



## Global Campaign News – Issue #81 25 May 2007

Welcome to the *Global Campaign News*! The *Global Campaign News* is a forum for international exchange on microbicide activities and information with an aim to build a more informed and integrated movement for microbicide development and other prevention options against HIV and other sexually transmitted infections. This and previous issues of *GC News* are available online at <http://www.global-campaign.org/gcarchives.htm>

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## Research update

### Statement on rectal safety of vaginal microbicides

#### Global

The International Rectal Microbicides Working Group (IRMWG) has issued a statement calling upon the microbicide community to support rectal safety trials of vaginal microbicides that have progressed to Phase III efficacy trials.

“The IRMWG strongly supports the collection of rectal safety data for all candidate vaginal microbicides in efficacy trials to ensure information is provided to eventual users through appropriate product labelling and community education efforts, said Jim Pickett, co-founder and chair of the IRMWG Steering Committee.

The statement has been endorsed by the Global Campaign for Microbicides (GCM), the African Microbicides Advocacy Group Network (AMAG) and the Alliance for Microbicides Development (AMD).

“We are delighted to see emerging consensus around this critical issue. We all share a bedrock commitment to getting effective vaginal microbicides into women’s hands as rapidly as possible – and to assuring that these products are accurately labelled if off-label rectal use could increase risk,” stated Anna Forbes, GCM Deputy Director.

Specifically the IRMWG statement urges:

- 1) Trial sponsors to fund rectal safety trials alongside all candidate vaginal microbicides in efficacy trials;
- 2) Donors to provide more resources for the field to conduct rectal safety trials; and,
- 3) Regulatory agencies to provide guidance describing reasonable rectal safety data needed to approve vaginal microbicides.

“The IRMWG does not recommend halting or delaying the introduction of vaginal microbicides. As a field, we should work diligently to gather rectal safety data but ensure that this process poses no delays to efficacy trials. Short rectal safety trials can be conducted in parallel to vaginal efficacy trials”, stated Dr. Ian McGowan, a rectal microbicides researcher from UCLA, and IRMWG Steering committee member.

IRMWG, GCM, AMAG and AMD have agreed to collaborate on the development of an “Advocate’s Brief” on rectal safety, as well as to collectively design and implement advocacy strategies connected with the statement.

For more information and to view the full statement, please visit [www.irmwg.org](http://www.irmwg.org)

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## Advocacy in action

### First Australian microbicides symposium

#### Asia-Pacific

On 10 May, the Australian Reproductive Health Alliance (<http://www.arha.org.au>) (ARHA) in partnership with a number of local organizations and GCM, hosted the first Australian Microbicides Symposium at the University of Sydney. Over 50 delegates representing industry, government, academia and community attended. While researchers within Australia have been engaged in microbicides R&D, until this year, there has not been a concerted effort to organize and share information among all key stakeholders, nor any efforts to advocate for more funding for research or policy surrounding microbicides.



Prominent Australian researchers and scientists made the case for microbicides within the context of HIV prevention and presented updates on R&D both globally and within Australia. Susan Chong, a member of the GCM steering committee, painted a picture of the global movement on microbicides with case studies from Canada and the UK. In the second half of the day, the delegates were divided into break out groups to discuss ways in which to move the microbicides agenda forward within Australia. Overall, the day was a great success and a good starting point for future advocacy efforts. ARHA is currently considering organizing a steering committee to initiate and guide an Australian Campaign for Microbicides.

*In picture: Bottom row: Dr. Louise Causer (National Centre for HIV Epidemiology and Clinical Research-NCHECR), Bridget Haire (Australian Federation of AIDS Organizations), Dr. Gilda Tachedjian (Burnet Institute), Dr. Andrew Grulich (NCHECR), Top row: Dr. John Kaldor (NCHECR), Dr. Tony Cunningham (Westmead Millennium Institute), Dr. Jeremy Paull (Starpharma)*

### North American microbicides advocates re-group in Washington DC

#### North America

In April 2007, over 40 microbicides advocates (pictured below) from the US and Canada gathered in Washington, DC for the second North American Advocates Meeting (NAAM).

Over 2 ½ days, advocates went through intensive training, discussions and strategic planning on a range of issues, including:

- Current and future challenges in clinical trial design
- Implications of partial efficacy on access and delivery
- Ethics and community participation in trials
- Microbicides within the context of other new prevention technologies
- Preparing for various clinical trial outcomes
- Positioning North American advocacy goals in the context of the global microbicides field

In addition, one of the main objectives of the meeting was to provide advocates with opportunities to learn from each other and to share tools and strategies that can be used in various settings. To that end, several networking opportunities were built into the meeting, as well as a “show-and-tell” of resources that advocates have developed locally.

By the end of the meeting, participants had identified several areas where additional training, information and resources are needed, and had established priority goals for North America for 2008-2010. These goals will be refined in the coming months, but currently include:

- Advocate for more resources for the field (research, development, and advocacy)
- Ensure the microbicides field responds to the needs of key constituents and end-users
- Maintain and advance scientific literacy of advocates and key partners
- Prepare advocates for responding to trial results (e.g., messaging, work with media, work with regulators, managing expectations)
- Coordinate efforts with other advocates working on new prevention technologies
- Push trial systems to involve communities in meaningful ways



## Keeping microbicides on the agenda of U.S. Congress North America

In an effort to continue educating U.S. legislators about the need for investment in new prevention technologies, Anna Forbes, deputy director of the Global Campaign presented at two high level congressional briefings for the House of Representatives this month.

On 16 May, GCM was invited to participate in a briefing hosted by the Congressional Human Rights Caucus (CHRC), a bipartisan working group of over 200 Members of the U.S. House of Representatives. The briefing focused on funding needs and opportunities in the global challenge of HIV/AIDS, and Anna presented alongside colleagues on a panel entitled: “Funding Needs for Evidence-based Prevention and Treatment Priorities”. In explaining the critical importance of governmental support, she said, “We won’t have to rely on governments and philanthropists to fund this research indefinitely. We know that market forces are likely to take over once the first microbicides become available and the concept is proven to work. But we urgently need the US Congress to pass the Microbicide Development Act and marshal the resources to get those first products out there and into women’s hands. We need you to get us over the hump and make the first microbicides a reality.”

On 21 May, she presented along side staff from the Center for Health and Gender Equity, ActionAID International, the PEPFAR Gender Technical Working Group, the National Institutes of Health, and The AIDS Institute at a briefing for House members and staffers entitled, “Addressing the Vulnerabilities of Women and Girls at Risk for HIV/AIDS Transmission”.

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## Highlighted Resources

### New Global Campaign advocacy brief: Evaluating safety of vaginal microbicides

The Global Campaign is pleased to announce our newest briefing paper for advocates: “Evaluating Safety of Vaginal Microbicides”. This paper explores the questions that scientists hope to answer when they conduct safety evaluations of microbicides, including how safety is evaluated and the strengths and limitations of current methods used. Readers will appreciate the way that the paper explains terms like mutagenicity, cytokines, and biomarkers in easy to understand language. This paper is essential reading for advocates who want to engage more in scientific discussions about microbicides. Download the paper at: <http://www.global-campaign.org/briefing.htm>

### New factsheet from AVAC on Data Safety Monitoring Boards (DSMBs)

Over the past 12 months, the HIV prevention research field has had several instances of trials being affected by DSMB recommendations. The trials of male circumcision, the trials of the microbicide candidate cellulose sulfate (CS), and a trial of the microbicide candidate Savvy are just a few examples of studies where a DSMB has made a recommendation that the trial halt its planned activities. In each case, the recommendation was made for a different reason. And in each case, the recommendation was an example of the healthy workings of the system of checks and balances that surround all ethical clinical trials.

Last month, AVAC released a new fact sheet that helps advocates understand how DSMBs work, what their most common recommendations are, and how these recommendations were made in the instances of male circumcision, CS and Savvy. It will help us collectively prepare for the many DSMB reviews that will happen in the coming months and years for trials of various HIV vaccine and microbicide candidates, pre-exposure prophylaxis and other research studies. The new fact sheet is available at <http://avac.org/pdf/AVAC-DSMB-fact-sheet-apr-2007.pdf>.

## Updates on U.S. government investment in microbicides (Factsheet #15)

Partially in response to the U.S. legislative strategy implemented by the Global Campaign, the Alliance, and their partner organizations, total U.S. government funding for microbicide research and development has increased dramatically over the last several years at the National Institutes for Health (NIH), U.S. Agency for International Development, and the Center for Disease Control (CDC).

Congress has stated its explicit support for this research in its annual appropriations bills and reports. Despite these welcome increases, NIH spending on microbicides still accounts for a tiny fraction (3%) of its AIDS-related research spending. As more microbicide candidates are advanced into later-stage clinical trials and as the development costs rise correspondingly, the current levels of funding will remain inadequate.

Thanks to the HIV Vaccines and Microbicides Resource Tracking Working Group and the Alliance for Microbicide Development, GCM has updated our Factsheet #15 that reviews the U.S. federal expenditure on microbicides since 1998, including a projection into fiscal year 2008. This fact sheet is available at our U.S. legislative resource center: [www.global-campaign.org/legislativeadvocacy.htm](http://www.global-campaign.org/legislativeadvocacy.htm)

## Check out RH Reality Check.org

RH Reality Check.org is an online publication based in the U.S. that provides the latest news in reproductive health, cutting-edge commentary from leading voices in the sexual and reproductive health community, global perspectives and experiment with new media tools to make your life easier! According to their site, "RH Reality Check is guided by the issues and recommendations identified in the Program of Action agreed on at the International Conference on Population and Development at Cairo in 1994. Protection is our watchword – we are contributing to the global effort to empower people with the information, services and leadership they need to safeguard their sexual and reproductive health and rights and to guard against false attacks and misinformation. RH Reality Check exists as a resource for evidence-based information, provocative commentary, and interactive dialogue." Many GC News readers will appreciate their combination of edge, humor, analysis, and interactive features. Sign up at [www.rhrealitycheck.org](http://www.rhrealitycheck.org) for their daily news feed - delivered to your email inbox without the need for a news feeder --or their weekly e-news with the week's round-up.

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