

108TH CONGRESS  
1ST SESSION

# S. 859

To amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other diseases.

---

## IN THE SENATE OF THE UNITED STATES

Mr. CORZINE (for himself, Ms. SNOWE, Ms. CANTWELL, Mr. SMITH, Mr. DODD, Mr. LEAHY, Mrs. MURRAY, Mr. DURBIN, Mr. LAUTENBERG, and Mr. BINGAMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other 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 “Microbicide Develop-  
5       ment Act of 2003”.

6       **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

1           (1) During 2002, AIDS caused the deaths of an  
2           estimated 3,100,000 people, including 1,200,000  
3           women and 610,000 children under 15 years of age.  
4           An estimated 14,000,000 children living today have  
5           lost one or both parents due to AIDS.

6           (2) Worldwide, heterosexual transmission is ac-  
7           counting for an increasing share of new HIV infec-  
8           tions, with adolescents, women, and disadvantaged  
9           people at particular risk.

10          (3) In the United States, for example, African  
11          American and Latina women account for 64 percent  
12          and 17 percent of all reported HIV cases, respec-  
13          tively, even though they represent only 25 percent of  
14          the total United States female population.

15          (4) Half of the 38,600,000 adults living today  
16          with HIV/AIDS are women.

17          (5) Biological, cultural, economic, and social  
18          factors combine to make women and girls particu-  
19          larly vulnerable to HIV and other sexually trans-  
20          mitted diseases (referred to in this section as  
21          “STDs”). In the hardest hit areas of Africa, almost  
22          one-quarter of 15 to 19 year-old girls are already in-  
23          fected with HIV, compared to 4 percent of their  
24          male peers.

1           (6) In addition to HIV, other STDs can cause  
 2           serious, costly, even deadly conditions for women  
 3           and their children, including infertility, pregnancy  
 4           complications, cervical cancer, infant mortality, and  
 5           higher risk of contracting HIV. When women be-  
 6           come infected with HIV, they risk passing along the  
 7           infection to their infants, either through pregnancy,  
 8           childbirth, or breastfeeding.

9           (7) Regrettably, today's HIV prevention meth-  
 10          ods do not meet the needs of the millions of women  
 11          worldwide who, for cultural, economic, and social  
 12          reasons, cannot insist on protective measures such  
 13          as abstinence, condom use, or mutual monogamy.

14          (8) A large majority of women become infected  
 15          with HIV with only one partner—their husbands.  
 16          Women need prevention options that they can use  
 17          consistently within ongoing, long-term relationships.

18          (9) Microbicides are a promising new tech-  
 19          nology, complementary to vaccines, that could put  
 20          the power of prevention into women's hands. Formu-  
 21          lated as gels, creams, or films, microbicides inac-  
 22          tivate, block, or otherwise interfere with the patho-  
 23          gens that cause HIV/AIDS and other STDs.

24          (10) Even a moderately effective microbicide  
 25          could have a substantial impact on the HIV epi-

1       demic. The London School of Hygiene and Tropical  
2       Medicine estimates that a 60 percent efficacious  
3       microbicide introduced into the 73 poorest countries  
4       could avert 2,500,000 HIV infections in men,  
5       women, and children over 3 years.

6           (11) Microbicides would also benefit men, be-  
7       cause their protective effect is likely to be  
8       bidirectional.

9           (12) Numerous potential microbicides are  
10      poised for successful development. Thirteen products  
11      are in clinical trials and approximately 50 com-  
12      pounds exist that could be investigated further.  
13      There is a backlog in the research and development  
14      pipeline, however, so that innovative and promising  
15      product concepts are languishing, while infection  
16      rates are growing.

17          (13) At present, there is insufficient economic  
18      incentive for large pharmaceutical companies to be-  
19      come actively engaged in microbicide research and  
20      development, thus, Federal support is crucial. Three  
21      Federal agencies—the National Institutes of Health,  
22      the Centers for Disease Control and Prevention, and  
23      the United States Agency for International Develop-  
24      ment—have played important roles in progress to  
25      date, but strong, effective, well-coordinated, and visi-

1 ble public sector leadership will be essential for the  
2 promise of microbicides to be realized.

3 (14) A microbicide could be available within 5  
4 to 7 years if sufficient public sector funding were  
5 made available to accelerate research and support  
6 the necessary clinical trials.

7 (15) Microbicide research and development cur-  
8 rently receive only 2 percent of the AIDS research  
9 budget of the National Institutes of Health, not  
10 nearly enough to keep pace with public health need  
11 and scientific opportunity.

12 (16) The United States Agency for Inter-  
13 national Development sustains strong partnerships  
14 with public and private organizations working on  
15 microbicide research, importantly including clinical  
16 trials in developing countries where its experience is  
17 extensive. The long experience of such Agency in lo-  
18 gistics management, service delivery, provider train-  
19 ing, and social marketing position it well to prepare  
20 for and implement the introduction of microbicides  
21 once they are available.

22 (17) The Centers for Disease Control and Pre-  
23 vention also engages in critical microbicide research  
24 and clinical testing, and has a long history of con-  
25 ducting field trials in developing countries.

1           (18) For the microbicide pipeline to advance  
 2           significantly and the essential clinical trials to be  
 3           fielded soon, the current amount of Federal invest-  
 4           ment needs to increase to \$130,000,000 in fiscal  
 5           year 2004 and to \$160,000,000 in fiscal year 2005.

6       **TITLE       I—MICROBICIDE       RE-**  
 7       **SEARCH AT THE NATIONAL**  
 8       **INSTITUTES OF HEALTH**

9       **SEC. 101. OFFICE OF AIDS RESEARCH; PROGRAM REGARD-**  
 10       **ING MICROBICIDES FOR PREVENTING TRANS-**  
 11       **MISSION OF HIV AND OTHER DISEASES.**

12       Subpart I of part D of title XXIII of the Public  
 13       Health Service Act (42 U.S.C. 300cc–40 et seq.) is  
 14       amended by inserting after section 2351 the following:

15       **“SEC. 2351A. MICROBICIDES FOR PREVENTING TRANS-**  
 16       **MISSION OF HIV AND OTHER DISEASES.**

17       “(a) FEDERAL STRATEGIC PLAN.—

18           “(1) IN GENERAL.—The Director of the Office  
 19       of AIDS Research shall expedite the development  
 20       and implementation of a Federal strategic plan for  
 21       the conduct and support of microbicide research and  
 22       shall biannually review and as appropriate revise the  
 23       plan.

1           “(2) COORDINATION.—In developing, imple-  
 2           menting, and reviewing the plan, the Director of the  
 3           Office of AIDS Research shall coordinate with—

4                   “(A) other Federal agencies, including the  
 5                   Director of the Centers for Disease Control and  
 6                   Prevention and the Administrator of the United  
 7                   States Agency for International Development,  
 8                   involved in microbicide research;

9                   “(B) the microbicide research community;  
 10                  and

11                  “(C) health advocates.

12           “(b) EXPANSION AND COORDINATION OF ACTIVI-  
 13           TIES.—The Director of the Office of AIDS Research, act-  
 14           ing in coordination with other relevant institutes and of-  
 15           fices, shall expand, intensify, and coordinate the activities  
 16           of all appropriate institutes and components of the Na-  
 17           tional Institutes of Health with respect to research on the  
 18           development of microbicides to prevent the transmission  
 19           of HIV and other sexually transmitted diseases.

20           “(c) MICROBICIDE DEVELOPMENT BRANCH.—In car-  
 21           rying out subsection (b), the Director of the National In-  
 22           stitute of Allergy and Infectious Diseases shall establish  
 23           within the Vaccine and Prevention Research Program of  
 24           the Division of AIDS in the Institute, a branch charged  
 25           with carrying out microbicide research and development.

1 In establishing such branch, the Director shall ensure that  
2 there are a sufficient number of employees dedicated to  
3 carry out the mission of the branch.

4 “(d) REPORT TO CONGRESS.—

5 “(1) IN GENERAL.—Not later than 1 year after  
6 the date on which the initial Federal strategic plan  
7 is developed under subsection (a), and biannually  
8 thereafter, the Director of the Office of AIDS Re-  
9 search shall submit to the appropriate committees of  
10 Congress a report that describes the strategies being  
11 implemented by the Federal Government regarding  
12 microbicide research and development. Each such re-  
13 port shall include—

14 “(A) a description of activities with respect  
15 to microbicides conducted and supported by the  
16 Federal Government;

17 “(B) a summary and analysis of expendi-  
18 tures, during the period for which the report is  
19 prepared, for activities with respect to  
20 microbicide-specific research and development,  
21 including the number of employees involved in  
22 these activities within each agency;

23 “(C) a description and evaluation of the  
24 progress made, during the period for which  
25 such report is prepared, towards the develop-



1           ment of effective, reliable, and acceptable  
2           microbicides;

3           “(D) a review of the remaining scientific  
4           and programmatic obstacles with respect to  
5           microbicides; and

6           “(E) an updated Federal Strategic Plan,  
7           including professional judgment funding projec-  
8           tions.

9           “(2) APPROPRIATE CONGRESSIONAL COMMIT-  
10          TEES DEFINITION.—For the purposes of this sub-  
11          section, the term ‘appropriate committees of Con-  
12          gress’ means the Committee on Energy and Com-  
13          merce and the Committee on Appropriations of the  
14          House of Representatives and the Committee on  
15          Health, Education, Labor, and Pensions and the  
16          Committee on Appropriations of the Senate.

17          “(e) HIV DEFINITION.—For purposes of this section,  
18          the term ‘HIV’ means the human immunodeficiency virus.  
19          Such term includes acquired immune deficiency syndrome  
20          (AIDS).

21          “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
22          purposes of carrying out this section, there are authorized  
23          to be appropriated such sums as may be necessary for  
24          each of fiscal years 2004 and 2005, and such sums as

1 may be necessary in subsequent fiscal years to sustain  
 2 multiyear funding at a productive level.”.

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

7 **SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION**  
 8 **OF HIV AND OTHER DISEASES.**

9 Part B of title III of the Public Health Service Act  
 10 (42 U.S.C. 243 et seq.) is amended—

11 (1) by transferring section 317R so as to ap-  
 12 pear after section 317Q; and

13 (2) by inserting after section 317R (as so trans-  
 14 ferred) the following:

15 **“SEC. 317S. MICROBICIDES FOR PREVENTING TRANS-**  
 16 **MISSION OF HIV AND OTHER DISEASES.**

17 “(a) DEVELOPMENT AND IMPLEMENTATION OF THE  
 18 MICROBICIDE AGENDA SUPPORTED BY THE CENTERS  
 19 FOR DISEASE CONTROL AND PREVENTION.—The Direc-  
 20 tor of the Centers for Disease Control and Prevention  
 21 shall fully implement the Centers’ 5-year topical  
 22 microbicide agenda to support microbicide research and  
 23 development. Such an agenda shall include—

24 “(1) conducting laboratory research in prepara-  
 25 tion for, and support of, clinical microbicide trials;

1           “(2) conducting behavioral research in prepara-  
2           tion for, and support of, clinical microbicide trials;

3           “(3) developing and characterizing domestic  
4           populations and international cohorts appropriate  
5           for Phase I, II, and III clinical trials of candidate  
6           topical microbicides;

7           “(4) conducting Phase I and II clinical trials to  
8           assess the safety and acceptability of candidate  
9           microbicides;

10          “(5) conducting Phase III clinical trials to as-  
11          sess the efficacy of candidate microbicides;

12          “(6) providing technical assistance to, and con-  
13          sulting with, a wide variety of domestic and inter-  
14          national entities involved in developing and evalu-  
15          ating topical microbicides, including health agencies,  
16          extramural researchers, industry, health advocates,  
17          and nonprofit organizations; and

18          “(7) developing and evaluating the diffusion  
19          and effects of implementation strategies for use of  
20          effective topical microbicides.

21          “(b) STAFFING.—In carrying out the microbicide  
22          agenda, the Centers for Disease Control and Prevention  
23          shall ensure that there are sufficient numbers of dedicated  
24          employees for carrying out the agenda under subsection  
25          (a).

1 “(c) REPORT TO CONGRESS.—

2 “(1) IN GENERAL.—Not later than 1 year after  
3 the date of enactment of this section, and biannually  
4 thereafter, the Director of the Centers for Disease  
5 Control and Prevention shall submit to the appro-  
6 priate committees of Congress, a report on the strat-  
7 egies being implemented by the Centers for Disease  
8 Control and Prevention with respect to microbicide  
9 research and development. Such report shall be sub-  
10 mitted alone or as part of the overall Federal stra-  
11 tegic plan on microbicides compiled annually by the  
12 National Institutes of Health Office of AIDS Re-  
13 search as required under section 2351A. Such report  
14 shall include—

15 “(A) a description of activities with respect  
16 to microbicides conducted and supported by the  
17 Centers for Disease Control and Prevention;

18 “(B) a summary and analysis of expendi-  
19 tures, during the period for which the report is  
20 prepared, for activities with respect to  
21 microbicide-specific research and development,  
22 including the number of employees involved in  
23 these activities;

24 “(C) a description and evaluation of the  
25 progress made, during the period for which

1           such report is prepared, towards the develop-  
2           ment of effective, reliable, and acceptable  
3           microbicides; and

4           “(D) a review of the remaining scientific  
5           and programmatic obstacles with respect to  
6           microbicides.

7           “(2) APPROPRIATE CONGRESSIONAL COMMIT-  
8           TEES DEFINITION.—For the purposes of this sub-  
9           section, the term ‘appropriate committees of Con-  
10          gress’ means the Committee on Energy and Com-  
11          merce and the Committee on Appropriations of the  
12          House of Representatives and the Committee on  
13          Health, Education, Labor, and Pensions and the  
14          Committee on Appropriations of the Senate.

15          “(d) DEFINITION.—For the purposes of this section,  
16          the term ‘HIV’ means the human immunodeficiency virus.  
17          Such term includes acquired immune deficiency syndrome  
18          (AIDS).

19          “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
20          purposes of carrying out this section, there are authorized  
21          to be appropriated such sums as may be necessary for  
22          each of fiscal years 2004 and 2005, and such sums as  
23          may be necessary in subsequent fiscal years to sustain  
24          multiyear funding at a productive level.”.

1 **TITLE III—MICROBICIDE RE-**  
 2 **SEARCH AT THE UNITED**  
 3 **STATES AGENCY FOR INTER-**  
 4 **NATIONAL DEVELOPMENT**

5 **SEC. 301. MICROBICIDES FOR PREVENTING TRANSMISSION**  
 6 **OF HIV AND OTHER DISEASES.**

7 Chapter 1 of part I of the Foreign Assistance Act  
 8 of 1961 (22 U.S.C. 2151 et seq.) is amended by inserting  
 9 after section 104 the following:

10 **“SEC. 104A. MICROBICIDES FOR PREVENTING TRANS-**  
 11 **MISSION OF HIV AND OTHER DISEASES.**

12 “(a) DEVELOPMENT AND IMPLEMENTATION OF THE  
 13 MICROBICIDE AGENDA SUPPORTED BY THE AGENCY FOR  
 14 INTERNATIONAL DEVELOPMENT.—The Office of HIV/  
 15 AIDS of the Agency for International Development, in  
 16 conjunction with other offices within the Agency for Inter-  
 17 national Development, shall fully implement the Agency’s  
 18 microbicide agenda to support the development of  
 19 microbicides, and facilitate wide-scale introduction once  
 20 microbicide products are available. Such an agenda shall  
 21 include—

22 “(1) support for the discovery, development,  
 23 and preclinical evaluation of topical microbicides;

24 “(2) support for the conduct of clinical studies  
 25 of candidate microbicides to assess safety, accept-

1 ability, and effectiveness in reducing HIV and other  
2 sexually transmitted diseases;

3 “(3) support for behavioral and social science  
4 research relevant to microbicide development, test-  
5 ing, acceptability, and use;

6 “(4) support for preintroductory and introduc-  
7 tory studies of safe and effective microbicides in de-  
8 veloping countries; and

9 “(5) facilitation of access to microbicides as  
10 they become available to women at highest risk of  
11 HIV and other sexually transmitted diseases as soon  
12 as possible.

13 “(b) STAFFING.—The Office of HIV/AIDS of the  
14 Agency for International Development shall ensure that  
15 there are sufficient numbers of dedicated employees for  
16 purposes of carrying out the agenda under subsection (a).

17 “(c) REPORT TO CONGRESS.—

18 “(1) IN GENERAL.—Not later than 1 year after  
19 the date of enactment of this section, and biannually  
20 thereafter, the Administrator of the Agency for  
21 International Development shall submit to the ap-  
22 propriate committees of Congress a report on the  
23 strategies being implemented by the Agency for  
24 International Development with respect to  
25 microbicide research and development. Such report

1 shall be submitted alone or as part of the overall  
2 Federal strategic plan on microbicides compiled an-  
3 nually by the National Institutes of Health Office of  
4 AIDS Research as required under section 2351A.  
5 Such report shall include—

6 “(A) a description of activities with respect  
7 to microbicides conducted and supported by the  
8 Agency for International Development;

9 “(B) a summary and analysis of expendi-  
10 tures, during the period for which the report is  
11 prepared, for activities with respect to  
12 microbicide-specific research and development,  
13 including the number of employees involved in  
14 these activities;

15 “(C) a description and evaluation of the  
16 progress made, during the period for which  
17 such report is prepared, towards the develop-  
18 ment of effective, reliable, and acceptable  
19 microbicides;

20 “(D) a review of the remaining scientific  
21 and programmatic obstacles with respect to  
22 microbicides; and

23 “(E) a description of the steps being taken  
24 to increase access and availability of approved



1           microbicides to prevent HIV and other sexually  
2           transmitted diseases.

3           “(2) APPROPRIATE CONGRESSIONAL COMMIT-  
4           TEES DEFINITION.—For the purposes of this sub-  
5           section, the term ‘appropriate committees of Con-  
6           gress’ means the Committee on International Rela-  
7           tions and the Committee on Appropriations of the  
8           House of Representatives and the Committee on  
9           Foreign Relations and the Committee on Appropria-  
10          tions of the Senate.

11          “(d) DEFINITION.—For the purposes of this section,  
12          the term ‘HIV’ means the human immunodeficiency virus.  
13          Such term includes acquired immune deficiency syndrome  
14          (AIDS).

15          “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
16          purposes of carrying out this section, there are authorized  
17          to be appropriated such sums as may be necessary for  
18          each of fiscal years 2004 and 2005, and such sums as  
19          may be necessary in subsequent fiscal years to sustain  
20          multiyear funding at a productive level.”.

○