



## Global Campaign News March 15, 2002

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.

We welcome your input and contributions. Correspondence can be addressed 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.

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### **International Regulators Meet to Discuss Microbicides**

From March 4 through 6th, 2002 thirty-five international experts met in the beautiful Alpine town of Villars-sur-Ollon, Switzerland to discuss regulatory issues related to the eventual approval and licensure of topical microbicides. The meeting was jointly convened by the World Health Organization, the Alliance for Microbicide Development, and the CONRAD program, to develop guidance for regulators from both industrialized and developing nations who will eventually be reviewing applications for microbicide approval in their countries. The goal was to build consensus around the key issues and tests that should guide regulatory decision-making in the microbicide arena. It represented an important step toward preparing the way for timely and efficient access to safe and effective products once they become available.

The meeting included representatives of the drug regulatory authorities of Botswana, China, Nigeria, Thailand, South Africa, United Kingdom, the United States, and Zambia as well as scientists and health officials from a range of countries. (Lori Heise attended from the Global Campaign, as did colleague Dr. Margaret Muganwa from Uganda). Participants broke down into groups to discuss requirements for pre-clinical testing of compounds, guidance for safety (Phase I) and expanded safety testing (Phase II), and requirements for effectiveness trials (Phase III). Many of the developing world participants emphasized the importance of capacity building among Southern drug regulatory authorities, especially in the area of microbicides -- a new and unfamiliar area for them.

The group emphasized the importance of empowering national regulators to evaluate effectiveness data in the context of their own local realities. It may be that a microbicide shown to be safe but only partially effective might be appropriate for approval in some

settings but not others. Modeling data demonstrate that even a 30 or 40 percent efficacious microbicide could have a substantial impact on the growth of the epidemic in high prevalence areas.

The group also agreed that a single well-designed and executed trial could provide sufficient data for approving a first generation microbicide, assuming the trial met certain criteria.

### **HPV often contracted at first sexual intercourse**

LONDON, Feb 13 (Reuters Health) - A new study suggests that many young women may contract human papillomavirus (HPV) infection during their first sexual experience. HPV infection can cause genital warts or be symptom-free -- and certain strains are linked to an increased risk of cervical cancer.

The study, conducted by Dr. Stuart Collins from the University of Manchester and colleagues, concluded that during the first 3 years after sexual intercourse, 46% of the women examined were at risk of cervical HPV infection. For half the women, the infection was detected within three months after their first sexual encounter. In addition, the chances of being infected with HPV increase as an individual's number of sexual partners rises.

Collins' team commented that advice on prevention of HPV would be difficult to develop as 74% of the women studied reported using barrier contraception, albeit intermittently, during first sexual intercourse. "Perhaps cervical human papillomavirus infection should now be considered an inevitable consequence of sexual activity," the team added. Certain "high-risk" strains of HPV are the primary cause of cervical cancer. However, HPV infection usually goes away on its own, and most women who get the virus do not develop cervical cancer. *For more information, see the January issue of the British Journal of Obstetrics and Gynecology.*

### **Advocates in Action**

On March 6, southern California advocates Jennifer Moore and Kevin Whaley co-presented with Global Campaign staff at the 2002 National STD Prevention Conference in San Diego. Hosted by the CDC and the American Social Health Association (ASHA), the conference attracted a large, multi-disciplinary audience. The microbicides workshop, introduced by ASHA Public Policy Director Deborah Arrindell, brought 45 conference participants out of the California sunshine and generated lively, cross-cutting discussion about the urgent need for microbicides for STD prevention.

Global Campaign staff also had the privilege of briefing 40 members and alumnae of the Los Angeles Chapter of Delta Sigma Theta Sorority on March 8. The African American AIDS Policy and Training Institute, a national training organization invited us to present the two-hour briefing on woman-controlled HIV prevention to the Delta Thetas and a few other community service providers on the eve of the organization's nationwide International Day of Service. The national sorority, founded in 1913 for African-

American women, chose to focus this year's Day of Service on HIV/AIDS prevention. The women of the Los Angeles chapter energetically embraced the Global Campaign's presentation and fact sheets on the female condom, microbicides and the need for prevention alternatives for women, noting that these would inform their HIV/AIDS prevention education efforts in their local communities.

The front page of the Baltimore City Paper, March 6-12<sup>th</sup> issue headlines, "Microbe Managers" and pictures Drs. Thomas Moench, Kristen Khanna and Richard Cone, directors of ReProtect LLC and scientists behind BufferGel. The article describes the need for microbicides while detailing the challenges of developing them. The Baltimore paper reaches thousands of people in Maryland -- perhaps microbicides will soon become a household word. Click [this link](#) to get the full article.