



Global Advocacy for Microbicides

A Call to Action

A Report by the
Advocacy Working Group

of the **Microbicide Initiative** funded by **The Rockefeller Foundation**

and the
Global Campaign for Microbicides

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Megan Gottemoeller, Imogen Fua, and Ananth Thambinayagum helped organize the international meeting for advocates involved in the Global Campaign for Microbicides, which was held in Warrenton, Virginia, from June 28 to July 1, 2001. Findings and ideas from this meeting, although outside the official "Working Group" process, also informed this document.

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The Working Group wishes to acknowledge and thank the hundreds of advocates who have been active for over a decade in helping to create the field of microbicide development. We stand on their shoulders.

Note: The views expressed in this document do not necessarily reflect the opinions of individual members of the Working Group, nor the policies of their respective agencies or organizations.

Twenty years into the HIV/AIDS epidemic, the world still has only limited options for preventing the sexual transmission of the virus. We can extol the virtues of monogamy, encourage people to use the male or female condom, and expand treatment for sexually transmitted infections (STIs).

Individuals everywhere—especially women—need an expanded array of tools for enhancing their ability to protect themselves and their partners from HIV and STIs. Many women do not have the social or economic power necessary to insist on condom use and fidelity, or to abandon partnerships that put them at risk. In the same way that successful treatment regimens require triple and quadruple therapy, successful prevention requires multiple forms of intervention and complementary tools aimed at meeting the needs of different people.

One approach on the horizon that deserves increased public and private sector support is topical microbicides. Microbicides are agents that can prevent the transmission of HIV and other sexually transmitted pathogens when applied in the vagina or rectum. The successful development of a microbicide would provide a critical adjunct to male and female condoms, as well as a needed complement to existing efforts to develop a therapeutic or prophylactic HIV vaccine. The search for safe, effective microbicides must persist in the face of vigorous research into an HIV vaccine. A microbicide is likely to become available more widely and more rapidly than a vaccine; will act at an earlier stage of infection; and may be able to interrupt the spread of other sexually transmitted pathogens, in addition to HIV (which an HIV vaccine would be unlikely to do).

Unlike those areas of science where the motives of profit and personal ambition are sufficient to propel innovation, microbicides will only become a reality if advocates mobilize sufficient political will to garner substantial investment on the part of governments and private foundations. Because microbicides represent a new product class, they remain relatively unattractive to private investors who shy away from projects whose up-front development costs and market potential are difficult to quantify. This works against microbicides when they compete within large pharmaceutical companies for access to research and development funds.

As a result, the task of microbicides research and development (R&D) has fallen to not-for-profit research institutes, university-based sciences, and small biotech companies, all of whom are dependent on government and foundation resources to take their product leads forward. This is why public education and advocacy are critical to the task of bringing public health goods—such as microbicides and vaccines—to market. Advocacy creates the political will and momentum necessary to propel the scientific enterprise forward—whether through highlighting the urgency of the task at hand, educating those in a position to make a difference, or fomenting political pressure for change.

In the case of microbicides, advocacy must extend beyond merely ensuring that a product is produced. It must include research, policy work, and political activism to ensure that the products developed are widely available and correctly and consistently used by individuals at risk of HIV and STDs, especially women. This requires focusing advocacy on issues of pricing,

accessibility, stigma, gender bias, and women's empowerment, in addition to efforts to accelerate product development and approval.

Moreover, because microbicides are a user-controlled technology and a global public health good, any successful microbicides strategy must be informed by user needs and perspectives, and engage users and civil society as active partners.

Conclusions and Recommendations

- Public and private monies for microbicide R&D must expand dramatically—and quickly—if the promise of microbicides is to be realized
- Advocacy is an essential and cost-effective component of an overall strategy to accelerate microbicide development and ensure widespread access and use
- Investment in advocacy yields positive returns to the field as a whole by mobilizing new resources and paving the way for the successful testing, introduction, and use of microbicides
- The infrastructure and interest exists among a wide range of actors to rapidly expand advocacy activities, given an infusion of resources
- Over the next two years, priority should be given to:
 - 1) strengthening existing and emergent advocacy initiatives (e.g., the Alliance for Microbicide Development, the Global Campaign for Microbicides);
 - 2) expanding advocacy, outreach, and resource mobilization in Europe;
 - 3) elevating the profile of microbicides on the “global stage” (e.g., among ministers and other political leaders, at the G-8, etc.);
 - 4) building the capacity of NGOs and their networks to advocate for microbicides and to participate actively in decision making around research agendas and clinical trial implementation;
 - 5) recruiting new scientists to the field and elevating the issue's stature within the scientific community; and
 - 6) using the media to raise awareness, manage scientific failure, and mobilize political will.
- During the next five years, a portion of the monies raised by any new microbicide initiative should be reserved to support advocacy and access issues
- Individuals representing the rights and interests of the public and end users should be included on the governance and advisory bodies of all microbicide-related initiatives and institutions

This report is a product of the Microbicide Initiative and the Global Campaign for Microbicides.

In July 2000 the Rockefeller Foundation invited an international group of scientists, research organizations, advocacy groups, pharmaceutical representatives, United Nations organizations, and donors to come together to find ways to accelerate the development and availability of a safe, effective and accessible microbicide. Working Groups were formed to examine five key elements in this process: (1) the potential economic returns to public and/or private sector investors in microbicide research; (2) the scientific and technical requirements for accelerating microbicide development; (3) ways to ensure widespread access and use of a final product; (4) advocacy, public education, and resource mobilization; and (5) the public health impact.

The reports from the other Working Groups are contained in companion volumes within this series. This document represents the consensus work of the “Advocacy Working Group.”

The Advocacy Working Group was co-chaired by Lori Heise, Director of the Global Campaign for Microbicides, and Susan Crane, President of International Family Health (IFH). Additional members included: Quarraisha Abdool Karim, Director of the Southern Africa Fogarty AIDS Training Programme at the University of Natal; Geeta Rao Gupta, President of the International Center for Research on Women; Elizabeth McGrory, Program Associate of the Population Council; and Sue Perl, consultant.

The group decided to remain small and to conduct the majority of its work via email, seeking outside input and guidance via two international consultative meetings. The first meeting—held in Warrenton, Virginia, from June 28 to July 1, 2001—was sponsored by the Global Campaign for Microbicides, and involved sixty advocates from twenty-eight countries. This important gathering—funded by the Ford Foundation—provided a rich opportunity for committee members to seek input from a wide range of developing-country partners (see appendix 3). The second meeting was convened specifically to inform the process initiated by The Rockefeller Foundation. It was held in Washington, D.C., on August 9 and 10, 2001. This meeting involved twenty participants, with a heavy emphasis on European actors (see appendix 4).

With the assistance of consultants, the Working Group mapped the landscape of existing advocacy actors and developed a framework for developing a global action plan for microbicide advocacy. At both of the consultative meetings, groups of advocates participated in exercises to identify priority goals, strategies, and activities for global advocacy on microbicides. The results of these exercises are synthesized in the Action Plan reproduced in appendix 1. This document is meant to serve as a resource for advocates and donors by identifying activities critical to realizing the promise of microbicides.



Global Advocacy for Topical Microbicides

// *A new bride in Chennai (Madras), India, knows that her husband visits prostitutes on the long truck drives up and down the country's eastern coast. She's afraid he may be HIV-infected, but if she doesn't conceive a child within the first few months of marriage, she risks abandonment or worse.*

Should this woman have to choose between having a child or becoming HIV-infected?

A high-school girl in Cleveland, Ohio, is dating a man in his mid-twenties who uses injection drugs. She's afraid he may be HIV-infected, but when she asks him to use a condom, he gets angry and forces her to have unprotected sex.

Is this woman choosing to have unprotected sex?

Millions of women worldwide lack the power either to avoid sex with men who may be HIV-infected or to ensure the use of condoms. They deserve a better choice.

Fortunately, there is a prevention method (known as a microbicide) that women could use without the cooperation or even the knowledge of their sexual partners.

The downside? It doesn't actually exist yet... **//**

—Excerpted from advocacy materials produced by amfAR (American Foundation for AIDS Research)

Introduction

Twenty years into the HIV/AIDS epidemic, the world still has only limited options for preventing the sexual transmission of the virus. We can extol the virtues of monogamy, encourage people to use the male or female condom, and expand treatment for sexually transmitted infections (STIs).

Individuals everywhere—especially women—need an expanded array of tools for enhancing their ability to protect themselves and their partners from HIV and STIs. Many women do not have the social or economic power necessary to insist on condom use and fidelity, or to abandon partnerships that put them at risk. In the same way that successful treatment regimens require triple and quadruple therapy, successful prevention requires multiple forms of intervention and complementary tools aimed at meeting the needs of different people.

Since the early 1990s, “topical microbicides” have attracted scientific attention as a possible new technology for preventing STIs, including HIV. Like today's spermicides, microbicides would be used vaginally or rectally by individuals to help protect themselves and their partners from the sexual transmission of HIV and other STIs.

When successfully developed, these compounds could be formulated in a number of ways—as a gel, film, sponge, or time-released capsule—and would provide an important fallback for women and couples who, for a variety of reasons, cannot use condoms to prevent HIV/STI transmission. For others, microbicides would provide an important adjunct to condom use, offering added protection in case of condom failure.

The goal of developing a safe, effective microbicide depends on more than just good science. It requires political will and willingness on the part of the public and/or the private sector to invest the necessary resources.

Despite enormous scientific and public health potential, microbicide research has been severely under-funded and politically marginalized, even within the HIV/AIDS community. Large pharmaceutical companies—the normal engines of product development—have been reluctant to invest in microbicides because of concerns about scientific uncertainty and competing opportunities to invest in products that are potentially more profitable. As a result, microbicide R&D has been conducted exclusively by nonprofit entities, academic researchers, and small biopharmaceutical companies, all of which are dependent on government and foundation grants to pursue their research.

This is why public education and advocacy are critical to the task of bringing public health goods¹—such as microbicides and vaccines—to market. Unlike those areas of science where the motives of profit and professional ambition are sufficient to propel innovation, microbicides will only become a reality if the advocacy community mobilizes sufficient political will to garner substantial investment on the part of governments and private foundations.

It is not for lack of compelling leads that progress is slow. In fact, there are nearly sixty product compounds poised for further development—most of which exist because of prior investment on the part of government agencies such as the U.K. Medical Research Council, the U.S. National Institutes of Health (NIH), and foreign assistance agencies such as the U.S. Agency for International Development (USAID) and the U.K. Department for International Development (DFID). But current government investment is insufficient to advance products through the set of complex clinical trials required for approval by

drug regulatory agencies. Once compounds enter human trials, research costs increase dramatically. And multiple products must advance through trials concurrently because compounds invariably drop out as testing reveals problems with their safety, acceptability, or effectiveness.

The Pharmaco-Economics Working Group estimates that to develop the existing portfolio of potential microbicidal products would require approximately US\$775 million in direct product development costs over the next five years.² This investment would guarantee a high likelihood of generating several safe, effective microbicides by 2010. But public-sector investment falls far short of this goal. In FY 2001, for example, the NIH invested less than 2 percent (US\$47 million) of its AIDS-related research budget in microbicide research and development, with US\$12 million allocated that year by USAID and an additional US\$2.6 million by the Centers for Disease Control and Prevention (CDC). Moreover, a significant portion of the U.S. government investment is not directly related to product development.

These sums are supplemented by modest but growing investments from venture capitalists and private foundations. In 2000, for example, the Bill and Melinda Gates Foundation made a grant of US\$25 million (over five years) to the CONRAD Program's Consortium for Industrial Collaboration in Contraceptive Research (CICCR) to expand development and testing of microbicides. The Hewlett, Buffett, Rockefeller, and Mellon Foundations have made more modest contributions to microbicide R&D, and the American Foundation for AIDS Research (amFAR) has distributed over US\$1.3 million in grants to microbicide-related science. The Rockefeller Foundation began investing in microbicides in 1993, and has publicly committed to greatly increasing its support in 2002. Additional donors, most notably the Ford Foundation, the Richard and Rhoda Goldman Foundation, the Moriah Fund, and the European Commission,

¹ The term "public health good" refers to products that yield a social or public health benefit but that fail to attract private capital.

² This amount does not include the costs of basic research, discovering additional leads, work on access and introduction, organizational overhead, or advocacy efforts.

have taken the lead in supporting work on access, advocacy, and the engagement of civil society actors in the microbicide field.

Public and private monies for microbicide research and development must expand dramatically—and quickly—if the promise of microbicides is to be realized.

While resource mobilization is critically important, advocacy for microbicides must extend beyond merely ensuring that a product is developed. It must include research, policy work, and political activism to ensure that the products developed are widely available and correctly and consistently used by people at risk of HIV and STIs, especially women. This requires focusing advocacy on issues of pricing, accessibility, stigma, gender bias, and women’s empowerment, in addition to efforts to accelerate product development and approval. The history of other novel technologies confirms that a range of initiatives must take place concurrent with product development to ensure that the new technology, once developed, will be widely accepted and accessible to the people who need it.

Finally, because microbicides are a user-controlled technology and a global public health good, any successful microbicides strategy must be informed by user needs and perspectives, and engage users and civil society as active partners. In the same way that consumer needs and interests drive the design and marketing of consumer products, the perspectives of users must be at the core of any strategy to save lives via the introduction and use of microbicides. This is in sharp contrast to the traditional approach to drug development, which is industry-led and science driven, and where access and use depend more on the prescribing patterns of physicians than on the behavior, skills, and attitudes of users.

What Is Advocacy?

Advocacy is a little-understood term that means different things to different people. In the

context of this document, “advocacy” means to shape or influence the ideas and decisions that inform policy and practice. The term advocacy has frequently been used to refer exclusively to efforts aimed at expanding the resource base for microbicide development. While “resource mobilization” is clearly one goal of advocacy, it is by no means the only one. Indeed, advocacy has a role to play in all phases of technology development and introduction—from helping to structure the research agenda and ensuring that community views and perspectives are included in the design of clinical trials, to creating political pressure for widespread and timely access to any resulting product.

Advocacy, in effect, creates the political will and momentum necessary to propel the scientific enterprise forward—whether through highlighting the urgency of the task at hand, educating those in a position to make a difference, or fomenting political pressure for change. For many of the tasks identified by the other Working Groups, there is an advocacy component that must be recognized and adequately resourced. The Access Working Group, for example, has identified a complicated set of regulatory questions and challenges that must be resolved in order to facilitate product approval and registration. It is the role of advocates to maintain a sense of urgency and to ensure that the sober realities of the HIV pandemic are not lost in Byzantine discussions of regulatory harmonization. Even in areas with complex technical questions, it is frequently competition or political inertia that bogs down progress. Advocates can monitor such deliberations and create pressure for action if the process fails to proceed expeditiously.

It is also the role of advocates to ensure that views and perspectives of all those who stand to gain or lose from the process have a voice in important decisions. Traditionally, key interest groups—end users, women’s health advocates, HIV+ individuals, among others—have largely been excluded from the drug development process. The global women’s health movement,

for example, has long protested the tendency of contraceptive developers to pursue new technologies with little or no input from the women’s community or end users. In the 1990s, this began to change as women’s health advocates and progressive forces in some research institutions began to experiment with different means to capture and use input from women’s advocates and end users.

The HIV community has also been very successful in making claims on the research community for greater involvement of non-scientists in the process of defining and implementing research agendas. In the context of microbicide development, this means working to ensure that the interests and perspectives of all those who have a stake in the outcome are supported to engage effectively in the process of scientific research—including consumer groups, NGOs, and the communities that will host and populate clinical trials. It also means working to ensure that the public interest is protected when negotiations are underway regarding licensing and other agreements that can affect the overall price and accessibility of a microbicidal product.

There are a variety of ways to effect change, and the “tool kit” of advocates extends far beyond the types of direct action and street demonstrations that are traditionally associated with activist groups. The tools of advocacy include:

- political mobilization
- constituency building
- public education and outreach
- policy analysis
- social science research
- media/communications
- activism and public demonstrations

Advocacy strategies can also be directed at a range of actors, from pharmaceutical executives and regulators to health care providers, opinion leaders, and the donor community. Box 1

summarizes both the primary targets of various advocacy strategies and the main tools of the trade. In the world of microbicide advocacy, social science and policy analysis can be as important as grassroots organizing and public demonstrations in influencing the course of product development, testing, and introduction. Any global movement on behalf of microbicide advocacy will require a range of actors, each of which relies on a different combination of strategies, from direct action to reasoned persuasion.

Goals for a Microbicide Advocacy Strategy

The ultimate goal of an advocacy strategy for microbicides is *to reduce the spread of HIV and other STIs by accelerating widespread access to, and use of, a topical microbicide.*

The choice to focus on “access and use” rather than “product development” is both deliberate and significant. As noted above and in the working paper on Access, the goal of any microbicide initiative must extend beyond developing a successful product to ensuring that those who need it have the means, access, and the skills necessary to use it successfully. This is even more true in the context of a consumer product, where effectiveness depends on widespread and consistent access and use.

Box 1: Advocacy = Influence/Shape

Tools of the Trade	Who?/ Target
Political mobilization	Legislators
Constituency-building	Policymakers
Public education/outreach	Providers
Policy analysis	Donors
Social science research	Regulatory agencies
Media/communications	Scientific establishment
Activism/public demonstrations	NGOs
	Opinion leaders

To achieve this goal, a microbicide strategy must accomplish the following five objectives:

1. It must familiarize the public with the concept of microbicides. *In short, people can't demand what they have yet to imagine.*
2. It must mobilize a political base in support of increased public-sector investment in microbicide R&D and related activities. *Political movements require active, informed constituencies.*
3. It must convince leaders in the AIDS, scientific, and public health establishments that microbicides are a viable prevention strategy that deserves their political, scientific, and financial support. *In effect, it must infiltrate the public policy mainstream.*
4. It must forge a provider, policymaker, and "user" environment supportive to the timely introduction of microbicides. *It must pave the way for widespread access and use.*
5. It must recruit and sustain the interest and political will of key agents critical to the successful introduction and availability of microbicides, including cutting-edge scientists, pharmaceutical executives, donors, and policymakers.

In addition, a successful public-education and advocacy strategy will have the following collateral benefits:

6. It will facilitate the testing of microbicides by increasing public understanding of trial design and ethics, and by helping local constituencies feel comfortable and engaged with the trials taking place in their community (e.g., through community advisory boards).
7. It will help protect the public interest by creating an informed constituency ready and able to intervene on the public's behalf.

Another way to conceptualize the advocacy agenda for microbicides is to use the framework of the four "A"s of advocacy, including:

Awareness-raising

Accelerating product development

Access

Accountability

Awareness

Strategies to create a supportive political, policy, and provider environment for the timely development, introduction, and use of microbicides

Objectives:

- Raise awareness of microbicides and the risks and the costs of STIs/HIV
- Create political pressure for increased investment in microbicides and other prevention technologies
- Foster a worldwide advocacy movement with strong participating organizations

Acceleration

Strategies designed to facilitate the timely development, approval, and registration of safe, effective, and "user-friendly" microbicides

Objectives

- Mobilize funds for microbicide research and related activities
- Recruit cutting-edge scientists to the microbicide field
- Foster a supportive regulatory environment
- Further engage industry in the field of microbicides research
- Build capacity of developing-country researchers and communities to engage in microbicide trials

Appendix 1 of this document contains a detailed activity plan for global advocacy on microbicides structured according to the four “A’s” below. This plan represents the combined insights of existing groups working on microbicide advocacy and the ideas and contributions of those who attended the August 9 – 10 advocacy consultation. Although much remains to be done, there is a firm foundation from which to build toward the full implementation of this ambitious plan.

Existing Building Blocks

It is no exaggeration to say that today’s interest and investment in microbicides is largely due to the concerted action of advocates working over the last decade to draw attention to the need for new HIV prevention tools to supplement the male condom. Individual and organizational champions have helped create and nurture the field of microbicide research and development, starting as early as 1987. Early leaders came from the field of women’s health and contraceptive research and development, and have been joined in recent years by advocates working on HIV/AIDS, STIs, and infectious diseases.

This history of activism provides a rich foundation upon which to build an expanded microbicide effort. The microbicide field has the advantage of operating at the crossroads of three relatively mature and vibrant movements: women’s health, family planning, and HIV/AIDS. All bring to the issue a network of sophisticated NGOs, active constituencies, experience with policy advocacy, and media sophistication.

Unfortunately, the issue of “*women and HIV*” has frequently fallen through the cracks—with women’s groups looking to the better-funded HIV/AIDS organizations to take the lead, and industrial-world AIDS groups prioritizing the needs of gay men over women. This is changing as the face of the epidemic changes, but microbicide advocates often have had to fight hard to gain a foothold among mainstream AIDS and women’s groups. When questioned, almost all groups endorse the importance of microbicides—but few have chosen to prioritize the issue, given the press of competing issues.

Access

Strategies designed to ensure that microbicides will be widely available and affordable for those who need them, and that individuals have the knowledge, skills, power, and social support necessary to use them

Objectives:

- Ensure that user needs and perspectives are taken into account when making key decisions affecting pricing, accessibility and formulation
- Ensure that widespread access and use are key principles guiding overall investment and decision making among key actors in the microbicide field
- Work to ensure that a program of research, policy analysis, and training is in place to support the timely introduction of microbicides in pilot countries

Accountability

Strategies designed to ensure that as science proceeds, the public interest is protected and the rights and interests of trial participants, end-users, and communities are fully represented and respected

Objectives:

- Public-sector resources are wisely and effectively invested to maximize both impact and cost-effectiveness
- Community groups and other civil-society agents are empowered (through information, resources, training, and networks) to manage expectations, identify and communicate needs, and advocate on their own behalf with the microbicide research establishment
- Individuals and communities have a voice in the decisions that affect their lives

In this gap, a number of microbicide-specific initiatives have evolved, aimed at encouraging a broader coalition of groups to engage in microbicide advocacy:

The **Global Campaign for Microbicides** is a broad-based, international effort designed to build support among policymakers, opinion leaders, and the general public for increased private- and public-sector investment in alternatives to the male condom. Through advocacy, policy analysis, and social science research, the Campaign works to accelerate product development, facilitate widespread access and use, and protect the needs and interests of end users, especially women. The Campaign presently has over one hundred co-sponsoring organizations worldwide that mobilize political will through education, constituency building, legislative advocacy, and a global petition drive.

The **Alliance for Microbicide Development** is a consortium that includes most of the major researchers and organizations involved in microbicide development, comprising developers from thirty-four biopharmaceutical companies, scientists from twenty-six nonprofit research institutions, and representatives from twenty health research and advocacy groups. The Alliance has positioned itself institutionally as a catalytic agent focused on convening, integrating, educating, networking, and developing strategies to identify gaps and eliminate obstacles in the field. The primary targets of the Alliance include U.S. Agencies such as the CDC, the NIH, the FDA, Congress, and researchers. Secondary targets include the scientific establishment and pharmaceutical companies.

More recently, the **International Working Group on Microbicides**, the **Population Council**, and the U.K.-based reproductive health NGO, **International Family Health (IFH)**, have worked to raise the profile of microbicides among the European donor and policy communities. In late 2000, the IFH applied to the European Union for funding to greatly expand microbicide advocacy in Europe and Asia and

Africa. Although approved, funding for this project was not released until April 2002, delaying the project's start.

Appendix 2 provides additional information on organizations and networks presently active in microbicide advocacy as well as a chart that visually summarizes the current landscape of advocacy efforts worldwide.

Where Are We Now?

Advocacy on microbicides stands at a critical juncture. Enormous effort has been expended over the last few years to lay the foundation for a step change in recognition of the need for, and feasibility of, developing new HIV prevention options. Progress has been made, but considerable work remains to consolidate even basic awareness of microbicides among the different constituencies that have a stake in the future of this technology.

To date, the greatest progress has been made in North America, where groups have succeeded in translating growing awareness of microbicides into concrete political action. Together the Alliance for Microbicide Development and the Global Campaign for Microbicides have ensured that microbicides have had a presence at all major conferences and venues touching on public health, HIV/AIDS, and reproductive health in the United States. They have sponsored workshops, panels, and exhibit booths, and have held individual meetings or briefings for key decision makers in Congress, the Administration, and at the National Institutes of Health, CDC, and USAID. Through lobbying and grassroots organizing, these efforts helped mobilize US\$21 million in new research dollars for microbicide R&D in FY 2000.

Advocates have also worked with Congress to demand greater coordination in the Federal research program for microbicides, and to establish a mechanism to monitor and track investment of Federal funds in microbicide R&D. In addition, the Campaign has been a catalyst in the creation of ten local Campaign sites, sponsored by

local family planning or HIV organizations, to serve as bases for Congressional organizing and public education. Both the Alliance and the Campaign have websites and listserves available to serve the wider microbicide community, and both serve as a point of first reference for their constituencies and for the press. With some exceptions, the issue of microbicides has penetrated the policy mainstream in the United States, but maintaining its place “front and center” on the agenda requires constant effort.

Internationally, a number of groups have made efforts to bring the message of microbicides and woman-controlled prevention to major international forums. Advocates have ensured a central presence for microbicides and female condoms at the global and regional HIV/AIDS conferences, as well as a number of other important venues, such as the conference for the Society for Women and AIDS in Africa; the national conference of the Indian Network of NGOs working on HIV; the global conference of Church Women United; and the South African Reproductive Health Priorities Conference. While these efforts have begun to influence the activist and NGO discourse on AIDS, many key policymakers and scientists in developing countries are still unfamiliar with the concept of microbicides.

Regrettably, the message that may have penetrated most deeply at the international level is the negative result of the UNAIDS-funded trial of COL-1492, released at the 13th World AIDS Conference in Durban, South Africa. Preliminary results of this trial, released during a plenary talk on microbicides and at an accompanying press conference, showed that COL-1492 (an existing over-the-counter spermicide containing N-9) did not protect against HIV, and may have actually facilitated transmission by causing disruptions in the vaginal epithelium. Due partly to inflammatory and misleading statements made during the press conference, the results of the study were widely misinterpreted by conference attendees and the press as suggesting that the concept of

microbicides—rather than simply one candidate—had been shown to be harmful. This experience emphasizes the importance of preparing up front to manage “failure” and to shape proactively the messages communicated through the press.

Organizing in Europe is poised for further growth. Several events were organized in the early 1990s to raise awareness of microbicides, including a scientific consultation sponsored by WHO; a policy consultation convened by IFH; and an NGO consultation organized by the Women’s Health Action Foundation of the Netherlands. More recently, the International Working Group on Microbicides (IWGM) and the Royal Society of Medicine, together with the U.K. Family Planning Association and the Population Council, held consultations on microbicides. The Rockefeller Foundation has initiated discussions and visits with several key donors, but only minimal work has been done to date to reach out to the wider NGO and policy community on the European continent. Much remains to be done, as well, to sensitize the press and to begin to translate rising awareness into political will for increased investment on the part of the European Union and member states.³ Several groups are primed for greater involvement, but have lacked funding to date.

A similar situation exists in many developing countries. There is ample evidence of widespread interest in microbicides among many groups and networks with substantial constituencies in developing countries, including the Society for Women and AIDS in Africa; the Latin American and Caribbean Women’s Health Network; and the International Community of Women Living with HIV/AIDS (ICW), among others. Many of these groups were first exposed to this issue through the workshops at international conferences or meetings sponsored by international networks, such as the Global Campaign for Microbicides. Several hundred groups have taken first steps toward engagement, such as publishing articles in their newsletters or becoming institutional co-

³ The U.K. Department of International Development recently gave a substantial grant (£16 million over five years) to the Medical Research Council and affiliated institutions to support a five-year integrated program of microbicide development, testing, and policy research.

sponsors of the Global Campaign. Many express a desire to become more involved but have lacked the resources to do so.

It is only recently that the issues of microbicides and woman-controlled prevention have begun to emerge on the “global stage.” In June, advocates helped ensure that both issues were front and center at the UN Special General Assembly on AIDS, and highlighted in the official Declaration of Commitment. At the same venue, the Rockefeller Foundation, together with DFID, the U.K. Mission to the UN, the Population Council, and UNAIDS, sponsored a high-level briefing on microbicides that included a presentation by the Honorable Clare Short, Secretary of State at the U.K. Department for International Development. In addition, through a coordinated campaign of letter writing and direct intervention, advocates were able to get Secretary General Kofi Annan to begin including mention of microbicides in his speeches on HIV/AIDS. Nonetheless, much more could be done to ensure that these themes are included in all high-level discussions of HIV/AIDS, TB, and malaria. Already the issue of HIV vaccines has been highlighted at meetings of the G-8 nations, at the World Economic Forum, and

at other regional venues, such as the meeting of African ministers held in Abuja, Nigeria. Microbicides and female condoms deserve a prominent role in these negotiations as well.

The Challenges Ahead

In some ways, microbicide advocates face many of the same challenges as do individuals advocating on behalf of other public health causes. Like breast cancer advocates or those fighting for more attention to Parkinson’s disease, microbicide advocates must compete against other compelling claims on public-sector dollars. Unlike these causes, however, the microbicide movement must draw its energy largely from the ranks of the *unaffected*.⁴ Most health movements draw their members from individuals or family members of those personally affected by a disease or condition. It is far more difficult to generate focus and commitment among individuals who have yet to be personally touched by an issue.

In other ways, microbicide advocates share common cause with other HIV advocates: those working on access to treatment or individuals working on behalf of HIV vaccines. A careful

Box 2: Political Landscape Faced by Advocates

	Microbicide	Vaccine	Treatment
Must mobilize around product that does not yet exist	✓	✓	
“Enemy” to rally around (Big Pharma)			✓
Policymakers and end users are familiar with the concept		✓*	✓
Ambivalence in the public health community	✓		✓
Must organize from the ranks of the “non-affected”	✓	✓	
Engages cultural discomfort with sexuality, vaginas, etc.	✓		
Confronts legacy of contraceptive R&D	✓		

* *Notions of vaccines as conferring lifelong immunity may also breed discontent if, as scientists expect, HIV vaccines confer only partial immunity for shorter periods of time.*

⁴ Although broadly true, HIV-positive women are becoming increasingly involved in microbicide advocacy worldwide.

comparison between these three movements suggests a number of interesting observations about the challenges that face the wider field of microbicide advocacy.

Like vaccine advocates, microbicide proponents face the challenge of having to mobilize interest around something that does not yet exist. This complicates the advocacy challenges for both vaccines and microbicides in comparison with treatment activists who can argue persuasively that justice demands that existing, life-extending HIV drugs should be made available to everyone who needs them.

However, both treatment and vaccine advocates share the advantage of promoting concepts readily recognized by the public and policy-makers. By contrast, the notion of a vaginal microbicide is an entirely new conceptual category—a reality that makes mobilizing support more difficult.

The notion of familiarity as an “advantage” for vaccines, however, may yet prove to be a double-edged sword (hence the asterisk near the checkmark in the vaccine column). In the short term, the public’s familiarity with childhood vaccines has worked to the field’s advantage because it evokes the notion of lifelong immunity—the “magic bullet.” (Indeed, early communications strategies of groups like IAVI capital-

ized on this perception). Given the emerging reality that an HIV vaccine may be only 30 to 50 percent effective and have other limitations, the final product may not live up to public expectations. Microbicide advocates have had to grapple from the beginning with the reality that they are advocating on behalf of a technology that will offer only partial protection. Having to confront this reality early may prove to be an advantage.

A number of challenges facing the field derive specifically from the issue’s association with women’s health and its origins in the women’s health movement. Microbicide advocacy necessarily requires talking about subjects that make some people uncomfortable—like vaginas, sexuality, power and gender. As drugs administered systemically by clinicians, vaccines and treatments have an aura of respectability that microbicides lack.

Microbicides also labor under the burden of being categorized as a “woman’s issue” rather than as a public health emergency.

In terms of science-related challenges (see box 3), developing an effective microbicide is generally considered less difficult than developing a vaccine. Although an asset from the perspective of public health, the field has acquired the reputation of being mundane and less intellectually engaging than other areas of research. In reality, microbicide research overlaps considerably with cutting-

Box 3: Science-Related Advocacy Challenges

	Microbicide	Vaccine	Treatment
Considered “kitchen sink” science	✓		
Research involves healthy people	✓	✓	
Lacks proof of concept	✓		
Different viral clades (sub-species) could affect effectiveness		✓	
No surrogate markers for efficacy	✓		
Concerns over user compliance	✓		✓
Fears of adverse reactions		✓	

edge HIV therapeutics research. Both involve investigations of compounds that inhibit viral entry, attachment, and/or fusion. The perception that microbicide research is “kitchen sink” science has limited the field’s ability to attract top talent and underlines the importance of advocacy *within* the scientific community.

Another complicating factor for both microbicides and HIV vaccines is that the trials necessary to evaluate their effectiveness must take place among *healthy* volunteers. The risk calculus appropriate to a prevention trial is decidedly different from that of a trial that enrolls extremely ill individuals and gives them access to a potentially effective new therapy. The fact that microbicide and vaccine trials must take place among vulnerable but not-yet-infected individuals greatly complicates both the ethics and politics of clinical testing.

What such an analysis illustrates is that even *within* the field of HIV and AIDS, the advocacy opportunities and challenges differ among different issues. Constructing a savvy and effective global strategy around any issue requires careful attention to specific political realities and historical antecedents. By virtue of its history, the microbicide movement inherits both the strengths and weaknesses of its affiliation with the women’s health movement and the field of contraceptive research and development. It is this reality—perhaps more than any other—that distinguishes the landscape of microbicide advocacy from that of other HIV-related issues.

Fleshing Out a Strategy

With this background in mind, the Working Group explored different strategies to achieve each of the four “A’s” of advocacy—Awareness, Acceleration, Access, and Accountability. In addition, the group held a productive discussion on the notion of “staging” activities over time and the need to prioritize different activities in different regions. The challenge is not to imagine all that would be useful, but to make strategic choices among competing priorities.

- What are the most important activities to undertake now (in the next two years)?
- What activities should be phased in over the next three to five years?
- How should activities be focused geographically?

Based on these and other discussions, the advocacy subcommittee developed the Detailed Action Plan reproduced in appendix 1 of this report. This Action Plan draws on both the August 9 – 10 consultation and the work plans and experiences of ongoing advocacy efforts.

The August consultation also yielded a number of crosscutting recommendations that complement the specific objectives and activities outlined in the Plan. We reproduce these here as overarching recommendations to guide future microbicide advocacy.

1. Build strategic alliances

The microbicide field should invest heavily in building strategic alliances with other issue areas. The notion of reaching out to “natural allies” in the fields of women’s health, HIV/AIDS, and family planning, among others, has been a core strategy of the movement to date. This strategy has been highly successful and deserves to be expanded.

The key is to identify where strategic interests coincide. The microbicide movement, for example, should make common cause with organizations such as Malaria Vaccine Initiative (MVI), the Global Alliance for TB Drug Development, and International AIDS Vaccine Initiative (IAVI) around efforts to recruit more pharmaceutical company interest into neglected health areas. There are clear opportunities for joint advocacy and lobbying around issues such as purchase funds, regulatory streamlining, tax credits, etc. There is also enormous opportunity for joint work around the ethics of clinical trials and in helping to prepare communities in the sites where trials will be taking place.

Advocates should also seek points of common interest to recruit new constituencies to the microbicide cause. U.S. advocates, for example, are reaching out to gay men and gay men's health groups by sponsoring a joint effort to publicize the negative health consequences of using products containing N-9 for anal sex.⁵ This strategy is designed both to impart an important health message and to spark gay men's interest in becoming more active in microbicide advocacy.

2. Elevate the issue on the global stage

Microbicide advocacy has strong roots in grassroots activism and NGO movements. It is time now to ensure that this support is recognized and echoed in the corridors of power. The microbicide field should work hard to ensure that the issue is endorsed by high-level political leaders and integrated into ongoing discussions around the Global Health Fund for HIV, Malaria and TB and in forums such as the World Health Assembly and the World Economic Forum. An important opportunity is the possibility of cultivating high-level champions among the female development ministers of Europe.

3. Build capacity at the grassroots and within the wider NGO community

Those who invest in science generally recognize the importance of capacity-building in order to achieve results. Donors don't just fund isolated experiments; they help sustain entire laboratories, establish centers of excellence, and support postdoctoral training programs. Long before there was an HIV vaccine ready to evaluate, for example, the U.S. government was investing in building the clinical trial infrastructure necessary to test one.

The need for capacity-building and core support is equally important to building successful political movements. Over the next five years, a portion of the monies raised for microbicide development should go to strengthen the capacity of NGOs and their networks to advocate for

microbicides and to participate actively in the development and testing process.

Such investments will yield positive returns to the field as a whole. In 2000, U.S. advocates were able to mobilize twenty-nine dollars in new funding for research for every dollar invested in advocacy.

Support should include small grants to allow groups to undertake their own outreach activities as well as training on key issues related to the science, political organizing, and clinical trial issues and ethics. In the same way that it is important for scientists to come together through meetings and conferences, it is essential that civil society actors have opportunities for networking and exchange.

A handful of donors have been at the forefront of supporting such efforts, including the Ford Foundation, the Moriah Fund, the Richard and Rhoda Goldman Foundation, the Turner Foundation, General Services Foundation, the John M. Lloyd Foundation, the Hewlett Foundation, and the European Commission. These groups should be commended for their early leadership in this area.

4. Design and implement a strategic communications plan

Communicating a coherent and consistent message about microbicides is essential for a number of reasons, including building public support, managing expectations, and bolstering other aspects of the field's science and access agenda.

The word "microbicides" is an intimidating term for an exciting idea. An essential goal for a communications strategy is to develop more appealing ways to describe and promote this concept to the general public. Another challenge is to identify and test different "messages" designed to appeal to different audiences. Which

⁵Research undertaken as part of evaluating N-9 as a possible microbicide has revealed that when used rectally, N-9 causes major sloughing of the rectal epithelium. These data suggest that the addition of N-9 to condoms or lubricants may actually increase, rather than decrease, risk of rectal transmission of HIV.

arguments resonate most effectively with different constituencies? Developing a sophisticated communications strategy will require up-front investment in focus groups and other means to better define target groups and refine messages. Moreover, successful strategies are likely to be regionally specific. The Global Campaign for Microbicides is presently supporting formative work in this area, but communications work is expensive and requires significant and sustained investment.

5. Promote evidence-based advocacy, based on policy analysis and social science research

Efforts to influence and shape agendas are more persuasive when they are based on solid evidence rather than ideology. The case for microbicides is compelling; the advocate's job is to present that case to different audiences in a language and form they will find compelling. Occasionally, this will require generating new data and analyses. More commonly, the challenge is to marshal existing evidence in a strategic and compelling way.

6. Develop synergy between local, national, and international action

Author Malcolm Gladwell borrows the term “tipping point” from epidemiology to describe when, if conditions are right, certain ideas can go from virtual obscurity to widespread cultural recognition almost overnight. Like an epidemic taking off, ideas can reach a “critical” mass and then spread swiftly throughout a community.

The issue of microbicides may well be nearing a “tipping point” with respect to recognition and legitimacy in the global health and HIV/AIDS communities. But to “tip the balance,” advocates must create synergy between activities taking place at local, national, and international levels. This requires coalition-building, open and frequent communication, and efforts to “capture” and publicize the many activities that *are* taking place.

When women in Kenya protest the lack of HIV prevention options for women, or Kofi Annan mentions microbicides on CNN, these events must be seen and experienced as interconnected—as part of a common effort. The strength of a message is stronger when individuals speak with one voice. It is important that donors support a common infrastructure to support such synergy—including an interactive web page, electronic networking, newsletters, and advocate networks.

7. Seek to recruit new scientific talent and further engage “Big Pharma”

The long-term health of microbicides as a field depends on its ability to attract top scientists and greater interest from the private sector. Any global advocacy plan must include activities directed specifically at achieving this goal, such as cultivating high-level scientific champions and supporting microbicide-related postdoctoral fellowships.

Although the participation of Big Pharma is a long-term goal, the Pharmaco-Economics report suggests that the economic return on a first-generation microbicide will be negative, making it unlikely that large pharmaceutical companies will be a major source of R&D funding in the near term. Nonetheless, advocates should continue to pressure industry to stay involved in the field and to engage in specific sub-projects, like formulation or applicator design.

8. Proactively prepare to manage scientific failure and political opposition

The long-term success of the microbicide field depends on the ability to manage scientific failure and anticipate potential opposition. The fallout from the UNAIDS COL 1492 trial is an example of what happens if proper measures are not taken to manage the release of negative trial results.⁶ This could have been avoided if a communications team had been in place to contextualize the findings and to help shape the subsequent press reporting.

⁶ This trial suggested that one candidate microbicide—COL 1492—did not work to prevent infection. Unfortunately, the press and many conference participants interpreted this finding to suggest that the entire concept of microbicides—rather than a particular product—did not work.

Furthermore, it is important to anticipate and prepare for opposition forces that may object to some aspect of a new technology. Given the Catholic Church's concerns with birth control and the "abstinence only" movement in the United States, it is conceivable that microbicides will eventually draw political fire. In the United States, for example, the religious right actively attempts to discredit the male condom because it ostensibly facilitates sex outside of marriage. These forces believe "abstinence" is the only legitimate form of safer sex. It is essential that such concerns be anticipated and managed.

Finally, it is important to help manage expectations with respect to microbicides and the scientific process. The public must be helped to understand the following realities of clinical trials: 1) reporting of failures is essential to scientific progress; 2) many failed trials generally precede the discovery of an effective product; 3) trials can deliver useful information even if candidate results are disappointing; and 4) even the best-designed safety trials cannot pick up all negative health consequences.⁷

9. Prioritize actions and proceed in stages

A key aspect of strategy is the ability to set priorities and to recognize that actions must be staged in both time and place. Advocates, for example, began their outreach and lobbying activities in donor nations, recognizing the early need for research dollars.

The amount of outreach and education appropriate to different countries will change over time as products enter clinical trials and/or approach approval and introduction. Given limited resources, it is strategic to concentrate advocacy and social-science efforts initially in those developing countries that will host clinical trials.

Staging is also important to avoid raising false hopes or expectations at the grassroots level in countries devastated by AIDS. For this reason,

most international outreach to date has focused on bringing the message of microbicides to NGOs and policymakers in developing countries, rather than to the public at large. In situations where people are dying of AIDS, it is problematic to concentrate on a product that may not be available for many years. As products get closer to approval and introduction, it may be appropriate to broaden the focus of outreach efforts to begin preparing users for their eventual introduction.

10. Protect the rights and interests of the public, end users, and trial participants

Advocates repeatedly stress "accountability" and human rights as centrally important to any microbicide strategy. "Accountability" is a term used by NGOs to mean that all projects—especially efforts funded with public money—should be held accountable to recognized standards of ethics, rights, and participation.

What this might mean in practice for the microbicide field is laid out in greater detail in the Action Plan. In essence, accountability requires that:

- public-sector resources are wisely and effectively invested to maximize both impact and cost-effectiveness;
- community groups and other civil-society actors are empowered (through information, resources, training, and networks) to manage expectations, identify and communicate needs, and advocate on their own behalf; and
- individuals and communities have a voice in the decisions that affect their lives.

The above goals are both laudatory and strategic. Creating avenues for community participation in clinical trials, for example, serves ethical, practical, and strategic ends. Early consultation can help avoid political problems later on by increasing transparency and building trust. It can provide a way for researchers to hear and address community concerns and dispel any misperceptions or confusion. Moreover,

⁷ Health effects that are long term or extremely rare cannot be picked up in normal safety trials. This is why regulatory agencies sometimes require post-marketing surveillance, designed to pick up rare events that may only become visible when hundreds of thousands of individuals begin using a product.

community input can help improve the scientific depth and implementation of trials.

In short, attention to these issues helps ensure that the product that emerges will be widely accessible and used, and that inattention to ethical issues or community concerns will not erupt into a political firestorm that could undermine the entire program of research.

Conclusions

The companion report of the Science Working Group demonstrates that the science behind microbicides is evolving rapidly and that the process for developing a marketable product is

increasingly clear. According to the estimates of the Public Health Working Group, introducing a 60-percent-efficacious microbicide in the world's seventy-three poorest countries could avert 2.5 million infections over three years, which would translate into US\$2.7 billion in health-care costs avoided and US\$1 billion in productivity benefits. The only missing ingredient is sufficient investment and the sustained will to ensure that the promise of microbicides is realized. It is the job of advocates to mobilize the will and passion to make this happen. It is the obligation of donors to ensure that, in addition to science, they fund the advocacy infrastructure necessary to do so.

Global Action Plan for Microbicide Advocacy

The following represents an action plan for microbicide advocacy over the next five years. It is divided into four sections, according to the four “A’s” of advocacy:

Awareness-raising

Accelerating product development

Access

Accountability

Each section offers a vision for success, a set of priority objectives, and a list of activities that should be funded and pursued in order to accelerate widespread access and use of a microbicide.

The plan draws heavily on the work plans of existing advocacy initiatives and input from the August 9 - 10 advocacy consultation.

Awareness-raising

Vision of success

Health providers, policymakers, and potential users appreciate the health burden and risk of STIs and HIV, and the role that microbicides could play in reducing that risk.

There is widespread political support for the investments necessary to ensure the timely development of and widespread access to microbicides.

Objectives

- Raise awareness of microbicides and the risks and the costs of STIs/HIV
- Create political pressure for increased investment in microbicides and other prevention technologies

- Foster a worldwide advocacy movement with strong participating organizations

Proposed activities

Objective 1: Raise awareness of microbicides and the risks and costs of STIs/HIV

- Reach out to key policymakers and opinion leaders (via personal meetings, formal briefings, etc.) in order to familiarize them with microbicides and solicit their support
- Develop easy-to-understand fact sheets and briefing papers, targeted to different audiences, that educate about STIs/HIV and the role that microbicides could play as part of a comprehensive program to address sexually transmitted infections
- Host meetings for policymakers, researchers, and advocates in key donor and developing countries, emphasizing first those countries where trials are likely to take place
- Support research and focus groups to determine the best way to describe and explain microbicides to different constituencies
- Develop and implement a strategic communications plan designed to introduce the concept of microbicides to key audiences
- Work with reporters to highlight microbicides and women’s prevention needs in the popular, scientific, and HIV-specific press
- Support “media training” for key microbicide spokespeople
- Develop tools such as computer models to help illustrate the potential impact of introducing microbicides, and use such models to

garner support for microbicides among policymakers in the industrial and developing world

- Quantify the “cost effectiveness” of microbicides for preventing future HIV cases; publicize these findings in the scientific press and at conferences

Objective 2: Create political pressure for increased investment in microbicides and other prevention technologies

- Encourage groups such as AIDS service organizations, women’s health groups, and other “natural allies” to integrate advocacy related to microbicides into their ongoing activities
- Cultivate an informed constituency in strategic locations that can put pressure on elected officials to increase public-sector support for microbicide research and development
- Fund a sustained legislative effort in the United States (and parallel efforts in Canada, Europe, and other donor nations) to directly increase government investment in microbicide R&D
- Ensure that relevant international agreements and declarations—such as the Cairo Programme of Action and the UN Declaration of Commitment on HIV/AIDS—call for increased investment in new prevention technologies
- Recruit high-level champions for the cause, including political allies, celebrities, and scientific spokespeople
- Organize direct actions if and when needed

Objective 3: Foster a worldwide advocacy campaign on behalf of microbicides with strong participating organizations

- Develop materials and mechanisms to facilitate grassroots involvement in the issue of microbicides (e.g., the petition drive of the Global Campaign)
- Use the issue of microbicides and women’s vulnerability to infection as a unifying theme to discuss links between global and local issues
- Build alliances with advocates working on treatment access, HIV vaccines, access to essential medicines, global health equity, etc.
- Fund strategic means for advocates to network and stay informed via meetings, the internet, travel grants, etc.
- Cultivate local “champions” for women’s prevention needs by sponsoring workshops and training for individuals interested in getting involved

Accelerate Product Development

Vision of success

A first-generation microbicide effective against HIV is approved for use in at least one country by 2007. The remaining pipeline is well funded, and product leads are moving forward in parallel.

Objectives

- Mobilize funds for microbicide research and related activities
- Recruit cutting-edge scientists to the microbicide field
- Foster a supportive regulatory environment
- Further engage industry in the field of microbicides research
- Build capacity of developing-country researchers and communities to engage in microbicide trials

Objective 1: Mobilize funds for microbicide R&D and related activities

Vision of success:

Sufficient funding exists so that “money is not an obstacle” to essential microbicide R&D and related access and advocacy activities.

Proposed activities:

- Provide sustained funding to the constituency-building and legislative/parliamentary strategies identified above as key to mobilizing government resources
- Develop evidence-based materials for potential donors on the current resource shortfall and what different levels of investment could realistically be expected to secure
- Catalyze and sustain a fundraising-and-communications team capable of mobilizing resources from governments, foundations, and private individuals on behalf of the microbicides field
- Advocate to make existing funding streams more responsive to researchers needs—for example, multi-year funding with core support to key microbicide teams
- Advocate for changes in existing scientific review processes to facilitate the funding of worthy microbicide projects (e.g., many review panels are biased against applied research)
- Simplify and streamline the application-and-review process necessary to access funds from the European Union and the European Commission
- Seek guidance and “lessons learned” from other fields (malaria, HIV therapeutics, and vaccines) about strategies and/or mechanisms to make government-sponsored research institutes more responsive to the needs of scientists working to develop new products

- Ensure that other areas essential to the overall microbicide enterprise—such as social science research and advocacy and access work—receive sufficient funds

Objective 2: Recruit cutting-edge scientists to the microbicide field

Vision of success:

High quality scientists from all relevant fields are actively involved in microbicide research and prestigious scientific spokespeople are advocating on behalf of the field.

Proposed activities:

- Host focused symposia to create cross-fertilization between the microbicide community and scientists working on mucosal immunity, viral entry inhibitors, therapeutic vaccines, etc.
- Actively cultivate a handful of scientific champions for microbicides from the ranks of respected scientists in allied fields; for example, virology and HIV therapeutics
- Continue to support bi-annual microbicides conferences as a means to further consolidate microbicide research as a cutting-edge and important field of HIV research
- Support a postdoctoral program to encourage young scientists to consider making microbicide research a part of their career focus
- Elevate microbicide presence at key scientific meetings such as the International AIDS Society meetings and the Retroviral Conference
- Submit review articles on microbicide science to the key journals that reach different areas of scientific expertise
- Explore opportunities to build capacity for microbicide research and testing among developing-country researchers (e.g., through the Fogarty research program at NIH)

Objective 3: Foster a supportive regulatory environment

Vision of success:

A clear, expedient, and responsible regulatory pathway exists for approving and registering microbicides, and all unnecessary delays have been eliminated.

Proposed activities:

- Explore routes to approval other than through the U.S. FDA—for example, approval and registration first in a European or a developing country
- Advocate for a high level, international effort to develop clear, consistent guidelines for the regulatory approval of microbicides
- Ensure that advocates and individuals representing the public interest and user perspectives are part of such dialogues
- Vigorously advocate for making safe, effective microbicides available immediately without a prescription
- Strengthen the capacity of national regulatory agencies to approve and register products based on local risk-benefit decisions
- Explore the appropriateness of “fast track” approval and registration procedures for microbicides
- Consider direct action or public demonstrations if regulatory action is delayed

Objective 4: Further engage industry

Vision of success:

One or more large pharmaceutical companies has a major microbicide R&D effort and small biopharmaceutical companies have access to sufficient resources and technical assistance to move their product leads forward.

Proposed activities:

- Explore ways to involve industry in specific areas, such as collaborating on specific sub-projects like formulation or applicator design
- Reach out to the marketing and public-relations divisions of Big Pharma to encourage their investment for its PR value as good corporate citizenship
- Commission pharmaco-economics and/or marketing studies to better define the market for microbicides

Ensure Widespread Access and Use

Vision of success

Strategies are in place to ensure that microbicides will be widely available and affordable for those who need them, and that individuals have the knowledge, skills, power, and social support necessary to use them.

Objectives

- Ensure that user needs and perspectives are taken into account when making key decisions affecting pricing, accessibility, and formulation
- Ensure that widespread access and use are key principles guiding overall investment and decision making among key actors in the microbicides field
- Work to ensure that a program of research, policy analysis, and training is in place to support the timely introduction of microbicides in pilot countries

Proposed activities

Objective 1: Ensure that user needs and perspectives are taken into account when making key decisions affecting pricing, accessibility, and formulation

- Advocate for the inclusion of advocates and consumer representatives on the governance and advisory bodies of key institutions involved in microbicide research

- Advocate for appropriate social science representation on clinical trial teams and on bodies charged with making investment decisions for public-sector resources
- Support research efforts to define user needs and preferences regarding formulation, pricing, delivery vehicle (e.g., applicator design, packaging options), preferred distribution outlets, etc.
- Advocate for greater investment in low-cost, user-friendly applicators that may be less expensive than existing plastic ones⁸

Objective 2: Ensure that widespread access and use are key principles guiding overall investment and decision making among key actors in the microbicides field

- Actively advocate for non-prescription access to first-generation microbicides, especially in areas with high incidence of HIV
- Advocate for the mandatory inclusion of “access” as a key pillar in any and all not-for-profit initiatives focused on microbicides
- Work to increase access to existing woman-controlled barrier methods such as the female condom, diaphragm, and cervical cap; encourage further research on their effectiveness for preventing sexually transmitted infections
- Advocate for including microbicides in ongoing plans to establish an international purchase fund for childhood vaccines, essential drugs, and other public health commodities
- Work to ensure that microbicides are included in discussions around different “push and pull” mechanisms to encourage greater private-sector investment in global public health goods
- Include efforts to educate the public and the advocacy community about the importance of tiered pricing (the practice where pharma-

ceutical companies are allowed to charge one price in industrial nations, but charge a much-reduced price to public sector/government providers for low-income populations) as a way to encourage broader access to drugs developed in the private sector

Objective 3: Work to ensure that a program of research, policy analysis, and training is in place to support the timely introduction of microbicides in pilot countries

- Commission case studies to examine “lessons learned” from the introduction of other recent technologies, including emergency contraception and HIV mother-to-child-transmission programs in resource-poor settings
- Identify potential “gatekeepers” at a country level (e.g., individuals who make commodity purchasing decisions at donor agencies) and develop concrete strategies to reach out and pave the way for eventual microbicide introduction
- Proactively develop sensitization materials for family-planning managers about HIV and STIs and the potential role that microbicides could play in future dual-protection strategies
- Advocate for a well-funded series of introductory studies in key countries to pilot and test ways to introduce and promote microbicides successfully at a country level; draw lessons from efforts to introduce other technologies such as the female condom
- Conduct action research to better understand the information needs and concerns of providers, policymakers, and users at a country level about microbicides

Ensuring Accountability

Vision of success

As science proceeds, the public interest is protected and the rights and interests of trial participants, end users, and communities are fully represented and respected.

⁸Among those products furthest along in testing, the applicator is far more expensive than the product itself.

Objectives

- Public-sector resources are wisely and effectively invested to maximize both impact and cost-effectiveness
- Community groups and other civil-society agents are empowered (through information, resources, training, and networks) to manage expectations, identify and communicate needs, and advocate on their own behalf with the microbicide research establishment
- Individuals and communities have a voice in the decisions that affect their lives

Proposed activities

Objective 1: Public-sector resources are wisely and effectively invested to maximize both impact and cost-effectiveness

- Monitor the flow and disposition of public-sector dollars invested in microbicide research and development, including staffing levels at key institutions
- Actively protest any duplication of effort, bureaucratic inertia, or non-strategic investment that waste scarce or limited public-sector resources
- Produce an annual “report card” that reviews the microbicide field, highlights progress, and makes pointed recommendations for improvement

Objective 2: Community groups and other civil-society agents are empowered (through information, resources, training, and networks) to manage expectations, identify and communicate needs, and advocate on their own behalf with entities involved in microbicide research, testing, and introduction

- Continue to sponsor training sessions for advocates to prepare them to manage expectations and to engage effectively with the media, policymakers, and the scientific establishment on issues relating to microbicides.
- Fund networking efforts (web pages, listserves, etc.) to keep information flowing

Objective 3: Individuals and communities have a voice in the decisions that affect their lives

- Design and implement a program of capacity-building for in-country NGOs around issues of clinical trial design, informed consent, research ethics, etc.
- Proactively fund the development of consensus statements on critical issues in clinical trial design efforts, being sure to engage civil society actors
- Advocate for the mandatory convening of national and local community advisory groups in the countries where trials will be carried out

Global Campaign for Microbicides

The Global Campaign for Microbicides is a broad-based, international effort designed to build support among policymakers, opinion leaders, and the general public for increased private- and public-sector investment in microbicides. Through advocacy, policy analysis, and social science research, the Campaign works to accelerate product development, facilitate widespread access and use, and protect the needs and interests of end users, especially women. The Campaign presently has over a hundred co-sponsoring organizations worldwide that mobilize political will through education, constituency-building, legislative advocacy, and a global petition drive.

In its first two years, the Global Campaign developed Action Kits for grassroots activists; raised awareness about microbicides via the media, workshops, and outreach to policymakers; and launched a major legislative strategy to increase U.S. government investment in microbicide research and development. The Campaign sponsors ten local Campaign sites in the United States, and recently sponsored a four-day strategy-and-training retreat attended by sixty advocates from twenty-eight countries.

The Global Campaign pursues its work through a small core staff and by funding partner organizations to pursue activities that directly advance the Campaign goals and objectives. Recently, the Campaign moved its secretariat to the PATH (Program for Appropriate Technology and Health), a global health organization that specializes in the health of women and children.

Alliance for Microbicide Development

The Alliance is a consortium that now includes most of the major researchers and organizations involved in microbicide development, comprising developers from thirty-four biopharmaceutical companies, scientists from twenty-six nonprofit research institutions, and representatives from twenty health research and advocacy groups. The Alliance holds two meetings yearly; distributes weekly bulletins, news compendia, and ad hoc alerts; maintains and circulates a product development database; advocates with the U.S. Congress and Administration; and works (through both research and action) to create a supportive business, regulatory, and policy environment for microbicide developers and researchers. The primary targets of the Alliance include U.S. agencies such as the CDC, NIH, FDA, Congress, and researchers. Secondary targets include pharmaceutical companies.

International Working Group on Microbicides

The International Working Group on Microbicides (IWGM) was established in 1994, with initial support from the World Health Organization's Global Programme on AIDS, to ensure closer coordination of a number of separate research programs. Although primarily involved in science, the IWGM has sponsored a number of awareness-raising activities, including a Symposium on Microbicides held in London in November 2000 and a presentation before the All-Party Parliamentary Group on AIDS at the U.K. House of Commons.

Organizations Active in Microbicide Advocacy, 2002

Targets & Activities	Media	Policymakers	Donors	NGOs	Resource mobilization	Engaging new science	Regulatory streamlining
US/Canada	Global Campaign	Global Campaign	Global Campaign	Global Campaign	Global Campaign		Global Campaign
	Alliance	Alliance	Alliance		Alliance	Alliance	Alliance
		Rockefeller Initiative	Rockefeller Initiative		Rockefeller Initiative		
		Pop Council		Pop Council			
	Canadian AIDS Society	Canadian AIDS Society			Canadian AIDS Society		
	amfAR	MAS		UNAIDS	amfAR	NIH	
Europe	IFH	IFH	IFH	IFH			
		Pop Council	Pop Council		Pop Council		
		Rockefeller Initiative	Rockefeller Initiative		Rockefeller Initiative		
		WHO	IWGM	ICW		IWGM	GMP/WHO
				Dutch STD Found. *			
Africa	Global Campaign	Global Campaign		Global Campaign			
		WHO		IFH			
				SWAA *			
Asia	Global Campaign	Global Campaign		Global Campaign			
		WHO		IFH			
				Indian Network of NGOs*			
Latin America	Global Campaign	Global Campaign		Global Campaign			
				IFH			

MAS=Microbicide Alliance of Alternative Solutions
 IWGM=International Working Group on Microbicides
 ICRW=International Center for Research on Women
 IFH=International Family Health

WHO=World Health Organization
 UNAIDS=Joint UN Programme on HIV/AIDS
 amfAR=American Foundation for AIDS Research
 NIH=National Institute of Health

* These organizations are carrying out activities with funding from (and in cooperation with) the Global Campaign

Engaging Big Pharma	Preparation of providers and community	Other access issues	Conduct and ethics of clinical trials	Protecting public interest	Monitoring	Representing user interests	Representing developer interests
				Global Campaign	Global Campaign	Global Campaign	
Alliance	Alliance		Alliance	Alliance			Alliance
Rockefeller Initiative		Rockefeller Initiative					
						Pop Council	
						MAS	
IFH							
						ICW*	
			WHO/UNAIDS			Global Campaign	
	Global Campaign		Global Campaign	Global Campaign		Global Campaign	
	ICRW/Pop Council	Pop Council	Pop Council				
	Global Campaign		Global Campaign	Global Campaign		Global Campaign	
	ICRW/Pop Council	Pop Council	Pop Council				
	Global Campaign		Global Campaign	Global Campaign		Global Campaign	
	ICRW/Pop Council	Pop Council					

Legend	Interested
	Ongoing
	Planned

The Population Council

The Population Council is an international, nonprofit, nongovernmental institution with staff in eighteen developing countries whose mission is to improve the well-being and reproductive health of current and future generations around the world, and to help achieve a humane, equitable, and sustainable balance between people and resources. The Center for Biomedical Research (CBR), a division of the Council, has developed a candidate microbicide, which is presently in expanded safety trials in South Africa and Thailand. It also administers and participates as a research partner in the Rockefeller-funded Microbicides Basic Science Network, which consists of five scientists charged with working on different, but complementary, aspects of research to facilitate the development of microbicides.

As an international organization, the Council has been concerned about ways to catalyze more interest in microbicides among donors and scientists in Europe. To that end, the Council, jointly with International Family Health, carried out a “mapping exercise” in April 2000 and published a Case Statement cataloguing the players and articulating the needs of the field. The Council has also sponsored efforts to help resolve key questions related to trial design and implementation, notably a symposium and 1998 report on Practical and Ethical Dilemmas in the Clinical Testing of Microbicides.

International Family Health

IFH is an international NGO based in London with a mission to improve the sexual and reproductive health and rights of disadvantaged people in resource-poor settings. IFH recently received a grant from the European Commission to raise microbicide awareness, investment, and demand in Europe, sub-Saharan Africa, and Asia. Collaborating partners in this venture include the London School of Hygiene and Tropical Medicine and Alan Stone, M.D. (formerly of the U.K.’s Medical Research Council). IFH has agreed to serve as the European secretariat of the Global Campaign for Microbicides.

amfAR (American Foundation for AIDS Research)

The American Foundation for AIDS Research is the nation’s leading nonprofit organization dedicated to the support of AIDS research (both basic-biomedical and clinical research), AIDS prevention, and the advocacy of sound AIDS-related public policy. Since 1985, amfAR has invested over US\$161 million in support for its programs, primarily through grants to nearly 1800 research teams. Through a series of fortuitous networking steps and the commitment of amfAR’s Washington staff, the Foundation became involved in the microbicides field. In October 1999, the foundation sponsored a one-day symposium focused on the need for microbicides and the status of the field. In December 1999, amfAR awarded ten one-year grants totaling US\$875,000 for microbicide-related research. In June of 2001, this was followed by five additional research grants totaling US\$446,000. The foundation has also made women’s prevention needs and microbicides the focus of their annual pro bono media campaign, sponsored by Kenneth Cole.

Appendix 3

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Microbicides Advocacy Workshop: The Next Stage

Hosted by the Advocacy Sub-Committee

August 9-10, 2001
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