

104TH CONGRESS
1ST SESSION

H. R. 761

To establish the AIDS Cure Project.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 1995

Mr. NADLER (for himself, Mr. DELLUMS, Ms. VELÁZQUEZ, Mr. OWENS, Mr. MILLER of California, Mr. ABERCROMBIE, Mr. Lewis of Georgia, Mr. McDERMOTT, Mr. TRAFICANT, Mr. PALLONE, Mr. ACKERMAN, Mr. DEUTSCH, Mrs. MALONEY, Mr. YATES, and Mr. ENGEL) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To establish the AIDS Cure Project.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “AIDS Cure Act”.

5 **SEC. 2. ESTABLISHMENT OF PROJECT TO CURE AIDS.**

6 (a) IN GENERAL.—The President shall in accordance
7 with this Act direct the Secretary of Health and Human
8 Services to establish a project for the purpose of develop-
9 ing a cure for acquired immune deficiency syndrome (in
10 this Act referred to as “AIDS”). The program may not

1 be administered by any officer or employee of the National
2 Institutes of Health. Subject to the preceding sentence,
3 the Governing Council shall designate an individual to
4 serve as a liaison between the Governing Council of the
5 project (established under section 4(a)), the Secretary,
6 and the President.

7 (b) DEFINITION.—For purposes of this Act, the term
8 “cure”, with respect to AIDS, means any and all ap-
9 proaches which will ensure a well-functioning immune sys-
10 tem and a normal life span with a reasonable quality of
11 life.

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

15 (1) The project shall pursue comprehensive
16 basic science investigations, based on diverse theo-
17 ries and schools of thought which elucidate the
18 pathogenesis of AIDS.

19 (2) The project shall identify, based on this
20 work, all promising curatives and oversee their time-
21 ly and adequate testing through the extraordinary
22 powers detailed in section 5.

1 **SEC. 3. OPEN AND PRODUCTIVE RESEARCH PATHS.**

2 The Governing Council, in carrying out the project
3 under section 2, shall ensure that the following require-
4 ments are met:

5 (1)(A) Thorough consideration shall be given to
6 both conventional and other medical approaches and
7 scientific theories, and researchers representing di-
8 vergent approaches shall be on the primary research
9 staff as well as be contributing researchers.

10 (B) The project shall aggressively pursue re-
11 search into all areas of AIDS pathogenesis, includ-
12 ing but not limited to—

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

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

20 (C) Examination shall be given to the full spec-
21 trum of pathogenesis theories, from those maintain-
22 ing that HIV is the sole and sufficient cause to
23 those considering HIV a primary cause together
24 with co-factors to those believing that HIV does not
25 necessarily play a causative role.

1 (D) Further work shall be done on the potential
2 role of recreational drugs and environmental toxins
3 in progression. The role of nutrition, exercise, and
4 adequate primary health care must also be re-
5 searched in the project. Psychoneuroimmunology
6 and the connections between psychological stress and
7 immune compromise shall also be studied.

8 (E) A diversity of theories should be developed
9 and tested through both laboratory experiments and
10 epidemiological research, including careful examina-
11 tion of cases of people with HIV and AIDS and
12 interviews with people with HIV and AIDS and their
13 care providers including but not limited to primary
14 care clinicians, gynecologists, nutritionists, alter-
15 native or holistic practitioners, and mental health
16 workers.

17 (F) All research funded in this Act shall be con-
18 ducted in conformity with the ethics and privacy of
19 current medical research.

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

24 (H) Consideration shall be given to the
25 hypotheses and results obtained in other countries.

1 Researchers from other countries shall be invited to
2 participate in the project. This may include agree-
3 ments with another country to reassign particular
4 researchers to the project for an indefinite commit-
5 ment. The project's progress shall not await the con-
6 clusion of such international agreements.

7 (2) The project's study of AIDS pathogenesis
8 and manifestations must focus on all populations of
9 people with AIDS and HIV. Equal consideration
10 shall be given to the differences between these popu-
11 lations as to their similarities or norms. This in-
12 cludes, but is not limited to people of all age groups
13 (including children and seniors), gender, sexual ori-
14 entation, women (regardless of reproductive health
15 status), gay men, lesbians, people of color (of var-
16 ious affected national-cultural groups), injection
17 drug users, prison inmates, people with hemophilia
18 and people with inadequate medical care or nutrition
19 (or both), and persons with disabilities and chronic
20 conditions related to AIDS.

21 (3) Basic science investigations and therapeutic
22 results shall be geared to people at every point on
23 the spectrum of AIDS and HIV—from the sickest to
24 the healthiest. Saving people considered near death

1 must be considered as important as early interven-
2 tion.

3 (4) Information generated by the project shall
4 be made freely available worldwide to researchers,
5 health care providers, people with AIDS and HIV
6 and their advocates as soon as it is available, with-
7 out being inhibited by professional publication prac-
8 tices. Funds shall be available as needed for the dis-
9 semination and translation of project materials.

10 (5) Curatives and therapies ultimately released
11 due primarily to project research shall not result in
12 financial gain to any private organization, and shall
13 be made available to all affected people worldwide
14 regardless of ability to pay. The project shall be re-
15 sponsible for establishing a mechanism for inter-
16 national funding and distribution of any such
17 curatives.

18 **SEC. 4. EFFICIENT AND COOPERATIVE MANAGEMENT OF**

19 **PROJECT.**

20 (a) GOVERNING COUNCIL.—

21 (1) IN GENERAL.—The project under section 2
22 shall be governed by, not merely advised by, a coun-
23 cil composed of scientists and clinicians representing
24 divergent approaches, and people with AIDS and
25 HIV, and their advocates, from all affected commu-

1 nities. This council shall set policy and oversee re-
2 search priorities, ethical standards, conflict of inter-
3 est rules and hiring of researchers, and administra-
4 tors.

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

8 (A) The council shall be composed of sci-
9 entists representing divergent approaches, clini-
10 cians with both research and community-based
11 experience and people with AIDS and HIV and
12 their advocates.

13 (B) The council shall have at least 21
14 members in order to adequately represent di-
15 verse communities, opinions and disciplines.
16 People with AIDS and HIV from diverse com-
17 munities shall be in the majority to ensure that
18 the project staff are ultimately accountable to
19 people directly affected by the course and out-
20 come of the research. Council members shall
21 step down and be replaced by new members on
22 a regular basis.

23 (C) The Council shall set policy for and
24 oversee research priorities. It shall develop
25 guidelines for and oversee the hiring of primary

1 research staff, ensuring both high quality (sci-
2 entific credentials and experience) and a diver-
3 sity of disciplines and perspectives (including
4 alternative” or holistic approaches). Having
5 pursued specific AIDS theories shall not be a
6 necessary prerequisite for hiring. The Council
7 shall have the power to create new research po-
8 sitions when necessary and to remove scientists
9 from their positions after due process and ap-
10 propriate review of their work.

11 (D) The Council shall be charged with
12 evaluating the work of the project, as well as
13 the pace of the research, to ensure that it
14 matches the urgency of the epidemic. Initially,
15 and throughout the life of the project, the
16 Council, in cooperation with the primary re-
17 search staff, shall solicit and evaluate theories
18 developed outside the project. It shall direct the
19 project scientists to evaluate and respond to de-
20 serving proposals and to devise new research
21 plans where desirable.

22 (E) The Council shall adopt strict, detailed
23 codes governing medical ethics and conflicts of
24 interest and shall monitor compliance with
25 these codes. Project scientists shall report di-

1 rectly to the council about the progress of their
2 work in a manner to be determined by the
3 council. The Council shall report to the Presi-
4 dent through the liaison about the progress of
5 the project.

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

19 (G) Members of the Governing Council will
20 not be paid employees of the project. However,
21 the Governing Council will be provided with an
22 operating budget, including but not limited to,
23 the following purposes: Support staff; creation
24 and dissemination of reports and other mate-
25 rials; funds for transportation and other per

1 diem expenses; and funds for convening public
2 meetings.

3 (b) REQUIREMENTS.—The Governing Council, in car-
4 rying out the project under section 2, shall ensure that
5 the following requirements are met:

6 (1) The project shall establish a primary loca-
7 tion for its work, in an area with a high incidence
8 of AIDS. All primary research staff shall work at
9 that location; contributing researchers located
10 around the world shall interact via video teleconfer-
11 encing, an international computer network, and reg-
12 ularly scheduled face-to-face meetings.

13 (2) The National Institutes of Health's existing
14 AIDS research programs shall be maintained. All
15 National Institutes of Health basic science research
16 supplementary to that done by the project shall be
17 performed cooperatively with the project in coordina-
18 tion with the Office of AIDS Research.

19 (3)(A) All primary research staff and adminis-
20 trators shall be financially compensated only by the
21 project and may not have conflicts of interests with
22 private or public organizations (including but not
23 limited to universities, pharmaceutical companies,
24 and private research organizations).

1 (B) All primary research staff and administra-
2 tors shall be required to suspend their relationship
3 with any private or public organizations for the du-
4 ration of their association with the project. These re-
5 quirements shall include full-time, part-time, or con-
6 sultant positions with a private or public organiza-
7 tion or other government agencies, and the suspen-
8 sion would include employment, consulting or board
9 membership fees, and stock or business ownership.

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

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

17 (5) The project shall, in addition to basic re-
18 search investigations, operate an on-site clinic to
19 conduct small scale research trials with human par-
20 ticipants if such trials are crucial for testing
21 hypotheses related to its basic research.

22 (c) COORDINATING COMMITTEE.—The Governing
23 Council shall ensure that a coordinating committee is es-
24 tablished for the project under section 2, in accordance
25 with the following:

1 (1) The community of scientists selected for the
2 project shall elect three of their members to serve as
3 the coordinating committee for the project, and de-
4 termine whether these positions should be perma-
5 nent or rotating.

6 (2) The coordinating committee shall be respon-
7 sible for facilitating communication among the dif-
8 ferent scientists working on the project, for evaluat-
9 ing the progress of its work, and for convening the
10 entire staff on a regular schedule (or when nec-
11 essary) to evaluate the progress of the project as a
12 whole, identify gaps in research, reevaluate the
13 project's direction, and to consider newly developed
14 theories emanating from both within and outside the
15 project.

16 (3) The coordinating committee shall also be re-
17 sponsible for keeping the Governing Council in-
18 formed of the progress of the project's work, at
19 times and in a manner to be determined by the Gov-
20 erning Council. The coordinating committee shall
21 also make decisions regarding the hiring of research
22 associates, technical staff, purchases of equipment
23 and other day-to-day needs.

24 (4) The first task of the coordinating committee
25 shall be to facilitate a preliminary review of all exist-

1 ing pathogenesis hypotheses, as well as other rel-
2 evant information about AIDS pathogenesis. At the
3 end of this review, which shall last no longer than
4 3 months, the primary research staff shall collec-
5 tively develop plans for evaluating and testing each
6 of the viable hypotheses, including timelines for eval-
7 uating the progress of this work, and submit these
8 plans to the Governing Council for review and com-
9 ments.

10 (d) SELECTION OF GOVERNING COUNCIL.—

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

1 Governing Council to the AIDS congress. The AIDS
2 congress will make recommendations to the Presi-
3 dent for the Governing Council. The President shall
4 select the Governing Council based on the rec-
5 ommendations of the AIDS congress. The AIDS
6 congress will consist of 2 representatives chosen by
7 each of the HIV health services planning councils
8 under section 2602(b) of the Public Health Service
9 Act, chosen in a forum that is open to the public
10 by each of the HIV planning councils. The President
11 shall widely publicize the request for nominations.

12 (2) DATE CERTAIN FOR SELECTION.—In keep-
13 ing with the emergency nature of this project, the
14 nomination and selection process must be completed
15 within 3 months of the enactment of this Act.

16 **SEC. 5. EXTRAORDINARY POWERS.**

17 In carrying out the project under section 2, the Gov-
18 erning Council shall have extraordinary powers to carry
19 out the following:

20 (1)(A) Utilize, in cooperation with the agencies,
21 any and all existing United States Government fund-
22 ed research entities nationwide (including but not
23 limited to the AIDS Clinical Trial Group (ACTG),
24 the Community Program for Clinical Research on
25 AIDS (CPCRA)), and their facilities to clinically

1 test promising cures developed on the basis of its re-
2 search and to direct the manner in which such re-
3 search shall proceed, including staffing, participants,
4 location, and timing. Such research shall be funded
5 by the project.

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

12 (C) The project shall provide funding for these
13 clinical trials of its own compounds. In areas of con-
14 flict, the project shall have the power to implement
15 its goals.

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

18 (A)(i) Obtain from public and private orga-
19 nizations, with just compensation, samples of
20 all potential curatives and all data (excluding
21 medical records) regarding their development
22 (including safety and efficacy data) as well as
23 other information, materials, or products
24 deemed crucial to the project, but protect the
25 privacy of research subjects and the researcher

1 over which the project will be exercising the
2 right of eminent domain. The project shall use
3 its power of eminent domain only after reason-
4 able attempts at cooperation have failed.

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

10 (iii) Once obtaining through eminent do-
11 main the research of an outside researcher, the
12 project shall make all efforts to preserve appro-
13 priate recognition of the scientist's work. The
14 project shall also afford any researcher, whose
15 work is acquired through eminent domain, an
16 opportunity to participate in the project with
17 just compensation.

18 (B) If a drug company is found to be im-
19 peding or halting the development of a promis-
20 ing compound, the project shall first attempt to
21 work with the company to develop the needed
22 timetable for research and trials. A company
23 lacking the resources to develop a compound
24 shall have the option of selling the patent to the
25 project for just compensation, or allowing por-

1 tions of its development to be undertaken by
2 the project.

3 (C) If, however, a company refuses to co-
4 operate with the project by not releasing needed
5 data, or by withholding samples of requested
6 compounds, whether under development or not,
7 the project is authorized to use powers of emi-
8 nent domain to procure samples and data. The
9 project shall have the power to obtain the pat-
10 ents of such compounds if, after reasonable at-
11 tempts at cooperation, it finds that a company
12 will not develop a promising compound accord-
13 ing to an approved timeframe by the coordinat-
14 ing committee. After notification by the project
15 that this power will be used, a company shall
16 have 30 days in which to develop, for the
17 project's approval, a plan for accelerated devel-
18 opment of the compound to avoid losing exclu-
19 sive rights to the patent. Unless said companies
20 adhere to an approved timeframe and are forth-
21 coming with their data as such work proceeds,
22 then the project can implement clinical testing
23 for potential curatives by private companies.

24 (D) Use existing pharmaceutical company
25 facilities (with just compensation) for the pro-

1 duction of promising curatives to be utilized in
2 project research and, if effective, to produce
3 such curatives in sufficient amounts to be dis-
4 seminated to all people needing them.

5 **SEC. 6. PLANNING FUNDS.**

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

11 **SEC. 7. REAUTHORIZATION OF PROJECT.**

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

○

HR 761 IH—2