



Global Campaign News – Issue #74

An exposé on unproven Genvia

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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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Unproven product claims watch

Chicago Reader exposes promoters of Genvia

Global

On November 23, the Chicago Reader ran an exposé by Tori Marlan on Genvia, a vagina spray that its promoter, Sam Evans, says “is 99.9 percent effective” as an HIV microbicide. The Global Campaign became aware of Evans’ claims last January and has repeatedly asked him and the board members of the Africa AIDS Fund for data to support these claims. The Fund is a US-based tax-exempt organization founded by Evans (see www.africaaidsfund.org) whose purpose is to stem the spread of HIV/AIDS in Africa primarily by shipping millions of doses of Genvia to the hardest-hit countries. To date, the Global Campaign has received no response to its inquiries.

“Genvia has been a focus of our Unproven Product Claims Watch for almost a year,” said Global Campaign Deputy Director Anna Forbes. Dr. Evans claims that he personally helped finance the development of Genvia in China and that the product has been approved as a microbicide by Chinese regulatory authorities. With assistance from the regional representative of the World Health Organization, the Global Campaign has confirmed that Genvia is actually povidine iodine, and that it has not been licensed by the Chinese government for use against HIV and other STIs, as Evans claims. The Campaign is pursuing several strategies to thwart the continued promotion of Genvia, including working through pro bono attorneys to get the US Internal Revenue Service to review the appropriateness of letting the Africa AIDS Fund solicit charitable contributions to support the distribution of a product with unproven HIV claims.

“Genvia is currently not available for purchase as far as we know,” Forbes explained, “although Evans insists that it is available for sale in China.” Although Genvia may not be easily accessible, povidine iodine is available over the

counter in many countries. The Liberian parliament recently passed a law requiring the mandatory use of Genvia for HIV prevention. "How do we know that such promotion won't trigger rumors that douching with iodine will protect a woman from HIV?" Forbes added. Since iodine can cause vaginal drying and irritation, Forbes wonders if this practice might increase a woman's risk of HIV infection. "If we don't counter these false claims effectively now," she noted, "we may face a situation where the popular promotion of an easily available substance encourages women to adopt practices that later prove to be harmful. This is exactly what happened with the promotion of lime juice as a possible "natural microbicide."

The full article in the Chicago Reader is available at: <http://www.chicagoreader.com/features/stories/hivspray/>

Research findings

Hormonal contraception does not increase risk of HIV acquisition

Global

Reprint from FHI News on December 7, 2006.

A study, published in the January 2, 2007 issue of the journal AIDS (now available on the journal's Web site, www.aidsonline.com) has found no overall statistically significant association between the use of either combined oral contraceptive (COC) pills or depot medroxyprogesterone acetate (DMPA) and HIV acquisition. This four-year, prospective study, funded by National Institute of Child Health and Human Development, was conducted among some 6,100 HIV-negative women in Uganda, Zimbabwe, and Thailand. The primary finding of this study provides the best reassurance to date for women in need of highly effective contraception in settings of high HIV risk.

The results from the study do not indicate that any changes should be made in the provision or use of DMPA or COCs. Neither the WHO nor the International Planned Parenthood Federation, which have reviewed the study results, plans at this time to change their guidelines for hormonal contraceptive use.

However, because hormonal contraceptive use has not been shown to protect against HIV infection, hormonal contraceptive users should still use condoms consistently and correctly with each sex act if they are not in mutually monogamous relationships with uninfected partners. Such individuals should also reduce their number of sex partners. These long-accepted recommendations remain unchanged regardless of the method of contraception a woman uses. Meanwhile, both members of a couple should be tested for HIV to learn whether they are infected or not. In most settings - even those with high HIV prevalence - most couples will not be infected. However, in areas of high HIV prevalence, even if both members of a couple are uninfected, condoms should still be used unless mutual monogamy is certain.

The study also explored whether sexually transmitted infections (STIs) modified the relationship between hormonal contraceptive use and HIV acquisition. Surprisingly, it found that among the approximately half of study participants testing negative for herpes simplex virus-2 (HSV-2) at enrollment, those who used either COCs or DMPA had a statistically significant increased rate of HIV acquisition compared to non-users. This finding was unexpected, has no clear biological mechanism, and may be due to chance. Thus, as is often the case with unexpected study findings, further research must evaluate this potential association.

In summary, the results of the present study:

- Provide family planning providers, women, and women's partners with important, new, and generally reassuring knowledge about the association between hormonal contraceptive use and HIV acquisition.
- Do not indicate that any changes should be made in the provision or use of DMPA or COCs.
- Serve as a reminder that while hormonal contraceptive use is safe and highly effective for preventing unintended pregnancy, only consistent and correct condom use and mutually monogamous relationships among uninfected individuals protect against STIs/HIV.

For further background information, please see: *NICHD press release, available:*
http://www.nichd.nih.gov/news/releases/hormonal_contraception.cfm

Advocacy in action

New European funding for microbicides

Europe

Belgium has become the latest European country to contribute to microbicide research and development with a three million euro grant to the International Partnership for Microbicides (IPM) over three years. Only a short while ago, the Belgian government believed itself to be too small to give funds to the development of vaccines and other new prevention technologies. At an event on World AIDS Day to mark the announcement hosted by Armand de Decker, the Belgian Minister of Development, and attended by Her Imperial and Royal Highness Princess Astrid of Belgium, IPM's CEO Zeda Rosenberg gave tribute to the hard work of the Global Campaign in pursuing Belgium's participation in the field.

Belgium's neighbour, the Netherlands, increased its contributions with a further 12 million euros to the IPM on 20 November. The Netherlands now leads the world in terms of per capita investment in microbicide research. These announcements send a strong message to other small donor nations that they can play a significant role in the search for a safe, effective and affordable microbicide. Katy De Clercq, of SENSOA, the Flemish NGO on sexual health and HIV, stated "This is a promising and important first step for the Belgian government to fund the search for a long term solution for the worldwide HIV epidemic."

World AIDS Day also saw the announcement of the first French public funding for the IPM. This was a small donation of 200,000 euros but again a signal of the increasing recognition of the need for research.



The Campaign's photographic exhibit 'Giving women power over AIDS' has recently been displayed in a series of high-profile venues including the European Parliament, the first European Union Development Days conference in Brussels and at the Dutch Ministry of Foreign Affairs on World AIDS Day itself. Speaking on behalf of the Global Campaign at the event in the Dutch Ministry, long-time campaigner for microbicides in the Netherlands, Monique van der Kroef said, "The Global Campaign is most of all a movement of persistence, without which we would not be celebrating this new funding today."

A coalition of 13 NGOs in Brussels came together to mark World AIDS Day in the European Parliament to push for universal access to prevention, treatment, care and support. The distribution of female condoms proved to be the star attraction at the GCM stand. Members of the European Parliament learned about the future formulations that microbicides could take. [pictured here from left to right Wanjiku Kamau and Celine Mias of the International Partnership for Microbicides with MEP Max van den Berg of the Netherlands, looking at potential formulations for microbicides.]

Bush Issues Order To Lift Ban on HIV-Positive Foreigners Entering U.S.

North America

Reprint from KaiserNetwork.org: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=41413
President Bush Friday on World AIDS Day issued an executive order to lift a provision of U.S. law that bans HIV-positive foreigners from entering the country without a special waiver, the San Francisco Chronicle reports (Russell, San Francisco Chronicle, 12/2). Congress in 1993 enacted legislation that prevented HIV-positive foreigners from obtaining visas or citizenship. According to the U.S. Department of State, if any foreigners traveling to the U.S., including people from countries not requiring visas, reveal that they have a "communicable disease of public health significance," they are prevented from entering the country. The same rule applies to foreigners seeking permanent residence in the U.S. (Kaiser Daily HIV/AIDS Report, 11/22). The current law allows waivers to be issued so HIV-positive people can enter the country to attend special events. Under the new rule proposed by Bush, HIV-positive people would obtain a "categorical waiver" for business or tourist visas for visits of no more than 60 days. It

is not clear whether visitors still would be required to declare their HIV status. HIV/AIDS advocates after the announcement praised Bush's decision but called for all restrictions on HIV-positive immigrants to be lifted. "It's a step away from a terribly discriminatory and inappropriate policy, but it doesn't go far enough," Physicians for Human Rights Executive Director Leonard Rubenstein said, adding, "If you want to remove stigma from AIDS, you have to go the whole distance and eliminate all restrictions on entry to the United States for people with HIV" (San Francisco Chronicle, 12/2).

A press release from Gay Men's Health Crisis (GMHC) and Immigration Equality about this ban is available at: <http://www.gmhc.org/about/releases/061206.html>

An additional article that describes some of the history of this ban is available at NAM's [aidsmap.org](http://www.aidsmap.com/en/news/5FAF6B5F-A486-4E50-A0A6-7C3AFD0530F5.asp): <http://www.aidsmap.com/en/news/5FAF6B5F-A486-4E50-A0A6-7C3AFD0530F5.asp>

IWHC's releases report on top ten wins for women's health and rights in 2006

Global

Microbicides made it to the list on the International Women's Health Coalition "top ten wins for women's health and rights in 2006". The full report summarizes the "win" and then goes on to describe what is coming up next.

The top ten are as follows:

1. Colombia recognizes women's right to abortion
2. African ministers commit to sexual and reproductive health
3. Head of World Health Organization declares women's health a top priority
4. A new weapon to fight cervical cancer
5. Women and HIV/AIDS become an international priority
6. India passes violence against women law
7. U.S. Voters reject extremist abortion policies
8. Emergency contraception goes on sale over the counter
9. Proving an important cause of maternal deaths
10. Microbicides enter final testing phases

The IWHC report is available at: <http://www.iwhc.org/resources/toptenindex.cfm>

U.S. Senator Obama talks about AIDS and microbicides at evangelical church

North America

At a politically charged time after the U.S. congressional elections, Senator Barack Obama (D-Illinois) and Senator Sam Brownback (R-Kansas) both spoke at an HIV/AIDS conference hosted by Rick Warren, the founding pastor of the evangelical Saddleback Church in Lake Forest, California. The talk took place on World AIDS Day and addressed the role of religion in the fight against the AIDS pandemic. According to E.J. Dionne, of the Washington Post, the conference "sent a signal: A significant group of theologically conservative Christians no longer wants to be treated as a cog in the Republican political machine."

Senator Obama spoke passionately about the HIV/AIDS prevention needs, and a role that microbicides could play: "Now, too often, the issue of prevention has been framed in either/or terms. For some, the only way to prevent the disease is for men and women to change their sexual behavior - in particular, to abstain from sexual activity outside of marriage. For others, such a prescription is unrealistic; they argue that we need to provide people with the tools they need to protect themselves from the virus, regardless of their sexual practices - in particular, by increasing the use of condoms, as well as by developing new methods, like microbicides, that women can initiate themselves to prevent transmission during sex. And in the debate surrounding how we should tackle the scourge of AIDS, we often see each side questioning the other's motives, and thereby impeding progress."

Read E.J. Dionne's article in the Washington Post, Message from a Megachurch at: http://www.washingtonpost.com/wp-dyn/content/article/2006/12/04/AR2006120401048_pf.html

Read Senator Obama's full speech at: http://obama.senate.gov/speech/061201-race_against_time_-_world_aids_day_speech/index.html

Thailand to issue a new compulsory license for HIV/AIDS drugs

Asia

The Global Campaign wishes our heartiest congratulations to our Thai colleagues for this positive outcome!

Article re-printed from Keith Alcorn at NAM, 29 November 2006.

<http://www.aidsmap.com/en/news/A774C0DF-0EB5-401B-A2DC-7E196831F8ED.asp>

Thailand's Government Pharmaceutical Organisation (GPO) said yesterday it plans to apply for a compulsory license to begin making its own versions of efavirenz and lopinavir/ritonavir next year.

Thailand's Ministry of Health signalled yesterday that it will issue a five-year compulsory license to allow the GPO to manufacture efavirenz, reducing the cost of the drug to \$20 a month. The patent holder Merck & Co will be paid a royalty of 1% on sales in Thailand.

GPO Director Mongkol Jivasantikarn told the *Bangkok Post* that the organisation plans to manufacture indinavir, saquinavir, lopinavir and ddI in the next two years, if necessary under compulsory license.

Civil society organisations, led by people living with HIV, have been campaigning for the introduction of compulsory licensing of HIV drugs in order to reduce the cost of antiretroviral treatment in Thailand.

Thailand has over 500,000 people living with HIV, and 80,000 are already receiving antiretroviral treatment. The World Bank has estimated that Thailand could reduce the cost of second-line therapy by 90% if it introduced compulsory licenses for all the drugs it needs in second-line therapy, saving itself \$3.2 billion over the next 20 years

First-line HIV treatment in Thailand currently consists of GPO-Vir, a Thai generic version of d4T, 3TC and nevirapine. However Thai doctors want to use efavirenz instead of nevirapine in patients with elevated liver enzyme levels.

Thailand's move follows months of controversy over a free trade agreement between Thailand and the United States that was attacked as endangering access to medicines by Thai AIDS activists and international non-governmental organisations. The US-Thai FTA included clauses providing far greater intellectual property protection than required under the TRIPS agreement – a so-called TRIPS-Plus agreement.

The Free Trade agreement negotiations are currently on hold until a democratically elected government is in place; a military coup in September removed Prime Minister Thaksin Shinawatra, who had been in office since 2001. Mr Thaksin had consistently resisted compulsory licensing, said Thai AIDS activists.

New Resources

Partnering for Care in the HIV Prevention Trials Network

In 2004 the Prevention Leadership Group (PLG) of the HIV Prevention Trials Network (HPTN) recommended that the Network strive to improve the standard of care that exists at HPTN sites and to document efforts, activities, and accomplishments towards this end. The PLG charged the Ethics Working Group to develop, with community input, a survey to document alliances already in place and to assess what the HPTN is doing at each site to provide or facilitate HIV-related care and, ultimately, other health-related care partnerships.

The Partnering for Care project was undertaken to meet this objective and the results are now available on-line in a comprehensive 2-part report. A description of the methods and overall findings from the project can be found in Part I of the report. The detailed case studies in Part II demonstrate the full complexity of the challenges faced by HPTN

sites; neither problems nor solutions are simple. The dedication, creativity, and initiative of the research teams and community members described in the case studies are a source of inspiration in this regard. Hopefully, this report will help to generate additional resources to support these and similar efforts as well as to address the broader health care access and delivery problems that make such efforts necessary.

Both parts of the report are available at: <http://www.hptn.org/ResearchEthics/PartneringForCare.htm>

New article on microbicide development and clinical trials by Ian McGowan

The December issue of the journal, *Biologicals*, features an article by Ian McGowan of the David Geffen School of Medicine at the University of California, Los Angeles. The article provides an excellent overview of microbicide development and an update on the candidate pipeline. The citation is: *Biologicals*, December 1, 2006; 34(4): 241-55, and it is available at: <http://www.sciencedirect.com/science/journal/10451056>

Microbicides Trials Network launches website

As announced in GC News #68 in July 2006, this summer, the U.S. National Institutes of Health launched a set of new trials networks, including the new Microbicides Trials Network (MTN). The MTN, part of the Magee-Women's Research Institute and Foundation with affiliations to Magee-Women's Hospital of UPMC and the University of Pittsburgh, will be a worldwide collaborative clinical trials network that evaluates the safety and efficacy of microbicides designed to prevent HIV transmission. The mission of the MTN is to reduce the sexual transmission of HIV through the evaluation of microbicide products. The MTN plans to develop and/or execute 15 separate clinical trials of microbicides between 2006 and 2013. Their new website is at: www.mtnstopshiv.org

Also, Dr. Sharon Hillier who leads the MTN presented an overview of the network on a recent International Rectal Microbicides Working Group call. See that powerpoint presentation, at: http://www.aidschicago.org/pdf/2006/adv_hillier_mtn.pdf

Call for Applications for WHO Sexual and Reproductive Health Research Course

The Special Programme for Research in Human Reproduction (HRP) at WHO in collaboration with the Geneva Foundation for Medical Education and Research will again sponsor a course on sexual health research from 26 February- 04 April 2007. The aim of this course is to update researchers from developing countries with the latest advances in the field of sexual health research; and to build capacity to conduct multi-disciplinary research on sexual health in diverse settings. Some scholarships are available from the coordination group. Others can be assisted if necessary to find funds to attend.

The application form, and brochure for the course can be accessed through the following web link: http://www.gfmer.ch/Medical_education_En/PGC_SH_2007/csh_application_form_2007.htm

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