

107TH CONGRESS  
1ST SESSION

# H. R. 2405

To amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other sexually transmitted diseases.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2001

Mrs. MORELLA (for herself, Ms. ESHOO, Ms. PELOSI, Mr. GREENWOOD, Mr. GANSKE, Mrs. LOWEY, Mr. SAWYER, Ms. DEGETTE, Mr. UPTON, Mrs. THURMAN, Ms. SLAUGHTER, Mr. JACKSON of Illinois, Mr. WAXMAN, Ms. MILLENDER-MCDONALD, Mrs. MALONEY of New York, Ms. DELAURO, and Mr. GEORGE MILLER of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 sexually transmitted diseases.

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 of 2001”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) Sexually transmitted diseases (“STDs”)  
4 and the human immunodeficiency virus (“HIV”) are  
5 producing serious and costly epidemics of infectious  
6 disease in populations worldwide.

7 (2) This year, 15,400,000 people in the United  
8 States will acquire a new STD.

9 (3) Globally, 36,100,000 people are infected  
10 with HIV, with more than 15,000 new infections oc-  
11 ccurring daily.

12 (4) Racial and ethnic minorities have been dis-  
13 proportionately infected with STDs, especially HIV.  
14 For example, although together African American  
15 and Latina women represent roughly 25 percent of  
16 the total U.S. female population, they account for 77  
17 percent of all reported female HIV cases.

18 (5) STDs cause serious, costly, even deadly con-  
19 ditions for women and their children: infertility,  
20 pregnancy complications, cervical cancer, infant mor-  
21 tality, and higher risk of contracting HIV.

22 (6) Estimated annual costs of STDs and their  
23 complications in the United States range from  
24 \$8,400,000,000 in direct medical costs to nearly  
25 \$20,000,000,000, including out-of-pocket costs and  
26 lost productivity.

1           (7) Microbicides are a promising new tech-  
2 nology for STD and HIV prevention.

3           (8) Microbicides are user-controlled products  
4 that could kill or inactivate the bacteria and viruses  
5 that cause STDs and HIV.

6           (9) Microbicides would fill a critical gap in the  
7 array of STD-prevention technologies, first as an  
8 important backup or alternative to the condom, and  
9 second, as a technology that, unlike most vaccines,  
10 could offer protection against various STDs, not just  
11 HIV.

12           (10) Several potential microbicides are poised  
13 for successful development; more than 20 products  
14 are in clinical trials and nearly 35 promising com-  
15 pounds exist that could be investigated further.

16           (11) Studies into the market potential for  
17 microbicides indicate that they would have broad ap-  
18 peal. One nationally representative survey indicated  
19 that at least 21,000,000 sexually active women in  
20 the United States would be interested in such prod-  
21 ucts, if they were available.

22           (12) Federal support for microbicide research  
23 and development is crucial.

24           (13) At present, there appear to be insufficient  
25 perceived economic incentives for pharmaceutical

1 companies to become actively engaged in microbicide  
2 research and development.

3 (14) Numerous small biotechnology companies  
4 and university researchers are actively engaged in  
5 microbicide research, but they are almost totally de-  
6 pendent on public-sector grants to continue their  
7 work and test their products.

8 (15) Despite public health need and tremendous  
9 scientific opportunity, microbicide research and de-  
10 velopment currently receives less than 1 percent of  
11 the Federal HIV research budget—not nearly  
12 enough to keep pace with the raging STD and HIV  
13 epidemics.

14 (16) Existing public sector grants for  
15 microbicides are too small and too short-term to  
16 move product leads forward, and the availability of  
17 clinical trial sites is limited by funding constraints.

18 (17) There is a backlog in the research and de-  
19 velopment pipeline, so that innovative and promising  
20 product concepts are languishing, while infection  
21 rates are growing.

22 (18) For significant progress to be made, the  
23 current amount of Federal investment needs to in-  
24 crease to \$75,000,000 in fiscal year 2002, to  
25 \$100,000,000 in fiscal year 2003, with

1       \$100,000,000 yearly in the successive out-years as  
2       required, in order to sustain multiyear funding at a  
3       productive level.

4       **TITLE       I—MICROBICIDE       RE-**  
5       **SEARCH AT THE NATIONAL**  
6       **INSTITUTES OF HEALTH**

7       **SEC. 101. NATIONAL INSTITUTE OF ALLERGY AND INFEC-**  
8                   **TIOUS DISEASES; PROGRAM REGARDING**  
9                   **MICROBICIDES FOR PREVENTING TRANS-**  
10                   **MISSION OF HIV AND OTHER SEXUALLY**  
11                   **TRANSMITTED DISEASES.**

12       Subpart 6 of part C of title IV of the Public Health  
13       Service Act (42 U.S.C. 285f et seq.) is amended by adding  
14       at the end the following section:

15       “MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV  
16       AND OTHER SEXUALLY TRANSMITTED DISEASES

17       “SEC. 447C. (a) EXPANSION AND COORDINATION OF  
18       ACTIVITIES.—The Director of the Institute shall expand,  
19       intensify, and coordinate the activities of the Institute  
20       with respect to research on the development of  
21       microbicides to prevent the transmission of HIV and other  
22       sexually transmitted diseases (in this section referred to  
23       as ‘microbicide research’).

24       “(b) COORDINATION WITH OTHER INSTITUTES.—  
25       The Director of the Institute shall coordinate the activities  
26       under subsection (a) among all appropriate institutes and

1 components of the National Institutes of Health to the ex-  
2 tent such institutes and components have responsibilities  
3 that are related to the development of microbicides.

4 “(c) RESEARCH PLAN.—

5 “(1) IN GENERAL.—The Director of the Insti-  
6 tute, acting in consultation with the Director of the  
7 Office of AIDS Research, shall develop a comprehen-  
8 sive research plan for the conduct and support of re-  
9 search and development of microbicides (in this sec-  
10 tion referred to as the ‘Research Plan’), and shall  
11 annually review and as appropriate revise the plan.

12 “(2) REQUIREMENTS.—The Research Plan  
13 shall—

14 “(A) identify current microbicide research  
15 and development activities conducted or sup-  
16 ported by the National Institutes of Health, in-  
17 cluding a description of each current grant and  
18 contract mechanism explicitly designed to facili-  
19 tate microbicide research, including support for  
20 preclinical product development and clinical  
21 trial capacity; and

22 “(B) describe microbicide research and de-  
23 velopment opportunities for the five year period  
24 beginning six months after the date of the en-  
25 actment of the Microbicide Development Act of

1           2001, including professional judgment funding  
2           projections, description of objectives with re-  
3           spect to microbicide research, description of the  
4           institutes involved and their role in microbicide  
5           research, plans for enhancing the capacity of  
6           such institutes to carry out the research oppor-  
7           tunities, including staffing and resources nec-  
8           essary for carrying out the activities of this sec-  
9           tion, and discussion of plans for increasing  
10          number of investigators in this area of research.

11           “(3) CONSULTATION.—In developing the Re-  
12          search Plan, the Director of the Institute shall work  
13          in close consultation with all appropriate institutes  
14          and components at the National Institutes for  
15          Health that have responsibilities that are related to  
16          the development of microbicides, with the  
17          microbicide research community, and with health ad-  
18          vocates.

19           “(4) SUBMISSION OF INITIAL PLAN TO PRESI-  
20          DENT AND CONGRESS.—

21           “(A) IN GENERAL.—The initial Research  
22          Plan shall be developed not later than six  
23          months after the date of the enactment of the  
24          Microbicide Development Act of 2001. The Di-  
25          rector of the Institute shall transmit such Plan

1 to the Director of NIH, who shall submit the  
2 Plan to the President and the Congress.

3 “(B) RELATION TO REQUIREMENT OF BI-  
4 ENNIAL NIH REPORT.—Subparagraph (A) shall  
5 be carried out independently of the process of  
6 reporting that is required in section 403.

7 “(d) PROGRAM FOR MICROBICIDE DEVELOPMENT.—

8 “(1) IN GENERAL.—In carrying out subsection  
9 (a), the Director of the Institute shall establish a  
10 program to support research to develop microbicides  
11 that can substantially reduce transmission of HIV  
12 and other sexually transmitted diseases. Activities  
13 under such program shall provide for an expansion  
14 and intensification of the conduct and support of—

15 “(A) basic research on the initial mecha-  
16 nisms of infection by sexually transmitted  
17 pathogens;

18 “(B) development of appropriate animal  
19 models for evaluating safety and efficacy of  
20 microbicides;

21 “(C) development of formulation and deliv-  
22 ery approaches;

23 “(D) research on targeted designs of  
24 microbicides;

1           “(E) manufacture of candidate products  
2           for testing in animals and humans;

3           “(F) conduct of HIV incidence and  
4           microbicide feasibility studies;

5           “(G) evaluation of microbicides in clinical  
6           trials, both domestically and internationally;  
7           and

8           “(H) behavioral research on use, accept-  
9           ability, and adherence to microbicides.

10          “(2) RESEARCH BRANCH.—The Director of the  
11          Institute shall establish, within the Vaccine and Pre-  
12          vention Research Program of the Division of AIDS  
13          in the Institute, an organizational unit to be known  
14          as the Microbicide Research Branch. Such Branch  
15          shall carry out the program under this subsection.

16          “(e) CONSTRUCTION OF FACILITIES.—The Director  
17          of the Institute may make awards of grants and contracts  
18          to public and nonprofit private entities for the construc-  
19          tion of facilities to conduct microbicide research, including  
20          clinical trials.

21          “(f) CENTERS FOR MICROBICIDE RESEARCH AND  
22          DEVELOPMENT.—

23                 “(1) IN GENERAL.—The Director of the Insti-  
24                 tute, after consultation with the advisory council for  
25                 the Institute, and in consultation with the Director

1 of the Office of AIDS Research, shall make awards  
2 of grants or contracts to public and nonprofit pri-  
3 vate entities for the development and operation of  
4 not less than four multidisciplinary research centers  
5 to conduct microbicide research.

6 “(2) REQUIREMENTS.—Each center assisted  
7 under this subsection shall—

8 “(A) use the facilities of a single institu-  
9 tion, or be formed from a consortium of cooper-  
10 ating institutions, meeting such requirements as  
11 may be prescribed by the Director of the Insti-  
12 tute; and

13 “(B) conduct basic research on mucosal  
14 transmission to design novel microbicide strate-  
15 gies for the prevention of HIV and STD infec-  
16 tion, including research into HIV and STD  
17 pathogenesis, reproductive tract biology and  
18 toxicology, concept testing in animal models,  
19 and formulation and delivery design.

20 “(g) REPORT TO CONGRESS.—Not later than one  
21 year after the date of the initial submission of the Re-  
22 search Plan under subsection (c)(1), and annually there-  
23 after, the Director of the Institute shall submit to the  
24 Committee on Energy and Commerce in the House of  
25 Representatives and the Committee on Health, Education,

1 Labor and Pensions in the Senate a report that describes  
2 the activities of the Institute regarding microbicide re-  
3 search. Each such report shall include—

4           “(1) an updated Research Plan, including pro-  
5 fessional judgment funding projections;

6           “(2) an assessment of the implementation of  
7 such plan;

8           “(3) a description and evaluation of the  
9 progress made, during the period for which such re-  
10 port is prepared, in the research on microbicides;

11           “(4) a summary and analysis of expenditures  
12 made, during the period for which the report is  
13 made, for activities with respect to microbicides re-  
14 search conducted and supported by the National In-  
15 stitutes of Health, including the number of full-time  
16 equivalent employees; and

17           “(5) such comments and recommendations as  
18 the Director of the Institute considers appropriate.

19           “(h) COORDINATION WITH OTHER FEDERAL AGEN-  
20 CIES.—The Director of the Institute shall consult with the  
21 Director for the Centers for Disease Control and Preven-  
22 tion and the United States Agency for International De-  
23 velopment in developing the Research Plan that takes into  
24 consideration research on HIV and other sexually trans-  
25 mitted diseases and microbicides carried out at the Cen-

1 ters for Disease Control and Prevention and the United  
2 States Agency for International Development.

3 “(i) DEFINITION.—For purposes of this section, the  
4 term ‘HIV’ means the human immunodeficiency virus.  
5 Such term includes acquired immune deficiency syndrome.

6 “(j) AUTHORIZATION OF APPROPRIATIONS.—For the  
7 purposes of carrying out this section, there are authorized  
8 to be appropriated such sums as may be necessary for  
9 each of the fiscal years 2002 through 2004.”.

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 SEXUALLY TRANSMITTED**  
16 **DISEASES.**

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

20 “MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV  
21 AND OTHER SEXUALLY TRANSMITTED DISEASES

22 “SEC. 317Q. (a) EXPANSION AND COORDINATION OF  
23 MICROBICIDE RESEARCH ACTIVITIES.—The Secretary,  
24 acting through the Director of the Centers for Disease  
25 Control and Prevention, shall expand, intensify, and co-  
26 ordinate the activities of such Centers with respect to re-

1 search on microbicides to prevent the transmission of HIV  
2 and other sexually transmitted diseases.

3 “(b) GRANTS REGARDING MICROBICIDE RE-  
4 SEARCH.—In order to contribute to the rapid evaluation  
5 of safe and effective microbicides for the prevention of  
6 HIV and other sexually transmitted diseases, the Sec-  
7 retary may in carrying out subsection (a) make grants to  
8 public and nonprofit private entities for the purpose of—

9 “(1) laboratory research in preparation for, and  
10 support of, clinical microbicide trials;

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

13 “(3) developing and characterizing domestic  
14 populations and international cohorts appropriate  
15 for Phase I, II, and III clinical trials of candidate  
16 topical microbicides;

17 “(4) conducting Phase I and II clinical trials to  
18 assess the safety and acceptability of candidate  
19 microbicides;

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

22 “(6) provide technical assistance to, and con-  
23 sultation with, a wide variety of domestic and inter-  
24 national entities involved in developing and evalu-  
25 ating topical microbicides, including health agencies,

1 extramural researchers, industry, health advocates,  
2 and non-profit organizations; and

3 “(7) developing and evaluating the diffusion  
4 and effects of implementation strategies for use of  
5 effective topical microbicides.

6 “(c) SELECTION OF AGENTS AND TRIAL DESIGNS;  
7 COORDINATION WITH OTHER AGENCIES.—In coordina-  
8 tion and collaboration with the Director of the National  
9 Institutes of Health and the Administrator of the United  
10 States Agency for International Development, the Sec-  
11 retary shall select agents and trial designs, develop clinical  
12 trial capacity as described in subsection (b), share experi-  
13 ence, and avoid duplication of effort.

14 “(d) ANNUAL REPORTS.—Not later than six months  
15 after the date of the enactment of the Microbicide Devel-  
16 opment Act of 2001, and annually thereafter, the Sec-  
17 retary shall submit to the Energy and Commerce Com-  
18 mittee in the House of Representatives and the Health,  
19 Education, Labor and Pensions Committee in the Senate  
20 a report on the activities carried out under this section  
21 by the Secretary. Each such report shall include—

22 “(1) description of research with respect to  
23 microbicide research and development;

1           “(2) description and evaluation of the progress  
2           made, during the period for which such report is  
3           prepared, in the research on microbicides; and

4           “(3) summary and analysis of expenditures  
5           made, during the period for which the report is  
6           made, for activities with respect to microbicides con-  
7           ducted and supported by the Centers for Disease  
8           Control and Prevention.

9           “(e) DEFINITION.—For the purposes of this section,  
10          the term ‘HIV’ means the human immunodeficiency virus.  
11          Such term includes acquired immune deficiency syndrome.

12          “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
13          purposes of carrying out this section, there are authorized  
14          to be appropriated such sums as may be necessary for  
15          each of the fiscal years 2002 through 2004.”.

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