



Global Campaign News January 15, 2003

Welcome to the biweekly *Global Campaign News*! The *Global Campaign News* is a forum for international exchange on microbicide activities and information with an aim to build a more informed and integrated movement for microbicide development and other prevention options against HIV and STDs.

We welcome your input and contributions. Correspondence can be addressed to info@global-campaign.org. If you would like to unsubscribe to the Global Campaign News, please reply to this e-mail with the subject line: UNSUBSCRIBE.

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University of Pittsburgh Awarded \$8 Million NIH Grant To Study HIV-Blocking Microbicide Gel. *From: Kaiser Daily AIDS Report, January 13, 2003*

The NIH has awarded an \$8 million grant to the University of Pittsburgh to conduct laboratory and clinical studies of UC781, a "powerful antiviral agent" that could potentially be used to develop a vaginal gel to block HIV transmission, the Pittsburgh Post-Gazette reports. The National Institute of Allergy and Infectious Diseases and the National Institute of Child Health and Development have granted four such awards as part of a program to develop a vaginal gel microbicide that would be effective against HIV and ultimately against all sexually transmitted diseases. The university will use the grant to study a microbicide containing UC781, a molecule that "tightly binds to HIV and prevents it from infecting cells," according to the Post-Gazette. UC781 belongs to the non-nucleoside reverse transcriptase inhibitor class of antiretroviral drugs, which directly inactivates the enzymes that HIV needs to replicate. Sharon Hillier, a senior investigator at the Magee-Women's Research Institute, the organization leading the effort, said that due to the potency of the agent, only a small amount would be needed, making the cost of the agent less than one cent per application (Spice, Pittsburgh Post-Gazette, 1/10). Hillier said that human testing to determine the safety of a gel formulation of UC781 is expected to begin by the end of this year. Clinical tests of the agent's effectiveness against HIV would be conducted through the HIV Prevention Trial Network, an international consortium of clinics and hospitals, and would require additional funding. Biosyn Inc., the Philadelphia-area pharmaceutical firm that developed the gel formulation, is researching the possibility of placing the microbicide in a vaginal ring (Pittsburgh Post-Gazette, 1/10).

VaxGen Officials Report Increased Statistical Confidence in Human Trial Results of HIV Vaccine. *From: Kaiser Daily AIDS Report, January 9, 2003*

VaxGen officials, who are preparing to release by early March results of late-stage human trials of an experimental HIV vaccine, called AIDSVAX, yesterday said that higher-than-expected patient retention rates and increased HIV incidence rates will lead to higher confidence levels, Dow Jones reports. Of the 5,400 people in the study -- which is taking place in the United States, Canada, the Netherlands and Puerto Rico -- 95% participated in the entire trial, 10% more than expected, and the incidence rate of HIV has risen from 1.5% four years ago to 3%, Dow Jones reports. Lance Ignon, a VaxGen spokesperson, said these figures are "good news from a bio-statistical standpoint," but they are not a guarantee of the vaccine's effectiveness or of FDA approval (Bennett, Dow Jones, 1/8). Researchers are trying to determine whether the vaccine candidate is effective in protecting against HIV infection, and trial results showing the effectiveness of the vaccine will be "certain to generate enormous attention."

Implication for Microbicides: The high follow-up rate achieved in the VaxGen trial bodes well for future microbicide trials, which also will face the challenge of enrolling thousands of participants in multiple trial sites around the world. Even more importantly, the release of the VaxGen results in early March represents a "teachable moment" that will have important implications for all HIV prevention advocates. If the AIDSVAX vaccine proves not to be effective, it will be important to emphasize that drug development normally involves many false starts before success is achieved. If the vaccine demonstrates some efficacy, it will be important to emphasize that on-going microbicide and vaccine research must proceed, even as we work to make this "first generation" vaccine available to those who need it most. The Global Campaign will be sending out "**talking points**" to help prepare advocates for responding to the AIDSVAX results.

Microbicide US Legislative Update

On January 7, the 108th Congress of the United States was sworn in. Because the 107th Congress failed to pass most of the federal spending bills for FY 2003, most government programs are currently functioning under a Continuing Resolution (CR) that expires on January 31. (A CR is a stopgap measure that Congress passes to allow money to continue to go to federally funded programs for a specific period of time). Continuing Resolutions essentially maintain the status quo during times when the old budget has expired and the new one is not yet in place.

One of the main US budget concerns for microbicide advocates is the amount of money allocated to the National Institutes of Health because that is the main branch of government investing in microbicides research. The FY 2003 budget currently being proposed by the House of Representatives includes relatively little funding for HIV/AIDS services but does propose a 14% increase for the NIH. This is consistent with the annual 15% increases that NIH has received in the past few years.

By contrast, the budget President Bush will be proposing for FY 2004 (which he is scheduled to unveil on February 3) is expected to include less than a 1% increase for the NIH budget. His proposed dramatic slow-down on NIH funding, together with a range of other factors, is likely to make our job as microbicide advocates more difficult in the coming year if his budget proposal succeeds.

Recognizing that we (like a lot of other advocacy constituencies) are facing a very challenging year, the Global Campaign for Microbicides is adopting a three-part legislative strategy for 2003. We plan to:

1) Update the "Microbicide Development Act " and have it re-introduced in both the House and Senate as soon as possible. This will involve recruiting some new prime sponsors in the House and Senate as Rep. Connie Morella (R-MD), who had consistently championed the bill over the last decade, is no longer in office. Her absence, together with new leadership in both the House and Senate, means we have to re-evaluate our political position, building some new alliances and strengthening others in order to maximize our chances of getting the legislation introduced and passed.

2) Continue to work on the appropriations process, trying to get our Congressional allies to include specific language in the FY 2004 budget strongly encouraging NIH to increase the percentage of its funding allocated specifically to microbicide research and development. We are currently analyzing NIH figures for FY 2002 to determine how much of the amount they claim was spent on microbicide research really was used for that purpose. In the most recent fiscal year we've analyzed (FY 2001), the NIH spent barely 2% of its AIDS research budget on microbicides. Without specific direction from Congress, it seems unlikely that that percentage will increase -- especially as NIH faces the possibility of shrinking funding overall. For this reason, it will be more important than ever this Spring to urge our legislators to fight for the incorporation of specific microbicides funding language in the FY 2004 appropriations bills.

3) Collaborate with our colleagues in other constituencies to develop legislation in which microbicide research is presented as part of a larger picture. Right now, we are working with HIV vaccine, Tuberculosis and Malaria prevention advocates to draft a "New Prevention Technologies Act" that would provide funding and support to the development of new technologies (including microbicides and vaccines) to prevent all three of these major global killers. That bill is still in the fairly early stages of development.

It may, in fact, end up being folded into a new version of the "U.S. Leadership Against HIV/AIDS, TB, and Malaria Act," the bill we fought to get passed before the conclusion of the last Congress. It is expected that some new version of the Leadership Act will be introduced by late 2003 or possibly early 2004. As it is developed, we need to continue to work to assure that microbicides are fairly and visibly included -- and making them a prominent part of the new Prevention Technologies Act may be a good way to do that.

As this legislative agenda develops, we will provide you with regular updates regarding what's happening and what grassroots action is needed to drive our success.

Action Alert on Global AIDS Funding

Join with thousands across the US in calling the White House Comment Line on Thursday, January 16th – 202-456-1111. The White House is planning its Budget Proposal right now. Callers are insisting President Bush present a serious plan to fight the epidemic in his FY 2004 Budget Proposal. WE NEED YOUR HELP to call for the resources needed to address the AIDS pandemic.

WHAT TO DO:

Call the White House Comment line at 202-456-1111 before 5pm Eastern Time. Follow the prompts to leave your message with a live operator. You can also email the President at www.StopGlobalAIDS.org

WHAT TO SAY:

I am calling to urge the President to offer an historic AIDS initiative and include significant new funding for programs in his FY 2004 budget. I urge President Bush to announce a bold, comprehensive US initiative. This should include at least \$3.5 billion to combat AIDS, TB and malaria with at least \$2.5 billion of that for the Global Fund to fight AIDS, TB and Malaria. These funds must be in addition to other spending to assist impoverished countries. Full support is also needed for development and promotion of female-controlled prevention methods, including microbicides.

BACKGROUND:

The US is still not doing its fair share to fight AIDS. Read the Washington Post Editorial: <http://www.washingtonpost.com/wp-dyn/articles/A27367-2002Dec22.html>

Over 300 organizations from across the country and every part of the world have called on President Bush to lead a new initiative to stop global AIDS. For info click here:

<http://www.globalaidsalliance.org/PAI.html>

Where would the funds go? The Global Fund to Fight AIDS, TB, and Malaria -- an innovative funding mechanism to channel resources to where they are most needed

For more info see www.globalfundatm.org. Questions? Call 202-397-7700

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