Global Campaign News – Issue #68
27 July 2006

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 STIs. This and previous issues of *GC News* are available online at http://www.global-campaign.org/gcnews.htm.

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Advocacy in Action

Working through concerns about trials in Thailand

Asia

In January 2006 (in GC News #62), we agreed to keep you updated about an announcement that Starpharma, an Australian bio-tech, had received Fast Track status from the U.S. Food and Drug Administration (FDA) for their product VivaGel™ and the public assertion that this candidate product could possibly reach the market by 2008.

Dr. Tom McCarthy, Vice President for Drug Development at Starpharma, has explained that VivaGel™ is being developed for the prevention of both HIV and HSV (Herpes Simplex Virus). Data regarding its efficacy against HSV may well be available before efficacy trials against HIV produce any results. But he agreed that the possibility of the product getting to market for any indication, even on HSV prevention, by 2008 was "very, very optimistic".

VivaGel™ is entering advanced safety trials in Australia and Thailand. Results from these trials are expected later this year and, if the product proves to be safe, efficacy trials may start as early as 2007. Dr. McCarthy explained that the FDA Fast Track status provides them with several advantages, including:

1. Enabling them to have more regular communication with the FDA as their trials progress
2. Enabling them to submit separate sections of an NDA (New Drug Application – the process through which drug sponsors formally ask the FDA to approve a new drug for sale and marketing in the U.S.) as they are completed, rather than having to compile all the pieces of the NDA to submit at one time
3. Ensuring that the FDA will expedite review of their NDA when it is completed

Even with FDA fast tracking, however, it is very possible that VivaGel™ (if proven safe and effective) will become publicly available in countries other than the U.S. before obtaining FDA approval. This could happen because other regulatory authorities might move more quickly to approve it than the FDA does, or because other countries may see the product, even if only partially effective, as beneficial to their populations even if the FDA feels that it's effectiveness rate isn't high enough to warrant distribution in the U.S.

The January 2006 announcement about VivaGel triggered serious concern among some Thai advocates. We were alerted to these concerns by colleagues working with the Thai Women & HIV/AIDS Task Force (TWAT), the Thai Red Cross Society Community Advisory Board (CAB) and the Thai AIDS Treatment Action Group (TTAG). These groups feel strongly that any trials to occurring in Thailand should be designed with comprehensive consultation with the HIV/AIDS community and women's community who will be recruited to this trial. They were concerned that they had not yet been consulted about how the proposed Thai trial of VivaGel was going to be designed, how participants would be recruited, what safety endpoints StarPharma was planning to track, etc.

Since the Global Campaign strongly supports the advocates' position, we started a process of documenting these concerns, relaying them to StarPharma with a request for answers and then forwarding the answers to the advocacy groups. To further the dialog, StarPharma sent representatives to Thailand in March to meet with some of the advocates. At the Microbicides 2006 conference in Cape Town, the Global Campaign and StarPharma arranged a lunch meeting with representatives of the above organizations as well as U.S. CDC staff working with the Thai Ministry of Public Health and Dr. Prapham Phanuphak, Director of the Thai Red Cross AIDS Research Center.

The face-to-face meeting in Cape Town provided advocates with an opportunity to air their concerns collectively and make initial plans with StarPharma for expanded community involvement in the upcoming Thai trial of VivaGel. StarPharma representatives agreed to meet with TWAT on an ongoing basis, in addition to continuing their existing collaboration with the Thai Red Cross CAB.

On 8 June, the Thai Red Cross held a public forum on microbicides to raise awareness of the VivaGel Trial in Thailand, at which Sureerat Treemanka of the AIDS Access Foundation presented the findings from the Southeast Asian mapping exercise conducted by APCASO (the Asia Pacific Council of AIDS Services Organizations) with support from the Global Campaign (see http://www.global-campaign.org/SEAsia.htm for the full report from the mapping exercise, Preparing Civil Society for Microbicides Advocacy in Southeast Asia).

During the Cape Town meeting, advocates also identified the need for educational materials on the trial that are written in Thai and designed to be easily accessible to readers in their communities. We talked about ways in which the Global Campaign, the CDC staff present, the advocates and StarPharma might collaborate on developing such materials.

Some Thai advocates have also expressed interest in learning more about how trials are being conducted elsewhere and specifically how ethical guidelines are being implemented, particularly in India and Africa. To this end, the Global Campaign has agreed to work with them on organizing a briefing on clinical trial ethics to occur in Thailand later this year.

Congressional briefing on microbicides features researchers and legislators

North America

Over 200 legislators, researchers, government officials, and advocates gathered on Capitol Hill for a lunch breifing on the status of microbicide research—*Microbicide Research, A Promising Prevention Strategy For HIV/AIDS: Can It Save Women's Lives?* The event was organized by Women's Policy, Inc., and co-sponsored by that organization, the Alliance for Microbicide Development, the Global Campaign for Microbicides, and the International Partnership for Microbicides, in cooperation with the lead sponsors of the Microbicide Development Act, the co-chairs of the International Task Force of the Congressional Caucus for Women's Issues, and the co-chairs of the Congressional Caucus for Women's Issues. The Kaiser Family Foundation has provided both a webcast and transcript, and the slide presentations, of the 18 July briefing at the following address:
http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=1773

Cindy Hall of Women's Policy, Inc. welcomed the participants to the briefing which was moderated by Renee Ridzon of the Bill and Melinda Gates Foundation. Zeda Rosenberg of the International Partnership for Microbicides spoke on the current state of microbicide research and development. Salim Abdool Karim of the University of KwaZulu-Natal and CAPRISA discussed the state of the epidemic among women in Africa and the challenges that arise in conducting microbicide clinical trials.

In addition, three leading legislators, Representative Ilena Ros-Lehtinen, Representative Lois Capps, and Senator Barack Obama thanked those working in the microbicides field for their work and for raising awareness in Congress. Senator Obama stated, "I want to commend the work of all of the sponsors of this wonderful event. Each of you, in one capacity or another, dare to dream and share a common vision about the development of a product that could make all the difference in women's lives, that could give them control over their own well-being and would potentially protect them from HIV infection."

He then encouraged the audience to continue to build support for microbicides research and development: "So make sure that all of you are emailing and writing and pushing and shoving your Congressmen and women to get behind this effort. If we have a strong grass roots base, then I am confident that we can actually get this done."

Microbicides at the Toronto International AIDS Conference
Global

The 16th International AIDS Conference (AIDS 2006) will take place from August 13 to 19 in Toronto, Canada. We wanted to alert you to three websites that provide information about the conference:

- The **official conference website** is: www.aids2006.org
- In addition, Kaisernetwork.org will feature **daily updates** and **webcasts** of the conference at: www.kaisernetwork.org/aids2006
- Finally, you can find out about presentations and activities related to **microbicides**, at the Global Campaign's Toronto website: www.global-campaign.org/toronto2006.htm

Please let us know if you will be at the conference by sending an email to info@global-campaign.org and we'll be sure to invite you to any related events!

New leadership for the Irish Campaign for Microbicides
Europe

On 7 June, Irish NGOs gathered to discuss microbicides and build support for increased Irish and European engagement and investment. About 40 participants from civil society, government agencies, and the media attended the "Giving Women Power Over AIDS" Conference, which featured the photographic exhibit of the same name.

Brian Melaugh, Chair of the Board for Cairde and Diarmuid McClean of Irish Aid opened the event, which featured presentations by Kim Mulji, Executive Director of the Naz Foundation International and Anna Forbes, Deputy Director of the Campaign. In his introduction to the exhibit, Senator David Norris told the audience that "microbicides will only become reality if community involvement is done in the right way" and congratulated the work of the Campaign and Cairde to ensure this happens.

The conference marked the joining of two new organisations to the Irish Campaign, the Irish Family Planning Association (IFPA) and the Gay and Lesbian Equality Network (GLEN). IFPA is a member of the International Planned Parenthood Federation, which has been a key partner of the Campaign for a number of years. Meanwhile GLEN (www.glen.ie) campaigns for changes in legislation and social policy in Ireland - in order to advance equality for lesbian, gay and bisexual people.

As a long-time partner of the Global Campaign in Ireland, Cairde led the initiative to give renewed impetus to advocacy efforts in Ireland. The organisation is now stepping aside from the leadership of advocacy efforts in Ireland but will remain part of the Global Campaign. We would like to take this opportunity to thank all the staff at Cairde for their excellent work to advance the microbicides cause over the past seven years and wish the organisation every success in its ongoing work.

Mobilising Nigerians communities to support NPT research and development

Africa

Written by: Morenike Ukpong [mukpong2@yahoo.com]

In May 2006, the steering committee of the Nigerian HIV Vaccine and Microbicide Advocacy Group (NHVMAG) met to define the way forward for the year. One of its targets was to reach out to specific communities in Nigeria with new prevention technologies (NPT) messages tailored to each group. Over the last two months, the NHVMAG secretariat has worked to implement this mandate.

In targeting the medical community, NHVMAG reached over 100 medical women in Nigeria during the organised Medical Women Association of Nigeria's ordinary general meeting held on the 9th of June, 2006. The Association was celebrating its 30th Anniversary and so it was a particularly large gathering of women. All those present received NPT resource materials which introduced them to Microbicide and HIV vaccine issues. Similarly, on 24 June, NHVMAG attended a gathering of over 220 resident doctors from all over Nigeria and held a two hour session with the doctors to discuss microbicide and HIV vaccine issues. The event generated a great deal of interest in the microbicide research and development process, and a principal investigator of an ongoing microbicide trial was on hand to answer dozens of questions.

NHVMAG also reached out to people living with HIV/AIDS (PLWHAs) at two programmes. It participated in a nationally organised candlelight memorial programme to discuss about microbicide and HIV vaccine and the roles for PLWHA in the research and development process. The organisation also partnered with the National Association of People Living with HIV/AIDS through the African Council of AIDS Services Organiations supported ATPP programme to build skills of over 20 PLWHAs with respect to NPT issues. This in turn has been yielding results as a PLWHA reported discussing about NPT during one of her organised television programme in her state following the training. The response has always been overwhelming. NHVMAG hopes to reach out to communities of medical students, women, men, sex workers, clinical trial participants and a host of others during the coming year. For more information about NHVMAG, visit their website, www.nhvmag.org

Policy makers introduced to microbicides at the Joint Parliamentary Assembly

Europe

At the eleventh meeting of the Joint Parliamentary Assembly (JPA) in Vienna, Austria, members of the European Parliament and representatives from the European Commission met together with policy makers from Africa and the Caribbean and the Pacific to discuss development issues. The Global Campaign was invited to speak at the Assembly's Women's Forum focused on Access to health care and how to achieve the three health Millenium Development Goals (MDGs). At the forum, a statement on microbicides and the MDGs.was read on behalf of Francoise Welter, policy director of GNP+ and a Global Campaign steering committee member. Members of Parliament welcomed her speech and discussed the ethics of the microbicides clinical trials.

In addition, British MEP and assembly Co-Chair, Glenys Kinnock, sponsored the Global Campaign to feature its exhibit "Giving Women Power Over AIDS" with a special opening reception on Monday 19th June. Portuguese MEP Ana Maria Gomes, chair of the Women's Forum opened the exhibit, highlighting he need for new prevention

technologies for women. She invited her colleagues from the European Parliament and the ACP countries (the Africa, Carribean, and Pacific countries that are signatories of the Lomé Convention) to read the exhibit and encouraged them to support the Campaign.

PATHWAY bill introduced in U.S. Congress

North America

On 22 June, U.S. Representative Barbara Lee (D-CA) along with 53 other members of Congress introduced a new bill called the Protection Against Transmission of HIV for Women and Youth Act of 2006 (PATHWAY Act of 2006). Some of the specific proposals in the bill include increasing access to female condoms; reducing the incidence of cross generational sex and early/child-marriage; reducing violence against women; supporting the development of micro-enterprise and job training programs; expanding educational opportunities; protecting property and inheritance rights; coordinating HIV prevention services with existing health care services; promoting gender equality; and encouraging the creation and enforcement of equal rights for women. The bill is focused on interventions that are possible today, and does not mention microbicides.

The goals of the bill are to:

- Require the Office of the Global AIDS Coordinator (OGAC) to establish a comprehensive and integrated HIV prevention strategy to address the vulnerabilities of women and girls in each country receiving U.S. assistance to combat HIV/AIDS, including efforts to address such factors as sexual violence and coercion and early marriage as an integral component of prevention efforts.
- Strike the funding earmark requiring that one-third of prevention funds be spent on abstinence-until-marriage programs.
- Ensure that *all* individuals at risk of HIV infection or secondary infection gain skills needed for, and have access to the information, methods and services necessary to protect themselves throughout their lifecycle, thereby ensuring the maximum number of infections are averted.
- Integrate HIV prevention services into basic health care services to ensure increased access.
- Require immediate development of clear program guidance on restrictions in U.S. law pertaining to organizations working with commercial sex workers.
- Increase access to and effective use of both male and female condoms.

The Global Campaign has joined dozens of advocacy organizations that are supporting the bill, with the Center for Health and Gender Equity and Advocates for Youth as the lead organizations. For more information about the PATHWAY bill, please visit www.pepfarwatch.org

Position available: Program Assistant to Global Campaign and Intercambios

North America

We are seeking a talented and energetic individual to support both the Global Campaign for Microbicides and PATH's Intercambios alliance. For more information or to apply, visit http://www.path.org/job.php?id=1938.

Trials Watch

Newly restructured HIV/AIDS clinical trials networks are announced

North America

On 29 June, the U.S. National Institute of Allergy and Infectious Diseases (NIAID) announced the clinical investigators and institutions that will lead NIAID's newly restructured HIV/AIDS clinical trials networks. NIAID, part of the National Institutes of Health (NIH), supports the world's largest portfolio of clinical HIV/AIDS research. These leadership group awards represent the first step of the two-part restructuring process of the HIV/AIDS clinical

trials networks. Awards for the Clinical Trials Units (CTUs), which will carry out the clinical research, are expected to be announced later this year.

Each leadership group will be led by a principal investigator and include a core operations group that will provide administrative and technical support; a statistical and data management center; and a network laboratory structure. The following principal investigators and institutions will lead the newly restructured HIV/AIDS networks:

- AIDS Clinical Trials Group (ACTG)—Constance A. Benson, M.D., University of California, San Diego
- HIV Prevention Trials Network (HPTN)—Sten Vermund, M.D., Ph.D., Vanderbilt University, Nashville
- HIV Vaccine Trials Network (HVTN)—Lawrence Corey, M.D., The Fred Hutchinson Cancer Research Center, Seattle
- International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)—Jay Brooks Jackson, M.D., Johns Hopkins University School of Medicine, Baltimore
- International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)—James D. Neaton, Ph.D., University of Minnesota, Minneapolis
- Microbicide Trials Network (MTN)—Sharon Hillier, Ph.D., Magee-Womens Research Institute, Pittsburgh

Total funding for both the network leadership and the CTUs is expected to reach $285 million during the first year of operation. Because the leadership awards represent the first of two sets of awards for the clinical trials networks, NIAID is issuing these awards with provisional funding. Final budgets will be determined once the CTUs are selected and linked with a leadership group(s) to fully constitute the networks.

The Global Campaign wishes these new Clinical Trial Networks the best of success, and we are committed to providing grassroots support that they require to move forward in the most efficient and effective manner. For additional information, visit the NIAID website: http://www3.niaid.nih.gov/news/QA/leadershipQA.htm

Phase 2 Study of tenofovir gel begins in India and U.S.

Asia and North America

The HPTN 059 study is the first study activated for the new Microbicide Trials Network (MTN) under the leadership of Dr. Sharon Hillier. The HPTN 059 is a multi-center phase II study to determine the safety of tenofovir 1% gel as a vaginal microbicide, and to gain additional information regarding product's acceptability. This study will be a four arm, randomized controlled trial, comparing two frequencies of use (once a day and shortly before sex), and corresponding placebo gel arms. All participants will be counseled to use, and will be provided with, male latex condoms. Participants will be counseled to use the study products daily or with each act of vaginal intercourse. Participants will receive single-use unit dose tube and single-use applicator to be filled by the participant to be used either once daily or with each act of intercourse.

The study will be conducted at three sites: Birmingham, Alabama, USA; Bronx, New York, USA; and Pune, India. The Birmingham Alabama site plans to start screening participants next week; the New York and the Pune, India site will start screening by the end of this month. The proposed study population will consist of up to 200 sexually active, HIV-uninfected women between the ages of 18 and 50, 100 will be enrolled in India and 100 here in the US. Dr. Hillier is also the Protocol Chair of the HPTN 059 Study with Dr. Craig Hoesley (Birmingham), Dr. Jessica Justman (NY), and Dr Smita Joshi (Pune) serving as co-chairs.

Tenofovir is an adenosine nucleoside monophosphate (nucleotide) belonging to the class of acyclic phosphonomethylether nucleosides, and is currently approved as antiretroviral therapy in the oral form. In nonclinical studies the 1% concentration of gel prevented SIV infection in rhesus macaques, and was well tolerated in rabbit vaginal toxicity tests. Preliminary results from the HPTN 050 study have shown tenofovir gel to be safe and acceptable.

Carraguard Phase 3 trial completes enrollment

Africa

The Population Council has recently announced the completion of enrollment for their Phase 3 trial of Carraguard. The trial, which is taking place at three sites in South Africa, began screening in March 2004 and enrollment in April 2004 and has now enrolled a total of 6,299 women. Participants will be followed for nine months, and the Population Council expects follow-up to be complete in March 2007. We offer our sincere congratulations to those who have worked so diligently to achieve this milestone.

Preparing for PREP, Managing Microbicides: Fewer Trials, more Tribulations

Global

Reprint from HHS Watch, May 2006

Below, you will find the May 2006 issue of HHS Watch, written by David Gilden, which focused on research on microbicides and pre-exposure prophylaxis (PrEP). HHSWatch, a watchdog newsletter from CHAMP, monitors and reports on activities related to HIV prevention at Health and Human Services agencies, including CDC, NIH, HRSA and SAMHSA. Special thanks to CHAMP for permission for reprinting the newsletter here. For more information about CHAMP and HHSWatch, visit www.champnetwork.org

Media interest in pre-exposure prophylaxis (PREP) has surged since this winter, when a CDC report at the annual Conference on Retroviruses and Opportunistic Infections described how drugs could protect monkeys from rectal infection with SHIV, a hybrid simian-HIV model virus. Community interest, on the other hand, has been slowly building since the original 1995 monkey study with the anti-HIV drug tenofovir.

There's great allure to the concept that you could take a pill before high-risk sex and not have to worry about condoms. A survey taken at 2004 minority gay pride events found that a substantial number of respondents had heard of the idea of taking antiviral medication to prevent HIV and a few said they had actually tried it. There are even jokes about amalgamating tenofovir and Viagra into one tablet -- both are sky-blue pills.

But is community speculation getting ahead of the research? This April, CHAMP hosted a community forum on PREP in New York City in which PREP researchers presented data and research activists discussed the context and challenges of this approach (All of the presenter's slides are available at: http://www.champnetwork.org/index.php?name=prep)

All the monkey studies have administered drugs on a daily basis, before and after exposing the monkeys to HIV. Participants in the five current human trials likewise take PREP drugs each day regardless of their expected sexual or drug-taking activities. Thus, current PREP strategies under investigation might be more accurately called "daily prophylaxis," similar in manner to prophylaxis taken by people with AIDS against pneumocystis pneumonia.

As with many of the biomedical approaches being studied at this time, including vaccines and microbicides, we may have to anticipate that PREP might not provide complete protection against HIV. PREP may supplement condoms rather than supplanting them. Abandonment of safe sex measures in favor of PREP might ironically leave a population with greater risk than before. CHAMP leaders are participating in a think tank in Los Angeles this week that will consider the implications of different possible results from the trial, ranging from ineffectiveness to partial to full effectiveness.

The monkey studies have used a range of doses and modes of administration that differ from what humans will use. Last winter[1]s CDC study was the first to use relatively normal doses of drugs. This study involved daily injections of tenofovir and emtricitabine (marketed for humans as a combination tablet called Truvada). Previous tests involved higher levels of tenofovir than humans receive.

Also the latest monkey experiment involved a series of 14 weekly rectal virus inoculations, which is closer to real-life circumstances than older studies. The exception was a 2004 CDC study that used tenofovir alone but was otherwise similar to the later combination PREP experiment. The CDC reported at the time that tenofovir delayed infection during weekly rectal challenges; it did not prevent them. It's logical that two drugs proved better than one, but there were only six monkeys. That's hardly enough to base prevention policy on, and underscores the need for careful additional study.

Tenofovir and emtricitabine do seem like the drugs of choice. Both attain very high levels in the genital tract. They also have comparatively few side effects, although there is concern about kidney damage and bone loss with tenofovir. Emtricitabine is exceptionally potent, but HIV develops resistance to it very rapidly. Tenofovir is a weaker drug, and resistance to it appears less frequently. The two together may well make a good knock-out punch, and two of the current human PREP trials, in Botswana and Peru, switched this spring from tenofovir to Truvada.

Even if PREP proves safe and effective in human trials, distributing it in the community will face an enormous economic barrier. The US price of Truvada is about $10,000 per year. Tenofovir alone costs $7,000. Both are made by Gilead Sciences, which supplies the drugs free of charge for the PREP trials but does not otherwise participate (the trials are sponsored by the NIH, CDC, Gates Foundation and Family Health International).

Gilead also has a "Global Access Program" that theoretically applies to 95 resource-poor countries. Gilead offers to sell Truvada and tenofovir in these countries for $360 and $300 yearly. The program was severely criticized last winter by Doctors without Borders. Among other things, the group noted that tenofovir and Truvada were approved in only a handful of countries. Obtaining them elsewhere is a bureaucratic nightmare. Gilead says that it is working with the World Health Organization to facilitate access worldwide. Gilead also has contracted South Africa¹s Aspen Pharmacare to manage its Global Access Program, including obtaining national regulatory approvals.

In any case, a price of $300-$400 a year is too high for millions of potential PREP recipients around the world and even in the United States. "Prevention is better than treatment, but access is an unresolved issue," said Peruvian researcher Pedro Goicochea, who spoke at the CHAMP forum, "A generic version could be the way."

But Goicochea worries that new Western Hemisphere free trade agreements will block this route. They contain a provision banning generic versions of patented drugs. Gilead patents or pending patents in countries with large pharmaceutical industries, like Brazil and India, already serve as a means for stopping independent companies from entering the market.

Managing Microbicides

Gilead is also supplying material for a new 200-woman trial of tenofovir gel as an anti-HIV vaginal microbicide. This NIH-sponsored, placebo-controlled trial is taking place in the US and India. It compares two use schedules, daily or two hours before sex, but is not large enough to measure efficacy, only safety.

A topical agent may well prove more effective than oral PREP. For one thing, you don't have to worry about drugs traveling through the body to reach the rectum or genital track. And the side effect issue is much reduced. Many cheaper agents, both antiretrovirals and more general antimicrobial compounds, would be alternatives as microbicides to Gilead¹s relatively expensive products. For example, UC781 and TMC 120 are non-nucleoside reverse transcriptase inhibitors similar to Sustiva and Viramune, which are widely used for treating HIV. Although highly active against the virus, the UC and TMC compounds are poorly absorbed orally. This lack of systemic absorption makes them bad choices for treatment but great candidates for an anti-HIV microbicide.

More general agents that prevent other STDs would provide additional HIV protection. At present, there are five candidate microbicides in advanced human testing. All of these have broad-spectrum activity. Three (Carraguard, cellulose sulfate gel and PRO2000) are charged polymers that coat viruses and bacteria to prevent them from infecting new cells. A fourth (Savvy) acts as a surfactant whose detergent actions breaks up the fatty layer surrounding HIV and other pathogens as well as sperm. The last is a buffer (BufferGel) that keeps the vaginal environment acidic despite the alkalizing effect of seminal fluid. Vaginal acidity suppresses sperm and many noxious microbes including HIV. These trials are recruiting nearly 25,000 women. Some are looking at other infections and pregnancy in addition to HIV.

Results should be available in 2007 or 2008, if all goes well. But the HIV-transmission rate was so low across all arms of the 2,000-woman Ghana Savvy trial that it was terminated this spring. Many of the other trials are also experiencing lower than expected HIV transmission rates in their placebo arms, possibly a sign that the safe-sex counseling and condoms given trial participants is having an effect. But maybe not: another issue is the higher than expected pregnancy rates. Women are dropped from these trials when their pregnancy becomes known for safety

reasons, although some researchers reconsidering the issue, as the effect of microbicides on pregnancies is a critical area of research.

There may be a relationship between the high pregnancy rate and lower HIV rate. Data from the Savvy trial in Ghana suggests that pregnant women reduce their sexual risk by having less intercourse overall, with fewer partners and more frequent condom use.

Microbicides 2006, the latest in a biennial series of international conferences, took place in Cape Town from April 23 to 26. Over 1,000 researchers and activists attended. At the outset of the conference, Gita Ramjee, conference co-chair and director of HIV prevention for South Africa¹s Medical Research Council estimated that if the trial results are positive and government regulators act quickly, the public could have access to one or more microbicides by 2010. "Quickly" is a problematic word according to Saul Johnson, director of research and evaluation for Health and Development Africa, a South African consulting firm. In a report to the conference, Johnson warned against undue optimism. Approval in countries such as South Africa could prove time-consuming, as will preparing for production and distribution.

In any case, microbicide approval would come none too soon. A 2003 Rockefeller Foundation Report ("The Public Health Benefits of Microbicides in Lower-Income Countries: Model Projections") estimated that providing a microbicide with 60% effectiveness against HIV to just 20% of the population in contact with services in 73 low-income countries would prevent 2.5 million new HIV infections over three years at a savings of $2.7 billion. Johnson, in turn, warned that that microbicide by themselves would not change gender dynamics and end the HIV epidemic.

Fewer trials, more tribulations

At a Microbicides 2006 symposium covering rectal agents, the International Rectal Microbicide Working Group presented an initial overview of the subject, which has long been a poor stepchild to vaginal microbicides. The Working Group, which is cosponsored by CHAMP as well as the Chicago AIDS Foundation and the Canadian AIDS Society, has published the overview in the form of a report, "Rectal Microbicides: Investments and Advocacy" (available at http://www.aidschicago.org/pdf/2006/adv_rectalreport.pdf). According to the Working Group, total annual world spending on rectal microbicide research has been inching upward but will amount to only $7.2 million in 2006. The report concluded by calling for a $350 million research investment to bring a rectal microbicide to market in the next ten to 15 years. Rectal microbicides have been a neglected field for both technical and cultural reasons. The lower gastrointestinal tract is much larger than the vagina. The outer rectal surface is also thinner and more fragile than the vaginal lining. It is consequently more vulnerable to rupture and infection. An effective rectal microbicide would have to cover a great deal of area without causing irritation. It also would have to be slippery and biologically active enough to prevent and protect lesions.

Despite these difficulties, there has been a proof-of-principle: In 2003, researchers described how a microbicide had protected 10 monkeys from a single rectal exposure to the hybrid SHIV virus whereas eight untreated monkeys had become infected. The compound used for this study was cyanovirin-N, an extract from blue-green algae that blocks HIV-cell fusion. There has been some sporadic testing of rectal microbicides in humans, including nonoxynol-9, which proved to be far too irritating. This summer, initial rectal trials of UC-781 will commence at UCLA.

The other major barrier to rectal microbicide research is the stigma attached to anything associated with anal intercourse, especially given the current political climate in Washington. There is, however, an awful lot of anal sex in the real world. Studies have found it is a common practice in heterosexuals, if not as common as in gay men. Condom use during heterosexual anal sex is particularly problematic.

Jim Pickett, policy director for the Chicago AIDS Foundation, put it bluntly in a recent column, "Many gay men are already foregoing condoms for a host of reasons. We know women often don¹t use protection during anal sex. Wouldn¹t it be marvelous to be able to provide these lovely ladies and gentlemen with something to keep their bootys happy and healthy?"

Yes, effective microbicides--or PREP--will help keep people happy, healthy and HIV-less. But the protective promise of these two, separately, together or with condoms, remains poorly charted. The research has plodded along

for over a decade. When compared to the movement on HIV treatment, it¹s a lesson for what happens in the absence of community pressure. Finally, at least, some answers are within sight.

New Resources

New European download centre in English, French, and Russian

We are pleased to announce our new download centre that features European versions of the Global Campaign factsheets in English, French, and Russian. We plan to continue translating our materials into these and other languages in the coming years. Please take some time to explore, and share these resources with your colleagues. http://www.global-campaign.org/EU-download.htm

Article on access to treatment in microbicides trials

The Public Library of Science (PLoS) Medicine website has just published a new article written by Global Campaign's Ann Forbes: "Moving Toward Assured Access to Treatment in Microbicide Trials". The website is open access, so we encourage you to share this link with anyone interested in reading, reproducing or distributing the paper. The article can be accessed at: http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030153

Microbicide Watch monitoring report

The Alliance for Microbicide Development recently announced the release of its inaugural issue of *Microbicide Watch*, a monitoring report that will regularly review the microbicide effort. It offers information, assessment, analysis, and recommendations, all of which provide a frame of reference for policy-makers and advocates. *Microbicide Watch* can be accessed as a PDF on the Alliance website at: http://www.microbicide.org/microbicideinfo/reference/MicrobicideWatch.April2006.FINAL.pdf

New resources on the female condom

The May issue of PATH's magazine, *Outlook*, features new information about the female condom as presented at the September 2005 Global Consultation on the Female Condom. An electronic version of the issue is available on the PATH website: http://www.path.org/publications/publications-listings.php?a=ser&f=Outlook

In addition, PATH and UNFPA produced a colorful and informative advocacy booklet entitled: *Female Condom: A Powerful Tool for Protection*. The booklet goes through a series of questions and answers them one by one, including:

- Can all women use the female condom?
- Does the female condom prevent transmission of STIs?
- Does the female condom have an impact on level of protected sex?
- Is the female condom cost-effective?
- Are there feasible strategies for increasing demand and access?
- Are there prospects for new female condom products?

Both of these new resources are available at: http://www.global-campaign.org/female-condom.htm#[femalecondom

USAID Report to Congress on microbicides funding

The U.S. Agency for International Development recently released its Annual Report to Congress on its health-related research and development activities. The "Report to Congress: Health-Related Research and Development Activities at USAID, May 2006" is available at: http://pdf.usaid.gov/pdf_docs/PDACH111.pdf

AIDS Vaccine Clearinghouse

The AIDS Vaccine Advocacy Coalition (AVAC) is delighted to announce the launch of its new AIDS Vaccine Clearinghouse, a comprehensive and interactive source of AIDS vaccine information on the Internet. The website, www.aidsvaccineclearinghouse.org, provides a gateway to information and a link to people and organizations interested in AIDS vaccine advocacy, research, and global delivery.

Why women should NOT use lemon or lime juice as a microbicide

The Global Campaign together with the AMAG and NHVMAG, recently released an updated fact sheet on why women should not use lemon or lime juice as a microbicide. The fact sheet cites results from three researchers that show that lime or lemon juice in the vagina could increase HIV risk. The fact sheet is available in Word and PDF format at our download centre: http://www.global-campaign.org/download.htm

Weekly and Quarterly publications from the Alliance for Microbicide Development

The Alliance *News Digest* is a weekly, unedited compilation of media; abstracts of; material on other reproductive health and HIV prevention technologies; and matters of policy and politics with importance for microbicide research, development, and advocacy. *The Microbicide Quarterly (TMQ)* covers product development, key discoveries in microbicide science, policy issues and updates, issues related to clinical trials, and highlights of recent media coverage in the field. Periodically, *TMQ* dedicates an entire issue to coverage of major conferences and meetings. View both publications at www.microbicide.org or subscribe by emailing Cfox@microbicide.org

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