A bill to amend the public Health Service Act to improve information and research on biotechnology and the human genome, and for other purposes ... : this act may be cited as the "Biotechnology competitiveness act of 1987" : Title I- National Center for Biotechnology Information.

Calendar No. 690

100TH CONGRESS
2D SESSION

S. 1966

[Report No. 100–359]

To amend the Public Health Service Act to improve information and research on biotechnology and the human genome, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 18 (legislative day, DECEMBER 15), 1987

Mr. CHILES (for himself, Mr. KENNEDY, Mr. DOMENICI, Mr. LEAHY, Mr. GRAHAM, Mr. WILSON, and Mr. BENTSEN) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

MAY 25 (legislative day, MAY 18), 1988

Reported by Mr. KENNEDY, with amendments

[Omit the part struck through and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to improve information and research on biotechnology and the human genome, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biotechnology Competitiveness Act of 1987".

TITLE I—NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

SEC. 101. FINDINGS.

Congress finds that—

(1) biotechnologies help to advance our understanding of the composition of human chromosomes and cells, and our knowledge of fundamental human development and disease processes;

(2) information on the map and sequence of the human genome, as well as the many other important fields of biotechnology research, is accumulating faster than can be reasonably assimilated by present methods;

(3) it is essential that advances in information science and technology be made so that this vast new knowledge can be organized, stored, and utilized;

(4) there are numerous independent computer data bases that hold portions of the burgeoning biotechnological discoveries and such data bases lack common technology, central coordination, and adequate support;

(5) it is important that information on research in biotechnology be available to researchers to allow coordination of the research efforts ongoing in public and private sector laboratories;

(6) the National Library of Medicine of the National Institutes of Health is highly suited, by virtue of its preeminence in the field of biomedical communications, service, and information research, to facilitate the rapid advance of biotechnology through information transfer; and

(7) a biotechnology information initiative could take advantage of the unique facilities of the National Library of Medicine to develop new communications tools and serve both as a repository and as a center for the distribution of molecular biology information to researchers and health practitioners.

SEC. 102. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

Part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following new subpart:

"Subpart 3—National Center for Biotechnology Information

"SEC. 478. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

"(a) ESTABLISHMENT.—To focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information tech-

nologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the 'Center') in the National Library of Medicine.

"(b) FUNCTIONS.—Through the Center and subject to section 465(d), the Secretary shall—

"(1) coordinate the design, development, implementation, and management of automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human, animal, and plant molecular biology, biochemistry, and genetics;

"(2) ~~perform research~~ *conduct a research program* into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds *using Center capabilities, as well as those in Federal, university, and private research laboratories*;

"(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2);

"(4) coordinate the efficient input of information regarding biotechnology from all government agencies

~~and agency grantees,~~ *as well as agency grantees and contractors*, and where applicable, inform granting agencies of duplications of research efforts;

"(5) encourage the input of information regarding biotechnology from the private sector, including professional scientific societies, foundations, and companies;

"(6) coordinate biotechnology research information provided by the center and other sources, including the biotechnology industry, other government agencies, and the private sector (including professional scientific societies, foundations, and companies); and

"(7) coordinate, to the maximum extent practicable, efforts to gather biotechnology information on an international basis.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1989 through 1993. Funds appropriated under this subsection shall remain available as specified in appropriations acts.".

TITLE II—NATIONAL BIOTECHNOLOGY POLICY BOARD AND ADVISORY PANEL

Subtitle A—National Biotechnology Policy Board

SEC. 201. ESTABLISHMENT, MEMBERSHIP, CHAIRMANSHIP, MEETING.

(a) ESTABLISHMENT.—There is established in the Executive branch of the Federal government a National Biotechnology Policy Board (hereinafter in this title referred to as the "Board").

(b) MEMBERSHIP.—The membership of the Board shall consist of the following individuals or their designees:

(1) The Director of the National Institutes of Health.

(2) The Director of the National Science Foundation.

(3) The Secretary of Agriculture.

(4) The Secretary of Commerce.

(5) The Secretary of Defense.

(6) The Secretary of Energy.

(7) The Commissioner of the Food and Drug Administration.

(8) The Administrator of the Environmental Protection Agency.

(9) The Director of the Office of Science and Technology *Policy*, who shall serve as an ex-officio, nonvoting member of the Board.

(10) The Director of the Office of Management and Budget, who shall serve as an ex-officio, nonvoting member of the Board.

(11) Four individuals representing the university research community, to be recommended by the National Academy of Sciences and appointed by the President, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act.

(12) Four individuals representing diverse United States biotechnology-related industries to be appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act.

(13) One individual with expertise in biomedical ethics, to be recommended by the National Academy of Sciences and appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act.

(14) One individual representing national foundations, medical institutes, and other philanthropic organizations involved in biomedical research, to be recommended by the National Academy of Sciences and appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act.

(c) TERM OF SERVICE.—

(1) IN GENERAL.—Except as provided in paragraph (3), Board members appointed under paragraphs (11) through (14) of subsection (a) shall serve 4-year terms and shall serve until a successor for such member is appointed and confirmed.

(2) VACANCIES.—Any individual appointed to fill a vacancy on the Board that occurs prior to the expiration of the term for which the predecessor was appointed shall be appointed for the remainder of such term.

(3) STAGGERED TERMS.—Terms of the initial Board members appointed under paragraphs (11) and (12) of subsection (a) shall be determined by the President at the time of the appointment in accordance with the following:

(A) One industry and one university representative shall be appointed for a term of 4 years.

(B) One industry and one university representative shall be appointed for a term of 3 years.

(C) One industry and one university representative shall be appointed for a term of 2 years.

(D) One industry and one university representative shall be appointed for a term of 1 year.

(4) REAPPOINTMENT.—Nongovernment Board members may be reappointed by the President with the advice and consent of the Senate.

(d) CHAIRMAN.—

(1) SELECTION.—The members of the Board shall select a Chairman from among its members to serve for a term of 2 years.

(2) VACANCY.—In the event of a vacancy in the Chairmanship, the Board shall elect a Chairman to serve the remainder of the unexpired term.

(3) RE-ELECTION.—Chairman may be re-elected by the members of the Board.

(e) MEETING.—

(1) INITIAL MEETING.—Within 90 days after the approval by the Senate of the last member of the initial Board, the Board shall meet to elect a Chairman.

(2) SUBSEQUENT MEETINGS.—The Board shall meet at least twice a year.

SEC. 202. DUTIES AND FUNCTIONS.

The Board shall—

(1) review and appraise the various programs and activities of the Federal Government relating to biotechnology, including the amount and type of biotechnology-related research conducted or funded by Federal agencies;

(2) review and appraise the extent and nature of privately-funded biotechnology activities, including *non-confidential* research, both basic and applied, and the development of commercial biotechnology-related industries and products;

(3) submit recommendations to the President and Congress, where appropriate, concerning—

(A) policies that will enhance the efficient and timely advance of basic and applied biotechnology-related research;

(B) methods to enhance the competitiveness of the United States in the development of commercial biotechnology-related industries and products;

(C) policies that will ensure the training of sufficient numbers of scientists, engineers, and laboratory personnel for the continued leadership of the United States in biotechnology-related basic

and applied research and the development of the biotechnology industries of the United States;

(D) Federal participation in proposed cooperative research initiatives involving governmental and private entities;

(E) regulatory policies that affect biotechnology industries and the products thereof; and

(F) policies that will enhance the transfer of technology from university and Federal research laboratories to commercial laboratories so as to allow the efficient and timely commercialization of Federally funded discoveries.

SEC. 203. REPORTS.

Not later than January 31, 1990, and not later than January 31, of each even-numbered year thereafter, the Board shall submit, to the President and to the Congress a report that contains recommendations described in section 2(3). The Board shall submit additional reports and recommendations as the Board considers necessary, or on the demand of the President or Congress. Reports shall be published and made available to the public.

SEC. 204. STAFF AND PERSONNEL.

(a) EXECUTIVE DIRECTOR.—

(1) APPOINTMENT.—The Board shall appoint an Executive Director, who shall serve at the pleasure of the Board.

(2) DUTIES.—The Executive Director shall report directly to the Board and perform such duties and functions as the Board may prescribe.

~~(3) COMPENSATION.—The Executive Director shall be compensated at a rate not to exceed that provided for a position at level 4 of the Executive Schedule under section 5315 of title 5, United States Code.~~

(b) OTHER PERSONNEL.—The Board may employ such other officers and employees as may be necessary to carry out the duties and responsibilities of the Board and its advisory panels~~, at rates not to exceed the rates prescribed for grade GS–14 of the General Schedule in section 5332 of title 5, United States Code.~~

(c) VOLUNTARY SERVICES.—Notwithstanding section 665(b) of title 31, United States Code, the Board may accept and employ voluntary and uncompensated services in furtherance of the purposes of the Board.

SEC. 205. COORDINATION WITH OTHER AGENCIES.

(a) IN GENERAL.—The Board shall work in consultation with other Federal agencies (including such agencies

represented on the Board) and in consultation with other Boards and Commissions as may be appropriate, including the Biomedical Ethics Board and the New Products Research Board.

(b) BIOMEDICAL ETHICS BOARD.—The Biomedical Ethics Board shall review prior to publication, and as appropriate comment, on reports issued by the Board and the advisory panels established pursuant to subsection (d)(2).

~~(b)~~ *(c)* INFORMATION.—Each department, agency, and instrumentality of the Executive branch of the Federal government and each independent agency and other governmental organization, including the Office of Technology Assessment, shall furnish the Board with such information as the Board shall consider necessary and appropriate to assist the Board in carrying out its functions and duties.

~~(c)~~ *(d)* CONSULTATIONS.—The Board may—

(1) utilize the services of consultants;

(2) establish advisory panels; and

(3) to the extent practicable, consult with—

(A) State and local governments;

(B) appropriate professional and industry groups;

(C) representatives of university, industry, labor, consumer and other public interest groups; and

(D) individuals as is appropriate.

~~(d)~~ *(e)* HEARINGS.—The Board may hold hearings and meetings in various parts of the United States as may be appropriate in carrying out the functions and duties of the Board.

~~(e)~~ *(f)* DUPLICATION AND REIMBURSEMENT.—

(1) DUPLICATION.—The Board shall utilize, to the fullest extent possible, the services, personnel, equipment, facilities, and information of public and private agencies and organizations, and individuals, in order to avoid duplication of effort and expense.

(2) REIMBURSEMENT.—The Board may transfer funds made available pursuant to this title to other Federal agencies as may be appropriate to reimburse such agencies for the utilization of agency personnel, services, facilities, equipment and information.

SEC. 206. COMPENSATION OF MEMBERS.

(a) NONGOVERNMENT MEMBERS.—Each member of the Board that is not otherwise in the service of the Federal government shall receive a sum equivalent to the compensation provided at level IV of the Executive Salary Schedule under section 5315 of title 5, United States Code, prorated on a daily basis for each day spent in service to the Board, and shall be paid actual travel expenses, and per diem in lieu of subsistence expenses in accordance with section 5703 of

title 5, United States Code, when such member is away from the members usual place of residence.

(b) GOVERNMENT MEMBERS.—Each member of the Board that is otherwise in the service of the Federal government shall serve without compensation in addition to that received for such other service, but while engaged in the work of the Board, such member shall be paid actual travel expenses, and per diem in lieu of subsistence expenses in accordance with subchapter I of chapter 57 of title 5, United States Code, when away from the members usual place of residence.

SEC. 207. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title $2,000,000 in fiscal year 1989, $2,500,000 in each of the fiscal years 1990 and 1991, and $3,000,000 in each of the fiscal years 1992 and 1993.

Subtitle B—Human Genome Research and Development

SEC. 211. FINDINGS.

Congress finds that—

(1) knowledge relating to the location and sequences of genes on human chromosomes and those of other organisms will enable more rapid elucidation of the basis for developmental processes and for human disease;

(2) comprehensive understanding of human genetic make-up, and the genetics of other organisms, will enhance our ability to develop methods for the prevention and treatment of disease states;

(3) advances in biomedical research and technologies have enabled rapid progress in the localization of genes to specific human chromosomes;

(4) a number of Federal agencies (including the National Institutes of Health, the Department of Energy, and the National Science Foundation) are presently funding research related to the mapping and sequencing of genes within the human genome or basic biomedical research, or the development of new technologies and instruments for this research; and

(5) in order to most efficiently expend research funds, and to most expeditiously advance our understanding of human genetics, it is essential that the agencies involved coordinate their research efforts.

SEC. 212. NATIONAL ADVISORY PANEL ON THE HUMAN GENOME.

(a) PURPOSE.—The purpose of this section is to establish a National Advisory Panel on the Human Genome that shall coordinate—

(1) national activities to ensure the construction of maps of human chromosomes and DNA of other orga-

nisms to be used as powerful research tools for biomedical research; and

(2) the development of new tools to analyze DNA, in cooperation with philanthropic, companies, and other private sector interests.

(b) ESTABLISHMENT.—There is established, as an advisory panel to the Board established in subtitle A, a National Advisory Panel on the Human Genome (hereinafter referred to in this subtitle as the "Panel") to advise the Board on matters concerning the mapping and sequencing of human genome.

(c) MEMBERSHIP.—The Panel shall consist of the following individuals or the designees of such individuals—

(1) the Secretary of Energy;

(2) the Director of the National Institutes of Health;

(3) the Director of the National Science Foundation;

(4) the Director of the National Library of Medicine;

(5) four individuals representing private industry, to be appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with members appointed within 90 days

after the date of enactment of this Act, but who shall not be members of the Board;

(6) four individuals representing the university research community, to be recommended by the National Academy of Science and appointed by the President, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act, but who shall not be members of the Board;

(7) one individual with expertise in biomedical ethics, to be recommended by the National Academy of Sciences and appointed by the President, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act; and

(8) one individual representing national foundations, medical institutes, and other philanthropic organizations involved in biomedical research, to be recommended by the National Academy of Sciences and appointed by the President, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act.

(d) CHAIRMEN.—The Panel shall be cochaired by the Secretary of Energy and the Director of the National Institutes of Health or the designees of such.

(e) FUNCTIONS.—The Panel shall—

(1) identify the optimal strategy for mapping and sequencing the human genome utilizing for guidance information and recommendations from previous reports, including those of the Office of Technology Assessment and the National Academy of Sciences;

(2) determine research and development goals that will ensure United States leadership in human genome research;

(3) ensure the quality of scientific and technical work, and establish standards for the collection and storage of data and materials;

(4) assess the need for common research resources such as materials repositories and new data-bases;

(5) monitor relevant research programs supported by Federal agencies and private funding sources;

(6) identify commercial opportunities arising from national research programs;

(7) oversee interagency cooperation through data-sharing, joint sponsorship of meetings, joint funding of research resources, and communication of annual budget plans;

(8) assess the need and benefit of international cooperation in mapping and sequencing the human genome; *and*

~~(9) evaluate the ethical considerations of research and development of products from mapping and sequencing the human genome; and~~

~~(10)~~ *(9)* evaluate patent rights and ownership of data on the human genome, and provide advice to interested Federal agencies, the scientific community, and private industry.

(f) REPORTS.—Not later than 18 months after the date of enactment of this section, the Panel shall submit to the Board a report that contains recommendations based on the functions of the Panel under section 212(e). Additional reports shall be submitted to the Board as the Panel considers necessary, or on demand of the Board.

(g) BIOMEDICAL ETHICS BOARD.—The Biomedical Ethics Board shall review, and as appropriate, comment on the ethical and social implications of human genome research.

TITLE III—BIOMEDICAL ETHICS BOARD REAUTHORIZATION

SEC. 301. BIOMEDICAL ETHICS BOARD REAUTHORIZATION.

Subsection (e) of section 381 of the Public Health Service Act (42 U.S.C. 275(e)) is amended to read as follows:

"(e) To enable the Board and the Committee to carry out their functions, there are authorized to be appropriated

$2,000,000 for fiscal year 1989, $2,500,000 for fiscal year 1990, and $3,000,000 for fiscal year 1991.".

Calendar No. 690

100TH CONGRESS
2D SESSION

S. 1966

[Report No. 100–359]

A BILL

To amend the Public Health Service Act to improve information and research on biotechnology and the human genome, and for other purposes.

MAY 25 (legislative day, MAY 18), 1988

Reported with amendments