

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

The Constitution provides:

Article II, Section 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.

Article XIII, Section 11. The State shall adopt an integrated and comprehensive approach to health development -xxx- There shall be priority for the needs of the underprivileged sick, elderly, disabled, women, and children.

Annually, at least 1 billion people worldwide contract one of eight sexually transmitted diseases (STDs) - chlamydia, gonorrhea, syphilis, trichomoniasis, hepatitis B, herpes, human immunodeficiency virus (HIV), and human papilloma virus. Of these, hepatitis B, herpes, HIV, and human papilloma virus are incurable and represent two-thirds of the new infections.

STDs impose high human costs in pain, diminished quality of life, disability, and mortality. In women, STDs other than HIV can produce infertility, cancers, and numerous pregnancy-related complications including ectopic pregnancy, spontaneous abortion, and stillbirth. Passed to a fetus or infant, these infections can cause low birth weight, pneumonia, neurologic damage, and congenital abnormalities. These infections also substantially enhance susceptibility to HIV infection.

Biologically and socially, women are more vulnerable to STDs than men. Many STDs are transmitted more easily from a man to a woman and are more likely to remain undetected in women, resulting in delayed diagnosis and treatment, and more severe complications.

Since the early 1990s, topical microbicides have attracted scientific attention as a possible new technology for preventing STDs, including HIV. Like today's spermicides, microbicides would be used vaginally by women to help protect themselves, their partners, and their infants from the sexual transmission of HIV and other STD pathogens. These compounds

could be formulated in a number of ways - as a gel, film, sponge or time-released capsule – and could be used in addition to condoms or as an alternative when condom use is not possible.

The social, health, and economic burdens of STDs are especially severe for developing countries such as the Philippines. Among women ages 15-49 in developing countries, STDs represent the second largest cause of mortality and disability. Only two maternal causes, that is, immediate complications of pregnancy and childbirth, rank higher. This bill seeks to facilitate the development of microbicides to prevent the transmission of STDs.¹

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MIRIAM DEFENSOR SANTIAGO

¹ This bill was originally filed during the Thirteenth Congress, First Regular Session.

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1 AN ACT
2 TO FACILITATE THE DEVELOPMENT OF MICROBICIDES
3 TO PREVENT SEXUALLY TRANSMITTED DISEASES

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

4 SECTION 1. Short Title. - This Act shall be known as the "Microbicides Development
5 Act."

6 SECTION 2. Definition of Terms. -As used in this Act, the term:

7 (A) "Microbicides" mean agents that destroy microbes, such as antiseptic.

8 (B) "STD" means any sexually transmitted disease, and includes chlamydia, gonorrhea,
9 syphilis, trichomoniasis, hepatitis B, herpes, human immunodeficiency virus (HIV)
10 (which includes acquired immuno deficiency syndrome or AIDS), and human
11 papilloma virus.

12 (C) "DOH" means the Department of Health.

13 (D) "Secretary" means the DOH Secretary.

14 SECTION 3. Microbicides for Preventing Transmission of Sexually Transmitted
15 Diseases. -

16 (A) Expansion of Activities. - The Secretary shall expand, intensify, and coordinate the
17 activities of the DOH with respect to research on the development of microbicides to
18 prevent the transmission of STDs, including HIV.

1 (B) Coordination. - The Secretary shall coordinate the activities under subsection (A) as
2 outlined in subparagraph (C)(I) among all appropriate government agencies and
3 components of the DOH to the extent such government agencies and components
4 have responsibilities that are related to the development of microbicides.

5 (C) Program for Microbicide Development. - In carrying out subsection (I), the DOH
6 shall establish a program to support research to develop microbicides that can
7 substantially reduce transmission of sexually transmitted infections. Activities under
8 such subsection shall provide for an expansion and intensification of the conduct and
9 support of –

10 (1) Basic research on the initial mechanisms of infection by sexually transmitted
11 pathogens;

12 (2) Development of appropriate animal models for evaluating safety and efficacy of
13 microbicides;

14 (3) Development of mucosal delivery systems;

15 (4) Research on approaches to the design of contraceptive and non-contraceptive
16 microbicides;

17 (5) Clinical trials; and

18 (6) Behavioral research on use, acceptability and compliance with microbicides.

19 (D) Implementation Plan. - The Secretary, in coordination with the Philippine Council for
20 Health Research and Development as described in subsection (B), shall develop and
21 implement a plan to ensure that the research programs described in paragraph (C) (I)
22 are implemented in accordance with a plan for such programs. Such plan shall include
23 the comments of the Secretary and shall include, but not be limited to, the following
24 information:

25 (1) Description of plan and objectives with respect to microbicides research.

26 (2) Description of the agencies involved and their role in microbicides research.

27 (3) Capacity of such agencies to conduct microbicides research as described in (CN).

(4) Description of grant and contract mechanisms available to facilitate microbicides research, including grant and contract mechanisms, support for preclinical product development and clinical trial capacity.

(5) Description of the plan for increasing number of investigators in this area of research.

(E) *Public Comment.* - The Secretary shall develop a mechanism to provide the public, including non-profit private entities concerned with microbicides research, opportunities to submit comments on the plan, including provisions relating to the selection of products for clinical evaluations.

SECTION 4. Reports to Congress. -The Secretary shall submit, not later than one year after the date on enactment, and annually thereafter, a report that describes the activities of the DOH, under the research programs referred to in Section (3)(C), that shall include --

(A) A description of the research plan with respect to microbicides research prepared under Section (3)(D);

(B) An assessment of the development, revision, and implementation of such plan;

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

(D) A 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 DOH;
and

(E) Such comments and recommendations as the Secretary considers appropriate.

SECTION 5. Coordination. - The Secretary, to the extent practicable, shall consult with the Director for the National Center for Disease Prevention and Control and Director for the Philippine Health Research and Development in developing the plan under Section 4 for research on microbicides that takes into consideration research on STDs and microbicides carried out at

1 the National Center for Disease Prevention and Control and Philippine Health Research and
2 Development.

3 SECTION 6. Implementing Agency. - The Secretary is hereby authorized and directed to
4 adopt a system to implement and carry out the provisions of this Act. The DOH shall, within
5 sixty (60) days from the effectivity of this Act, promulgate rules and regulations, including those
6 of disciplinary nature, to carry out and enforce the provisions of this Act.

7 SECTION 7. Coordinating Agency. - The Philippine Council for Health Research and
8 Development is hereby authorized to assist the DOH in conducting the research for microbicides.

9 SECTION 8. Appropriations. - Such sums as may be necessary to carry out this program
10 are hereby authorized to be appropriated from the National Treasury.

11 SECTION 9. Separability Clause. - If any provision or part hereof, is held invalid or
12 unconstitutional, the remainder of the law or the provision shall remain valid and subsisting.

13 SECTION 10. Repealing Clause. - Any law, presidential decree or issuance, executive
14 order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent
15 with the provisions of this Act is hereby repealed, modified or amended accordingly.

16 SECTION 11. Effectivity Clause. - This Act shall take effect fifteen (15) days after its
17 publication in at least two (2) newspapers of general circulation.

Approved.