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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

Phase 1 Trials of a New Type of Microbicide Due to Begin in the UK Europe

The European Microbicides Project (EMPRO), one of the largest microbicide research projects in Europe, has announced that it will begin Phase 1 trials in London this October of a new compound containing a mixture of monoclonal antibodies. Antibodies are one of several new mechanisms of action that the 10-country consortium will be looking into over the next five years.

EMPRO is a consortium of 27 European and African academic institutions funded by the European Union’s Sixth Framework Programme for Research (FP6). Coordinated by Professor Charles Kelly at King’s College London, the network aims to develop a pipeline of novel microbicides and enter the first of these new candidate microbicides into the first stages of clinical testing. Successful compounds will be taken forward into Phase 2 and Phase 3 trials – if funding from the European and Developing Countries Clinical Trials Partnership (EDCTP) or another channel can be mobilized.

The Phase 1 trial will enroll 46 women and ask them to apply one of three forms of topical gel. One third of the test group will be given a high dose of the antibodies, a second third a low dosage, and the remaining subjects will be administered a placebo. The antibodies have been designed to guide the immune system’s defences towards their target by: 1) directly eliminating invading agents (e.g. in mucosal surfaces); 2) neutralising infectious agents by blocking essential steps in the infective process; and 3) activating sterilising immune functions (e.g. via the complement system or cytotoxic cells).

The three monoclonal antibodies to be tested, C2F5, C2G12 and C4E10, were developed by the Austrian partner Polymun, and selected due to therapeutic effects shown in previous lab tests. “The antibodies are widely used by the scientific community for research and described in many publications. In addition their unique neutralisation properties, consistent quality, high purity and absence of protein additives make them very attractive microbicide candidates,” commented Professor Kelly. “That’s why we have high hopes for the results of the phase one clinical

trial and that it will prove the first step in the speedy development of an effective formulation.”

For more information about EMPRO, you can visit their website: www.empro.org.

Advocacy in action

A Screening of “In Women’s Hands” in New Delhi, India

India

On the 5th of April, the Global Campaign for Microbicides in India (GCM, India) screened the film “In Women’s Hands” in New Delhi, India to recognize World Health Day (7th of April) (<http://www.global-campaign.org/film.htm>).

The event drew a broad range of audiences from the reproductive and sexual health and rights field, organizations working on other health issues, and researchers from the Indian Council of Medical Research, (a government body coordinating biomedical research in India). GCM India staff member, Anandi Yuvaraj moderated a discussion following the film.

The discussion touched on a host of issues from the role of new technologies in HIV prevention to the importance of addressing structural factors such as Indian society’s reluctance to discuss sexuality. Most of the discussants and the participants strongly recommended that the film be made more India-specific to better address a range of Indian stakeholders including policymakers, civil society, and community. There were also comments on how the film could portray microbicides as one of the many options and highlight female condoms as an existing female initiated method. Moving beyond technologies, participants and the panelists also voiced how female initiated prevention methods like microbicides could help challenge power structures and oppressive norms around sexuality. By the end of the event, most of the audience had signed the GC petition (<http://www.global-campaign.org/petition.htm>), joined the India microbicides listserv, and signed up to receive GC News. Copies of the film and fact sheets on microbicides were disseminated to the audience.

Tobias Resigns

North America

Advocates were stunned by the news that Ambassador Randall Tobias abruptly resigned, Friday, April 27, as head of the Bush administration’s foreign aid programs. According the official State Department press release, Tobias is returning to private life for personal reasons. Press reports, however, widely reported that Tobias resigned after having his name exposed as a patron of a local “escort service” under criminal investigated for prostitution.

President Bush nominated Tobias in July 2003 to lead the President’s Emergency Fund for AIDS relief (PEPFAR), as the first Global AIDS Coordinator. With the rank of ambassador, he was responsible for a start-up program designed to spend \$15 billion over five years, with the largest share going to 12 African and two Caribbean countries that account for roughly half the world population living with HIV/AIDS.

In 2006, Tobias was named the first Director of U.S. Foreign Assistance, raising his rank to Deputy Secretary of State, and giving him the task of both running USAID and coordinating all US foreign aid. In his role as Global AIDS Coordinator, Tobias oversaw, and staunchly defended, policies such as the abstinence-until marriage restriction on PEPFAR prevention funding and a Bush Administration policy requiring that all USAID grantees, among others, sign a pledge denouncing prostitution and human trafficking. What impact, if any, his resignation will have on global AIDS programming remains unclear.

Advocacy Links: Vaccines & Microbicides

India

The need for aligned advocacy – particularly between the worlds of vaccines and microbicides - was crystal-clear last month at a meeting on the impact of HIV vaccine introduction in India, hosted by the International AIDS Vaccine Initiative (IAVI) and the India Council of Medical Research (ICMR). The meeting had drawn high-level policy makers, the heads of several biotech firms as well as key advocates – partly a result of IAVI’s ability to gain support on the issue from members of parliament, leaders in the private sector and even the honorable president of

India. The meeting introduced the results of a mathematical model commissioned by IAVI – similar to one developed for microbicides introduction. The model, presented by Robert Hecht of IAVI, US, estimates that *the impact of a 50% effective vaccine given just to 30% of the population could cut the number of new HIV infection in the developing world by more than half over 15 years.*

Feedback from the audience and panelists on the predictions of the model echoed the same issues that have been articulated around microbicides. Policy-makers immediately insisted that models and research in general must be tailored to India, and even specific regions, if they are to have an impact among leaders. Others expressed concerns around a partially-effective vaccine, especially if introduction would bring about increased promiscuity and dropping the condom with an illusion of full-protection from an injection. Advocacy and researchers stressed that we must continue to prioritize gender issues and empowerment and couch some of the nuanced information around vaccines and other new prevention methods in sex education – as a technology alone will not turn around the epidemic.

The challenge now lies in how, if we find a proof of concept for any of these methods, we will move a product from the scientific bench to trials, through a complicated approval process and gatekeepers who are still grappling with some of the fundamentals, into the hands of those who need them. For vaccines, IAVI has recommended establishing a research and development support fund, which commits long-term financial assistance to developers of novel vaccines; strengthens and improves regulatory responsiveness in India and extends fiscal incentives for the private sector vaccine efforts. Should advocates for microbicides in India push for similar mechanisms or should we start with the basics? Last month two states in India overruled the introduction of sexual education into schools. Will all of our efforts to build a vaccine or microbicides be lost at the ground-level of introduction if policies like these continue to be supported?

However we move forward it is clear that new prevention technologies in India share a common ground. We can only benefit by working together.

Resources

GCM Resource Highlight #1: *Microbicides Research in Kenya: What is going on? (Factsheet #21)*

The Global Campaign announces a new resource for advocates! Fact sheet #21, Microbicides Research in Kenya: *What is going on?* (<http://www.global-campaign.org/clientfiles/FS21-Kenya.doc>).

The microbicides field is relatively new in Kenya, however, various research sponsors, international organizations, and local institutions and organizations are engaging in microbicides-related activities. Most of the research activities so far are cross-sectional surveys measuring HIV incidence among different populations of women and exploring the sexual behavior and related practices among these populations.

This fact sheet summarizes in table form the various microbicide-related ethnographic/incidence, acceptability, safety and efficacy studies currently being conducted in Kenya.

We hope that you find it useful.

GCM Resource Highlight #2: *Who's Who in the Microbicides Field (GCM #4)*

Read the Global Campaign's updated Who's Who in the Microbicides Field to learn more about a selection of groups involved in microbicide advocacy, research and development. Please note that this list is not comprehensive but is meant to give an overview of the field and information on some of the key players.

View the *Who's Who* online at <http://www.global-campaign.org/clientfiles/GCM4-WhosWhoApril07.doc>

We welcome your input and contributions for future issues! Please send emails 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