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**January 2004 • Volume 19, Number 1 • Pages 1-12**


## IN THIS ISSUE





# Government prevention research 'hit list' draws protests from scientists

*Recent NIH 'hit list' is unprecedented, they say*

HIV-prevention researchers say the current administration and Congress are undermining scientifically sound behavioral research through political scrutiny of investigators who are working to understand the transmission of a deadly epidemic.

The most recent assault on HIV behavioral research came in October when more than 150 investigators discovered that their names were on a list of about 250 questionable grants circulated by Republican members of Congress and the National Institutes of Health (NIH).

Called a "hit list" and "scientific McCarthyism" by U.S. Rep. Henry A. Waxman (D-CA), the list included the names of HIV investigators and other scientists who have worked in the areas of sexual behavior and HIV risk taking.

Some members of Congress, scientists, and professional organizations quickly denounced the NIH list and said they hoped that such deliberate intimidation would not have a chilling effect on HIV and behavioral research.

"It's hard enough to get an NIH grant without having people worrying about whether the grant title or abstract will raise eyebrows," says **Kenneth Mayer**, MD, professor of medicine and community health at Brown University in Providence, RI. Mayer is on the board of the American Foundation for AIDS Research (amfAR) of New York City, an organization that encourages and helps to fund AIDS research, and also is the medical research

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**AIDS Alert**® (ISSN 0887-0292), including **AIDS Guide for Health Care Workers**®, **AIDS Alert International**®**,** and **Common Sense About AIDS**®, is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **AIDS Alert**®, P.O. Box 740059, Atlanta, GA 30374.

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**Editorial Questions**

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director at Fenway Community Health in Boston, and is an infectious disease specialist at Miriam Hospital in Providence.

"Particularly with HIV people, who often are socially or economically disenfranchised, this is not easy research to do," he says. "So having this kind of ideological intrusion is not going to help us solve the AIDS epidemic, and it only wastes time." Mayer has collaborated on some of the projects on the NIH list, although his own name was not on the list.

This well-orchestrated attack on HIV behavioral research is unprecedented, according to HIV prevention scientists and prevention service providers.

"I don't recall anything of this magnitude and this almost very deliberate attempt to stifle research and to politicize research," says **Ronald Johnson**, associate executive director of the Gay Men's Health Crisis in New York City. "This is really unprecedented from our perspective," he adds.

## *A case of micromanagement?*

Mayer concurs. "I've never seen this kind of micromanagement or manipulation of specific grants and investigators on specific lists," Mayer says.

One scientist, who occupied 12 lines on the list with a half-dozen projects, says it would be a huge mistake if Congress continues to attempt to micromanage NIH-funded science.

"People on the list are unfairly singled out for work that turns out to be meritorious," says **Tom Coates**, PhD, a professor of infectious diseases at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). "It seems to me that the work is being singled out because of titles and populations, and it has nothing to do with anything about scientific merit."

Some professional organizations have come to the defense of researchers.

"We think this type of research is critical research, very important public health research, and what NIH chooses to fund ought to be based on what NIH scientific committees deem good science, sound methodology, and relevant scientific questions, and those issues ought to be the only determinants," says **Rhea Farberman**, director of communications for the American Psychological Association (APA) of Washington, DC.

"Specific researchers have been targeted for interrogation, and their subjects of inquiry denigrated," **Judith Auerbach**, PhD, amfAR vice president for public policy, said in a statement released shortly after the list's existence was made public. "Solving the mysteries of the body, human behavior, and the natural world that surrounds them demands faithful adherence to intellectual curiosity alone, not to politics, opinion polling, or prejudice."

The list, which she and some media reports attributed to the Traditional Values Coalition, an organization that represents churches and a fundamentalist Christian political agenda, included some oddities, such as a study on post-exposure prophylaxis and a training grant for postdoctoral fellows. Also, some names on the list were scientists who died years earlier, including Evelyn Hooker, known for her groundbreaking work in the area of homosexuality.

The Center for AIDS Prevention Studies in San Francisco had about 20 scientists on the list, says **Cynthia Gomez**, PhD, co-director of the center and an assistant professor at the University of California, San Francisco (UCSF).

After the initial shock wore off the center's researchers renewed their personal and professional commitments to HIV research, she says.

"We have even a stronger commitment now," Gomez adds. "Some of these scientists who were not on the list but who do similar research said, 'Maybe we should be put on the list to highlight the importance of the research that's being conducted here.'"

Some of the researchers on the list were contacted by NIH and told that the studies for which they had already received funding were being further reviewed and they might want to submit an updated abstract, she says.

"I believe what was happening is there was an attempt when the list became known to explain the significance of each study on the list," Gomez explains. "Some institutes could do this by providing an updated abstract."

The request came in the form of "Can you give us succinct paragraphs on the significance of your study?" she says.

Gomez, who has been an NIH reviewer, says that any additional scrutiny of research grants that have been approved is problematic, particularly if the scrutiny is of a philosophical nature.

"I don't know if there's a clear understanding by the general public on how rigorous the grant-review process is. I've been a reviewer for NIH, and we have strict criteria by which we allow any research to move forward, and one of the

principles any study has to pass is their significance in terms of advancing the cause of knowledge," she says.

Some involved in HIV-prevention work say that the people who made up such a list and who have used it to intimidate scientists are not concerned with advancing knowledge and science.

"We see to a certain extent these attacks as cousin to the attacks on HIV-prevention providers in the last three to four years," says **Mark McLaurin**, associate director for prevention policy with the Gay Men's Health Crisis.

"One of the main avenues of attack against HIV-prevention programs has been that there's no science behind them, no scientific basis for interventions," he says. "So on one hand, they are attacking the interventions as not being scientifically based; and on the other hand, they are attacking the scientists who are conducting the research that would provide the scientific basis for HIV-prevention interventions."

Even HIV-prevention organizations that have not been targeted have become sensitive to the changing ideological environment.

Founded in 1989, the Black Educational AIDS Project of Baltimore is a small prevention project run with a $400,000 budget that provides prevention interventions to high-risk populations, such as male commercial sex workers. In the last few years, the organization has been concerned that its funding will end because there appear to be fewer grants for which its work would qualify, says **J. Lawrence Miller**, PhD, executive director.

Miller, who has a theology background, insists that the organization's prevention projects include abstinence messages, but he acknowledges that it would be futile to make that the only message when one is dealing with young, black, and homeless sex workers who are in and out of jail for the hustling.

"I'm a black, gay Republican, who is HIV-negative, and [the action against HIV-prevention programs and research] really does surprise me," he explains. "I'm very, very surprised that the public health agenda seems to be driven more by feeling than by science."

Since President George W. Bush took office, the HIV-prevention community has noticed changes in how prevention organizations and prevention researchers have been treated. First, there were federal audits of specific prevention programs that target men who have sex with men (MSM), and this was followed by a congressional floor debate in which Rep. Patrick Toomey (R-PA) asked for a vote to include an amendment that would stop NIH funding of five ongoing projects, most of which dealt with HIV risk behaviors. The amendment failed by two votes. **(See story on recent attacks involving HIV-prevention work and research, p. 5.)**

Since so much of the research presented on the NIH list involved MSM populations and other high-risk HIV populations, a more cynical view of the political attacks on HIV prevention research would be that the attackers don't care about the impact of AIDS on these populations because the right wing finds them unacceptable, says **Daniel Ciccarone**, MD, MPH, assistant professor in family and community medicine and anthropology, history, social medicine at UCSF.

Ciccarone, who was not on the list, says that the very existence of such a list has had a chilling effect among HIV investigators and has changed the way researchers write their grant proposals and abstracts.

## Passing political muster

"There's a lot of hearsay of how to get around [public scrutiny]," he says. "So we're no longer doing studies of MSM; we're doing studies of men and HIV risk." The point is that scientists are changing titles of their research so that when the titles are published in the *Congressional Record* they will pass political muster, Ciccarone says.

He admits to making changes to one of his own grant proposals to make sure it is appropriate for the new political ideology.

Coates says he won't make any changes to future grant proposals. "If we start doing that in response to this kind of pressure, then we're dead in the water," he says. "We've got to do the work that's important, and I'm very committed to doing that."

The other danger is that researchers who haven't worked in the area of HIV behavioral study but are encouraged to do so by a seed grant from a group, such as amfAR, now will decide not to make the switch, Mayer says.

"Some people who may be uncomfortable with that process, when they have two to three ideas or directions they might do work in might pick the easier one because they don't want to be embroiled in controversy," he says.

Ideologically, the attack on HIV-risk behavior research sets the entire field back several decades to the very old arguments that if you study or put any money toward studying problem behaviors

then you are, in essence, liberalizing the problem and giving the behaviors more credence, states Ciccarone.

"We show time and time again that research sheds light on how risk happens in certain groups, and if you want to address the problem, then you have to address it in a culturally savvy way," he adds. "The head-in-the-sand approach, which we've seen before, doesn't work."

So the greatest danger from the political attacks on HIV prevention research is that it will prevent investigators from studying and creating prevention social marketing tools that are the most effective, Ciccarone says.

"We're now developing a much more culturally savvy approach to studying high-risk populations, and it's going to be a lot more effective," he says. "But to do that, you need to get in close to risk populations and understand them well." ■

## Attacks on prevention work have increased

*One researcher experienced in-depth federal audit*

The HIV-prevention community could be forgiven for a little paranoia at the beginning of 2004. In recent years, they have experienced increased public political scrutiny and threats that funding will be pulled on projects aimed at reducing the transmission of HIV among men who have sex with men (MSM), injection drug users, and other high-risk groups.

HIV-prevention programs first came under fire in the fall of 2001. First, former Inspector General Janet Rehnquist investigated Centers for Disease Control and Prevention (CDC)-funded prevention programs at STOP AIDS Project Inc. of San Francisco and called the programs obscene. **(See story about Rehnquist and STOP AIDS, *AIDS Alert*, March 2002, p. 29.)**

Then Claude Allen, deputy secretary for the Department of Health and Human Services (HHS), was assigned to examine all HHS-funded HIV/AIDS activities. And AIDS service organizations and others who receive CDC grants received letters reminding them to adhere to 1992 requirement for content of AIDS-related written materials.

Within months of this increased federal scrutiny and search for obscenity among HIV prevention work, a chilling effect was experienced by new applicants for CDC prevention grants.

For example, the South Dakota Department of Health in Pierre turned down grant applications for two MSM risk-reduction seminars to be conducted by the Sioux Empire Red Cross in Sioux Empire. It also turned down a proposal by The Center, a gay and lesbian counseling service, that had planned to use CDC funds to expand its HIV/AIDS peer education system.

According to South Dakota officials, the state's secretary of health was concerned the Sioux Empire program might not meet with federal approval.

By early 2003, HIV-prevention researchers were hearing rumors about additional scrutiny of their own work, and this fear was confirmed July 10, 2003, when the U.S. House of Representatives held a floor debate on an amendment to the appropriations bill to fund the departments of Labor, Health and Human Services, and Education.

Researchers say the amendment was written to pull National Institutes of Health (NIH) funding from five ongoing research projects that some congressmen said they found repugnant. After the American Psychological Association of Washington, DC, and other behavioral science and public health organizations intervened, the amendment failed with a 210-212 vote.

The projects singled out by Rep. Patrick Toomey (R-PA) were:

- **Grant HD04368: Mechanisms Influencing Sexual Risk-Taking.** This grant funded a study of emotions and moods that influence sexual risk-taking behavior.
- **Grant RD01HD039789: Spatial and Temporal Interrelationships between Human Population and the Environment.** This grant, awarded to Michigan State University, funded a five-year project that examines interactions between human population and the environment in the Chinese Wolong Nature Reserve, which conserves endangered giant pandas.
- **Grant R03HD039206: Longitudinal Trends In The Sexual Behavior Of Older Men.** This grant was awarded for the study of changes over time in a range of behavioral and cognitive factors associated with male sexual functioning and behavior.
- **Grant R01DA013896: HIV Risk Reduction Among Asian Women.** This grant funded a study of drug use and HIV risk behaviors among Asian female commercial sex workers at massage parlors in San Francisco.
- **Grant R01MH065871: Health Survey of**

**Two-Spirited Native Americans.** This grant was awarded for the study of Native American gay, lesbian, bisexual, and transgender individuals, who are an understudied, but at risk for multiple psychological and health problems.

Also, at least one of the investigators singled out by Republican congressmen found that his research projects were scrutinized by several federal agencies from which he received funding.

Tooru Nemoto, PhD, an investigator and assistant professor at the University of California, San Francisco, who works at the Center for AIDS Prevention Studies in San Francisco and who conducted the research on Asian sex workers, was audited by members of each agency that funded his project, all of which were under HHS, says **Cynthia Gomez**, PhD, co-director of the Center for AIDS Prevention Studies.

"The outcome was that there was nothing out of order," she says. "But he did have to dedicate quite a bit of time going through the audit with the investigators."

The center has about 70 studies funded through HHS at any given time, and Nemoto's study was the only one that was selected for an audit, Gomez adds. "His was the only one that went through that process, and it certainly had been targeted and identified as a research study that people disagreed with," she says.

Then came the latest assault on HIV-prevention research and other behavioral research when NIH director Elias Zerhouni, MD, was asked at an Oct. 2 House hearing for an explanation of the medical benefits of a list of 10 research projects, including the five that had been in Toomey's amendment in July.

When NIH officials asked for a copy of the 10-study list, they were sent a list of more than 250 grants for research involving HIV, high-risk sexual behaviors, substance abuse, and MSM. While the original source of the list was left undetermined, there were reports that it originated within NIH at the instigation of a group called Traditional Values Coalition.

On the Traditional Values Coalition's web site, it states, "For [more than] four years, we have been researching and studying the grant proposals that the National Institutes of Health have been giving to groups to study certain kinds of sexual behaviors. Now we have discovered that nearly $100 million has been given to study sexual habits and trends of different groups. These studies are awful and pornographic. Now we are lobbying our friends in the Congress to hold hearings so we can show everyone how the Homosexual Agenda gets millions of dollars to promote their lifestyle. We are on the front lines for you, and we are your voice here at the Capitol for Christian Values."

The ministry group's web site also provides links to NIH research the group finds unacceptable, including the largest category of HIV-prevention research of every type, including HIV prevention among the general population, youths, gays and lesbians, injection drug users, etc. From a quick look at the web site's listed grants, it would appear that the only prevention research to which it does not object are abstinence-only projects.

Rep. **Henry A. Waxman** (D-CA) wrote HHS Secretary Tommy G. Thompson Oct. 27, 2003, to protest the NIH list and to urge him to denounce scientific McCarthyism.

"This hit list appears to be part of a calculated effort to subvert science and scientists at NIH to a right-wing ideological agenda," Waxman said in the letter.

He also called for the NIH to stop contacting scientists on the list and asking them for further details and explanations about their studies when there already is plenty of information contained within the lengthy grant applications.

"This atmosphere of intimidation is unacceptable," Waxman wrote. "If past is any prelude, no amount of detail about grants involving sexuality or condom use will satisfy those who are ideologically opposed to such research. ■

# Jails in unique position to ID high-risk population

*Cook County in Illinois serves as model*

Ten million people pass through the United States correctional system each year, and 2 million of these people are incarcerated, while a large proportion of the remaining 8 million spend at least a little time behind bars.

Since studies have shown that people in the correctional system are at greater risk for HIV than the general population, it makes good public health policy to provide prevention, testing, and counseling services to people in jails and prisons, says **James B. McAuley**, MD, MPH, director of

pediatric infectious diseases and associate professor of pediatrics and internal medicine at Rush-Presbyterian-St. Luke's Medical Center in Chicago. McAuley also was the medical director of Cook County Jail until September 2003.

A blinded study of the HIV rate among people incarcerated in the Cook County jail, located in Chicago, found that 2.5% of the 2,500 people tested for HIV had the virus, he says.

While that rate is lower than the HIV infection rate of New York prisons, it still is five times the HIV prevalence rate of the Chicago area, McAuley adds.

"What's fascinating is that the vast majority of people in jail will go back into the community, and these often are individuals who don't have easy access to health care," he explains. "The vast majority are poor and disenfranchised; 85% are male, and poor men between the ages of 17 and 40 do not typically have health insurance because most public health insurance is geared toward women and children."

The opportunity to intervene with this at-risk population often is a brief one because the median length of stay in the Cook County Jail is nine days, McAuley says. "Why do HIV care and prevention in jail? That's because that's where the patients are."

Also, people who are incarcerated are going to bring their illnesses and problems back into the community once they are released from jail, he says. "These are people who don't have insurance and will ultimately end up in Cook County health care, and they'll come in sicker and need more care, and it will end up costing you more to care for them than if you started to treat them in jail."

While money spent on HIV testing, prevention, and care services for prisoners is not a popular cause politically, it makes good sense from a public health perspective because the work that's done in the jails will benefit the entire community, McAuley explains.

"It's really a matter of going where you might get the most impact for your dollar, but the problem is that in corrections, it's a hard sell," he says. "There's no political lobby; it's a disenfranchised population, and getting resources is more difficult than it is for the gay community or other communities."

Through a grant from the Centers of Disease Control and Prevention (CDC) of Atlanta, the Cook County correctional system has developed an HIV prevention and testing program that has succeeded in identifying about 60% of the inmates who are HIV-infected, McAuley says.

About 40,000 of the 100,000 people who passed through the Cook County jail system agreed to participate in the voluntary HIV education system, and about 10,000 of these people agreed to be tested for the virus, he points out.

"The rest of the people passed through the system far too quickly for us to engage them in any meaningful way," McAuley says.

Although the testing rate is low, the blind HIV prevalence study indicated that the people who chose to be tested were among those at greatest risk for infection, so the program appeared to identify more than half of the people who were HIV-positive, McAuley adds.

Once an inmate is identified as HIV-positive, the care portion of the program begins. It works this way:

- **Get HIV-infected inmates into care as soon as possible.**

"We engage them as quickly as possible into care," he says.

Clinicians conduct a history, physical, and viral load testing, and the patient is evaluated by an HIV specialist.

"Depending on the person's disease status, we make a decision about treatment," McAuley says.

Cook County has an antiretroviral formulary for inmates, but most inmates are incarcerated too briefly to receive the treatment. Then there is the state of Illinois' rule that prohibits people who are incarcerated from receiving AIDS Drug Assistance Program (ADAP) drugs, he adds.

"Say someone has HIV, and they come to the jail and are there six days and then leave," McAuley says. "Is it the jail's responsibility to give them the medication as they leave, or is it the public sector's responsibility?"

This why it's important for a corrections system HIV program to include a transition strategy and team, he stresses.

- **Provide team that helps with transition to community.**

"When they are ready for discharge we offer them the same disease specialist team at a place called the Core Center, that is the Cook County Bureau of Health Services, a public medicine provider for Cook County's uninsured poor," McAuley says. "Core is one of the largest HIV providers in the country with a patient census of [more than] 3,000."

Of those eligible to follow-up with Core, about 60% attend their follow-up visit, he says.

After a few visits, the Core team may turn the

patient over to another team or clinic for care, but the goal is to provide consistency in HIV treatment during the transition period, McAuley says.

"Our goal is to give them, during transition, a sense of belonging to an individual provider and then to the Core Center in general," he explains. "That's the theory behind it, and we think it's been reasonably successful at this point."

- **Offer case management:**

There are two case managers who work within the jail to provide intakes, and there are four case managers who work with patients when they've left the jail.

"The case manager's main goal is to try to get the patients on ADAP, but if that's unsuccessful while they're in jail, then they can do that when they're at Core," McAuley points out.

Also, case managers can provide patients with HIV-prevention education, job training, and housing assistance.

The Cook County jail does not provide condoms to inmates, so clients receive only educational services while incarcerated, but once they are discharged, they may receive harm reduction services and condoms, he says.

Although the CDC grant soon will expire, McAuley says he is optimistic that the county will continue the jail prevention program.

"The Cook County Bureau of Health Services under Ruth M. Rothstein has really been unusually committed to both the health care of the underserved, but also supportive of health care in corrections," he says. "Mrs. Rothstein and others have really understood that if we're interested in the health care of the citizens of Chicago, then we have to focus at some level on the population in jails." ■

# Studies shed light on youth sex and drinking

*Parents and teens don't see eye to eye*

Researchers looking into early sexual behavior and attitudes about sex among youths have found that alcohol use does play a role in sexual initiation. They also have found that children have different attitudes about sexual behavior even as young as preteens.

"The bottom line is we don't think parents are doing a very good job of explaining their expectations to kids," says **Nicholas Long**, PhD, professor of pediatrics at the University of Arkansas for Medical Sciences in Little Rock.

"They're not explaining their standards and beliefs on sexual issues, and it's going to be harder to relate their values regarding sexual behavior later on," he says.

Long's study found that fourth- and fifth-graders had different ideas about acceptable sexual behavior and dating than did their parents. Also, the study found that preteens are less concerned about AIDS and teen pregnancy than are their parents, he says.

Another study found that alcohol use was more consistently related to early initiation of sexual activity and the number of sexual partners than it was to condom use among youth in three high-risk groups. These groups included females in inner-city housing developments, males in detention facilities, and young men who have sex with men (MSM) in Midwestern gay and bisexual youth groups, says **Rick Zimmerman**, PhD, professor of communication at the University of Kentucky in Lexington.

"Alcohol use was least in the adolescent females in inner-city housing developments," he notes. "Marijuana use was the next most prevalent substance we looked at in all three groups, and it was at least as prevalent as alcohol use in each of them."

The study offered some clues as to interventions that might work with young people, and one potential intervention design would be to target younger adolescents, between ages 10 and 14, for education that might lead to a delay in alcohol use, Zimmerman says.

"If we can delay initiation of drinking or excessive drinking, we may be able to delay sexual activity, so that's one of the most important implications," he adds.

"Beyond that, I think it's probably still useful — even though the data are mixed for adolescents who are both using alcohol and engaging in sexual behavior — to encourage ways for the adolescent to separate the two behaviors." For example, if a youth is going to drink and already is having sex, then the youth could hang out with friends to drink one night and have sex with a sexual partner on a night when there is no drinking, suggests Zimmerman.

"The good news is that at least for many of the adolescents in these groups we've been looking at, the convergence of alcohol use and sexual behavior is not that regular," he says. "The vast majority of times they were having sex, they were

not under the influence of alcohol."

On the other hand, a majority of the detention center population said they had sex when they were under the influence of marijuana, adds Zimmerman. "But across these groups, when they were having sex, they were not drinking, and that's a potentially promising sign."

The preteens and parents' attitudes study was part of a larger project designed to look at the effectiveness of interventions to reduce risky sexual behavior among adolescents and young adults. Long's portion of the research focused on children, ages 9 to 12, and their parents.

Specifically, investigators and staff worked with parents of these preteens in interventions designed to make them feel more comfortable talking about sex with their children and teaching them strategies to become sex educators, Long says.

The families, all of whom were African-American, were provided one of three different interventions, including a full intervention of five sessions of 2.5 hours each; a single 2.5 hour presentation with the same material, but without role playing and group discussions; and a comparison group that had a 2.5 hour presentation on various health issues, but not on sexual education, Long says.

Investigators found that 79% of the preteen boys thought it was OK to have a girlfriend at their age, and 17% of the parents thought it was OK. Among preteen girls, 55% thought having a boyfriend was OK, and 3% of their parents agreed, Long says.

"The other issue was the seriousness of AIDS and the difference between kids and parents and perception," Long says. "For example, 97% of the parents of boys thought AIDS was a serious problem, and 94% of the boys thought so."

Among families with preteen girls, 99% of the parents thought AIDS was a serious problem, while 93% of the girls thought it was a serious problem, Long adds. ■

# CDC emphasizing role of STDs in HIV care

With recent surveillance data showing increases in the rates of some sexually transmitted diseases (STDs), health care professionals need to remember to screen patients for curable STDs and counsel both HIV-negative and HIV-positive patients about how STDs increase the risk of transmitting the virus.

The Centers for Disease Control and Prevention (CDC) of Atlanta, along with the Advisory Committee for HIV and STD Prevention (ACHSP), which provides oversight and guidance to the CDC, have said that early detection and treatment of STDs is an effective strategy for preventing sexually transmitted HIV infection. A CDC report on STDs and HIV notes that ACHSP makes these recommendations:

- Early detection and treatment of curable STDs should become a major, explicit component of comprehensive HIV-prevention programs at national, state, and local levels.
- In areas where STDs that facilitate HIV transmission are prevalent, screening and treatment programs should be expanded.
- HIV- and STD-prevention programs in the United States, together with private and public sector partners, should take joint responsibility for implementing this strategy.

The CDC also has published sample case examples and guidance for providing prevention messages to HIV-infected patients. These sample case situations are as follows:

**Examples of Case Situations for Prevention Counseling**

**Example 1.** A patient with newly diagnosed HIV infection comes to your office for initial evaluation. Of the many things that must be addressed during this initial visit (e.g., any emergent medical or psychiatric problems, education about HIV, history, physical, initial laboratory work — if not already done), how do you address prevention? What is the minimum that should be done, and how can it be incorporated into this visit?

**CDC:** Assuming no emergent issues preclude a complete history and physical examination during this visit, the following should be done:

- During the history, question how the patient might have acquired HIV, current risk behaviors, current partners and whether they have been notified and tested for HIV, and current or past STDs.
- During the physical examination, include genital and rectal examinations, evaluation and treatment of any current STD, or if asymptomatic, appropriate screening for STDs.
- Discuss current risk behavior, at least briefly. Emphasize the importance of using condoms; address active injection-drug use.
- Discuss the need for disclosure of HIV serostatus

to sex and needle-sharing partners, and discuss potential barriers to disclosure.
- Note issues that will require follow-up; e.g., risk behavior that will require continuing counseling and referral and partners who will need to be notified by either the patient or a health department.

**Example 2.** A patient with chronic, stable HIV comes to you with a new STD. What prevention considerations should be covered in this visit?

**CDC:** For the patient who has had a stable course of disease, a new STD can be a sign of emerging social, emotional, or substance abuse problems. These potential problems should be addressed in addition to the STD.
- During the history, cover topics related to acquisition of the new STD — number of new partners, number of episodes of unsafe sex, and types of unsafe sex.
- Address the personal risks associated with high-risk behavior, e.g., viral superinfection and HIV/STD interactions.
- Address personal or social problems (including substance abuse and domestic violence) that might have led to a change in behavior resulting in the acquisition of the new STD; refer to social services, if necessary.
- Address other issues (e.g., adherence to HAART) that may be affected by personal or social problems. Check viral load if nonadherence is evident or is suspected.
- During the physical examination, include a careful genital and rectal examination and screen for additional STDs, such as syphilis, trichomoniasis, (for women), chlamydia infection (for sexually active women ages $\leq$ 25 and selected populations of men and women), and gonorrhea (for selected populations of men and women).
- Discuss the need for partner notification and referral for counseling and testing.
- Note in the chart that risk behavior should be addressed in future visits and that tailored counseling may be needed for the patient.

**Example 3.** A patient with chronic, stable HIV has been seen regularly in a health care setting. What should be included in this patient's routine clinical care?

**CDC:** Discussion of sexual and needle-sharing practices should be integrated into a routine part of clinical care.
- Periodically (e.g., annually) screen for STDs. STDs to be included in screening should be determined by patient's sex, history of high-risk behavior, and local epidemiology of selected STDs.
- Reiterate general prevention messages and patient education regarding partner notification, high-risk behaviors associated with transmission, prevention of transmission, or condom use, as deemed appropriate by the clinician.

**Example 4.** A patient who has been treated with HAART for two years comes to you. At the time of treatment initiation, $CD4^+$ count was 200 cells/µL and the viral load was 50,000 copies/ml. The response to therapy was prompt; $CD4^+$ count increased to 500 cells/µL, and the viral load has been undetectable since soon after treatment began. The patient now has mildly elevated cholesterol, some mild lipodystrophy, and facial wasting. He states that he would like to stop HAART because of the side effects. What should you tell this patient?

**CDC:** Take the following steps:
- Inform the patient that upon stopping HAART, $CD4^+$ count and viral load will likely return to pretreatment levels with risk for opportunistic infections and progression of immune deficiency.
- Inform the patient that an increase in viral load to pretreatment levels likely will result in increased infectiousness and risk for transmission of HIV to sex or needle-sharing partners.
- Counsel the patient regarding the option of changing the HAART regimen to limit progression of metabolic side effects.

For patients who are not infected with HIV, diagnoses of STDs could be an important factor to consider. According to the CDC, the United States has the highest rates of STDs in the industrialized world, and the potential impact of STDs in facilitating HIV transmission depends on these factors:
- magnitude of the STD cofactor effects;
- overall STD prevalence rates;
- extent to which STDs are concentrated disproportionately among persons and subpopulations likely to be exposed to HIV.

HIV coinfection with other STDs is more likely among people with ulcerative STDs, such as early syphilis, genital ulcer disease, which suggests that it's very important to diagnose STDs early and offer HIV prevention messages at the time of STD diagnosis.

One of the challenges faced by health care

workers is getting the message across that anyone who is sexually active is at risk for an STD and that other STDs facilitate HIV transmission, according to the CDC.

Finding STD services also presents a challenge to many Americans, as only half of the local health departments offer STD prevention services, according to the CDC.

In the CDC's *Recommendations for Public Health Surveillance of Syphilis in the United States*, published March 2003, this guidance is offered:

- Assure proper diagnosis, treatment, and partner management for all cases of early syphilis.
- People infected with primary syphilis have an increased risk of acquiring HIV infection, and people coinfected with syphilis and HIV are at increased risk of transmitting HIV, so patients who are infected with syphilis are good candidates for HIV prevention messages.
- Assess the effectiveness of syphilis prevention and control programs through monitoring trends of reported cases.
- Monitor syphilis outbreaks and trends within certain populations.
- Identify characteristics of infected persons and generate hypotheses regarding risk factors.
- Identify gaps in health care and missed opportunities for intervention.
- Target interventions at populations at increased risk for STDs and HIV.

*(Editor's note: For more information about HIV and syphilis and prevention, go to the CDC's web site at www.cdc.gov.)* ■

# FDA Notifications

## FDA grants approval to fosamprenavir calcium

The FDA in October approved fosamprenavir calcium (Lexiva), which is manufactured by GlaxoSmithKline of Research Triangle Park, NC, and Vertex Pharmaceuticals Inc. of Cambridge, MA.

It is a prodrug of amprenavir, a protease inhibitor used to treat infection with HIV-1 by

## CE/CME *questions*

1. HIV prevention researchers say recent political scrutiny of their projects misses the point that interventions work best when what occurs?
   A. Abstinence-only messages are given.
   B. Prevention messages are directed toward people already infected with HIV.
   C. Research sheds light on how risk happens in certain groups, and interventions are designed in culturally savvy ways.
   D. none of the above
2. Research of HIV risk among those in Chicago-area jails show studying and providing interventions for this population works for what reason?
   A. Most of those found in county jails are poor, disenfranchised, male, and have no health insurance, and their behaviors often place them in a high-risk category for HIV infection.
   B. They typically stay in county jails for eight to 12 months, giving prevention workers plenty of time to address this population.
   C. There are high numbers of injection drug users and commercial sex workers in jails.
   D. all of the above
3. A recent study of at-risk young women, MSM, and youths in detention centers found that use of which substance was consistently related to early initiation of sexual activity and the number of sexual partners a person has?
   A. marijuana
   B. club drugs
   C. alcohol
   D. heroin
4. A recent study assessing attitudes about dating, AIDS, and premarital sex among preteens and their parents/caregivers had which findings?
   A. 79% of preteen boys thought it was OK to have a girlfriend at their age, while only 17% of their parents thought it was OK.
   B. 55% of preteen girls thought it was OK to have a boyfriend at their age, while only 3% of their parents agreed.
   C. 97% of the parents of boys; 99% of the parents of girls; and 94% of preteen boys and 93% of preteen girls thought AIDS was a serious problem.
   D. all of the above

## CE/CME *directions*

Study the questions and determine the correct answers. After you have finished, check the answers **on p. 12**. If any of your answers are incorrect re-read the article to verify the correct answer. At the end of each semester, you will receive an evaluation form to complete and return to receive your credits.

rapidly converting to amprenavir by cellular or serum phosphatases in the body.

Fosamprenavir calcium is indicated in combination with other antiretroviral agents for the treatment of HIV infection in adults. The approval was based on two studies in antiretroviral-naive patients and one study in protease inhibitor-experienced patients.

The FDA says these points should be considered when initiating therapy with Lexiva/ritonavir in protease inhibitor-experienced patients.

- The protease inhibitor-experienced patient study was not large enough to reach a definitive conclusion that Lexiva/ritonavir and lopinavir/ritonavir are clinically equivalent.
- Once-daily administration of fosamprenavir calcium plus ritonavir is not recommended for protease inhibitor-experienced patients.

The most common treatment-emergent adverse events in clinical studies of the drug were diarrhea, nausea, vomiting, headache, and rash and were generally mild to moderate in severity.

Treatment discontinuation due to adverse events occurred in 6.4% of patients receiving the medication and in 5.9% of patients receiving comparator treatments.

Tablets are available for oral administration in a strength of 700 mg fosamprenavir as fosamprenavir calcium (equivalent to approximately 600 mg amprenavir).

Tablets may be taken with or without food. The recommended oral dose of Lexiva, alone or in combination with ritonavir, is as follows:

**Therapy-Naive Patients:**

- Lexiva 1,400 mg twice daily (without ritonavir).
- Lexiva 1,400 mg once daily plus ritonavir 200 mg once daily.
- Lexiva 700 mg twice daily plus ritonavir 100 mg twice daily.

The twice-daily plus ritonavir dose is supported by pharmacokinetic and safety data.

**Protease Inhibitor-Experienced Patients:**

- Lexiva 700 mg twice daily plus ritonavir 100 mg twice daily.

Once-daily administration of Lexiva plus ritonavir is not recommended in protease inhibitor-experienced patients. Ritonavir is used to increase the plasma concentration of Lexiva. ■

## CE/CME *answers*

1. C
2. A
3. C
4. D



# CE objectives

After reading this issue of *AIDS Alert*, CE participants should be able to:

- identify the particular clinical, legal, or scientific issues related to AIDS patient care;
- describe how those issues affect nurses, physicians, hospitals, clinics, or the health care industry in general;
- cite practical solutions to the problems associated with those issues, based on overall expert guidelines from the Centers for Disease Control and Prevention or other authorities and/or based on independent recommendations from specific clinicians at individual institutions. ■