

109TH CONGRESS  
1ST SESSION

# H. R. 3854

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 2005

Mr. SHAYS (for himself, Ms. SCHAKOWSKY, Mr. DAVIS of Illinois, Mr. GEORGE MILLER of California, Mr. BROWN of Ohio, Ms. MILLENDER-MCDONALD, Mr. PAYNE, Mr. LEACH, Ms. LEE, Mr. EVANS, Ms. SCHWARTZ of Pennsylvania, Mr. CROWLEY, Mr. WAXMAN, Mr. KIRK, Mr. EMANUEL, Mr. BERMAN, Mr. GRIJALVA, Mr. JACKSON of Illinois, Mr. LARSON of Connecticut, Ms. BEAN, Mr. MCNULTY, Mr. OWENS, Mr. WEXLER, Mr. RUSH, Mr. GUTIERREZ, Mr. MCDERMOTT, Mr. MCGOVERN, Mr. VAN HOLLEN, Mr. STARK, and Mr. HONDA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on International Relations, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Microbicide Develop-  
3 ment Act”.

4 **SEC. 2. FINDINGS.**

5 Congress makes the following findings:

6 (1) Women and girls are the new face of HIV/  
7 AIDS, and are increasingly affected by the disease  
8 in each region of the world. Women account for  
9 nearly ½ of the 37,000,000 adults living with HIV  
10 and AIDS worldwide as of 2005. Approximately  
11 7,000 women are newly infected with HIV each day.

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

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

23 (4) An increasing number of women who be-  
24 come infected with HIV have only 1 sexual partner,  
25 their husband. Unfortunately, marriage is not nec-  
26 essarily effective protection against HIV, because to

1 protect themselves from HIV, women have to rely on  
2 their male partners to be faithful or to use condoms.  
3 Many women in the developing world are unable to  
4 insist on mutual monogamy or negotiate condom  
5 use, especially in long-term relationships.

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

14 (6) Married couples need a method of HIV pro-  
15 tection that will allow them to conceive a child and  
16 start a family. No existing HIV prevention method  
17 also allows conception. Some microbicides are being  
18 developed with the objective that they will allow con-  
19 ception while protecting from disease.

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

24 (8) Women in the United States also need HIV  
25 prevention tools like microbicides. AIDS is now the

1 number 1 cause of death among African-American  
2 women between the ages of 25 and 34.

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

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

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

21 (12) The microbicide field has achieved an ex-  
22 traordinary amount of scientific momentum, with  
23 several first-generation candidates now in large scale  
24 human trials around the world. At same time, new

1 products, based upon recent advances in HIV treat-  
2 ment, have advanced into early safety trials.

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

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

20 (15) As of 2005, microbicide research at NIH  
21 is conducted under several institutes with no single  
22 line of administrative accountability, no specific  
23 funding coordination, and highly variable levels of  
24 interest and commitment across institute leadership.

1 Only a few NIH staff can claim microbicides as their  
2 sole focus.

3 (16) The President's Emergency Plan for AIDS  
4 Relief ("PEPFAR") recognizes the urgency of devel-  
5 oping safe and effective microbicides to prevent  
6 HIV. In addition, NIH documents state that "the  
7 US government is firmly committed to accelerating  
8 the development of safe and effective microbicides to  
9 prevent HIV," recognizing that microbicides may  
10 provide "one of the most promising preventative  
11 interventions given that could be inexpensive, readily  
12 available, and widely acceptable". But as of 2005,  
13 NIH spends barely 2 percent of its HIV/AIDS re-  
14 search budget on microbicides. As more microbicide  
15 candidates are advanced into later-stage clinical  
16 trials and development costs rise correspondingly,  
17 2005 funding levels are simply inadequate.

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

1 to facilitate the introduction of microbicides once  
2 they are available. The CDC also engages in critical  
3 microbicide research and clinical testing, and has a  
4 long history of conducting field trials in developing  
5 countries.

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

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

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

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

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

24 “(a) FEDERAL STRATEGIC PLAN.—

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

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

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

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

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

19          “(B) the microbicide research community;  
20 and

21          “(C) health advocates.

22          “(b) EXPANSION AND COORDINATION OF ACTIVI-  
23 TIES.—The Director of the Office of AIDS Research, act-  
24 ing in coordination with other relevant institutes and of-  
25 fices, shall expand, intensify, and coordinate the activities

1 of all appropriate institutes and components of the Na-  
2 tional Institutes of Health with respect to research and  
3 development of microbicides to prevent the transmission  
4 of the human immunodeficiency virus (‘HIV’) and other  
5 sexually transmitted diseases.

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

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

22       “(e) REPORTS TO CONGRESS.—

23               “(1) IN GENERAL.—Not later than 6 months  
24 after the date of enactment of the Microbicide De-  
25 velopment Act, and annually thereafter, the Director

1 of the Office of AIDS Research shall submit to the  
2 appropriate committees of Congress a report that  
3 describes the strategies being implemented by the  
4 Federal Government regarding microbicide research  
5 and development.

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

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

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

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

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

1           “(3) APPROPRIATE COMMITTEES OF CONGRESS  
 2           DEFINED.—In this subsection, the term ‘appropriate  
 3           committees of Congress’ means the Committee on  
 4           Health, Education, Labor, and Pensions and the  
 5           Committee on Appropriations of the Senate and the  
 6           Committee on Energy and Commerce and the Com-  
 7           mittee on Appropriations of the House of Represent-  
 8           atives.

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

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

16       **SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION**  
 17                               **OF HIV AND OTHER DISEASES.**

18          Part B of title III of the Public Health Service Act  
 19          (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
 20          tion 317S the following:

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

23          “(a) DEVELOPMENT AND IMPLEMENTATION OF THE  
 24          MICROBICIDE AGENDA SUPPORTED BY THE CENTERS  
 25          FOR DISEASE CONTROL AND PREVENTION.—The Direc-

1 tor of the Centers for Disease Control and Prevention  
2 shall fully implement such Centers' topical microbicide  
3 agenda to support microbicide research and development.

4 Such an agenda shall include—

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

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

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

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

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

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

12 (1) by redesignating subsection (g) as sub-  
13 section (h); and

14 (2) by inserting after subsection (f) the fol-  
15 lowing:

16 “(g) MICROBICIDES FOR PREVENTING TRANS-  
17 MISSION OF HIV AND OTHER DISEASES.—

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

1 availability of such products after such development.

2 The program shall be known as the ‘microbicide  
3 agenda’ and shall include—

4 “(A) support for the discovery, develop-  
5 ment, and preclinical evaluation of topical  
6 microbicides;

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

12 “(C) support for behavioral and social  
13 science research relevant to microbicide develop-  
14 ment, testing, acceptability, and use;

15 “(D) support for preintroductory and in-  
16 troductory studies of safe and effective  
17 microbicides in developing countries; and

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

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;

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

1 year toward the development of effective  
2 and acceptable microbicides;

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

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

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

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

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