

110TH CONGRESS
1ST SESSION

H. R. 1420

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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 8, 2007

Ms. SCHAKOWSKY (for herself, Mr. SHAYS, Mrs. CAPPIS, Ms. BEAN, Mr. BERMAN, Mr. DAVIS of Illinois, Mr. EMANUEL, Mr. GRIJALVA, Mr. KIRK, Ms. LEE, Ms. MATSUI, Mr. McDERMOTT, Mr. McNULTY, and Ms. SCHWARTZ) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Foreign Affairs, 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

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”.

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 every region of the world. As of 2006, nearly half
6 of the 37,200,000 adults living with HIV and AIDS
7 worldwide were women. In sub-Saharan Africa, that
8 proportion was 59 percent.9 (2) Because of their social and biological
10 vulnerabilities, young women are particularly at risk
11 of HIV infection. In sub-Saharan Africa, the preva-
12 lence of HIV/AIDS is three times higher among
13 women ages 15 to 24 than it is among men in that
14 same age group.15 (3) Women infected with HIV can transmit the
16 infection to their infants during pregnancy, labor,
17 delivery, or breast-feeding. The most effective way to
18 interrupt mother-to-child transmission is to ensure
19 that mothers are not infected in the first place.20 (4) Many women who become infected with
21 HIV have just one sexual partner—their husband.
22 Marriage is not necessarily effective protection
23 against HIV, because to protect themselves from
24 HIV, women have to rely on their male partners to
25 be faithful or to use condoms. Many women, espe-
26 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 vuln-
16 erable 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.

(12) Microbicides are a public health good with potential for large social benefits but limited economic incentives for private investment, so that public funding is required to fill the gap. As is the case for vaccines and other public goods, microbicide development must depend heavily on government leadership and investment.

(13) The Federal Government needs to make a strong commitment to microbicide research and development. Three agencies, the National Institutes of Health, Centers for Disease Control and Prevention, and United States Agency for International Development, have played important roles in the progress to date, and each makes a valuable and unique contribution. As the primary Federal agency for conducting and supporting medical research and the largest single Federal Government contributor to microbicide research, the National Institutes of Health supports the Microbicide Trials Network as 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 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 and develop-
18 ment community; 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 relevant institutes and offices,
23 shall expand, intensify, and coordinate the activities of all
24 appropriate institutes and components of the National In-
25 stitutes of Health with respect to research and develop-

1 ment of microbicides to prevent the transmission of the
2 human immunodeficiency virus ('HIV') and other sexually
3 transmitted infections.

4 “(c) MICROBICIDE DEVELOPMENT BRANCH.—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 branch charged with carrying out
9 microbicide research and development. In establishing
10 such branch, the Director shall ensure that there are a
11 sufficient number of employees dedicated to carrying out
12 its mission.

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
17 Microbicide Trials Network and other programs for sup-
18 porting microbicides clinical trials, with particular empha-
19 sis on implementation of trials leading to product licen-
20 sure.

21 “(e) REPORTS TO CONGRESS.—

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

1 appropriate committees of Congress a report that
2 describes the strategies being implemented by the
3 Federal Government regarding microbicide research
4 and development.

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

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

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

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

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

1 Committee on Energy and Commerce and the Com-
2 mittee on Appropriations of the House of Represent-
3 atives.

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

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

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

13 Part B of title III of the Public Health Service Act
14 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
15 tion 317S the following:

16 **“SEC. 317T. MICROBICIDES FOR PREVENTING TRANS-**
17 **MISSION OF HIV/AIDS AND OTHER DISEASES.**

18 “(a) DEVELOPMENT AND IMPLEMENTATION OF THE
19 CENTERS FOR DISEASE CONTROL AND PREVENTION’S
20 MICROBICIDE AGENDA.—The Director of the Centers for
21 Disease Control and Prevention shall fully implement such
22 Centers’ microbicide agenda to support microbicide re-
23 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 President shall di-
15 rect the head of the Office of HIV/AIDS of the
16 United States Agency for International Develop-
17 ment, in conjunction with other offices of such Agen-
18 cy, to develop and implement a program to support
19 the development of microbicides for the prevention of
20 the transmission of HIV/AIDS and other diseases,
21 and facilitate wide-scale availability of such products
22 after such development.

23 “(2) STAFFING.—The head of the Office of
24 HIV/AIDS shall ensure that the Agency has a suffi-

1 cient number of dedicated employees to carry out the
2 microbicide agenda.

3 “(3) REPORTS TO CONGRESS.—

4 “(A) IN GENERAL.—Not later than one
5 year after the date of enactment of the
6 Microbicide Development Act, and annually
7 thereafter, the President shall submit to the ap-
8 propriate congressional committees a report on
9 the activities of the Agency to carry out the
10 microbicide agenda and on any other activities
11 carried out by the Agency related to microbicide
12 research and development.

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

16 “(i) a description of activities with re-
17 spect to microbicides conducted or sup-
18 ported by the Agency;

19 “(ii) a summary and analysis of the
20 expenditures made by the Agency during
21 the preceding year for activities with re-
22 spect to microbicide-specific research and
23 development, including the number of em-
24 ployees of the Agency who are involved in
25 such activities; and

1 “(iii) a description and evaluation of
2 the progress made during the preceding
3 year toward the development of effective
4 microbicides, including activities in support
5 of eventual product access.

6 “(C) CONSULTATION.—The President shall
7 consult with the Director of the Office of AIDS
8 Research of the National Institutes of Health in
9 preparing the report required under subpara-
10 graph (A).

11 “(D) APPROPRIATE CONGRESSIONAL COM-
12 MITTEES DEFINED.—In this paragraph, the
13 term ‘appropriate congressional committees’
14 means the Committee on Foreign Affairs and
15 the Committee on Appropriations of the House
16 of Representatives and the Committee on For-
17 eign Relations and the Committee on Approp-
18 riations of the Senate.

19 “(4) AUTHORIZATION OF APPROPRIATIONS.—
20 There are authorized to be appropriated to the
21 Agency such sums as may be necessary for each fis-
22 cal year to carry out this subsection.”.

