



## Global Campaign News – Issue #76 12 February 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 Updates

### CONRAD and FHI Announce Discontinuation of Phase III Cellulose Sulfate Trials Global

On January 31, CONRAD and Family Health International (FHI) announced discontinuation of their Phase III effectiveness trials of the microbicide candidate, cellulose sulfate (CS). This decision was made following the emergence of early data suggesting that CS may be contributing to an increased risk of HIV infection among the trial participants using it. Scientists are baffled about this result because eleven earlier safety studies of the product did not reveal any problems. No biological cause for this increased risk has yet been determined.

This is a great setback to the field of women's HIV protection needs and microbicide research. One piece of good news; however, is that the trial was suspended at the first suggestion that a problem existed. Typically, in microbicide trials, the data is double-blinded, meaning that both the women participating in the trial and researchers are unaware of which participants are receiving the active gel and which are receiving the comparator gel. Independent, expert review panels called Data Safety Monitoring Boards (DSMBs) are convened for every microbicide trial to periodically review the un-blinded data emerging from a trial. When the DSMB un-blinds the data they are then able to see which participants received the active gel and which received the comparator gel, compare the two groups and see if there are any striking differences between the two. These “early looks” enable them to recommend halting the trial if they see either compelling evidence of product effectiveness or suggestions of harm. In the case of CS, the CONRAD DSMB saw data suggesting potential harm so they recommended that the trials be stopped.

Not surprisingly; however, this development has raised many questions in the wider HIV prevention advocacy community and generated sensationalized media coverage – especially in South Africa. The Global Campaign for Microbicides (GCM) and the African Microbicides Advocacy Group (AMAG) have been collecting questions from

advocates and seeking answers to them from site investigators, sponsors and microbicide experts. On February 1, we held a conference call in which 40 international advocates discussed their questions and concerns with two members of the DSMB that recommended stopping the trial. We are working hard to ensure that all advocates have the information they need to feel fully briefed and prepared to counter distortions and misinformation that spread rapidly, if unchecked. We have developed a body of materials to help advocates and other stakeholders see this news in the broader research context and not as something that should delay or hinder future microbicide research. We are all painfully reminded that, although it very rarely happens, it is not impossible for a woman's risk of infection to be increased by trial participation. Every single HIV infection that occurs is a human tragedy.

In a public statement on January 31, GCM Director Lori Heise noted that “the real heroines and heroes in this are the people who enroll in clinical trials because they know how urgently new prevention tools are needed. In South Africa, for example, 48% of the women who volunteered for the CS trial were unable to participate because they were already HIV positive at the time of their screening visit. In Uganda, the rate was 32%”, she added. “It is essential to build on what has been learned here and proceed with the research as rapidly as possible. Millions of women's lives are at stake.”

See <http://www.global-campaign.org/Cellulose-Sulfate.htm> for more information.

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## **Advocacy in Action**

### **The Global Campaign Welcomes Marc-André LeBlanc! North America**

The Global Campaign for Microbicides invites you to join us in welcoming the newest addition to our staff, Marc-André LeBlanc! This month, Marc-André is taking over for Bindiya Patel in coordinating our North American outreach and activities. Marc-André will also be supporting our European staff.

Marc-André has over 10 years of experience working in the HIV/AIDS field in Canada, and a wealth of experience in microbicides advocacy. Most recently, Marc-André was working with Health Canada and before that coordinated the Microbicides Advocacy Group Network (MAG-Net) at the Canadian AIDS Society. He is an excellent and experienced organizer and advocate, and we are certain he will provide a new burst of creativity, talent, and energy in his support to microbicides advocates across the U.S. and Canada. Marc-André will be based in Ottawa, Canada and can be reached at [mleblanc@global-campaign.org](mailto:mleblanc@global-campaign.org).

Bindiya Patel will continue to be involved in pieces of the Campaign's North American work – most notably U.S. legislative activities and outreach to African American women and HIV positive women. Bindiya will also continue to work with the Global Campaign on its strategic planning process and the development of an on-line training course on microbicides.

### **Chicago Hosts Giving Women Power Over AIDS North America**



The Chicago Coalition for Microbicides (CCM) welcomed a crowd of nearly 200 people to their first event of 2007 entitled *Giving Women Power Over AIDS: A Community Dialogue*. This evening of art, performance, and community driven conversation focused on the particular HIV prevention needs of women and girls on Chicago's south side and potential solutions to address them. The event featured the Global Campaign for Microbicides' exhibit *Giving Women Power Over AIDS*, as well as an original collection of video and photography called *Soulful Living*.

Created by the youth of the Little Black Pearl Art and Design Center, *Soulful Living* tells the experiences and realities many African Americans living with HIV in Chicago face. The creative youth of Global Girls, Inc. kicked off the conversation with a powerful spoken word and dance performance that explored girls' attitudes toward talking about sex and HIV. Panelists and audience members echoed one another in stating that a holistic approach to preventing HIV among women and girls is essential and must include comprehensive sex education, partner negotiation skills, an end to violence against women, and the availability of a safe and effective microbicide.



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## ***New Resources***

### ***Introduction to AIDS Vaccines from AVAC***

The AIDS Vaccine Advocacy Coalition's (AVAC) *Introduction to AIDS Vaccine* is now available via their website. This online presentation provides a basic overview of what vaccines are, how they might work and highlights key issues around AIDS vaccine research.

The presentation can be accessed at [http://www.aidsvaccineclearinghouse.org/vax\\_101/index.html](http://www.aidsvaccineclearinghouse.org/vax_101/index.html).

## ***GCM Resource Highlight: Resources worth revisiting***

### ***Fact Sheet # 5: Clinical trials: Are they ethical?***

Read up on how microbicides are tested, how trials test to see if a microbicide is effective, why Phase III trials take place in developing countries and how the rights of trial participants are protected.

### ***Fact Sheet # 18: Addressing Questions and Common Misperceptions about Microbicide Clinical Trials***

Get the answers to common questions and misperception about community involvement in microbicide trials, how microbicides are tested, condoms and microbicides, access to microbicides, the use of placebos and who is conducting microbicide research and development.

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## ***In Memoriam***

### ***Farewell to Professor Job Bwayo***

The HIV/AIDS community says farewell to yet another lead personality in the fight against HIV/AIDS in Africa, Professor Job Bwayo; Kenya AIDS Vaccine Initiative (KAVI).

Professor Bwayo was a great man who dedicated his life to advancing the teaching of medicine and research in HIV and other STIs. He spent the latter part of his life as the Principle Investigator for HIV vaccine research at KAVI. Professor Job Bwayo met his death through senseless violence as he was shot during a carjacking incident in one of Nairobi's suburbs.

The public health fraternity in Kenya and the global HIV/AIDS community mourns his untimely death as we have lost a friend, a colleague and a dedicated researcher.

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We welcome your input and contributions for future issues! Please send emails to: [info@global-campaign.org](mailto: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