



Global Campaign News – Issue #38 July 16, 2004

Welcome to the biweekly *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 STDs. This and previous issues of GC News are available online at <http://www.global-campaign.org/gcnews.htm>

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Global Campaign Petitions Debut in Dublin Europe

On June 24th, petitions signed by more than 200,000 people around the globe calling for accelerated research into microbicides and vaccines were delivered to governments gathered in Dublin for the first EU conference on new HIV prevention technologies.

Hosted by the Irish and Dutch Ministers of Development, the “Conference on New Preventive Technologies: Providing New Options to Stop the Spread of HIV/AIDS” was attended by representatives of EU member states, developing country governments, NGOs and multilateral organizations. Over 150 participants listened as the many political and scientific challenges standing in the way of a safe, effective and affordable user-controlled technology against HIV were presented and action by EU leaders was called upon to overcome them.

The universally regarded high point of the meeting occurred when civil society representatives from India, Nigeria, the Netherlands, the UK, South Africa, Spain and Belgium unfurled an enormous display of petitions containing thousands of signatures, some of them simply thumbprints, collected by the Global Campaign for Microbicides since its inception in 1998.



Paper petitions by the hundreds (a sampling of the thousands collected by Global Campaign advocates to date) were attached to 75 foot giant scrolls displayed on June 24. These signatures symbolically joined the hundreds of thousands that International AIDS Vaccine Initiative (IAVI) has also collected on-line since 2001 via its "Global Call for Action for AIDS Vaccines." Speaking for signers in more than 175 countries, these petitions dramatically articulated the breadth of grassroots demand for additional HIV prevention tools.

HIV/AIDS has been on the forefront of Ireland's EU Presidency. This meeting symbolizes the Irish handing over of this critical agenda item to the Dutch, who will hold the EU Presidency for the remainder of 2004. The Irish government concluded with a plea for the Dutch presidency to ensure that HIV/AIDS remains top of the EU agenda through the Luxembourg and British presidencies into 2005.

The meeting also featured a significant reconciliation. Mr. Jean Stephenne, President of GSK Biologicals, apologised on behalf of his company for taking the South African government to court for manufacturing generic versions of ARV drugs. Dr. Helen Rees, Executive Director of the Reproductive Health Research Unit at the University of Witwatersrand, one of the scientists called on during the trial to defend the case, accepted the apology.

All eyes on Bangkok

Global

As policy makers, scientists, advocates, and journalists have been gathering in Bangkok for the 15th International AIDS Conference, numerous articles have featured microbicides in the past several days. For the latest on the Bangkok conference, log on at <http://www.aids2004.org/> For a smattering of the media coverage, follow these links:

- A five minute National Public Radio (NPR) story in the US: "A Prophylactic Gel to Stop Transmission" Listen at <http://www.npr.org/rundowns/segment.php?wfid=3384027>
- Today Online from Singapore: Why More Women are getting AIDS <http://www.todayonline.com/articles/22323.asp>
- New York Times: Tests to Begin on New Drugs to Protect Women From Contracting H.I.V.
- <http://www.nytimes.com/2004/07/14/international/asia/14bang.html?pagewanted=print&position=>
- An article that was published on numerous websites and newspapers from the Associated Press entitled Women's Issues Crucial in AIDS Fight - http://abcnews.go.com/wire/World/ap20040714_517.html

The next edition of GC News will have full coverage of discussions and events related to microbicides at the Bangkok conference!

U.S. House approves \$30 million for USAID microbicide research

North America

On July 15th, the full House of Representatives voted to approve \$30 million for microbicide research at the U.S. Agency for International Development (USAID) – an \$8 million increase over funding from last year. Rep. Jim Kolbe (R-AZ) and Rep. Nita Lowey (D-NY) led this effort with support from Rep Mark Kirk (R-IL) and Rep Jesse Jackson Jr. (D-IL) by ensuring that this funding was included in the foreign operations spending bill for fiscal year 2005. Our community now must ensure that this level of microbicide funding for USAID is included in the Senate's Appropriations bill. Please contact the Global Campaign if you are interested in getting involved with U.S. legislative advocacy – info@global-campaign.org

AIDS Vote Free Call-In Seminar for American Non-Profits on July 22

North America

Non-profit organizations play an important role in educating voters and candidates on critical issues during election seasons. But lots of folks aren't sure exactly what's allowable and what's not.

To help you and your organization understand what is safe, legal and allowable during an election year, AIDSVote.org has invited the Alliance for Justice to conduct a call-in forum for all interested organizations next Thursday at 4:00 pm EST. Thanks to Housing Works and the Human Rights Campaign for organizing the call.

Created in 2003 by a national coalition of AIDS advocacy organizations, AIDSVote.org promotes a full set of domestic and global HIV/AIDS policy recommendations to educate presidential candidates and voters of the critically important policies needed to make progress against the pandemic. Hundreds of organizations and thousands of individuals have endorsed the AIDSVote.org non-partisan platform.

Agenda: Safe and Legal Election-Year Advocacy by Non Profits

July 22, 4pm – 5pm EST. Call 866-393-8073. Code: *1296221*

Presenter: Liz Towne, Alliance for Justice (www.afj.org)

Materials: Available at www.aidsvote.org on Monday July 19.

Questions: email info@aidsvote.org

1. Basic rules on election activity: what's electioneering?
2. The "facts and circumstances" test for election-related activities
3. Issue advocacy examples: voter registration, get out the vote and voter mobilization, legislative scorecards, issue forums/debates, voter guides and educational materials, candidate questionnaires
4. Candidate education: allowable work with candidates and staff
5. Individual/off-the-clock activities vs. organizational activities
6. Questions and answers from participants (last 20 minutes of the call)

Ibis Reproductive Health launches new website on cervical barriers

Global

One June 30, Ibis Reproductive Health launched the Cervical Barrier Advancement Society (CBAS), an international networking organization for professionals in the reproductive health and HIV/AIDS communities. CBAS aims to raise the profile of cervical barrier methods for preventing pregnancy and potentially also HIV and other sexually transmitted infections. "Our vision is for CBAS, through its website and electronic newsletter, to serve as a key communication hub for individuals and organizations working on cervical barrier issues around the world," said Katy Backes, the Executive Director of CBAS. Membership is free and open to all who are interested in joining. Although you do not need to join CBAS to use the website, Ibis does hope you will consider signing up.

The CBAS website (www.cervicalbarriers.org) contains information about cervical barriers, research updates, downloadable materials, and images of cervical barriers. CBAS also publishes a newsletter several times a year. We invite you to visit the website, join CBAS, and sign up for the newsletter. Please share this email with your colleagues and friends and encourage them to join as well. For more information, contact Katy Backes, kbackes@cervicalbarriers.org

New Report on Microbicides 2004

Global

We are pleased to announce a new report that provides an overview of the discussions and research updates that took place at Microbicides 2004. The report was written by Julian Meldrum for the UK National AIDS Trust and the Global Campaign for Microbicides. You can find the report from the Global Campaign's home page or at www.global-campaign.org/microbicides2004.htm

As we have previously reported, Microbicides 2004 was an interdisciplinary meeting attended by 800 people from 53 countries from March 28-31 in London, England. Whether you were at Microbicides 2004 or not, this report provides an excellent snapshot of the entire conference. Key topics like advocacy, the need for microbicides, planning for field trials, candidates in the pipeline, devices to aid delivery, and microbicides for men are showcased in an easy to read and comprehensive format. After each section, Meldrum has included references to specific abstracts and presentations that are available on the Microbicides 2004 Conference website. In sum, the report is highly recommended for any and all microbicides advocates.

Two new UNAIDS Reports highlight Women and AIDS.

Global

Last week, UNAIDS released its 4th report on the Global AIDS Epidemic. The report, especially the 18 page table at the end, is an excellent source of up to date statistics on the AIDS epidemic at a global, regional, and country level. At the end of 2003, 37.8 million people were living with AIDS globally. Seventeen million people, or 48% of the total, are women. The report also provides a regional breakdown of women as a proportion of people living with HIV/AIDS:

Globally 48%	
Sub-Saharan Africa 57%	Caribbean 49%
North Africa/Middle East 48%	Latin America 36%
Eastern Europe/Central Asia 33%	South/South-East Asia 29%
North America 25%	Western Europe 25%
East Asia 22%	Oceania 19%

UNAIDS reports that in Sub-Saharan Africa, 75% of HIV infected young people, aged 15-24, are women and girls. In other words, young women are three times as likely to be infected with HIV than their male counterparts.

This week, UNAIDS in collaboration with UNFPA and UNIFEM, released a report that provides more statistics and context, *Women and HIV/AIDS: Confronting the Crisis*. The report is broken down into the following topics: HIV prevention, treatment, care-giving, education, gender-based violence and women's rights.

Both reports are quite large, but are available for download on the UNAIDS website.

Global Epidemic: <http://www.unaids.org/bangkok2004/report.html> (smaller factsheets are also available here)
Confronting the Crisis: <http://womenandaids.unaids.org/>

Measuring microbicide efficacy: intermediate versus full-scale trials

Science

In November 2004, researchers are expected to begin enrollment of clinical trial participants in a Phase II/II b trial in India, Africa, and the USA that will evaluate the safety and efficacy of Buffergel and Pro 2000.

The article below is adapted from one appearing in VAX by Emily Bass, IAVI, Ebass@iavi.org that explains the differences between Phase II b and Phase III trials in the context of AIDS vaccine research. Although the article was written about vaccines, it highlights some important differences between these two types of trials that are directly applicable to microbicides research. Therefore, we have re-produced excerpts from the original article, replacing the word "vaccine" where appropriate with "[microbicide]".

In addition, there are some key questions for microbicides Phase II B trails that do not apply to vaccines, and therefore are not addressed in this article, such as the design of a confirmatory trial if a Phase IIb shows efficacy, how would trial sponsors address gel sharing, pooling, and the feasibility of a condom-only arm.

The original article was printed in the May 2004 IAVI Report, VAX and is available at: <http://www.iavireport.org/VAX/CurrentVAX.asp#4>. A longer, more technical version is also available at <http://www.iavireport.org/Issues/0404/IIbnotIIb.asp>

"...Comparing Phase IIb and Phase III trials

Phase IIb and Phase III trials take the same overall approach to measuring [microbicide] efficacy. Both trials divide volunteers into two groups: volunteers in one group receive the experimental [microbicide], and volunteers in the other group receive an inactive substance called a placebo. Neither the trial staff nor the volunteers know who has been assigned to receive the [microbicide] or the placebo until the study is over. This is called a double-blinded, placebo-controlled study.

All volunteers in both types of trials are regularly tested for HIV and receive condoms and risk reduction counseling which emphasizes that volunteers should not assume that they have received, or are protected by, the experimental [microbicide]. However some volunteers still become infected with HIV despite these services. It is important to remember that the [microbicide] cannot cause HIV and that no volunteers in these trials are ever intentionally exposed to HIV.

The number of volunteers and the duration of both Phase IIb and Phase III trials are determined by the rate of HIV infections or “incidence” in the community where the trial is going to take place. The higher the incidence, the fewer volunteers and/or shorter the follow-up period required. A Phase IIb trial would enroll fewer volunteers than a Phase III trial done in the same population. In general, Phase IIb trials are likely to be about half the size of a Phase III trial.

At the end of the study, researchers “unblind” the study, which means that they learn who received the [microbicide] and who received the placebo. They then look for evidence that the [microbicide] helped protect against HIV infection...To do this, researchers compare the number of new HIV infections in the [microbicide] and placebo groups...If differences are detected, statistical tests are performed to determine whether they are due to the [microbicide] or just [chance].

The main difference between Phase IIb and Phase III trials lies in the precision of the conclusions that can be drawn from a trial. A Phase III trial can make more accurate estimates of [microbicide] efficacy than a Phase IIb trial done in the same population. Phase III trials can also detect lower levels of efficacy than Phase IIb trials. This is because accuracy is directly related to the number of people studied in a trial. When there are more volunteers, there are likely to be more people who become infected through sexual exposure. These infections are the key “endpoints” for a [microbicide] trial. The more endpoints there are, the more confident sponsors can be that a possible [microbicide] effect is real and not a coincidence.

Phase IIb trials are not as precise. A Phase IIb trial would only be able to tell if a [microbicide] candidate was very effective or not effective at all, and could not reliably detect moderate or low levels of efficacy. Instead, a Phase IIb trial might provide “inconclusive” data about a candidate with moderate efficacy, meaning that it wouldn’t be known for certain if it had any beneficial effects.

Why Phase IIb trials?

The risk of conducting a Phase IIb trial is that sponsors may end up with an inconclusive answer. The possible benefit is that sponsors may be able to find out relatively quickly whether or not a particular candidate shows signs of efficacy or has very high efficacy. This is sometimes called a “proof of concept” trial. Drug developers sometimes test early versions of promising candidates in “proof of concept” trials before investing in design, testing and manufacturing of a final candidate in a large efficacy trial....

New challenges

As Phase IIb trials move ahead, the [microbicide] field will have to do additional education and outreach to explain that some efficacy trials will be designed as information-gathering tools, and will not lead directly to a “license” for widespread use, even if that candidate appears effective. One reason for this is that sponsors may choose to conduct a Phase IIb trial of an earlier version of the candidate while they are developing manufacturing plans for their final product. In this case, another efficacy trial would be tested once the final product had been completed. Another reason is to gain more precise information, since Phase IIb trials usually provide a general idea of whether a candidate is effective or not.

Phase IIb trials are a new development in [microbicide] research and communities, researchers and sponsors will need to work together to find effective ways of explaining the contribution that these studies can make to the field.”

We welcome your input and contributions for future issues! Correspondence can be addressed to info@global-campaign.org. If you would like to unsubscribe to the Global Campaign News, please reply to this e-mail with the subject line: UNSUBSCRIBE.