I

103D CONGRESS
2D SESSION

H. R. 4370

To establish the AIDS Cure Project.

IN THE HOUSE OF REPRESENTATIVES

MAY 10, 1994

Mr. NADLER (for himself, Mr. DELLUMS, Ms. VELÁZQUEZ, Mr. OWENS, and Mr. MILLER of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To establish the AIDS Cure Project.

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 ''AIDS Cure Act''.

SEC. 2. ESTABLISHMENT OF PROJECT TO CURE AIDS.

(a) IN GENERAL.—The President shall in accordance with this Act direct the Secretary of Health and Human Services to establish a project for the purpose of developing a cure for acquired immune deficiency syndrome (in this Act referred to as ''AIDS''). The program may not be administered by any officer or employee of the National

Institutes of Health. Subject to the preceding sentence, the Governing Council shall designate an individual to serve as a liaison between the Governing Council of the project (established under section 4(a)), the Secretary, and the President.

(b) DEFINITION.—For purposes of this Act, the term ''cure'', with respect to AIDS, means any and all approaches which will ensure a well-functioning immune system and a normal life span with a reasonable quality of life.

(c) CERTAIN REQUIREMENTS.—The Governing Council, in carrying out the project under subsection (a), shall ensure that the following requirements are met:

(1) The project shall pursue comprehensive basic science investigations, based on diverse theories and schools of thought which elucidate the pathogenesis of AIDS.

(2) The project shall identify, based on this work, all promising curatives and oversee their timely and adequate testing through the extraordinary powers detailed in section 5.

SEC. 3. OPEN AND PRODUCTIVE RESEARCH PATHS.

The Governing Council, in carrying out the project under section 2, shall ensure that the following requirements are met:

(1)(A) Thorough consideration shall be given to both conventional and other medical approaches and scientific theories, and researchers representing divergent approaches shall be on the primary research staff as well as be contributing researchers.

(B) The project shall aggressively pursue research into all areas of AIDS pathogenesis, including but not limited to—

(i) virological/immunological theories about how immune system damage occurs, including understudied approaches; and

(ii) theories about co-factors which may precede, activate or even substitute for HIV in the process of immune system damage leading to AIDS.

(C) Examination shall be given to the full spectrum of pathogenesis theories, from those maintaining that HIV is the sole and sufficient cause to those considering HIV a primary cause together with co-factors to those believing that HIV does not necessarily play a causative role.

(D) Further work shall be done on the potential role of recreational drugs and environmental toxins in progression. The role of nutrition, exercise, and adequate primary health care must also be re-

searched in the project. Psychoneuroimmunology and the connections between psychological stress and immune compromise shall also be studied.

(E) A diversity of theories should be developed and tested through both laboratory experiments and epidemiological research, including careful examination of cases of people with HIV and AIDS and interviews with people with HIV and AIDS and their care providers including but not limited to primary care clinicians, gynecologists, nutritionists, alternative or holistic practitioners, and mental health workers.

(F) All research funded in this Act shall be conducted in conformity with the ethics and privacy of current medical research.

(G) Researchers shall study epidemiological and blood studies of long-term survivors from diverse populations to attempt to isolate the factors that have sustained them.

(H) Consideration shall be given to the hypotheses and results obtained in other countries. Researchers from other countries shall be invited to participate in the project. This may include agreements with another country to reassign particular researchers to the project for an indefinite commit-

ment. The project's progress shall not await the conclusion of such international agreements.

(2) The project's study of AIDS pathogenesis and manifestations must focus on all populations of people with AIDS and HIV. Equal consideration shall be given to the differences between these populations as to their similarities or norms. This includes, but is not limited to people of all age groups (including children and seniors), gender, sexual orientation, women (regardless of reproductive health status), gay men, lesbians, people of color (of various affected national-cultural groups), injection drug users, prison inmates, people with hemophilia and people with inadequate medical care or nutrition (or both), and persons with disabilities and chronic conditions related to AIDS.

(3) Basic science investigations and therapeutic results shall be geared to people at every point on the spectrum of AIDS and HIV—from the sickest to the healthiest. Saving people considered near death must be considered as important as early intervention.

(4) Information generated by the project shall be made freely available worldwide to researchers, health care providers, people with AIDS and HIV

and their advocates as soon as it is available, without being inhibited by professional publication practices. Funds shall be available as needed for the dissemination and translation of project materials.

(5) Curatives and therapies ultimately released due primarily to project research shall not result in financial gain to any private organization, and shall be made available to all affected people worldwide regardless of ability to pay. The project shall be responsible for establishing a mechanism for international funding and distribution of any such curatives.

SEC. 4. EFFICIENT AND COOPERATIVE MANAGEMENT OF PROJECT.

(a) GOVERNING COUNCIL.—

(1) IN GENERAL.—The project under section 2 shall be governed by, not merely advised by, a council composed of scientists and clinicians representing divergent approaches, and people with AIDS and HIV, and their advocates, from all affected communities. This council shall set policy and oversee research priorities, ethical standards, conflict of interest rules and hiring of researchers, and administrators.

(2) CERTAIN AUTHORITIES.—The Secretary shall ensure that the following requirements are met with respect to the council under paragraph (1):

(A) The council shall be composed of scientists representing divergent approaches, clinicians with both research and community-based experience and people with AIDS and HIV and their advocates.

(B) The council shall have at least 21 members in order to adequately represent diverse communities, opinions and disciplines. People with AIDS and HIV from diverse communities shall be in the majority to ensure that the project staff are ultimately accountable to people directly affected by the course and outcome of the research. Council members shall step down and be replaced by new members on a regular basis.

(C) The Council shall set policy for and oversee research priorities. It shall develop guidelines for and oversee the hiring of primary research staff, ensuring both high quality (scientific credentials and experience) and a diversity of disciplines and perspectives (including alternative'' or holistic approaches). Having

pursued specific AIDS theories shall not be a necessary prerequisite for hiring. The Council shall have the power to create new research positions when necessary and to remove scientists from their positions after due process and appropriate review of their work.

(D) The Council shall be charged with evaluating the work of the project, as well as the pace of the research, to ensure that it matches the urgency of the epidemic. Initially, and throughout the life of the project, the Council, in cooperation with the primary research staff, shall solicit and evaluate theories developed outside the project. It shall direct the project scientists to evaluate and respond to deserving proposals and to devise new research plans where desirable.

(E) The Council shall adopt strict, detailed codes governing medical ethics and conflicts of interest and shall monitor compliance with these codes. Project scientists shall report directly to the council about the progress of their work in a manner to be determined by the council. The Council shall report to the Presi-

dent through the liaison about the progress of the project.

(F) Council meetings, including those at which all decisions are made, shall be public and shall be held at least quarterly, with time allotted for public comment. In addition, the Council shall hold an annual public hearing on its priorities and progress. A complete report of the project's goals and accomplishments shall be updated by the Council, submitted to the President and released to the public at least once quarterly. The Council shall evaluate its structure and process at least once per year and make changes which allow it to function more effectively.

(G) Members of the Governing Council will not be paid employees of the project. However, the Governing Council will be provided with an operating budget, including but not limited to, the following purposes: Support staff; creation and dissemination of reports and other materials; funds for transportation and other per diem expenses; and funds for convening public meetings.

(b) REQUIREMENTS.—The Governing Council, in carrying out the project under section 2, shall ensure that the following requirements are met:

(1) The project shall establish a primary location for its work, in an area with a high incidence of AIDS. All primary research staff shall work at that location; contributing researchers located around the world shall interact via video teleconferencing, an international computer network, and regularly scheduled face-to-face meetings.

(2) The National Institutes of Health's existing AIDS research programs shall be maintained. All National Institutes of Health basic science research supplementary to that done by the project shall be performed cooperatively with the project in coordination with the Office of AIDS Research.

(3)(A) All primary research staff and administrators shall be financially compensated only by the project and may not have conflicts of interests with private or public organizations (including but not limited to universities, pharmaceutical companies, and private research organizations).

(B) All primary research staff and administrators shall be required to suspend their relationship with any private or public organizations for the du-

ration of their association with the project. These requirements shall include full-time, part-time, or consultant positions with a private or public organization or other government agencies, and the suspension would include employment, consulting or board membership fees, and stock or business ownership.

(C) The Governing Council members shall be required to suspend their relationship with for-profit organizations which represent a conflict of interest.

(4) The project shall be funded by public, not private monies. Appropriations for the project shall not be diverted from other health research, health care, or human service programs.

(5) The project shall, in addition to basic research investigations, operate an on-site clinic to conduct small scale research trials with human participants if such trials are crucial for testing hypotheses related to its basic research.

(c) COORDINATING COMMITTEE.—The Governing Council shall ensure that a coordinating committee is established for the project under section 2, in accordance with the following:

(1) The community of scientists selected for the project shall elect three of their members to serve as the coordinating committee for the project, and de-

termine whether these positions should be permanent or rotating.

(2) The coordinating committee shall be responsible for facilitating communication among the different scientists working on the project, for evaluating the progress of its work, and for convening the entire staff on a regular schedule (or when necessary) to evaluate the progress of the project as a whole, identify gaps in research, reevaluate the project's direction, and to consider newly developed theories emanating from both within and outside the project.

(3) The coordinating committee shall also be responsible for keeping the Governing Council informed of the progress of the project's work, at times and in a manner to be determined by the Governing Council. The coordinating committee shall also make decisions regarding the hiring of research associates, technical staff, purchases of equipment and other day-to-day needs.

(4) The first task of the coordinating committee shall be to facilitate a preliminary review of all existing pathogenesis hypotheses, as well as other relevant information about AIDS pathogenesis. At the end of this review, which shall last no longer than

3 months, the primary research staff shall collectively develop plans for evaluating and testing each of the viable hypotheses, including timelines for evaluating the progress of this work, and submit these plans to the Governing Council for review and comments.

(d) SELECTION OF GOVERNING COUNCIL.—

(1) IN GENERAL.—The Secretary of Health and Human Services (HHS) shall convene a national AIDS congress to make recommendations to the President for selecting the Governing Council. The AIDS congress will meet only once, and for the sole purpose of nominating the initial Governing Council. The Secretary of HHS shall solicit nominations from a wide variety of sources, including, but not limited to, each of the following: AIDS activist groups; health care providers; AIDS advocacy organizations; AIDS service organizations; community-based AIDS research organization; biomedical researchers and nonmainstream (including alternative or holistic) medical organizations; and health care planning agencies, who shall send their nominations for the Governing Council to the AIDS congress. The AIDS congress will make recommendations to the President for the Governing Council. The President shall

select the Governing Council based on the recommendations of the AIDS congress. The AIDS congress will consist of 2 representatives chosen by each of the HIV health services planning councils under section 2602(b) of the Public Health Service Act, chosen in a forum that is open to the public by each of the HIV planning councils. The President shall widely publicize the request for nominations.

(2) DATE CERTAIN FOR SELECTION.—In keeping with the emergency nature of this project, the nomination and selection process must be completed within 3 months of the enactment of this Act.

SEC. 5. EXTRAORDINARY POWERS.

In carrying out the project under section 2, the Governing Council shall have extraordinary powers to carry out the following:

(1)(A) Utilize, in cooperation with the agencies, any and all existing United States Government funded research entities nationwide (including but not limited to the AIDS Clinical Trial Group (ACTG), the Community Program for Clinical Research on AIDS (CPCRA)), and their facilities to clinically test promising cures developed on the basis of its research and to direct the manner in which such research shall proceed, including staffing, participants,

location, and timing. Such research shall be funded by the project.

(B) The project shall design its own protocols and work with these existing clinical trial programs to develop research designs and methods appropriate to the project's goals, assuring that data gathered by the NIH would accurately reflect the use of these compounds in all populations and stages of illness.

(C) The project shall provide funding for these clinical trials of its own compounds. In areas of conflict, the project shall have the power to implement its goals.

(2) Exercise the right of eminent domain to carry out the following:

(A)(i) Obtain from public and private organizations, with just compensation, samples of all potential curatives and all data (excluding medical records) regarding their development (including safety and efficacy data) as well as other information, materials, or products deemed crucial to the project, but protect the privacy of research subjects and the researcher over which the project will be exercising the right of eminent domain. The project shall use

its power of eminent domain only after reasonable attempts at cooperation have failed.

(ii) To use eminent domain power, the project must determine and identify whether this research is essential information to the project's research and that it is unavailable other than through eminent domain.

(iii) Once obtaining through eminent domain the research of an outside researcher, the project shall make all efforts to preserve appropriate recognition of the scientist's work. The project shall also afford any researcher, whose work is acquired through eminent domain, an opportunity to participate in the project with just compensation.

(B) If a drug company is found to be impeding or halting the development of a promising compound, the project shall first attempt to work with the company to develop the needed timetable for research and trials. A company lacking the resources to develop a compound shall have the option of selling the patent to the project for just compensation, or allowing portions of its development to be undertaken by the project.

(C) If, however, a company refuses to cooperate with the project by not releasing needed data, or by withholding samples of requested compounds, whether under development or not, the project is authorized to use powers of eminent domain to procure samples and data. The project shall have the power to obtain the patents of such compounds if, after reasonable attempts at cooperation, it finds that a company will not develop a promising compound according to an approved timeframe by the coordinating committee. After notification by the project that this power will be used, a company shall have 30 days in which to develop, for the project's approval, a plan for accelerated development of the compound to avoid losing exclusive rights to the patent. Unless said companies adhere to an approved timeframe and are forthcoming with their data as such work proceeds, then the project can implement clinical testing for potential curatives by private companies.

(D) Use existing pharmaceutical company facilities (with just compensation) for the production of promising curatives to be utilized in project research and, if effective, to produce

such curatives in sufficient amounts to be disseminated to all people needing them.

SEC. 6. PLANNING FUNDS.

Funds shall be allocated immediately to be used for planning of the project under section 2 (including creating facilities, selection of staff, funding, structure, and schedules), so that the project can begin functioning as soon as is possible.

SEC. 7. REAUTHORIZATION OF PROJECT.

After 5 years of operation, the Congress shall have the power to reauthorize the project under section 2.

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