I

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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Microbicide Development Act of 2001''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Sexually transmitted diseases (''STDs'') and the human immunodeficiency virus (''HIV'') are producing serious and costly epidemics of infectious disease in populations worldwide.

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

(3) Globally, 36,100,000 people are infected with HIV, with more than 15,000 new infections occurring daily.

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

(5) STDs cause serious, costly, even deadly conditions for women and their children: infertility, pregnancy complications, cervical cancer, infant mortality, and higher risk of contracting HIV.

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

(7) Microbicides are a promising new technology for STD and HIV prevention.

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

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

(10) Several potential microbicides are poised for successful development; more than 20 products are in clinical trials and nearly 35 promising compounds exist that could be investigated further.

(11) Studies into the market potential for microbicides indicate that they would have broad appeal. One nationally representative survey indicated that at least 21,000,000 sexually active women in the United States would be interested in such products, if they were available.

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

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

companies to become actively engaged in microbicide research and development.

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

(15) Despite public health need and tremendous scientific opportunity, microbicide research and development currently receives less than 1 percent of the Federal HIV research budget—not nearly enough to keep pace with the raging STD and HIV epidemics.

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

(17) There is a backlog in the research and development pipeline, so that innovative and promising product concepts are languishing, while infection rates are growing.

(18) For significant progress to be made, the current amount of Federal investment needs to increase to $75,000,000 in fiscal year 2002, to $100,000,000 in fiscal year 2003, with

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

TITLE I—MICROBICIDE RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH

SEC. 101. NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; PROGRAM REGARDING MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV AND OTHER SEXUALLY TRANSMITTED DISEASES.

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

''MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV AND OTHER SEXUALLY TRANSMITTED DISEASES

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

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

components of the National Institutes of Health to the extent such institutes and components have responsibilities that are related to the development of microbicides.

''(c) RESEARCH PLAN.—

''(1) IN GENERAL.—The Director of the Institute, acting in consultation with the Director of the Office of AIDS Research, shall develop a comprehensive research plan for the conduct and support of research and development of microbicides (in this section referred to as the 'Research Plan'), and shall annually review and as appropriate revise the plan.

''(2) REQUIREMENTS.—The Research Plan shall—

''(A) identify current microbicide research and development activities conducted or supported by the National Institutes of Health, including a description of each current grant and contract mechanism explicitly designed to facilitate microbicide research, including support for preclinical product development and clinical trial capacity; and

''(B) describe microbicide research and development opportunities for the five year period beginning six months after the date of the enactment of the Microbicide Development Act of

2001, including professional judgment funding projections, description of objectives with respect to microbicide research, description of the institutes involved and their role in microbicide research, plans for enhancing the capacity of such institutes to carry out the research opportunities, including staffing and resources necessary for carrying out the activities of this section, and discussion of plans for increasing number of investigators in this area of research.

''(3) CONSULTATION.—In developing the Research Plan, the Director of the Institute shall work in close consultation with all appropriate institutes and components at the National Institutes for Health that have responsibilities that are related to the development of microbicides, with the microbicide research community, and with health advocates.

''(4) SUBMISSION OF INITIAL PLAN TO PRESIDENT AND CONGRESS.—

''(A) IN GENERAL.—The initial Research Plan shall be developed not later than six months after the date of the enactment of the Microbicide Development Act of 2001. The Director of the Institute shall transmit such Plan

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

''(B) RELATION TO REQUIREMENT OF BIENNIAL NIH REPORT.—Subparagraph (A) shall be carried out independently of the process of reporting that is required in section 403.

''(d) PROGRAM FOR MICROBICIDE DEVELOPMENT.—

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

''(A) basic research on the initial mechanisms of infection by sexually transmitted pathogens;

''(B) development of appropriate animal models for evaluating safety and efficacy of microbicides;

''(C) development of formulation and delivery approaches;

''(D) research on targeted designs of microbicides;

''(E) manufacture of candidate products for testing in animals and humans;

''(F) conduct of HIV incidence and microbicide feasibility studies;

''(G) evaluation of microbicides in clinical trials, both domestically and internationally; and

''(H) behavioral research on use, acceptability, and adherence to microbicides.

''(2) RESEARCH BRANCH.—The Director of the Institute shall establish, within the Vaccine and Prevention Research Program of the Division of AIDS in the Institute, an organizational unit to be known as the Microbicide Research Branch. Such Branch shall carry out the program under this subsection.

''(e) CONSTRUCTION OF FACILITIES.—The Director of the Institute may make awards of grants and contracts to public and nonprofit private entities for the construction of facilities to conduct microbicide research, including clinical trials.

''(f) CENTERS FOR MICROBICIDE RESEARCH AND DEVELOPMENT.—

''(1) IN GENERAL.—The Director of the Institute, after consultation with the advisory council for the Institute, and in consultation with the Director

of the Office of AIDS Research, shall make awards of grants or contracts to public and nonprofit private entities for the development and operation of not less than four multidisciplinary research centers to conduct microbicide research.

''(2) REQUIREMENTS.—Each center assisted under this subsection shall—

''(A) use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute; and

''(B) conduct basic research on muscosal transmission to design novel microbicide strategies for the prevention of HIV and STD infection, including research into HIV and STD pathogenesis, reproductive tract biology and toxicology, concept testing in animal models, and formulation and delivery design.

''(g) REPORT TO CONGRESS.—Not later than one year after the date of the initial submission of the Research Plan under subsection (c)(1), and annually thereafter, the Director of the Institute shall submit to the Committee on Energy and Commerce in the House of Representatives and the Committee on Health, Education,

Labor and Pensions in the Senate a report that describes the activities of the Institute regarding microbicide research. Each such report shall include—

''(1) an updated Research Plan, including professional judgment funding projections;

''(2) an assessment of the implementation of such plan;

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

''(4) a summary and analysis of expenditures made, during the period for which the report is made, for activities with respect to microbicides research conducted and supported by the National Institutes of Health, including the number of full-time equivalent employees; and

''(5) such comments and recommendations as the Director of the Institute considers appropriate.

''(h) COORDINATION WITH OTHER FEDERAL AGENCIES.—The Director of the Institute shall consult with the Director for the Centers for Disease Control and Prevention and the United States Agency for International Development in developing the Research Plan that takes into consideration research on HIV and other sexually transmitted diseases and microbicides carried out at the Cen-

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

''(i) DEFINITION.—For purposes of this section, the term 'HIV' means the human immunodeficiency virus. Such term includes acquired immune deficiency syndrome.

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

TITLE II—MICROBICIDE RESEARCH AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION

SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV AND OTHER SEXUALLY TRANSMITTED DISEASES.

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

''MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV AND OTHER SEXUALLY TRANSMITTED DISEASES

''SEC. 317Q. (a) EXPANSION AND COORDINATION OF MICROBICIDE RESEARCH ACTIVITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of such Centers with respect to re-

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

''(b) GRANTS REGARDING MICROBICIDE RESEARCH.—In order to contribute to the rapid evaluation of safe and effective microbicides for the prevention of HIV and other sexually transmitted diseases, the Secretary may in carrying out subsection (a) make grants to public and nonprofit private entities for the purpose of—

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

''(2) conducting behavioral research in preparation for, and support of, clinical microbicide trials;

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

''(4) conducting Phase I and II clinical trials to assess the safety and acceptability of candidate microbicides;

''(5) conducting Phase III clinical trials to assess the efficacy of candidate microbicides;

''(6) provide technical assistance to, and consultation with, a wide variety of domestic and international entities involved in developing and evaluating topical microbicides, including health agencies,

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

''(7) developing and evaluating the diffusion and effects of implementation strategies for use of effective topical microbicides.

''(c) SELECTION OF AGENTS AND TRIAL DESIGNS; COORDINATION WITH OTHER AGENCIES.—In coordination and collaboration with the Director of the National Institutes of Health and the Administrator of the United States Agency for International Development, the Secretary shall select agents and trial designs, develop clinical trial capacity as described in subsection (b), share experience, and avoid duplication of effort.

''(d) ANNUAL REPORTS.—Not later than six months after the date of the enactment of the Microbicide Development Act of 2001, and annually thereafter, the Secretary shall submit to the Energy and Commerce Committee in the House of Representatives and the Health, Education, Labor and Pensions Committee in the Senate a report on the activities carried out under this section by the Secretary. Each such report shall include—

''(1) description of research with respect to microbicide research and development;

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

''(3) summary and analysis of expenditures made, during the period for which the report is made, for activities with respect to microbicides conducted and supported by the Centers for Disease Control and Prevention.

''(e) DEFINITION.—For the purposes of this section, the term 'HIV' means the human immunodeficiency virus. Such term includes acquired immune deficiency syndrome.

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

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