

HHS WATCH: JUNE 2005

Welcome to the third issue of HHSWatch, a watchdog newsletter from CHAMP that monitors and reports on activities related to HIV prevention at Health and Human Services agencies, including CDC, NIH, HRSA and SAMHSA.

HHSWatch is a resource for community members, policy advocates, researchers and anyone interested in more fully understanding and tracking the committees, panels and administrators whose recommendations and decisions affect our work.

HHSWatch is committed to providing an outlet for those concerned about infringements upon science-based HIV prevention and treatment, and will respect your wishes for confidentiality. If you are interested in contributing information or suggesting a story, please contact champ@champnetwork.org.

HPV Vaccine on the Way – but for Whom? HPV (human papillomavirus) is spread by body surface contact during sexual activities. Some varieties of this very common virus cause genital and anal warts. The more serious kinds are carcinogenic. Fortunately, an HPV vaccine is nearly here. Merck plans to bring its version to the FDA later this year, and Glaxo is only a few months behind. It's not a moment too soon -- even with widespread monitoring via Pap smears, the United States records some 14,000 cases of cervical cancer per year, including around 5,000 deaths. For the world as a whole, there are nearly 300,000 deaths annually.

Molecular tests have revealed that all these cases are due to persistent infection with the carcinogenic strains of HPV. Over 90% of persons clear HPV within 6 to 24 months, and any existing lesions or warts disappear. Persistent infection with the cancer-causing strains can lead to serious trouble in a small proportion of cases. Men and women infected anally run the risk of anal cancer as much as women with cervical infections risk cervical cancer.

HPV is related to HIV transmission, too. Though there are few studies of the question, it is widely thought that active infection – and certainly the lesions associated with such infection – make people vulnerable to acquiring HIV. HPV also may increase genital HIV levels, and this would be

another way HPV promotes HIV transmission. HPV is certainly more progressive in persons who already have HIV.

HPV is sexually transmitted, is incurable if persistent and ubiquitous, and half of sexually active Americans have been infected with one strain or another. Condoms are only partially protective (though they do reduce the chance that HPV will lead to cervical cancer). For these reasons, HPV has become a favorite subject for abstinence promoters. "Giving the HPV vaccine to young women could be potentially harmful, because they may see it as a license to engage in premarital sex," Bridget Maher told *New Scientist* magazine this spring.

The response by Merck and Glaxo diverges considerably and mirrors the content of their vaccines. Glaxo's *Cervarix* includes only HPV strains 16 and 18, which are responsible for 70% of cervical malignancies. It plans to market the vaccine exclusively to women, as a cancer prevention agent. The company claims it would not be cost-effective to also vaccinate men and has conducted no studies with males or on anal cancer. Merck's version, *Gardasil*, includes HPV 6 and 11 in addition to 16 and 18. Strains 6 and 11 are implicated in 90% of genital warts. Merck has an ongoing study in 4,000 young men that includes an anal cancer component. A government study is evaluating *Gardasil* in HIV-infected preteen boys and girls. It provides an opportunity to evaluate its preventive potential in persons with HIV. "We see the vaccine as an addition to the toolbox for controlling HPV," said Kelly Dougherty of Merck.

Such talk brings up the issue of how resources will be apportioned among the various anti-HPV "tools." With the arrival of the vaccines, cash-strapped government agencies and other healthcare payers may see an opportunity to save money. Screening programs, in that case, could tend to become vaccination programs, with fewer resources devoted to ferret out and manage chronic infection. Such a trend has already occurred in hepatitis B.

The HPV vaccines in any case have compelling supportive data. Initial efficacy trials for both vaccines have demonstrated close to 100% prevention of precancerous cervical lesions over the short term – up to 36 months. Another compelling factor is that the vaccines – at an expected price of \$300 – promise to be a marketing bonanza. So what will the FDA do? Both companies claim confidence that the agency will recognize the medical consensus that vaccines will be a great help in controlling HPV-associated disease. This momentum may well overcome any counterpressure from the right.

Approval will be just the beginning of the story. Broad public access will require determined effort, especially to see that the vaccines reach teens before sexual debut and uninfected gay men. If availability is limited to affluent adult women, the vaccines' public health benefits will be greatly circumscribed.

Congressional “Witch-hunt” Targets Harm Reduction Proponents: On February 16, surprising memos were sent out to the State Department's USAID staff working on programs for containing HIV and intravenous drug use. They requested detailed information on the use of USAID funding of “harm reduction” efforts, needle exchanges, in particular. (The United States Agency for International Development – USAID – is the unit in charge of distributing foreign aid.) The source of the request was the House of Representative's Subcommittee on Criminal Justice, Drug Policy, and Human Resources and its chair Mark Souder (R-IN). They wanted the information for an “on-going investigation of the international harm reduction/drug legalization movement.” There followed a list of detailed questions about national programs in specific countries, their needle exchange efforts and the connection of those efforts with their USAID funding and certain other funders, especially those founded by multibillionaire George Soros. The Soros groups support harm reduction policies and services for drug users around the globe.

February 16 was also the day on which the Souder subcommittee held a hearing on “Harm Reduction or Harm Maintenance – Is There a Such Thing as Safe Drug Abuse?” In his introduction to the hearing Souder stated, “Instead of addressing the symptoms of addiction... we should break the bonds of [drug users'] addiction and make them free from needles and pushers and pimps once and for all... Some of these “harm reduction” programs, I must add with embarrassment and with apology... are financed by the United States Agency for International Development, the federal government's foreign aid agency.” Souder also singled out Soros-connected organizations for particular criticism.

The USAID staff was originally given five days to comply with the request. That was only the beginning. Some 7,000 documents later, the effort continues to this day. Insiders and outsiders agree that USAID has done nothing that violates the law against US funding of needle exchanges. USAID does support many “wraparound” activities such as educate and methadone substitution therapy. Observers say that Souder is confused about the aims of these harm reduction activities, which attempt to keep people alive until they can receive treatment.

According to Holly Burkhalter, senior policy analyst at Physicians for Human Rights, Souder's underlying aim is to break any connection with George Soros. Meanwhile, his subcommittee is "forcing USAID to go through papers rather than work with most needy people on earth."

The net result could be a chilling effect in which the USAID staff takes care to increase its distance from anything related to needle exchanges. Burkhalter says, "Seventeen government studies show that needle exchanges save lives. We'll see a tidal wave of AIDS cases unless we can provide clean needles one way or another."

ACLU suit aims to stop Silver Ring Thing: The American Civil Liberties Union has sued the HHS in Boston federal court over another attempt to fund religious-based abstinence programs. The focus in this case is the Silver Ring Thing (SRT), which has received more than \$1 million from HHS to support its three-hour abstinence pledge spectacles. The elaborately staged shows, replete with high-tech lighting effects, music and skits, end with teenagers coming forward to take an abstinence pledge. For this and \$12, they receive a silver ring (to be removed on their wedding day and given to their spouses) plus a special version of the new testament that contains abstinence lessons. Pledgers are also asked to accept Jesus as their personal savior.

SRT's newsletter and follow-up program is rife with religious content, too. Last year, SRT founder Denny Pattyn explained his apocalyptic vision to the BBC, "I actually believe that we are approaching the return of Christ, which is a huge event... We're not really putting our energy into abstinence as much as we're putting it into faith. Abstinence is the tool that we're using to reach children."

Carol Rose, executive director of the Massachusetts Civil Liberties Union, responds, "The federal government should not underwrite the religious indoctrination of Massachusetts students. The 'Silver Ring Thing' is nothing more than a vehicle for converting young people to Christianity. Our taxpayer dollars should play no part in such a program."

David Gilden researched and wrote this issue of HHSWatch.