

104TH CONGRESS
2D SESSION

H. R. 3176

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

MARCH 27, 1996

Mrs. MORELLA 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 1996”.

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 gyne-
12 cological 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, and clinical evaluation of new
8 and existing products; and

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

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

21 “(A) the use of spermicides and other con-
22 traceptive methods;

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

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

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

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

9 “(e) INTERAGENCY STUDY.—With respect to the
10 study (known as the Women’s Interagency HIV Study)
11 that, as of March 1996, is being carried out by the Sec-
12 retary through various agencies of the Public Health Serv-
13 ice for the purpose of monitoring the progression in
14 women of infection with the human immunodeficiency
15 virus, and determining whether such progression is dif-
16 ferent in women than in men, the following applies:

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

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

23 “(3) With respect to markers of human
24 immunodeficiency virus disease progression and viral
25 activity (including the cells commonly known as CD4

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

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

15 “(g) AUTHORIZATIONS OF APPROPRIATIONS.—

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

19 “(A) For the purpose of carrying out sub-
20 section (c)(1), there are authorized to be appro-
21 priated \$20,000,000 for fiscal year 1997, and
22 such sums as may be necessary for each of the
23 fiscal years 1998 through 1999.

24 “(B) For the purpose of carrying out sub-
25 section (c)(2), there are authorized to be appro-

1 appropriated \$10,000,000 for fiscal year 1997, and
2 such sums as may be necessary for each of the
3 fiscal years 1998 through 1999.

4 “(C) For the purpose of carrying out sub-
5 section (c)(3), there are authorized to be appro-
6 priated \$10,000,000 for fiscal year 1997, and
7 such sums as may be necessary for each of the
8 fiscal years 1998 through 1999.

9 “(D) For the purpose of carrying out sub-
10 section (c)(4), there are authorized to be appro-
11 priated \$15,000,000 for fiscal year 1997, and
12 such sums as may be necessary for each of the
13 fiscal years 1998 and 1999.

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

17 “(A) For the purpose of carrying out sub-
18 section (d)(1), there are authorized to be appro-
19 priated \$10,000,000 for fiscal year 1997, and
20 such sums as may be necessary for each of the
21 fiscal years 1998 through 1999.

22 “(B) For the purpose of carrying out sub-
23 section (d)(2), there are authorized to be appro-
24 priated \$10,000,000 for fiscal year 1997, and

1 such sums as may be necessary for each of the
2 fiscal years 1998 through 1999.

3 “(3) INTERAGENCY STUDY.—In addition to any
4 other authorizations of appropriations that are avail-
5 able for the purpose of carrying out subsection (e),
6 there are authorized to be appropriated for such
7 purpose \$6,000,000 for fiscal year 1997, and such
8 sums as may be necessary for each of the fiscal
9 years 1998 through 1999.”.

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