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. Capps, 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.
 - (2) Because of their social and biological vulnerabilities, young women are particularly at risk of HIV infection. In sub-Saharan Africa, the prevalence of HIV/AIDS is three times higher among women ages 15 to 24 than it is among men in that same age group.
 - (3) Women infected with HIV can transmit the infection to their infants during pregnancy, labor, delivery, or breast-feeding. The most effective way to interrupt mother-to-child transmission is to ensure that mothers are not infected in the first place.
 - (4) Many women who become infected with HIV have just one sexual partner—their husband. Marriage is not necessarily effective protection against HIV, because to protect themselves from HIV, women have to rely on their male partners to be faithful or to use condoms. Many women, especially in the developing world, are unable to insist on

- mutual monogamy or negotiate condom use, particu larly in long-term relationships.
 - (5) Scientists are working on a promising new prevention tool that could slow down the spread of the HIV/AIDS epidemic—microbicides. Formulated as gels, creams, tablets or rings, microbicides are being designed to stop the transmission of the pathogens that cause AIDS and other sexually transmitted infections (referred to in this section as "STIs"). Microbicides could allow a woman to protect herself from disease.
 - (6) Couples need a method of HIV protection that will allow them to conceive a child and start a family. No existing HIV prevention method also allows conception. Some microbicides in development may allow women to become pregnant while at the same time protecting them from infection.
 - (7) According to UNICEF, worldwide, the lack of HIV/AIDS prevention and treatment has left over 15,000,000 children as orphans. Of these, more than 12,000,000 live in sub-Saharan Africa. The number of AIDS orphans in sub-Saharan Africa alone is expected to grow to nearly 16,000,000 by 2010.
 - (8) HIV prevention tools like microbicides could also be valuable for women in the United States,

- who account for an increasing proportion of new HIV and AIDS cases among Americans. Minority women in the United States are particularly affected. Both African-American and Latina women account for a disproportionate number of new AIDS cases, and HIV/AIDS was the leading cause of death in 2002 for African-American women ages 25 to 34.
- (9) With nearly 20,000,000 new cases of sexually transmitted infections occurring every year, the United States has the highest STI rates of any industrialized nation. Like HIV, STIs pose significant health threats and costs, with young people and women bearing a disproportionate burden. Nearly half of new STI cases each year occur in people under 25 years of age with women both more vulnerable to infection and more likely to experience serious and lasting health consequences when they do become infected. Some microbicides could help prevent STIs.
 - (10) HIV/AIDS threatens national and global security. Beyond its burdens on individuals, families, and communities, the pandemic reduces economic growth, decimates health budgets, undermines civil society, and burdens the armed forces of many nations, including the United States military.

- (11) The microbicide field has gained considerable scientific momentum. Several first-generation products are in large-scale human trials to measure effectiveness, and new products based on recent advances 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.
- 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

United States Agency for International Development sustains strong partnerships with public and private organizations working on microbicide research, including trials in developing countries where its experience is extensive, and is well positioned to facilitate introduction of microbicides once available. The Centers for Disease Control and Prevention has a long history of conducting field trials in developing countries, but the extent of its current engagement remains quite limited.

(14) According to the National Institutes of Health's strategic plan, microbicides may provide "one of the most promising primary preventative interventions that could be safe, effective, readily available, affordable, and widely acceptable". In a recent report to Congress, the United States Agency for International Development states that "the US government is firmly committed to accelerating the development of safe and effective microbicides to prevent HIV". In addition, the President's Emergency Plan for AIDS Relief recognizes the urgency of developing safe and effective microbicides.

(15) The National Institutes of Health, United States Agency for International Development, and 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	ING MICROBICIDES FOR PREVENTING TRANS- MISSION OF HIV/AIDS AND OTHER DISEASES.
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17	MISSION OF HIV/AIDS AND OTHER DISEASES.
17 18	MISSION OF HIV/AIDS AND OTHER DISEASES. Subpart I of part D of title XXIII of the Public
17 18 19	MISSION OF HIV/AIDS AND OTHER DISEASES. Subpart I of part D of title XXIII of the Public Health Service Act (42 U.S.C. 300cc-40 et seq.) is
17 18 19 20	MISSION OF HIV/AIDS AND OTHER DISEASES. Subpart I of part D of title XXIII of the Public Health Service Act (42 U.S.C. 300cc–40 et seq.) is amended by inserting after section 2351 the following:
17 18 19 20 21	MISSION OF HIV/AIDS AND OTHER DISEASES. Subpart I of part D of title XXIII of the Public Health Service Act (42 U.S.C. 300cc-40 et seq.) is amended by inserting after section 2351 the following: "SEC. 2351A. MICROBICIDES FOR PREVENTING TRANS-
17 18 19 20 21 22	MISSION OF HIV/AIDS AND OTHER DISEASES. Subpart I of part D of title XXIII of the Public Health Service Act (42 U.S.C. 300cc–40 et seq.) is amended by inserting after section 2351 the following: "SEC. 2351A. MICROBICIDES FOR PREVENTING TRANSMISSION OF HIV/AIDS AND OTHER DISEASES.

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
- after the date of enactment of the Microbicide De-
- velopment Act, and annually thereafter, the Director
- of the Office of AIDS Research shall submit to the

appropriate committees of Congress a report that
describes the strategies being implemented by the
Federal Government regarding microbicide research
and development.
"(2) Contents of Reports.—Each report
submitted under paragraph (1) shall include—
"(A) a description of activities with respect
to microbicide research and development con-
ducted and supported by the Federal Govern-
ment;
"(B) a summary and analysis of the ex-
penditures made by the Director of the Office
of AIDS Research during the preceding year
for activities with respect to microbicide-specific
research and development, including basic re-
search, preclinical product development, clinical
trials, and behavioral science; and
"(C) a description and evaluation of the
progress made, during the preceding year, to-
ward the development of effective microbicides.
"(3) Appropriate committees of congress
DEFINED.—In this subsection, the term 'appropriate
committees of Congress' means the Committee on
Health, Education, Labor, and Pensions and the

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.
- 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
- the date of enactment of the Microbicide Develop-
- ment Act, and annually thereafter, the Director of
- the Centers for Disease Control and Prevention shall
- submit to the appropriate committees of Congress, a
- report on the strategies being implemented by the
- 17 Centers for Disease Control and Prevention with re-
- spect to microbicide research and development. Such
- 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
- 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—N	AICR (DBICI	DE	RE-
2	SEAR	CH A	ND D	EVEL	OPM	ENT
3	\mathbf{AT}	THE	UNI'	TED	STA	TES
4	AGEN	ICY	FO	\mathbf{R}	IN	ΓER-
5	NATI	ONAL	DEVE	LOPI	MENT	.
6	SEC. 301. MICH	ROBICIDES	FOR PRE	VENTING	TRANSM	IISSION
7	(OF HIV/AID	S AND OT	HER DISE	ASES.	
8	Section 1	104A of th	e Foreigr	n Assista	nce Act o	of 1961
9	(22 U.S.C. 2	151b–2) is	s amende	ed by ado	ding at t	the end
10	the following i	new subsec	tion:			
11	"(h) Ma	ICROBICIDI	ES FOR	Preve	NTING	Trans-
12	MISSION OF H	IIV/AIDS A	AND OTH	ER DISEA	SES.—	
13	"(1)	DEVELOR	PMENT AN	ND IMPLE	EMENTAT	ION OF
14	THE MICE	ROBICIDE .	AGENDA	—The Pr	esident s	shall di-
15	rect the	head of	the Office	e of HI	V/AIDS	of the
16	United	States Ag	ency for	Interna	tional D	evelop-
17	ment, in	conjunctio	n with ot	her office	es of such	ı Agen-
18	cy, to de	velop and	impleme	nt a prog	gram to	support
19	the devel	opment of	microbici	des for t	he prevei	ntion of
20	the trans	smission o	f HIV/Al	IDS and	other d	iseases,
21	and facil	itate wide-	scale ava	ilability o	of such p	roducts
22	after suc	h developn	nent.			
23	"(2)	Staffin	G.—The	head of	the Of	ffice of
24	HIV/AID	S shall en	sure that	the Age	ncv has	a suffi-

1 cient number of dedicated employees to carry out the 2 microbicide agenda. 3 "(3) Reports to congress.— "(A) IN GENERAL.—Not later than one 4 vear 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— "(i) a description of activities with re-16 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 the preceding year for activities with re-21 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 Appro-
18	priations 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-

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cal year to carry out this subsection.".