

110TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

Mr. OBAMA (for himself, Ms. SNOWE, Mr. DURBIN, Mr. DODD, and Mrs. CLINTON) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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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/AIDS 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”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1           (1) Women and girls are the new face of HIV/  
2           AIDS, and are increasingly affected by the disease  
3           in every region of the world. As of 2006, nearly half  
4           of the 37,200,000 adults living with HIV and AIDS  
5           worldwide were women. In sub-Saharan Africa, that  
6           proportion was 59 percent.

7           (2) Because of their social and biological  
8           vulnerabilities, young women are particularly at risk  
9           of HIV infection. In sub-Saharan Africa, the preva-  
10          lence of HIV/AIDS is three times higher among  
11          women ages 15 to 24 than it is among men in that  
12          same age group.

13          (3) Women infected with HIV can transmit the  
14          infection to their infants during pregnancy, labor,  
15          delivery, or breast-feeding. The most effective way to  
16          interrupt mother-to-child transmission is to ensure  
17          that mothers are not infected in the first place.

18          (4) Many women who become infected with  
19          HIV have just one sexual partner--their husband.  
20          Marriage is not necessarily effective protection  
21          against HIV, because to protect themselves from  
22          HIV, women have to rely on their male partners to  
23          be faithful or to use condoms. Many women, espe-  
24          cially in the developing world, are unable to insist on

1 mutual monogamy or negotiate condom use, particu-  
2 larly 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, tablets or rings, microbicides are  
7 being designed to stop the transmission of the  
8 pathogens that cause AIDS and other sexually  
9 transmitted infections (referred to in this section as  
10 "STIs"). Microbicides could allow a woman to pro-  
11 tect herself from disease.

12 (6) Couples need a method of HIV protection  
13 that will allow them to conceive a child and start a  
14 family. No existing HIV prevention method also al-  
15 lows conception. Some microbicides in development  
16 may allow women to become pregnant while at the  
17 same time protecting them from infection.

18 (7) According to UNICEF, worldwide, the lack  
19 of HIV/AIDS prevention and treatment has left over  
20 15,000,000 children as orphans. Of these, more than  
21 12,000,000 live in sub-Saharan Africa. The number  
22 of AIDS orphans in sub-Saharan Africa alone is ex-  
23 pected to grow to nearly 16,000,000 by 2010.

24 (8) HIV prevention tools like microbicides could  
25 also be valuable for women in the United States,

1 who account for an increasing proportion of new  
2 HIV and AIDS cases among Americans. Minority  
3 women in the United States are particularly af-  
4 fected. Both African-American and Latina women  
5 account for a disproportionate number of new AIDS  
6 cases, and HIV/AIDS was the leading cause of death  
7 in 2002 for African-American women ages 25 to 34.

8 (9) With nearly 20,000,000 new cases of sexu-  
9 ally transmitted infections occurring every year, the  
10 United States has the highest STI rates of any in-  
11 dustrialized nation. Like HIV, STIs pose significant  
12 health threats and costs, with young people and  
13 women bearing a disproportionate burden. Nearly  
14 half of new STI cases each year occur in people  
15 under 25 years of age with women both more vulner-  
16 able to infection and more likely to experience seri-  
17 ous and lasting health consequences when they do  
18 become infected. Some microbicides could help pre-  
19 vent STIs.

20 (10) HIV/AIDS threatens national and global  
21 security. Beyond its burdens on individuals, families,  
22 and communities, the pandemic reduces economic  
23 growth, decimates health budgets, undermines civil  
24 society, and burdens the armed forces of many na-  
25 tions, including the United States military.

1           (11) The microbicide field has gained consider-  
2           able scientific momentum. Several first-generation  
3           products are in large-scale human trials to measure  
4           effectiveness, and new products based on recent ad-  
5           vances in HIV treatment are well into safety trials.

6           (12) Microbicides are a public health good with  
7           potential for large social benefits but limited eco-  
8           nomic incentives for private investment, so that pub-  
9           lic funding is required to fill the gap. As is the case  
10          for vaccines and other public goods, microbicide de-  
11          velopment must depend heavily on government lead-  
12          ership and investment.

13          (13) The Federal Government needs to make a  
14          strong commitment to microbicide research and de-  
15          velopment. Three agencies, the National Institutes of  
16          Health, Centers for Disease Control and Prevention,  
17          and United States Agency for International Develop-  
18          ment, have played important roles in the progress to  
19          date, and each makes a valuable and unique con-  
20          tribution. As the primary federal agency for con-  
21          ducting and supporting medical research and the  
22          largest single Federal Government contributor to  
23          microbicide research, the National Institutes of  
24          Health supports the Microbicide Trials Network as  
25          well as other important research activities. The

1 United States Agency for International Development  
2 sustains strong partnerships with public and private  
3 organizations working on microbicide research, in-  
4 cluding trials in developing countries where its expe-  
5 rience is extensive, and is well positioned to facilitate  
6 introduction of microbicides once available. The Cen-  
7 ters for Disease Control and Prevention has a long  
8 history of conducting field trials in developing coun-  
9 tries, but the extent of its current engagement re-  
10 mains quite limited.

11 (14) According to the National Institutes of  
12 Health’s strategic plan, microbicides may provide  
13 “one of the most promising primary preventative  
14 interventions that could be safe, effective, readily  
15 available, affordable, and widely acceptable.” In a  
16 recent report to Congress, the United States Agency  
17 for International Development states that “the US  
18 government is firmly committed to accelerating the  
19 development of safe and effective microbicides to  
20 prevent HIV.” In addition, the President’s Emer-  
21 gency Plan for AIDS Relief recognizes the urgency  
22 of developing safe and effective microbicides.

23 (15) The National Institutes of Health, United  
24 States Agency for International Development, and  
25 the Centers for Disease Control and Prevention have

1 expanded their microbicide portfolios, but overall  
2 Federal leadership and coordination is required to  
3 eliminate costly inefficiencies and unproductive du-  
4 plication of effort.

5 (16) HIV prevention options available as of  
6 2006 are insufficient in general. Most critically, they  
7 fail to recognize women's particular needs and  
8 vulnerabilities. If women are to have a genuine op-  
9 portunity to protect themselves, their best option is  
10 the rapid development of new HIV-prevention tech-  
11 nologies like microbicides, which women can initiate.

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

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

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

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

23 **“(a) FEDERAL STRATEGIC PLAN.—**

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

1           “(A) expedite the implementation of Fed-  
2           eral strategic plans for the conduct and support  
3           of microbicide research and development; and

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

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

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

16           “(B) the microbicide research and develop-  
17          ment community; and

18           “(C) health advocates.

19          “(b) EXPANSION AND COORDINATION OF ACTIVI-  
20          TIES.—The Director of the Office of AIDS Research, act-  
21          ing in coordination with relevant institutes and offices,  
22          shall expand, intensify, and coordinate the activities of all  
23          appropriate institutes and components of the National In-  
24          stitutes of Health with respect to research and develop-  
25          ment of microbicides to prevent the transmission of the

1 human immunodeficiency virus (‘HIV’) and other sexually  
2 transmitted infections.

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

12 “(d) MICROBICIDE CLINICAL TRIALS.—In carrying  
13 out subsection (c), the Director of the National Institute  
14 of Allergy and Infectious Diseases shall assign priority to  
15 ensuring adequate funding and support for the  
16 Microbicide Trials Network and other programs for sup-  
17 porting microbicides clinical trials, with particular empha-  
18 sis on implementation of trials leading to product licen-  
19 sure.

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 behavioral science; and

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

20 “(3) APPROPRIATE COMMITTEES OF CONGRESS  
21 DEFINED.—In this subsection, the term ‘appropriate  
22 committees of Congress’ means the Committee on  
23 Health, Education, Labor, and Pensions and the  
24 Committee on Appropriations of the Senate and the  
25 Committee on Energy and Commerce and the Com-

1       mittee on Appropriations of the House of Represent-  
2       atives.

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

6       **TITLE       II—MICROBICIDE       RE-**  
7       **SEARCH AT THE CENTERS**  
8       **FOR DISEASE CONTROL AND**  
9       **PREVENTION**

10       **SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION**  
11               **OF HIV/AIDS AND OTHER DISEASES.**

12       Part B of title III of the Public Health Service Act  
13       (42 U.S.C. 243 et seq.) is amended—

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

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

18       **“SEC. 371S. MICROBICIDES FOR PREVENTING TRANS-**  
19               **MISSION OF HIV/AIDS AND OTHER DISEASES.**

20       “(a) DEVELOPMENT AND IMPLEMENTATION OF THE  
21       CENTERS FOR DISEASE CONTROL AND PREVENTION’S  
22       MICROBICIDE AGENDA.—The Director of the Centers for  
23       Disease Control and Prevention shall fully implement such  
24       Centers’ microbicide agenda to support microbicide re-  
25       search and development. Such an agenda shall include—

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

4           “(2) conducting behavioral research in prepara-  
5           tion for, and support of, clinical microbicide trials.

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

10          “(c) REPORT TO CONGRESS.—

11           “(1) IN GENERAL.—Not later than 1 year after  
12           the date of enactment of the Microbicide Develop-  
13           ment Act, and annually thereafter, the Director of  
14           the Centers for Disease Control and Prevention shall  
15           submit to the appropriate committees of Congress, a  
16           report on the strategies being implemented by the  
17           Centers for Disease Control and Prevention with re-  
18           spect to microbicide research and development. Such  
19           report shall be submitted alone or as part of the  
20           overall Federal strategic plan on microbicides com-  
21           piled annually by the National Institutes of Health  
22           Office of AIDS Research as required under section  
23           2351A.

24           “(2) CONTENTS OF REPORT.—Such report shall  
25           include—

1           “(A) a description of activities with respect  
2           to microbicides conducted or supported by the  
3           Director of the Centers for Disease Control and  
4           Prevention;

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

11          “(C) a description and evaluation of the  
12          progress made, during the preceding year, to-  
13          ward the development of effective microbicides.

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

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

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

6 **SEC. 301. MICROBICIDES FOR PREVENTING TRANSMISSION**  
7 **OF HIV/AIDS AND OTHER DISEASES.**

8 Section 104A of the Foreign Assistance Act of 1961  
9 (22 U.S.C. 2151b–2) is amended by adding at the end  
10 the following new subsection:

11 “(h) MICROBICIDES FOR PREVENTING TRANS-  
12 MISSION OF HIV/AIDS AND OTHER DISEASES.—

13 “(1) DEVELOPMENT AND IMPLEMENTATION OF  
14 THE MICROBICIDE AGENDA.—The head of the Office  
15 of HIV/AIDS of the United States Agency for Inter-  
16 national Development, in conjunction with other of-  
17 fices of such Agency, shall develop and implement a  
18 program to support the development of microbicides  
19 for the prevention of the transmission of HIV/AIDS  
20 and other diseases, and facilitate wide-scale avail-  
21 ability of such products after such development.

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

1 “(3) REPORTS TO CONGRESS.—

2 “(A) IN GENERAL.—Not later than 1 year  
3 after the date of enactment of the Microbicide  
4 Development Act, and annually thereafter, the  
5 Administrator of the Agency shall submit to the  
6 appropriate committees of Congress a report on  
7 the activities of the Administrator to carry out  
8 the microbicide agenda and on any other activi-  
9 ties carried out by the Administrator related to  
10 microbicide research and development.

11 “(B) CONTENTS OF REPORT.—Each report  
12 submitted under subparagraph (A) shall in-  
13 clude—

14 “(i) a description of activities with re-  
15 spect to microbicides conducted or sup-  
16 ported by the Administrator;

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

24 “(iii) a description and evaluation of  
25 the progress made during the preceding

1                   year toward the development of effective  
2                   microbicides, including activities in support  
3                   of eventual product access.

4                   “(C) CONSULTATION.—The Administrator  
5                   shall consult with the Director of the Office of  
6                   AIDS Research of the National Institutes of  
7                   Health in preparing a report required by sub-  
8                   paragraph (A).

9                   “(D) APPROPRIATE COMMITTEES OF CON-  
10                  GRESS DEFINED.—In this paragraph, the term  
11                  ‘appropriate committees of Congress’ means the  
12                  Committee on Foreign Relations and the Com-  
13                  mittee on Appropriations of the Senate and the  
14                  Committee on Foreign Affairs and the Com-  
15                  mittee on Appropriations of the House of Rep-  
16                  resentatives.

17                  “(4) AUTHORIZATION OF APPROPRIATIONS.—  
18                  There are authorized to be appropriated such sums  
19                  as may be necessary for each fiscal year to carry out  
20                  this subsection.”.

1       **TITLE IV—ADVANCE MARKET**  
2                                   **COMMITMENTS**

3       **SEC. 401. REPORT ON ADVANCE MARKET COMMITMENTS**  
4                                   **AS INCENTIVES FOR MICROBICIDE DEVELOP-**  
5                                   **MENT.**

6           (a) REPORT.—Not later than 180 days after the date  
7 of the enactment of this Act, the Secretary of State shall  
8 submit to the appropriate committees of Congress a report  
9 on the feasibility and impediments to the Government of  
10 the United States entering into advanced market commit-  
11 ments of microbicides to prevent HIV infection as a means  
12 of creating incentives for the private sector to invest in  
13 research, development, and manufacturing of  
14 microbicides.

15           (b) APPROPRIATE COMMITTEES OF CONGRESS DE-  
16 FINED.—In this section, the term “appropriate commit-  
17 tees of Congress” means the Committee on Health, Edu-  
18 cation, Labor, and Pensions and the Committee on For-  
19 eign Relations of the Senate, and the Committee on En-  
20 ergy and Commerce and the Committee on Foreign Affairs  
21 of the House of Representatives.