THE FIRST 55 STEPS:

Executive Summary of a
Report of the Microbicide Development Strategy’s
Civil Society Working Group

February 2008
In 2005–2006, the Microbicide Donors Committee — representing 14 funding agencies and governments currently supporting microbicide research — spearheaded a consultative process to develop a *Microbicide Development Strategy* (MDS). The MDS analyses the field’s progress and remaining critical gaps in the areas of:

- Basic and preclinical science,
- Clinical research,
- Manufacturing and formulation, and
- Commercialization and access.

It does not, however, explicitly address progress and gaps regarding civil society engagement as a sometimes integrated, sometimes discrete effort that needs to occur across the entire arc of microbicide research, development, approval, access planning, and monitoring. When this omission was identified, a donor agreed to underwrite the process of exploring how civil society groups can and should be involved in the field now and in the future.

The Global Campaign for Microbicides led this process by convening a Civil Society Working Group in 2006–2007. This tightly focused group explicitly chose not to assemble a “laundry list” of all the complex changes that need to be effected to realize its goal. Like the MDS, it focused on articulating “a strategic framework for action by identifying the gaps where action is urgently needed and by proposing ways to move forward”—but this time from a civil society perspective.

To accomplish this, the Civil Society Working Group:

- Explored the ways in which civil society actors, working hand-in-hand with research institutions, industry, and governments, can contribute to creation of an enabling environment for microbicide research and development,
- Assessed gaps, from a civil society perspective, in the current microbicide research and development process,
- Generated recommendations aimed at promoting stronger civil society engagement and ensuring that critical elements of the enabling environment are supported.

The Working Group defined “civil society” as a wide spectrum of nongovernmental organisations (NGOs) and advocates, inclusive of both of the groups usually identified by clinical trials as “community members,” and stakeholders outside the parameters of the geographic locale surrounding a research site. Thus, civil society engagement refers to a broader scope of activities and a wider range of actors than is generally the case for community involvement as it is commonly understood.
The Civil Society Working Group pinpointed dozens of gaps that need attention but chose to focus its analysis specifically on the seven issues that were both of greatest concern to civil society and that, if addressed with targeted investments of energy and resources, could result in the most immediate benefit to the field. It then articulated seven priority actions needed to address those gaps. To make its recommendations as specific as possible, the Working Group broke down those priority actions into 55 interlocking implementation steps—concrete activities that, if undertaken, should generate real progress toward the goal of assuring full civil society integration into the field at all levels.

The seven gaps that met the aforementioned Working Group criteria, and the priority actions needed to address them, are:

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<th>Highest Priority Gaps</th>
<th>Priority Actions</th>
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<td>Insufficient investment in building sustainable research capacity and health care delivery infrastructure in trial communities.</td>
<td>Use microbicide trial site development investments as opportunities to ratchet up local health care infrastructure and expand human capacities for research and health care delivery in ways that provide durable local benefit.</td>
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<td>Lack of formal mechanisms and opportunities for civil society engagement and transparent communication with researchers throughout the research process.</td>
<td>Develop mechanisms to increase civil society’s engagement across the entire arc of research, development, and product introduction and to improve communication among researchers, sponsors, developers, and civil society.</td>
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<td>Inadequate civil society participation in monitoring and accountability across the field.</td>
<td>Create more structural opportunities and build capacity for civil society participation in the monitoring bodies that guide microbicide research and development.</td>
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<td>Insufficient investment in science-focused microbicide advocacy.</td>
<td>Invest in initiatives to increase advocacy participation by microbicide scientists and the scientific expertise of microbicide advocates.</td>
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<td>Lack of widespread, timely dissemination of results to microbicide stakeholders and the general public.</td>
<td>Improve systems for rapid and user-friendly dissemination of trial results and their implications to stakeholder groups and the general public through multiple communications channels.</td>
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<td>Lack of civil society involvement in defining plans for acceptability, affordability, sustainable access, and marketing work to maximize microbicide uptake among key populations.</td>
<td>Utilize the existing expertise of civil society actors in current efforts to develop product introduction, distribution and marketing plans.</td>
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<td>Lack of effective civil society influence on product regulatory bodies.</td>
<td>Create structural opportunities and build capacity for civil society to have meaningful input into regulatory processes.</td>
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The Civil Society Working Group then assessed the role that each of the four sectors within the microbicide field—researchers, donors and trial sponsors, government policymakers, and civil society actors—plays in addressing these gaps and assigned each of the 55 interlocking action steps to a specific sector. These proposed assignments, together with a picture of how the steps connect with each other, comprise the body of The First 55 Steps: A Report of the MDS Civil Society Working Group.

### EXAMPLE. ACTION STEPS BY SPECIFIC SECTOR FOR PRIORITY ACTION #2:
Developing mechanisms to increase civil society’s engagement

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<tr>
<th>Civil Society</th>
<th>Governments/ Policymakers</th>
<th>Researchers/ Principal Investigators</th>
<th>Funders/Sponsors/ Research Institutions</th>
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<td>Work to develop the knowledge base needed to serve on peer review committees, advisory and planning boards, institutional review boards, etc. effectively; request such opportunities.</td>
<td>Increase the number of dedicated civil society seats on national planning and regulatory bodies.</td>
<td>Identify civil society actors who can impact the achievement of research goals and establish transparent opportunities for ongoing communication with them.</td>
<td>Fund mechanisms to facilitate communication between researchers and civil society, including efforts by civil society to build their own science literacy and, thus, capacity for productive participation in the microbicide development and access process.</td>
</tr>
</tbody>
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Each sector is uniquely positioned to take the specific actions assigned to it. Each also benefits in its own way — and the field benefits as a whole — from greater civil society involvement across the entire arc of microbicide research, development, introduction, and access.

### Solving the Money Problem
The life blood of civil society engagement is money, capacity, and access. Most civil society entities simply cannot afford to “skill up” and “staff up” to the extent necessary for greater engagement. To maintain their current workloads and follow through on their share of the activities outlined in this report, they need more leaders, more managers, more staff training and development (especially in the area of “research literacy”), and enhanced access to communications technology. Without these, they will fail, even if offered every opportunity for full participation in the microbicide research and development process. They will simply be too over-stretched and under-prepared to take on the additional work.

At present, very limited support is available through foundations and other funders for HIV prevention advocacy, much less for the kind of capacity-building that full civil society integration into the field requires. Large funders have understandable difficulties with making grants to small and medium-sized NGOs. A grants-making window, designed to funnel resources from larger grantmakers to smaller NGOs, is one potential method of efficiently routing much-needed capacity-building money to well-situated civil society entities that are demonstrably committed to increasing their active involvement in this field.
THE ENABLING ENVIRONMENT

In addition to analysing specific gaps and how they can best be addressed, the Working Group focused on (1) defining the enabling environment required for the field to advance as swiftly and ethically as possible and (2) identifying actions needed to create this environment.

An enabling environment is one in which:

- Government policies and regulations facilitate research,
- Science professionals from the relevant disciplines are available in sufficient numbers,
- Adequate clinical research facilities exist,
- A pool of properly trained staff is on hand for recruitment,
- Public awareness of and support for microbicide research and development exists, as does consumer demand, and
- Media coverage of trials is supportive, balanced, and well-informed.

Adequate financial resources, political will, and public support are all essential to creating and maintaining this enabling environment. Civil society entities have the leverage, positioning, and political legitimacy needed to generate these ingredients. But civil society cannot and will not carry out this function fully if it is not appropriately integrated into the field at every other level as well.

The full report of the MDS’ Civil Society Working Group is a blueprint for bridging the gap between where we are now (with minimal, scatter-shot and under-resourced civil society participation) to where we need to be (with civil society engaging as a full partner). Thus, it serves as the missing chapter of the MDS and is understood as such by the MDS authors.

The Global Campaign for Microbicides (GCM) is an international coalition created in 1998 to serve as an interface between the scientific establishment and citizens whose lives will be influenced by microbicides — as eventual users, trial participants, taxpayers, and/or individuals at risk of, or living with, HIV/AIDS. The GCM agenda is twofold: to accelerate access to safe and effective microbicides, and to transform how science is done. GCM’s staff supports microbicide advocacy and civil society engagement in the scientific process, through its direct work and in collaboration with hundreds of nongovernmental organisations worldwide who use GCM’s resources to advance their own microbicide advocacy goals. These diverse allies include women’s health and rights advocates, gay men’s health activists, international development entities, gender equality organisations, and HIV/AIDS service providers. Unlike other actors in the field, GCM does not fund or develop products. Instead, it works to build a sustained political base among civil society groups for microbicide research and access and to empower them to engage productively in the scientific process.
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The views and opinions expressed herein do not necessarily state or reflect those of USAID or the U.S. Government.

The full text of this report is available online at www.global-campaign.org/mds.htm

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Susan Chong, MA (Southeast Asian Studies), Asian/Pacific Coalition of AIDS Service Organisations, Malaysia
Janet Frohlich, PhD, Centre for the AIDS Programme of Research in South Africa (CAPRISA), South Africa
Miriam Katende, The AIDS Service Organisation (TASO), Uganda
Alex Menezes, International AIDS Vaccine Initiative (IAVI), Brazil
Dr. Chidi Nweneka, Pro-Hope International, The Gambia
Dr. Sai Subbastree Raghavan, Solidarity & Action Against The HIV Infection in India (SAATHII), India
Seema Sahay, PhD, National AIDS Research Institute (NARI), India
Laurie Sylla, MHSA, Yale AIDS Program, USA
Dr. Morenike Ukpong, Nigeria HIV Vaccine and Microbicide Advocacy Group (NHVMAG), Nigeria
Sydney West, Global Campaign for Microbicides, USA
Lydia Zigomo, Interact Worldwide, UK

Staff
Anna Forbes, Global Campaign for Microbicides, USA
Rachel Yassky, Consultant