



**Global Campaign  
FOR Microbicides**

## **The Global Campaign News August 19, 2003**

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.

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### **Dialogue on Community Involvement in Trials Sparks Interests and Imagination**

On July 28-30, the Global Campaign for Microbicides and the South African Microbicide Research Initiative co-hosted a dialogue for community outreach and social science staff of eight microbicide trial sites in four countries in southern Africa. Thirty-five representatives of sites in South Africa, Botswana, Zambia and Zimbabwe gathered to share ideas and experiences and seek out each other's input on the challenging issues they face in their communities.

Participants discussed practical approaches to difficult or unexpected concerns raised by the community. For example, how do you respond to a volunteer who understands that she has been randomly assigned to use either a microbicide or a placebo, yet becomes convinced over the course of the study that she has "the one that works" due to an unrelated improvement in her health or appearance? What is the appropriate answer to the common, often suspicious question, "Why are you doing this study *here*, in this community?" How do you go about the critical task of involving men in the research and community initiative without compromising women's autonomy and reinforcing harmful gender norms?

The benefits and limitations of community advisory boards (CABs) in the context of Southern Africa's microbicide trials were also discussed. CABs have a long history and in some sites have morphed into Community Advisory Groups, Community Working Groups, or even Participant Advisory Groups to better represent their role in the research process. Teams shared both their successes and frustrations with CABs, and made many suggestions on how to improve representation and the functionality of CABs. All participants agreed that even the ideal CAB is not the only way to achieve meaningful community involvement in a research enterprise.

Additional and complementary strategies included: general community mobilization around health and HIV issues, working with local NGOs to include microbicide awareness-raising, developing a role of an independent ombudsman, involving the community in participatory action research related to the issue, and many more. These strategies and future steps will be discussed in detail in the meeting report.

Perhaps the most exciting and least tangible outcome of the meeting was a shift away from understanding “community involvement” as one project or task attached to a single clinical trial to an ongoing enterprise that complements the research process as well as generating results for the community on its own. This emerging vision cannot be accomplished by a research entity on its own. There is a need to establish partnerships with government, donors, and international agencies as well as local NGOs and organizing structures outside of the specific research itself, that can help support the broader goals of community-building, community development and community empowerment.

The meeting report will be available on our website in mid September at [www.global-campaign.org](http://www.global-campaign.org). Watch out for the announcement in an upcoming GC News.

## **Unproven “Freedom Lube” sold on internet**

Advocates across North American have been contacting the Global Campaign in recent weeks to inquire about a product called “Freedom Lube” that is being promoted through internet outreach as “an anti-viral sexual lubricant that helps to prevent transmission of sexually transmitted diseases (STDs).”

The makers of Freedom Lube advertise their products as containing a broad pastiche of ingredients “shown to be very effective in preventing transmission of the HIV virus”. The web site ([http://freedomantiviral.com/antiviral\\_lube.htm](http://freedomantiviral.com/antiviral_lube.htm)) describes the product as containing twelve categories of active ingredients -- many of them, ironically, compounds that are now in individual clinical trials as potential microbicides. It goes on to state that “[u]sing Freedom Lube greatly reduces the risk of contracting HIV” and notes that “[a]lthough many microbicidal lubricants are under development, Freedom Lube is the only one currently on the market”

The Freedom Lube line includes a range of products including, at the high end, a 100 ml. bottle of the “Pre-Fix Invisible Condom” costing \$54. This miraculous product, they state, is “[c]linically proven to help prevent the transmission of Herpes, HIV virus that causes AIDS, Genital Warts, HPV, Chlamydia, Gonorrhea, and other STDs”.

We have contacted the promoters of this product requesting citations for the data supporting these claims but have received no response. It is once again our obligation, therefore, to remind the public that NO sexual lubricant has yet been to be proven to have microbicidal or antiviral properties sufficient to justify promoting it for HIV prevention among humans.

Our Campaign partner, the National Women's Health Network, is also pursuing this issue with the Federal Trade Commission (FTC) which is responsible for regulating advertising of dietary

supplements and other "natural" products. This issue has come up previously in relation to similar products (see Erogel and Irish Moss discussed in June 30 issue of the GC News). Alerted by our eyes and ears in the field to the unsupported claims being made for unproven products, the Campaign will push both the FDA and the FTC, as appropriate, to hold these manufacturers accountable for any unsubstantiated or false claims and for misleading advertisements.

*Please contact Anna Forbes, Global North Programs Coordinator, at [asforbes@path-dc.org](mailto:asforbes@path-dc.org) if you become aware of any other products designed for vaginal or rectal use that are currently being promoted as proven microbicides.*

## **New WHO Guidelines for the Re-use of the female condom**

(Excerpt from Female Condom Update, Female Health Foundation)

In July 2002 WHO published a clinical protocol with guidelines for re-use of the female condom. Although the protocol states that a new condom is always preferable, in situations where they are not available or affordable, evidence suggests that the female condom can be used safely at least 5 times if the WHO guidelines are followed. In August 2003 WHO released the programmatic guidelines to compliment the clinical guidelines.

To support these guidelines the Female Health Foundation and John Snow International (UK) are launching a website to address issues around reuse [www.reusefemalecondom.org](http://www.reusefemalecondom.org). This DFID funded website aims to assist program managers in deciding whether or not to support re-use of the female condom within their program/client base.

On-line discussion of the WHO program guidelines is planned for August. However the website will be live from the 28<sup>th</sup> of July and we hope that less formal online discussions will start immediately with program managers and other interested parties posting questions and comments on reuse of the FC.

If you would like to be keep informed about the online discussions by email, and therefore avoid having to check the website, please e-mail [info@reusefemalecondom.org](mailto:info@reusefemalecondom.org) with Reuse Website List Serve in the subject line. If you have problems with internet access and would prefer receiving printed or e-mail summaries of discussions, please contact [info@reusefemalecondom.org](mailto:info@reusefemalecondom.org).

This on-line facility will remain live after the initial discussions of the WHO programmatic guidelines and information collated from the website will be used to provide practical decision making tools for those managing female condom program and will be a supplement to the existing WHO guidelines.

## **Strange Bedfellows on Condoms: Right wing Congress staffer echoes AIDS groups on spermicide warning**

(From Gay City News, August 2003, by Duncan Osborne)

AIDS and public health groups concerned that gay men may be using lubes that contain nonoxynol-9 because of a mistaken belief that the spermicide protects them from HIV have an unexpected ally in their effort to warn consumers about the dangers of its use in condoms and lubricants.

On April 9, Roland Foster, a senior staffer on the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources, wrote to the Food and Drug Administration questioning whether proposed regulations that would require warning labels on vaginal contraceptives that contain nonoxynol-9 went far enough.

“The Subcommittee applauds the FDA for taking this action to protect the health of those who may otherwise put themselves at increased risk for HIV infection by utilizing N-9,” Foster wrote. “Unfortunately, the FDA’s proposed warnings ignore the dangers of using products containing N-9 for non-vaginal sexual activity, including anal sex.”

The subcommittee chair is Mark Souder, an Indiana Republican, who has been a leading voice calling for federal audits of AIDS spending. He has also been questioning the efficacy of HIV prevention programs and whether the federal dollars that fund those programs are being wasted. Foster is also seen as a driving force behind the audits.

Some AIDS leaders have said that Souder and Foster’s efforts have singled out prevention efforts aimed at gay and bisexual men for particular scrutiny.

The proposed FDA regulations, issued in January, would require manufacturers of vaginal contraceptives to state on the product label that nonoxynol-9 “does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs)” and that if products with nonoxynol-9 are used frequently they may increase the risk of acquiring HIV or sexually transmitted diseases.

The regulations—the FDA has not yet issued a final version—would include condoms and vaginal gels, but not the lubricants that are popular among gay men.

Such a warning would be especially important for some gay and bisexual men who have sex without condoms and use a lube with nonoxynol-9 in the belief that it gives them, at least, some protection from HIV and sexually transmitted diseases.

A number of recent studies have found that nonoxynol-9 can strip away layers of cells in the rectum and vagina leading to inflammation. That can make a person having unprotected anal or vaginal sex more susceptible to HIV or other infections.

The Planned Parenthood Federation of America, the Alan Guttmacher Institute, and the Global Campaign for Microbicides are just some of the groups that have urged the FDA to expand the warning to include products with nonoxynol-9 used for anal sex.

“We have been very, very strongly asking them to do that,” said Anna Forbes, the global north programs coordinator at the microbicides group. “We have been urging them to consider products that are used rectally.”

There are many gay and AIDS groups among the 180 co-sponsors of the microbicides campaign. Foster agreed that the FDA should expand the warning requirement.

“Such warnings are particularly important since researchers with the San Francisco Public Health Department reported last year that a significant number of gay men continue to use N-9 products, erroneously, for prevention purposes,” he wrote. “According to a recent study, more than 40 percent of San Francisco men interviewed said they used N-9 condoms because they believed it would protect them against HIV.”

Forbes greeted Foster’s comments with more than a little suspicion.

“I’m very surprised to hear that he is raising so many of the same questions that we have raised and I wonder what his real agenda is for doing this,” she said. “I am concerned that he may be planning to use this as part of a campaign to discredit condoms overall... We would like to see N9 condoms pulled off the market, but we believe that condoms are a wonderful, practical way of preventing infection.”

Foster and the activists appear to part company on whether nonoxynol-9 should be banned entirely. The April 9 letter asks why FDA has not banned products containing the spermicide.

For some women, nonoxynol-9 products are effective in preventing pregnancy when used with a barrier such as a condom or a diaphragm. Those products are used by women who cannot tolerate hormone-based birth control methods.

“The last thing we want to do is reduce women’s contraceptive opportunities,” Forbes said. “We do support the FDA’s labeling proposal although we don’t believe it goes far enough because it doesn’t include products used rectally.”

The FDA, in its July 15 response to Foster, noted the “limited number of non-hormonal contraceptive methods available to consumers” and that it was “reasonable to allow N-9 containing products to remain on the market” if they could be used safely.

Last year, a coalition of roughly 85 scientists and health groups called on manufacturers of condoms and lubes to stop using nonoxynol-9 in their products, but they did not seek a government ban.

## **USAID reports to Congress on microbicide and vaccine efforts**

The Office of HIV/AIDS at USAID has released a report to Congress on USAID-funded microbicide and vaccine research efforts. You can access the report at:  
[http://www.usaid.gov/pop\\_health/aids/TechAreas/research/microb\\_vacc.pdf](http://www.usaid.gov/pop_health/aids/TechAreas/research/microb_vacc.pdf).

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