

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1429

To amend the Public Health Service Act to establish programs of research with respect to women and cases of information with the human immunodeficiency virus, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

AUGUST 6 (legislative day, JUNE 30), 1993

Mr. SIMON (for himself, Mrs. MURRAY, Mr. RIEGLE, Ms. MOSELEY-BRAUN, and Mrs. BOXER) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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## A BILL

To amend the Public Health Service Act to establish programs of research with respect to women and cases of information with the human immunodeficiency virus, and for other purposes.

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  
5       Research Initiative Amendments of 1993”.

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

4 Part B of title XXII of the Public Health Service Act  
5 (42 U.S.C. 800cc-11 et seq.) is amended by adding at  
6 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—

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, and clinical trials which examine the  
24 question of the how the level of HIV infection can  
25 be prevented by finding and treating sexually trans-  
26 mitted diseases in women;

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

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; and

14          “(E) the development and dissemination of  
15 prevention programs and materials whose pur-  
16 pose 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; and

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

6           “(c) CLINICAL TRIALS.—

7           “(1) GYNECOLOGICAL EVALUATIONS.—In clini-  
8 cal trials under this title in which women participate  
9 as subjects, the Secretary shall ensure that—

10           “(A) each female subject who is infected  
11 with the human immunodeficiency virus—

12           “(i) undergoes a gynecological exam-  
13 ination as part of the evaluation of the  
14 medical status of the woman prior to par-  
15 ticipation in the trial; and

16           “(ii) receives appropriate follow-up  
17 services regarding such examination; and

18           “(B) the results of the gynecological ex-  
19 aminations are analyzed to determine the rela-  
20 tionship between gynecological conditions and  
21 the infection with such virus.

22           “(2) STANDARD TREATMENTS FOR GYNECO-  
23 LOGICAL CONDITIONS.—The Secretary shall conduct  
24 or support clinical trials under subsection (a) to de-  
25 termine whether standard methods of treating gyne-

1       cological conditions are effective in the case of such  
2       conditions that arise as a result of infection with the  
3       human immunodeficiency virus.

4           “(3) EFFECTIVENESS OF CERTAIN TREATMENT  
5       PROTOCOLS.—With respect to cases of infection with  
6       the human immunodeficiency virus, the Secretary  
7       shall conduct or support clinical trials under sub-  
8       section (a) to determine whether treatment protocols  
9       approved for men with such cases are effective for  
10      women with such cases.

11          “(4) SUPPORT SERVICES.—

12           “(A) In conducting or supporting clinical  
13      trials under this title in which women partici-  
14      pate as subjects, the Secretary shall provide the  
15      women with such transportation, child care, and  
16      other support services (including medical and  
17      mental health services, treatment for drug  
18      abuse, and social services), including services  
19      addressing domestic violence as may be nec-  
20      essary to enable the women to participate as  
21      such subjects.

22           “(B) Services under subparagraph (A)  
23      shall include services designed to respond to the  
24      particular needs of women with respect to par-  
25      ticipation in clinical trials under this title, in-

1 including, as appropriate, training of the individ-  
2 uals who conduct the trials.

3 “(d) PREVENTION PROGRAMS.—

4 “(1) SEXUAL TRANSMISSION.—

5 “(A) With respect to preventing the sexual  
6 transmission of the human immunodeficiency  
7 virus, the Secretary shall conduct or support re-  
8 search under subsection (a) on barrier methods  
9 for the prevention of sexually transmitted dis-  
10 eases, including HIV disease, that women can  
11 use without their sexual partner’s cooperation  
12 or knowledge.

13 “(B) In carrying out subparagraph (A),  
14 the Secretary shall give priority to identified re-  
15 search needs and opportunities identified at the  
16 National Institutes of Health sponsored meet-  
17 ing on Development of Topical Microbicides  
18 that was held in May of 1993, including re-  
19 search on—

20 “(i) the early stages in infectious  
21 processes;

22 “(ii) the identification, formulation  
23 and preclinical evaluation of new prepara-  
24 tions;

1           “(iii) clinical testing for safety and ef-  
2           ficacy; and

3           “(iv) studies concerning the accept-  
4           ability and compliance of safe, effective  
5           microbicides.

6           “(2) EPIDEMIOLOGICAL RESEARCH.—The Sec-  
7           retary shall conduct or support epidemiological re-  
8           search under subsection (a) to determine the factors  
9           of risk regarding infection with the human  
10          immunodeficiency virus that are particular to  
11          women, including research regarding—

12               “(A) the use of various contraceptive  
13               methods;

14               “(B) the use of tampons;

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

17               “(D) the relationship between such infec-  
18               tion and various forms of substance abuse (in-  
19               cluding use of the form of cocaine commonly  
20               known as crack); and

21               “(E) the relationship between such infec-  
22               tion and sexual activity.

23          “(e) INTERAGENCY STUDY.—With respect to the  
24          study being carried out by the Secretary (as of June 1993)  
25          through various agencies of the Public Health Service for

1 the purpose of monitoring the progression in women of  
2 infection with the human immunodeficiency virus, and de-  
3 termining whether such progression is different in women  
4 than in men, which study is known as the Women's Inter-  
5 agency HIV Study, the following applies:

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

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

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

14          “(4) With respect to the human cells commonly  
15          known as CD4 cells, the Secretary shall ensure that  
16          the study adequately addresses the relationship be-  
17          tween the number of such cells and other markers  
18          in women with such infection and the development  
19          of serious illnesses in such women. For purposes of  
20          the preceding sentence, the study shall address gyne-  
21          cological conditions, and other conditions particular  
22          to women, that are not currently included in the list  
23          of conditions arising from such infection that, for  
24          surveillance purposes, is maintained by the Director  
25          of the Centers for Disease Control and Prevention.

1       “(f) DEFINITION.—For purposes of this section, the  
2 term ‘human immunodeficiency virus’ means the etiologic  
3 agent for acquired immune deficiency syndrome.

4       “(g) AUTHORIZATIONS OF APPROPRIATIONS.—

5           “(1) CLINICAL TRIALS.—

6                   “(A) For the purpose of carrying out sub-  
7 section (c)(1), there are authorized to be appro-  
8 priated \$20,000,000 for fiscal year 1994, and  
9 such sums as may be necessary for each of the  
10 fiscal years 1995 through 1996.

11                   “(B) For the purpose of carrying out sub-  
12 section (c)(2), there are authorized to be appro-  
13 priated \$10,000,000 for fiscal year 1994, and  
14 such sums as may be necessary for each of the  
15 fiscal years 1995 through 1996.

16                   “(C) For the purpose of carrying out sub-  
17 section (c)(3), there are authorized to be appro-  
18 priated \$10,000,000 for fiscal year 1994, and  
19 such sums as may be necessary for each of the  
20 fiscal years 1995 through 1996.

21                   “(D) For the purpose of carrying out sub-  
22 section (c)(4), there are authorized to be appro-  
23 priated \$15,000,000 for fiscal year 1994, and  
24 such sums as may be necessary for each of the  
25 fiscal years 1995 and 1996.

1           “(2) PREVENTION PROGRAMS.—

2                   “(A) For the purpose of carrying out sub-  
3           section (d)(1), there are authorized to be appro-  
4           priated \$30,000,000 for fiscal year 1994, and  
5           such sums as may be necessary for each of the  
6           fiscal years 1995 through 1996.

7                   “(B) For the purpose of carrying out sub-  
8           section (d)(2), there are authorized to be appro-  
9           priated \$10,000,000 for fiscal year 1994, and  
10          such sums as may be necessary for each of the  
11          fiscal years 1995 through 1996.

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

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