

Campaign to Accelerate Microbicide Development for STD Prevention Gets Under Way

By Heather Boonstra

In the face of the global AIDS epidemic and heightened concern about the impact of other sexually transmitted diseases (STDs), scientists for a number of years have been working to develop a range of vaginal microbicides that women could use to prevent these diseases (see box). Now, as the centerpiece of a burgeoning public education campaign, legislation is being drafted in

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Congress with the aim of heightening the visibility of microbicide research and making the case that increased attention—and public investment—is warranted. Armed with new survey data indicating that large numbers of women potentially would be interested in these products, women's health advocates inside and outside of Congress are convinced that microbicides could have a significant impact on public health worldwide. But most also believe that microbicidal products for a variety of reasons may never reach the market without intensified collaboration between government and the private sector.

The Case for Microbicides

Scientists and women's health advocates have long argued that given the growing prevalence of HIV and other STDs in the United States and around the world, new—and, especially, female-controlled—means of protection are desperately needed.

Each year, an estimated 15 million people acquire a new STD in the United States alone, and not all of these diseases are curable. Those caused by viruses—including genital herpes and human papillomavirus, the infection that can cause genital warts or cervical cancer—can only be treated for their worst symptoms. The most threatening of infections, HIV, can be treated with drugs that are very expensive and have complex regimens, but despite their ability to delay the development of AIDS, the virus is still fatal.

Moreover, whether curable or not, STDs can cause serious and long-term health problems for women and their children, including infertility, pregnancy complications, cervical cancer and infant mortality. In the United States, AIDS is the fourth leading cause of death among women aged 25–44, with women of color disproportionately affected. Worldwide,

women constitute close to half of the more than 15,000 people who become infected with HIV each day, mostly through heterosexual intercourse with their primary partner.

Advocates contend that the development of microbicidal products would be a quantum leap forward in the fight against STDs and HIV.

Currently, condoms offer the only reliable means of protection. (While the spermicide nonoxynol-9 offers some protection against bacterial STDs and may also offer some protection against viral STDs such as HIV, the compound can irritate the vaginal lining when used frequently and at higher doses, which itself may make HIV transmission easier.) A major limitation of condoms is that their use needs to be “negotiated.” Many women may risk alienating their partner if they seek to protect themselves against STDs, advocates note, since a request for condom use could be interpreted as suspicion of their partner's infidelity or acknowledgment of their own. Microbicides would not require women to admit that they consider themselves at risk; they would be within women's personal control and could be used without a man's permission, or even his knowledge. Microbicides also have the advantage of allowing for

What Are Microbicides?

Microbicides are agents that kill or deactivate disease-causing microorganisms, technically known as pathogens. Various types of pathogens cause STDs; therefore, a microbicide that works against one pathogen does not necessarily work against others. Accordingly, scientists are seeking to develop products that will be effective against a wide range of pathogens, including HIV. These products would be applied to the vaginal wall in the form of a gel, cream or suppository, or used in conjunction with a sponge or vaginal ring. They would provide protection either by blocking or killing the pathogens directly or by preventing viral replication, should infection occur.

Approximately 60 microbicidal products currently are in various stages of development. Some are based on existing products used in new ways or new combinations; others are based on completely new compounds. Some, but not all, of these products would prevent pregnancy as well as provide protection against STDs. Development of a noncontraceptive microbicidal product is considered especially important for women whose partner may be HIV-positive but who want to have a child.

skin-to-skin contact, increasing pleasure and intimacy.

In 1998, The Alan Guttmacher Institute conducted a nationally representative survey of U.S. women aged 18–44 to gauge women’s perceptions of their risk of contracting an STD, including HIV, and their interest in using a microbicide product if one were available. Even though only a theoretical possibility at this point, the notion of a topical microbicide product seems to have broad-based appeal. The vast majority of women surveyed, 94%, said they would be at least a little interested in using such a product if they ever found themselves at possible risk of contracting an STD. Findings from the survey suggest that 15–16 million sexually active U.S. women are worried about contracting an STD. Of these, 12.6 million would be interested in using a microbicide.

Research Challenges

Despite the importance of new female-controlled technologies for the prevention of HIV and other STDs, microbicide research and development has been inadequately financed and painfully slow. No large pharmaceutical company has a significant program in microbicide research; instead, university scientists or small biopharmaceutical companies that do not have the capital necessary to carry a microbicide from the laboratory to the pharmacy shelf are pursuing existing leads.

Microbicide research shares many of the same difficulties that exist in any frontier of science. But, as Lori Heise of the Center for Health and Gender Equity puts it, “in other fields, a challenge is a motivating reason to do something; in the field of microbicides, a challenge becomes a reason to put your money elsewhere.” Heise and other advocates cite a variety of reasons why this may be the case. First, microbicides face the same social and political challenges that contraceptives and other reproduc-

tive health products historically have faced. According to Polly Harrison, who directed a 1996 Institute of Medicine study exploring barriers to contraceptive research and development, this area has always lagged

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behind other areas of product development, in large part because of the social controversy surrounding matters of sexuality, reproduction and women’s empowerment. This problem, she suggests, is over and above the historic bias against scientific endeavors addressing women’s health needs generally, identified by the Institute of Medicine in its seminal 1994 study on obstacles to women’s health research.

Moreover, the fact that a major goal of microbicide research is to develop products that can be sold at a low cost worldwide has made investors fear that their costs will never be recovered from sales. Investor concern is especially great given the high cost of microbicide clinical trials. To produce reliable estimates of safety and efficacy, these trials must be conducted among very large numbers of sexually active people who are at risk of HIV and other STDs. The trials typically involve vulnerable individuals, such as sex workers, in developing countries where the levels of HIV infection are high. Because of the ethical need to protect research subjects against infection, investigators face a trade-off between their duty to encourage participants to use condoms along with the microbicide being tested and their mandate to determine as quickly and efficiently as possible what effect the microbicide has. Under these conditions, the precise efficacy of microbicides will be difficult to establish.

Finally, microbicides constitute a new product category that in some

ways does not quite fit with those already established. For example, a microbicide product could conceivably require review and approval by as many as three separate centers at the Food and Drug Administration (FDA), creating a complex and uncertain regulatory process. The field has also “fallen between the cracks” in the advocacy community. Because family planning and STD prevention traditionally were—and, to some extent, still are—different fields, microbicide research and development has been considered part of the STD “account” and largely ignored by the family planning community. And among AIDS activists, who put their major hope for prevention in HIV vaccines, microbicides are a low priority when resources are scarce.

For all these reasons, advocates for microbicides argue that government support for microbicide development is crucial. “The natural engines that drive new drug development have failed in the case of microbicides,” says Heise. “As a result, the government will have to take the lead, encouraging microbicide development with research grants and forming partnerships with private-sector companies to help evaluate their products.”

Mobilizing for Action

In 1998, the Alliance for Microbicide Development was founded as a non-profit coalition to catalyze the field by bringing together scientists, developers and advocacy groups on a regular basis to advance the microbicide agenda. More recently, the Global Campaign for STD Prevention Alternatives for Women was formed to spearhead a public education and advocacy effort on behalf of greater investment in microbicide research and development by the U.S. government. The campaign has been working with Rep. Connie Morella (R-MD) and other members of Congress to develop federal legislation that they hope will catalyze public support for

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microbicides and eventually result in a significant infusion of new funding for microbicidal product development.

The legislation is expected to be introduced shortly, in advance of an international conference, dubbed Microbicides 2000, in the District of Columbia this spring. It will autho-

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rize the Department of Health and Human Services (DHHS) to expand and intensify microbicide-focused activities at the National Institutes of Health and the Centers for Disease Control and Prevention, as well as to

coordinate with other relevant agencies, including the FDA and the U.S. Agency for International Development. The bill also will authorize targeted funding, probably for a five-year period, with the aim of significantly increasing the approximately \$25 million DHHS says is now being spent annually on microbicide-related activities (less than \$20 million of which, however, is specifically earmarked for product development and testing).

Advocates hope to use the legislation as an organizing tool for grassroots activities. "A strong—albeit latent—grassroots demand for microbicides has been proven to exist," says Anna Forbes, the global campaign's U.S. grassroots coordinator. "We're working to give voice and visibility to this demand and will be organizing a range of activities in at least 10 sites across the United States to educate individuals and community organizations on this issue." For her part,

Morella says the time for action is now. "There is little doubt," she declared in a recent letter on the global AIDS epidemic, "that with sufficient investment, a microbicide could be available within five years. The women of the world, as well as their partners and children, desperately need and deserve more options." ⊕
