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

GOVERNMENT

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HEARING

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BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON

LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

NINETY-SECOND CONGRESS

SECOND SESSION

ON

S. 3323

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ENLARGE
THE AUTHORITY OF THE NATIONAL HEART AND LUNG INSTI-
TUTE IN ORDER TO ADVANCE THE NATIONAL ATTACK
AGAINST DISEASES OF THE HEART AND BLOOD VESSELS, THE
LUNGS, AND BLOOD, AND FOR OTHER PURPOSES

AND RELATED BILLS

MARCH 24, 1972



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

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

FRIDAY, MARCH 24, 1972

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

The subcommittee met, pursuant to notice, at 10:05 a.m. in room 4200, New Senate Office Building, Senator Edward M. Kennedy, (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Schweiker, and Javits.

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

Senator KENNEDY. The subcommittee will come to order.

STATEMENT OF HON. EDWARD M. KENNEDY, A U.S. SENATOR FROM THE STATE OF MASSACHUSETTS, CHAIRMAN, HEALTH SUBCOM- MITTEE OF THE COMMITTEE ON LABOR AND PUBLIC WELFARE

Cardiovascular diseases—diseases of the heart and blood vessels—collectively cause more than 1 million or half of all of the deaths each year in the United States. These diseases account for half of all of the deaths among Americans in the productive years of 35 to 64, and for two-thirds of all of the deaths among Americans over 65. Within this family of diseases, three—heart attacks, strokes and peripheral vascular disease—have reached epidemic proportions.

One million, two hundred and forty thousand Americans experience heart attacks each year; of these, more than 500,000 die and of these, more than 250,000 die so quickly that they are not reached by medical assistance.

More than 200,000 Americans die of stroke, the arteriosclerotic disease in which blood vessels to the brain are affected.

More than 150,000 Americans are initially affected by the clinical manifestations of peripheral vascular disease, each year causing pain and disability among all who experience the disease.

The direct costs for medical care related to these diseases is probably more than \$4 billion per year. If we add to that days of work lost by those suffering from these diseases, another \$1 billion per year must be added for the value of labor lost. In addition, the present value of future earnings for those who die is several times the direct cost figure.

If the cardiovascular diseases could be eliminated as significant causes of disability and death, the average American's life expectancy

would be increased by about 11 years, and the annual savings to the economy in lost wages, productivity, cost of medical care, and earnings eliminated by premature cardiovascular death could exceed \$30 billion per year. We know enough to do far more than we are now doing to lead this country toward a significant reduction in these massive figures, if we start a concerted attack. That is what these hearings and the bill that I have introduced are all about.

Chronic lung diseases have been gaining steadily in importance as causes of disability and death. These diseases affect people of all ages. In the newborn, the most common cause of death is dreaded RDS—respiratory distress syndrome—which affects between 50,000 and 100,000 babies in the United States each year, about half of whom die. Emphysema, chronic bronchitis and asthma were the underlying causes of more than 30,000 deaths in the United States in 1970 and were a contributing cause of twice that number of deaths.

Most alarming has been the rate of increase in such deaths; until recently, the number of deaths from emphysema and chronic bronchitis had been doubling every 5 years. Emphysema alone is the fastest rising of any cause of death in the country today and is second only to coronary heart disease in disabling the Nation's workers.

The disabling effect of lung diseases is also important: an estimated 10 million Americans suffer from chronic respiratory diseases, one million from emphysema, four million from chronic bronchitis, and five million from asthma—and social security payments to persons disabled by these diseases currently exceeds \$90 million a year. If we are to find new ways to prevent, to detect, and to treat these diseases, current programs must be expanded.

Thrombosis—the formation of blood clots in the vessels—causes 80 percent of the 200,000 strokes per year in this country and is heavily implicated in causing death from heart attack as well. Thrombosis is a problem which affects people in the prime of life. It affects women of child-bearing years, particularly some who take contraceptive pills; it affects middle-aged individuals, and it affects the aged.

Blood is an essential human resource whose value in saving life and promoting health cannot be assessed in dollar terms. Nevertheless, our society fails to realize the fullest possible benefits from the blood available to it. This failure is a consequence of deficiencies in all phases of the current "nonsystem" of meeting blood demands in procurement, processing, distribution and utilization. These shortcomings may be summarized as follows: (1) fragmentation of effort and lack of unified direction lead to inefficiency in utilizing blood resources. Supply and demand are not coordinated because of the existence of multiple independent entities in the blood service complex. (2) though blood is precious, it is nonetheless wasted: whole blood is administered to patients in situations wherein components should be utilized; avoidable outdated of blood units occurs, and present commercial techniques of blood fractionation produce low yields of critical components. (3) current regulations do not provide adequate standardization of blood resources, and are sometimes not consonant with present knowledge and needs. (4) inequity of access to blood services exists. Although blood is a scarce resource whose procurement and distribution should be controlled by society for the greatest attainable good, a unit of blood may carry a dollar price tag reflecting the unrestrained play of

commercial forces. (5) no identifiable agency is responsible for the integration of blood services into the general health care delivery system.

The bill that I have introduced, S. 3323, along with a distinguished bipartisan list of cosponsors, amends the Public Health Service Act to enlarge the authority of the National Heart and Lung Institute of the NIH in order to advance the national attack against these crippling diseases. It is important to note that the program proposed by this bill is one which builds upon the accomplishments of the heart and lung programs at the NIH. These programs date back to the founding of the Institute in 1948.

The bill calls for the Director of the Institute, with the advice of the Advisory Council, to develop a plan for heart, blood vessel, lung and blood disease programs to expand and intensify the activities of the Institute respecting these diseases. Specifically, the program to be developed will include research into the causes and ways to prevent all forms and aspects of heart and lung and blood diseases, studies and research into basic biological processes and mechanisms involved in abnormal heart and lung function; research into the development, trial and evaluation of drugs and devices used in the diagnosis, treatment and prevention of heart and lung diseases; the establishment of programs and special centers for the direction of field studies and large-scale testing and evaluation of new approaches to the treatment of these diseases; and studies and research into blood diseases such as sickle cell anemia and hemophilia; education and training of scientists and clinicians in these fields; public education programs into all aspects of heart and lung diseases; and establishment of programs and centers for study and research into heart, lung and blood diseases of children, including cystic fibrosis, hyaline membrane, and hemolytic and hemophilic diseases.

The bill also creates heart, blood vessel, lung and blood disease control programs to be carried out in cooperation with State, local and regional public health agencies for the prevention and treatment of these diseases.

In addition, the bill authorizes the Director of the Heart and Lung Institute to provide for the development of 15 new centers for clinical research into training in, and demonstration of, advanced diagnostic treatment methods for cardiovascular diseases and 15 new centers for clinical research into, training in, and demonstration of advanced diagnostic and treatment methods for chronic pulmonary diseases.

For the purpose of carrying out these programs, the bill authorizes \$1.3 billion over a 3-year period.

Finally, I want to point out that I consider the passage of comprehensive heart disease legislation to be one of the highest priorities before the Senate Health Subcommittee this year, and I am hopeful that based upon the testimony the subcommittee will receive today, as well as whatever statements may be submitted for the record, that it will be possible to promptly report to the full Senate legislation to implement these needed programs. I certainly plan to do all that I can to insure that that is the case."

At this point I order a copy of S. 3323 and related bills printed in the record.

(A copy of S. 3323 and related bills follow:)

1 tively cause more than half of all the deaths each year in
2 the United States and the combined effect of the disabili-
3 ties and deaths from such diseases is having a major
4 social and economic impact on the Nation;

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

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

15 (4) chronic respiratory diseases affect an estimated
16 ten million Americans, emphysema an estimated one
17 million, chronic bronchitis an estimated four million, and
18 asthma an estimated five million;

19 (5) thrombosis (the formation of blood clots in the
20 vessels) may cause, directly or in combination with
21 other problems, many deaths and disabilities from heart
22 disease and stroke which can now be prevented;

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

1 (7) the greatest potential for advancement against
2 diseases of the heart and blood vessels, the lungs, and
3 blood lies in the National Heart and Lung Institute of
4 the National Institutes of Health whose research insti-
5 tutes have brought into being the most productive scien-
6 tific community centered upon health and disease that
7 the world has ever known.

8 (b) It is the purpose of this Act to enlarge the author-
9 ity of the National Heart and Lung Institute in order to ad-
10 vance the national attack upon the diseases of the heart and
11 blood vessels, the lungs, and blood.

12 HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES

13 PROGRAMS

14 SEC. 3. Part B of title IV of the Public Health Service
15 Act is amended (1) by redesignating section 413 as section
16 419A, (2) by redesignating section 414 as section 418, and
17 (3) by adding after section 412 the following new sections:

18 “NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD

19 DISEASE PROGRAM

20 “SEC. 413. (a) The Director of the Institute, with the
21 advice of the Council, shall within one hundred and eighty
22 days after the effective date of this section, develop a plan for
23 a heart, blood vessel, lung, and blood disease program (here-
24 after in this part referred to as the ‘program’) to expand,
25 intensify, and coordinate the activities of the Institute re-

1 specting such diseases (including its activities under section
2 412). The program shall provide for—

3 “(1) investigation into the epidemiology, etiology,
4 and prevention of all forms and aspects of cardiovascular,
5 lung, and blood diseases, including investigations into
6 the social, environmental, behavioral, nutritional, bio-
7 logical, and genetic determinants and influences involved
8 in the epidemiology, etiology, and prevention of such
9 diseases;

10 “(2) studies and research into the basic biological
11 processes and mechanisms involved in the underlying
12 normal and abnormal cardiovascular, pulmonary, and
13 blood phenomena;

14 “(3) research into the development, trial, and eval-
15 uation of techniques, drugs, and devices used in, and
16 approaches to, the diagnosis, treatment, and prevention
17 of cardiovascular and pulmonary diseases and the reha-
18 bilitation of patients suffering from such diseases;

19 “(4) establishment of programs and centers for the
20 conduct and direction of field studies, large-scale testing
21 and evaluation, and demonstration of preventive, diag-
22 nostic, therapeutic, and rehabilitative approaches to car-
23 diovascular and pulmonary diseases;

24 “(5) studies and research into blood diseases (such
25 as sickle cell anemia and hemophilia) and blood, its uses

1 for clinical purposes and all aspects of the management
2 of its resources in this country, including the collection,
3 preservation, fractionalization, and distribution of it and
4 its products;

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

9 “(7) public and professional education relating to
10 all aspects of cardiovascular, pulmonary, and blood dis-
11 eases and the use of blood and blood products and the
12 management of blood resources; and

13 “(8) establishment of programs and centers for
14 study and research into cardiovascular, pulmonary, and
15 blood diseases of children (including cystic fibrosis,
16 hyaline membrane, and hemolytic and hemophilic dis-
17 eases) and for the development and demonstration of
18 diagnostic, treatment, and preventive approaches to these
19 diseases.

20 “(b) (1) The plan required by subsection (a) of this
21 section shall be transmitted to the Congress and shall set out
22 the Institute’s staff requirements to carry out the program
23 and recommendations for appropriations for the program.

24 “(2) The Director of the Institute shall, as soon as prac-
25 ticable after the end of each calendar year, prepare in con-

1 sultation with the Council and submit to the President for
2 transmittal to the Congress a report on the activities, prog-
3 ress, and accomplishments under the program during the
4 preceding calendar year and a plan for the program during
5 the next five years.

6 “(c) In carrying out the program, the Director of the
7 Institute, after consultation with the Council and without
8 regard to any other provisions of this Act, may—

9 “(1) if authorized by the Council, obtain (in ac-
10 cordance with section 3109 of title 5, United States
11 Code, but without regard to the limitation in such section
12 on the number of days or the period of such service) the
13 services of not more than fifty experts or consultants who
14 have scientific or professional qualifications;

15 “(2) acquire, construct, improve, repair, operate,
16 and maintain cardiovascular and pulmonary disease cen-
17 ters, laboratories, research, and other necessary facilities
18 and equipment, and related accommodations as may be
19 necessary, and such other real or personal property (in-
20 cluding patents) as the Director deems necessary; and
21 acquire, without regard to the Act of March 3, 1877 (40
22 U.S.C. 34), by lease or otherwise through the Adminis-
23 trator of General Services, buildings or parts of buildings
24 in the District of Columbia or communities located adja-

1 cent to the District of Columbia for the use of the Insti-
2 tute for a period not to exceed ten years; and

3 “(3) enter into such contracts, leases, cooperative
4 agreements, or other transactions, without regard to sec-
5 tions 3648 and 3709 of the Revised Statutes of the
6 United States (31 U.S.C. 529, 41 U.S.C. 5), as may
7 be necessary in the conduct of his functions, with any
8 public agency, or with any person, firm, association, cor-
9 poration, or educational institution.

10 “HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE

11 CONTROL PROGRAMS

12 “SEC. 414. (a) The Director of the Institute, under
13 policies established by the Director of the National Institutes
14 of Health and after consultation with the Council, shall estab-
15 lish programs as necessary for cooperation with other Federal
16 health agencies, State, local, and regional public health agen-
17 cies, and nonprofit private health agencies in the diagnosis,
18 prevention, and treatment of heart, blood vessel, lung, and
19 blood diseases.

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

1 "NATIONAL CLINICAL RESEARCH AND DEMONSTRATION
2 CENTERS FOR CARDIOVASCULAR AND PULMONARY
3 DISEASES

4 "SEC. 415. (a) The Director of the Institute may pro-
5 vide for the development of—

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

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

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

17 " (b) The Director of the Institute, under policies es-
18 tablished by the Director of the National Institutes of
19 Health and after consultation with the Council, may enter
20 into cooperative agreements with public or nonprofit private
21 agencies or institutions to pay all or part of the cost of plan-
22 ning, establishing, or strengthening, and providing basic
23 operating support for, existing or new centers (including
24 centers established under subsection (a)) for clinical re-
25 search into, training in, and demonstration of advanced

1 diagnostic and treatment methods for cardiovascular and
2 chronic pulmonary diseases. Funds paid to centers under
3 cooperative agreements under this subsection may be used
4 for—

5 “(1) construction, notwithstanding section 405,

6 “(2) staffing and other basic operating costs, in-
7 cluding such patient care costs as are required for re-
8 search,

9 “(3) training, including training for allied health
10 professions personnel, and

11 “(4) demonstration purposes.

12 The aggregate of payments (other than payments for con-
13 struction) made to any center under such an agreement may
14 not exceed \$5,000,000 in any year. Support of a center
15 under this subsection may be for a period of not to exceed
16 five years and may be extended by the Director of the
17 Institute for additional periods of not more than five years
18 each, after review of the operations of such center by an
19 appropriate scientific review group established by the
20 Director.

21 “INTERAGENCY TECHNICAL COMMITTEE

22 “SEC. 416. (a) The Secretary shall establish an Inter-
23 agency Technical Committee on Heart, Blood Vessel, Lung,
24 and Blood Diseases and Blood Resources which shall be

1 responsible for coordinating those aspects of all Federal
2 health programs and activities relating to diseases of the
3 heart, blood vessels, the lung, and blood and to blood
4 resources to assure the adequacy and technical soundness
5 of such programs and activities and to provide for the full
6 communication and exchange of information necessary to
7 maintain adequate coordination of such programs and
8 activities.

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

14 “NATIONAL HEART AND LUNG ADVISORY COUNCIL

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

18 “(1) The Secretary, the Director of the National
19 Institutes of Health, the chief medical officer of the
20 Veterans' Administration (or his designee), and a
21 medical officer designated by the Secretary of Defense
22 shall be ex officio members of the Council.

23 “(2) Eighteen members appointed by the Sec-
24 retary.

25 Each of the appointed members of the Council shall be

1 leaders in the fields of fundamental sciences, medical sciences,
2 or public affairs. Nine of the appointed members shall be
3 selected from among the leading medical or scientific au-
4 thorities who are skilled in the sciences relating to diseases
5 of the heart, blood vessels, lungs, and blood; two of the ap-
6 pointed members shall be selected from full-time students
7 enrolled in health professions schools; and seven of the ap-
8 pointed members shall be selected from the general public.

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

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

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

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

24 “(2) A vacancy in the Council shall not affect its ac-

1 tivities, and twelve members of the Council shall constitute
2 a quorum.

3 “(3) The Council shall supersede the existing National
4 Advisory Heart Council appointed under section 217, and
5 the appointed members of the National Advisory Heart
6 Council serving on the effective date of this section shall
7 serve as additional members of the National Heart and Lung
8 Advisory Council for the duration of their terms then exist-
9 ing, or for such shorter time as the Secretary may prescribe.

10 “(4) Members of the Council who are not officers or
11 employees of the United States shall receive for each day
12 they are engaged in the performance of the functions of the
13 Council compensation at rates not to exceed the daily equiva-
14 lent of the annual rate in effect for grade GS-18 of the Gen-
15 eral Schedule, including traveltime; and all members, while
16 so serving away from their homes or regular places of busi-
17 ness, may be allowed travel expenses, including per diem in
18 lieu of subsistence, in the same manner as such expenses are
19 authorized by section 5703, title 5, United States Code, for
20 persons in the Government service employed intermittently.

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

24 “(d) The Director of the Institute shall (1) designate
25 a member of the staff of the Institute to act as executive

1 secretary of the Council, and (2) make available to the
 2 Council such staff, information, and other assistance as it
 3 may require to carry out its functions.

4 “(e) The Council shall meet at the call of the Director
 5 of the Institute or of the Chairman, but not less often than
 6 four times a year.”

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

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

12 “AUTHORIZATION OF APPROPRIATIONS

13 “SEC. 419B. For the purpose of carrying out this part
 14 (other than section 414), there are authorized to be appro-
 15 priated \$350,000,000 for the fiscal year ending June
 16 30, 1973, \$400,000,000 for the fiscal year ending June 30,
 17 1974, and \$450,000,000 for the fiscal year ending June 30,
 18 1975.”

19 DIRECTOR'S AUTHORITY TO APPROVE GRANTS

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

22 (1) by striking out “grants-in-aid” in subsection
 23 (a) and inserting in lieu thereof “except as provided
 24 in subsection (c), grants-in-aid”; and

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

3 “(c) Under procedures approved by the Director of
4 the National Institutes of Health, the Director of the Na-
5 tional Heart and Lung Institute may approve grants under
6 this Act for research and training in heart, blood vessel,
7 lung, and blood diseases—

8 “(1) in amounts not to exceed \$35,000 after ap-
9 propriate review for scientific merit but without review
10 and recommendation by the Council, and

11 “(2) in amounts exceeding \$35,000 after appro-
12 priate review for scientific merit and recommendation
13 for approval by the Council.”

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

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

20 (b) Section 412 of such Act is amended—

21 (1) by striking out “heart” each place it occurs
22 (except in the headings) and inserting in lieu thereof
23 “heart, blood vessel, lung, and blood”;

24 (2) by striking out “Surgeon General” and insert-
25 ing in lieu thereof “Secretary”;

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

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

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

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

11 (c) Section 418 of such Act (as so redesignated by sec-
12 tion 3 of this Act) is amended—

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

16 "(b) (1) The Council shall advise and assist the Direc-
17 tor of the Institute with respect to the program established
18 under section 413. The Council may hold such hearings, take
19 such testimony, and sit and act at such times and places, as
20 the Council deems advisable to investigate programs and
21 activities of the program.

22 "(2) The Council shall submit a report to the President
23 for transmittal to the Congress not later than January 31 of
24 each year on the progress of the program toward the accom-
25 plishment of its objectives."

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

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

7 (4) by striking out "Surgeon General" in para-
8 graph (f) and inserting in lieu thereof "Secretary, the
9 Director of the National Institutes of Health, and the
10 Director of the National Heart and Lung Institute"; and

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

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

16 (1) in subsection (a), by (A) striking out "Sur-
17 geon General" and inserting in lieu thereof "Secretary",
18 and (B) striking out "heart" and inserting in lieu there-
19 of "heart, blood vessel, lung, and blood"; and

20 (2) in subsection (b), by (A) striking out "The
21 Surgeon General shall recommend to the Secretary ac-
22 ceptance of conditional gifts, pursuant to section 501,"
23 and inserting in lieu thereof "The Secretary may, in ac-
24 cordance with section 501, accept conditional gifts", and

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

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

5 "PART B—NATIONAL HEART AND LUNG INSTITUTE".

6 CONFORMING AMENDMENTS TO OTHER PROVISIONS OF THE
7 PUBLIC HEALTH SERVICE ACT

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

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

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

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

17 REPORT TO CONGRESS

18 SEC. 8. The Secretary of Health, Education, and Welfare
19 shall carry out a review of all administrative processes under
20 which the national heart, blood vessel, lung, and blood dis-
21 ease program, established under part B of title IV of the
22 Public Health Service Act, will operate, including the proc-
23 esses of advisory council and peer group reviews, in order to
24 assure the most expeditious accomplishment of the objectives

1 of the program. Within one year of the date of enactment of
2 this Act, the Secretary shall submit a report to the Congress,
3 of the findings of such review and the actions taken to facili-
4 tate the conduct of the program, together with recommenda-
5 tions for any needed legislative changes.

6 EFFECTIVE DATE

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

92^d CONGRESS
1st SESSION

S. 2909

IN THE SENATE OF THE UNITED STATES

NOVEMBER 29, 1971

Mr. HARTKE (for himself and Mr. PERCY) introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To establish a Federal program to encourage voluntary donation of pure and safe blood, to require licensing and inspection of all blood banks, and to establish a national registry of blood donors.

1. *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

SHORT TITLE

4 SECTION 1. This Act may be cited as the "National
5 Blood Bank Act of 1972".

FINDINGS

7 SEC. 2. The Congress finds that human blood is necessary
8 for medical treatment and that an adequate supply of pure
9 and safe blood throughout the United States is essential to the

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1 welfare of the Nation. Congress further finds that interstate
2 shipment of pure and safe whole blood and blood components
3 is necessary for the welfare of the United States; that since
4 human blood is a living tissue which cannot be manufactured,
5 an adequate interstate supply of blood depends upon the will-
6 ingness of individuals to donate their blood; that since the
7 virus hepatitis is transmitted in human blood and is found sig-
8 nificantly more often in the blood of persons who donate for
9 monetary compensation than in the blood of voluntary donors,
10 the purity and safety of the national blood supply is seriously
11 threatened by the inadequate level of voluntary donation and
12 by monetary compensation of blood donors. The Congress
13 therefore finds that the welfare of the United States will be
14 promoted by development of a 100 per centum voluntary
15 blood supply as soon as feasible, that voluntary donation
16 should therefore be encouraged and promoted, and that cer-
17 tain procedures and standards should be established with re-
18 spect to the operation of all blood banks in the United States.

19 ESTABLISHMENT OF PROGRAM; DIRECTOR

20 SEC. 3. There is established in the Department of
21 Health, Education, and Welfare a National Blood Bank Pro-
22 gram to be under the supervision of a Director appointed
23 by the Secretary of Health, Education, and Welfare. The
24 Director of the National Blood Bank Program (hereinafter
25 in this Act referred to as the "Director") shall be appointed

1 subject to the provisions of title 5, United States Code, gov-
2 erning appointments in the competitive service, and shall be
3 paid in accordance with the provisions of chapter 51 and
4 subchapter III of chapter 53 of such title relating to classi-
5 fication and General Schedule pay rates.

6 FUNCTIONS AND DUTIES OF DIRECTOR

7 SEC. 4. (a) NATIONAL BLOOD BANK SYSTEMS.—Upon
8 the application of any group or organization of blood banks,
9 the Director shall designate such group or organization as a
10 national blood bank system under this Act if the group or
11 organization—

12 (1) includes member blood banks in not less than
13 ten States, which member banks have drawn an aggre-
14 gate of not less than two million units of blood in the
15 year preceding application;

16 (2) requires by written contract member blood
17 banks, which are not maintained and operated directly
18 by the group or organization, to adhere and be bound
19 by the rules and regulations of the group or organization;

20 (3) requires all member blood banks to maintain a
21 program for the recruitment of voluntary blood donors;

22 (4) adopts rules and regulations for the operation of
23 member blood banks which rules and regulations are ap-
24 proved by the Director and certified to be equal to or
25 more stringent than the standards for blood banks and

1 transfusion services of the American Association of
2 Blood Banks and the applicable standards of the Ameri-
3 can Red Cross;

4 (5) provides for—

5 (A) accreditation of member blood banks which
6 operate in conformity with the rules and regulations
7 referred to in paragraph (4) ;

8 (B) a program approved by the Director of
9 annual, unannounced inspection of accredited mem-
10 ber blood banks to determine adherence to such
11 standards; and

12 (C) recommend the fining, suspension, or ter-
13 mination of accreditation of member blood banks
14 which fail to adhere to such standards;

15 (6) requires that accredited member blood banks—

16 (A) designate named individuals in such ac-
17 credited member blood banks to have express re-
18 sponsibility for recruitment of voluntary blood
19 donors;

20 (B) be open for business on days and at hours
21 most convenient for voluntary blood donors;

22 (C) cooperate with other blood banks in the
23 recruitment of voluntary blood donors and in other
24 functions; and

25 (D) label clearly each unit of blood collected as

1 “low risk” when it is from a voluntary blood donor
2 or “high risk” when it is from a paid blood donor.

3 (b) PROMOTION OF VOLUNTARY BLOOD DONATION.—

4 In order to assure an adequate supply of pure and safe blood
5 throughout the Nation, the Director shall—

6 (1) develop, by grant or contract, new procedures,
7 materials, and techniques to inform the public of the need
8 to voluntarily donate blood;

9 (2) provide direct assistance to establish an ade-
10 quate supply of voluntary blood in those parts of the
11 country where it is presently unavailable;

12 (3) develop a national program to honor and recog-
13 nize all voluntary donors;

14 (4) establish yearly goals of voluntary donors for
15 each blood bank;

16 (5) conduct evaluations of the effectiveness of var-
17 ious recruitment techniques and inform the licensed blood
18 banks of the most effective techniques;

19 (6) classify blood banks which collect no more than
20 a specified percentage of their blood from paid donors
21 as “Class A Blood Banks” and classify all other blood
22 banks as “Class B Blood Banks”;

23 (7) annually increase the allowable percentage of
24 paid donors to qualify as a “Class A Blood Bank” to the

1 highest level consistent with an adequate national blood
2 supply.

3 (c) DONOR REGISTRY.—The Director shall maintain a
4 registry of all persons who give blood after July 1, 1972, to
5 a licensed blood bank and shall identify individuals on such
6 registry who may have been implicated in the transmission
7 of hepatitis or who should otherwise be disqualified as blood
8 donors. The Director shall notify all blood banks of such dis-
9 qualifying information.

10 LICENSE TO OPERATE AS A BLOOD BANK

11 SEC. 5. (a) LICENSE REQUIRED.—No person may op-
12 erate as a blood bank unless such person is licensed under
13 this section.

14 (b) REQUIREMENTS OF LICENSE.—Upon application
15 therefor the Director shall issue a license to operate as a blood
16 bank to any person if—

17 (1) such person agrees to require identification of
18 each blood donor and such other information relating to
19 each blood donor as the Director may prescribe; and

20 (2) such person agrees to transmit to the Director
21 such information (including information indicating that
22 the donor may be infected with hepatitis) as the Direc-
23 tor may require; and

24 (3) the application therefor contains or is accom-
25 panied by such information as the Director finds neces-

1 sary and the applicant agrees and the Director deter-
2 mines that the blood bank will be operated in accordance
3 with standards the Director issues to carry out the pur-
4 poses of this Act, including standards for purity, potency,
5 and safety of blood, donor selection, allowable percentage
6 of paid donors, regulations covering the management of
7 blood inventories; and a requirement that all blood be
8 tested by the best practical test for the presence of hep-
9 atitis; and

10 (4) such person agrees to clearly label each unit of
11 blood collected as "low risk" when it is from a voluntary
12 donor and "high risk" when it is from a paid donor.

13 (c) PERIOD OF VALIDITY.—A license issued under
14 this section shall be valid for a period of three years, or such
15 shorter period as the Director may establish for any blood
16 bank or class or classes thereof.

17 (d) FEES.—The Director may require payment of fees
18 for the issuance and renewal of licenses, but the amount of
19 any such fee shall not exceed \$125 per annum.

20 (e) The Director or his designee shall conduct an an-
21 nual inspection of each blood bank licensed under this sec-
22 tion to determine compliance with standards issued under
23 this Act. The time of such inspections shall not be announced
24 prior to the inspection.

25 (f) The Director may designate a national blood bank

1 system as his inspecting agent for purposes of this section.
2 He may accept accreditation by a national blood bank sys-
3 tem in lieu of this inspection requirement.

4 (g) REVOCATION, SUSPENSION, OR LIMITATION; NO-
5 TICE AND HEARINGS; GROUNDS.—A blood bank license
6 may be revoked, suspended, or limited if the Director finds,
7 after reasonable notice and opportunity for hearing to the
8 licensee blood bank, that such licensee or any employee of
9 the blood bank—

10 (1) has been guilty of misrepresentation in obtain-
11 ing the license;

12 (2) has engaged or attempted to engage or repre-
13 sented himself as entitled to perform any procedure or
14 category of procedures not authorized in the license;

15 (3) has failed to comply with reasonable requests
16 of the Director for any information or materials or work
17 on materials, he deems necessary to determine the blood
18 bank's continued eligibility for its license hereunder or
19 continued compliance with the Director's standards here-
20 under;

21 (4) has refused a request of the Director or any
22 Federal officer or employee duly designated by him
23 for permission to inspect the blood bank and its opera-
24 tions and pertinent records at any reasonable time; or

25 (5) has violated or aided and abetted in the viola-

1 tion of any provisions of this section or of any rule
2 or regulation promulgated thereunder.

3 (h) LEGAL PROCEDURE; IMMINENT HAZARD TO PUB-
4 LIC HEALTH; JURISDICTION OF DISTRICT COURT; TEM-
5 PORARY INJUNCTIONS OR RESTRAINING ORDERS; BOND;
6 FINAL ORDERS.—Whenever the Director has reason to be-
7 lieve that continuation of any activity by a blood bank
8 licensed under this section would constitute an imminent
9 hazard to the public health, he may bring suit in the district
10 court for the district in which such blood bank is situated
11 to enjoin continuation of such activity and, upon proper
12 showing, a temporary injunction or restraining order against
13 continuation of such activity pending issuance of a final
14 order under this section shall be granted without bond by
15 such court.

16 (i) APPEALS; PETITIONS; RECORD; ADDITIONAL EVI-
17 DENCE; MODIFIED OR NEW FINDINGS; JURISDICTION OF
18 COURT OF APPEALS; CONCLUSIVENESS OF FINDINGS; RE-
19 VIEW BY SUPREME COURT.—

20 (1) Any party aggrieved by any final action taken
21 under subsection (e) of this section may at any time
22 within sixty days after the date of such action file a
23 petition with the United States court of appeals for
24 the circuit wherein such person resides or has his prin-
25 cipal place of business, for judicial review of such action.

1 A copy of the petition shall be forthwith transmitted
2 by the clerk of the court to the Director or other officer
3 designated by him for that purpose. The Director there-
4 upon shall file in the court the record on which the
5 action of the Director is based, as provided in section
6 2112 of title 28.

7 (2) If the petitioner applies to the court for leave
8 to adduce additional evidence, and shows to the satisfac-
9 tion of the court that such additional evidence is material
10 and that there were reasonable grounds for the failure
11 to adduce such evidence in the proceeding before the
12 Director, the court may order such additional evidence
13 (and evidence in rebuttal thereof) to be taken before
14 the Director, and to be adduced upon the hearing in
15 such manner and upon such terms and conditions as the
16 court may deem proper. The Director may modify his
17 findings as to the facts, or make new findings, by
18 reason of the additional evidence so taken, and he
19 shall file such modified or new findings, and his recom-
20 mendations, if any, for the modification or setting aside
21 of his original action, with the return of such additional
22 evidence.

23 (3) Upon the filing of the petition referred to in
24 paragraph (1) of this subsection, the court shall have
25 jurisdiction to affirm the action, or to set it aside in whole

1 or in part, temporarily or permanently. The findings of
2 the Director as to the facts, if supported by substantial
3 evidence, shall be conclusive.

4 (4) The judgment of the court affirming or setting
5 aside, in whole or in part, any such action of the Director
6 shall be final, subject to review by the Supreme Court
7 of the United States upon certiorari or certification as
8 provided in section 1254 of title 28.

9 (j) VIOLATIONS AND PENALTIES.—Any person who
10 willfully violates any provision of this section or any rule
11 or regulation promulgated thereunder shall be guilty of a
12 misdemeanor and shall on conviction thereof be subject to
13 imprisonment for not more than one year, or a fine of not
14 more than \$1,000, or both such imprisonment and fine.

15 ADVISORY COUNCIL

16 SEC. 6. (a) ESTABLISHMENT.—There is established
17 an Advisory Council to be composed of the following nine
18 members appointed by the President:

19 (1) two representatives from each national blood
20 bank system, one of whom shall be a person with not
21 less than five years' recent experience in blood bank
22 administration;

23 (2) three representatives of blood consumer groups
24 including:

25 (A) one hospital administrator,

1 (B) one representative of organized labor,

2 (C) one representative of business manage-

3 ment; and

4 (3) two persons experienced in advertising and
5 public relations neither of whom may be employed or
6 retained during their service on the Council by any
7 firm or other organization which is engaged in operating
8 a blood bank.

9 (b) DUTIES OF COUNCIL.—The Advisory Council
10 shall—

11 (1) make recommendations to the Director with
12 respect to long-term policy goals for the National Blood
13 Banks Program established under section 3 of this Act;

14 (2) make recommendations to the Director with
15 respect to the encouragement of blood donation and the
16 motivation, recruitment, and recognition of blood do-
17 nors; and

18 (3) make recommendations to the Director relating
19 to reciprocal transactions between national blood bank
20 systems to the extent that no agreement relating to such
21 transactions exists between such systems.

22 (c) TRAVEL EXPENSES; PER DIEM.—While away
23 from their homes or regular places of business in the per-
24 formance of services for the Council, members of the Council
25 shall be allowed travel expenses, including per diem in lieu

1 of subsistence, in the same manner as persons employed
2 intermittently in the Government service are allowed expenses
3 under section 5703 (b) of title 5 of the United States Code.

4 ANTITRUST EXEMPTION

5 SEC. 7. Notwithstanding any antitrust law, as defined
6 in section 2 (a) of the Antitrust Civil Process Act (76
7 Stat. 548; 15 U.S.C. 1311 (a)), a national blood bank sys-
8 tem may exclude or reject from membership in such system
9 any blood bank which does not qualify for tax-exempt status
10 under section 501 (c) (3) or 501 (c) (4) of the Internal
11 Revenue Code of 1954.

12 BLOOD ASSURANCE PROGRAMS

13 SEC. 8. No person other than a blood bank which is
14 classified as a "Class A Blood Bank" may maintain any
15 program in which individuals deposit blood in advance of
16 their need for blood or pledge to give blood upon request.

17 ADMINISTRATION OF PROGRAM

18 SEC. 9. No provision of this Act and no part of any
19 program established under this Act shall be administered
20 by or under the supervision of the National Institutes of
21 Health.

22 PURCHASE OF BLOOD BY FEDERAL GOVERNMENT

23 SEC. 10. No agency, department, or other instrumen-
24 tality of the Government of the United States shall contract
25 for or pay for the provision of blood from any person other

1 than a "Class A Blood Bank" and such agency, department,
2 or other instrumentality shall take such measures as may be
3 necessary to insure that such blood has been tested accord-
4 ing to the best available test for hepatitis.

5 DEFINITIONS

6 SEC. 11. For the purposes of this Act, the term—

7 (a) "Blood" means human whole blood, or any com-
8 ponent thereof.

9 (b) "Blood bank" means any person or other entity
10 engaged in the bleeding of individuals and performing two
11 or more of the following functions—

- 12 (1) recruitment of blood donors;
13 (2) processing of blood for transfusions;
14 (3) storage of blood;
15 (4) crossmatching of blood;
16 (5) administration of blood to individuals; or
17 (6) preparation of blood components for transfusion.

18 (c) "Blood donor" means a paid blood donor or a
19 voluntary blood donor.

20 (d) "Paid blood donor" means an individual who re-
21 ceives monetary compensation or an adjustment in his sched-
22 uled period of prison confinement for his donation of blood
23 or any component thereof.

24 (e) "Voluntary blood donor" means any individual
25 donating his blood other than a paid donor.

1 (f) "Accredited blood bank" means a blood bank ac-
2 credited by a National Blood Bank System.

3 AUTHORIZATION

4 SEC. 13. There is authorized to be appropriated \$10,-
5 000,000 for the fiscal year 1973, \$10,000,000 for the fiscal
6 year 1974, and \$10,000,000 for the fiscal year 1975 to carry
7 out the purposes of this Act.

92^D CONGRESS
2^D SESSION

S. 3046

IN THE SENATE OF THE UNITED STATES

JANUARY 20, 1972

Mr. MONDALE introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To provide for accelerated research, development, training, and public education in the field of heart, lung, and blood disease.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3

SHORT TITLE

4 SECTION 1. That this Act shall be known as the
5 “National Heart, Lung, and Blood Act of 1972”.

6

STATEMENT OF FINDINGS AND PURPOSE

7 SEC. 2. (a) The Congress hereby finds and declares
8 that—

9 (1) cardiovascular disease accounts for more than
10 one-half of all deaths in the United States;

II

1 (2) pulmonary disease is increasing in incidence
2 and severity and is a leading cause of disability;

3 (3) blood disease affects millions of Americans and
4 a supply of wholesome blood for transfusions is essential
5 to a healthy society;

6 (4) existing knowledge of preventive measures and
7 techniques for care in cardiovascular, lung, and blood
8 diseases is inadequately disseminated to and used by pro-
9 fessionals and the public, thus preventing the rapid reduc-
10 tion in the incidence and severity of these diseases which
11 is, or may be, possible;

12 (5) a great potential for improving management of
13 these diseases is offered through the development and
14 refinement of technological devices to assist, replace, or
15 monitor vital organs and a substantial unused capacity
16 exists in our engineering and scientific pools to work on
17 such problems;

18 (6) there is a need to involve all appropriate ele-
19 ments of the Department of Health, Education, and Wel-
20 fare as well as other Federal agencies and voluntary
21 associations in order to carry out a comprehensive public
22 health program in the field of heart, lung, and blood
23 diseases.

24 (b) It is therefore the purpose of this Act to strengthen
25 and expand the authorities of the National Heart and Lung

1 Institute and the Department of Health, Education, and Wel-
2 fare in order to permit a comprehensive attack on heart, lung,
3 and blood diseases.

4 PROGRAM COORDINATION AND MANAGEMENT

5 SEC. 3. The Secretary of Health, Education, and Wel-
6 fare (hereinafter referred to as the "Secretary") is directed
7 to develop and implement a comprehensive program dealing
8 with heart, lung, and blood diseases utilizing the National
9 Heart and Lung Institute and all other appropriate elements
10 of the Department of Health, Education, and Welfare as well
11 as providing for cooperative efforts with other Federal agen-
12 cies and voluntary associations.

13 ANNUAL REPORT

14 SEC. 4. The Secretary shall, as soon as practicable after
15 the end of each calendar year, prepare and submit to the
16 President for transmittal to the Congress a report on the
17 activities of the department during the preceding calendar
18 year with regard to this Act.

19 ADMINISTRATIVE PROVISIONS

20 SEC. 5. The Secretary, in carrying out his functions
21 under this Act, is authorized—

22 (1) to the extent that he deems such action to be
23 necessary to the discharge of his functions under this
24 Act, to appoint not more than twenty-five of the scien-
25 tific, professional, and administrative personnel of the

1 Department without regard to the provisions of title 5,
2 United States Code, relating to appointments in the com-
3 petitive service, and he may fix the compensation of
4 such personnel without regard to the provisions of chap-
5 ter 51 and subchapter III of chapter 53 of such title
6 relating to pay rates, at rates not in excess of the highest
7 rate paid for GS-18 of the General Schedule under sec-
8 tion 5332 of such title;

9 (2) to the extent that he deems necessary to recruit
10 specially qualified scientific or other professional per-
11 sonnel on a temporary basis without regard to the provi-
12 sions concerning competitive service he may establish
13 the entrance grade therefore at not to exceed two grades
14 above the grade otherwise established for such person-
15 nel under such provisions and appoint not more than
16 fifty such persons for periods of time which he deems
17 appropriate;

18 (3) employ experts and consultants in accordance
19 with section 3109 of title 5, United States Code.

20 AUTHORIZATION OF APPROPRIATIONS

21 SEC. 6. (a) There are hereby authorized to be appro-
22 priated for research into the causes, prevention, diagnosis,
23 and treatment of cardiovascular disease (including clinical
24 trials, demonstrations, and administrative expenses) \$270,-
25 000,000 for the fiscal year ending June 30, 1973, \$275,-

5

1 000,000 for the fiscal year ending June 30, 1974,
2 \$285,000,000 for the fiscal year ending June 30, 1975,
3 \$295,000,000 for the fiscal year ending June 30, 1976, and
4 \$320,000,000 for the fiscal year ending June 30, 1977.

5 (b) There are hereby authorized to be appropriated for
6 research into the causes, prevention, diagnosis, and treatment
7 of lung diseases (including clinical trials, demonstrations, and
8 administrative expenses) \$40,000,000 for the fiscal year
9 ending June 30, 1973, \$40,000,000 for the fiscal year end-
10 ing June 30, 1974, \$45,000,000 for the fiscal year ending
11 June 30, 1975, \$60,000,000 for the fiscal year ending June
12 30, 1976, and \$70,000,000 for the fiscal year ending June
13 30, 1977.

14 (c) There are hereby authorized to be appropriated for
15 research into the causes, prevention, diagnosis, and treat-
16 ment of blood disease (including clinical trials, demonstra-
17 tions, and administrative expenses) and for improvement of
18 blood banking programs, \$50,000,000 for the fiscal year end-
19 ing June 30, 1973, \$55,000,000 for the fiscal year ending
20 June 30, 1974, \$55,000,000 for the fiscal year ending June
21 30, 1975, \$50,000,000 for the fiscal year ending June 30,
22 1976, and \$45,000,000 for the fiscal year ending June 30,
23 1977.

24 (d) There are hereby authorized to be appropriated for
25 information, public education, and professional training (in-

6.

1 cluding training grants, fellowships, continuing education,
2 and administrative expenses) \$40,000,000 for the fiscal year
3 ending June 30, 1973, \$40,000,000 for the fiscal year
4 ending June 30, 1974, \$45,000,000 for the fiscal year end-
5 ing June 30, 1975, \$50,000,000 for the fiscal year ending
6 June 30, 1976, and \$55,000,000 for the fiscal year ending
7 June 30, 1977.

8 (e) There are hereby authorized to be appropriated for
9 research, development, and testing (including administrative
10 expenses) of technological devices to assist, replace, and
11 monitor the performance of the heart and lung, \$45,000,000
12 for the fiscal year ending June 30, 1973, \$55,000,000 for
13 the fiscal year ending June 30, 1974, \$60,000,000 for the
14 fiscal year ending June 30, 1975, \$70,000,000 for the fiscal
15 year ending June 30, 1976, and \$85,000,000 for the fiscal
16 year ending June 30, 1977.

TRANSFER AUTHORITY

17
18 SEC. 7. Notwithstanding any limitation on appropria-
19 tions for any program or activity under section 6 of this Act
20 or any Act authorizing appropriations for such program or
21 activity, not to exceed 15 per centum of the amount appro-
22 priated or allocated for each fiscal year from any appropri-
23 ation for the purpose of allowing the Secretary to carry out
24 any such program or activity under section 6 of this Act
25 may be transferred and used by the Secretary for the pur-

1 pose of carrying out any other such program or activity
2 under this Act.

3 OTHER AUTHORITY WITH RESPECT TO HEART, LUNG, AND
4 BLOOD DISEASES

5 SEC. 8. This Act shall not be construed as superseding
6 or limiting the functions or authority of the Secretary, or of
7 any other officer, agency, or advisory council of the United
8 States, relating to the study of the causes, prevention, diag-
9 nosis, and treatment of heart, lung, and blood diseases.

92^D CONGRESS
2^D SESSION

S. 3201

IN THE SENATE OF THE UNITED STATES

FEBRUARY 21, 1972

Mr. SCHWEIKER introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SHORT TITLE

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

6 STATEMENT OF PURPOSE

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

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

II

1 “(3) training, including training for allied health
2 professions personnel; and

3 “(4) demonstration purposes.

4 “(c) Support under this section shall not exceed \$10,-
5 000,000 per year per center. Support of a center may be
6 for a period of not to exceed three years and may be extended
7 by the Director for additional periods of not more than three
8 years each, after the review of the operation of such center
9 by an appropriate scientific review group.

10 “CARDIOVASCULAR DISEASE PREVENTION CLINICS

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

16 “(1) to develop improved methods of detecting high
17 risk individuals;

18 “(2) to develop improved methods of intervention
19 against high risk factors; and

20 “(3) to develop highly skilled manpower in cardio-
21 vascular disease prevention.

22 “(b) Such clinics shall be served by a central coordi-
23 nating unit that shall be responsible for the development of
24 standardized procedures for diagnosis, treatment, and data
25 collection in relation to cardiovascular disease.

1 "OFFICE OF HEART HEALTH EDUCATION

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

10 "AUTHORIZATION OF APPROPRIATIONS

11 "SEC. 418. There are authorized to be appropriated for
12 the purposes of sections 415, 416, and 417, \$50,000,000 for
13 the fiscal year ending June 30, 1973; \$75,000,000 for the
14 fiscal year ending June 30, 1974; \$100,000,000 for the fiscal
15 year ending June 30, 1975; \$100,000,000 for the fiscal year
16 ending June 30, 1976; and \$100,000,000 for fiscal year end-
17 ing June 30, 1977."

Senator KENNEDY. We are considering today one of the most important and significant pieces of legislation that this Health Subcommittee will consider during the course of this year. The statistics are well known which attribute the cause of death to so many heart and lung related diseases.

I think all of us are looking for ways in which we in the legislative as well as in the executive branch can play a more constructive and positive role in trying to address ourselves to this problem.

We have legislation here which can be an effective instrument for moving this whole country down the road toward a more responsible position, and I am hopeful we can get expeditious action on it. The support of the administration can make a great deal of difference in moving this toward completion.

Senator Mondale had to be at the Education Subcommittee for Secretary Richardson's testimony on school desegregation. He asked that I place a statement by him in the hearing record. We will include that in the record as well.

PREPARED STATEMENT BY HON. WALTER F. MONDALE, A U.S. SENATOR
FROM THE STATE OF MINNESOTA

Mr. Chairman, I am delighted at the prompt scheduling of hearings on bills to combat heart, lung and blood disease. It was my privilege to introduce the first Senate bill on this subject this year. It was on the same day as the President's state of the Union message, in which he endorsed a substantial new effort to fight heart and lung disease.

I welcome the President's commitment and I look forward to hearing whether the administration will support the legislation before the subcommittee. I am also pleased to be a cosponsor of the bill introduced by the subcommittee chairman, which is very similar to my own bill.

Several features of my bill would, I think, give needed emphasis to certain programs of the National Heart and Lung Institute. In particular, these include the earmarking of funds for lung diseases and blood diseases, as well as for cardiovascular diseases. The specific focus on public information and preventive medicine is another major element of my bill. Finally, my bill would greatly augment efforts in the development of technological devices to assist, replace, or monitor vital organs and processes. The recent report on the promising development of an artificial heart shows how important these provisions are.

Last year, the Congress succeeded in creating a new, national program to fight cancer. There were some who were not with us at the beginning but all ultimately realized the importance of this effort. I hope that we will move forward with dispatch to enact legislation to deal with heart, lung and blood diseases, which is equally vital.

Senator KENNEDY. I want to welcome this morning Dr. DuVal, the Assistant Secretary for Health and Scientific Affairs at the Department of HEW. A graduate of Dartmouth College and Cornell University Medical College, Dr. DuVal has both practiced and taught surgery. In addition, he has held many offices, has edited various publications, and is an outstanding doctor and administrator.

I also want to welcome Dr. Marston and Dr. Zapp whom we see so many times outside these conference rooms as well as in the conference rooms. It is great to have you with us; and also you, Dr. Cooper.

STATEMENT OF MERLIN K. DUVAL, M.D., ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY JOHN ZAPP, M.D., DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH); ROBERT Q. MARSTON, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH; AND TED COOPER, M.D., DIRECTOR, HEART AND LUNG INSTITUTE

Dr. DuVAL. Good morning, Mr. Chairman.

It is a pleasure for me to be here today to present the views of the administration on several legislative proposals which are before your committee on a major national health problem that the President himself has characterized as "deeply disturbing," the high incidence and prevalence of diseases of the heart, blood vessels, and lungs. Your continued interest, Mr. Chairman, as well as that of other members of the subcommittee in the health of the American people 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." We anticipate that this Panel will be announced very shortly, and we look forward to receiving their recommendations on the best approach to this research field.

I think for the record and for your pleasure, Mr. Chairman, it would be well if I told you at this time that Dr. John Millis has agreed to serve as chairman of that Panel, and we will shortly have the other names for you.

In view of the fact that the bulk of this testimony, Mr. Chairman, is a repetition somewhat as to the type of comments you have already made, I would suggest that we submit it for the record, and if you will not mind I will jump right to our conclusions.

Senator KENNEDY. Very good. It will be included in the record in its entirety.

Dr. DuVAL. 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.

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.

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 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 is a more difficult problem. Research on cystic fibrosis is now being performed and supported by the National Institute of Arthritis and Metabolic 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.

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.

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.

Senator KENNEDY. Thank you very much. That is a good statement, and I like the conclusions in it best of all.

Do you see any real inconsistency with the moving ahead of this legislation and the appointment by the President of this Panel?

Dr. DuVAL. No inconsistency; as a matter of fact, I think they can probably with some comparable effort on our part be made to come together quite comfortably.

Senator KENNEDY. You have requested certain sums that may be necessary to authorize the legislation. You are aware that cancer was

\$400,000, \$500,000, \$600,000. Heart is \$350,000, \$400,000 and 450,000. In other words, less money is authorized for heart than for cancer. Do you have any feeling about this other than your general budgetary constraints which I know you are under. Is there any reason that should not be the same?

Dr. DuVAL. My feeling is probably better expressed in the testimony.

We would like to postpone a judgment about the levels that should be established until after we have heard the recommendations of the President's Panel. I think we can have the results available relatively rapidly.

Senator KENNEDY. When is the Panel to conclude? Could you tell us what the schedule is?

Dr. DuVAL. Yes. The chairman has already indicated he would serve, and we are hoping that the names of the Panel will be released before the week is out, maybe even this week.

We expect that they will begin meeting as promptly as possible and, since their first assignment will be to review the information already available from several sources, we would expect their first recommendations in approximately 60 to 90 days.

Senator KENNEDY. Am I correct in gathering a sense of urgency about this legislation as far as the administration is concerned?

Dr. DuVAL. We feel, as you do, that the immediacy of the concern of the American people appropos heart disease is well served by the joint interest of the administration and Congress, and specifically this committee, in getting this legislation through; yes.

Senator KENNEDY. I do not know whether any of the others have comments.

Dr. Marston.

Dr. MARSTON. Perhaps, Mr. Chairman, just to follow up on the point of your question concerning authorization ceilings, we have always thought at the National Institutes of Health where we are involved with programs that span many years of continuity of effort that there is an advantage in not having an arbitrary upper limit in either time or dollar amount.

We have had examples in the past where such limits would have made it impossible to move forward rapidly. So in principle I would agree with and extend the point that Dr. DuVal made that we certainly want to know the results of the Presidential Panel's deliberations on this point, but we feel that in the area of research one generally does better with open ended authorizations and without ceilings.

Senator KENNEDY. Dr. Zapp, do you have anything you would like to add?

Dr. ZAPP. I think Mr. Chairman, that we have pointed out a couple of things today that we would like to work with the committee. It is just that we would like the opportunity to continue that on some of the administrative details contained in the bill.

Senator KENNEDY. Dr. Cooper?

Dr. COOPER. I have no additional comments.

Senator KENNEDY. Dr. Marston, one final thought. We have been over the problem of the impact of giving priority to different institutes in the National Institutes of Health. I remember it was one of the basic questions we were wrestling around with over the cancer program last year.

Do you see any sort of threat to the integrity of NIH by the establishment of this kind of machinery?

Dr. MARSTON. Mr. Chairman, the main concern I have about this specific bill is that of having to come before Congress for renewed authority every 3 or every 5 years with the possible consequence of disruption of policy and procedures.

As you know, this bill does not have some of the areas of concern that we encountered in the earlier versions of the cancer bill.

I think as we worked out the cancer bill we arrived at a reasonable solution, and indeed the cancer hearings have apparently been helpful in drafting this bill. I have no concern. The history of the National Institutes of Health has been one of focusing on major problems of the health of the American people. This is the nature of our categorical institutes.

It is a fact that we are a mission-oriented agency, and therefore I see no problem in focusing special efforts on areas of opportunity among the various diseases that effect the American people.

Senator KENNEDY. Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

First I would like to say that I am delighted to see the chairman open hearings on this very important problem. I am cosponsor of S. 3323 also.

Also I have a bill of my own, S. 3201, because I feel the priority and urgency is very high.

I think probably the most interesting statistic of all is that we have six times the heart disease mortality rate that Japan has. This to me is most significant, because if through environment, diet, whatever it is, we can get our rate anywhere near equivalent to Japan's rate, we will save a lot of American lives.

The fact is we are the worst industrial nation in the world in terms of heart disease mortality. This is not only alarming but holds out a lot of hope for improvement, so I am delighted to see us going into this program in this way, and I commend the administration for its position, which I think is very constructive in this area.

I ask you now to insert my statement in the record.

Senator KENNEDY. It will be included in the record at this point.

PREPARED STATEMENT BY HON. RICHARD S. SCHWEIKER, A U.S. SENATOR
FROM THE STATE OF PENNSYLVANIA

Today the Senate Health Subcommittee begins the work of seeking ways in which the attention and focus of the Federal Government can be directed to an expanded program to deal with the Nation's No. 1 health problem, cardiovascular disease.

We will be undertaking to examine the nature and scope of the cardiovascular problem and to create the legislative foundation for an effective program. The statistics with which we are all painfully familiar are not very encouraging. We recognize that we are dealing with the Nation's No. 1 killer, estimated to kill over 1 million Americans in 1972.

However, the situation is far from hopeless. Obviously, there are factors which when identified and included in an expanded effort to control and eliminate cardiovascular diseases can drastically reduce the incidence of cardiovascular disease. As an industrialized nation

with the world's worst rate of heart disease we certainly need to know more about these factors affecting heart and lung diseases. This is particularly apparent when we know that Japan has one-sixth the mortality rate from heart disease per unit of population than we do, while at the same time their incidence of stroke is higher. The Scandinavian countries have approximately half the heart attack rate we do. In fact, in certain regions of our country the rate differs significantly.

Although much new information is being developed in the Nation's research laboratories, it is time to reduce the period of time it takes to transform a research development into a test, and subsequently into practical clinical use for the people who need it, the growing number of victims. It is time to accelerate the national effort and to create and enhance the apparatus to deal with this problem.

The research effort must be enlarged. The public needs useful information it can utilize and understand in order to prevent the occurrence of cardiovascular disease. This will take more than money. It will require a plan and an organization properly designed to deal with the problem. A number of ideas and proposals are currently before the committee including my own bill, S. 3201, designed to expand the scope of the National Heart and Lung Institute. The three major provisions of the legislation would establish—

National centers for the prevention of arteriosclerosis;

Cardiovascular disease prevention clinics; and

An Office of Health Education within the National Heart and Lung Institute.

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

I look forward to these hearings so that we can meet our responsibility as legislators to design the program which when properly funded will enable more Americans to live longer than they do today.

Senator SCHWEIKER. Senator Dominick could not be here. He is very interested in the problem, and he did have some questions.

Dr. DuVal, you may have already answered one or two of these, but I do not know whether you want to elaborate any further in view of some of things you have said in your statement.

Senator Dominick has made it clear that he is delighted to see the administration supporting the program, and he is aware of some of the differences you have of a minor nature with the bill, and he wanted to know if you would care to elaborate any more than you have on some of these, or whether this is something you will be doing as the hearings go forward in the markup.

Dr. DuVal. Senator, I appreciate the opportunity to reinforce what we said earlier, but I think the words of the testimony that I gave probably speak to this issue, plus the subsequent comments by Dr. Zapp that we would like to iron out a few differences in the language of the bill.

We are very appreciative.

Senator SCHWEIKER. That is all I have to say.

Senator KENNEDY. Thank you very much.

(The prepared statement of Dr. DuVal follows:)



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

by

Dr. Merlin K. DuVal

Assistant Secretary for Health and Scientific Affairs

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

before the

Subcommittee on Health

Committee on Labor and Public Welfare

United States Senate

March 24, 1972

STATEMENT BY
DR. MERLIN K. DUVAL
ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
BEFORE THE
SUBCOMMITTEE ON HEALTH
COMMITTEE ON LABOR AND PUBLIC WELFARE
UNITED STATES SENATE
FRIDAY, MARCH 10, 1972

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 which are before your Committee on a major national health problem that the President himself has characterized as "deeply disturbing," the high incidence and prevalence of diseases of the heart, blood vessels and lungs. Your continued interest, Mr. Chairman, as well as that of other Members of the Subcommittee in the health of the American people 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."

We anticipate that this panel will be announced very shortly, and we look forward to receiving their recommendations on the best approach to this research field.

Now, Mr. Chairman, I should like to briefly describe 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. 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 other causes of death in 1900, with a death rate of about 200 per 100,000 population.

And in 1968, it maintained its rank, but the death rate further increased to 373 per 100,000.

The most common form of heart and blood vessel disease is arteriosclerosis. 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 many women beyond 50 years of age have moderately advanced arteriosclerosis even though they have not yet manifested any symptoms.

The major clinical manifestations of arteriosclerotic heart disease are angina pectoris (heart pain); heart attacks, sudden death, disturbances of rhythm and electrical activity of the heart, and congestive heart failure.

Each year about one and one quarter million Americans suffer heart attacks; of these, more than a half million die of the attack, and of them one half die so suddenly that they are dead before they receive medical attention.

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. The direct costs for 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 apart from cancer of the lung or respiratory infections such as tuberculosis. More than 13,000 of these are under the age of 65 years and are in addition to the 20,000 infants who die each year with respiratory distress syndrome or hyaline membrane disease. Emphysema, chronic bronchitis and asthma were principal causes of more than 30,000 deaths in 1970, and were a contributing cause of twice that number.

These diseases pose a large problem in terms of national health because (1) their prevalence is rapidly increasing, (2) they represent a significant economic burden because they have a long, debilitating course, and (3) present therapeutic regimens do not, in most cases significantly alter the course of the disease.

BLOOD AND BLOOD DISEASES

Disease of the blood and circulatory system are also a major national health problem. Thrombosis--the formation of clots within blood vessels--is thought to be implicated in strokes, in gangrene

of the limbs, in blindness of sudden onset, and in heart attacks. In the latter instance, death may ensue.

There are some 10 to 15 thousand severe hemophiliacs in this country who must exercise extraordinary caution at all times because their blood will not clot normally. Continued research is needed before we can do more than health damage already caused by this disease.

Continued research is needed to deal with the basic mechanisms of blood coagulation and clot-dissolution as well as to evaluate drugs permitting manipulation of these mechanisms for preventive or therapeutic purposes.

Attention must also be paid to the management of blood resources. Although human blood is an essential resource, our society fails to realize the full potential from blood because of deficiencies in the current arrangements for meeting blood demand. We need improvements in the efficiency of procurement, processing, distribution, and usage methods. The President in recognition of the problems 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 to detect the presence of hepatitis in blood prior to its use in transfusions. Post-transfusion hepatitis is a debilitating disease. While some progress has been made in development of a test for a hepatitis-associated antigen, a completely effective test remains to be discovered.

Mr. Chairman, this Committee has already heard considerable testimony concerning sickle cell disease, the result of a genetically determined abnormality in the hemoglobin molecule. Roughly 2 million black Americans carry sickle cell trait, having inherited the abnormal hemoglobin from just one parent. These individuals are usually, although not invariably, without symptoms and can lead normal productive lives. Often they are not even aware that they carry the trait. On the other hand, it is estimated that approximately 25 thousand black Americans have inherited the abnormal hemoglobin from both parents. These individuals have the painful, debilitating and life-shortening form of the disease called sickle cell anemia.

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 development of open-heart surgery, pacemakers, the use of cardiac assistance devices, and progress toward an artificial heart are among the more widely publicized accomplishments in this field. Even more importantly, deaths from hypertension have been reduced by at least 50 per cent, rheumatic heart disease by at least 80 per cent, and the primary risk factors in heart attacks--high blood pressure, cigarette smoking, and cholesterol (high blood fats)--have been identified.

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 programming for diseases of the heart, blood vessels, lung and blood and is the primary focus within the Federal Government for research on these diseases.

The National Heart Institute, with the National Advisory Heart Council as its advisory body, was created in 1948. In 1969, by administrative action, the name was changed to the National Heart and Lung Institute to reflect expansion of its functions and responsibilities. On March 16, 1968, Dr. Theodore Cooper, who is internationally known for his research contributions in the areas of innervation of the heart, cardiovascular physiology and

pharmacology, and cardiac transplantation, became the seventh Director of the Institute.

The mission of the Institute includes research within its own laboratories (intramural research); contracts and research grants to academic and scientific institutions and grants for training programs (extramural research); coordination of research efforts and the dissemination of information concerning heart, blood vessel, lung and blood diseases.

The National Heart and Lung Institute, whose growth is reflected in the increase of appropriations for grants and direct operations, had a budget of less than 11 million dollars in 1950. 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 FY 1973. As I stated earlier, the President has indicated his desire to have a panel of distinguished experts advise him on the most appropriate means for conducting research on heart disease.

PRESSENT EFFORTS OF THE NATIONAL HEALTH AND LUNG INSTITUTE

The scope of the Institute's current cardiovascular, lung and blood programs includes research and development programs and

related training programs. Cardiovascular and blood programs of the Institute are directed toward developing the means for prevention, diagnosis and control of heart disease. These programs include extensive fundamental research on the structure, function, metabolism, performance, and regulation of heart and circulatory systems as well as programs designed to achieve more sharply defined objectives. Some of the specific programs include studies on heart attacks, arteriosclerosis, heart failure, shock, thrombosis, hemorrhagic diseases, and medical device development. Research on arteriosclerosis alone will account for over \$69 million of the Institute's budget in 1972 and will increase to \$79 million in 1973. The National Blood Resources Program conducts tests and studies of the components, safety, procurement, and distribution of blood and will be funded at over a level of \$6 million in 1973. The Medical Devices Application Program of the Institute includes development of an artificial heart, as well as a variety of circulatory assist devices, and will increase from a level of \$13.6 million in 1972 to over \$18 million in 1973. The new information and insights accumulated in these programs will serve as the knowledge base for the continued effort in the research on diseases of the heart and blood vessels.

The Institute's present efforts to combat lung disease are estimated to reach a level of over \$19 million in 1972 and \$23 million in 1973 and include: (1) a program of Pulmonary

-10-

Specialized Centers of Research where scientists and physicians can work together in a focused, multidisciplinary attack on problems of lung diseases, (2) a pilot program of Pulmonary Academic Awards, designed to capture the interest of physicians and biomedical scientists early in their careers and encourage them to channel these interests into the neglected field of research on pulmonary diseases, and (3) a number of research projects on understanding diseases of the lung.

SUMMARY

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 Metabolic 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.

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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.

Senator KENNEDY. I would like to welcome our next witnesses, who represent the American Heart Association. They are Dr. Willis Hurst, current President of the AHA and professor of medicine at Emory University in Atlanta; Dr. Gordon Barrow, director of Georgia RMP, and Dr. Paul Yu, president-elect of the American Heart Association and professor of medicine at Rochester University, Rochester, N.Y.

The American Heart Association was formed in 1948 in a marriage of doctors and laymen to achieve the control of the cardiovascular diseases. Since that time, it has sponsored research and public education programs to bring to the public the full benefits of processes in medicine. In the last several years, it has been giving increasing attention to making certain that the Federal Establishment in all its branches is geared to carry out the Government's responsibilities making sure that everybody has the best heart care available.

STATEMENT OF WILLIS HURST, M.D., PRESIDENT, AMERICAN HEART ASSOCIATION AND PROFESSOR OF MEDICINE, EMORY UNIVERSITY; ACCOMPANIED BY GORDON BARROW, M.D., CHAIRMAN OF THE COMMITTEE ON COMMUNITY PROGRAM OF THE AMERICAN HEART ASSOCIATION; AND PAUL YU, M.D., PRESIDENT-ELECT, AMERICAN HEART ASSOCIATION AND PROFESSOR OF MEDICINE, UNIVERSITY OF ROCHESTER SCHOOL OF MEDICINE

Dr. HURST. Thank you, Senator Kennedy.

First I would like to thank you for allowing us to come and present our point of view to you. My testimony will be shorter than the previous witness.

We really congratulate those who have done their homework in looking carefully at all the important things. We find all the elements here that we feel should have been looked at. We would have no disagreement with the principles outlined here, and perhaps I should stop at that point, because we think it is a terribly important document. It has been done very well.

In the small points that I make I do not wish to detract from that overall statement of excellence. Just a few minor points that have a few ramifications, very simple ones.

On the first page we would like to see the word "stroke" included there which would be associated with the words "blood vessels." That means stroke.

Then as we move along I would wish to emphasize on various pages, for example on page 50, items 6 and 7; page 9, item 3, that wherever we see the words "education and training", we simply want to underscore that.

The words are there and clear to see, but I would underscore it because the job we have ahead of us both in basic research and clinical work requires a large amount of training for the scientist and for the clinician, and this kind of support must be guaranteed in order to accomplish the goals.

Then on page 8, just a very small change, where it uses the word "new," referring to 15 new centers. I would leave out the word "new" for the following reason.

We would like it possible to have an old center, for example, now in trouble financially to have the opportunity to remain alive. If we could rephrase that slightly to give the incentive for new centers but not to forget some old are currently in trouble, this I think would perhaps prevent the loss of good facilities at the present time.

I would also suggest that we include the words "for basic and clinical research in both items 1 and 2 there. As it is stated it is limited to clinical research. I think simply adding "basic and clinical" in items 1 and 2 makes it possible to develop more than the current statement but yet may not cost a great deal more money.

Then on page 13 I would urge an increase in the amount suggested for appropriations to make it \$400 million for the first; \$450 million for the second; \$500 million for the third, because if we do fund 30 centers this will take a large amount of money.

By simple calculation my best guess would be that this would require about \$50 million for each year more than the current statement suggested for appropriations.

To restate, we really feel that the people who wrote this had done their homework and have looked at the right things, and that the principals presented here are those that we support, and that I have only added a few small changes that I think would prevent being restricted and offer a slightly more flexible presentation.

I would like you to hear from my colleagues.

Dr. BARROW. I am Gordon Barrow.

In the American Heart Association as such we have the responsibility of directing the application of research knowledge to the community, and you have spoken to this in your section 414(a), in the control programs.

We think this is extremely important, and we certainly wish to commend you for including this in it. With the expiration of the heart disease control programs in the old Public Health Service these functions were taken over by the regional medical program to some extent, but limitations in funding of the regional medical programs and their expansion into many new areas in the past 2 years has made it impossible for them to provide the amount of money that is necessary to do the job in this area.

To give you some examples, in the field of hypertension we know that we now have enough knowledge to definitely and markedly decrease the mortality from hypertension if we can identify it in the community and get people under treatment.

We know that only one out of six people with high blood pressure are identified and treated at the present time. Five out of six are not receiving treatment for that disease.

Another example is identifying those who have a high risk of heart attack (a "coronary"). If we can identify people before the coronary occurs, we can reduce the rate markedly. Just these two things can make a major impact.

This knowledge is already with us, yet it is my estimate that anything less than \$1 million per State would be unreasonably low for this.

For this reason I question the authorization of \$20 million, \$30 million, and \$40 million in succeeding years. I do not believe this is sufficient for the program in order to do the job that we have before us to apply this knowledge.

Senator KENNEDY. I think you were here, doctor, when the administration expressed some reservations about that aspect of the program.

You have given some examples which did seem to me excellent. I am just wondering, given their reasoning and justification, whether you find their arguments persuasive.

Dr. BARROW. No. I do not. I feel there is good reason to think we have enough evidence and enough knowledge to move ahead right now very strongly in these fields. There are others that I have not given examples of, but these are two major ones where I feel we are ready to apply this to the community.

Senator KENNEDY. As I understand, the NIH never really welcomes the service types of programs. As I was just reviewing the administration's testimony, they feel that the regional medical centers can provide services that are necessary; do you take issue with that?

Dr. BARROW. No, I do not. I am director of a regional medical program, but I do not take issue with this, because I think there are other mechanisms as well.

This bill will allow the NIH to contract with public health agencies, with voluntary health agencies, and other nonprofit organizations as well as RMP to carry out the use functions.

Senator KENNEDY. Do you see it as a sort of extension and expansion of the opportunity of providing services to people?

Dr. BARROW. Exactly; and using multiple sources.

Senator KENNEDY. Do I understand further that you are sufficiently convinced about development of treatment techniques that this provision could be particularly meaningful in terms of saving lives?

Dr. BARROW. Absolutely.

Senator KENNEDY. You are also convinced that it would not be of disservice to the research aspect of the program?

Dr. BARROW. No. I think it would fit right in. After all, of what value is research unless we apply it to the community?

Senator KENNEDY. Amen.

Dr. YU. I am Paul Yu, President-Elect of the American Heart Association.

I certainly want to congratulate you, Mr. Chairman, as sponsor of this bill. I think it is an excellent bill aimed at solving the number one health problem in this country.

I think it is a very urgent problem because of the high mortality rate, the loss of man hours, and the financial drain caused by this problem is really tremendous.

I just want to say a few words here to support what Dr. Hurst and Dr. Barrow said. As far as the centers are concerned we would like the bill to say it should not just establish 15 "new" centers for the reasons Dr. Hurst has already mentioned.

I think another point is, as you know, some of the established centers, because of the lack of support at the present time, do not have enough manpower, enough resources and facilities, so in the meantime the first year some of those centers might be beefed up by this excellent support.

On the other hand, in future years, in the new centers they have to recruit new members and facilities, so the new centers may be established and at that time the word "new" 15 centers would probably be more appropriate.

Another thing, I think a most important point here is really research into the etiology and prevention of heart disease. As you know, we still do not know the cause of heart disease, so if we do not know the cause, then we cannot prevent a disease.

It is very important to include the word "basic" here. I think basic research is going to be our key to the solution of the problem and we would be in favor of using basic and applied or critical research to these centers.

The funds of course may not be adequate for the first few years, particularly if we try to include all the States. I think Dr. Barrow already alluded to that, and we feel that it is very important to cover a large territory.

So, in conclusion, there is no question in our minds that this is a very urgent matter, and we hope that the Senate will pass this bill very soon so that the country will benefit from the provisions of this new program.

Senator KENNEDY. Dr. Hurst, tell us what it would cost to keep the present specialized centers going each year. Do you have that information?

Dr. HURST. No, I really do not.

Senator KENNEDY. Could you get it to us later?

Dr. HURST. Yes, I will be glad to try to get that for you.

(The information referred to above follows:)

Depending on the size, complexity and scope of presently supported specialized centers of research they range in NHLI support from \$400,000 to \$2.5 million. These centers are, of course, much more limited in scope and clinical activity than are the centers proposed in this Bill.

Senator KENNEDY. I think you have gone over the bill very well, and I know you did not have a great deal of time. We appreciate your adjusting your schedule. We are going to keep the record open for 10 days in any event, and perhaps over the period of the next few days you could review the testimony and submit any additional comments, because I think these points are very worthwhile.

The Administration made the point that cystic fibrosis should not be included in the legislation. Would you care to make any comment on that, as to whether it should or should not be?

Dr. HURST. This is the first time I have considered that type of question.

Senator KENNEDY. If you would rather, you may give it some thought and submit your opinion later.

Dr. HURST. My own reaction would be that the "lung" should encompass lung disease, and cystic fibrosis is lung disease, but it is perhaps more than that.

Children who have this form of lung disease also have diseases in other parts of their bodies, so it may well be that someone would think it could be better handled somewhere else since it is not coronary lung disease.

They frequently do have lung disease, but there are difficulties in the pancreas and other parts of the body. I am not at all sure it would be worth a real argument about where it is handled. It could be handled under lung, I can say that.

Senator KENNEDY. Senator Schweiker.

Senator SCHWEIKER. I have no questions. Thank you, Mr. Chairman.

Senator KENNEDY. Thank you very much, gentlemen.

Our next witness this morning is Dr. John A. D. Cooper, president of the Association of American Medical Colleges. Prior to coming to the AAMC as full-time president, Dr. Cooper was dean of sciences at Northwestern University and a member of the faculty there for 32 years.

He has also served as a former consultant to the Director of the National Institutes of Health, as a former consultant to the Division of Physician and Health Professions Education for the Bureau of Health Manpower Education, and is presently a professional lecturer on community medicine and international health at Georgetown University.

Dr. Cooper, you have testified before the Health Subcommittee before. I have always been very impressed with your testimony and am interested in hearing your statement today.

STATEMENT OF JOHN A. D. COOPER, M.D., PRESIDENT OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ACCOMPANIED BY JOSEPH MURTAUGH, DIRECTOR, DEPARTMENT OF PLANNING AND POLICY DEVELOPMENT

Dr. COOPER. Mr. Chairman, I have with me Mr. Joseph Murtaugh who is director of the department of planning and policy development at the association.

We have submitted a written statement and I would ask with your permission that it be incorporated into the testimony.

Senator KENNEDY. Fine, your statement will be inserted following your testimony.

Dr. COOPER. I would like to highlight the statement we have prepared.

We appreciate very much this opportunity to testify before the subcommittee as it considers legislation on the National Heart and Lung Institute to advance the national attack against cardiovascular and pulmonary diseases.

The association which we are representing has a very broad interest in health. This interest goes well beyond the education of medical students; we are concerned about delivery of health care, the education and training of persons in other related health professions, and in allied health occupations.

As you know, many of our institutions carry on a very substantial part of the biomedical research supported through the National Institutes of Health. We are increasingly involved in the transfer of knowledge from the laboratories to improvement in the care of the sick and the maintenance of health.

The legislation the subcommittee is considering today is extremely important because it addresses itself to the problems of heart, lungs, blood and blood vessels; diseases which have reached epidemic proportions in this country.

Heart and blood vessel diseases are the major causes of death in the United States. They kill more than 1 million people each year. Cardiovascular disease is responsible for 54.1 percent of all deaths in the United States, killing old and young alike.

Myocardial infarctions (heart attacks) kill some 600,000 people annually. More than 12 million Americans will suffer some kind of heart attack in the next 10 years unless we find some way to prevent this disease, which appears to be a consequence of our modern civilization.

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

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

This kind of data indicates the need for a concerted attack on diseases of the heart, blood vessels and the lungs. It is clearly in the national interest to act on these problems. We think that the fact these diseases affect people in their prime, most productive years, makes it even more important to seek ways to reduce the suffering and economic effects of these diseases on the community.

The association has studied the various legislative proposals before the subcommittee which deal with diseases of the heart, lungs, blood and blood vessels.

S. 3046, the National Heart, Lung and Blood Act of 1972, was introduced by Senator Mondale. This bill strengthens and expands the authorities of the National Heart and Lung Institute and the Department of Health, Education, and Welfare to permit a comprehensive attack on heart, lung and blood diseases. It provides specific 5-year authorizations for programs of cardiovascular, pulmonary and blood diseases within the National Heart and Lung Institute. For fiscal 1973, \$400 million is authorized to be appropriated.

S. 3201, the Heart Disease Prevention Act of 1972, which was introduced by Senator Schweiker, calls for the establishment of national multidisciplinary centers for the prevention of arteriosclerosis; establishment of 10 model cardiovascular disease prevention clinics; and creation of an Office of 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 5 years, beginning in fiscal 1973 with \$50 million and rising to \$100 million in fiscal 1977.

S. 3323, the National Heart, Blood Vessel, Lung and Blood Act of 1972, was introduced by the chairman of this subcommittee, Senator Kennedy, and others. This legislation is to enlarge substantially 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.

This is a very comprehensive bill which mounts a broad attack on these diseases. Senator Kennedy's bill provides for several things which we think are important.

S. 3323 provides the following: development of a national heart, blood vessel, lung and blood disease program to expand, intensify and coordinate the activities of the National Heart and Lung Institute; reestablishment of heart, blood vessel, lung and blood disease control programs; establishment of 30 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, and certainly will make it possible to speed up the action upon the grant request.

For fiscal year 1973 \$370 million is authorized to be appropriated.

In examining the various bills to extend and expand our efforts to conquer diseases of the heart, lungs, and blood, we would like to restate a position the association made when we testified on the National Cancer Act of 1971. We would like to again point out that we cannot overlook the fact that the present understanding of diseases of the heart, blood vessels and lungs as well as of cancer, is a direct result of broad advance across the full scope of the biomedical sciences. It has been basic research in fields related to heart, blood vessels, lung disease that has brought us to the point where we can really consider a concerted attack on these diseases.

It is important that we continue to develop the basic knowledge in the biomedical sciences about the major killer diseases. We do agree, however, that there are great opportunities in targeted areas of research, and it has not been possible to exploit these to the extent possible under the present NIH programs and the present levels of support.

We would like to comment very briefly on the three bills. We feel that Senator Mondale's bill, the National Heart, Lung and Blood Act of 1972, would tend to limit rather than enhance the development of a comprehensive research attack upon the problems of heart, lung and blood disease.

The imposition of specific, separate authorizations on existing programs would force arbitrary compartmentalization of these research efforts and diminish program flexibility and the capability of directing resources to the changing research prospects and opportunities.

Senator Schweiker'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 this 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.

Senator Kennedy's bill, the National Heart, Blood Vessel, Lung and Blood Act of 1972, would provide a considerably broader and, we believe, a more effective framework to deal with the problems of cardiovascular and pulmonary diseases. This bill authorizes the Director of the National Heart and Lung Institute, with the advice of the newly created National Heart and Lung Advisory Council, to develop a plan for a program to confront more effectively heart, blood vessel, lung and blood diseases within 180 days after enactment of the legislation.

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 recommendations on 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 S. 3323 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 Senator Kennedy's 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 and 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 Senator Kennedy's 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, 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.

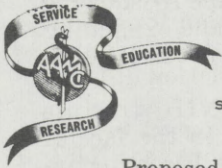
Thus, despite congressional establishment of appropriation authorizations and action on appropriation requests, there is no direct way for the Congress to insure that support for this area of basic research is sufficient to undergird the various categorical efforts.

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. However, almost all these additional funds were provided through real but hard-to-perceive reductions in other NIH programs.

Senator KENNEDY. Would you give us a little breakdown on that afterward?

Dr. COOPER. Yes.

(The information referred to follows:)



ASSOCIATION OF AMERICAN MEDICAL COLLEGES

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Proposed Reductions in President's Budget Requests for NIH Funding

The following data show the reductions proposed in the President's budget requests for fiscal year 1972 from the levels of funding appropriated by the Congress in fiscal year 1971 for the programs identified:

	Amount (in millions)
NIH Fellowships and Research Training Programs	\$-37.1
General Research Support Program	-11.5
New & Competing Research Grants	-10.0
Categorical Clinical Research Centers	- 4.2
Cooperative Heart-Drug Study	- 1.3
Scientific Activities Overseas	- 5.9
TOTAL	<u>\$-70.0</u>

Dr. COOPER. 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 has been cut back.

In simpler terms, Mr. Chairman, this is tantamount to starving the goose that lays 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 effective framework for its support.

Senator SCHWEIKER. I just want to respond a little bit to your remarks on my bill.

I would like to point out that my bill was patterned after a study made by the National Heart and Lung Institute Task Force on Arteriosclerosis. I think the reason they came up with the recommendation, which I encompassed in my bill, was they found that 62 percent of all cardiovascular attacks were due to arteriosclerosis. This is the major killer.

It was felt that an investment in this area would probably be more productive than any other type. In terms of singling out a disease, we recently singled out cancer. But, if you look at the statistics, you find that arteriosclerosis causes twice as many deaths as cancer.

So the bill addresses itself to a disease that has a higher mortality rate than cancer.

I think they also found that because a number of well known factors such as smoking, hypertension, diet, cholesterol, obesity, apparently contributed to the disease, they could educate and train the public to avoid some of these things.

So, in terms of a dollar investment and saving of life there would be a higher rate of return by means of education, along with some research programs.

So I think a case can be made that an emphasis and major attack should be in the area where we do know what is causing some problems, where we can educate the public.

I happen to be a sponsor of Senator Kennedy's bill, and I agree with the broad approach, but I do not think we ought to lose sight of the fact in terms of saving more American lives and bringing down the rate compared to Japan's and some other areas, this is probably the most fertile field of all.

A lot of it is just education, not research. That is the thrust of the bill.

Dr. COOPER. Senator Schweiker, we found as we pointed out in this testimony, that there are many, many useful recommendations in your bill for how to get at this disease which, as you point out, is one of the major ones confronting us in the area of heart disease and blood vessel disease.

However, we think that there are opportunities in a variety of other diseases related to the heart and lungs and blood vessels and blood

which can also be looked at in a much larger effort than we have had in the past, and we can also reduce death and suffering in these other diseases.

We think that this is, as we pointed out, a good bill. Our concern was that we had a broad enough bill to permit us to attack these other diseases as well.

Senator KENNEDY. We will recess for just a few minutes. I have a few questions.

(Recess.)

Senator SCHWEIKER (presiding pro tempore). Senator Kennedy has been detained on the floor. He asked me to resume the hearings, so we will ask our witnesses to come back.

Senator Kennedy had some questions to ask, and I will ask them in his absence.

Dr. Cooper, one question that I would like to ask for Senator Kennedy is whether you feel the money is adequate, or should there be more money? Just what do you feel an initial money figure should be in terms of our authorizing legislation.

Dr. COOPER. Senator Schweiker, we did not talk about the authorization level in our prepared statement. We believe that the authorized level of appropriations should be based on a determination of the measure of support needed to accomplish national objectives, and that the determination of the level of need will be brought out in the course of this hearing.

We would like to point out, however, that because of the special opportunities which do exist for research and treatment, the subcommittee may well wish to recommend higher authorizations than are presently contained in the bill.

Diseases of the heart and lung, blood vessels and blood are of such importance that some relationship to the amount of the authorizations in the cancer bill, might be a target for the subcommittee to consider.

Senator SCHWEIKER. The President has called for a panel to study the problem. Do you think at this point legislation should await the recommendation of the panel, or should we proceed with the bill as is?

Dr. COOPER. We think that the President's suggestion is a very admirable one, but we think it really falls short of what is needed. We think that we ought to move right ahead. There are opportunities for attack now, not months after the panel completes its study.

The National Heart and Lung Institute has constituted several panels of expert witnesses that have examined the important areas of heart and lung disease, and have made recommendations. These can serve as the basis for discussion by the Council in devising the plan for the specific ways in which an attack on the diseases of the heart and lungs will be prosecuted.

So we think that it is not necessary to have the President's Panel study this matter, because S. 3323 provides a mechanism by which an effective program can be developed with the National Heart and Lung Advisory Council.

Senator SCHWEIKER. Dr. Cooper, you have heard discussion earlier about whether cystic fibrosis should or should not be included in this approach. What is your opinion on this?

Dr. COOPER. We pointed out in the written testimony that for some diseases there are multiple interests at the National Institutes of

Health. For example, cystic fibrosis research has been of interest to the Institute of Arthritis and Metabolic Diseases.

What we would like to suggest is that the committee, in consultation possibly with the Director of NIH, look at ways in which these research efforts now centered in a number of institutes can be coordinated so there is avoidance of overlap, and so that the present programs are not disturbed to the point that they cannot continue to make their contributions to an understanding of these diseases.

Cystic fibrosis not only affects the lungs it also affects the pancreas and other organs. Other efforts against this disease will advance our knowledge generally about cystic fibrosis and develop information which will be useful in understanding the aspects related to the lungs. Other institutes also have an interest in some of the diseases of the blood.

We would recommend that there is coordination of the efforts within the NIH among the various institutes that do have a legitimate interest and involvement in these particular diseases of concern to the National Heart and Lung Institute.

Senator SCHWEIKER. Doctor, do you see any problem with the bill as structured in terms of either NIH or the scientific community? Do you see any conflict?

Dr. COOPER. No sir. I think this bill will receive the full endorsement and support of the academic science community.

Senator SCHWEIKER. Thank you very much, Dr. Cooper. I think that pretty well concludes our questions. We appreciate very much your testimony.

Next I would like to welcome Dr. Samuel M. Fox III, who is representing the American College of Cardiology. In addition to being president of the college, Dr. Fox is also professor of medicine at the George Washington School of Medicine.

Dr. Fox is a graduate of Haverford College and the University of Pennsylvania School of Medicine, with a speciality in cardiology. From 1965 to 1970 he was Chief of the Public Health Service heart disease and stroke control program, and placed special emphasis on coronary care services computer applications and physical activity programs aimed at the prevention and rehabilitation of coronary disease. He has contributed about 100 papers on this subject to medical literature, plus serving on numerous councils of the American Heart Association and on the International Society of Cardiology.

STATEMENT OF DR. SAMUEL M. FOX, III, PRESIDENT, AMERICAN COLLEGE OF CARDIOLOGY, PROFESSOR OF MEDICINE, GEORGE WASHINGTON UNIVERSITY, ACCOMPANIED BY WILLIAM HELLIGAN, EXECUTIVE DIRECTOR, AMERICAN COLLEGE OF CARDIOLOGY

Dr. Fox. Senator, we certainly appreciate this opportunity to appear on behalf of the American College of Cardiology. With me is Mr. William Nelligan, executive director of the college.

Mr. Chairman and members of the subcommittee:

I am Samuel M. Fox, III, president of the 5,000-member American College of Cardiology, and with me is William D. Nelligan, executive director of the college.

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. More than one third of all deaths among persons under age 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 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 Senate 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 sizably 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 70 percent of deaths in the United States.

We believe the best location for the planning and programing 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 practitioners 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 reactivating this valuable cadre of interested and dedicated workers. The health services and Mental Health Administration, Social and Rehabilitation Service and other Federal groups should have significant roles to play in this heart effort. These groups 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 Senate, 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 body's 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.

(Senator Kennedy assumed the chair:)

Dr. Fox. Mr. Chairman, it is a pleasure to have an opportunity to appear here.

Senator KENNEDY. It is nice to have you here.

Dr. Fox. A great need exists to evaluate scientifically both the long-term value and contraindications relating to the exciting new techniques of coronary bypass 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 Intersociety 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 deaths 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 by the National Heart and Lung Institute and perhaps six more will start soon, but even 12 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 Veterans' Administration. In the area of hypertension, as Dr. Barrow speaking here a few minutes ago indicated, we are trying to find answers to a condition involving over 20 million 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. A whole new effort must be started relative to the management of abnormalities and trends toward abnormalities in our youth.

Among other identified coronary risk factors, the contribution of diabetes, obesity, physical inactivity, and psychological 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 national heart disease 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 reconditioning program. This is also applicable to many deconditioned Americans prior to their suffering heart attacks. 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 atherosclerotic process that blocks the arteries to the brain and heart can be studied in the arms and legs if we use modern instruments. The use of present measurement techniques, and the application of biophysical and engineering talent to develop new noninvasive techniques, will permit us to evalu-

ate the effects of diet, drugs and changes in life style on the peripheral 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 and development in this area is now being supported, even in the lipid centers, due to stringent fiscal limitations. Too few investigators have found adequate support for their interests and with this lack have not been able to attract others.

There is also grossly inadequate support for the development and validation of new measurement techniques needed for disease detection and evaluation.

Senator Schweiker, we certainly support your interest in this area of development and application.

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 demonstrations 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. We believe the National Heart and Lung Institute should conduct such "operations research."

There is great enthusiasm in many areas concerning early coronary care and other emergency services outside—that is, before admission to the hospital. Programs in Seattle, San Francisco, Columbus, Miami and our neighboring Montgomery County, Md. 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. A total of 60,000 saved lives is an estimate they envisage in the near future if adequate emergency services can be made available nationally.

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 damage delays in program effectiveness unless corrected. News 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, and you, Senator Schweiker, likewise in your bill speak to this.

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 programing efforts. Competition for personnel in these areas is keen and appropriate inducements must be available.

We applaud the recognition of this committee of these needs for increased heart disease prevention and control. We support the committee'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.

We will be glad to try to answer any questions you might have.
(Senator Schweiker assumed the chair.)

Senator SCHWEIKER (presiding pro tempore). Thank you very much, Dr. Fox. I think your testimony is very interesting and very helpful. I have a number of questions right off that I would like to pursue.

In your statement you say: "We therefore believe that most elements of stroke research should be supported and coordinated from within the strengthened National Heart and Lung Institute."

I wonder if you would just elaborate, because I am sure you are well aware of the present structure of the National Heart and Lung Institute with stroke being separated to another institute. Are you suggesting a little change, or just some kind of coordination with a higher degree of control than before?

What do you mean?

Dr. Fox. We are suggesting that the main focus of stroke research be returned to the National Heart Institute. My understanding of the past is that there was a joint intercouncil commission on strokes for vascular disease prior to the redesignation of the National Institute of Neurological Disease and Stroke as such.

This intercouncil commission, or joint council committee perhaps it was, tried to coordinate these functions and this type of coordination would still be very appropriate.

At that time, prior to designating the Neurological Institute as Neurological and Stroke Institute the vascular elements, those which we look to for the primary prevention of cerebro-vascular disease and

stroke I think were quite appropriately in the Heart and Lung Institute as it now is. I believe this is the place to which it should return.

Senator SCHWEIKER. We certainly appreciate having your opinion on it because I think it is something the committee will certainly want to seriously consider.

Also you made a very interesting statement that I would like to explore a minute. In the third paragraph you say, "It has been calculated that at least 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."

I wonder if you would be specific in terms of some of the things we do know from education or usage of technology which would be beneficial in this case. What would be some of the things that you are thinking of here?

Dr. Fox. It is only 10 years ago that there was a creative effort by Dr. Hughes Day in Kansas City to put together in a special area in the hospital the techniques that had been developed all over the country and the world with the support of the Heart Association, as well as the Federal Government, in what was called the coronary care unit.

This concept was a specific unit for treating those who were suspected to have or who had experienced a documented heart attack. Above all the most important ingredient of the coronary care unit was and is the trained personnel capable and authorized to apply the new science of preventive and corrective therapy for acute heart problems such as occur with myocardial infarction—the all too common heart attack.

Secondly, new drugs and the application of established drugs in new ways have made the prevention and treatment of acute cardiac catastrophes most rewarding in terms of lives saved and disability prevented.

The application of depolarizing current—to defibrillate the electrical chaos of ventricular fibrillation—was the third element combined into the coronary care concept. Portable defibrillators can now be carried into "the field" and applied a number of times without needing a direct electrical power source.

The fourth element was a new set of "monitoring" devices for continuously picking up and displaying the electrocardiogram and other physiologic information that permits instantaneous detection of abnormalities.

Special architectural design permitting rapid and effective action in a room in which the patient can be continuously under surveillance from the nursing station was the fifth development.

These five elements and the policies that permitted nonphysicians to apply the new products or research have changed the whole practice of cardiology in only 10 years.

Outside of the hospital there is a tremendous delay. Individuals threatened with such attacks try to make up their minds as to whether they need to go to the hospital or not. These delays are often accompanied by the occurrence of changes in the electrical pattern of stimulation of the heart which can be lethal within a matter of seconds.

It is the carrying out into the community of these same services by competent personnel in ambulances (manner probably by some of our brighter fire and rescue squad personnel as opposed to pulling people

out of hospitals to do it) that will make a great difference. By applying these techniques, that have been so well demonstrated to reduce deaths in coronary units, out in the community we believe we can provide services that will markedly reduce out-of-hospital deaths.

Our experience in Montgomery County with the "heartmobile," with which some here may be familiar, has indicated you can train personnel, and that they do not have to have a full physician's training to undertake the appropriate application of an electrical defibrillator current which will eliminate the chaotic electrical activity in the disordered rhythm of the heart, and thus permit reinstitution of a more organized and cleanly transmitted stimulus.

These allied health personnel have to use drugs in support of this electrical defibrillation, and it has been found that individuals coming from the rescue squad, if carefully selected, can understand within a "Mission Rules" set of circumstances the type of drug therapy in appropriate amounts and their indications.

This has been fortunately tied in with radio communications with physicians, of which I happen to be one in Montgomery County, who provide the legal authority now required under the Medical Practices Acts, to permit allied health personnel to undertake these actions.

I think we have a very favorable experience in Montgomery County, and likewise in many of these other areas we have mentioned. We have people who are now living in their second year, having essentially died at their homes, or their offices or on the street, and then having been picked up, resuscitated and transported to a coronary care unit and back into a useful life.

These people are not impaired in their mental functions, and in many cases are again productive members of society.

Senator SCHWEIKER. What you are saying in layman's terms I suppose is that this is an extension of the intensive care unit in the hospital, extending it to a mobile system of bringing the patient in and utilizing some of the techniques and technology of the in-hospital unit in the mobile unit.

Dr. Fox. Exactly, and I am sorry if I slipped into professional jargon.

Senator SCHWEIKER. No. I did as a matter of fact, see on television the other night a program—I do not know if this is accurate or Buck Rogers—where they had one of the "heartmobile" units.

By radiotelephone in the "heartmobile" unit this person was piping a cardiac beat over the telephone to be read on the scope in the hospital. Is that feasible technology today?

Dr. Fox. Every fourth or fifth day I carry my little American Optical Oscilloscope from my office to my home and plug it in to take my turn backing up our Montgomery County "heartmobile." They call me up, and even at the hospital with one of these Bell Boy rigs that we carry around, I know when and where to run when the "heartmobile" responds to a call. I can converse with the crew over the phone lines and also get an electrocardiographic signal over the phone to be displayed on a portable oscilloscope.

So it is a "state of the art" technique and in practice today, and it is being explored, I might add, by quite a few of the medical groups in your State of Pennsylvania.

Senator SCHWEIKER. I think this point is very significant because this was the basis for some of the thinking in the other bill that you referred to before. There is a state of the art, that we have today that we can utilize today.

I think it is very important because with a disease that strikes the overwhelming bulk of our population, you have so many people that you can help just by doing a little bit. That was the thrust of my bill, with the thought that we incorporate some of its features in the broader bill in order to put an emphasis where the most people can be helped in the shortest amount of time with the knowledge we have now.

In sickle cell anemia we do not have the technology, we do not have the expertise yet to help people, except to alleviate some suffering. Here we have an area as you have just pointed out, where we can have a mobile unit extended to pick up the person with the heart attack. That was the thrust of this thought, that we ought to put the money where we know we can save lives first, because we always have a priority problem around Congress about how to spend money.

The later dollars are to go where we have to experiment, for research and development.

I think you have pointed out throughout your whole testimony the availability of information if we just coordinate it, study it further, or correlate it in a way that meaningfully could help us. I think your testimony is very good.

I did have a few questions here from Senator Kennedy who had to go to another committee meeting.

Do you see anything in the bills at all before us that would threaten the scientific concept of peer review?

Do you as a professional scientist see any complications or problems in the legislation that we are talking about to impinge on this in any way?

Dr. Fox. I personally do not, but in some of our discussions in the cardiology community we were concerned, but I think only in passing, that the granting of the authority to the Director of the Institute to be able to approve those grants that were of less than \$35,000—this is on page 14 of the bill, S.3323—might start erosion of the valuable concept of peer review at two levels.

My personal acquaintance with the mechanisms, and my personal respect for Dr. Theodore Cooper is such that I see no great hazard, but some of my colleagues did speak to the fact that in a sense we are establishing a lower limit below which the Institute staff could expend perhaps not much in any individual grant, because \$35,000 does not get much research done these days, but a sizable part of the funds could be spent in many such grants without dual review.

I believe that we have adequate language here in the initiation of the words stated—"under procedures approved by the Director of the National Institutes of Health—" and that this does not represent a hazard.

Likewise, the Heart and Lung Council should have an overall review as to the volume of such approvals, and be able to make itself clearly understood if it felt that there were any subversion of the peer review process.

In other respects I see no problem.

Senator SCHWEIKER. This was modeled after what we did in the cancer bill, but I think it is wise to take another look at it, and look at the whole concept in view of your remarks and some others in the scientific community.

What is your feeling about the level of authorizations? Do you have any specific reaction as to inadequacy, adequacy, or feeling about the funding authorization levels?

The heart bill we are talking about is \$350 million the first year, \$400 million and then \$450 million. The cancer was \$500 million, \$500 million and \$600 million.

Of course, these are authorizations and not appropriations, which makes a big difference.

Do you have any general reactions at all?

Dr. Fox. Senator, I suspect I cannot go home to my colleagues having not put in a plug for equity. I believe that we should be given equal opportunity.

These are large numbers. It is hard to rapidly and intelligently initiate programs at the levels that we all would like to see come to pass. I think that the President's Commission, through its deliberations, and with other input, a much clearer understanding of what can appropriately be utilized will be defined without exciting the concern that we are trying to spend money rather than do that which is justified for its scientific value or human benefit.

There is no reason why the heart effort—with all that can be visualized of useful things that are just begging to be done and applied—research leads which I think we clearly have in mind—and directions of research clearly outlined, why the heart effort should not have support equal to any other effort.

Senator SCHWEIKER. What is your feeling about cystic fibrosis? You have heard us discuss whether or not it should be included in this approach.

Dr. Fox. This is a new question today, as was expressed by Dr. Hurst very well.

There are major elements of the disease that are treated through appropriate management of the lung complications and I think these are quite appropriately within the purview of the Heart and Lung Institute.

However, I agree with Dr. Joseph Cooper, and others, who spoke of the importance of not diminishing the support provided for research into the basic mechanisms producing the total disease and that to localize all efforts in cystic fibrosis in the Heart and Lung Institute might be damaging.

I believe I would be well advised not to go beyond that because I certainly would like to have an opportunity to think further on this question.

Senator SCHWEIKER. Yes; and if you have any additional thoughts, we would be glad to have them for the record. I realize you did not have time to prepare an opinion on this in advance.

Dr. Fox. Thank you.

Senator SCHWEIKER. I think, Dr. Fox, that concludes our questioning this morning. I want to say again I think you have made a very fine statement. I think it certainly is going to have a bearing on our markup of this legislation.

Dr. Fox. We thank you for the opportunity.

Senator JAVITS. Mr. Chairman, may I have one minute as I am due at Education Subcommittee hearing momentarily.

Mr. Chairman, I just wish the record to show my respect for and greeting to Dr. Paul Yu, president-elect of the American Heart Association, who is a New Yorker who has already testified, and Dr. Robert J. Anderson, of the National Tuberculosis and Respiratory Disease Association, who is also from New York, who will testify.

I joined with Senator Kennedy in sponsoring this bill. I just came here to offer my support of it.

You might recall that I am the author of the first bill to establish the National Heart Institute when I was a Member of the House in 1940.

Senator SCHWEIKER. Thank you, Senator Javits. We certainly appreciate your coming, and we know of your strong support and interest in this bill, and we appreciate your taking the time to come here.

Without objection your remarks will be placed in the record.

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

I commend the chairman for initiating prompt hearings on S. 3323—of which I am a cosponsor—and other related legislation which seeks to launch a national attack against major killer diseases—heart, blood vessel, lung, and blood—through enlarging the authority of the National Heart and Lung Institute.

Two of the witnesses at today's hearing, Dr. Paul Yu, president-elect of the American Heart Association and professor of medicine at Rochester University, and Dr. Robert J. Anderson, managing director of the National Tuberculosis and Respiratory Disease Association, are from New York. I am confident their background and expertise will provide a significant contribution to a better understanding by the committee of the impact of the killer diseases and their toll on human life.

Mr. Chairman, the tragic consequences of cardiovascular and pulmonary diseases—pain, suffering, and death—have long been of deep concern to me. Twenty-five years ago, in June 1947, I introduced with Senator, now Congressman Pepper of Florida, a bill which I believe was the first to focus attention on the issue of the need to establish a National Heart Institute. I am, therefore, particularly pleased to join with the chairman in the introduction of the "National Heart, Blood Vessel, Lung, and Blood Act of 1972," which allows us to combat these dread diseases through an expanded intensified and better coordinated program under the auspices of the National Heart and Lung Institute with broadened authorities.

Regrettably, the statistic I cited in 1948 when I testified in support of my National Heart Institute bill (H.R. 3762) is as true now as it was then about heart disease: "It was the No. 1 killer." The time has come when we must recognize the serious proportion of cardiovascular and pulmonary diseases, and their threatening effects on the health and well-being of the American people. The need for the legislation we are considering today can, and I quote from my testimony in 1948, "be justified as a national security investment." The elimination of many

cardiovascular diseases could provide the economy with significant annual savings—\$30 billion per year—in lost wages, productivity and costs of medical care.

Senator SCHWEIKER. Our next witness represents the American College of Chest Physicians. He is Dr. Arthur Olsen, past president of the college and former head of the Department of Thoracic Medicine, Mayo Clinic.

Senator Mondale, I might say, had hoped to come by and introduce you, Dr. Olsen, being from the Mayo Clinic in his State. Unfortunately he is now involved with the Education Subcommittee, which is holding hearings related to busing, so I think you will understand why he is not here at this moment. He did want me to say that he wanted to have the opportunity to do that.

You may proceed.

STATEMENT OF ARTHUR OLSEN, M.D., PAST PRESIDENT, AMERICAN COLLEGE OF CHEST PHYSICIANS

Dr. OLSEN. Mr. Chairman, I am indeed grateful to you for the opportunity of representing the American College of Chest Physicians today. With your permission I would like to say a word or two about this organization. The American College of Chest Physicians has approximately 5,500 members in the United States. Thirty-five percent are internists who devote at least 50 percent of their time to pulmonary and cardiovascular diseases; 23 percent are specialists in pulmonary disease and 18 percent are cardiologists. Twenty percent are surgeons specializing in thoracic and cardiovascular surgery. The remaining 4 percent are in allied specialties such as allergy, radiology, pediatrics, anesthesiology, and the basic sciences.

Our organization is devoted primarily to education in the cardiopulmonary field. With the cooperation of leading medical centers, we sponsor postgraduate courses in cardiopulmonary medicine and surgery. During 1971, 18 such courses were put on by the college throughout the United States and Canada. Nearly 2,500 physicians and surgeons attended these courses, each of which lasted from 3 to 5 days. Our programs provide continuing education for chest specialists and usually are devoted to indepth study of various pulmonary and cardiac diseases including emphysema, high blood pressure, arteriosclerosis, chest injuries, and so forth. In addition, our annual scientific assembly attracts 2,700 physicians, surgeons and other scientists from all over the United States. This annual meeting is primarily an educational experience for all those who attend. The college publishes a scientific journal called *Chest* which has a circulation of 15,000 which brings to the medical profession recent advances in the diagnosis and treatment of cardiopulmonary diseases.

The American College of Chest Physicians is very much in favor of legislation such as that proposed in this bill. I am indeed sorry I did not have the opportunity of reading your bill, Senator Schweiker, before coming to this meeting. I am aware of the major points at least in Senator Mondale's bill. However, my critique is largely directed toward Senator Kennedy's bill (S. 3323), because that is the one I had the opportunity of studying.

I am going to confine my remarks largely to the pulmonary or thoracic field. I have spent the major portion of my professional life in pulmonary disease. Until recently it was my privilege to serve as chairman of the division of thoracic diseases at the Mayo Clinic.

The specialty of lung diseases is quite young as compared with cardiology. Although I was fortunate in having a thorough training in internal medicine, many of my contemporaries in chest disease 30 years ago confined their activities to the treatment of tuberculosis. In fact, many of the early lung doctors came into the specialty because they themselves had tuberculosis.

Today, the pulmonary specialist has had just as sophisticated a training as his colleagues in other disciplines. Although he is still interested in tuberculosis, most of his time is spent with patients who have emphysema, bronchitis, bronchiectasis, lung cancer, and a variety of diffuse diseases of the lung. He has become an expert in the management of respiratory failure.

One of his great challenges is the rehabilitation of the pulmonary cripple. Whether he be a surgeon or clinician, he must have a strong background in physiology, pathology, biochemistry, immunology, genetics, et cetera, and he must develop a considerable number of technical skills.

However, the specialty of pulmonary disease has a long way to go to catch up with cardiology. With the tremendous increase in pulmonary diseases, especially emphysema and lung cancer, we do not have nearly enough chest specialists. The American College of Chest Physicians and its sister organization, the American Thoracic Society, have a joint committee headed by Dr. John Murray of San Francisco which is studying the manpower problems in chest disease. This study is still in progress and they have released no information as yet. However, there are certain things that we do know.

A recent survey showed that a very significant number of our Nation's medical schools have no faculty teaching pulmonary diseases. Many of these schools have funds for pulmonary teachers but have been unable to find suitable candidates for the posts. In other words, there is a critical shortage of teachers in pulmonary disease.

By the same token, there are not nearly enough postgraduate training programs in pulmonary disease and there are not enough students in the existing training programs. In addition, there is a very large number of hospitals throughout the country with inadequate facilities for the care of respiratory problems. Even if these hospitals did have such facilities they could not get adequately trained medical and paramedical personnel—and I emphasize paramedical because they are extremely important both in intensive respiratory and cardiac care units—to staff their respiratory care units or even operate their pulmonary function laboratories. Finally, it is well recognized that if the pulmonary specialty is to keep pace with other medical subspecialties, much research is necessary. Most major advances in medical knowledge are made in the laboratory.

However, such advances are usually made by research workers who are also teachers and who are experienced in the care of the sick. If we are to make headway in our search for the causes of pulmonary disease and find answers for their prevention or treatment, we must augment our research and teaching programs. Only then will we be

able to provide adequate care for the respiratory ills of the people of our Nation.

It would appear to me that a bill such as that which we have before us will do much to strengthen the National Heart and Lung Institute in its fight against diseases of the heart, blood vessels, lungs and blood. Because of my strong feeling that pulmonary diseases are particularly in need of support, I would hope that provisions could be written into the bill which would make certain that research and education in lung diseases would receive its fair share. It is my understanding that this is one of the features of Senator Mondale's bill.

It would appear that the development of 15 new centers for research and training in pulmonary disease is a step in the right direction. Unquestionably, funds for construction must be included. Likewise, it would be well to make provision for the recruitment of both medical and paramedical pulmonary trainees. This undoubtedly will require an educational effort directed at students of medicine and the general public. Both the needs and the opportunities in the pulmonary field must be given adequate publicity.

I should like to make some comment regarding the composition of the Advisory Council of the National Heart and Lung Institute. You will recall that Senator Kennedy's bill provides for a membership of members, 18 to be appointed by the Secretary of HEW. Nine of these would be scientists, seven would represent the public, and two would be students in the health professions' schools.

Although the Council receives a great deal of help from study groups, site visit teams and other advisory or review groups, the final responsibility for allocation of funds rests with the Council. Traditionally, the Advisory Council—and I believe this is true of most institutes—has had three scientists for each public member. This ratio in my estimation has worked out well. I would question the desirability of altering this ratio as suggested in the proposed bill. I can speak from personal experience that a great deal of homework must be done by the members of the Advisory Council, and most of it requires scientific knowledge. In other words, we need more rather than fewer scientific council members.

Furthermore, the selection of two students from the health professions' schools requires some clarification. I applaud the principal of encouraging students to take an interest in governmental affairs and in the problems of research and training in their chosen specialties. However, I doubt that their contribution to the deliberations of the Council would be very significant, certainly at a medical school level. If students are to be appointed, I think they should be advanced fellows in cardio-pulmonary training programs.

Speaking as a former member of the Advisory Council of the National Heart and Lung Institute I have tremendous respect for the professional staff of the Institute. They are competent, very dedicated people, they have shown great qualities of leadership. I am very pleased to note that the bill provides for enlargement of the scientific, professional and administrative staff.

The Director of the National Institutes of Health or his deputy, the Director of the National Heart and Lung Institute, has served as Chairman of the Advisory Council and run the meetings with great efficiency, invariably utilizing the special knowledge of his depart-

ment heads. My confidence in the present administration of the Institute is so great that I can see nothing to be gained by asking the Secretary to appoint a chairman from among the appointed members of the Council.

With the reservations that I have just expressed, I wish to speak for the American College of Chest Physicians in strongly endorsing this bill.

Senator SCHWEIKER. Thank you very much, Doctor. As an expert in lung disease, what is your professional opinion about the desirability of including cystic fibrosis in the bill?

Dr. OLSEN. I do not see how we can avoid including cystic fibrosis in the field of pulmonary disease, just as we include the respiratory disease syndrome.

So many advances have been made in prolonging the lives of these unfortunate individuals who have the pulmonary manifestations of cystic fibrosis, that lung specialists, as well as pediatricians, are responsible for their care. To divorce them completely from our Institute I think would be a mistake. Whether one wants to leave the epidemiologic and research aspects of cystic fibrosis where they are, or move them to the National Heart and Lung Institute is something else again.

I do not feel that NHLI should ignore cystic fibrosis. The techniques of therapy that we utilize to treat adult pulmonary disease are the very ones that we are using to prolong the lives of these people with cystic fibrosis.

Senator SCHWEIKER. We have heard some earlier testimony indicating that we ought to also encompass a little shift in the "stroke" assignment within NIH.

What would your reaction be to moving the stroke segment from one institute to the Heart and Lung Institute?

Dr. OLSEN. This is a difficult question to answer. However, we know very well that arteriosclerosis is a major factor not only in heart disease but also in cerebrovascular disease. Stroke is the commonest vascular manifestation of brain disease. Many of our better known neurologists today have become experts in the field of stroke.

When a person has arteriosclerosis, we do not know whether that patient is going to have a stroke or a heart attack first. Personally I would like to see stroke brought under the jurisdiction of the National Heart and Lung Institute.

Senator SCHWEIKER. Those are all the questions that I have. Thank you very much, Dr. Olsen. We certainly appreciate your appearance here today.

I would like to welcome now Dr. Robert Anderson, Managing Director of the National Tuberculosis and Respiratory Disease Association.

STATEMENT OF ROBERT J. ANDERSON, M.D., MANAGING DIRECTOR, NATIONAL TUBERCULOSIS AND RESPIRATORY DISEASE ASSOCIATION

Dr. ANDERSON. Mr. Chairman and members of the committee, I have a prepared statement which I believe you have in front of you, and as I read through it, I will depart in certain places to try to take up

some of the matters which have come up in the questioning of other witnesses.

Senator SCHWEIKER. Very good.

Dr. ANDERSON. The National Tuberculosis and Respiratory Disease Association is strongly in favor of legislation to advance the campaign against diseases of the heart, blood vessels, lung and blood, which certainly constitute the country's largest disease problem.

Our organization includes 600 affiliated TB-RD associations and an active medical section, the American Thoracic Society. During the last decade, it has been in the forefront of efforts to enlist more support for a stepped-up national program to combat lung diseases such as emphysema and chronic bronchitis.

Until late 1969 when the title of the National Heart Institute was changed to the National Heart and Lung Institute, attention within the Federal health establishment was not focused on the chronic pulmonary disease problem in such a way as to encourage development of a vital program. Even now, the National Heart and Lung Institute is restricted in its ability to implement a program which is commensurate with the problem.

The chronic pulmonary disease problem: emphysema, chronic bronchitis and asthma, as a group, have increased rapidly in recent years to the point where they are a major cause of illness and death. Among white males, they are now the fifth cause of death from disease. Emphysema is the second cause for which workers are retired prematurely under the social security program. Relevantly it is arteriosclerosis and coronary heart disease that are the first cause.

Benefits under that program for respiratory disease disability amount to approximately \$400 million annually. This estimate is exclusive of payments for "black lung." It excludes medical costs incurred by the millions of persons who suffer from these conditions.

Environmental agents are undoubtedly involved to some extent in the development of certain respiratory conditions. The pulmonary system is the organ most directly and massively assaulted by such agents. However, other causative factors are involved whose identity is either obscurely delineated or still unknown. The country must vastly enlarge its research efforts before we will have the answer to the etiology of these conditions which are so terrifying because they affect man's very ability to breathe.

In the meantime, the shortage of medical and other health manpower restricts our ability to take care of the people who are already ill. There continues to be a dearth of qualified specialists in pulmonary disease. The attempts of the leadership of the National Heart and Lung Institute to correct this situation are both very recent and necessarily limited because of budgetary pressures, although their conscientious efforts have been gratifying.

National Heart and Lung Institute pulmonary disease program: The Director of the Institute and his deputy in pulmonary diseases have moved swiftly to plan a dynamic pulmonary disease program. However, progress has not been as rapid as needed; since 1969 the program for pulmonary disease is now operating at somewhat less than \$25 million.

I am sorry I cannot be more precise in the figure. I will come back to that later.

Senator SCHWEIKER. I wonder if you would be kind enough to let us recess for about 2 minutes. I must see someone who has been waiting for over an hour to see me.

Dr. ANDERSON. Certainly.

(Recess.)

Senator SCHWEIKER. Please proceed, Dr. Anderson.

Dr. ANDERSON. In order to move ahead, the National Heart and Lung Institute needs the kind of enlarged authority and support which these bills provide. By means of this legislation, the National Heart and Lung Institute will not only be able to substantially increase its own research and training efforts in pulmonary disease, as well as those of the outside research community, it will be able to coordinate the various pulmonary disease programs of the Federal Government.

This latter assignment is an important one. Several institutes are actively working in respiratory disease research. In addition, there are important Federal control programs which are involved with environmental and occupational hazards that affect respiratory health. All contribute to the body of knowledge about pulmonary disease. To obtain optimal results the pulmonary program of all Federal agencies must be in close touch with one another. S. 3323, does provide for a technical coordinating committee under the chairmanship of the Heart and Lung Institute, and we are delighted to see that feature included.

Proposed bills: The NTRDA is opposed to weakening the Federal medical research capability and identity of the National Institutes of Health. Therefore, it favors the approach of S. 3323 and S. 3046 and the other bills, which strengthen the authorities of the National Heart and Lung Institute but do not place responsibility for its budget or overall direction of its program outside of NIH.

Before speaking to specific provisions of S. 3323, we would like the committee to give thorough consideration to the possible need for specific overall authorization for each of the organ entities the bill encompasses, as is done in S. 3046 on somewhat of a different basis. Even though there would be specific authorizations in S. 3046, the bill has administrative flexibility provided. There would be a 15 percent shift in moneys permitted between the programs to take care of any unforeseen development in program.

(Senator Kennedy assumed the chair.)

Dr. ANDERSON. Prior to the enlargement of the National Heart and Lung Institute's pulmonary program, the greatest impediment to promoting a stronger pulmonary effort was the fact that no satisfactory measurement of the then existing pulmonary program of NIH was possible.

There was no uniform accounting of what resources went into that program and hence no way of evaluating from year to year the emphasis the various Institutes were placing on pulmonary disease in terms of money spent. Although the National Heart and Lung Institute today makes a more adequate accounting of the sum devoted to pulmonary disease, there is still no way for the Congress, the administration, and the public to assure themselves that the pulmonary program will receive the attention it requires. Therefore, the possibility still exists that progress in the pulmonary program will continue to be unsatisfactory. With a specific authorization, or with some instruction that the appropriation structure should include identification of

the resources that are being devoted to some of these areas, only through these devices can it be ascertained if the pulmonary program is actually receiving the amount of support which Congress believes it needs.

I would like to comment about other important aspects of these bills and will do so by referring to specific sections of S. 3323 :

Section 413(a) (6) : We believe the part of the program described in this subsection should provide for training of teachers as well as scientists and clinicians. One of the greatest barriers to increasing the number of pulmonary disease specialists is the inadequate number of pulmonary disease faculty in medical schools who can inspire students to enter the field. Dr. Arthur Olsen has referred to this in his testimony.

It may interest you to know that close to 20 percent of all pulmonary disease faculty positions cannot be filled because of lack of qualified teachers. This means 200 positions are vacant.

Section 413(c) (2) : For the same reason, the authority of the Director under this subsection should be extended to include facilities for training as well as for scientists and researchers. The lack of these is going to be one of the possible stumbling blocks that would impede the development of a program of the scale and scope that is envisioned and is motivating the Congress to move legislation of this sort.

Section 414(a) : We are very pleased that the bill includes provision for control programs. The lack of these has been acutely felt in the pulmonary disease area.

Community control programs in respiratory diseases were beginning to be established by the former chronic respiratory disease program when that program was terminated by the Department of Health, Education, and Welfare in 1969. At that time the Department went through a reorganization and shifted responsibilities for the chronic respiratory disease program and the heart disease control program from the Center for Disease Control into the Regional Medical Programs Service.

The staff went there, the responsibilities went there. Since that time however the focus of the Regional Medical Programs Service has enlarged, and it has become more concerned with general matters, such very important things as the promotion of neighborhood health centers in disadvantaged areas, and in primary care, and in the stimulation of a development of mechanisms for health maintenance organizations.

However, what has happened at the same time is that the staff and the national direction for disease control activities in regional medical programs have dropped out.

Dr. Fox pointed out that it is extremely important as we develop the techniques for prevention, control and treatment of disease, that we have an active mechanism at the national level that is working to promote the development of these control services out in the community.

At the present I believe the only program that still has specialized talent in the Regional Medical Programs' national headquarters is the kidney program because of the interest in kidney dialysis. It is our opinion that Federal programs to demonstrate control of specific diseases provide considerable impetus to improving and expanding diagnostic and treatment facilities.

It is our observation that such control programs are also an excellent resource for training of personnel and for dissemination of information to the public. Therefore, we recommend that public education and training be included as a part of these programs' authorities. Your bill, Senator Schweiker, recognizes the need in this area.

Section 415(a)(2): We welcome the addition of 15 new centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods in chronic pulmonary diseases. The centers form a very important and promising component of the revitalized pulmonary disease program of the National Heart and Lung Institute.

However, the wording of section 415(a)(2) implies that all pulmonary diseases of children could be handled by these centers but not necessarily all adult pulmonary diseases. We believe the wording would reflect the obvious intent more accurately if this section were reworded to say: "chronic pulmonary diseases of adults and children, including but not limited to bronchitis, emphysema, asthma and cystic fibrosis."

Actually those four conditions are only the ones that are prominent currently in the public mind for various reasons. They are also major diseases of the respiratory tract, but there are many other conditions of the lungs which also deserve both research and training.

With regard to questions about the inclusion of cystic fibrosis, I think you can tell from my remarks that I think in a way it is a mistake to try to identify specific diseases here because of the fact that we are really talking about the problems of the lung, and this can involve many conditions.

In cystic fibrosis there are techniques for prevention of disability, and techniques for diagnosis and treatment that relate to the lungs. Therefore, I think it would be perfectly appropriate for the Heart and Lung Institute to work in this area of lung.

With regard to research on the genetics of cystic fibrosis or the metabolic defects in cystic fibrosis, I think it is perfectly appropriate that other parts of NIH should work on these with crossover collaboration between them as appropriate. This would be my approach to the problem of stroke.

Our organization is also interested in tuberculosis, a problem of the lungs, but fundamentally this condition is an infectious disease process and there are mechanisms in the Allergy and Infectious Disease Institute and in the Center for Disease Control where the other aspects of tuberculosis can be investigated.

The Heart and Lung Institute, however, should be very much concerned with other pulmonary disabilities resulting from tuberculosis which require special emphasis with regard to handling those defects such as destruction of the lung from the tuberculosis process, and the emphysema that might result.

Section 417(a)(2): We agree that membership of the National Heart and Lung Advisory Council should be increased in view of the strengthened authorities and enlarged workload proposed in the bill for the various disease interests involved. In order to assure that these categorical disease interests are represented in the persons of qualified specialists, there should be mention of the varieties of talents that would be needed on the Council, or specific numbers of members from some of these areas such as heart and lung and blood disease might be

specified in the bill, and assurance provided that all will be represented in the first appointments made.

However, the Council presently has 12 scientific members. Under section 417(a)(2) there would be a reduction of the scientific membership to nine—a number which is not adequate, in our opinion, for representation of the different disciplines or for the very technical and large workload the program requires. With the expanded emphasis on the program, I am sure that this workload is going to go way up.

We believe that the number of scientific members should exceed the number currently on the council. We believe that the inclusion of health professions' students has a simple mechanical problem in it that by the time such persons would be named they would probably have only 2 years before they would lose that student status and would be either working in the community or in advanced graduate education.

I think particularly what we seek is to have appropriate membership on the Council and subcouncil committees that are addressing themselves to various problems.

For example, if the control program were to be instituted, one of the possibilities would be a special committee under aegis of the Council for the development and surveillance of control program activities of the National Heart and Lung Institute. So we would support Dr. Olsen's comments with regard to medical students and lay participation in the Council.

Section 419(b): Total authorizations are probably sufficient for 1973, and I say that because S. 3323 calls for a development of a plan within 180 days after the passage of the legislation, and it would seem to me that until such a plan is developed, even though there is provision for centers and so on, all of these things are going to take time to be elaborated and to be presented, reviewed and approved.

So I think that the 1973 authorization level is all right, but, in our opinion, not for the ensuing years when the program gathers momentum. As demands rise in response to the challenge of this new emphasis on diseases of the circulatory and respiratory systems, they should not be frustrated by inadequate authorizations.

We note that authorizations are for 3 years whereas the director has responsibility under section 413(b)(2) for planning a program of 5 years duration. We recommend that the authorizations for 1974 and 1975 be increased to \$450 and \$550 million respectively. If 5 years are authorized, which would seem necessary to insure the sustained support being proposed, we recommend that \$650 and \$700 million respectively be authorized for 1976 and 1977.

Extension of authorization would also involve control programs whose authorization could be increased \$10 million each year for 1976 and 1977 (section 414 (b)).

Finally, we are very pleased that both S. 3323 and S. 3046 recognize the need for research into the etiology of these diseases through epidemiological investigations of social, genetic, and other nonbiological influences. Epidemiological studies have contributed heavily to the knowledge we have about tuberculosis and there is every reason to think that such studies will be equally important in the diseases with which this bill is concerned.

I might say too that we support the administrative facilitating provisions of the bill with regard to personnel ceilings and grades, because with an expanded program this is going to be necessary.

We appreciate this invitation to testify on an expanded pulmonary disease program, which is long overdue. We commend the authors of the respective bills for their recognition of the threat these diseases pose and the need to accelerate the attack on them.

Senator KENNEDY. Thank you, Dr. Anderson. I am glad to have your sense of urgency about the importance of the legislation, and I think your statement and comments have been extremely helpful to the subcommittee. I want to thank you very much.

Senator SCHWEIKER. I have no questions. I want to thank you too, Doctor, for appearing before us today and bringing us the benefit of your judgment.

Senator KENNEDY. We now receive for the record the statements of the Senator from Indiana and the Senator from Illinois, Messrs. Hartke and Percy.

PREPARED STATEMENT OF HON. VANCE HARTKE, A U.S. SENATOR FROM
THE STATE OF INDIANA

NATIONAL BLOOD BANK ACT

Mr. HARTKE. There will be more than 2 million blood transfusions performed in the United States this year. One out of every 150 of these will cause a death from serum hepatitis in the over 40 age group. Many more transfusions will cause sickness in younger people.

Hepatitis is a growing menace to our Nation's health. Dr. J. Garrot Alleh, of Stanford Medical Center, has estimated that at least 455,000 hospital bed-days are devoted to this disease every year. Effective measures, however, can go far to wiping out this disease. The bill I have introduced, S. 2909, to establish a Federal program to encourage voluntary donation of pure and safe blood, to require licensing and inspection of all blood banks, and to establish a national registry of blood donors, is designed to provide the means necessary to accomplish that goal.

In many communities throughout the Nation, there is a critical shortage of blood. To meet this need, blood banks have been established. Most of these blood banks are highly reputable and have performed invaluable service to those in need; but there are far too many unscrupulous blood banks which have failed to screen properly those who donate their blood.

Much of that serum hepatitis in this country comes from the paid blood donor. He may be an alcoholic or a drug addict seeking money for his habit, and some commercial blood banks are all too willing to give him the few dollars he seeks without checking into his background.

Profitmaking blood banks have been established because—regrettably—the voluntary donor system has not been able to meet the demand for blood. Hospitals have no choice but to turn to the commercial blood bank for their supply, yet reliable studies have shown that the risk of contracting hepatitis from the blood of paid donors is from 11 to 70 times greater than the risk from voluntarily donated blood.

On November 29, 1971, I introduced, on behalf of myself and the senator from Illinois, Mr. Percy, the National Blood Bank Act. This legislation is identical to a bill introduced in the House by Congressman Victor Veysey of California. In essence, this bill requires all blood banks to live up to reasonable standards.

Although the Federal Government is already involved in the regulation of blood banks, the National Institute of Health license only 166 of the 7,000 blood banks in this country. They do not license or inspect the companies that import massive quantities of human blood from foreign countries, nor do they require that blood be tested for the presence of hepatitis. Even the practices of those 166 licensed blood banks have been clouded with doubt.

To meet the problems of regulation, my bill would establish a new office in the Department of Health, Education, and Welfare, to license, inspect, and regulate all blood banks in this country. The poor track record of NIH's Division of Biological Standards is proof enough that this responsibility must be placed elsewhere.

Because the lack of voluntary blood is the only justification for using paid donors, my bill provides for a national effort to recruit voluntary donors. It also requires that the source of each pint of blood be clearly stated on its label.

Under my proposal, the Director of the National Blood Bank is to inspect, license, and regulate all blood banks. It authorizes \$9 million for a national program to recruit voluntary donors, including efforts to develop new procedures and techniques to inform the public of the need to donate blood voluntarily.

The Director will be assisted by an advisory council made up of representatives of blood banks, consumers, and the public relations industry. The council will advise in the development of long-range policy for the blood bank program and provide expert advice on proposed regulations and voluntary recruitment efforts.

Recognizing that the national blood bank systems of the American Red Cross and the American Association of Blood Banks deserve special attention, the bill authorizes the Director to accept their inspection and accreditation program in lieu of Federal inspections.

Among its other provisions, it would establish two classes of accredited blood banks. Class A blood banks are those having a maximum percentage of voluntary donors. Class B blood banks are all others. The Director is required to update annually the percentage to qualify for class A status to the highest level consistent with an adequate national blood supply. Federal agencies are prohibited from purchasing blood from other than class A blood banks.

Seventeen States have no laws governing blood banks. Another 21 have laws which prevent patients infected by contaminated blood from collecting monetary damages. It is time that the Federal Government acted to protect the health of the American public.

A serious illness or accident is tragedy enough without the danger of receiving contaminated blood. The quality of blood available to hospitals is nothing short of disgraceful. The legislation I introduced will make it possible for us to eradicate this disgrace without further delay.

PREPARED STATEMENT OF HON. CHARLES H. PERCY, A U.S. SENATOR
FROM THE STATE OF ILLINOIS

Mr. PERCY. Mr. Chairman, members of the subcommittee, I appreciate this opportunity to present a statement in support of the National Blood Bank Act (S. 2909) which Senator Hartke and I introduced on November 29. I regret, however, not having the opportunity to testify in person. Being informed at the close of business on March 23, that the subcommittee would consider S. 2909 the subsequent morning, unfortunately, left me no other alternative but to submit this prepared statement.

No one can be as pleased as I that this subcommittee is dealing with this country's number one cause of death—cardiovascular diseases—with such dispatch. I am a proud cosponsor of the National Heart, Blood Vessel, Lung, and Blood Act of 1972, and I have time and again supported and worked for the eradication of all dread diseases. I can, therefore, understand the subcommittee's eagerness in dealing with one of this country's most urgent health problems. However, I urge the subcommittee not to overlook in its good-intentioned haste another equally urgent national health problem.

I am speaking of this country's blood problem.

According to Stanford University's Dr. J. Garrott Allen, whom many health specialists regard as the Nation's leading expert on the blood problem, blood transfusions now kill at least 3,500 Americans and medically injure another 50,000 each year. Dr. Allen further estimates that of every 150 patients over 40 years of age who receive blood transfusions, one dies.

The common reliance on commercial blood is the biggest contributor to the serum-hepatitis rate among transfusion patients. No less than eight studies conducted by scientists in leading institutions from 1968 to 1971, have shown that the risk of hepatitis from commercial blood runs from 11 to 70 times greater than the risk from voluntarily donated blood. The Government's Center for Disease Control (CDC) in Atlanta reports that no one knows exactly how high the transfusion hepatitis rate is because physicians often fail to report serum-hepatitis cases. The CDC estimates that the real serum-hepatitis rate could be two to 10 times Dr. Allen's estimate, or 35,000 deaths and 500,000 illnesses each year. Whether it is 3,500 or 35,000 that die each year, the fact is that no one should have to die. Even one death is too many.

Newsmen have corroborated many of the above findings. NBC's Chronolog program last October carried a critical report of this country's blood banking systems based on 9 months of research. One of the best articles to come from newspaper investigations was a series by that fine Illinois paper, the Chicago Tribune. A three-reporter task force found that paid donors accounted for 60 percent of the 250,000 pints drawn annually in Chicago. They pictured the paid donor as "most likely to be an alcoholic or drug addict who needs the money for a bottle of cheap wine or a bag of heroin." They also found "winos who sold blood so often that they had scar tissue on their arms." They learned that suspected hepatitis carriers were rejected by one bank and then accepted by others. They discovered that one commercial

blood bank paid skid-row donors with vouchers cashable only at a nearby liquor store. This same blood bank firm paid the same way in Washington, D.C.

Clearly, there is a lack of adequate inspection and supervision of blood banks. Seventeen States have no blood-banking laws whatsoever, and 21 others only have laws that exempt blood banks from legal claims of patients harmed by contaminated blood. Only seven States license blood banks, and only five provide for blood inspection. The Division of Biological Standards of the National Institute of Health, responsible for "some supervision, some research and some inspection" of this country's blood banking systems, licenses only 166 of the 7,000 blood banks in this country.

The transfusion hepatitis risk would be minimal if doctors had an infallible laboratory test to detect serum hepatitis in blood. The most reliable detector is the Australia-antigen test which researchers have found to be effective only 25 percent of the time. Because hepatitis detection is still unreliable, many authorities say the only solution to the Nation's blood problem is to use only low-risk volunteer blood. And this, most agree, means the creation of a nationally coordinated non-commercial blood banking system under a single agency.

The National Heart, Blood Vessel, Lung, and Blood Act of 1972 is an excellent heart bill. However, its provisions dealing with blood and blood products are totally inadequate in bringing adequate supervision to blood banking and in creating a national voluntary blood program that can guarantee every American high quality blood at a price he can afford. What is needed to deal with this country's blood problem are the most comprehensive blood banking provisions contained in the National Blood Bank Act, introduced by myself and Senator Hartke in the Senate and by Congressman Veysey in the House.

Following is a summary of the provisions of the National Blood Bank Act. I hope the subcommittee will give the bill the serious consideration that it deserves—either as a component of the National Heart, Blood Vessel, Lung and Blood Act of 1972, or as an independent bill.

MAJOR PROVISIONS OF NATIONAL BLOOD BANK ACT

(Introduced By : Senator Vance Hartke and Senator Charles Percy)

GOALS

To encourage voluntary donation of blood, to minimize paid donors and thereby minimize hepatitis;

To establish adequate federal supervision of blood banking and provide a basis for the eventual prohibition of commercial blood banks.

1. Establishes a National Blood Bank Program in the Department of HEW—expressly prohibits vesting the program in N.I.H.
2. The National Blood Bank Program Director is to inspect, license and regulate *all* blood banks. He is directed to include in his regulations standards for donor selection, management of blood inventories aimed at minimizing outdated, and for maximum permissible number of paid donors. He is directed to require that all blood collected be labeled either "high risk" if it comes from a paid donor, or "low risk" if it is collected from a voluntary donor. A range of penalties is established for failure to comply.

3. A \$9 million national program to recruit voluntary donors is established. The Director is to develop new procedures and techniques to inform the public of the need to donate blood voluntarily. He is directed to assist in making adequate supplies of voluntary blood available in areas where it is not now available. He is to develop a program to honor and recognize all voluntary donors and take other steps to attain the goal of a 100% voluntary blood system.

4. The Director is to be assisted by an Advisory Council made up of representatives of blood banks, blood consumers and public relations. The Council will advise in the development of long range policy for the Blood Bank Program, and provide expert advice on proposed regulations and voluntary donor recruitment efforts.

5. Establishes a special status for National Blood Bank Systems—which are the American Red Cross and the American Association of Blood Banks. If the Director approves the NBBS's inspection and accreditation program, he may accept it in lieu of direct federal inspections.

6. Establishes two classes of accredited blood banks within the NBBS. "Class A Blood Banks" are those having a maximum percentage of voluntary donors. "Class B Blood Banks" are all others. The Director is required to annually update the percentage to qualify for "Class A" status to the highest level consistent with an adequate national blood supply. Federal agencies are prohibited from purchasing blood from other than "Class A Blood Banks." To minimize the chance of contracting hepatitis from blood delivered under a blood assurance program, only "Class A Blood Banks" are permitted to operate these.

7. An express antitrust exemption is included to allow NBBS to exclude for-profit blood banks.

8. The Director is to establish and operate a national registry of all donors to allow cross-checking by blood banks for hepatitis carriers.

Senator KENNEDY. We have with us today Dr. Giulio J. Barbero, representing the National Cystic Fibrosis Research Foundation, who is chairman of the General Medical and Scientific Advisory Council of the Foundation and chief of the department of pediatrics at Hahnemann Medical College and Hospital in Philadelphia.

STATEMENT OF GIULIO BARBERO, M.D., CHAIRMAN, GENERAL MEDICAL AND SCIENTIFIC ADVISORY COUNCIL, NATIONAL CYSTIC FIBROSIS RESEARCH FOUNDATION

Dr. BARBERO. Mr. Chairman, and members of the committee, I wish to thank you very much for the opportunity to come before you on behalf of the volunteers and scientific membership of the National Cystic Fibrosis Research Foundation.

I have prepared a statement of brief nature which I would like to submit in the formal testimony, but I would like to high light and comment briefly on a number of areas.

Senator KENNEDY. Very well. It will be entered at the end of your testimony.

Dr. BARBERO. First I would like to mention the nature of the National Cystic Fibrosis Research Foundation. This is a foundation that has 140 chapters geographically distributed throughout the country.

It supports or participates in 55 clinics, and 45 teaching, care, and research centers. It is a foundation that has about \$4 million annual program which it has raised, and as you can readily see, we find great difficulty in being able to meet the large number of pulmonary problems which go to these centers and clinics.

It is unquestionably a major reason why we are so interested in the nature of this bill. It is urgent and immediate in its requirements be-

cause of its broad implications, not only in the nature of training and research but also in trying to demonstrate some of the implementation which is so crucial and is already available in the management of these patients with lung disease.

The second point I would like to indicate is that which pertains to children. I think it is absolutely wonderful that the word children has been incorporated. The main bulk of population being adults, it is so often that children are left out of many of the councils.

They require advocacy and the inclusion of the word children to me represents an important spirit incorporated in this bill.

Children are the roots in many ways also for some of the diseases that ultimately emerge at a later point in life. Those of us who are pediatricians see them as an arrow which is started at the point of conception and moves in ascendancy to the point of adulthood. So it is in this sense that we feel that this bill is also most sound.

The next feature that we would like to present is the very nature of the fact that research has been carried out in diverse areas of the Institutes. Without question we do wish very much that, with support, this research continue in the various components of the National Institutes of Health.

It would be tragic if these were diminished. However, it is also clear that cystic fibrosis as a specific disease is one of a spectrum of illnesses with which children are involved, and not infrequently the children will come with a question of cystic fibrosis and have also myriad pulmonary process problems, ending up not having the disease of cystic fibrosis.

Our centers are consulted frequently with almost a 10 to 1 ratio of this nature. Plus it would be very unsound to separate out cystic fibrosis because of the research that may exist in other institutes.

It is a lung disease. The children suffocate and die prevailingly, and almost entirely from the overwhelming secretions which pile up in their lung.

Measures have been built up over the past decade which have clearly shown that early diagnosis, various approaches toward management, including antibiotics, therapy, pulmonary drainage, and various kinds of medicinal and other approaches are crucial in the preventive or minimization of the handicap present.

This by its very nature falls within the description of your bill, and it is for this purpose that we would think it would be most unsound and inappropriate to separate it off in any fashion.

There is another reason that this is also true. It is that cystic fibrosis is the most serious pulmonary disease of man, it acts as a key model in understanding the research aspects for pulmonary disease, and therefore must exist in some juxtaposition to at least a spectrum of understanding of the disturbances which are involved in the nature of the pulmonary disease in man.

I would like to next turn to the question of the composition of the Advisory Council which has been described in the bill. Just as research, as I mentioned, the advocacy of children, it must be brought to your attention that the current Advisory Council does not have any lung specialists in children.

I think that this kind of representation, of the advocacy for children, and in a key area, because about 50 percent of the health problems in children are respiratory, this representation must be considered.

Lastly, in looking at what is exciting about this bill, it strikes us that first the demonstration of the multidisciplinary requirements involved in any kind of chronic pulmonary disease are clearly highlighted.

Second, it is supportive of a viewpoint that the child and adult is a continuum in lung disease, and it is just this broad nature which must not be embarrassed by any modification.

Third, it lays the groundwork for bringing back and also developing some of the control, and hopefully preventive measures which would diminish our health load.

We would also like to indicate in closing that we collectively endorse the testimony of Dr. Goddard who represents the Association of Pediatric Pulmonary Disease, and who follows me.

Senator KENNEDY. I want to thank you for your presentation. You have heard earlier the comments that were made about whether we ought to include cystic fibrosis or not. I think your addressing yourself to that particular point is terribly important, and I think that you have been very convincing.

We will keep the record open, and if you care to file any additional kinds of information, given the testimony of the administration on that particular point, it might be useful.

I think you have summarized your point of view very well in an extremely convincing manner, but if you care to add anything further we would welcome that.

Dr. BARBERO. Thank you.

Senator KENNEDY. I certainly ought to know, but what is the impact of cystic fibrosis on children? What are we talking about in terms of numbers?

Dr. BARBERO. In our centers we have approximately 7,000 children. It is our estimate that on the basis of the gene frequency which is exceedingly high in the United States, roughly around 10 million carry the capacity to transmit this gene.

Over and over we seem to be able to find as we move into the community that there are more and more such examples of cystic fibrosis. It is one of the major genetic burdens that does exist, and I think this must be very openly discussed.

Senator KENNEDY. It is interesting in terms of this genetic significance because we have included in here research in the genes, particularly sickle cell anemia. Obviously these are related; it is a different kind of genetic difficulty, but we are doing some sort of research in one area; and trying to develop treatment methods and cures would certainly, it seems to me, necessitate review in the other areas.

You mentioned 7,000 children. How many should be in these clinics or receiving treatment who are not?

Dr. BARBERO. Actually these clinics and centers end up having the greater part of the pulmonary load in the geographic area in which they exist.

I stand corrected. My colleagues point out there are 12,000 children. We do an annual review on this, and have just brought this into current focus.

Senator KENNEDY. How many die from it?

Dr. BARBERO. Fifty percent of the children die by adolescence.

Interestingly enough, a decade ago, Senator, we would have said that 50 percent would have died by the age of 2 or 3. This shows that there are preventive and control measures which can be utilized.

The tragedy of this is that so frequently both in terms of education, training and kinds of application of the tools that the capacity to deliver is limited, and as a result we question ourselves how many of these earlier deaths are influenced by our inadequacies.

Senator KENNEDY. It is a very heart-rending situation.

I appreciate your presence here. Again, if you felt it would be useful, being given a chance to review the administration's position—we just received it this morning ourselves—if you felt there were some additional points to justify, we would welcome and include those as part of the record.

Senator SCHWEIKER. Doctor, I want to thank you too for coming because I know, coming from my home area, you are well known as a medical authority there as well as nationally.

We appreciate your participation.

I just would like to ask a few educational questions from my own point of view. How soon can a physician detect the problem in a child when the physician is specifically looking for the disease?

At just about what age level or how early can it be determined, and what kinds of tests are used?

Dr. BARBERO. Detection can occur actually in the first few months of life in many instances. The problem of course is that children are susceptible to many and repeated respiratory infections. This is where the rub arises.

In other words, there are so many children who have recurrent respiratory infections, in the midst of those there are a group of children who have cystic fibrosis, so it is really a detection of suspicion that starts off the process.

One can identify this without any clinical signs within the first week of life, because our tools of diagnosis are probably the most simple that exist in all of medicine.

The diagnosis is based on collecting sweat. For some reason there seems to be some disturbance which ends up in a great deal of mucus

in the lungs, but ends up in more salt in the sweat. So it is a relatively simple test to determine the amount of salt in the sweat that identifies the disease. It is increased in cystic fibrosis.

Senator SCHWEIKER. Because it is genetically related, what about parents as genetic carriers? Is there any test involved that we can study?

Dr. BARBERO. Yes; there has been an increasing number of clues and evidences in the past 4 or 5 years using tissue cells and other determinants by logical approaches that have indicated that there is some subtle difference that is present in the heterozygote. I think this is going to be an interesting new area that may have some other implications in health that we do not understand at the present.

Senator SCHWEIKER. Thank you very much.

Senator KENNEDY. Right now, Doctor, as I understand, in terms of these tests every child is tested for silver nitrate in the PKU in just certain States.

Dr. BARBERO. That is right.

Senator KENNEDY. What kind of success did you have in trying to get States to give these tests that are required?

Dr. BARBERO. There has not yet been any such statewide program. There have been a number of localwise ones. Dr. Warden Warwick in Minnesota has been exploring this.

Senator KENNEDY. What are you talking about as to cost? It seems to be quite incidental.

Dr. BARBERO. I am really unable to respond to this.

Senator KENNEDY. I am just interested. I do not know whether you are the person to ask, but, thinking out loud, should we not have a package kind of test that infants are given in this country?

Would it not be useful for every newborn to have certain kinds of tests to try to find out whether the child would be affected by this or perhaps sickle cell anemia or some other problems?

I do not know all the other kinds of problems that might easily be detected, but should we not be thinking about this?

Dr. BARBERO. Oh yes; I think this is a most forward thought because the ability to early demonstrate certainly not only gives you some more appropriate sense of the health burden with which we are confronted, but also makes possible some ability to do some of the preventive approaches that might be useful.

This I think is a key area that also must be examined, and I would hope the kinds of centers that are incorporated in this bill would imply some continuing examination of just that kind of application.

Senator KENNEDY. Thank you very much.

(The prepared statement and other material submitted by Dr. Barbero follows:)

Statement

of

GIULIO J. BARBERO, M.D.

Chairman, Department of Pediatrics
Hahnemann Medical College
Philadelphia, Pennsylvania

on behalf of the

THE NATIONAL CYSTIC FIBROSIS RESEARCH FOUNDATION

THE SENATE OF THE UNITED STATES
92nd Congress

Committee on Labor and Public Welfare
Health Sub-Committee

March 1972

Giulio J. Barbero, M.D.
Testimony before Senate Subcommittee, 1972

Mr. Chairman, distinguished members of the health committee, I am Dr. Giulio J. Barbero, Chairman of the Department of Pediatrics, Hahnemann Medical College, Philadelphia, Pennsylvania, and Chairman of the General Medical and Scientific Advisory Council of the National Cystic Fibrosis Research Foundation. The NCFRF is a foundation concerned not only with cystic fibrosis but with the pediatric pulmonary problems of 5 million lung-damaged children of all races from birth to adulthood. I wish to thank you for the opportunity to testify in support of Senate Bill S. 3323, National Heart, Blood Vessel, Lung and Blood Act of 1972. I wish to complement Senator Kennedy and the other sponsors for their leadership, interest and support in this most important area of health, and I acknowledge the indicated interest of the Administration in also promoting further support. This legislation, as proposed, is vital to the health of this country, and we endorse it, but our main area of concern here today is to comment upon those provisions which specifically refer to the lungs. At the onset, we should like to make perfectly clear that we do not advocate transferring all of the cystic fibrosis programs in existence at NIH to the Heart and Lung Institute. We request that only those programs concerned with the pulmonary aspects of cystic fibrosis which now resides within the Regional Medical Programs become a part of the lung programs of the Heart and Lung Institute. We believe that this transfer of the pediatric pulmonary program provisions to the Heart and Lung Institute will be a progressive and positive step because it will result in a closer interaction between the adult lung programs

and the pediatric lung programs. Children's lung diseases include such conditions as hyaline membrane disease, bronchitis, bronchiectosis, allergies and asthma. Many contributing causes, genetic and non-genetic, known and unknown, are involved. Cystic Fibrosis is one of the most common serious lung diseases. Cystic fibrosis is not the only one and much more research is needed for all to understand the continuum of disease development from childhood and to adulthood. We believe that prevention of disease in the adult may lie in understanding the early developments of pulmonary disease in children. Research that will be conducted ⁱⁿ on children and adults will have, ultimately, implications for both. The specialists on pediatric pulmonary disease must become aware of the problems that will face his patient as the patient becomes older and specialists on adult medicine must likewise understand the problems facing the specialist for children's lung disease. The provisions of the proposed act are essential to the overall needs of a coordinated national program.

Our Foundation feels that the pediatric pulmonary programs authorized under the Regional Medical Program leave much to be desired. We feel strongly that centers for pediatric pulmonary disease have proven themselves as an essential and effective instruments of disease control. A network of such centers, adequately supported and on ^a long-term basis, located throughout the U.S., is an essential component for any national program for lung disease.

In conclusion gentlemen, we enthusiastically endorse Senate Bill 3323 and believe this Bill, if enacted and implemented, will do much to meet the challenges of lung disease. It will help meet the need for more

trained medical and paramedical personnel, for more researchers and more research and development. The control program is not regarded as a health-care program, but as a means to permit development of models and demonstrations of new techniques for diagnosis and treatment. A need that is not being met by any existing program.

In closing, I would like to say that I endorse the testimony of Dr. Goddard, who represents the Association of Pediatric Pulmonary Centers.

Cystic Fibrosis: The Disease and Its Treatment

Cystic fibrosis is a "new" disease in that it was not discovered until the mid-1930s. One of the pioneers in its study and treatment has been Dr. Harry Shwachman. Dr. Shwachman, Clinical Professor of Pediatrics at Harvard University, is director of the Cystic Fibrosis Center at The Children's Hospital Medical Center, Boston. He is also chairman of the Professional Education Committee of the National Cystic Fibrosis Research Foundation. In an interview with the *Journal of Practical Nursing* Dr. Shwachman has answered a number of questions of particular interest to licensed practical/vocational nurses.



Q. Dr. Shwachman, is it correct to say that cystic fibrosis is a fatal disease of infants and children, and that the aim of nursing care is to make the patient as comfortable as possible until he succumbs?

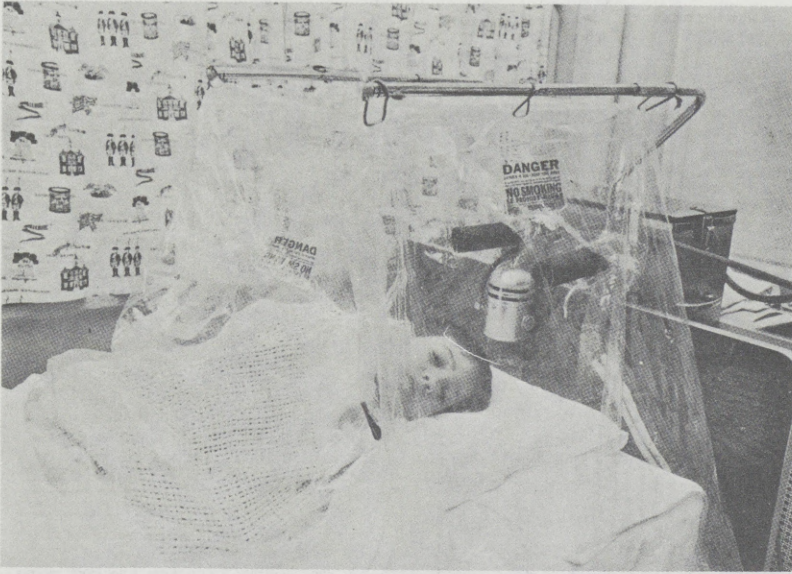
A. Not at all. This used to be the opinion in many quarters, and some doctors diagnosing C/F still tell parents, "Take your baby home and enjoy him for as long as you have him." But those who work closely with the disease know that it ranges from severe to mild, and we have seen many patients grow into their teens and twenties, and beyond, with proper care.

Q. What are the main characteristics of cystic fibrosis?

A. First of all, it is marked by a disturbance of the exocrine glands—glands that secrete mucus, saliva, and sweat. In C/F these substances are chemically or physically abnormal.

Most of the symptoms and complications of C/F are associated with the unusually thick and sticky mucus, which interferes with the functioning of the lungs and digestive system. In the lungs, the gluey mucus obstructs the smaller breathing tubes. This leads to bronchitis, pneumonia, and other infections which can damage the airway walls and lung tissue. Rapid breathing, wheezing, frequent coughing, "pouter-pigeon" chest, and clubbing of fingers and toes from poor circulation are often part of the picture.

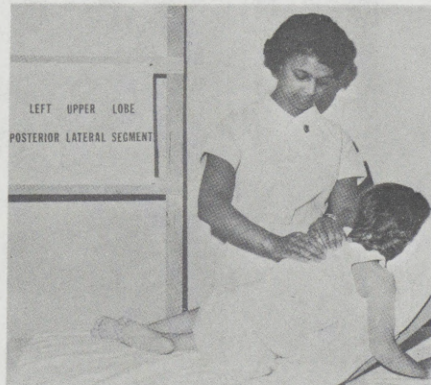
When mucus plugs the ducts of the pancreas, enzymes needed for digestion cannot reach the small intestine. The child has foul, bulky bowel movements and may suffer from malnutrition. Some C/F babies at birth have obstruction of the intestine (meconium ileus) and require lifesaving surgery.



A mist consisting of 90 per cent distilled water with 10 per cent propylene glycol is pumped continuously into the tent in which this patient sleeps. In use, the tent should contain a mist so dense that it is difficult to see the patient. Nightly mist tent use as prophylactic therapy is recommended by many doctors.



Water and medications in aerosol form are inhaled by many patients several times a day.



In postural drainage, the patient is placed in various positions and clapped and vibrated to loosen and help bring up mucus from the lungs.

Q. It is true that the sweat of persons with cystic fibrosis is unusually salty?

A. Yes, that's one of the most distinctive features of the disease. In hot weather or during a fever the patient may lose dangerous amounts of salt. But the fact that sodium and chloride are at such high levels in the sweat gives the doctor a reliable diagnostic tool. A test has been developed to measure these levels, and when they pass a certain point there is a strong likelihood of C/F being present. Mothers or grandmothers have often been the first to alert the doctor to C/F in a baby by saying the little one tastes salty when kissed. Apart from the salt, C/F is not always easy to recognize because the child may simply seem to have pneumonia or asthma or whooping cough, or to be suffering from some nutritional problem.

Q. Is cystic fibrosis common or rare?

A. Originally it was thought to be rare. Now we realize it is quite common, occurring in something like one in 1,000 to 1,500 live births. Upward of 10-

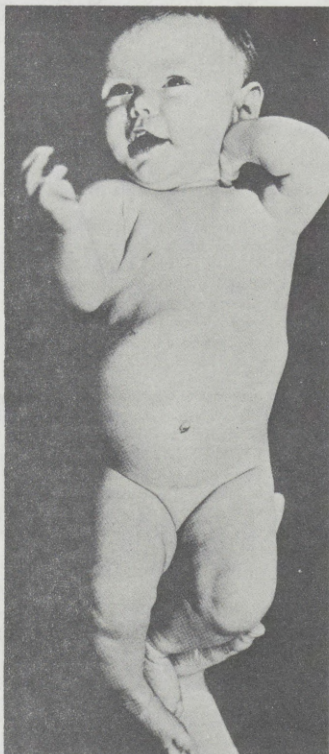
million individuals in this country alone probably carry a gene for the condition. Negroes are much less frequently affected than Caucasians, and Orientals have it rarely. I should like to stress here that C/F is not contagious.

Q. You speak of a gene. Is it definitely known that cystic fibrosis is inherited?

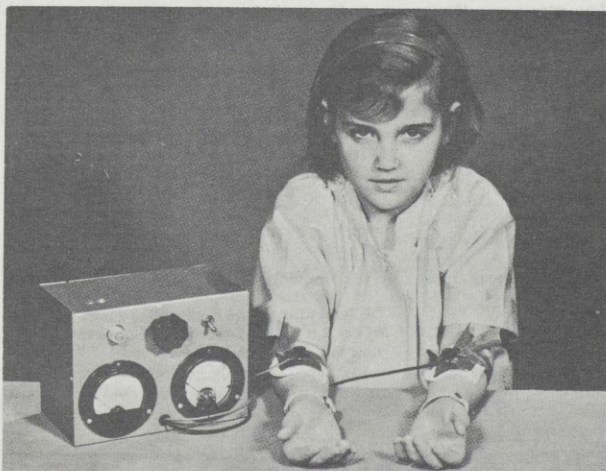
A. There's no longer any doubt of it. Research has shown that patients, and also their parents, have a factor in the blood that other members of the population don't have. Even more recently, there have been reports of some unique material in the cells of patients, their parents, and sometimes their siblings.

Q. That certainly seems to indicate the disease is familial. But why is it that some children inherit cystic fibrosis while others with the same parents escape it?

A. It takes a defective gene from both parents to produce C/F in the offspring. If the child inherits such



Baby with cystic fibrosis before treatment. Same baby after treatment.



The most useful and reliable diagnostic test for cystic fibrosis is the quantitative analysis of sweat for both sodium and chloride. Illustrated here is the pilocarpine iontophoresis method of obtaining sweat. Local sweat glands are stimulated by application to a small area of skin of a dilute solution of pilocarpine and a weak electric current. Sweat is collected on a weighed gauze pad or filter paper under a plastic barrier.

a gene from just one parent, he or she will be free of the disorder but be a carrier for it, just like the parents. If he doesn't inherit the faulty gene from either parent, he will neither have C/F nor be a carrier.

Q. Can carriers be identified before they have children?

A. Not yet, but new findings such as those I've just mentioned promise to provide a basis for a carrier test. This is an important object of current research. Another is to learn the chemical composition of the unique substances in the blood and the cells, and then figure out what they have to do with the disease. The more we know about C/F at the cellular and molecular level, the better we should be able to fight it.

Q. In the meantime, as you say, increasing numbers of patients are living longer with proper care. Could you tell our LPN/LVNs something about treatment and how they can help?

A. Many LPN/LVNs are already helping in the 40 Cystic Fibrosis Centers and 58 clinics across the country. These facilities have been established and are maintained with the support of the National Cystic Fibrosis Research Foundation. Much the same treatment that is given in the Centers and clinics is carried on by the families in the home.

To bring up the mucus that clogs the lungs, a form of physical therapy called postural or bronchial, drainage is performed. This consists in placing the patient in various positions so that gravity can exert its pull on the thick secretions in the different lobes of the lung; then the nurse, or therapist, or parent claps and

vibrates over the lobe to be cleared. The child coughs up and expectorates the mucus.

Q. How often is bronchial drainage performed?

A. It is often recommended two or three times daily. Also, several times a day, many patients inhale aerosol solutions through masks. These solutions contain water and medications; they wet and thin the mucous secretions in the lungs. Another therapeutic, or prophylactic, measure is sleeping in a plastic tent into which a mist of water is continuously pumped. In addition, breathing exercises are recommended to improve efficiency of respiration and ventilation, and other exercises and sports can be very useful.

Q. Children with cystic fibrosis take a lot of pills, don't they?

A. Yes indeed. Extracts of animal pancreas are needed where there is pancreatic insufficiency, to supply the missing digestive enzymes. Certain vitamins, especially A and D, are given in twice the usual dosage. And then there are salt tablets to make up for salt loss during the summer. Cystic fibrosis is such a complex disease that I could go on for a long time without describing it completely or outlining all the variations in treatment. The main point I should like to make is that with early diagnosis and prompt initiation of treatment, the outlook is much more hopeful now than it was a dozen years ago. And with research making real strides, a control for the condition should be found. So the role of the LPN/LVN, important as it is today, will be even more important tomorrow. ☐



National Cystic Fibrosis Research Foundation

3379 Peachtree Road, N.E. • Atlanta, Georgia 30326 • (404) 262-1100

Fighting Children's Lung Diseases

MRS. RICHARD M. NIXON, Honorary National Chairman

HUGH O'BRIAN, National Campaign Chairman

ESTIMATED RELATIVE INCIDENCE OF CYSTIC FIBROSIS and SICKLE CELL ANEMIA

1. <u>INCIDENCE OF THE GENE</u> (Carriers/Heterozygotes)			
	<u>CYSTIC FIBROSIS</u>	<u>SICKLE CELL ANEMIA</u>	<u>RELATIVE GENE FREQUENCY</u>
a) In total population	5% = 10,000,000	1% = 1,900,000	CF 5 times more common than SCA in total population
b) In blacks	2% = 450,000	8.5% = 1,900,000	SCA 4 times more common than CF in blacks
2. <u>INCIDENCE PER LIVE BIRTHS</u>			
	<u>CYSTIC FIBROSIS</u>	<u>SICKLE CELL ANEMIA</u>	
Total population	1 in 2,000 = 1,750/yr	1 in 3,250 = 1,077/yr	
Black population	1 in 12,000 = 44/yr	1 in 500 = 1,062/yr	
3. <u>LIVING PATIENTS</u>			
15 yrs life expectancy = 26,250	20 yrs life expectancy = 21,540		
20 yrs life expectancy = 35,000	25 yrs life expectancy = 26,925		

SOURCES:

Scott, Robert B.: Health Care Priority and Sickle Cell Anemia. JAMA 214: 731-734, Oct. 26, 1970.

di Sant'Agnese, Paul A., and Talamo, Richard C.: Pathogenesis and Physiology of Cystic Fibrosis of the Pancreas. New Eng. J. Med. 277:1287, Dec., 1967.

Nat'l. Center for Health Statistics for 1968: Total births in U.S. 3,501,564
Total black births in U.S. 531,152

Bureau of the Census: 1968 total population in the U.S. = 201,152,000
1968 total black population in the U.S. = 22,344,000



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STATISTICS GLEANED FROM 1970-71 REPORTS FROM 29 CARE, TEACHING and RESEARCH CENTERS

	C/F	OTHER PULMONARY	G.I.
Total patients registered and seen at least once in past year	3,952 pts.	2,477 pts.	764 pts.
number of centers with 0 patients	0 ctrs.	5 ctrs.	4 ctrs.
" " " " 1-40 "	2	8	9
" " " " 41-100 "	10	9	4
" " " " 101-200 "	15	4	3
" " " " 201-300 "	1	2	0
" " " " 500+ "	1 (800)	1 (670)	
Patients registered and seen at least four times/year	2,682 pts.	1,121 pts.	290 pts.
Number of centers with 0 patients	0 ctrs.	6 ctrs.	18 ctrs.
" " " " 1-40 "	5	16	8
" " " " 41-100 "	18	3	4
" " " " 101-200 "	6	2	0
" " " " 300+ "	1 (525)	1 (350)	
New patients seen for consultation	237 pts.	1,668 pts.	753 pts.
New patients followed regularly	485	916	109
Average number of days hospitalized	47.5 days	28.7 days	? days
Number of patients hospitalized	928 pts.	662 pts.	180 pts.
Deaths	156	25	6

Average number of patients visits/year: 4.7

Senator KENNEDY. Our final witness this morning is Dr. Roy F. Goddard, who is director of the Pediatric Research Department at the Lovelace Foundation and chairman of the Pediatric-Pulmonary Association.

Dr. Goddard is a graduate of New Mexico State University and the College of Physicians and Surgeons of Columbia University. He has a distinguished background in treatment of heart and lung problems in children.

Your statement and exhibits will be included in the record in their entirety at the end of your testimony.

STATEMENT OF ROY F. GODDARD, M.D., DIRECTOR OF PEDIATRIC RESEARCH, LOVELACE FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH

Dr. GODDARD. Senator Kennedy, distinguished members of the committee thank you for the opportunity to appear before you in behalf of Senate bill S3323.

As the Senator has said, I am president of, and represent the Association of Pediatric Pulmonary Centers of America. This is probably the youngest organization in the field of pediatric or any other pulmonary disease programs.

We are an organization of centers and individuals dedicated to establishing early diagnosis, control and preventive medicine in infants, children and young adults. We work together with the Pediatric Pulmonary Liaison Council—representatives from the American Academy of Pediatrics, American College of Chest Physicians, American Thoracic Society, American Academy and College of Allergists, and National Cystic Fibrosis Research Foundation.

You have heard from Dr. Olsen of the American College of Chest Physicians and Dr. Anderson of the American Thoracic Society. Because you are here I presume you are interested in the problems that are expanded in exhibit A.

I do not believe I need to get into these any further, only to say that 50 percent of the population today—and I am going to expand a little bit and include young adults, because cystic fibrosis is now also a young adult disease—as you heard Dr. Barbero testify, children are now surviving. When some of us first started in the field of cystic fibrosis 20 years ago, life expectancy for these children was 2 years of age. Now the average life expectancy is sixteen, and these children are surviving into young adults.

So I am talking now about 50 percent of our population which is under the age of 24.

Seven million children—and these are broken down for you in exhibit A—in this country today suffer from chronic respiratory disease. I am not even getting into the acute diseases which cause a major portion of illness in children and which cause loss of many schooldays.

Senator KENNEDY. I have one of them too.

Dr. GODDARD. In order to discuss the bill, S. 3323, I would like to comment on certain areas. To meet this enormous need, of respiratory diseases in children—and Dr. Barbero said he is very delighted to know that we even talk about children today—it seems because we are little people sometimes people do not talk about us, but we are little people that grow up. We now have a bill which includes children.

To further address this problem I would like to refer to section 415(a) (2), page 8, which mentions 15 new centers. We have made a proposal which I believe you have, Senator, and certainly Congressman Rogers has, in which we would propose 12 new centers for clinical research into training in, and demonstration of advanced diagnostic and treatment methods for chronic pulmonary diseases of infants, children and adults, including treatment of respiratory diseases of infancy, allergies and asthma, bronchitis and bronchiectasis, cystic fibrosis and other pulmonary diseases of children.

These centers would be for children, young adults, and would be set up on a developmental or incremental pattern; 12 in the first year, an additional 12 the second and third years, making a total of 36 such centers at the end of 3 years.

You must insure continuity of these programs in each center, and they must be funded for a minimum of 3 years. I believe exhibits B, C, and D cover these in considerable detail.

Such a multidisciplinary approach, we believe, can be effectively administered through the Heart and Lung Institute as outlined in section 416(a) and (b), page 9 which specifies that the secretary shall establish an interagency technical committee—I repeat this is very essential and important—shall establish an interagency technical committee, which shall be responsible for coordinating all Federal health programs and activities.

We believe that in section 416(b) page 10, representation should include particularly the National Institutes of Allergy and Infectious Diseases, Arthritis and Metabolic Diseases, Child Health and Human Development, and Health Manpower Education; and the Maternal Child Health Division of Health Services and Mental Health Administration. All of these governmental agencies are concerned in children's programs.

Pertaining to section 417(a) 2, page 10, we would recommend that of the 18 members to be appointed by the secretary, 12 of these should be selected from among the leading medical and scientific authorities, two of whom should be pediatric oriented.

We note that there has been much discussion about whether these appropriations are sufficient or not sufficient. We certainly would like to see \$10 million per year as a basic minimum for the pediatric portions of the program, and in the comments that have been made I am sure this would almost be doubled by the consideration of the various educational and training aspects and research that have been discussed here today.

We believe that an adequate network of pediatric-pulmonary centers can be built around exemplary locations already in existence with the assistance of the appropriations so authorized. Some of these are designated in the bill as new centers, but I believe we should emphasize that these already well established centers should be called upon to continue or be considered in this category.

Reference is now made to section 415(b) which specifies that funds paid to centers under cooperative agreements may be used for construction, staffing and other basic operating costs, including such patient care costs as are required for research, also training, including training for allied health professions personnel and demonstration purposes.

In much of your other testimony today you have heard about lay education and the very importance of getting the message to the American public. I would certainly second this.

We believe this is a practical method of attacking this major health problem of today and will substantially reduce the mortality and morbidity in these chronic pulmonary diseases of infancy, childhood and young adulthood, and build toward a stronger, more healthy America of the future.

One of the most important factors to be considered in this total program is the aspect of preventive medicine. Recognizing that today's distressed child becomes tomorrow's citizen, productivity depends upon his well being, and the economy of the Nation is synonymous with humanitarian principles in health care.

As a final comment, I would like to endorse the testimony given here today by Dr. Guilio G. Barbero, and urge that we may receive favorable responses.

I think you have aired the cystic fibrosis situation well enough, so that I would only reiterate what Dr. Barbero, Dr. Olsen, and Dr. Anderson have said. Cystic fibrosis must be included in this heart-lung bill.

As to the RMP programs which have been mentioned covering some of these educational and control areas, you have in exhibit E a letter from Secretary Richardson which emphasizes the point that many such programs will no longer be covered by RMP funding.

You have heard doctors this morning talk about the knowledge that we have which will be lost with the phasing out of these RMP programs. Dr. Fox has talked about control programs; that we have the "state of the art" today which can be utilized if we put this into effect.

In essence we have intensive care units, including respiratory intensive care units, in this country not just for adults but for children, and we are able to save many of these babies, as pointed out by Dr. Barbero.

With reference to this and other conditions, lipid and other diseases start in early life. We are emphasizing that any chronic pulmonary disease obviously affects the total cardiac picture and must therefore be also cardiac connected in this respect.

The sociopsychological impact of chronic disease I believe has just been barely touched upon. Rehabilitation, special education, manpower education and control and survey must be emphasized.

I would tell you that the association of pediatric pulmonary centers is also involved in the joint committee with the Thoracic Society and College of Chest Physicians in this manpower survey. We are grossly lacking in not just chest physicians, but even more so in those trained in pediatric pulmonary problems.

As Dr. Barbero has told you, we start as young individuals. We may have our disease at an early age, we may develop it later on, but our biggest effort we believe should be early recognition, better treatment of these patients and management, rehabilitation, and prevention for the future.

I believe that if we follow this we are certainly going to meet one of the major problems of today, and we are going to take care of many of the things that Senator Kennedy has included in his bill, including treatment of the respiratory distress syndrome of infants, a disease of which your own nephew died some years back.

I will be glad to answer any questions.

Senator KENNEDY. Very fine. We appreciate your presence here, and I want to thank you very much for coming.

Everyone had rather short notice today, but we had a very difficult scheduling program, inasmuch as many of us were on the Judiciary Committee looking into the Kleindienst nomination. We appreciate very much your presence here.

In terms of asthmatics, what can you tell us? Are you making any progress in this area? I have a son who is asthmatic, and I think Senator Robert has two children, my sister Pat has one. I think even little John is asthmatic, so we have about five that are affected.

Dr. GODDARD. Some people say you inherit asthma. I believe you inherit a respiratory constitution or system that perhaps is more susceptible to asthma.

We have learned that there is a critical threshold, beyond which a child does get into trouble. There are allergic factors, respiratory infections, draining ears and sinuses, metabolic considerations that Dr. Barbero has talked about, environmental and emotional factors (see exhibit F).

Why one child has asthma and the next one does not may be in part determined by this critical threshold. Actually asthma is simply an allergic manifestation lower down in the respiratory tract of the same allergic condition in the upper nasopharyngeal area.

Therefore what I am saying, Senator, is that I believe the child with asthma reaches a threshold when a number of these conflicting factors—we label as 10—reach this boiling point or threshold.

It is like adding blocks. One more block and the blocks tumble down. (see fig. 10, app. F).

I think we can add to this research investigation. Some of the things that we have learned in studying cystic fibrosis, some of the things we have accomplished in biochemistry in this multiplicity of National Institutes of Health research fields that we are talking about, have allowed us to recognize, just as in the coronary patient, and predict the child who not only has asthma, but we can predict the child who is going to have it continuously and have more serious problems with asthma as he grows older.

To be classified as cystic fibrosis there have to be three manifestations: the GI, the sweat imbalance, and the pulmonary complications. One can be a less severe case if all three of these manifestations do not coexist. Approximately 50 percent of chronic conditions in our children are respiratory and 33 percent of these are due to allergies and asthma. All of these children are not going to be in trouble all the time. We have developed several tests, such as one of our most recent research projects, which indicates the transfer or diffusion of oxygen from the lungs to the circulatory system, which allows us to study the oxygen level in the cardiopulmonary system and this determine how severely that child is affected (see app. F).

These techniques require further refinement. These are the techniques that your bill will help us to make available to the American public after they are refined and help these children whom we want to prevent from becoming emphysemous adults; and we can do these things with your help.

Senator KENNEDY. That is very good. As one who talks about changing the priorities in this country, I see all the more reason for it after listening to you. We want to thank people like you and your organizations.

(The prepared statement of Dr. Goddard with attachments follows:)

Statement

of

ROY F. GODDARD, M.D.
Director of Pediatric Research,
Lovelace Foundation for Medical Education and Research
Albuquerque, New Mexico

on behalf of

The Association of Pediatric Pulmonary Centers of America

THE SENATE OF THE UNITED STATES
92nd Congress

Committee on Labor and Public Welfare
Health Sub-Committee

March 1972

Testimony of Roy F. Goddard, M.D.
Committee on Labor and Public Welfare, March 1972

Mr. Chairman and gentlemen, I am Dr. Roy F. Goddard, and I am President of and represent the Association of Pediatric Pulmonary Centers of America. We are an organization of centers and individuals dedicated to establishing early diagnosis, control and preventive medicine in infants, children and young adults. Because you are here today gentlemen, your interest is obvious and therefore there is no need for me to iterate the serious aspects of lung disease referred to in Exhibit A.

Of the statistic quoted in Section 2(a)-4, it should be noted that 7,228,000 children are thus afflicted:

In order to meet this enormous need, we would like to address ourselves next to section 415 (2) which we would want to see included 12 new centers for clinical research into training in and demonstration of advanced diagnostic and treatment methods for chronic pulmonary diseases of infants, children and young adults, including respiratory diseases of infancy, allergies, and asthma, bronchitis and bronchiectasis, cystic fibrosis and other pulmonary diseases of children. For the proper development of trained manpower, development of growth patterns and eventual substantial geographical coverage, we would like to recommend that 12 Pediatric Pulmonary Centers be established the first year, an additional 12 the second year, and third years, making a total of 36 such centers at the end of three years: To insure continuity of programs each center should be funded for a minimum of three years (See Exhibits B. C. and D).

Such a multidisciplinary approach, we believe, can be effectively administered through the Heart and Lung Institute as outlined in Section

416(a) which specifies that the Secretary shall establish an inter-agency technical committee which shall be responsible for coordinating all Federal health programs and activities. In section 416(b) we believe this representation should include particularly the National Institutes of: Allergy and Infectious Diseases

Arthritis and Metabolic Diseases

Child Health and Human Development

Health Manpower Education

and the Maternal Child Health Division of Health Services and Mental Health Administration.

Pertaining to Section 417(a)2, we would recommend that of the 18 members to be appointed by the Secretary, 12 of these should be selected from among the leading medical and scientific authorities, two of whom should be pediatric oriented.

Gentlemen, in section 419(b) wherever it specifies the funds to be appropriated for each fiscal year, we would hope that this would provide for \$10,000,000 per year as a basic minimum for the pediatric portions of the program. Pertinent to this and as outlined in Section 414(b), we believe that an adequate network of Pediatric Pulmonary Centers can be built around exemplary locations already in existence with the assistance of the appropriations so authorized. Reference is now made to Section 415(b) which specifies that funds paid to Centers under cooperative agreements may be used for construction, staffing and other basic operating costs including such patient care costs as are required for research. Also training, including training for allied health professions personnel and demonstration purposes.

Gentlemen, this practical method of attacking this major health problem of today will substantially reduce the mortality and morbidity in these chronic pulmonary diseases of infancy, childhood and young adulthood and build towards a stronger, more healthy America of the future.

One of the most important factors to be considered in this total program is the aspect of preventive medicine. Recognizing that today's distressed child becomes tomorrow's citizen, productivity depends upon his well being and the economy of the nation is synonymous with humanitarian principles in health care.

As a final comment, I would like to endorse the testimony given here today by Dr. Giulio J. Barbero and urge that we may receive favorable responses.

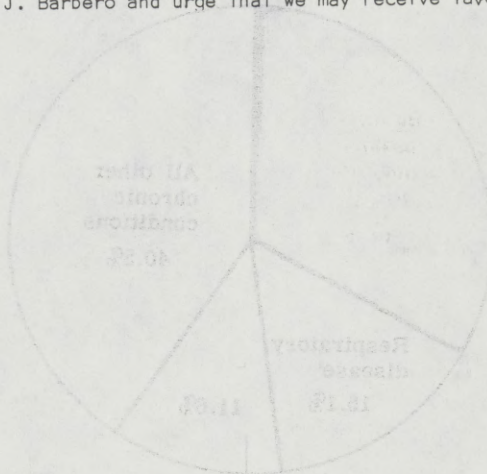


EXHIBIT A

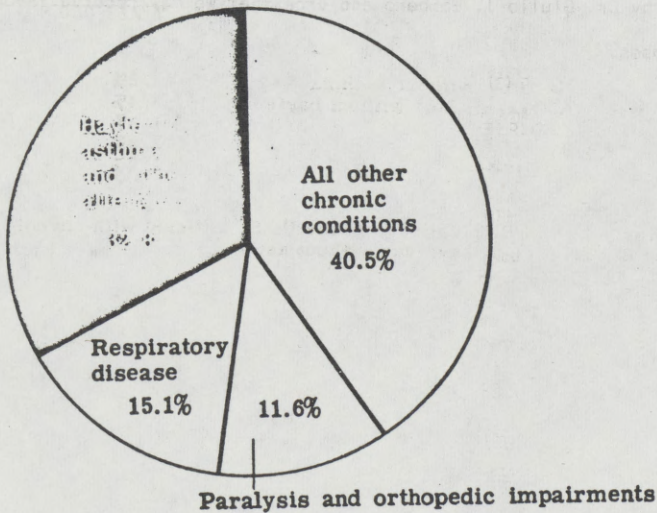
INCIDENCE OF PULMONARY DISEASE IN INFANTS AND CHILDREN

THE RECOGNITION AND EVALUATION OF
CHRONIC RESPIRATORY DISEASES IN CHILDREN AND YOUNG ADULTS

Roy F. Goddard, M. D.

Incidence and Importance of Recognition of Chronic Pulmonary Disease in Children

Forty-eight percent of all chronic conditions in children under the age of seventeen are due to allergy-respiratory conditions. This is a significant part of pediatric practice, so much so that we believe more emphasis needs to be turned to early recognition and treatment of these problems.



Incidence of Chronic Diseases of Children Under 17 Years of Age

DATA ON CHRONIC PULMONARY DISEASE IN CHILDREN

Source - National Center for Health Statistics - HEW, Washington

Unpublished figures from interview survey of civilian population, non-institutionalized.

1967 - Prevalence of Selected Chronic Pulmonary Disease among Children under 15 years

Hayfever without Asthma	1,934,000
Asthma with or without hayfever	2,040,000
Sinusitis	1,130,000
Bronchitis	1,401,000
Other	723,000
	<u>7,228,000*</u>

Rate per 100 Population

Hayfever without Asthma	3.2%
Asthma with or without hayfever	3.4%
Sinusitis	1.9%
Bronchitis	2.3%
Other	1.2%

* The figure of 5 million children in the U. S. afflicted with chronic pulmonary disease did not include hayfever without asthma.

THE IMPACT OF ACUTE AND CHRONIC ILLNESS
IN RESTRICTING CHILDREN'S ACTIVITIES
(National Health Survey, 1968)

	LIMITED IN SCHOOL OR PLAY FOR ILLNESSES	LIMITED IN SCHOOL (alone) FOR ILLNESSES	DAYS SPENT IN BED FOR ILLNESSES
	(age 0 - 15)		(age 0 - 15)
CHILDREN WITH CHRONIC CONDITIONS (1966-1967)	1,097,000		
PER CENT OF ALL CHILDREN WITH CHRONIC CONDITIONS			
TOTAL DAYS OF RESTRICTED ACTIVITIES FOR ALL CHILDREN (1968)	597,133,000 (almost 10 days lost by every child)		267,655,000 (4.5 days lost by every child)
	(age 0 - 17)	(age 6 - 16)	(age 0 - 17)
DAYS LOST FOR LISTED <u>ACUTE</u> CONDITIONS (1968)	605,629,000	191,562,000	266,973,000
1. Infections	98,020,000	33,209,000	49,561,000
2. Acute Respiratory	343,605,000	122,683,000	169,288,000
a. Acute URI's (colds)	(175,067,000)	(59,005,000)	(73,211,000)
b. Influenza	(143,409,000)	(60,719,000)	(84,996,000)
c. Other Acute Resp.	(20,128,000)	(2,959,000)	(11,080,000)
3. Gastro-Intestinal	25,563,000	7,772,000	10,459,000
4. Injuries	81,180,000	12,035,000	15,388,000
5. All Other Acute	57,261,000	15,073,000	22,277,000
DAYS LOST FOR LISTED <u>CHRONIC</u> CONDITIONS (1968)	62,912,000	27,667,000	11,067,000
1. Asthma (22.9% rate set in 1959-1961)		6,336,000	
2. Other Allergies (4.5%)		1,245,000	
3. Other Respiratory Diseases (27.6%)		7,636,000	
4. All Other Chronic Conditions (45.0%)		12,450,000	
DAYS LOST FOR ACUTE AND <u>CHRONIC</u> CONDITIONS	668,541,000	219,229,000	278,040,000

PREVALENCE OF CHRONIC CONDITIONS AMONG CHILDREN
IN THE UNITED STATES OF AMERICA
(National Health Survey, 1968)

	<u>BOYS</u>		<u>GIRLS</u>		<u>BOTH</u>
TOTAL POPULATION	51.90%	34,776,000	48.10%	32,230,000	67,006,000
ALL CHRONIC LISTED CONDITIONS	25.42%	8,840,000	21.04%	6,780,000	15,620,000
1. Hayfever, Asthma & other allergies*	10.67%	3,711,000	9.02%	2,907,000	6,618,000
2. Other Respiratory Conditions*	5.99%	2,083,000	5.10%	1,644,000	3,727,000
3. Orthopedic & Paralytic	2.48%	862,000	2.20%	709,000	1,571,000
4. Skin Diseases	1.43%	497,000	1.58%	509,000	1,006,000
5. Digestive	1.32%	459,000	0.85%	274,000	733,000
6. Speech Disorders	1.19%	414,000	0.50%	161,000	575,000
7. Hearing Problems	0.96%	334,000	0.63%	203,000	537,000
8. Visual Disorders	0.65%	226,000	0.56%	180,000	406,000
9. Mental & Nervous Conditions	0.73%	254,000	0.60%	193,000	447,000
* ALL CHRONIC RESPIRATORY	16.66%	5,794,000	14.12%	4,551,000	10,345,000 (15.4%)

CHILDREN WHOSE ACTIVITIES ARE RESTRICTED
BY CHRONIC DISEASES

	NUMBER	PER CENT OF ALL CHILDREN	PER CENT OF ALL CHRONIC CONDITIONS
ALL CHRONIC CONDITIONS	15,620,000	23.3%	100.0
THOSE WITH ANY LIMITATIONS	1,427,000	2.1%	9.2%
THOSE WITH SOME LIMITATIONS IN SCHOOL OR PLAY ACTIVITIES	825,000	1.2%	5.3%
THOSE WITH "LESSER" LIMITATIONS	602,000	0.9%	3.9%

(Data from the National Health Survey, 1968)

EXHIBIT B

MODEL FOR A DIVISION OF PEDIATRIC
RESPIRATORY DISEASES

- A. Purpose: To establish a comprehensive and coordinated diagnostic, treatment, training, clinical and basic research program in pediatric pulmonary diseases.

B. Introduction

The prevalence, mortality and morbidity statistics emphasize the importance of acute and chronic lung disease as a health problem in children. The establishment of pediatric pulmonary disease centers is the most practical and economical method of increasing the availability of professional personnel and improving the quality of care in this field.

C. Objective

The primary objective of this program is to bring together in a teaching center personnel with special skills for a coordinated approach to the diagnosis and comprehensive management of children with acute and chronic respiratory diseases. This center will represent an optimal program unit which is structured to: (1) Serve as a training area for physicians of various disciplines, medical students, nurses and paramedical personnel; (2) Provide optimal diagnostic and treatment services for children having acute and chronic respiratory diseases; (3) Stimulate and conduct clinical research in the pathophysiological changes associated with chronic respiratory diseases thus improving the clinical management of these afflictions; (4) Develop and improve communications between the pediatric respiratory unit and the medical and/or paramedical personnel in the outlying communities. This will permit the prompt application of new diagnostic

and therapeutic measures in the treatment of neonatal and pediatric pulmonary diseases; and (5) Provide an opportunity for the longitudinal study of children with chronic respiratory diseases thus obtaining information concerning the natural course of pulmonary diseases, and the effectiveness of preventive or prophylactic measures.

D. Services

The pediatric respiratory center will coordinate the existing broad diagnostic treatment and rehabilitation and research programs found at the university medical center in order to provide a comprehensive and exemplary care for children with chronic and acute respiratory diseases. The center must have the required personnel and facilities to provide the exact diagnosis and subsequent optimal care of the patient and the family afflicted with any type of respiratory disease (allergic, congenital, immunologic defect, infectious, etc.).

Inpatient services should include: (1) nursery; (2) intensive care respiratory unit; (3) facilities and personnel for diagnosis and treatment of patients with infectious, acute and chronic respiratory diseases; (4) rehabilitation.

Outpatient facilities and personnel should complement and extend the inpatient services.

Services will be offered at a level and phase appropriate to the nature and severity of the individual child's basic pulmonary problem. An attempt will be made to provide comprehensive outpatient evaluation, therapy and followup, with hospitalization reserved for patients requiring special diagnostic studies or intensive therapeutic measures. Such care will necessitate the interaction of the

entire medical team of the respiratory center. In addition, for optimal care a close liaison will be developed among the center staff, local physicians, public health authorities and community services.

All children seen at the center, especially those handicapped by their respiratory diseases, will have a thorough followup with the aid of the vocational and social services in order to make certain that the child realized the full potential for rehabilitation. Since the results of the rehabilitation with pediatric problems is directly related to the enthusiasm and effectiveness of the therapeutic program provided by the parents or other members of the household, special instructions will be given to the family members at the center as well as the local community in the medical and emotional management of the child with chronic pulmonary disease.

The longitudinal study of children with chronic respiratory disease provides an opportunity to obtain data concerning the natural course of pulmonary disease especially the subsequent development of chronic obstructive respiratory diseases in adulthood. The effectiveness of various therapeutic regimens will also be evaluated by developing a multiple parameter computerized evaluation system.

E. Training

An equally important objective of the center is to provide a training ground for pediatric pulmonary disease specialists. Pediatricians, specialists, and trainees in the field of pulmonary disease, child psychiatry, clinical psychology,

nursing, physical therapy, inhalation therapy, radiology, social work, and education will have an opportunity to train at this institute. The center is expected to play a key role in training a broad spectrum of pediatric pulmonary disease professional personnel to serve in the pulmonary clinic facilities across the area served by the medical center.

Clinical training:

- a. Fellowship training for periods of 1-2 years will be available to board certified pediatricians.
- b. Selected training programs for periods of 1-4 weeks will be made available for physicians in practice.
- c. Elective programs will be available for medical students.
- d. Specific programs will be made available for physician assistants, inhalation therapists, public health nurses, nurses.

F. Research

A clinical research unit should be available to perform appropriate investigative studies concerning the etiology and pathophysiology of pulmonary affliction in children.

Normal values for pediatric patients must be secured especially in regard to pulmonary function testing. An attempt should be made to obtain simpler diagnostic tests especially in patients less than 6 years of age.

Specific therapeutic programs should be instituted and evaluated.

Consultative Services

Other medical and paramedical services and facilities should be available for integration into the care, research and teaching programs. These include:

1. Anesthesiology
2. Biostatistics
3. Cardiology
4. Radiology
5. Thoracic Surgery
6. ENT
7. Environmental Health
8. Infectious Diseases
9. Allergy
10. Immunology
11. Psychiatry and Psychology
12. Community medicine and Public Health
13. School teacher; Vocational and Occupational Therapy
14. Social Worker.

EXHIBIT C

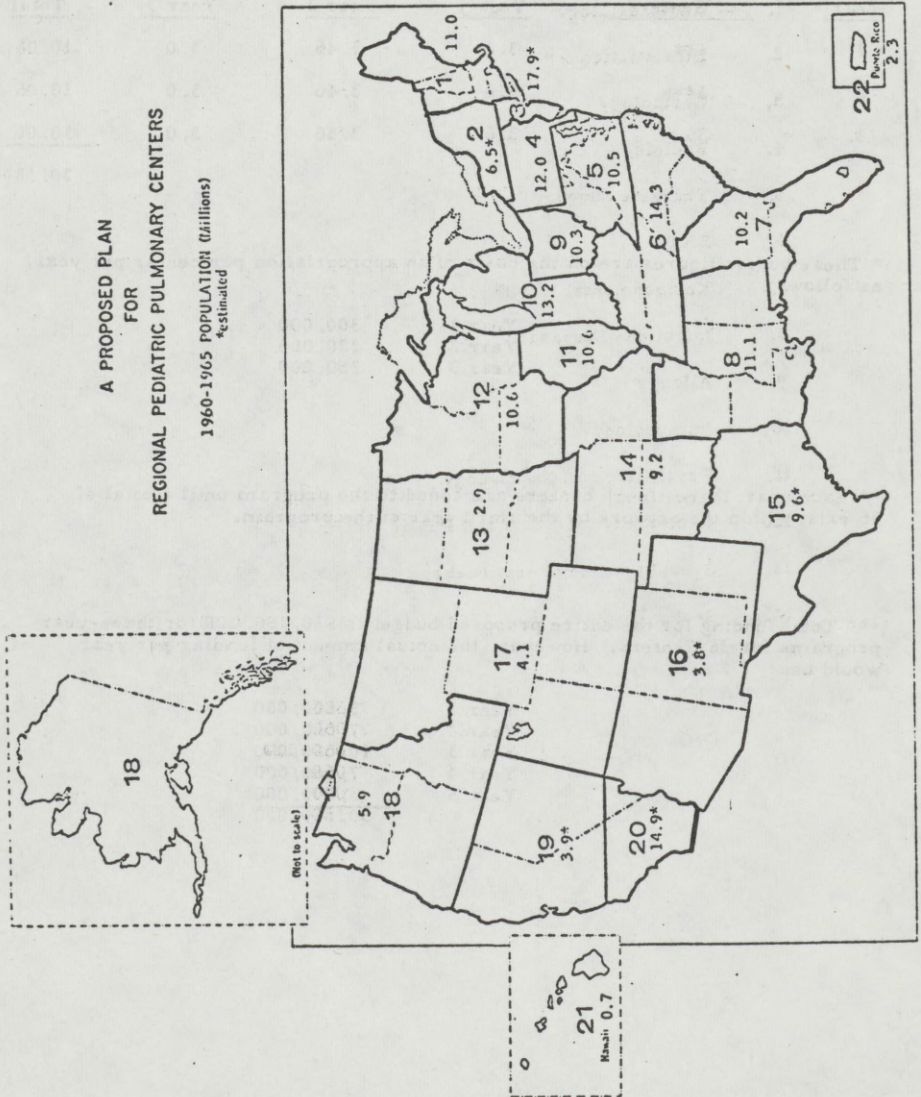


EXHIBIT D

PROPOSED INCREMENTAL FUNDING OF CENTERS

(Millions of Dollars)

<u>Year</u>	<u>Proposed No. of Centers</u>	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>	<u>Total</u>
1	12*	3.6	3.46	3.0	10.06
2	24**	3.6	3.46	3.0	10.06
3.	36	3.6	3.46	3.0	<u>10.06</u>
					30.18***

* These budget figures are on the basis of an appropriation per center per year, as follows:

Year 1	300,000
Year 2	280,000
Year 3	250,000

** Each year, 12 additional centers are added to the program until a total of 36 exist within the network by the third year of the program.

*** Total funding for the entire proposed budget is \$30,180,000 for three-year programs for 36 Centers. However, the actual amount of funding per year would be:

Year 1	3,600,000
Year 2	7,060,000
Year 3	10,060,000
Year 4	7,060,000
Year 5	<u>3,000,000</u>
	30,180,000

EXHIBIT E



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

FEB 25 1972

Honorable Hiram L. Fong
United States Senate
Washington, D. C. 20510

Dear Senator Fong:

Thank you for your letter of January 25 about the pediatric pulmonary projects supported by several Regional Medical Programs (RMP's). Following is the current status of the four you mentioned.

	1971 <u>Funded</u>	1972 <u>Request</u>	
Hawaii	\$107,028	\$121,222	(fourth year)
New Mexico	99,134	95,024	(third year)
New York	172,060	- - -	(fifth year)
Washington/Alaska	- - -	58,313	(first year) <u>1/</u>

1/ For a six month period 7/1/72 - 12/31/72.

Regional Medical Programs do not provide long-term support for continuing health care services. Since their inception, Regional Medical Programs have provided a unique arrangement with 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. Federal resources are used as "start-up funds" to initiate three-year, demonstration projects. The grants are made with the prior understanding that local support will be found for any parts of the activities that are to be continued after the awards expire.

It should also be pointed out that very soon the 56 RMP's will be receiving increased amounts based on the December 27, 1971, decision to obligate all appropriated funds. Each RMP will be free to fund any approved projects it wishes. This means, for example, that the Hawaii RMP could fund its pediatric pulmonary project for a fourth year should they decide to do so.

Individual Projects

Hawaii

It is our understanding that the Hawaii Regional Medical Program's Regional Advisory Group has taken the position that it will not support the project, even with increased funding, because they believe the needs in other health care areas are greater than those in the pediatric pulmonary field.

New Mexico

The New Mexico RMP sought and received approval for funding this project in 1972, and is currently funding it at the level indicated above.

New York

The New York Metropolitan Regional Advisory Group has decided that these funds should now be utilized to extend and improve other types of health care services. As a result, the New York Metropolitan RMP did not seek funding approval for 1972 nor has it, as yet, indicated an interest in doing so.

Washington/Alaska

The Washington/Alaska RMP recently submitted a new project proposal (out of cycle with its regular application) which received final review and approval by the National Advisory Council when they met February 8-9.

As we understand the above status reports, to insure funding of two of these pediatric pulmonary projects would require a Federal directive contrary to the need as perceived by those who live in

the region and have carefully studied their health care problems. Further, we believe that such a directive would unnecessarily endanger valuable relationships and would set a precedent which could prove most harmful in the future.

You may be assured that your continued interest in the pediatric pulmonary projects is appreciated and that the 1971 funding level of \$1 million for this program will be available to the 56 RMP's in 1972 and 1973.

With best regards,

Sincerely,

Frederick H. Richardson

Secretary

TUFTS UNIVERSITY SCHOOL OF MEDICINE - BOSTON CITY HOSPITAL

MAURICE S. SEGAL, M.D.
 ASSISTANT PROFESSOR OF MEDICINE
 DIRECTOR, LUNG STATION (TUFTS) AND
 DEPARTMENT OF INHALATION THERAPY



LUNG STATION (TUFTS)
 BOSTON CITY HOSPITAL
 810 HARRISON AVENUE
 BOSTON, MASSACHUSETTS 02118
 TELEPHONE AREA CODE 617
 424-5421 (2 - 3)

February 10, 1971

Roy F. Goddard, M.D.
 Lovelace Clinic
 4800 Gibson Boulevard, S.E.
 Albuquerque, New Mexico

Dear Roy:

After spending a lifetime in the management of obstructive lung problems in adults, I have become convinced that rehabilitation of the young patient is the key. I think this may be the area that I will work in after my emeritus status in a couple of years. I would like to spend a few days to a week visiting with you for I have been impressed with the work you have been doing with children.

If you would suggest the better time of year for a visit with you, I would go ahead and make plans. I would prefer comfortable hotel or lodge accommodations that would provide pool and tennis facilities not too far from your hospital unit. If you feel that my monosyllabic utterings on deaths in bronchial asthma or the management of respiratory failure could be useful I would be pleased to talk on these subjects while in Albuquerque.

At any rate, I hope this brief note finds you well. It is some time since our paths have crossed.

Sincerely,

Maurice S. Segal
 Maurice S. Segal, M.D.

MSS:drb
 enc.

EXHIBIT F

THE EARLY EVALUATION AND DIAGNOSIS OF

ALLERGY-RESPIRATORY DISEASES IN CHILDREN

*From the Booklet entitled, "Respiratory Problems and Related Allergies in Children," by Roy F. Goddard, M. D., Lovelace Foundation Manual No. 1, Seventh Printing, April, 1972.



Factors Contributing to Allergy-Respiratory Problems

It is very rare that any single factor is a major cause of allergic or respiratory problems. Usually a combination of factors from three main categories contribute to allergy-respiratory problems:

Allergenic Factors

1. **Ingestants** — These include foods as well as medicines that are ingested or eaten.
2. **Inhalants** — These include all of the various agents which are breathed in and irritate either the upper or the lower respiratory system, such as animal dander, dust (including house), pollen from the trees, grasses and weeds, fungus and molds.

Respiratory Factors

1. **Infection** — This includes infection in the upper respiratory system, such as a cold, naso-pharyngitis, tonsillitis, laryngitis, or infection in the lower respiratory system, such as bronchitis or pneumonia.
2. **Organic** — Included here are disorders of the structures associated with the respiratory system, such as the sinuses and the ears.
3. **Respiratory Stress** — Many times activities such as riding a bicycle or running and playing, will initiate wheezing and considerable respiratory distress in children. Occasionally this is seen in older subjects following hearty laughing.

Other Influencing Factors

1. **Metabolic** — (a) The gamma globulin levels, which are a measure of the ability of the body to manufacture antibodies for protection against infection, may be lower than normal; (b) Excessive sweating frequently occurs in some respiratory disorders, resulting in loss of electrolytes (salts). while local irritants are those that come in contact with the body such as adhesive tape, rubber pants or gloves, etc.
3. **Environmental** — It is well known that changes in humidity and temperature play an important role in the incidence of allergies and respiratory conditions. Frequently a change of climate may be of some value. Some of this may be due to a lowering of incidence of respiratory infections in a warmer, drier climate.
4. **Constitutional** — While one does not inherit an allergy, one may inherit a respiratory constitution or system which is more sensitive to the factors which contribute to disorders of this system.
5. **Emotional** — It is well known that emotional upsets may influence the breathing pattern and cause bronchial constriction.

Critical Thresholds

This is the name given to a situation resulting from a combination of several factors which produce the symptoms of an illness. The critical threshold may be viewed as analogous to placing many blocks on top of each other until the addition of one more block causes all of them to topple. (See Fig. 10). Except for a rare instance in which a person is highly sensitive to something he has eaten, such as shellfish, or to an insect bite, a critical threshold usually results from the simultaneous occurrence of all, or at least a majority of the factors mentioned above. Thus, a child with several factors may feel no distress until one more factor is added to cause him to wheeze, have shortness of breath, or develop other symptoms of respiratory illness.

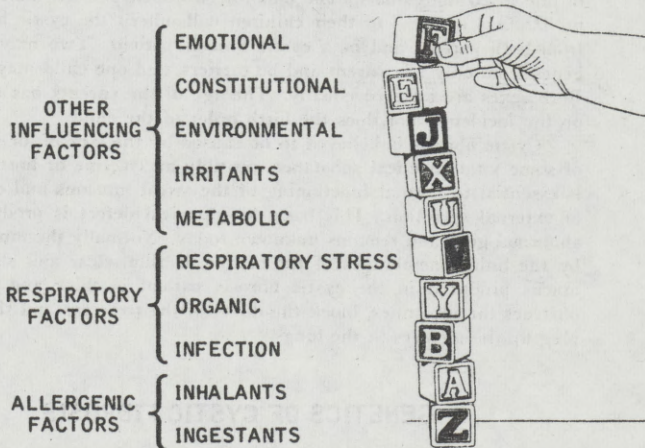


Figure 10— Critical Threshold in Allergy-Respiratory Problems

Page 18 and Page 19 from the booklet entitled, "Respiratory Problems and Related Allergies in Children," By Roy F. Goddard, M. D., Lovelace Manual No. 1, Seventh Printing, April, 1972.



Cystic Fibrosis (C/F)

Cystic fibrosis is a congenital defect, or an inherited condition. It is not a contagious disease and cannot be transferred from one child to another. Both parents must carry the genetic trait. (See Genetic Chart, Figure 28.) This is said to be a Mendelian recessive genetic trait present in one in 20 individuals. The odds of two such persons marrying is one in 400. One out of 4 of their children will inherit the cystic fibrosis gene from both parents and be a cystic fibrosis patient. Two may inherit the genes from only one parent and be carriers, and one child may be normal. Both sexes are affected equally. The age of the parents has no influence on the incidence, nor does the birth order of the child.

Cystic fibrosis is believed to be caused by the lack of, or insufficiency of some vital chemical substance, possibly an enzyme or hormone, which is essential to normal functioning of the sweat, mucous and other glands of external secretion. This basic bio-chemical defect is produced by the abnormal gene and remains unknown today. Normally the mucus secreted by the lining membranes of the organs, is thin, clear and slippery. The mucus produced in the cystic fibrosis patient is thick and sticky, may obstruct the intestines, block the ducts of the pancreas and the liver, and plug up the airways in the lungs.

GENETICS OF CYSTIC FIBROSIS

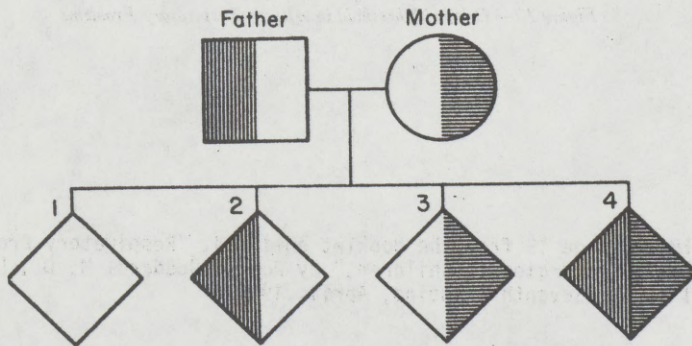


Figure 28—Inheritance Pattern of Cystic Fibrosis

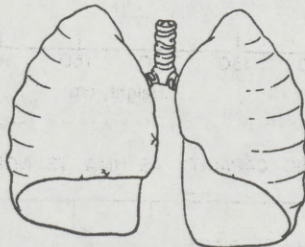
The Clinical Manifestations of C/F

The clinical manifestations can be divided according to the various systems affected:

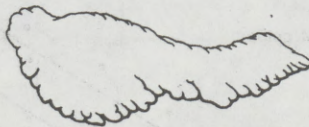
1. **Sweating and Heat Prostration** — Among the non-mucus producing glands of the endocrine system which are affected are the sweat glands, the tear glands, and the salivary glands. In the sweat glands, the absence



Sweating and heat prostration



Chronic Lung disease



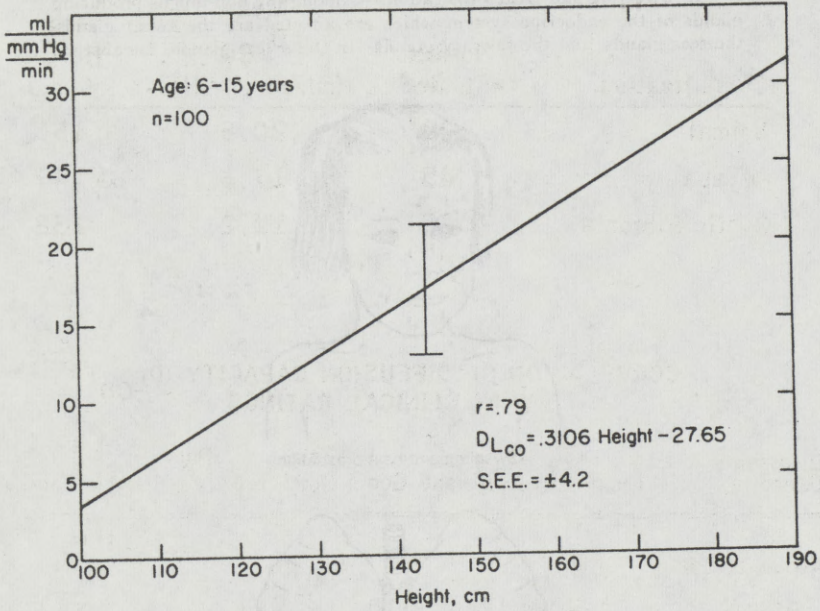
Pancreatic Insufficiency

Figure 29—The Main Clinical Features of Cystic Fibrosis

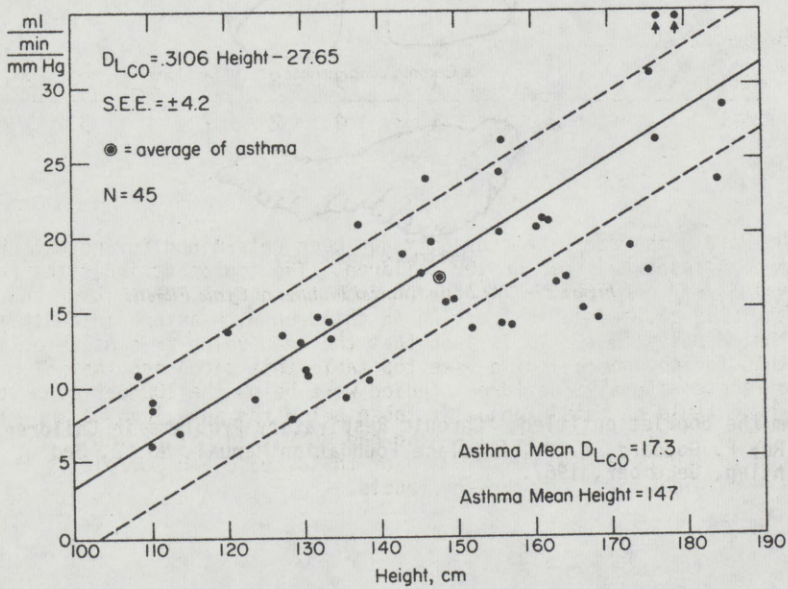
From the booklet entitled, "Chronic Respiratory Problems in Children," by Roy F. Goddard, M. D., Lovelace Foundation Manual, No. 2, 3rd printing, December, 1967.

DIFFUSING CAPACITY STUDIES

DIFFUSING CAPACITY (STEADY STATE) IN CHILDREN



DIFFUSING CAPACITY ASTHMA VS. NORMAL CHILDREN



MEAN DIFFUSION CAPACITY OF CHILDREN AND YOUNG ADULTS

Classification	Number Studied	Mean D_{LCO} (ml/min/mmHg)	Mean Height (cm.)
Normal	100	20.5	155
Asthma	45	17.3	147
Cystic Fibrosis	25	12.2	138

CORRELATION OF DIFFUSION CAPACITY (D_{LCO}) WITH CLINICAL RATINGS

Diffusion Capacity	Excellent	Good-Excellent	Good	Fair-Good	Fair	Poor-Fair	Poor	Total	%
Above 100%									
Asthma	1		10	3	1			15	37.5
C/F	1	1	3		1			6	24.0
Below 100%									
Asthma		1	9	8	4	3		25	67.5
C/F	2	1	4	2	7		3	19	76.0

On Page 5 the diffusing capacity has been determined for normal children from a research study on 100 children. The top chart indicates the normal values and one standard deviation from the normal. The lower chart shows the values obtained in studying 45 children with asthma in contrast to the normal values. It is seen that the mean value is considerably lower than for the normal child (see top table this page) and that 67.5 per cent of these asthmatic children studied were below the 100 per cent value (see lower table on this page). Of those below the normal value the majority with poor diffusing capacity also had poor clinical ratings. Thus, this new test determines the severity of the disease and correlates this with the clinical condition and prognosis.

NATIONAL COMMITTEE FOR RESEARCH IN NEUROLOGICAL DISORDERS

Paul C. Bucy, *Chairman*
251 East Chicago Ave., Suite 1230
Chicago, Illinois 60611

March 29, 1972

Honorable Edward M. Kennedy
Chairman, Health Subcommittee
Room 4226
New Senate Office Building
Washington, D. C.

Dear Senator Kennedy:

I am Dr. Paul C. Bucy, Professor of Surgery (Neurological Surgery) at Northwestern University Medical School, Chicago; Chairman of the National Committee for Research in Neurological Disorders; and President of the American Neurological Association. Unfortunately, it has not been possible for me to appear before you to testify regarding S. 3323, a Bill to enlarge the authority of the National Heart and Lung Institute (NHLI). Accordingly, it is requested that this letter be printed along with the other public testimony being considered by your Committee.

You and your Committee are to be complimented on having produced an excellent Bill. I hope that it will be passed by Congress and signed into law in its present form. It is noteworthy that this Bill, although recognizing the relationship between diseases of the heart, blood and blood-vessels, and "stroke", does not transfer the responsibility for research on "stroke" from the National Institute of Neurological Diseases and Stroke to this expanded NHLI. If we are to achieve a greater understanding of "stroke" and improve prevention and treatment for the cerebrovascular disorders which include "stroke" it is important that the prime responsibility for research in this area remains with the neurologists. It is obvious that there is much overlap between the activities of the heart and the neurological institutes. It is important that in these areas of mutual interest the two institutes will cooperate and collaborate.

"Stroke" is an involvement of the brain. The problems experienced by victims of "strokes" arise because of dysfunction of the brain. The involvement of the blood-vessels of the brain differs in many respects from the involvement of blood-vessels in other parts of the body. The structure of blood-vessels in the brain is different. The nerve supply to these blood-vessels is different. The control of blood flow and blood pressure in the brain is different. The effects of impairment of the circulation of the blood within the brain is different from impairment of circulation in other organs of the body.

The National Institute of Neurological Diseases and Stroke has concerned itself actively with the problems of "stroke" and cerebral circulation. It has supported the collaborative study on intracranial aneurysms and subarachnoid hemorrhage. It has joined with the American Neurological Association in

the formation of a Joint Commission on Stroke Centers. It has supported many research projects dealing with these problems. Much has been learned and progress has been made, but much more remains to be done. It would be a serious mistake to interrupt this well organized research thrust and place the responsibility in another agency largely unfamiliar with this highly specialized field.

As an illustration of these differences, the statement has been made that "strokes" will be prevented when the heart institute learns to control or prevent high blood pressure. The control of high blood pressure is important but it will not abolish either "strokes" or other cerebral vascular diseases. They result from many factors of which high blood pressure is only one. In fact, most strokes arise from other causes.

Concern for "stroke" and other problems involved in cerebral vascular diseases should remain a primary responsibility of NINDS. In order that NINDS may increase its efforts and achieve what is needed in the "stroke" field a new Bill expanding the authority of NINDS similar to that now being developed for NHLI is badly needed. We sincerely request that you and your Committee give your attention to preparing such a Bill along the excellent lines which characterize S. 3323.

Respectfully submitted,

Paul C. Bucy, M.D.

PCB:rrl

cc: Dr. A. L. Sahs
Dr. Joe R. Brown
Dr. A. B. Baker
Dr. Fletcher McDowell
Dr. Fred Plum

Senator KENNEDY. The subcommittee will stand in adjournment.
(Whereupon at 1:20 p.m., the subcommittee adjourned.)

The Board of Directors of the Corporation is composed of seven members, three of whom are elected by the stockholders and four by the Board of Directors. The Board of Directors is authorized to elect and remove the members of the Board of Directors and to fill any vacancies that may occur.

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Very respectfully,

 Secretary

Witness my hand and seal this 1st day of January, 1901.
 (Witnessed at 1:30 p.m. the 1st day of January, 1901.)

