment for hemophiliacs (an inherited bleeding disorder) throughout the United States. Unfortunately, no good standardized method now exists for production of this material. Consequently the therapeutic effects of transfusion of hemophiliacs with cryoprecipitate are extremely variable. In FY 1971 the National Blood Resources Program undertook a project to study the variables important in preparing AHF and to develop a standard process whereby blood banks can be assured of maximum yields of this material from blood. An important result of this work could be an AHF concentrate that could be prepared in sufficiently large quantities at sufficiently low cost to permit its use as a routine rather than an emergency procedure for preventing or controlling hemorrhage in hemophiliacs.

D. Sickle cell disease

Sickle cell disease is an inherited disorder of the blood found almost exclusively in blacks. It is due to a genetically determined change in the chemical substance (hemoglobin) responsible for the oxygen-carrying capacity of the blood. The presence of the changed hemoglobin (hemoglobin S) leads to distortions in the shape of the normally biconcave red blood cells carrying the hemoglobin, making these cells less able to survive in the blood circulation and less able to move freely through the smaller blood vessels. Thus, the presence of hemoglobin S in the blood cells may have serious consequences such as anemia (a reduction below normal of the number of blood cells) and also intermittent blockage of blood vessels, usually termed sickle cell vaso-occlusive crisis. These crises are characterized by severe pain, fever and anemia and require costly, recurrent hospitalization throughout the patient's life.

In spite of the degree of refined molecular knowledge about sickle cell hemoglobin, little is known about the pathophysiological mechanisms involved in precipitating and sustaining the painful vaso-occlusive crisis of sickle cell disease; and no treatment of proven efficacy is yet available to deal with it. The National Blood Resources Program has initiated a collaborative program to test the efficacy of promising approaches to the therapy of sickle cell crisis.

The NHLI is coordinating the HEW Sickle Cell Disease Program initiated by the President in 1971. The major objectives of this new program are: 1) To foster research and development both at the fundamental and clinical level; 2) To initiate and expand community education, screening and counseling programs; 3) To educate medical and allied health professsions about the problems of sickle cell disease; 4) To explore ways in which to broaden the monetary support base through federal, state, local, and non-government agency participation; 5) To strengthen and expand the base of black professional and technical personnel; and 6) To improve clinical care for victims of sickle cell disease, including the application of current technical knowledge. Current planning is proceeding along two major avenues: research and development, and community services.

HISTORY

In 1950, NHI was designated to administer the research and development phase of an intensified National Blood Program aimed at insuring an adequate supply of blood and blood products for military and civilian needs. The experience gained with this program was to make NHI the choice as the focal point of the National Blood Resource Program begun sixteen years later.

The National Blood Resource Program was initiated late in 1966 at the behest of the Congress, which appropriated an additional $1,950,000 to the NHI for this purpose. A National Blood Resources Branch was established within the Collaborative Research and Development Program of the Institute to provide a mechanism for research contracts for highly targeted research in this area. Although headquartered at NHI, the Program is a cooperative endeavor involving a number of Institutes and Divisions of the National Institutes of Health and other federal and non-federal agencies concerned with the acquisition, processing, distribution, usage, or study of blood and blood products. Cooperation has been maintained with the American National Red Cross, the National Hemophilia Foundation, and the Council on Thrombosis of the American Heart Association.

In 1966 the Task Force on Thrombosis of the National Research Council pointed out that thrombosis was not being properly appreciated as a public health problem, especially since the lesion probably represented the leading cause of serious acute morbidity and mortality in this country today (e.g. from acute heart attacks, strokes, and pulmonary infarction (damage to the lungs caused by clots in the blood vessels). The Task Force stressed the need for the development of an appropriate focus on thrombosis, and recommended that measures be instituted which could accelerate significantly the prevention and solution of this most important clinical problem.

A number of important measures have been taken since the Task Force Report. These events, which have laid the groundwork for a major attack on the thrombosis problem in this country, include: an International Conference on Thrombosis of the American Heart Association; the founding of the International Society of Thrombosis and Hemostasis; and most recently (FY 1971) the institution of NHLI supported Special Centers of Research in Thrombosis (SCORs).

On October 26, 1968, NHI received the National Hemophilia Foundation's Research and Scientific Achievement Award for its "medical leadership . . . tremendous stimulation and support of research activities directly related to the study and treatment of hemophilia."

In 1968 and 1969 the Institute undertook a complete analysis of all its research in thrombosis and hemorrhage through a contract with an expert in this field, and recommendations for future research and development were prepared for consideration by the Institute and its advisors.

In the NHI 1969 reorganization of the Institute's Extramural Programs a branch for Thrombosis and Hemorrhagic Diseases was established along with four other program branches along disease category lines.

In FY 1971 the NHLI's blood program underwent a large expansion in response to the pressing need for programmed research in blood banking and blood therapy. A systematic study of blood banking techniques and blood therapy in the United States was initiated through a contract with a major management consultant firm. Staff of the National Blood Resource Branch are working closely with members of the consultant firm in this effort.

A program in stickle cell disease was initiated by the Institute during FY 1971 as well, and later, in February 1971 in his message to Congress, President Nixon identified sickle cell anemia as a high-priority target and called for $5 million

increase in Federal expenditures for this disease during FY 1971. The National Heart and Lung Institute was assigned responsibility for coordinating the joint efforts of the DHEW Sickle Cell Disease Program and a Sickle Cell Disease Branch was established within the Institute.

Tables I and II show the budget and staffing history of NHLI programs in blood diseases.

OPPORTUNITIES AND OPTIONS

The Institute's programs in blood management have identified many new opportunities for solving the critical problems relative to the limited national supply of blood and blood components for transfusion, and have significantly increased the options available in blood therapy. Specifically, the development of blood fractionation techniques has resulted in an increasing identification of blood components as separately useful in patient therapy. Thus, the usefulness of a unit of blood from a single donor can be multiplied by giving each part to a different recipient as his need dictates. However, there remains a serious technological lag which prevents the large-scale application of this knowledge. This problem is made acute by the rapidly increasing civilian and military needs for blood components. Studies by the Institute have determined that these critical demands can be met if component blood transfusion therapy rather than whole blood was more extensively employed and if non-utilization of whole blood due to outdating in storage could be diminished. Methods have been developed for utilizing stored blood in a more intelligent and effective fashion, and systems are being developed for computerized automation of donor blood inventory, donor-recipient information, and other elements of blood banking techniques and blood therapy. The Institute's programs have also led to considerable improvement in the safety of blood transmission in blood and blood products. All these developments are of direct benefit to the millions of Americans requiring blood transfusions each year. The Institute has identified a number of new opportunities for improvements in blood therapy, opportunities which will extend the options still further for using blood and/or related blood products such as bone marrow. Future opportunities include platelet typing to further identify the type of blood to be used; blood bank tissue typing of organs, bone marrow transplantation to correct inherited blood cell disorders, further fractionation of blood into useful components, and the preparation from blood of hepatitis-free diagnostic agents such as radioisotope-tagged fibrinogen for diagnosis of blood clots within blood vessels.

In the area of thrombosis (or clotting of blood in blood vessels) new opportunities exist for the development of improved diagnosis of clots through new radiographic contrast media, radioisotope tagging with substances which absorb onto or into the clot, ultrasonic techniques, and the identification of breakdown products from the clot. There is considerable promise that clot-dissolving therapy may be of value in heart attacks, and the possibility exists that the formation of clots in thrombosis-prone patients may be prevented by small prophylactic doses of a drug called heparin.

Additional progress can be expected in the control of hemorrhagic diseases such as hemophilia. It is likely that home therapy may become feasible and economical in the near future. Self-administration of anti-hemophilic factor (AHF) immediately upon the first sign of bleeding may help prevent the serious side effects of immobilized joints that may occur as a consequence of uncontrolled, massive bleeding into these sites, and there is the further possibility that AHF may eventually be used prophylactically by the patient in his home to prevent bleeding altogether. In the future it may become possible to transplant normal blood forming tissue into these patients.

In the case of sickle cell disease, early diagnosis, treatment, and careful management, as well as the eventual possibility of transplantation of normal blood forming tissue at or before birth offer significant improvements in the outlook for the future of these patients. The possibility of identifying carriers of the sickle cell trait, and prenatal diagnosis offer additional options to the individual patient and his family.

III. Lung Programs

ISSUES

Lung disease afflicts the young and the old. In the newborn the most common cause of death is the dreaded respiratory distress syndrome (RDS) which affects between 50,000 and 100,000 babies in the United States each year, about

half of whom die. RDS is implicated in the development of adult respiratory diseases as well.

Of the adult respiratory diseases emphysema and chronic bronchitis are the major killers. Emphysema, chronic bronchitis and asthma were the underlying cause of more than 30,000 deaths in 1970, and the contributing cause of twice that number. These diseases represent a particularly pressing health problem since the death rate and prevalence of these conditions has been increasing at an alarming rate over the past fifteen years. The number of deaths from emphysema and chronic bronchitis [chronic obstructive pulmonary diseases (COPI)] is currently doubling every five years. Emphysema alone is the fastest rising of any cause of death in the United States today. As a disabling disease, it is second only to heart disease.

The exact causes of emphysema are largely unknown, but a number of factors, such as cigarette smoking, air pollution, allergy, and respiratory infections, are strongly suspected of playing important roles in its development. While recognition of these factors has led to reasonable programs to prevent severe disability, and while they may indicate promising research leads, it is apparent that we do not understand either the causes of emphysema or its mode of development.

DESCRIPTION OF PROGRAMS

A joint United States-United Kingdom Study on Cardiopulmonary Disease was initiated in 1959. This program is a comparison of British- and Norwegian-born residents of the United States, with nonmigrant siblings, regarding morbidity and mortality from chronic bronchitis and heart disease. These are studies in relation to country of origin and length of residence in the United States. Parallel data on lung cancer are being obtained from the same group of subjects under support from NCI. The expected occurrence of these diseases in Britons and Norwegians is appreciably modified by migration to the United States, the effect being most marked for chronic bronchitis and least for cancer.

The Institute's Lung Program is carried out through a variety of mechanisms including grants and contracts to investigators and groups of investigators. The complexities posed by these diseases require a diversity of research approaches. The Institute places special emphasis on those respiratory diseases that represent national health problems. These include chronic obstructive pulmonary diseases, acute respiratory distress syndromes, and interstitial diseases. While the public health problems of COPD and RDS are well documented, it is less well recognized that almost 200 different syndromes have been identified as interstitial diseases of infectious, allergic, or occupational origin. These are diseases of extreme morbidity; they are on the increase; they are a major cause of respiratory problems in the young adult; and they may be implicated as a cause of COPD.

In the past several years since becoming the National Heart and Lung Institute, the Institute has moved rapidly ahead to identify critical problems in respiratory diseases. These efforts have included studies to obtain up-to-date information on incidence, prevalence, and morbidity from respiratory diseases; a review and analysis of the Institute's total grant and contract programs in terms of pulmonary disease categories and research approaches; a review of epidemiology of chronic respiratory disease; and a critical review of literature on epidemiology of chronic respiratory disease in children; and a series of meetings with consultants who are experts in the field.

In June, 1970, the Institute sponsored a meeting of Pulmonary Directors to discuss the research and training needs in the pulmonary disease field. The topics considered included: 1) training in pulmonary disease control; 2) research opportunities and needs in the pulmonary field; 3) intensive respiratory care; and 4) problems of clinical management of patients with chronic lung disease. The report and recommendations of this group of 150 scientists and physicians have proved valuable in shaping the Institute's pulmonary disease program. One of the key problems identified was the need for more physicians well trained to treat pulmonary diseases. As mentioned below under Manpower Development a Pulmonary Academic Award was established later in the year in response to this need.

A Task Force on Research in Respiratory Diseases was initiated in October, 1971, which will report to the Institute in June, 1972. This Task Force is part of a long range effort by the Institute to sharpen the focus of its research planning so that it will be particularly responsive to national health requirements. The desire is to make the emphasis of the Lung Program directly related to the mag-

nitude of the morbidity, mortality, and economic, social and psychological consequence of the various respiratory diseases. The Task Force has the following specific objectives: 1) review of up-to-date health statistics for respiratory diseases; 2) quantitative and qualitative assessments of the national research effort addressed to these diseases; 3) professional judgments on which problems and research approaches are likely to have the greatest payoff in terms of public health; 4) critical appraisals of the state of the art in areas important to pulmonary diseases; and 5) recommendations relative to problems and approaches that are either presently neglected, currently overemphasized, or timely and promising in view of the current state of the art.

During 1971 the Institute established eleven Pulmonary Specialized Centers of Research throughout the United States. These centers will develop clinically relevant programs designed to bridge the gap between basic research and clinical care. The major efforts of the centers will be directed toward respiratory distress syndrome in infants and chronic obstructive respiratory diseases. The approaches used include epidemiology and population studies, pathogenesis, disease mechanisms, pulmonary function and diagnosis, treatment, and pathology.

Currently, the Institute's Lung Program as a whole includes the following program activities: A. Epidemiological studies; B. Treatment of lung diseases; C. Importance of Pollutants in lung disease; D. Pediatric pulmonary disease; E. Mechanisms of disease; F. Lung pathology; and G. Pulmonary training program.

A. Epidemiological studies

These studies are aimed at determining prevalence, incidence, etiological factors and risk factors in respiratory diseases, particularly emphysema and chronic bronchitis.

B. Treatment of lung diseases

Treatment of lung diseases, particularly chronic lung diseases, is notably ineffective and a variety of approaches are being explored to tackle this problem. These include inhalation therapy, intensive respiratory care, rehabilitative therapy, and transplantation.

C. Importance of pollutants in lung diseases

The importance of environmental pollutants as causative or aggravating agents in respiratory diseases cannot be overstated, and several studies are being conducted in this area. The role of cigarette smoking in developing pulmonary disease other than cancer is also being explored.

D. Pediatric pulmonary disease

Pediatric pulmonary disease is an important facet of the Institute's Lung Program, not only because of the public health problems that these diseases present in themselves but also because chronic pulmonary disease in the adult may have its inception in childhood.

E. Mechanisms of disease

Insight into the mechanisms by which respiratory diseases develop and by which therapeutic regimens delay or reverse the clinical course are essential to an effective program of prevention and treatment. Fundamental genetic, biochemical, immunological, physiologic and pharmacologic studies are underway to develop further information in this area.

F. Lung pathology

Lung pathology is an important area of study, particularly in the grant program, but is currently receiving insufficient attention by investigators. For this reason, the Lung Program arranged a workshop to alert investigators in the Pulmonary Centers to the need and opportunities in this discipline and to encourage the development of this facet of their programs.

HISTORY

The Institute has a longstanding history of support of research in cardiopulmonary diseases both through its intramural and extramural programs.

During the NHI reorganization on August 12, 1969, a Pulmonary Disease branch was established within the Extramural Programs.

In November 1969, the name of the National Heart Institute was changed to the National Heart and Lung Institute to reflect the amplification of its mission to include the support of research, investigations, and demonstrations relating to the lung as well as to the circulatory system. The Institute's Advisory Council was expanded to provide expertise in pulmonary diseases and on June 23, 1970, an Office of the Associate Director for Lung Programs was established to implement diagnosis, prevention and treatment of pulmonary disease and for the training of professional manpower in this categorical disease area by evaluating current resources in each area and identifying operational objectives for satisfying the program plan for meeting the identified objectives. It established and maintains cooperative working relationships with organizational units within the federal structure, and with the National Advisory Heart and Lung Council and other advisory committees.

In order to implement the Lung Program goals a Respiratory Diseases Branch within the Institute's Collaborative Research and Development Program was established in 1971. This branch is planning, developing, and administering a directed program in the field of detection and prevention of chronic respiratory disease, and the identification and improvement of methods of care for respiratory patients.

A Pulmonary Branch in Intramural Research was established in March, 1972, for the purpose of developing a broad and comprehensive program of pulmonary research including clinical respiratory, basic research in non-respiratory functions of the lung, and investigations of the pulmonary response to various types of injury such as pollutants and trauma.

OPPORTUNITIES AND OPTIONS

During the last 25 years, the research in pulmonary diseases has expanded considerably. However, recent analysis by the Institute of this field of research has revealed that certain lines of research have been grossly neglected while others have advanced rapidly. The bulk of the effort has been devoted to a limited number of clinical diseases and been rather one-sided in their emphasis of physiology and pathology. As a result a paradox has developed in that most clinical disease entities can now be readily recognized through well developed pulmonary function tests, whereas understanding of the mechanisms of development of disease and of effective therapy have not kept pace. Also, there is a market lack of adequate information on the incidence and prevalence of these diseases in the United States. Finally, the lack of sensitive tests for detecting early stages of disease has held back efforts to develop programs of early prevention for patients afflicted with these diseases.

This numerous opportunities exist for advancing the knowledge in pulmonary diseases and for improving the outlook for patients. The Institute is moving ahead rapidly to identify areas of immediate and future need and to develop plans for attacking these problems according to their apparent priorities.

There is considerable optimism with regard to the potential of advancing the field of respiralogy. The tremendous advances made in many biomedical disciplines such as biochemistry, pharmacology, immune and allergic mechanisms, and molecular biology in general have not yet been fully utilized in this field of research. It can be expected that the influx of knowledge from these fields will have considerable impact on respiratory disease control in the future, that many new options will be created, and that new opportunities for understanding, treating, and preventing these diseases will result.

Obviously, limitation of resources will not permit simultaneous development of all potential leads. Accordingly, a series of studies will be implemented as determined by their relative priority. Considerations in reaching decisions on priorities include: (1) the urgency of the need, (2) the readiness of current research to provide solutions, and (3) the lack of current efforts in the field. Among the current top priorities are studies of interstitial diseases of the lung, populations living in environments associated with high incidence of respiratory disease, occupations involving exposure to specific air pollutants, and genetic factors which may predispose to lung disease under certain environmental conditions. Other high priority areas are improved therapy for chronic obstructive pulmonary disease, extension of treatment technology through engineering approaches, studies of resources and manpower, and perhaps most importantly, improved coordination of efforts.

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IV. Technological Development

ISSUES

Modern research in detection, prevention, diagnosis, treatment, and rehabilitation of patients with cardiovascular, respiratory, and blood diseases depends heavily on the parallel development of a variety of new techniques, new instrumentation, medical devices, control systems, monitoring systems, automation of clinical laboratories, and computer facilities.

DESCRIPTION OF PROGRAMS

The Institute has supported a number of programs which are intimately related to advances in technology, and which would not be possible without these aids. Some of the most prominent areas are: cardiovascular surgery, pacemaker development, and development of cardiovascular and respiratory life support devices, new diagnostic procedures.

A. Cardiovascular surgery

Before surgery could be used to correct any but the simplest of heart defects, methods had to be developed to sustain patients during direct-vision operations in widely opened hearts. Development of two such life-support techniques, hypothermia and extracorporeal circulation, has not only made such surgery possible, but further development and refinement of these techniques has also made possible all of the progress made during recent years in the field of open-heart surgery, and hypothermia, or body cooling, slows metabolism and reduces tissue-oxygen needs so that the heart and brain can withstand short periods of interrupted or reduced bloodflow.

To sustain the patients for longer periods, techniques of extracorporeal circulation have been developed. In these techniques blood bypasses the heart and lungs completely. It is pumped and oxygenated by a so-called heart-lung machine located outside the body. Modern heart-lung machines may also chill the blood to produce hypothermia as well.

Modern life-support techniques provide the opportunity for direct vision access to the heart for periods long enough to correct many of the most complicated congenital or acquired heart defects.

As a result of these developments, which have improved both the effectiveness and safety of open-heart surgery, surgeons are now performing remedial heart operations for more newborn infants than ever before, instead of recommending that a child try to live with a life-threatening defect for several years before operative correction is attempted.

Spectacular strides have been made during recent years in the development of better artificial heart valves. With the development of improved methods of sustaining the patient during prolonged open-heart operations, surgeons can repair or replace as many as three damaged heart valves during a single operation with good prospects of success.

Improved artificial blood vessels and new techniques of blood vessel surgery make it possible to open up obstructured blood-vessel segments and remove the obstruction or severely diseased portions may be bypassed or replaced by synthetic blood vessel grafts in the larger and medium-sized arteries. Many cases of cerebral insufficiency or stroke result from obstruction to the brain's major arterial feedlines located in the chest or neck. Approximately 75 percent of such obstructions are operable, and over half of these patients are likely to be helped by blood reconstruction.

B. Pacemaker development

A variety of ingenious, totally implantable artificial pacemakers have been developed to restore and maintain normal heartbeat in patients in whom the electrical conduction system of the heart has been interfered with or disrupted by disease or injury.

Most pacemakers in current clinical use are compact, completely implantable devices, powered by long-lived batteries requiring replacement only every 24–36 months. Most are fixed rate pacemakers, i.e., they are set to pace the heart at a fixed rate. Once implanted, their rate cannot be changed.

More recent models make provision for changing the firing rate of the artificial pacemaker to make allowances for increased circulatory needs resulting from exertion or other factors. An even more sophisticated pacemaker retains the services of nerve and hormonal control mechanisms that ordinarily regulate heart

beat by their influences on the heart's natural pacemaker. Thus, the impulse rate of the pacemaker is not fixed, but varies with the body's circulatory requirements. If unaccountably, the natural control mechanisms should fail, the pacemaker contains a fixed-rate circuit that automatically assumes control to the heartbeat.

Modern pacemakers are highly reliable devices, but they sometimes do fail. Battery failure has been a common cause of pacemaker failure. And, although the replacement of run-down batteries requires relatively simple surgery, usually performed under local anesthesia, a pacemaker requiring no batteries at all would be a significant improvement. Such a pacemaker is already well along in its development. This device is powered by a piezoelectric crystal that converts mechanical energy to electricity.

The Institute is also supporting research directed toward the development of long-lived pacemakers powered by an isotopic heat source. This work has been carried out with the cooperation and support of the Atomic Energy Commission. The goal is a safe, implantable, nuclear-powered pacemaker that would last for 10 years or more. The Institute has completed preliminary tests of such a device.

C. Medical device applications program

The Medical Device Applications Program seeks to reduce death and disability from heart disease through the development of devices and techniques for providing temporary or permanent assistance to a failing circulation and a total replacement for hearts damaged beyond salvage. In 1970, the scope of the program was enlarged to encompass the areas of biomaterials, instrumentation, and pulmonary assist and replacement devices. This program provides for contract support of research attacking specific bioengineering, physiological, biochemical, and related problems of artificial and respiratory device development.

This program utilizes a modified systems development approach, enlisting the collaboration and expertise of scientists, physicians, and engineers located at universities and medical centers, chemical and engineering firms, electronic corporations and other elements of private industry.

Considerable technological progress has been achieved in recent years. Several new materials and surfaces have been developed that will not cause blood to clot when used in implanted devices. An improved capillary membrane oxygenator, which has been under development by the Program since early 1969, represents a significant advance over previously available systems. An electrically powered assist device has been used in calves and has functioned satisfactorily for more than 3 months and a radio-isotope powered model has undergone preliminary testing in animals.

The Institute is currently engaged in a study of the need for pulmonary assist devices and plans are underway for a comprehensive technology assessment of artifical organs.

Two comprehensive Test and Evaluation Centers have been established to provide thorough objective evaluation of devices developed by the Program.

D. New diagnostic procedures

New diagnostic procedures have been developed which make it possible to recognize the presence of arteriosclerotic lesions in the blood vessels during life by special x-ray examinations after injecting radio-opaque materials into the blood stream, thereby allowing visualization of the arteries. This technique is referred to as angiography or arteriography. This development has made it possible to arrive at accurate diagnosis prior to decision regarding surgical intervention or other therapy. However, as a means of following the natural evolution of the disease and the effect of therapeutic interventions, angiography is not feasible as a routine diagnostic procedure in asymptomatic individuals because of the need for hospitalization, occasional serious complications, and practical difficulties associated with repeated examinations.

Accordingly, noninvasive diagnostic techniques suitable for screening are urgently needed to enable the earlier identification of the individual with presymptomatic arteriosclerotic disease. Several promising new techniques are being developed, one of them being the use of ultrasound to outline diseased blood vessel segments.

Techniques are also being developed for localizing blood clots by means of radio-isotope tagged substances which absorb onto or into clots.

HISTORY

Research in technical development is a long-standing Institute activity.

The Laboratory of Technical Development was established within the Intramural Program in November, 1948. Its initial objectives were the design and development of instrumentation and apparatus for application in cardiovascular patients. In December, 1969, the scope of the laboratory was enlarged to include development, control and application of cardiovascular and pulmonary assistance systems.

An Artificial Heart Program was established in 1964 within the Collaborative Research Program. The name of this program was changed to Medical Devices Applications Program in 1970 to reflect the broadened mandate of the program. Current responsibilities of this contract research program include development of devices needed to support patients with chronic lung disease.

OPPORTUNITIES AND OPTIONS

The opportunities created by the past several years of technological development are far-reaching, and have implications in terms of social, ethical, legal, and economic consequences, including definitions of life and death, quality of life after technological replacement of vital functions of heart and lungs, and acceptance by society of these now modes of human life.

These technological advances have generated many new options both for prevention, diagnosis and treatment of disease, and thus affects all stages of disease. The prospects for further progress are almost unlimited from the standpoint of technology and science but will need to be seasoned with considerable wisdom in implementation.

V. Manpower Development

ISSUES

Clinical and basic research in cardiovascular, pulmonary and blood diseases and blood management systems requires highly qualified clinicians, scientists, engineers, and technologists with specialized training both for the conduct of the research itself as well as for the subsequent implementation and follow-up of the results. The availability of highly skilled manpower is vital to the quality and innovative aspects of research, whether it be investigator-initiated or targeted cooperative ventures between investigator groups inside and outside the Federal government.

In addition to the clinician in both the medical and surgical specialties, the National Heart and Lung Institute must promote manpower development in other areas where there presently are shortages. These include programs to train epidemiologists, biostatisticians, and scientists interested in the psychological and behavioral aspects of these diseases.

DESCRIPTION OF PROGRAMS

The Institute, through its training grants and awards programs, has as its ultimate goal the provision of high quality medical care in sufficient quantity to meet the needs of patients with cardiovascular, pulmonary, and blood diseases.

This goal is being approached by programs aimed at attracting a sufficient number of promising young trainees, providing them with high quality training, and encouraging the most capable among those inclined towards an academic career to undertake advanced scientific training and supervised research experience. Specifically, the Institute's current training programs include undergraduate training grants, graduate training grants, fellowships, career development awards, and pulmonary academic awards.

A. Undergraduate training grants

One problem recognized at the beginning by the NHI staff and the National Advisory Heart Council was the need for greater emphasis on cardiovascular diseases in the undergraduate teaching of the medical schools. The most direct attempt to resolve this problem would be to make funds for this purpose available annually to each school. Thus, the NHI initiated its program of "teaching grants", which soon came to be called "'undergraduate training grants." It was decided that there would be one and only one such grant awarded to a school and that one would be awarded to each school, including any new medical school

as soon as the new school had appointed a chairman of the Department of Medicine. The Institute supported 96 such programs in medical schools, 6 in schools of osteopathy, and 13 in schools of public health. It is now felt that although this program was worthwhile in the past, it has now served its primary purpose and a decision has been made to discontinue the program.

B. Cardiovascular training program

The cardiovascular training grant is designed to provide support for advanced training programs for physicians and scientists intending to pursue an academic career devoted to teaching, clinical service and/or research in the general area of cardiovascular or renal disease. These grants are made on a competitive basis to medical schools, universities, and other research-educational organizations in order to assist the institution in providing high quality, educational and training opportunities.

C. Pulmonary training program

The pulmonary training training grant is designed to provide support for advanced training programs for physicians and scientists intending to pursue an academic career in the general area of pulmonary disease. Grants are made on the same basis as those awarded under the Cardiovascular Training Program. With the new emphasis placed on the pulmonary disease area by the NHLI, the number of training grant applications in this area has been steadily increasing.

D. Pulmonary academic award program

The Pulmonary Academic Award Program was initiated in 1971. This Award is designed to develop and/or strengthen the pulmonary program in schools of medicine or osteopathy and, at the same time, to provide financial support, encouragement, and opportunities for academic career growth to young physicians or scientists interested in pulmonary diseases. Each eligible institution may nominate one candidate for a Pulmonary Academic Award. The Award is made for a five year period and may be renewable for a maximum of three years. With the limited funds available the Institute has only been able to issue four of these awards so far.

E. Fellowships

The two primary objectives of the Fellowship Program are: (1) to increase the number of trained cardiovascular and pulmonary investigators, and (2) to assure the continuing flow of skilled and imaginative research workers into the cardiovascular, pulmonary, and related fields. Promising scientists, selected on a national competitive basis, receive these awards enabling them to obtain advanced scientific training and supervised research experience. These awards serve to encourage the research interests of young persons who show promise of becoming competent research scientists; they serve to provide mature investigators with additional or specialized research experience and thus further develops their research skills; and they serve to provide stable support for the advanced investigator in an attempt to insure retention of the most qualified individuals within the field of cardiovascular research.

F. Career development awards

The Career Development Award Program is designed to provide stable career opportunities for scientists with outstanding potential and competence in cardiovascular, pulmonary, and renal research and teaching. This award carries an implied commitment from the institute for long-term retention of the awardees. It supports the younger investigator or scientist of demonstrated ability who needs further experience to qualify for more senior positions.

The Institute is currently conducting a thorough review and analysis of its total training needs, and the results of these studies will be available during the summer of 1972.

HISTORY

The undergraduate training grants were initiated in 1948 and initially carried a stipend of $14,000 and $8,000 for four-year schools and two-year schools respectively. Since 1953 the undergraduate training grants have been $25,000 and $15,000. Within broad policy and legal limitations, the funds were to be used in whatever way the program director and the grantee institution would consider best to achieve the purpose for which the grant was awarded, since it was believed that the schools themselves could best make these decisions. As mentioned above, these awards are now being terminated.

The training programs were established in 1949. Over the total period FY 1946 through 1958, the undergraduate exceeded the graduate training grants in both number of awards and money granted, but beginning with FY 1956, graduate training grants in both these respects began to increase at a faster rate than the undergraduate program.

The primary purpose of the direct traineeship program, established in fiscal year 1949 and terminated at the end of fiscal year 1958, was to encourage young physicians to take advanced training in the clinical aspects of cardiovascular and related diseases, and to help stimulate the development of additional and improved training in this area.

Heart research fellowships were awarded for the first time in FY 1949, starting with 67 fellowships. The number of fellowships gradually rose, particularly during the late fifties and the early sixties, and numbered 165 in 1970.

The Pulmonary Academic Awards were initiated in 1971 to fill the need for more physicians well trained to treat pulmonary diseases.

OPPORTUNITIES AND OPTIONS

By 1969 the total number of persons who had had Institute-supported training was 10,023. An analysis of these persons was carried out in 1970, and revealed that of these former trainees and fellows approximately 3,400 were in teaching, 860 in research, 3,500 in hospital service, 2,500 in private practice, 160 in administration, 2,100 in some other activity, 3,800 on medical school faculties, 500 on university or college faculties, 4,000 on hospital staffs, 378 on staffs of other organizations, 2,227 with professorial rank in medical schools and hospitals, and 998 with professorial rank equivalent in other organizations. Many additional statistics were gathered, however, the most important fact is that 7,762 out of a total 10,023 former trainees and fellows are in teaching, research and hospital service as their main professional activities. To have this many of the former trainees and fellows carry their NHI training into these activities suggests the NHI training program as a whole must have had an important impact not only on the trainees and fellows themselves but also on the medical institutions in which they were located.

Thus past training programs have resulted in the development of a unique pool of individuals trained in such areas as biochemistry, physiology, pathology, and pharmacology, and their applications to clinical problems. It is important that the development of new opportunities and options for the prevention and treatment of cardiovascular, pulmonary, and blood diseases, will depend on the continuous entry of these individuals into the field.

The basic sciences such as biochemistry, endocrinology, physiology, and pharmacology must be encouraged to produce more and better equipped physicians and scientists to meet the escalating needs of modern medicine.

Mr. ROGERS. I know right now regulation of blood banks is not in your purview. This committee is going into that question. But certainly you must be aware of some of the problems that exist in this situation, particular with commercial outlets. Could you just comment on that for us briefly?

Dr. COOPER. Yes. The national blood resource program has been very much concerned with the special problems of blood banking. Although they are not responsible for regulation or the development of the system, I think we have been concerned with some of the special problems. These are hepatitis in blood transfusion, the inadvertent human errors in cross-matching and typing the blood, unanticipated contamination, the use of specific fractions in order to avoid protein challenges that might be unnecessary; in other words, more specific therapy; the prolongation of the shelf life of the blood in order to reduce the blood loss on the shelf.

These have been particular areas that we have been concerned with in the national blood resource program.

Mr. ROGERS. Do you have any authority to deal with any of these problems presently?

Dr. COOPER. Not in any regulatory sense. Merely in the research sense.

Mr. ROGERS. Does the Department have authority in this area?

Dr. ZAPP. No. I might add, Mr. Chairman, we identified this as a problem and the President directed the Department, as part of the health message this year—and Dr. DuVal currently has the assignment—to develop a position to recommend to the Secretary for us on this whole blood banking and blood regulations, with the traditional patterns of people contributing for members of their own community and so forth. We realize it is a much more complex thing than it looks, but we hope to have a position by the time you are ready to hold hearings.

Mr. ROGERS. I am also going to give you, so you can comment on these you have not yet commented on, the amendments that were added in the Senate. I think you did some of it in your statement. I think there were some, and I will give you this comparison and ask you to have official comment made for the record.

Dr. ZAPP. We would be pleased to incorporate that in our answer to the record.

Mr. ROGERS. Any other questions?

Thank you. I think if you will supply this information for the record as rapidly as possible this would be helpful. We appreciate your coming back this afternoon.

(The following material was received for the record:)

COMMENTS ON SENATE AMENDMENTS TO S. 3323

EMERGENCY SERVICES PROVISIONS

A cause for concern arises from the inclusion in the Senate-passed bill of an emergency medical services program for victims of heart, blood vessel, lung, and blood diseases. The President has recently directed the Department of Health, Education, and Welfare to "develop new ways of organizing emergency medical services (EMS)." Accordingly, we are now implementing an "EMS Initiative" to meet this directive under existing legislative authorities in the agency in the Department responsible for health service delivery demonstrations, the Health Services and Mental Health Administration. Under this initiative, we will be supporting the planning, development, initia operation, and evaluation of several area-wide comprehensive emergency medical service systems through which the resources of communities will be coordinated for the provision of a full-range of emergency medical services regardless of the medical diagnosis. Also under this initiative, we will be establishing and maintaining effective communications and coordination among those Federal departments and agences, including NHLI, with responsibilities and activities in EMS. The addition of separate and duplicating responsibilities within the NHLI could, in our opinion, be disruptive to the effort underway and would lead to unnecessary duplicating costs and responsibilities.

OFFICE OF HEART AND LUNG HEALTH EDUCATION

S. 3323 would also mandate the creation of an Office of Heart and Lung Health Education in the Department of Health, Education, and Welfare. We strongly oppose this provision. It will serve as a dangerous precedent for creating an office to discharge a similar public information function for each major category of disease on which the National Institutes of Health conducts research. Moreover, the statutory creation of such an office restricts the flexibility of the Secretary in organizing the Department and would simply add another organizational layer on top of ongoing activities. Also, Section 412(e) of the Public Health Service Act currently provides that the National Heart and Lung Institute shall:

Establish an information center on research, prevention, diagnosis, and treatment of heart diseases, and collect and make available . . . information as to, and the practical application of research and other activities carried on pursuant to this part.

Since the NHLI currently has an ongoing heart and lung public information program, we believe that the proposal to establish a statutory office is unnecessary.

FIXED PERCENTAGE OF NHLI APPROPRIATIONS

To specify a fixed percentage of the NHLI appropriation as proposed by S. 3323 for research on diseases of the lungs and blood would limit the flexibility and professional discretion to set the funding for research at levels commensurate with the scientific opportunities in the field. As well as limiting the flexibility desirable for exploiting new departments in all areas of the NHLI, earmarking funds such as this would tend to discourage discontinuance of programs that have outlived their usefulness.

ESTABLISHMENT OF 10 MODEL CARDIOVASCULAR DISEASE PREVENTION CLINICS

The Department of HEW does not oppose the establishment of these disease-prevention clinics. We recognize an important aspect of health programs is bridging the gap between the laboratory and day-to-day use of knowledge in the practice of medicine, but we believe that the NHLI should concentrate its efforts on research activities. The delivery of services should only be included in a research institute where essential to the achievement of the medical research, and research and development of health services delivery are more appropriately located in the Health Services and Mental Health Administration.

Mr. ROGERS. The committee will stand adjourned until 10 o'clock tomorrow morning.

(Whereupon, the hearing adjourned, to reconvene at 10 a.m., Wednesday, April 26, 1972.)