

105TH CONGRESS
1ST SESSION

H. R. 1571

To amend the Public Health Service Act to establish programs of research with respect to women and cases of infection with the human immunodeficiency virus.

IN THE HOUSE OF REPRESENTATIVES

MAY 8, 1997

Mrs. MORELLA (for herself, Mr. SHAYS, Ms. MOLINARI, Ms. WATERS, Ms. PELOSI, Mrs. MEEK of Florida, Mr. BOEHLERT, Mr. DELAHUNT, Mr. CUMMINGS, Mr. GILCHREST, Mr. McDERMOTT, Mr. FILNER, Mr. HORN, Mr. HINCHEY, Mr. PAYNE, Mrs. MALONEY of New York, Ms. LOFGREN, Mr. BOUCHER, Mr. CONYERS, Ms. CHRISTIAN-GREEN, Ms. WOOLSEY, Mr. STARK, Mr. THOMPSON, and Ms. BROWN of Florida) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act to establish programs of research with respect to women and cases of infection with the human immunodeficiency virus.

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 “Women and AIDS Re-
5 search Initiative Amendments of 1997”.

1 **SEC. 2. ESTABLISHMENT OF GENERAL PROGRAM OF RE-**
2 **SEARCH REGARDING WOMEN AND ACQUIRED**
3 **IMMUNE DEFICIENCY SYNDROME.**

4 Part B of title XXIII of the Public Health Service
5 Act (42 U.S.C. 300cc-11 et seq.) is amended by adding
6 at the end the following section:

7 **“SEC. 2321. RESEARCH REGARDING WOMEN.**

8 “(a) IN GENERAL.—With respect to cases of infec-
9 tion with the human immunodeficiency virus, the Sec-
10 retary shall establish a program for the purpose of con-
11 ducting biomedical and behavioral research on such cases
12 in women, including research on the prevention of such
13 cases. The Secretary may conduct such research directly,
14 and may make grants to public and nonprofit private enti-
15 ties for the conduct of the research.

16 “(b) CERTAIN FORMS OF RESEARCH.—In carrying
17 out subsection (a), the Secretary shall provide for research
18 on the following:

19 “(1) The manner in which the human
20 immunodeficiency virus is transmitted to women, in-
21 cluding the relationship between cases of infection
22 with such virus and other cases of sexually transmit-
23 ted diseases, including clinical trials which examine
24 the question of how much human immunodeficiency
25 virus infection can be prevented by finding and
26 treating sexually transmitted diseases in women.

1 “(2) Measures for the prevention of exposure to
2 and the transmission of such virus, including re-
3 search on the following:

4 “(A) The prevention of any sexually trans-
5 mitted disease that may facilitate the trans-
6 mission of the virus.

7 “(B) Rapid, inexpensive, easy-to-use sexu-
8 ally transmitted disease diagnostic tests for
9 women.

10 “(C) Inexpensive single dose therapy for
11 treatable sexually transmitted diseases.

12 “(D) The development of methods of pre-
13 vention for use by women.

14 “(E) The development and dissemination
15 of prevention programs and materials whose
16 purpose is to reduce the incidence of substance
17 abuse among women.

18 “(3) The development and progression of symp-
19 toms resulting from infection with such virus, in-
20 cluding research regarding gynecological infections
21 as well as breast changes, hormonal changes, and
22 menses and menopause changes, whose occurrence
23 becomes probable as a result of the deterioration of
24 the immune system.

1 “(4) The treatment of cases of such infection,
2 including clinical research.

3 “(5) Behavioral research on the prevention of
4 such cases and research on model educational pro-
5 grams for such prevention.

6 “(6) Research leading to an understanding of
7 social, economic, and legal factors whose impact con-
8 tributes to an increased risk of such infection.

9 “(7) Research leading to an understanding of
10 social, economic, and legal factors whose impact con-
11 tributes to—

12 “(A) low levels of participation by women
13 in clinical trials; or

14 “(B) inadequate access to health care serv-
15 ices, or inadequate utilization of such services.

16 “(c) CLINICAL RESEARCH.—

17 “(1) GYNECOLOGICAL EVALUATIONS.—In clini-
18 cal trials regarding the human immunodeficiency
19 virus in which women participate as subjects, the
20 Secretary shall ensure—

21 “(A) that the designs of the trials include
22 adequate evaluation of prospective subjects
23 prior to enrollment, and adequate evaluation of
24 subjects during the course of the trials, includ-
25 ing evaluation of the reproductive tract, and ap-

1 appropriate follow-up services regarding such eval-
2 uations; and

3 “(B) the conduct of studies related to the
4 propensity for cases of infection with such virus
5 to cause abnormalities in the reproductive tract,
6 or to alter the natural history of other repro-
7 ductive-tract infections and diseases.

8 “(2) STANDARD TREATMENTS FOR GYNECO-
9 LOGICAL CONDITIONS.—The Secretary shall conduct
10 or support clinical trials under subsection (a) to de-
11 termine whether standard methods of treating gynec-
12 ological conditions are effective in the case of such
13 conditions that arise as a result of infection with the
14 human immunodeficiency virus.

15 “(3) EFFECTIVENESS OF CERTAIN TREATMENT
16 PROTOCOLS.—With respect to cases of infection with
17 the human immunodeficiency virus, the Secretary
18 shall conduct or support clinical research under sub-
19 section (a) to determine the effectiveness, on such
20 cases in women, of approved treatment protocols.

21 “(4) SUPPORT SERVICES.—

22 “(A) In conducting or supporting clinical
23 trials regarding the human immunodeficiency
24 virus in which women participate as subjects,
25 the Secretary shall take into account factors

1 that can facilitate such participation, including
2 consideration of employment schedules and the
3 provision of support services. The Secretary
4 may provide such services accordingly, including
5 transportation services, child care services, med-
6 ical and mental health services, treatment for
7 drug abuse, social services (including services
8 addressing domestic violence), and other sup-
9 port services.

10 “(B) Services under subparagraph (A)
11 shall include services designed to respond to the
12 particular needs of women with respect to par-
13 ticipation in the clinical trials involved, includ-
14 ing, as appropriate, training of the individuals
15 who conduct the trials.

16 “(d) PREVENTION PROGRAMS.—

17 “(1) SEXUAL TRANSMISSION.—

18 “(A) With respect to preventing the sexual
19 transmission of the human immunodeficiency
20 virus and other sexually transmitted diseases,
21 the Secretary shall conduct or support research
22 under subsection (a) on topical microbicide and
23 physical barrier methods of prevention that
24 women can use without their sexual partner’s
25 cooperation or knowledge.

1 “(B) In carrying out subparagraph (A),
2 the Secretary shall—

3 “(i) give priority to carrying out the
4 topical microbicide research agenda of the
5 National Institutes of Health, including
6 agendas regarding basic research, product
7 development, clinical evaluation of new and
8 existing products, and behavioral science
9 related to acceptance and compliance of
10 new and existing products; and

11 “(ii) give special consideration to re-
12 search on topical microbicides that are not
13 spermicides and that otherwise are meth-
14 ods that do not pose a threat to the ability
15 of women to conceive and bear healthy
16 children.

17 “(2) EPIDEMIOLOGICAL RESEARCH.—The Sec-
18 retary shall conduct or support epidemiological re-
19 search under subsection (a) to determine the factors
20 of increased risk regarding infection with the human
21 immunodeficiency virus that are particular to
22 women, including research regarding—

23 “(A) the use of spermicides and other con-
24 traceptive methods;

1 “(B) the use of vaginal products, including
2 douches, tampons, and vaginal medications;

3 “(C) the relationship between such infec-
4 tion and other sexually transmitted diseases;

5 “(D) the relationship between such infec-
6 tion and various forms of substance abuse (in-
7 cluding use of the form of cocaine commonly
8 known as crack); and

9 “(E) the relationship between such infec-
10 tion and noncoital forms of sexual activity.

11 “(e) INTERAGENCY STUDY.—With respect to the
12 study (known as the Women’s Interagency HIV Study)
13 that, as of April 1997, is being carried out by the Sec-
14 retary through various agencies of the Public Health Serv-
15 ice for the purpose of monitoring the progression in
16 women of infection with the human immunodeficiency
17 virus, and determining whether such progression is dif-
18 ferent in women than in men, the following applies:

19 “(1) The Secretary shall ensure that not less
20 than 2,500 women with such infection are included
21 in the study, and that the demographic variability of
22 the cohort is maintained.

23 “(2) The Secretary shall ensure that the study
24 period is extended for a minimum of 5 years.

1 “(3) With respect to markers of human
2 immunodeficiency virus disease progression and viral
3 activity (including the cells commonly known as CD4
4 cells and including quantitative viral load measures),
5 the Secretary shall ensure that the study adequately
6 addresses the relationship between such markers and
7 the development of serious illnesses in such women.
8 For purposes of the preceding sentence, the study
9 shall address gynecological conditions, and other
10 conditions particular to women, that are not cur-
11 rently included in the list of conditions arising from
12 such infection that, for surveillance purposes, is
13 maintained by the Director of the Centers for Dis-
14 ease Control and Prevention.

15 “(f) DEFINITIONS.—For purposes of this section, the
16 term ‘human immunodeficiency virus’ means the etiologic
17 agent for acquired immune deficiency syndrome.

18 “(g) AUTHORIZATIONS OF APPROPRIATIONS.—

19 “(1) CLINICAL RESEARCH.—In addition to any
20 other authorizations of appropriations that are avail-
21 able for the following purposes:

22 “(A) For the purpose of carrying out sub-
23 section (c)(1), there are authorized to be appro-
24 priated \$20,000,000 for fiscal year 1998, and

1 such sums as may be necessary for each of the
2 fiscal years 1999 and 2000.

3 “(B) For the purpose of carrying out sub-
4 section (c)(2), there are authorized to be appro-
5 priated \$10,000,000 for fiscal year 1998, and
6 such sums as may be necessary for each of the
7 fiscal years 1999 and 2000.

8 “(C) For the purpose of carrying out sub-
9 section (c)(3), there are authorized to be appro-
10 priated \$10,000,000 for fiscal year 1998, and
11 such sums as may be necessary for each of the
12 fiscal years 1999 and 2000.

13 “(D) For the purpose of carrying out sub-
14 section (c)(4), there are authorized to be appro-
15 priated \$15,000,000 for fiscal year 1998, and
16 such sums as may be necessary for each of the
17 fiscal years 1999 and 2000.

18 “(2) PREVENTION PROGRAMS.—In addition to
19 any other authorizations of appropriations that are
20 available for the following purposes:

21 “(A) For the purpose of carrying out sub-
22 section (d)(1), there are authorized to be appro-
23 priated \$10,000,000 for fiscal year 1998, and
24 such sums as may be necessary for each of the
25 fiscal years 1999 and 2000.

1 “(B) For the purpose of carrying out sub-
2 section (d)(2), there are authorized to be appro-
3 priated \$10,000,000 for fiscal year 1998, and
4 such sums as may be necessary for each of the
5 fiscal years 1999 and 2000.

6 “(3) INTERAGENCY STUDY.—In addition to any
7 other authorizations of appropriations that are avail-
8 able for the purpose of carrying out subsection (e),
9 there are authorized to be appropriated for such
10 purpose \$6,000,000 for fiscal year 1998, and such
11 sums as may be necessary for each of the fiscal
12 years 1999 and 2000.”.

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