

109TH CONGRESS  
1ST SESSION

# S. 550

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

---

## IN THE SENATE OF THE UNITED STATES

MARCH 8, 2005

Mr. CORZINE (for himself, Mr. OBAMA, Ms. SNOWE, Mr. BINGAMAN, Mrs. BOXER, Ms. CANTWELL, Mrs. CLINTON, Mr. DODD, Mr. DURBIN, Mrs. FEINSTEIN, Mr. KENNEDY, Mr. LAUTENBERG, Mr. LEAHY, Ms. MIKULSKI, Mrs. MURRAY, Mr. SCHUMER, Mr. SMITH, and Mr. KERRY) 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, 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 “Microbicide Develop-  
5       ment Act”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Women and girls are the new face of HIV/  
4 AIDS, and are increasingly affected by the disease  
5 in each region of the world. Women account for  
6 nearly 1/2 of the 37,000,000 adults living with HIV  
7 and AIDS worldwide as of 2005. Approximately  
8 7,000 women are newly infected with HIV each day.

9 (2) Because of their social and biological  
10 vulnerabilities, young women are particularly at risk.  
11 In Sub-Saharan Africa, 76 percent of the young peo-  
12 ple (between ages 15 and 24) with HIV are girls  
13 under 20.

14 (3) When women become infected with HIV,  
15 they can pass along the infection to their children  
16 during pregnancy, labor and delivery, or breast-feed-  
17 ing. The most effective way to halt mother-to-child  
18 transmission is to ensure that mothers are not in-  
19 fected in the first place.

20 (4) An increasing number of women who be-  
21 come infected with HIV have only 1 sexual partner,  
22 their husband. Unfortunately, marriage is not nec-  
23 essarily effective protection against HIV, because to  
24 protect themselves from HIV, women have to rely on  
25 their male partners to be faithful or to use condoms.  
26 Many women in the developing world are unable to

1       insist on mutual monogamy or negotiate condom  
2       use, especially in long-term relationships.

3           (5) Scientists are working on a promising new  
4       prevention tool that could slow down the spread of  
5       the HIV/AIDS epidemic, microbicides. Formulated  
6       as gels, creams, or rings, microbicides inactivate,  
7       block, or otherwise interfere with the transmission of  
8       the pathogens that cause AIDS and other sexually  
9       transmitted diseases (“STD”s). Microbicides could  
10      allow a woman to protect herself from disease.

11          (6) Married couples need a method of HIV pro-  
12      tection that will allow them to conceive a child and  
13      start a family. No existing HIV prevention method  
14      also allows conception. Microbicides are being devel-  
15      oped to allow women to both conceive children and  
16      protect themselves from HIV.

17          (7) Households in developing countries often  
18      dissolve when a mother dies. In the hardest hit  
19      countries, the number of children who are orphaned  
20      by AIDS is increasing dramatically.

21          (8) Women in the United States also need HIV  
22      prevention tools like microbicides. AIDS is now the  
23      number 1 cause of death among African-American  
24      women between the ages of 25 and 34.

1           (9) In addition to HIV, other STDs continue to  
2       be a major health threat in the United States. The  
3       United States has the highest rates of sexually  
4       transmitted diseases of any industrialized nation.  
5       Nineteen million STD infections occur every year. It  
6       is estimated that by age 25, 1/2 of all sexually active  
7       people in the United States can expect to be infected  
8       with an STD.

9           (10) HIV and AIDS represent a threat to na-  
10      tional security and economic well being, with direct  
11      medical costs of up to \$15,500,000,000 per year.  
12      The pandemic undermines armies, foments unrest,  
13      and burdens the United States military.

14          (11) As the Nation's largest single provider of  
15      HIV/AIDS care, the Veterans Affairs health care  
16      system spent \$359,000,000 to provided care to more  
17      than 20,000 American veterans with HIV/AIDS in  
18      fiscal year 2004.

19          (12) The microbicide field has achieved an ex-  
20      traordinary amount of scientific momentum, with  
21      several first-generation candidates now in large scale  
22      human trials around the world. At same time, new  
23      products, based upon recent advances in HIV treat-  
24      ment, have advanced into early safety trials.

1           (13) Microbicides are a classic public health  
2           good for which the social benefits are high but the  
3           economic incentive to private investment is low. Like  
4           other public health goods, such as vaccines, public  
5           funding must fill the gap. Microbicide research de-  
6           pends in large part on Government leadership and  
7           investment.

8           (14) The Federal Government needs to make a  
9           strong commitment to microbicide research and de-  
10          velopment. Three agencies—the National Institutes  
11          of Health (“NIH”), the Centers for Disease Control  
12          and Prevention (“CDC”), and the United States  
13          Agency of International Development (“USAID”)—  
14          have played important roles in the progress to date,  
15          but further strong, well-coordinated, and visible pub-  
16          lic sector leadership will be essential for the promise  
17          of microbicides to be realized.

18          (15) As of 2005, microbicide research at NIH  
19          is conducted under several institutes with no single  
20          line of administrative accountability, no specific  
21          funding coordination, and highly variable levels of  
22          interest and commitment across institute leadership.  
23          Only a few NIH staff can claim microbicides as their  
24          sole focus.

1           (16) The President’s Emergency Plan for AIDS  
2       Relief (“PEPFAR”) recognizes the urgency of devel-  
3       oping safe and effective microbicides to prevent  
4       HIV. In addition, NIH documents state that “the  
5       US government is firmly committed to accelerating  
6       the development of safe and effective microbicides to  
7       prevent HIV,” recognizing that microbicides may  
8       provide “one of the most promising preventative  
9       interventions given that could be inexpensive, readily  
10      available, and widely acceptable”. But as of 2005,  
11      NIH spends barely 2 percent of its HIV/AIDS re-  
12      search budget on microbicides. As more microbicide  
13      candidates are advanced into later-stage clinical  
14      trials and development costs rise correspondingly,  
15      2005 funding levels are simply inadequate.

16           (17) USAID and the CDC have expanded their  
17      microbicide portfolios, but without overall Federal  
18      coordination, costly inefficiencies and unproductive  
19      duplication of effort may result. USAID sustains  
20      strong partnerships with public and private organi-  
21      zations working on microbicide research, importantly  
22      including clinical trials in developing countries where  
23      its experience is extensive. USAID is well positioned  
24      to facilitate the introduction of microbicides once  
25      they are available. The CDC also engages in critical

1       microbicide research and clinical testing, and has a  
 2       long history of conducting field trials in developing  
 3       countries.

4               (18) HIV prevention options available as of  
 5       2005 are not enough. HIV prevention strategies  
 6       must recognize women’s needs and vulnerabilities. If  
 7       women are to have a genuine opportunity to protect  
 8       themselves, their best option is the rapid develop-  
 9       ment of new HIV-prevention technologies like  
 10      microbicides, which women can initiate and control.

11   **TITLE       I—MICROBICIDE       RE-**  
 12       **SEARCH AT THE NATIONAL**  
 13       **INSTITUTES OF HEALTH**

14   **SEC. 101. OFFICE OF AIDS RESEARCH; PROGRAM REGARD-**  
 15               **ING MICROBICIDES FOR PREVENTING TRANS-**  
 16               **MISSION OF HIV AND OTHER DISEASES.**

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

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

22       “(a) FEDERAL STRATEGIC PLAN.—

23               “(1) IN GENERAL.—The Director of the Office  
 24       of AIDS Research shall—

1           “(A) expedite the implementation of a  
 2           Federal strategic plan for the conduct and sup-  
 3           port of microbicide research and development;  
 4           and

5           “(B) annually review and, as appropriate,  
 6           revise such plan, to prioritize funding and ac-  
 7           tivities in terms of their scientific urgency.

8           “(2) COORDINATION.—In implementing, review-  
 9           ing, and prioritizing elements of the plan described  
 10          under paragraph (1), the Director of the Office of  
 11          AIDS Research shall coordinate with—

12           “(A) other Federal agencies, including the  
 13           Director of the Centers for Disease Control and  
 14           Prevention and the Administrator of the United  
 15           States Agency for International Development,  
 16           involved in microbicide research;

17           “(B) the microbicide research community;  
 18           and

19           “(C) health advocates.

20          “(b) EXPANSION AND COORDINATION OF ACTIVI-  
 21          TIES.—The Director of the Office of AIDS Research, act-  
 22          ing in coordination with other relevant institutes and of-  
 23          fices, shall expand, intensify, and coordinate the activities  
 24          of all appropriate institutes and components of the Na-  
 25          tional Institutes of Health with respect to research and



1 development of microbicides to prevent the transmission  
2 of the human immunodeficiency virus (‘HIV’) and other  
3 sexually transmitted diseases.

4 “(c) MICROBICIDE DEVELOPMENT UNIT.—In car-  
5 rying out subsection (b), the Director of the National In-  
6 stitute of Allergy and Infectious Diseases shall establish  
7 within the Division of AIDS in the Institute, a clearly de-  
8 fined organizational unit charged with carrying out  
9 microbicide research and development. In establishing  
10 such unit, the Director shall ensure that there are a suffi-  
11 cient number of employees dedicated to carrying out the  
12 mission of the unit.

13 “(d) MICROBICIDE CLINICAL TRIALS.—In carrying  
14 out subsection (c), the Director of the National Institute  
15 of Allergy and Infectious Diseases shall assign priority to  
16 ensuring adequate funding and support for the integration  
17 of basic science and clinical research, with particular em-  
18 phasis on implementation of trials leading to product li-  
19 censure.

20 “(e) REPORTS TO CONGRESS.—

21 “(1) IN GENERAL.—Not later than 6 months  
22 after the date of enactment of the Microbicide De-  
23 velopment Act, and annually thereafter, the Director  
24 of the Office of AIDS Research shall submit to the  
25 appropriate committees of Congress a report that

1 describes the strategies being implemented by the  
2 Federal Government regarding microbicide research  
3 and development.

4 “(2) CONTENTS OF REPORTS.—Each report  
5 submitted under paragraph (1) shall include—

6 “(A) a description of activities with respect  
7 to microbicide research and development con-  
8 ducted and supported by the Federal Govern-  
9 ment;

10 “(B) a summary and analysis of the ex-  
11 penditures made by the Director of the Office  
12 of AIDS Research during the preceding year  
13 for activities with respect to microbicide-specific  
14 research and development, including basic re-  
15 search, preclinical product development, clinical  
16 trials, and process development and production;

17 “(C) a description and evaluation of the  
18 progress made, during the preceding year, to-  
19 ward the development of effective and accept-  
20 able microbicides; and

21 “(D) a review of scientific and pro-  
22 grammatic obstacles to expediting the commer-  
23 cial availability of microbicide products.

24 “(3) APPROPRIATE COMMITTEES OF CONGRESS  
25 DEFINED.—In this subsection, the term ‘appropriate

1 committees of Congress’ means the Committee on  
 2 Health, Education, Labor, and Pensions and the  
 3 Committee on Appropriations of the Senate and the  
 4 Committee on Energy and Commerce and the Com-  
 5 mittee on Appropriations of the House of Represent-  
 6 atives.

7 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
 8 are authorized to be appropriated such sums as may be  
 9 necessary for each fiscal year to carry out this section.”.

10 **TITLE II—MICROBICIDE RE-**  
 11 **SEARCH AT THE CENTERS**  
 12 **FOR DISEASE CONTROL AND**  
 13 **PREVENTION**

14 **SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION**  
 15 **OF HIV AND OTHER DISEASES.**

16 Part B of title III of the Public Health Service Act  
 17 (42 U.S.C. 243 et seq.) is amended—

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

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

22 **“SEC. 371S. MICROBICIDES FOR PREVENTING TRANS-**  
 23 **MISSION OF HIV AND OTHER DISEASES.**

24 “(a) DEVELOPMENT AND IMPLEMENTATION OF THE  
 25 MICROBICIDE AGENDA SUPPORTED BY THE CENTERS

1 FOR DISEASE CONTROL AND PREVENTION.—The Direc-  
2 tor of the Centers for Disease Control and Prevention  
3 shall fully implement such Centers’ topical microbicide  
4 agenda to support microbicide research and development.  
5 Such an agenda shall include—

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

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

10 “(3) developing and characterizing domestic  
11 populations and international cohorts appropriate  
12 for Phases I, II, and III clinical trials of candidate  
13 topical microbicides;

14 “(4) conducting Phases I and II clinical trials  
15 to assess the safety and acceptability of candidate  
16 microbicides;

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

19 “(6) providing technical assistance to, and con-  
20 sulting with, a wide variety of domestic and inter-  
21 national entities involved in developing and evalu-  
22 ating topical microbicides, including health agencies,  
23 extramural researchers, industry, health advocates,  
24 and nonprofit organizations; and

1           “(7) developing and evaluating the diffusion  
2           and effects of implementation strategies for use of  
3           effective topical microbicides.

4           “(b) PERSONNEL.—The Centers for Disease Control  
5           and Prevention shall ensure that there are sufficient num-  
6           bers of dedicated employees for carrying out the  
7           microbicide agenda under subsection (a).

8           “(c) REPORT TO CONGRESS.—

9           “(1) IN GENERAL.—Not later than 1 year after  
10          the date of enactment of the Microbicide Develop-  
11          ment Act, and annually thereafter, the Director of  
12          the Centers for Disease Control and Prevention shall  
13          submit to the appropriate committees of Congress, a  
14          report on the strategies being implemented by the  
15          Centers for Disease Control and Prevention with re-  
16          spect to microbicide research and development. Such  
17          report shall be submitted alone or as part of the  
18          overall Federal strategic plan on microbicides com-  
19          piled annually by the National Institutes of Health  
20          Office of AIDS Research as required under section  
21          2351A.

22          “(2) CONTENTS OF REPORT.—Such report shall  
23          include—

24                 “(A) a description of activities with respect  
25                 to microbicides conducted or supported by the

1 Director of the Centers for Disease Control and  
2 Prevention;

3 “(B) a summary and analysis of the ex-  
4 penditures made by such Director during the  
5 preceding year, for activities with respect to  
6 microbicide-specific research and development,  
7 including the number of employees of such Cen-  
8 ters involved in such activities;

9 “(C) a description and evaluation of the  
10 progress made, during the preceding year, to-  
11 ward the development of effective and accept-  
12 able microbicides; and

13 “(D) a review of scientific and pro-  
14 grammatic obstacles to expediting the commer-  
15 cial availability of microbicide products.

16 “(3) APPROPRIATE COMMITTEES OF CONGRESS  
17 DEFINED.—For the purposes of this subsection, the  
18 term ‘appropriate committees of Congress’ means  
19 the Committee on Health, Education, Labor, and  
20 Pensions and the Committee on Appropriations of  
21 the Senate and the Committee on Energy and Com-  
22 merce and the Committee on Appropriations of the  
23 House of Representatives.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
 2 are authorized to be appropriated such sums as may be  
 3 necessary for each fiscal year to carry out this section.”.

4 **TITLE III—MICROBICIDE RE-**  
 5 **SEARCH AT THE UNITED**  
 6 **STATES AGENCY FOR INTER-**  
 7 **NATIONAL DEVELOPMENT**

8 **SEC. 301. MICROBICIDES FOR PREVENTING TRANSMISSION**  
 9 **OF HIV AND OTHER DISEASES.**

10 Section 104A of the Foreign Assistance Act of 1961  
 11 (22 U.S.C. 2151b–2) is amended by adding at the end  
 12 the following new subsection:

13 “(h) MICROBICIDES FOR PREVENTING TRANS-  
 14 MISSION OF HIV AND OTHER DISEASES.—

15 “(1) DEVELOPMENT AND IMPLEMENTATION OF  
 16 THE MICROBICIDE AGENDA.—The head of the Office  
 17 of HIV/AIDS of the United States Agency for Inter-  
 18 national Development, in conjunction with other of-  
 19 fices of such Agency, shall develop and implement a  
 20 program to support the development of microbicides  
 21 products for the prevention of the transmission of  
 22 HIV and other diseases, and facilitate wide-scale  
 23 availability of such products after such development.  
 24 The program shall be known as the ‘microbicide  
 25 agenda’ and shall include—

1           “(A) support for the discovery, develop-  
2           ment, and preclinical evaluation of topical  
3           microbicides;

4           “(B) support for the conduct of clinical  
5           studies of candidate microbicides to assess the  
6           safety, acceptability, and effectiveness of such  
7           microbicides in reducing the transmission of  
8           HIV and other sexually transmitted diseases;

9           “(C) support for behavioral and social  
10          science research relevant to microbicide develop-  
11          ment, testing, acceptability, and use;

12          “(D) support for preintroductory and in-  
13          troductory studies of safe and effective  
14          microbicides in developing countries; and

15          “(E) facilitation of access to microbicides  
16          by women at highest risk of contracting HIV or  
17          other sexually transmitted diseases, at the ear-  
18          liest possible time.

19          “(2) STAFFING.—The head of the Office of  
20          HIV/AIDS shall ensure that the Agency has a suffi-  
21          cient number of dedicated employees to carry out the  
22          microbicide agenda.

23          “(3) REPORTS TO CONGRESS.—

24                 “(A) IN GENERAL.—Not later than 1 year  
25                 after the date of enactment of the Microbicide



1 Development Act, and annually thereafter, the  
2 Administrator of the Agency shall submit to the  
3 appropriate committees of Congress a report on  
4 the activities of the Administrator to carry out  
5 the microbicide agenda and on any other activi-  
6 ties carried out by the Administrator related to  
7 microbicide research and development.

8 “(B) CONTENTS OF REPORT.—Each report  
9 submitted under subparagraph (A) shall in-  
10 clude—

11 “(i) a description of activities with re-  
12 spect to microbicides conducted or sup-  
13 ported by the Administrator;

14 “(ii) a summary and analysis of the  
15 expenditures made by the Administrator  
16 during the preceding year for activities  
17 with respect to microbicide-specific re-  
18 search and development, including the  
19 number of employees of the Agency who  
20 are involved in such activities;

21 “(iii) a description and evaluation of  
22 the progress made during the preceding  
23 year toward the development of effective  
24 and acceptable microbicides;

1 “(iv) a review of scientific and pro-  
 2 grammatic obstacles to expediting the com-  
 3 mercial availability of microbicide products;  
 4 and

5 “(v) a description of the activities car-  
 6 ried out to increase the availability of  
 7 microbicides approved to prevent the trans-  
 8 mission of HIV or other sexually trans-  
 9 mitted diseases.

10 “(C) CONSULTATION.—The Administrator  
 11 shall consult with the Director of the Office of  
 12 AIDS Research of the National Institutes of  
 13 Health in preparing a report required by sub-  
 14 paragraph (A).

15 “(D) APPROPRIATE COMMITTEES OF CON-  
 16 GRESS DEFINED.—In this paragraph, the term  
 17 ‘appropriate committees of Congress’ means the  
 18 Committee on Foreign Relations and the Com-  
 19 mittee on Appropriations of the Senate and the  
 20 Committee on International Relations and the  
 21 Committee on Appropriations of the House of  
 22 Representatives.

23 “(4) AUTHORIZATION OF APPROPRIATIONS.—  
 24 There are authorized to be appropriated such sums

- 1 as may be necessary for each fiscal year to carry out
- 2 this subsection.”.

