I

103D CONGRESS
1ST SESSION

H. R. 2394

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

JUNE 10, 1993

Mrs. MORELLA (for herself, Mr. BIELENSON, Mr. FRANK of Massachusetts, Mr. FROST, Mr. GIBBONS, Mr. GILMAN, Mr. JEFFERSON, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. MATSUI, Mr. MCDERMOTT, Mrs. MEEK, Mr. MILLER of California, Mrs. MINK, Ms. MOLINARI, Ms. NORTON, Mr. PAYNE of New Jersey, Mr. SANDERS, Mrs. SCHROEDER, Ms. SNOWE, Mr. STUDDS, Mr. TOWNS, Mrs. UNSOELD, Ms. WATERS, Mr. WHEAT, Mr. WYDEN, and Mr. YATES) introduced the following bill; which was referred to the Committee on Energy and 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.

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 ''Women and AIDS Research Initiative Amendments of 1993''.

SEC. 2. ESTABLISHMENT OF GENERAL PROGRAM OF RESEARCH REGARDING WOMEN AND ACQUIRED IMMUNE DEFICIENCY SYNDROME.

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

"SEC. 2321. RESEARCH REGARDING WOMEN.

''(a) IN GENERAL.—With respect to cases of infection with the human immunodeficiency virus, the Secretary shall establish a program for the purpose of conducting biomedical and behavioral research on such cases in women, including research on the prevention of such cases. The Secretary may conduct such research directly, and may make grants to public and nonprofit private entities for the conduct of the research.

''(b) CERTAIN FORMS OF RESEARCH.—In carrying out subsection (a), the Secretary shall provide for research on—

''(1) the manner in which the human immunodeficiency virus is transmitted to women, including the relationship between cases of infection with such virus and other cases of sexually transmitted diseases, including clinical trials which examine the question of how much human immunodeficiency virus infection can be prevented by finding and treating sexually transmitted diseases in women;

''(2) measures for the prevention of exposure to and the transmission of such virus, including research on—

''(A) the prevention of any sexually transmitted disease that may facilitate the transmission of the virus;

''(B) rapid, inexpensive, easy-to-use sexually transmitted disease diagnostic tests for women;

''(C) inexpensive single dose therapy for treatable sexually transmitted diseases;

''(D) the development of methods of prevention for use by women; and

''(E) the development and dissemination of prevention programs and materials whose purpose is to reduce the incidence of substance abuse among women;

''(3) the development and progression of symptoms resulting from infection with such virus, including research regarding gynecological infections as well as breast changes, hormonal changes, and menses and menopause changes, whose occurrence becomes probable as a result of the deterioration of the immune system;

''(4) the treatment of cases of such infection, including clinical research; and

''(5) behavioral research on the prevention of such cases and research on model educational programs for such prevention.

''(c) CLINICAL TRIALS.—

''(1) GYNECOLOGICAL EVALUATIONS.—In clinical trials regarding the human immunodeficiency virus in which women participate as subjects, the Secretary shall ensure that—

''(A) each female subject who is infected with the human immunodeficiency virus—

''(i) undergoes a gynecological examination as part of the evaluation of the medical status of the woman prior to participation in the trial; and

''(ii) receives appropriate follow-up services regarding such examination; and

''(B) the results of the gynecological examinations are analyzed to determine the relationship between gynecological conditions and the infection with such virus.

''(2) STANDARD TREATMENTS FOR GYNECOLOGICAL CONDITIONS.—The Secretary shall conduct or support clinical trials under subsection (a) to de-

termine whether standard methods of treating gynecological conditions are effective in the case of such conditions that arise as a result of infection with the human immunodeficiency virus.

''(3) EFFECTIVENESS OF CERTAIN TREATMENT PROTOCOLS.—With respect to cases of infection with the human immunodeficiency virus, the Secretary shall conduct or support clinical trials under subsection (a) to determine whether treatment protocols approved for men with such cases are effective for women with such cases.

''(4) SUPPORT SERVICES.—

''(A) In conducting or supporting clinical trials regarding the human immunodeficiency virus in which women participate as subjects, the Secretary shall provide the women with such transportation, child care, and other support services (including medical and mental health services, treatment for drug abuse, and social services, including services addressing domestic violence) as may be necessary to enable the women to participate as such subjects.

''(B) Services under subparagraph (A) shall include services designed to respond to the particular needs of women with respect to par-

ticipation in the clinical trials involved, including, as appropriate, training of the individuals who conduct the trials.

''(d) PREVENTION PROGRAMS.—

''(1) SEXUAL TRANSMISSION.—

''(A) With respect to preventing the sexual transmission of the human immunodeficiency virus, the Secretary shall conduct or support research under subsection (a) on barrier methods for prevention of sexually transmitted diseases, including human immunodeficiency virus disease, that women can use without their sexual partner's cooperation or knowledge.

''(B) In carrying out subparagraph (A), the Secretary shall give priority to identified research needs and opportunities identified at the National Institutes of Health sponsored meeting on Development of Topical Microbicides held in May 1993, including research on—

''(i) the early steps in infectious processes;

''(ii) identification, formulation, and preclinical evaluation of new preparations;

''(iii) clinical testing for safety and efficacy; and

''(iv) studies on acceptability and compliance of safe, effective microbicides.

''(2) EPIDEMIOLOGICAL RESEARCH.—The Secretary shall conduct or support epidemiological research under subsection (a) to determine the factors of risk regarding infection with the human immunodeficiency virus that are particular to women, including research regarding—

''(A) the use of various contraceptive methods;

''(B) the use of tampons;

''(C) the relationship between such infection and other sexually transmitted diseases;

''(D) the relationship between such infection and various forms of substance abuse (including use of the form of cocaine commonly known as crack); and

''(E) the relationship between such infection and noncoital forms of sexual activity.

''(e) INTERAGENCY STUDY.—With respect to the study (known as the Women's Interagency HIV Study) that, as of June 1993, is being carried out by the Secretary through various agencies of the Public Health Service for the purpose of monitoring the progression in women of infection with the human immunodeficiency

virus, and determining whether such progression is different in women than in men, the following applies:

''(1) The Secretary shall ensure that not less than 5,000 women with such infection are included in the study.

''(2) The Secretary shall provide for an increase in the number of sites at which the study is to be conducted.

''(3) The Secretary shall ensure that the study period is for a minimum of 8 years.

''(4) With respect to markers of human immunodeficiency virus disease progression and viral activity, including the cells commonly known as CD4 cells, the Secretary shall ensure that the study adequately addresses the relationship between such markers and the development of serious illnesses in such women, including the relationship between the number of such cells and the development of such illnesses. For purposes of the preceding sentence, the study shall address gynecological conditions, and other conditions particular to women, that are not currently included in the list of conditions arising from such infection that, for surveillance purposes, is maintained by the Director of the Centers for Disease Control and Prevention.

''(f) DEFINITIONS.—For purposes of this section, the term 'human immunodeficiency virus' means the etiologic agent for acquired immune deficiency syndrome.

''(g) AUTHORIZATIONS OF APPROPRIATIONS.—

''(1) CLINICAL TRIALS.—

''(A) For the purpose of carrying out subsection (c)(1), there are authorized to be appropriated $20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996.

''(B) For the purpose of carrying out subsection (c)(2), there are authorized to be appropriated $10,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996.

''(C) For the purpose of carrying out subsection (c)(3), there are authorized to be appropriated $10,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996.

''(D) For the purpose of carrying out subsection (c)(4), there are authorized to be appropriated $15,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

''(2) PREVENTION PROGRAMS.—

''(A) For the purpose of carrying out subsection (d)(1), there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996.

''(B) For the purpose of carrying out subsection (d)(2), there are authorized to be appropriated $10,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996.

''(3) INTERAGENCY STUDY.—For the purpose of carrying out subsection (e), there are authorized to be appropriated $15,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996.''.

○