

106TH CONGRESS  
2D SESSION

# H. R. 3891

To amend the Public Health Service Act with respect to facilitating the development of microbicides to prevent the transmission of sexually transmitted diseases.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2000

Mrs. MORELLA (for herself, Ms. PELOSI, Mrs. KELLY, Mrs. MALONEY of New York, Mr. BOEHLERT, and Mr. GREENWOOD) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend the Public Health Service Act with respect to facilitating the development of microbicides to prevent the transmission of sexually transmitted diseases.

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 “Microbicides Develop-  
5 ment Act of 2000”.

6 **SEC. 2. FINDINGS.**

7 (a) IN GENERAL.—The Congress finds as follows:

8 (1) Annually at least 1 billion people worldwide  
9 contracted one of eight sexually transmitted diseases

1 (“STDs”)—chlamydia, gonorrhea, syphilis, tricho-  
2 moniasis, hepatitis B, herpes, human immuno-  
3 deficiency virus (HIV), and human papilloma virus.  
4 Of these, hepatitis B, herpes, HIV, and human pap-  
5 illoma virus are incurable and represented two-thirds  
6 of the new infections.

7 (2) In 1999, 15.4 million people in the United  
8 States acquired at least one of these eight diseases,  
9 the highest rate in the industrialized world. Five of  
10 the top 10 most frequently reported infectious dis-  
11 eases (87 percent of all cases) are sexually trans-  
12 mitted. At least 66 million Americans, over 1 in 3  
13 adults aged 15–65, are now living with an incurable  
14 viral STD.

15 (3) The total costs to the U.S. economy of  
16 STDs, excluding HIV infection, were approximately  
17 \$16 billion. When the costs of sexually-transmitted  
18 HIV infection are included, that total rises to \$23  
19 billion.

20 (4) STDs impose high human costs in pain, di-  
21 minished quality of life, disability, and mortality. In  
22 women, STDs other than HIV can produce infer-  
23 tility, cancers, and numerous pregnancy-related com-  
24 plications, including ectopic pregnancy, spontaneous  
25 abortion, and stillbirth. Passed to a fetus or infant,

1 these infections can cause low birthweight, pneu-  
2 monia, neurologic damage, and congenital abnor-  
3 malities. These infections also substantially enhance  
4 susceptibility to HIV infection.

5 (5) Individuals of every age and every geo-  
6 graphic, racial, cultural, socioeconomic, and religious  
7 background are affected by STDs. Some infections  
8 are so prevalent that almost everyone is at risk, with  
9 many perhaps unaware of their infected status.

10 (6) Biologically and socially, women are more  
11 vulnerable to STDs than men. Many STDs are  
12 transmitted more easily from a man to a woman and  
13 are more likely to remain undetected in women, re-  
14 sulting in delayed diagnosis and treatment, and  
15 more severe complications.

16 (7) In the United States, HIV morbidity and  
17 mortality remain highest among African Americans,  
18 who make up 13% of the U.S. population but ac-  
19 counted for almost half of AIDS deaths and new  
20 AIDS cases in 1998. For African American women  
21 between the ages 25 and 44 in the United States,  
22 AIDS now occupies second place as the cause of  
23 death.

24 (8) In the United States as well as globally,  
25 adolescents and young adults are at highest risk of

1 acquiring a sexually-transmitted infection. At least a  
2 quarter of all new cases of STDs occur in teens,  
3 two-thirds in people ages 15–24, so that by age 24,  
4 at least 1 in 3 sexually-active Americans will have  
5 contracted an STD. Teenage girls are at particular  
6 risk, behaviorally and physiologically.

7 (9) The social, health, and economic burdens of  
8 STDs are especially severe for developing countries.  
9 Among women ages 15–49 in developing countries,  
10 STDs represent the second largest burdens of mor-  
11 tality and disability. Only “maternal causes,” that  
12 is, immediate complications of pregnancy and child-  
13 birth, rank higher.

14 (10) AIDS is rapidly becoming a “women’s epi-  
15 demic.” In the United States, women now constitute  
16 the fastest growing group of those newly infected  
17 with HIV and in Africa, more women are becoming  
18 infected with HIV than are men. Worldwide, almost  
19 half of the approximately 14,000 adults infected  
20 daily with HIV in 1998 were women, of whom 9 out  
21 of 10 live in developing countries.

22 (b) MICROBICIDES.—The Congress finds as follows:

23 (1) Since the early 1990s, “topical  
24 microbicides” have attracted scientific attention as a  
25 possible new technology for preventing STDs, includ-

1 ing HIV. Like today’s spermicides, microbicides  
 2 would be used vaginally by women to help protect  
 3 themselves, their partners, and their infants from  
 4 the sexual transmission of HIV and other STD  
 5 pathogens. These compounds could be formulated in  
 6 a number of ways—as a gel, film, sponge or time re-  
 7 leased-capsule—and could be used in addition to  
 8 condoms or as an alternative when condom use is  
 9 not possible.

10 (2) For individuals needing to use them without  
 11 partner knowledge or consent, safe, effective, accept-  
 12 able, and affordable topical microbicides could be  
 13 formulated to be undetectable.

14 **TITLE I—MICROBICIDE RE-**  
 15 **SEARCH AT THE NATIONAL**  
 16 **INSTITUTES OF HEALTH**

17 **SEC. 101. PROGRAM REGARDING MICROBICIDES FOR PRE-**  
 18 **VENTING TRANSMISSION OF SEXUALLY**  
 19 **TRANSMITTED DISEASES.**

20 Part B of title IV of the Public Health Service Act  
 21 (42 U.S.C. 284 et seq.) is amended by adding at the end  
 22 following section:

23 “MICROBICIDES FOR PREVENTING TRANSMISSION OF  
 24 SEXUALLY TRANSMITTED DISEASES

25 “SEC. 409B. (a) EXPANSION AND COORDINATION OF  
 26 ACTIVITIES.—The Director of NIH (referred to in this

1 section as the ‘Director’) shall expand, intensify, and co-  
2 ordinate the activities of the Institute with respect to re-  
3 search on the development of microbicides to prevent the  
4 transmission of sexually transmitted diseases, including  
5 HIV (in this section referred to as ‘microbicide research’).

6 “(b) COORDINATION.—The Director shall coordinate  
7 the activities under subsection (a) as outlined in subpara-  
8 graph (c)(1) among all appropriate institutes and compo-  
9 nents of the National Institutes of Health to the extent  
10 such institutes and components have responsibilities that  
11 are related to the development of microbicides.

12 “(c) PROGRAM FOR MICROBICIDE DEVELOPMENT.—  
13 In carrying out subsection (a), the Institute shall establish  
14 a program to support research to develop microbicides  
15 that can substantially reduce transmission of sexually  
16 transmitted infections. Activities under such subsection  
17 shall provide for an expansion and intensification of the  
18 conduct and support of—

19 “(1) basic research on the initial mechanisms of  
20 infection by sexually transmitted pathogens;

21 “(2) development of appropriate animal models  
22 for evaluating safety and efficacy of microbicides;

23 “(3) development of mucosal delivery systems;

24 “(4) research on approaches to the design of  
25 contraceptive and non-contraceptive microbicides;

1           “(5) clinical trials; and

2           “(6) behavioral research on use, acceptability  
3           and compliance with microbicides.

4           “(d) IMPLEMENTATION PLAN.—The Director, in co-  
5           ordination with institute directors as described in sub-  
6           section (b), shall develop and implement a plan to ensure  
7           that the research programs described in paragraph (c)(1)  
8           are implemented in accordance with a plan for such pro-  
9           grams. Such plan shall include the comments of the Direc-  
10          tor and shall include, but not be limited to, the following  
11          information for the five year period beginning upon enact-  
12          ment of such section:

13           “(1) Description of plan and objectives with re-  
14          spect to microbicide research.

15           “(2) Description of the institutes involved and  
16          their role in microbicide research.

17           “(3) Capacity of such institutes to conduct  
18          microbicide research as described in (c)(1).

19           “(4) Description of grant and contract mecha-  
20          nisms available to facilitate microbicide research, in-  
21          cluding grant and contract mechanisms, RFA’s,  
22          SBIR/STTRs, support for preclinical product devel-  
23          opment and clinical trial capacity.

24           “(5) Description of the plan for increasing  
25          number of investigators in this area of research.

1           “(e) PUBLIC COMMENT.—The Director shall develop  
2 a mechanism to provide the public, including non-profit  
3 private entities concerned with microbicide research, op-  
4 portunities to submit comments on the plan, including  
5 provisions relating to the selection of products for clinical  
6 evaluations and to the SBIR and STTR program referred  
7 to in subparagraph (d)(4).

8           “(f) REPORT TO CONGRESS.—The Director shall pre-  
9 pare, and the Secretary shall submit, not later than 1 year  
10 after the date on enactment, and annually thereafter, a  
11 report that describes the activities of the Institute, under  
12 the research programs referred to in subsection (c), that  
13 shall include—

14                 “(1) a description of the research plan with re-  
15 spect to microbicide research prepared under sub-  
16 section (d);

17                 “(2) an assessment of the development, revi-  
18 sion, and implementation of such plan;

19                 “(3) a description and evaluation of the  
20 progress made, during the period for which such re-  
21 port is prepared, in the research on microbicides;

22                 “(4) a summary and analysis of expenditures  
23 made, during the period for which the report is  
24 made, for activities with respect to microbicides con-



1 ducted and supported by the National Institutes of  
2 Health; and

3 “(5) such comments and recommendations as  
4 the Director considers appropriate.

5 “(g) COORDINATION.—The Director, to the extent  
6 practicable, shall consult with the Director for the Centers  
7 for Disease Control and Prevention and the United States  
8 Agency for International Development, in developing the  
9 plan under subparagraph (d) for research on microbicides  
10 that takes into consideration research on sexually trans-  
11 mitted diseases and microbicides carried out at the Cen-  
12 ters for Disease Control and Prevention and the United  
13 States Agency for International Development.

14 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the  
15 purposes of carrying out this section, there are authorized  
16 to be appropriated \$50,000,000 for fiscal year 2001,  
17 \$75,000,000 for fiscal year 2002, \$100,000,000 for fiscal  
18 year 2003, and such sums as may be necessary for each  
19 of the fiscal years 2004 and 2005.”.

1 **TITLE II—MICROBICIDE RE-**  
2 **SEARCH AT THE CENTERS**  
3 **FOR DISEASE CONTROL AND**  
4 **PREVENTION**

5 **SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION**  
6 **OF SEXUALLY TRANSMITTED DISEASES.**

7 Part B of title III of the Public Health Service Act  
8 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
9 tion 317G the following section:

10 “MICROBICIDES FOR PREVENTING TRANSMISSION OF  
11 SEXUALLY TRANSMITTED DISEASES

12 “SEC. 317H. (a) EXPANSION AND COORDINATION OF  
13 MICROBICIDE RESEARCH ACTIVITIES.—The Secretary,  
14 acting through the Director of the Centers for Disease  
15 Control and Prevention, shall expand, intensify, and co-  
16 ordinate the activities of such Centers with respect to re-  
17 search on microbicides to prevent the transmission of sex-  
18 ually transmitted diseases, including HIV.

19 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the  
20 purposes of carrying out this section, there are authorized  
21 to be appropriated \$7,000,000 for fiscal year 2001,  
22 \$11,000,000 for fiscal year 2002, \$15,000,000 for fiscal  
23 year 2003, and such sums as may be necessary for each  
24 of the fiscal years 2004 and 2005.”.

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