

110TH CONGRESS
1ST SESSION

S. 823

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 SENATE OF THE UNITED STATES

MARCH 8, 2007

Mr. OBAMA (for himself, Ms. SNOWE, Mr. DURBIN, Mr. DODD, Mrs. CLINTON, Mrs. BOXER, Mr. SCHUMER, 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/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.

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