

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

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

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 ½ 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 essarily 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, 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.

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

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

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 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, develop-
2 ment, 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 troductory 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—

11 “(i) a description of activities with re-
12 spect to microbicides conducted or sup-
13 ported by the Administrator;

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

21 “(iii) a description and evaluation of
22 the progress made during the preceding
23 year toward the development of effective
24 and acceptable microbicides;

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

○