

103^D CONGRESS
1ST SESSION

H. R. 3310

To establish the Barbara McClintock Project to Cure AIDS.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 19, 1993

Mr. NADLER introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To establish the Barbara McClintock Project to Cure AIDS.

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 “Barbara McClintock
5 AIDS Cure Act”.

6 **SEC. 2. ESTABLISHMENT OF BARBARA MCCLINTOCK**
7 **PROJECT FOR CURING AIDS.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services shall in accordance with this Act estab-
10 lish a project for the purpose of developing a cure for ac-
11 quired immune deficiency syndrome (in this Act referred
12 to as “AIDS”). The program may not be administered by

1 any officer or employee of the National Institutes of
2 Health. Subject to the preceding sentence, the Secretary
3 shall designate an official of the Department of Health
4 and Human Services to be the head of such project, and
5 shall carry out this Act acting through such official.

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

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

14 (1) The project shall pursue any and all basic
15 science investigations, based on diverse theories and
16 schools of thought which elucidate the pathogenesis
17 of AIDS.

18 (2) The project shall identify, based on this
19 work, all promising curatives and to oversee their
20 timely and adequate testing through the extraor-
21 dinary powers detailed in section 5.

1 **SEC. 3. EFFICIENT AND COOPERATIVE MANAGEMENT OF**
2 **PROJECT.**

3 (a) IN GENERAL.—The Secretary, in carrying out the
4 project under section 2, shall ensure that the following re-
5 quirements are met:

6 (1) The project shall establish one central loca-
7 tion for its work. All primary research staff shall
8 work at that location; contributing researchers lo-
9 cated around the world shall interact via video tele-
10 conferencing, an international computer network,
11 and regularly scheduled face-to-face meetings.

12 (2) The National Institute of Health's existing
13 AIDS research programs shall be maintained. All
14 National Institute of Health basic science research
15 supplementary to that done by the Project shall be
16 performed cooperatively with the project.

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

23 (B) All primary research staff and administra-
24 tors shall be required to suspend their relationship
25 with any private organizations for the duration of
26 their association with the project. Policy council

1 members shall be required to suspend their relation-
2 ship with for-profit organizations which represent a
3 conflict of interest.

4 (C) These requirements shall include full-time,
5 part-time, or consultant positions with a private or-
6 ganization or other government agencies, and the
7 suspension would include employment, consulting or
8 board membership fees, and stock or business own-
9 ership.

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

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

19 (b) GOVERNING COUNCIL.—

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

1 search priorities, ethical standards, conflict of inter-
2 est rules and hiring of researchers.

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

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

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

21 (C) The Council shall set policy for and
22 oversee research priorities. It shall develop
23 guidelines for and oversee the hiring of primary
24 research staff, ensuring both high quality (sci-
25 entific credentials and experience) and a diver-

1 sity of disciplines and perspectives. Have pur-
2 sued specific AIDS theories shall not be a nec-
3 essary prerequisite for hiring. The Council shall
4 have the power to create new research positions
5 when necessary and to remove scientists from
6 their positions after due process and appro-
7 priate review of their work.

8 (D) The Council shall be charged with
9 evaluating the work of the project, as well as
10 the pace of the research, to insure that it
11 matches the urgency of the epidemic. Initially,
12 and throughout the life of the project, the
13 Council, in cooperation with the primary re-
14 search staff, shall solicit and evaluate all new
15 theories developed outside the Project. It shall
16 direct the Project scientists to evaluate and re-
17 spond to deserving proposals and to devise new
18 research plans where desirable.

19 (E) The council shall adopt strict, detailed
20 codes governing medical ethics and conflicts of
21 interest and shall monitor compliance with
22 these codes. Project scientists shall report di-
23 rectly to the council about the progress of their
24 work in a manner to be determined by the

1 council. The council shall report directly to the
2 President about the progress of the project.

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

16 (c) COORDINATING COUNCIL.—The Secretary shall
17 ensure that a coordinating committee is established for the
18 project under section 2, in accordance with the following:

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

24 (2) The coordinating committee shall be respon-
25 sible for facilitating communication among the dif-

1 ferent scientists working on the project, for evaluat-
2 ing the progress of its work, and for convening the
3 entire staff on some regular schedule (or when nec-
4 essary) to evaluate the progress of the project as a
5 whole, reevaluate its direction, and to consider newly
6 developed theories emanating from both within and
7 outside the project.

8 (3) The coordinating committee shall also be re-
9 sponsible for keeping the policy council informed of
10 the progress of the project's work, at times and in
11 a manner to be determined by the policy council.
12 The coordinating committee shall also make deci-
13 sions regarding the hiring of research associates,
14 technical staff, purchases of equipment and other
15 day-to-day needs.

16 (4) The first task of the coordinating committee
17 shall be to facilitate an intensive preliminary review,
18 lasting no more than three months, of all existing
19 pathogenesis hypotheses, as well as other relevant
20 information about AIDS pathogenesis. At the end of
21 this review, the primary research staff shall collec-
22 tively develop plans for evaluating and testing each
23 of the viable hypotheses, including timelines for eval-
24 uating the progress of this work.

1 **SEC. 4. OPEN AND PRODUCTIVE RESEARCH PATHS.**

2 The Secretary, in carrying out the project under sec-
3 tion 2, shall ensure that the following requirements are
4 met:

5 (1)(A) Equal consideration shall be given to
6 conventional and other medical approaches and sci-
7 entific theories, and researchers representing diver-
8 gent approaches shall be on the primary research
9 staff well as be contributing researchers.

10 (B) The project shall aggressively pursue re-
11 search into all areas of AIDS pathogenesis. The two
12 broad categories of theories to be researched by the
13 project are—

14 (i) understudied virological/immunological
15 theories about how immune system damage oc-
16 curs; and

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

21 (C) Further work shall be done on the potential
22 role of recreational drugs (including alcohol) in pro-
23 gression. Nutritional research must also be included
24 in the Project. Several chemical and heavy-metal
25 toxins (including cigarette smoke) must be explored.
26 Psychoneuroimmunology and its connections between

1 psychological stress, lack of social support, and im-
2 mune compromise, shall be studied.

3 (D) Examination shall be given to the full spec-
4 trum of pathogenesis theories, from those maintain-
5 ing that HIV is the sole and sufficient cause to
6 those considering HIV a primary cause together
7 with co-factors to those believing that HIV does not
8 necessarily play a causative role.

9 (E) A diversity of theories should be developed
10 and tested through both laboratory experiments and
11 epidemiological research, including careful examina-
12 tion of existing medical records of people with HIV
13 and AIDS.

14 (F) Researchers shall research epidemiological
15 and blood studies of long-term survivors from di-
16 verse populations to attempt to isolate the factors
17 that have sustained them. Subjective evidence, in-
18 cluding asking people with AIDS and HIV and their
19 care providers what factors they think may be play-
20 ing a role, and how the factors may have interacted,
21 shall be collected to supplement, and help to syn-
22 thesize quantifiable data.

23 (G) Consideration shall be given to the
24 hypotheses and results obtained in other countries,
25 and the best and brightest researchers from other

1 countries shall be aggressively pursued by the
2 project. This may include agreements by another
3 country to reassign particular researchers to the
4 project for an indefinite commitment. The project's
5 progress shall not await the conclusion of such inter-
6 national 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 women, children, gay men, lesbians, people of
13 color (of various affected national-cultural groups),
14 injection drug users, hemophiliacs and people with
15 inadequate medical care and/or nutrition.

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

22 (4) Information generated by the Project shall
23 be made freely available to researchers, health care
24 providers, people with AIDS and HIV and their ad-

1 vocates as soon as it is available, without being in-
2 hibited by professional publication practices.

3 (5) Curatives ultimately released due primarily
4 to project research shall not result in financial gain
5 to any private organization, and shall be made avail-
6 able to all affected people regardless of ability to
7 pay.

8 **SEC. 5. EXTRAORDINARY POWERS.**

9 In carrying out the project under section 2, the Sec-
10 retary shall have extraordinary powers to carry out the
11 following:

12 (1)(A) Direct the utilization of any and all ex-
13 isting United States Government funded research
14 entities and their facilities to clinically test promis-
15 ing cures developed on the basis of its research and
16 to direct the manner in which such research shall
17 proceed, including staffing, participants, location,
18 and timing. Such research shall be funded by the
19 project.

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

1 (C) The project shall provide funding for these
2 clinical trials of its own compounds. In areas of con-
3 flict, the project shall have the power to implement
4 its goals.

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

7 (A) Obtain from public and private organi-
8 zations, with just compensation, samples of all
9 potential curatives and all data regarding their
10 development (including safety and efficacy
11 data) as well as other information, materials, or
12 products deemed crucial to the Project.

13 (B) Implement clinical testing for potential
14 curatives owned by private companies, whether
15 under development or not, unless said compa-
16 nies adhere to an approved time frame and are
17 forthcoming with their data as such work pro-
18 ceeds.

19 (C) Use existing pharmaceutical company
20 facilities (with just compensation) for the pro-
21 duction of promising curatives to be utilized in
22 project research and, if effective, to produce
23 such curatives in sufficient amounts to be dis-
24 seminated to all people needing them.

1 (D) If a drug company is found to be im-
2 peding or halting the development of a promis-
3 ing compound, the project shall first attempt to
4 work with the company to develop the needed
5 timetable for research and trials. A company
6 lacking the resources to develop a compound
7 shall have the option of selling the compound to
8 the project for a just compensation, or allowing
9 portions of its development to be undertaken by
10 the project.

11 (E) If, however, a company refuses to co-
12 operate with the project by not releasing needed
13 data, or by withholding samples of requested
14 compounds, the project is authorized to use
15 powers of eminent domain to procure samples
16 and data. The project shall have the power to
17 obtain the patents of such compounds if, after
18 reasonable attempts at cooperation, it finds that
19 a company will not develop a promising
20 compound in an accelerated fashion. After noti-
21 fication by the project that this power will be
22 used, a company shall have 30 days in which to
23 develop, for the project's approval, a plan for
24 accelerated development of the compound to
25 avoid losing its patent.

1 **SEC. 6. PLANNING FUNDS.**

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

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