

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

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## 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

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# 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 cessarily 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,  $\frac{1}{2}$  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.

(14) The Federal Government needs to make a strong commitment to microbicide research and development. Three agencies—the National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), and the United States Agency of International Development (“USAID”)—have played important roles in the progress to date, but further strong, well-coordinated, and visible public sector leadership will be essential for the promise 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.

(16) The President's Emergency Plan for AIDS Relief ("PEPFAR") recognizes the urgency of developing safe and effective microbicides to prevent HIV. In addition, NIH documents state that "the US government is firmly committed to accelerating the development of safe and effective microbicides to prevent HIV," recognizing that microbicides may provide "one of the most promising preventative interventions given that could be inexpensive, readily available, and widely acceptable". But as of 2005, NIH spends barely 2 percent of its HIV/AIDS research budget on microbicides. As more microbicide candidates are advanced into later-stage clinical trials and development costs rise correspondingly, 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 organiza-  
21 tions 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 fered) 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 eval-  
22           uating 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;

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, development,  
2               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              introductory 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—

1                             “(iv) a review of scientific and pro-  
2                             grammatical 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.”.

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