



## Global Campaign News – Issue #90 6 February 2008

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*

### FDA requires contraceptives to be labeled re: N-9 risk, but not condoms

#### North America

On Dec 18, 2007, the US Food and Drug Administration issued a new rule to require over-the counter vaginal contraceptives (gels, foams, crèmes, etc) containing nonoxynol-9 (N-9) to carry warning labels indicating that such products do not reduce HIV or STI risk. The mandatory warning will also note that N-9 use may lead to vaginal irritation that could actually increase a woman's risk of becoming infected or re-infected if she is exposed to HIV during sex.

While advocates applaud action to correct the misconception that N-9 can reduce HIV risk, the Global Campaign for Microbicides is frustrated by the agency's failure to mandate similar labeling for condoms coated with N-9. The FDA classifies condoms as "medical devices" and topical contraceptives as drugs, and notes that it has to consider labeling requirements for each classification separately.

In 1992, the Global Campaign formed the "Call to Discontinue N-9 for Rectal Use", an advocacy initiative endorsed by women's health groups, HIV/AIDS organizations, state and local public health officials, and research scientists that called on manufacturers to remove N-9 from condoms and lubricants. If used rectally, even very small amounts of N-9 in these products may exacerbate HIV risk by damaging the fragile rectal lining. While the Call was successful in its appeal to lubricant producers and three major condom manufacturers, the two largest US-based condom companies (Church and Dwight, the makers of the Trojan brand, and Ansell, the maker of the LifeStyles brand) declined to stop selling condoms coated with N-9. The companies maintain that, since N-9 is spermicidal, the small amount on condoms must logically provide additional contraceptive protection if the condom breaks or

slips. They further assert that, since their N-9 condoms are not promoted for rectal use, they cannot be responsible for any impact they may have on rectal tissue.

Two years ago, the Global Campaign and other Call endorsers sent a sign-on letter to the FDA urging its prompt attention to the risks posed by N-9 condoms, particularly when used rectally. The FDA expects the first phase of its condom labeling study to be completed next month. After analysing their first phase data, the FDA will initiate a second phase of the study that is expected to take about 17 weeks. Church and Dwight and Ansell, meanwhile, have steadily urged the FDA not to require warning labels on N-9 condoms, arguing that these might confuse consumers and, thus, decrease their condom use.

The World Health Organization issued a report back in 2001 concluding that N-9 condoms do not provide users with any additional contraceptive benefit and "should not be promoted."

Anna Forbes, the Global Campaign's Deputy Director noted that, "we have repeatedly asked the N-9 condom manufacturers to provide evidence supporting their claim that N-9 condoms offer additional contraceptive protection. They have not done so, and meanwhile the data are available clearly showing that even the very small amounts of N-9 can damage rectal tissue and possibly increase HIV risk. It seems to us that the FDA has an obligation to either warn consumers of the risk of using N-9 condoms or remove N-9 condoms from the market."

## **Protein in Semen Enhances HIV Infection**

### **Global**

In the recent issue of the scientific journal *Cell*, Scientists at the University Clinic of Ulm in Germany report the discovery of a naturally-occurring compound in semen that seems to enhance HIV's ability to infect cells. In laboratory experiments, the German research team found that the chemical, called prostatic acidic phosphatase (PAP), can increase viral infectivity up to 100,000-fold, particularly under conditions that mimic sexual transmission of HIV.

PAP seems to boost infectivity by forming a large network of sticky fibers called amyloid. Resembling a tangled fishing net, this network of fibers are believed to act as a "ferry" by collecting virus floating in the semen and delivering them to the very immune cells that HIV targets.

Several prominent HIV researchers, including Jonathan Weber of Imperial College London, believe that this discovery could lead to the development of PAP-blocking agents that, when added to topical vaginal microbicides, help women protect themselves from infection. There is still a lot of work to be done, however, before a new microbicide that blocks PAP could be developed and tested in clinical trials.

## **New Mouse Model Shows Power of PrEP**

### **Global**

In recent study published in the open-access journal *PLoS Medicine*, researchers in Texas use a new kind of laboratory mouse to demonstrate proof-of-concept for pre-exposure prophylaxis (PrEP) to prevent HIV acquisition.

Researchers have long struggled with the lack of good animal models to study HIV transmission and infection. The most useful models to date use macaque monkeys infected either with simian immunodeficiency virus (SIV), a virus closely related to HIV, or a genetically-modified virus containing parts of the HIV genome and parts of the SIV genome called SHIV. Some researchers, most notably those developing vaccines, also use chimpanzees, which are the only other animal species can be infected with HIV. As valuable as this model is, however, chimpanzees are expensive and do not develop AIDS in the same way as humans.

A new animal model, however, uses mice which have been transplanted with human blood cells, liver, and thymus tissue. Dubbed "BLT" mice, these animals have genital tracts populated with the very same human immune cells that HIV targets. These cells, when infected, also produce and spread the virus in a way that researchers believe mimics vaginal transmission of HIV in humans.

It is hoped that these mice will be a useful model for evaluating microbicides and other HIV prevention technologies. When the Texas-based research team used these mice to study the efficacy of oral PrEP using tenofovir, for example, they found that none of the treatment mice showed signs of HIV infection versus 90 percent of the untreated mice.

A lot of work still needs to be done to determine whether data from pre-clinical studies in these mice will prove a useful tool for developing and screening potential microbicide candidates or other HIV prevention modalities like PrEP. BLT mice, however, represent a significant advance in the research community's efforts to develop useful animal models of HIV transmission and disease progression.

For information about the study itself, please see <http://medicine.plosjournals.org>.

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## **Advocate Highlight**

### **Stéphane Verguet & Alex Cox of the California Microbicides Initiative (CaMI) North America**

The California Microbicides Initiative (CaMI) is a statewide collaborative which aims to facilitate the development of safe, effective, acceptable and accessible microbicides for the benefit of Californians and people around the globe.



At the University of California, Berkeley, CaMI members Alex Cox and Stéphane Verguet are educating students on microbicides through information sessions and presentations. Stéphane recently spoke at a World AIDS Day panel on the HIV/AIDS epidemic. He has been interacting with student groups from Stanford and UC Davis as well. Most students never heard of microbicides before and become enthusiastic in realizing the new hope for reproductive health empowering women, and putting them at the center of the debate. Meanwhile, Alex has been working to raise awareness at University Health Services by educating the school's team of Sexual Health Peer Educators about microbicides. The peer educators were shocked that they had not heard of microbicides previously but were extremely responsive to the presentation and are eager to get involved with the cause and helping to expand CaMI's Berkeley outreach.

Alex Cox is a 4th year undergraduate student in Molecular and Cell Biology, specializing in Infectious Disease Immunology. She is also a Sexual Health Peer Educator at the campus's University Health Services. She joined CaMI in June 2006.

Stéphane is a Ph.D. candidate in Mechanical Engineering studying the fluid mechanics and biophysical properties of microbicides. He is also a master's student at the Goldman School of Public Policy. Advocating for the technological potential and social change perspective of microbicides, he joined CaMI in September 2007.

For more information please contact [CaMI@CaMI-Health.com](mailto:CaMI@CaMI-Health.com) or consult [www.cami-health.com](http://www.cami-health.com).

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## **Advocacy in action**

### **Midwives for Microbicides**

#### **Africa**

On December 13, 2007, Sydney West, the Global Campaign's Global South Coordinator presented "Microbicides: What You Need to Know" at the 7<sup>th</sup> Annual Congress of the Society of Midwives of South Africa.

According to UNICEF figures, women in South Africa are 40 times more likely to die in childbirth than women in the US. As the midwives of South Africa are the front-line caregivers and backbone of maternal and child health care in the country, it has become increasingly imperative for midwives to continuously improve their clinical skills and knowledge base. Midwives can play a key role in advocating for microbicide funding and research. When microbicides become available in South Africa, midwives will play a key role in counseling patient on this new technology and its potential to allow women to protect themselves from infection.

The theme of the conference was “Midwives Accelerating the Attainment of the Millennium Development Goals”, and during her presentation Ms. West described how microbicides can help midwives accelerate the attainment of the Millennium Development Goals. She also described what microbicides are, how they work, why they are needed, and the status of clinical trial research in South Africa.

The conference, held at the International Convention Center in Durban, was an important step for the South African Society of Midwives as it was the bellwether for their as lead in to their hosting of the 29<sup>th</sup> Triennial International Confederation of Midwifery to be held in 2011, the first time ever held on the African continent.

## **Global Campaign Hosts a Community Involvement Meeting in South Africa**

On November 27-28, the Global Campaign hosted a planning meeting on “Community Involvement in Microbicides Clinical Trials” in Muldersdrift, Johannesburg South Africa. Many different groups in the field are working in the overlapping areas of community involvement and preparedness at trial sites as well as trying to widen the engagement of civil society groups in HIV prevention research. Thus, the purpose of this informal two-day meeting was to bring together community representatives from different networks and entities to share information and discuss current and emerging needs in the areas of community involvement and civil society engagement in microbicide clinical trials.

The first day of the meeting participants focused on exercises and discussion to frame the definition of community and share experiences and locate gaps.

They acknowledged that different actors in the field of HIV prevention research defined “community” and “community involvement” differently. Global Campaign shared its model of locating the community based on the “spheres of involvement.” This model identifies four levels namely: Trial Participants & Study Staff, Host Community, National Stakeholders and International Civil Society.

Lori Heise, Director of the Campaign presented a review of the history of community involvement. Noting that CAB model seen today is an export from treatment work in the US in 80s and 90s . While it has been useful, it may not be sufficient to meet all the diverse challenges of community involvement. She noted that sites had begun to use other mechanisms to help educate, respond to, protect, collaborate with and seek ongoing input from communities.

Following a round robin, participants shared some of the innovative community involvement activities that they were undertaking, such as, participating in existing events like world AIDS day and 16 days of activism against gender-based violence to help raise awareness, educate, dialogue with and respond to community concerns regarding microbicides and clinical trials. However gaps exist.

Gaps cited were the insufficient budget allocation for community involvement activities; low microbicides and research literacy; limited engagement of civil society; need for conduct of socio-behavioural studies prior to commencement of clinical trials to gain in depth understanding of community issues and integration of social science work with community involvement work at trial sites; and challenges around communication between researchers and communities and across networks.

The meeting acknowledged that there have been efforts to address some of the needs in community involvement work. Two such initiatives include the GPP document and the HANC. The GPP sets normative guidelines for community involvement in trials while the HANC has been an attempt to coordinate and improve cross-network communication.

The participants felt that there was a need to create a space for interaction between various sites and networks on community involvement issues and to share materials and tools that they were using.

On the second day, Lori Heise introduced the concept of a Community of Practice (CoP) i.e. a network of people bound together by shared expertise and passion for a joint enterprise. It is an informal network that fosters collective strategic planning and/or problem solving and creates a level playing field where all experiences and information are valued. CoPs offer the opportunity for people to enter and exist as it serves their needs. The participants felt this was a model they would be interested in however, issues to be addressed include cost of participation in the CoP, channels of communications between members, and ensuring that it does not generate work overload among members.

The participants identified some of the topics that would be discussed in the CoP sessions. These included: co-enrollment in trials; providing results feedback; managing confidentiality of CABs, staff, participants; partner involvement and inclusion of men/partners co-using the product and their role in adherence; Microbicides & HIV positive women; community education around adherence and why it's important; and working with adolescents.

In small groups, the participants then discussed the outline of the Global Campaign's Community Involvement toolkit. The exercise provided an opportunity to share examples and techniques that the sites were using in their community involvement work.

The meeting concluded by giving Global Campaign the go ahead to set up a CoP on community involvement in clinical trials and create a web-based resource centre for materials on community involvement staff at site level and other stakeholders can use. The Campaign will also actively seek opportunities for the staff involved in community work to interact and maintain an enriching exchange between the sites.

## **Victory for Microbicides R&D in U.S. Appropriations Bill**

### **North America**

In late December, President Bush signed a \$555 billion Consolidated Appropriations Act (Omnibus) into law. Despite a somewhat contentious budget year, the FY08 International Affairs Budget received a 5.2% increase above FY07 levels. Perhaps most meaningful, however was the victory for microbicides research and development, as government funding in this area will significantly increase for Fiscal Year (FY) 2008.

The bill provides \$96.4 million for microbicides research and development funding at the National Institutes of Health (NIH), a 12.8% increase in over the last year. In addition, the bill also provides \$45 million for microbicides research and development at the US Agency for International Development (USAID) in Fiscal Year 2008, an increase of more than \$5 million 13.6% more than fiscal year (FY) 2007. Interestingly, unlike last year's bill, the Microbicides "account" at USAID did not include earmarks.

Meanwhile, work has already begun to determine the FY09 budget. President Bush's FY09 budget request is expected to be released February 4, 2008.

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## ***Highlighted Resources***

### **Your Resources at M2008!**

The African Microbicides Advocacy Group, Global Campaign for Microbicides, Indian Network of NGOs (INN) Gujarat, International Rectal Microbicides Advocates, National Health Coalition Initiative and Nigerian HIV Vaccine & Microbicide Advocacy Group are hosting an Advocate's Corner at the upcoming M2008 Conference. The Advocates Corner is an interactive and participatory area where M2008 conference delegates representing community, advocacy and civil society groups can come to dialogue, exchange ideas, network, and build solidarity.

**Are you a M2008 conference delegate and you are wondering how to disseminate your own materials at the Advocates Corner?** If you wish to take advantage of the opportunity to share information about your work via our specially designated “Community Materials Table”, please contact Arwa Meijer on [ameijer@path.org](mailto:ameijer@path.org) to sign up for a space. You will be responsible for putting out the materials and collecting them at the end of the conference. Since space is limited, please book early to avoid disappointment!

### **New Access Resources from the International Partnership for Microbicides**

The International Partnership for Microbicides (IPM) has recently announced a series of resources around future access to and introduction of microbicides. Most of these resources can be found by visiting the [Preparing for Success: Future Use and Access](#) portion of their website, or by following the direct links below.

#### [Microbicide Manufacturing Survey](#)

*A global survey of manufacturers, with an emphasis on developing countries*

#### [Product Attribute Study I Report](#)

*Acceptability of three gel formulations among women and their partners in Kenya, South Africa and Zambia*

#### [Country Profiles](#)

*Data on demographics, epidemiology, health systems and other indicators relevant to microbicide introduction in India, Nigeria, Rwanda, South Africa, Tanzania and Zambia*

#### [Planning for Microbicide Access in Developing Countries: Lessons from the Introduction of Contraceptive Technologies](#)

*Research report*

#### [Presentations from the 2007 Nairobi Microbicide Access Forum](#)