



Global Campaign News – Issue #59 November 8, 2005

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 STIs.

In this issue:

Merck and Bristol-Myers Squibb Donate Candidate Microbicides; Public Funding Still a Priority
Journalists and advocates meet for microbicides training in Chennai, India
Studies Ask: Do Diaphragms Reduce the Risk of HIV and Other STIs?
Pregnancy Shown to Increase Risk for HIV in Uganda
Briefing in Brussels Secures New Commitment to Microbicides
Rectal Microbicides Make an Impression in Debut at GLMA Conference
Early Findings Give Promise for Microbicidal Vaginal Rings
First Women Volunteers Enrolled in British Sponsored Trial of Pro-2000
Upcoming Events: Fall 2005

Merck and Bristol-Myers Squibb Donate Candidate Microbicides; Public Funding Still a Priority

U.S.

On October 31, the International Partnership for Microbicides announced that it had finalized arrangements with two major pharmaceutical companies, Merck & Co. and Bristol-Myers Squibb Co., to gain access to new compounds that merit testing as candidate microbicides. Under the two separate agreements, Merck and Bristol-Myers Squibb will each grant the non-profit group a royalty-free license to develop, manufacture and distribute their compounds for use as microbicides in resource-poor countries.

The Global Campaign congratulates the two companies for their contribution to the goal of expanding prevention options for women around the world. This fantastic news means that any successful microbicides made out of these compounds will be marketed in the developing world on a non-profit basis. These types of agreements are vital to meeting the challenge of making a safe, effective microbicide accessible in the Global South. [Click here for a copy of the press release](#) issued by the Alliance for Microbicide Development and the Global Campaign on this announcement.

These agreements represent a welcome contribution from the pharmaceutical industry to the field of microbicides because they widen the research pipeline. It is important for microbicide advocates to understand clearly, however, that this is not the same thing as companies investing their own research dollars directly in the development of microbicides. The royalty-free licenses mean that Merck and BMS have donated their rights to profits that might be generated by the sale of a successful microbicide using these compounds in the developing world. But IPM will be funding the cost of this research (which could total \$60 million dollars or more per product) with the government and philanthropic grants that it has so successfully garnered for microbicide research, as well as the costs of registering, manufacturing and distributing the product, if successful.

This is no time to let up on the demand for increased public funding for microbicide research and development. If more corporate sponsors are willing to follow the lead of Merck and BMS and enter into similar agreements – and we certainly hope they will – even greater funding will be needed to test and develop the new products entering the research pipeline.

Read the full press release at http://www.global-campaign.org/clientfiles/Merk_BMS%20PressRelease.pdf

Journalists and advocates meet for microbicides training in Chennai, India

India

Indian journalists learned about microbicides and clinical trials in India at a workshop on October 18 in Chennai. The city in the southern state of Tamil Nadu is host to both the Indian National Conference on AIDS, which took place from October 20-23, and microbicides trials conducted by the YRG Care clinic. Advocates from South India AIDS Action Programme, Freedom Foundation, Asha, Centre for Advocacy and Research, and Positive Women's Network joined more than 20 journalists from local and national news outlets for a discussion of the need for alternative prevention methods for women in India, as well as the basics of microbicides and the research landscape in the country. Dr. Suniti Solomon, director of YRG Care and principal investigator in some of the Indian microbicides trials, presented a scientific overview. Bobby Ramakant of the India Campaign for Microbicides discussed the role of civil society, including representatives of media, in moving the microbicides agenda forward in ways that respond to the needs and priorities of affected people and communities.

The training is one of a series of events meant to increase public awareness of microbicides and microbicides research in India through well-informed media coverage that brings the nuances and complexities of the research endeavor to a broad civil society audience. The combination of journalists, scientific experts and NGOs allowed participants to raise questions, hear a range of perspectives, and develop comprehensive messages. The training resulted in significant national and regional coverage of the issue, some of which readers can see at the following links:

<http://www.hindu.com/2005/10/20/stories/2005102017580300.htm>
<http://news.webindia123.com/news/showdetails.asp?id=138405&cat=Health>
<http://www.newkerala.com/news.php?action=fullnews&id=36481>

Studies Ask: Do Diaphragms Reduce the Risk of HIV and Other STIs?

Africa

Ibis Reproductive Health and the Medical Research Council are conducting MIRA (Methods for Improving Reproductive Health in Africa) trials in South Africa and Zimbabwe to determine whether diaphragms will reduce a woman's risk of contracting HIV and other STDs.

It has been shown that the cervix has a high number of HIV receptors and is therefore a likely candidate to be the primary transmission point for HIV and STIs. The trials will investigate whether a cervical barrier like the diaphragm reduces the risk for HIV, if risk reduction is increased with the use of a lubricant, and long-term acceptability of diaphragm use.

Read the full article at <http://www.aidsmap.com/en/news/DF32E5F0-F352-494A-97E1-5DAA5786E639.asp?wk=1>

Pregnancy Shown to Increase Risk for HIV in Uganda

Africa

A new study from the Rakai district of Uganda warns of the increased risk of contracting HIV while pregnant due to physiological changes in the genital tract. Researchers have called for the study to be repeated in areas outside of Uganda to confirm the initial results. The findings of the study were originally published in the October 1st, 2005 edition of The Lancet.

Read the full article at:

<http://www.aidsmap.com/en/news/E4405364-04D0-4F58-83F1-C0FD43653AA3.asp?wk=1>

Briefing in Brussels Secures New Commitment to Microbicides

Europe

On 7th October, the Global Campaign hosted a joint briefing in Brussels with the International Partnership for Microbicides (IPM) entitled "Microbicides: Meeting the Challenge of HIV Prevention in Women". The event was designed to capture the attention of European Union (EU) officials, policymakers,

parliamentarians, African governments and industry at a time when microbicides are still not well-understood in the corridors of the EU institutions.

Despite a national transport strike which paralysed most of the city, the turn out for the event was still considerable, thanks to an impressive array of panelists, including H.E. Maria Manuela dos Santos Lucas, Ambassador of Mozambique to the EU and Mr. Michel Lastschenko, Belgium's Special AIDS Envoy.

Opening the meeting, Ambassador Manuela dos Santos Lucas issued a strong call to her colleagues: "we are here today to remind you that we are losing women on a daily basis in ever greater numbers, that we have failed collectively to prevent women and their children from succumbing to infection and to eventual death. We have failed to address the factors of gender inequality that fuel the AIDS pandemic. The time that it will take to get a microbicide depends on us. It depends on political will, on our political will".

The morning saw a number of high-level commitments pledged to microbicides from key figures. Mr. Lastschenko announced that Belgium would support the next international conference on microbicides in Cape Town 2006. Mr. Brian Grathen Bowler, Ambassador of Malawi to the EU, vowed his time and support to the microbicides cause, urging the Campaign and IPM to develop a formal relationship with the African, Caribbean and Pacific (ACP) states and inclusion of microbicides in their agreements.

Passionate speeches in support of new options for women were delivered by Dr Lieve Fransen, Head of Human and Social Development at the Development Directorate of the European Commission, and Anne van Lancker, Belgian Socialist MEP and Chair of the Working Group on Reproductive Health, HIV/AIDS and Development in the European Parliament. Ms Van Lancker told the audience: "This is a human rights issue. The right to protection against infection is a human right." Francoise Welter of the Global Network of People Living with HIV/AIDS (GNP+) spoke eloquently to the need in her own country, Rwanda, and that of her own daughter growing up in the Netherlands. She called for attention to microbicides that positive women could use: "microbicides are a heaven sent opportunity, but only if they challenge gender inequality and are available to every woman that needs them".



The Ambassador of Malawi, Mr. Brian Grathen Bowler and Dr Lieve Fransen of the European Commission, thank Francoise Welter of GNP+ for her excellent presentation

After in-depth presentations by Dr Zeda Rosenberg, CEO of the International Partnership for Microbicides and Lori Heise, Director of the Global Campaign, on the science and policy of microbicides respectively, a second panel examined private and public responses within Europe. Dr Jens Van Roey shared the experience of his pharmaceutical company, Tibotec, which focuses on delivery solutions to African health needs. Tibotec is a Belgian company that became the first to partner with IPM in 2004. However Dr Van Roey warned that "access to microbicides will be limited unless we tackle stigma".

In spite of the industrial action, the Ambassadors of Bénin, Cote d'Ivoire, Malawi, South Africa, Uganda and Zambia and a senior representative of Rwanda were in attendance, alongside government officials from four EU member states - Germany, Belgium, Spain and the Czech Republic. Altogether, there were 70 participants including staff from the Research, Development and Health Directorate Generals of the European Commission, as well as representatives of the European Parliament, industry, research institutions and civil society. "I do support microbicides and I hope they are available in less than 5 years. African women have no rights over sex. They are at a terrible disadvantage," commented Ambassador Deo Rabita of Uganda.

To view all the presentations, speeches and discussion, as well as photographs of the event, please consult: <http://www.global-campaign.org/GCEurope.htm>

Rectal Microbicides Make an Impression in Debut at GLMA Conference

U.S.

The 23rd Annual Conference of the Gay and Lesbian Medical Association (www.glma.org) entitled "Access, Diversity and Advocacy" was held in Montreal, Quebec September 22 – 24, 2005. For the first time ever, the conference featured a session on rectal microbicides --in this case a plenary. Dr. Ian McGowan, a renown rectal microbicide researcher from UCLA collaborated with advocates Marc-André LeBlanc of the Canadian AIDS Society and Jim Pickett of the AIDS Foundation of Chicago on a presentation called "Rectal Microbicides: Moving Toward Expanding Gay Men's Prevention Options." The PowerPoint presentation, available online at www.lifelube.org, provided the attendees with a dynamic overview of rectal microbicide research and development, summarizing the complex scientific, political and multi-tiered social challenges the field faces. The three also described current efforts and new strategies around engaging gay men in microbicide advocacy in general and rectal microbicide advocacy -- in particular to build political momentum in the gay community for these important prevention tools. Over one hundred LGBT medical professionals participated in the session and by all accounts were interested and enthusiastic in their response. Issues raised by participants included concerns such as microbicide availability leading to condom migration and how to develop clear and consistent prevention messaging for gay youth around microbicides and sexual harm reduction.

Early Findings Give Promise for Microbicidal Vaginal Rings

U.S.

Early tests using silicone elastomer vaginal rings to deliver an anti-retroviral (ARV)-based microbicide look promising. The tests, conducted *in vitro* over a 71 day period give new promise to future microbicide versatility. Deliverance of a microbicide through a vaginal ring that women could insert and leave in place for up to a month at a time alters the field's options of how we can talk about microbicides, dissociating protection from intercourse and increases women's options and usability when it comes to protecting themselves from HIV and other sexually transmitted infections. Read more about the findings at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16155060&query_hl=3.

First Women Volunteers Enrolled in British Sponsored Trial of Pro-2000

Africa/Europe

In Johannesburg, South Africa, nine women have become the first of 10,000 people to participate in the largest microbicide trial conducted to date. The Phase 3 trial will test the effectiveness of PRO 2000, a topical vaginal microbicide in preventing HIV and is also expected to show some activity against herpes, gonorrhoea and chlamydia. The British Microbicides Development Programme (MDP) is a partnership aimed at developing vaginal microbicides for the prevention of HIV transmission. In addition to Johannesburg, MDP has established sites at clinics in two other South African provinces and in Tanzania, Uganda and Zambia.

The trial is coordinated by the British Medical Research Council's (MRC) Clinical Trials Unit, where the data from the sites will be combined for analysis. The clinical trials manager, Julie Bakobaki said, "Early safety studies of this particular microbicide have been extremely encouraging. It's very exciting after four years of preparatory work to reach the point of enrollment into this trial. Showing this microbicide protects against HIV would represent a tremendous breakthrough in the fight against the spread of HIV/AIDS."

MDP selected PRO 2000 (developed by Indevus Pharmaceuticals) on the basis of its strong safety data and potential to combat a range of serious STIs. Taking the form of a clear gel, the compound 'polynaphthelene sulphonate' works by binding to pathogens so that they cannot enter the body's cells. Pre-clinical studies and initial trials were carried out in small numbers of women and men in London and

the U.S. to ensure there were no serious side-effects. Each woman enrolled in the Phase 3 trial will be assigned at random to receive one of two PRO 2000 strengths (0.5% or 2%) or a placebo gel. All participants will receive condoms and risk-reduction counseling and safety data will be reviewed regularly by an independent data safety monitoring committee.

Speaking at a news briefing to announce the launch of the trial, South Africa's controversial Health Minister, Manto Tshabalala-Msimang said "If there is any other mechanism for women to protect themselves using their own power, then that is absolutely critical". Dr. Anatoli Kamali of the MRC unit in Uganda and the lead scientist for the Ugandan site said, "There is a significant need among sexually active women for female-controlled methods of HIV and STI prevention. The highest HIV infection rates are found in sub-Saharan Africa, which is why these large-scale trials are being conducted in this area." Dr. Sibongile Walaza of the Reproductive Health Research Unit in Johannesburg added, "If microbicides are shown to be effective, they would ideally be used in addition to condoms, but even on their own they could significantly reduce transmission of HIV and STIs."

Should the water-based gel prove effective, Indevus has agreed not to assert their intellectual property rights so that the microbicide can be distributed at a very low cost or even free via the usual channels such as governments, the European Commission and the Global Fund. Funding for the PRO 2000 trial comes from DFID, the British Department for International Development and the UK's Medical Research Council.

Another large-scale clinical trial to assess the safety and preliminary effectiveness of 0.5% PRO 2000 gel compared to a similar candidate microbicide, Buffergel, (Protocol HPTN 035) is currently underway in Africa and the U.S., sponsored by the U.S. National Institutes of Health.

Sources: UK Medical Research Council, Indevus Pharmaceuticals and NY Times.

Upcoming Events: Fall & Winter 2005

Campaign to End AIDS

After much planning, the [Campaign to End AIDS \(www.c2ea.org\)](http://www.c2ea.org) Five Days of Action has arrived! Check out C2EA's website to see how you can get involved. Also, read about the Campaign's demands and front-burner issues including the "development of promising prevention methods, like microbicides" by visiting http://www.campaigntoendaids.org/atf/cf/{0872318F-86CE-4DDB-B02B-C3678AF1FCB6}/C2EA_FOURDEMANDSFOURISSUES.pdf.

Microbicides 2006

The closing date for abstract submissions and scholarship applications is December 14th. For more information on how to submit an abstract to the conference and/or how to apply for scholarship funds, visit the Microbicides 2006 website at www.microbicides2006.org. Also, early registration will be open until December 31st.

133rd APHA 2005 Annual Meeting & Exposition

Registration is still open for the 2005 American Public Health Association's Annual Meeting to be held December 10th -14th in Philadelphia, PA. The conference this year will feature several presentations on microbicides including one by the Global Campaign for Microbicides and a screening of the Global Campaign's film, *In Women's Hands*. For more information, visit their website at <http://www.apha.org/meetings/>.

We welcome your input and contributions. 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.