

Global Campaign for Microbicides

AND PREVENTION OPTIONS FOR WOMEN



HOME OF THE "LOOKING FOR
MRS. MCCORMICK" FUNDRAISING DRIVE

UPDATE

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SIX MICROBICIDE CANDIDATES READY FOR LARGE-SCALE TRIALS

The resource mobilization activities of the Global Campaign are ever more important in light of recent progress in microbicide research. Six candidate products are nearing large scale effectiveness trials.

As with all new drugs, microbicides must pass through rigorous testing to prove that they are safe and effective before they can be manufactured and distributed. After demonstrating that a product is effective against HIV or other STI pathogens in laboratory tests and that it appears safe and non-toxic in animal studies, candidate microbicides move to clinical trials in humans. There are three phases of clinical

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US CONGRESS SUPPORTS GLOBAL AIDS, MICROBICIDES

Even with the threat of anthrax and other distractions on Capitol Hill, microbicides and global AIDS remained priority issues for supportive lawmakers. During this legislative cycle, the Global Campaign and its allies experienced many small victories in return for hard work and perseverance by Washington-based and US Campaign Site advocates.

The Foreign Operations Bill, which appropriates funding for the US Agency for International Development (USAID), dedicated \$415 million for global AIDS programs. Included in this amount is \$15 million explicitly meant to support microbicides research and development. USAID funds several of the non-profit organizations that are currently involved in microbicide research and development.

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WHY WOMEN IN KENYA NEED MICROBICIDES

In Mumias, a rural district in Kenya where the Society For Women and AIDS in Kenya (SWAK) has enlisted 4,000 members, Mariam Yusuf is a mother of six, who is living with HIV.

Mariam was infected on her marriage bed by her husband who has since died, leaving her at the mercy of her clan and in-laws. If she does not consent to the traditional practice of wife inheritance and the ritual cleansing that goes with it, she risks losing her property rights and ownership of the home her husband left behind. He wrote no will.

Mariam performed part of the ritual cleansing by agreeing to have sex with the would-be inheritor, but she was able to insist on using a condom, thanks to the empowerment she felt through SWAK's work. However, there are millions of women like Mariam throughout Africa, who daily face threats to their sexual rights, their health and their lives that women in the United States can hardly imagine. The demand for women-controlled prevention comes from women like Mariam, for whom a safe, effective microbicide represents the only power they may have in their intimate relationships.

Pauline Ngunjiri is a journalist, community educator and co-director of SWAK.

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LETTER FROM THE DIRECTOR

Dear Friends of the Campaign,

It is with great hope that I write to you this New Year. Many people have said that after September 11th, the world will never be the same. In one fell swoop, our nation was blown apart and came together in ways that few of us have ever experienced.

September 11th showed us that as a nation we *can* mobilize quickly under threat. I am hopeful that as we enter 2002, we will take with us both our newfound sense of vulnerability and the knowledge that when motivated, we can work together successfully to overcome common dangers.

One threat that remains on our horizon is the global specter of AIDS. While death rates have fallen in the West, rates of new infections have not. In hard-hit towns in Kenya and Zambia, 15-24% of 15-19 year old girls are already infected. If current trends persist, 40 million children will lose one or more parents to AIDS in the next ten years, and there will be a hundred million AIDS cases by 2005.

But these numbers need not materialize. An important and very concrete step we can take as citizens is to demand that our government and the governments of other donor nations substantially increase funding for global AIDS programs. Experts estimate that US \$7-10 billion a year is needed to mount an effective campaign against HIV in the developing world. So far the new Global Fund for AIDS, TB and Malaria called for by UN Secretary General Kofi Annan has attracted only US \$1.5 billion dollars, including a paltry US \$200 million commitment from the US government.

In addition to fighting for microbicide-specific monies, we must work in coalition to greatly increase the overall funding available for AIDS programming. Our staff here in Washington D.C. work actively to support global AIDS funding in addition to pursuing our more focused agenda on microbicides and the female condom. We encourage all co-sponsoring groups to do likewise.

As former President Clinton observed in a recent speech in the United Kingdom: "The spread of AIDS is not a misfortune; it is a tragedy – in the Shakespearean sense, which means – a horrible event that didn't have to happen." Activism on microbicides and global AIDS offers both an opportunity and a duty to help re-write this script. For more information on how to get involved, contact our web page at www.global-campaign.org

In peace,

Lori Heise



Mary Ann Stein after receiving her award with (from top left) Bernice Heloo, Ghana; Francoise Bigirimana, Burundi; Salimata Niang, Senegal; Cecile Ndoli, Rwanda; (bottom left) Charlotte Faty Ndiaye, Senegal; and Alice Lamptey, Ghana.

CAMPAIGN HONORS ITS FIRST MRS. MCCORMICK

The Global Campaign for Microbicides honored Mary Ann Stein at an awards dinner attended by nearly seventy advocates from 25 different countries. Mary Ann Stein is the first individual to support the "Looking for Mrs. McCormick" fund-raising initiative. Based on the story of heiress Katherine McCormick's single-handed financing of initial research into the oral contraceptive pill, this initiative draws parallels between development of the Pill and microbicides research today. "Mrs. McCormicks" are women of vision and means who have the opportunity to protect future generations from sexually transmitted infections as Katherine McCormick helped protect earlier generations from unwanted pregnancy.

Held during the Global Campaign Advocates' Meeting on June 29, the awards dinner reminded everyone of the power of one woman to make a difference. Global Campaign Director Lori Heise told the audience of the tremendous strength she has drawn from Mary Ann's confidence and support over the years. The international attendees were impressed by Mary Ann's enormous contribution to microbicides advocacy, and the award presentation was accompanied by the ululations of a dozen African women. As a participant from Kenya wrote to Mary Ann, "Where are the others like you? We women from Africa salute you! Your contribution could save an entire generation in Africa!"

Mary Ann was inspired to see so many powerful advocates together in one place, wrestling with difficult issues, and ready to "lead us into a millennium free from fear of sexual disease..."

LEGISLATIVE ADVOCACY UPDATE

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Likewise, the Labor, Health and Human Services Bill, which appropriates funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) directs the NIH to report to Congress by March 31, 2002 on the status of their new microbicide program. The report also calls upon the CDC to fully fund the clinical trials outlined in its five-year research agenda.

The Global Campaign supported the introduction of the Microbicides Development Act of 2001 in the House of Representatives. The bill (HR-2405) was introduced by Representatives Connie Morella (R-MD) and Nancy Pelosi (D-CA), who also introduced a similar bill in the last Congress. Currently HR-2405 has nearly 40 Congressional co-sponsors. In the Senate, Senator John Corzine (D-NJ) introduced the Microbicide Development Act of 2002 on World AIDS Day. These complementary bills would authorize Congress to spend such sums necessary to accelerate microbicide research and development, and calls for a strategic plan among federal agencies working in the field.

SUCCESS COMES FROM WORKING TOGETHER

Napoleon once said that "ten people who speak up make more noise than ten thousand who are silent." The Global Campaign understands that

microbicides are a public health good that must be supported by public funding. The US government is our primary target in leveraging the investment necessary to ensure that women and men have access to safe and effective microbicides within five years. We are "speaking up" locally and nationally to demand increased and better-coordinated US government support for microbicides research and development. A Washington-based advocacy group, led by legislative advisor Pam Norick and comprising the Global Campaign, Alliance for Microbicide Development, National Women's Health Network, the Alan Guttmacher Institute, Planned Parenthood Federation of America and others, carry the message directly to the offices

of members of Congress and the Administration. Simultaneously, grassroots Global Campaign Sites across the country are contacting, educating and visiting key legislators and staff in their district offices — voicing local interest among the legislators' own constituencies, a crucial activity for getting the attention of policy-makers.

All voices are needed to make our legislative strategy work. Without our collective voices, speaking in our own ways and to our own government, all that our elected officials will hear about microbicides is the silence of Napoleon's ten thousand. Visit our website: www.global-campaign.org for more details and information about how to get involved.

GLOBAL ADVOCATES SHARE EXPERIENCES, RENEW COMMITMENTS

The Global Campaign for Microbicides was inaugurated in July 1998 by a handful of advocates collecting petition signatures in the line for the ladies' room at the 12th International AIDS Conference in Geneva. Three years later, in July 2001, the Global Campaign hosted an International Advocates Meeting for over 60 people from 25 countries.

The meeting brought together both veterans of microbicides advocacy and recent recruits, in order to update their knowledge of microbicides and the female condom, share past successes and useful experiences, and to strategize for the future. For both the US and foreign participants, the encounter reinforced the sense of belonging to a global effort increase prevention options for women

From the Advocates:

"Coming from Africa which currently has over 70% of all HIV infections and meeting all those people so committed to the fight against HIV/AIDS was so refreshing for me. I felt a bond of unity and hope."

Alice Lamptey, Ghana

"Success stories from the African delegates in promotion of female condoms and their persistent efforts for its availability and use were learning experiences. I left with a lot of appreciation for the commitment of all members of the Global Campaign."

Renu Seth, India

"I've been to four international advocates meetings in the past three years and this one is the most motivating and ACTION oriented by far! The others were excellent for sharing information and experiences but the Advocates meeting is leading to some real concrete results and advancement beyond shared knowledge."

Deborah Meacham, Chile

"I have spent four weeks since the conference slipping microbicides into every conversation I can find. It's a good party trick - and I'm starting to hear others get back to me about microbicides."

Robin Gorna, Australia

and men.

During the three-day meeting, advocates from different areas developed strategies for adapting the Global Campaign's agenda to the needs and context of their regions. Advocates from India are now preparing a national meeting on women-controlled prevention, several groups from Latin America are adding female condom education and advocacy to their programs, and organizations in the US are working to include men's needs for microbicides in their advocacy messages.

WHAT YOU CAN DO

In the US, supporters of the Global Campaign can call any member of Congress (Representative or Senator) toll free by dialing the Congressional Switchboard at 1-800-648-3561 and asking for him or her by name. Then ask to talk to the staffer who handles health issues.

Your message doesn't have to be complicated. Two simple things to say are:

I want _____ (your Representative's name here) to co-sponsor HR 2405, Microbicide Development Act of 2001, if he/she hasn't done so already.

I want _____ (your Senator's name here) to co-sponsor S 1752 the Microbicide Development Act of 2002, if he/she hasn't done so already.

MICROBICIDE TRIALS

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trials. In Phase I, a product is tested among a few healthy, low-risk women to investigate whether it is non-irritating and safe. Phase II trials enroll a larger number of women and again examine the safety of the product for women whose risk may be higher. Safety studies are conducted among men as well to establish the safety of candidate products for women's male partners. Phase III involves a large-scale trial enrolling thousands of participants to determine if a product actually works to prevent HIV or STIs and also to collect longer term safety data. No drug or technology can proceed to Phase III effectiveness trials without first going through Phase I and II safety trials.

Two microbicides, Buffer Gel™ and Pro-2000™, will go head to head in Phase III trials next year. Buffer Gel is a "dual-action" product that is both a contraceptive and an anti-HIV agent. It works by maintaining the vagina's natural acidity, even in the presence of alkaline semen, thereby creating an environment inhospitable for sperm and HIV to survive. Pro-2000™ gel contains a synthetic polymer that interferes with a virus' ability to bind with target cells, thereby preventing infection. Because its mechanism of action does not interfere with sperm, Pro-2000™ is non-contraceptive. Buffer Gel and Pro-2000™ will be compared head to head within the same clinical trial in at least four sites in South Africa, Thailand, India, and Tanzania. Conducting one larger trial rather than two separate ones for the different products maximizes resources and speeds the answer of whether either product really works to protect women from HIV and other STIs.

Another microbicide ready for Phase III clinical trials is Carraguard™, derived from the seaweed extract carrageenan. A popular food additive, carrageenan is non-toxic and relatively inexpensive. Like Pro-2000™, it inhibits HIV from binding with host cells and would potentially be another non-contraceptive microbicide, representing an important advance for women and men wishing to conceive without risking infection.

Other microbicides are poised for expanded safety and efficacy trials as well. Two of these, dextrin sulfate and cellulose sulfate, are also inhibitors of viral binding and cell fusion. Developed under the brand name Ushercell™, cellulose sulfate may protect against chlamydia and herpes and could be a contraceptive as well. Emmelle™, under research in the UK, would be non-contraceptive and specifically protect against HIV. Another possibility for a microbicide is lactin vaginal capsules, which enhance the vagina's natural defense system by boosting the presence of lactobacillus - the "good" bacteria that help to keep the pH of a healthy vagina low. The absence of lactobacillus is associated with higher incidence of bacterial vaginosis, a condition that can facilitate HIV infection.

Microbicide development will only keep pace with the accelerating science if sufficient resources are dedicated to testing these products in parallel. This requires recognition by scientists and policy makers that the development of a safe and effective microbicide is a high priority in women's health and HIV prevention, and that progress should not be limited by lack of resources for clinical trials. The Global Campaign is committed to mobilizing sufficient resources for such research, and to ensuring that community and public interests are represented throughout the process of microbicide development and testing. *Taken from The Guttmacher Report on Public Policy (10.01) and the Alliance for Microbicide Development Product Database (12.01)*



Clockwise: Jane Meyer (IO), Mara Kennedy (NY), Kerry Barthel (PA), and Dr. Kim Dickson-Tetteh (South Africa). Advocates meet for dinner at the International Advocates Meeting in Warrenton, VA.

FROM THE FIELD: GLOBAL CAMPAIGN, IOWA

Iowa microbicide activists kicked off the establishment of their Global Campaign site with a Community Forum in Davenport, Iowa on June 6. Hosted by Planned Parenthood of Greater Iowa, the forum drew an enthusiastic audience of service providers, advocates and policy makers, including a representative of Senator Harkin's office. It featured presentations by Anna Forbes, US Field Organizer for the Global Campaign, and Dr. Radium Bhattacharya, Director of the Gujarat AIDS Awareness and Prevention Project in Ahemdabad, India. Dr. Bhattacharya also serves as Coordinator of the Indian Network of NGOs on HIV/AIDS. Both organizations are co-sponsors of the Global Campaign.

"Supporting the development of microbicides offers one more way that Iowa can claim its global commitment to the health and development of people everywhere," said Jane Meyer, Vice-President for Education at Planned Parenthood of Greater Iowa. "The awareness and excitement is building as we tell the story."

Following the Forum, Iowa site organizers identified members for an initial steering committee and hosted their first informational meeting. Sixteen people representing family planning, international understanding, health care, higher education, and advocacy organizations attended.

The Global Campaign Iowa site has also set a goal to obtain 6,300 signatures on the Petition for Greater Investment in Microbicides by February 1, 2002 and to send 630 letters or emails to US legislators for support of the Microbicides Development Act of 2002 and for funding appropriations. The 6,300 signatures and 630 letters are a symbolic acknowledgment of the 6,300 women worldwide who contract HIV each day.

MICROBICIDES AT UN SPECIAL SESSION

This summer, the United Nations held its first General Assembly dedicated to a single health topic: the global HIV/AIDS pandemic. The Special Session (known as UNGASS) brought together heads of state from many countries, as well as Ministers of Health, Finance, and other high-ranking national leaders. Their task: to create a Declaration of Commitment to serve as a blueprint for the global fight against AIDS.

The Global Campaign was involved from the beginning, commenting on the numerous drafts and working with advocacy groups to ensure the full participation of civil society in the UNGASS proceedings. Despite controversy at times, the Declaration was unanimously approved and lays out an ambitious plan for responding to HIV/AIDS.

The final document recognizes that "effective prevention, care, and treatment will require... increased availability of and non-discriminatory access to... microbicides..." In addition, the Declaration includes a commitment to expand access to female condoms, and to "increase national and international investment in HIV/AIDS-related research and development including...female controlled methods and microbicides."

The Global Campaign sponsored advocates from Ghana, India, Kenya, Nigeria, Rwanda, Senegal, Trinidad, Uganda, and Zimbabwe at UNGASS. These advocates were acknowledged publicly for their work during a panel entitled, "Microbicides: What? Why? How? When?" co-sponsored by the Population Council, the Rockefeller Foundation, UNAIDS, and the UK Mission. The panel featured the Honorable Clare Short, Secretary of State for International Development of the United Kingdom, who acknowledged that "a more intensified and coherent international effort to maximize the prospects for a microbicide product soon is urgently needed."

Dr. Peter Piot, Executive Director of UNAIDS, described himself as a long-time advocate for



Participant at the Church Women United Conference in Milwaukee, Wisconsin signs the petition to increase microbicide research and funding

microbicides and spoke of his agency's commitment to the issue. Dr. Lincoln Chen of the Rockefeller Foundation acknowledged that ten years ago when women's groups encouraged him to pay attention to microbicides, he did not listen. Today, the Rockefeller Foundation is coordinating an initiative to facilitate microbicide research and advocacy.

In the Meantime...

While advocates, scientists, and supportive donors are working to get safe, effective microbicides to people within five years, there are alternatives to the male condom available today, or will be soon. The female condom and the panty condom provide two such options that could help protect women and men from HIV and STIs right now.

THE FEMALE CONDOM: AN IMPORTANT OPTION FOR WOMEN WORLDWIDE

The Reality™ female condom was approved by the FDA in 1993 and has spread to over 70 countries. Research indicates high interest and willingness to use female condoms among women from many populations. Women report some major advantages of the female condom, including its effectiveness for both STD and pregnancy protection, the ease of use, and increased sexual pleasure. Many women also like the fact that they have greater control over safer sex negotiation and behavior and that the female condom

offers a viable alternative for men who dislike the male condom.¹

Though attention has focused on use of the female condom internationally, women and men in the United States have also shown interest. In one study, African-American women in New Orleans enthusiastically approved of the female condom because they felt it gave them greater ability to practice safe sex without challenging the power of their male partner.² Studies in Philadelphia and Alabama showed that providing women with female condoms and training to use them increased the likelihood that women used protection during sex.^{2,3} Despite poor press in the US that has portrayed the female condom as less popular than it actually is, 40-60% of couples who try the female condom not only like it, they continue to use it.⁴ The Reality Female Condom is produced by the Female Health Company (www.femalehealth.com).

PREVENTION CAN BE PRETTY: THE FEMALE PANTY CONDOM

Another tool for female-controlled disease pre-

vention and contraception is under development through a collaborative effort between the Pacific Institute for Women's Health and the Zebra Foundation. The female panty condom is a biodegradable, disposable panty with a latex center that fits inside a woman with specially designed panties that are worn during intercourse. The latex center of the panties extends into the vagina and covers the entire genital area, providing expanded protection against STIs, including HIV. The panty comes in several attractive styles, fabrics and colors and breaks new ground by creating a "sexy" method of prevention.

The panty condom is currently in Phase II clinical trials in California and moving through the process of US FDA approval (expected in early 2002). Already supported by women's health activists and public health researchers, the female panty condom could offer a much-needed prevention option for women around

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HIV AND STI RATES RISE IN THE US, UK

The rate of HIV infection from heterosexual sex among adolescent girls in the US skyrocketed by an alarming 117 percent between 1994 and 1998, according to a recent report in the *Journal of the American Medical Women's Association* (2001; 56: 94-99). The report, based on data from 25 states, also highlighted that females aged 15 to 19 experienced a 90 percent increase in the rate of HIV infection due to injection drug use during the same period.

"As young women reach the age where HIV risk behaviors like drug use and sexual activity are initiated, the number and rate of HIV diagnoses increase," noted Dr. Lisa M. Lee, study co-author at the Center for Disease Control and Prevention in Atlanta. "This signals the need for intensive, focused, culturally-appropriate HIV prevention efforts among adolescent women before they initiate risk behavior."

Another study reported that cases of STDs are rising in the UK, and a reluctance to practice safe sex has been a contributing factor. Cases of gonorrhea among men have soared from 261 in 1995 to more than 700 last year, and cases of genital warts and herpes are also on the rise. Of the 6,223 new cases of gonorrhea among women, 40 percent were in the 16 to 19 age group. A record 3,425 cases of HIV were reported in the UK last year - a 14 percent increase from 1999, and the highest figure recorded in any year since testing became widely available 16 years ago. Currently 30,000 people are estimated to be HIV positive in England, of whom 10,000 are aware of their condition.

In an even more startling report, forty percent of boys in the UK have never heard of AIDS or HIV, according to the survey "Young People in 2000." The report was compiled by the United Kingdom Schools Health Education Unit by quizzing more than 42,000 young people between ages 10 and 15. In addition, more boys than girls said they would not take care to avoid infection with the virus. Fifty-seven percent of older males said they did not know where they could go to get free condoms. *Taken from HIV, Reuters Health (07.20.01), BBC News Online (11.9.01), and Bristol Evening Post (United Kingdom) (07.30.01)*

FEMALE PANTY CONDOM

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the world who are struggling to protect themselves for HIV and STIs.

In 2000, the Pacific Institute for Women's Health conducted discussions with high-ranking government representatives, female sex workers and NGOs in South Africa, Uganda, Senegal, Nigeria and Zimbabwe. In each country, the female panty condom was seen as an urgently needed alternative to both male and female condoms. Sex workers in particular indicated great interest in using the panty condom, citing its attractiveness to men, as well as the possibility that male clients would not realize that it was in use. Men interviewed said they would encourage a female partner to use it, citing both the panty condom's attractiveness to them as well as their desire to share the responsibility for HIV/AIDS prevention with women. Both men and women confirmed that male resistance to using traditional male condoms remains high.

The most promising prospects for the introduction of the female panty condom is in Uganda, where several high-level government officials have expressed a strong commitment to being part of introduction efforts. The Pacific Institute is currently planning to initiate these introduction efforts in Uganda in collaboration with the Zebra Foundation. For more information, visit www.janesway.tierranet.com.

¹ Cecil, H., et al. The Female Condom: What We Have Learned Thus Far. *AIDS and Behavior* 2(3): 241-256 (1998)

² Latka, M. et al. Male Condom and Female Condom Use Among Women After Counseling in a Risk-Reduction Hierarchy for STD Prevention. *Sexually Transmitted Diseases* 27(8):431-437 (2000)

³ Artz, L. et al. Effectiveness of an Intervention Promoting the Female Condom to Patients at STD Clinics. *American Journal of Public Health* 90(2):237-244 (2000)

⁴ Boston Women's Health Book Collective.

<http://www.ourbodiesourselves.org/female.htm>. 8/22/01

CALENDAR OF EVENTS 2002

- Jan 8: Alliance for Microbicide Development Meeting, Washington, DC
- Jan 16-18: 5th Bangkok Symposium on HIV Medicine
- Mar 4-7: STD Prevention Conference, San Diego, CA
- Mar 19-22: 14th National HIV/AIDS Update Conference San Francisco, CA
- May 12: Global Campaign Pre-Conference to Microbicides 2002, Antwerp, Belgium
- May 12-15: Microbicides 2002, Antwerp, Belgium
- May 28-31: Global Health in Times of Crisis, Washington, DC
- Jun 14-16: International Society for Equity in Health Toronto, Canada
- July 7-12: XIV International Conference on AIDS, Barcelona, Spain
- Aug 13-18: 9th International Women and Health Meeting, York University, Toronto, Ontario, Canada
- Sept 19-22: 6th Annual United States Conference on AIDS, Anaheim, CA

MICROBICIDE UPDATE

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