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President's HIV funding proposal is dead on arrival, HIV advocates say

Congress likely will decide spending in 2009

HIV/AIDS advocates say President Bush's FY 2009 appropriations for federal HIV/AIDS programs, which flat-funds HIV programs, is dead on arrival. They say it seals his legacy as being apathetic towards the domestic epidemic and science-based prevention interventions.

All signs point to a delayed budget battle, with Congress waiting to meet the next president before finalizing a budget, they say.

Meantime, the president's proposed budget changes no minds about Bush's attitude toward the HIV/AIDS epidemic in the United States.

"We were disappointed, to say the least, with the president's budget request for HIV/AIDS, particularly with the domestic programs," says **Ronald Johnson**, deputy director of AIDS Action of Washington. DC.

The president's proposed budget cuts $7.7 million from Ryan White Care Act, Title I, which would shortchange already hard-hit cities. **(See AIDS Action's annual AIDS budget chart, p. 39.)**

"Title I money goes to 51 metropolitan areas that are most impacted by HIV/AIDS," Johnson says. "The $7.7 million cut is what we consider a significant cut when one takes into consideration that caseloads are rising."

The president's proposed budget also flat-funds HIV prevention, even in light of the fact that many believe the next surveillance numbers coming from the CDC of Atlanta, GA, will show an increase in the number of new HIV infections, Johnson says.

"It just reflects the administration's continued retreat from responding to the domestic HIV/AIDS agenda," he adds.

The president's proposed budget requests a $28 million increase in abstinence education funding, a $27 million increase for community health centers, and $6 million more for the AIDS Drug Assistance Program (ADAP).

But this is part of the cards shuffle in which the areas that receive an increase do so at the expense of cuts in other areas, says **Ryan Clary**, director of public policy for Project Inform of San Francisco, CA.

For instance, the proposed budget calls for a $20 million increase in substance abuse block grant funding, but a $63 million decrease in funding for the Center for Substance Abuse Treatment and a $36 million decrease for the Center for Substance Abuse Prevention.

And some of the areas that are proposed to have increases this year were ones that were cut by those same amounts last year, Clary notes.

"An increase is great, but you can't have year after year, first a cut, then an increase, then a cut," Clary says. "The agencies can't do their planning if the money is fluctuating from year to year because they'll develop a program or increase their health care services, and then they'll have to decrease them."

While the proposed increase for ADAP is a step in the right direction, it is only a very tiny step when the need is considered, says **Bill Arnold**, director of the ADAP Working Group of Washington, DC.

"In a $1.4 billion program, a $6 million increase is small," Arnold says.

Beginning in April, existing ADAP funding will be released. The federal FY 2008 budget for ADAP of $808.5 million was a $19 million increase over the FY 2007 budget.

But it wasn't that increase that eliminated the ADAP waiting lists, Arnold says.

States came through where needed, and the Medicare Part D prescription drug money helped, he says.

Although Medicare Part D is a mixed bag and a moving target, it did help HIV patients who were eligible for its low income subsidy, Arnold says.

"The shifting around in the distribution of money and the new way the ADAP supplemental works have all conspired for the moment to make sure there are no waiting lists," he adds.

Bad publicity for states that have waiting lists also helps.

For example, South Carolina had a long waiting list last year, and while waiting for their HIV medications through ADAP, at least four people died, Arnold recalls.

"There are always other factors in the deaths, but the people were on an ADAP waiting list," Arnold says.

South Carolina received national negative publicity from these deaths, and activists protested at the state's capitol. As a result of the reauthorization of the Ryan Care Act bill, South Carolina began to receive more ADAP supplemental money, and so the waiting lists evaporated, Arnold says.

To keep HIV patients off the ADAP waiting lists, the program needs a $135 million increase this year, Arnold says.

But since this year's federal budget is expected to be delayed until after a new president takes the oath of office, ADAP really needs $55 million in emergency funding, Arnold says.

"What will we do if we don't get it?" he says. "Maybe some states will cough up a little more

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Editor: **Melinda Young**, (864) 241-4449.
Senior Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcmedia.com).
Associate Publisher: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@ahcmedia.com).
Managing Editor: **Leslie Hamlin**, (404) 262-5416, (leslie.hamlin@ahcmedia.com).

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Editorial Questions?
Call **Leslie Hamlin** at (404) 262-5416.

AIDS BUDGET AND APPROPRIATIONS COALITION

FY 2009 Appropriations for Federal HIV/AIDS Programs

February 19, 2008

(Increases or decreases from previous fiscal year are shown in parentheses; fiscal year 2009 requests reflect increase over FY 2008)

	PROGRAM	FY 2007 Final	FY 2008 Final	FY 2009 President's Budget Request	FY 2009 Coalition Request
HRSA	HRSA: Ryan White CARE Act Total	$2,138 m (+ $75.8 m)	$2,166.8 m (+$29 m)	$2,167.9 m (+$1.1 m)	$2,781.6 m (+$614.49 m)
	Title I (Part A)	$604 m (+ $0 m)	$627.15 m (+$23.16 m)	$619.42 m (-$7.7 m)	$840.4 m (+ $213.25 m)
	Title II: Care (Part B)	$406 m (+$75.8m)	$386.75 m (-$19.25 m)	$394.94 m (+$8.2 m)	$481.9 m (+$95.3 m)
	Title II: ADAP (Part B)	$789.5 m (+$0 m)	$808.5 m (+$19 m)	$814.5 m (+$6 m)	$943.5 m (+$134.6 m)
	Title III (Part C)	$193.7m (+ $0 m)	$198.75 m (+$5 m)	$198.75 m (+$0 m)	$299.3 m (+$100.5 m)
	Title IV (Part D)	$71.8 m (+ $0 m)	$73.7 m (+$1.9 m)	$73.7 m (+$0 m)	$122.5 m (+$48.8m)
	Part F: AETCs	$34.7 m (+ $0 m)	$34.1 m (-$.6 m)	$28.7 m (-$5.4 m)	$50.0 m (+ $15.9 m)
	Part F: Dental	$13.1 m (+$0 m)	$12.86 m (-$.23 m)	$12.86 m (+$0 m)	$19 m (+$6.14 m)
	SPNS	$25 m	$25 m	$25 m	$25 m
	HRSA: Community Health Centers	$1.988 b (+$206.9 m)	$2,065 m (+$77 m)	$2, 092 m (+$27 m)	TBD
	HRSA: Title X	$283 m (- $.04 m)	$300 m (+$17 m)	$300 m (+$0 m)	$400 m (+$100 m)
CDC	Total - HIV, STD, TB, Hep line	$1002.5 m (+$39.1 m)	$1,002 m (-$0.5 m)	$1,000 m (-$2 m)	$1,834.9 m (+$832.6 m)
	HIV Prevention & Surveillance	$695.5 m (+$43.8 m)	$692 m (-$3.5 m)	$691 m (-$1 m)	$1.3 b (+$608 m)
	STD Prevention	$155 m (-$2.2 m)	$152 m (-$3 m)	$152 m (+$0 m)	$167.3 m (+$15 m)
	TB Prevention	$135 m (-$2.1 m)	$140 m (+$5 m)	$140 m (+$0 m)	$300 m (+$159.6 m)
	Viral Hepatitis	$17.4 m (-$.2 m)	$17.6 m (+$.2 m)	$17.5 m (-$.08 m)	$67.6 m (+$50 m)
	DASH - HIV Prevention Education	$40.9 m (+$0 m)	$40.2 m (-$.7 m)	$40.1 m (- $.1 m)	$66.6 m (+$26.4 m)
	Minority HIV/ AIDS Initiative (across multiple programs)	$400 m (+$1.1 m)	$402.6 m (+$2.6 m)	$387 m (-$15.6 m)	$610 m (+$223 m)
	HUD: HOPWA	$286.1 m (+$0 m)	$300.1 m (+$14 m)	$300.1 m (+$0 m)	$470 m (+$169.9 m)

Global HIV/AIDS Programs

PROGRAM	FY 2007 Final	FY 2008 Final	FY 2009 President's Budget Request	FY 2009 Coalition Request
Foreign Operations Portfolio				
HIV/AIDS in USAID Child Survival and Health Programs Fund	$346 m (- $0.5 m)	$350 m (- $4 m)	$342 m (- $8 m)	$1 b (+ $650 m)
Global HIV/AIDS Initiative	$2.870 b (+ $1.093 b)	$4.7 b ($4.15 b for 15 focus countries) (+ $1.28 b)	$4.8 b ($4.1 b for 15 focus countries) (-$50 m)	$8.4 b (+ $3.7 b)
Global Fund	$624 m (+ $174 m)	$550 m (- $74 m)	$200 m (- $350 m)	$2 b (+ $1.45 b)
TB	$79 m (- $141 m)	$153 m (+ $74 m)	$84.5 m (-$68.5 m)	$550 m (+ $397 m)
Malaria	$248 m (+ $148 m)	$350 m (includes $270m for PMI) (+ $102 m)	$385 m (all for PMI) (+$35 m)	$450 m (+ $100 m)
Labor/HHS Portfolio and Total				
Global Fund	$99 m (+ $0 m)	$300 m (+ $201 m)	$300 m (+$0 m)	$0 m[2]
CDC Global AIDS Program	$123 m (+ $1.0 m)	$121 m (-$2 m)	$119 m (-$2 m)	TBD
Total	$4.38 b (+ $1.32 b)	$5.86 b (+ $1.48 b)	$5.53 b (-$443.5 m)	TBD

2 The Global Fund allocation as part of the Labor/HHS portfolio that passes through the National Institutes of Health (NIH). This does not constitute additional funding to NIH for research efforts. The AIDS Budget and Appropriations Coalition supports full Global Fund appropriations out of the Foreign Operations portfolio.

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state money, but 30-odd states are projecting pretty severe budget crunches, and California is actively trying to cut money from the state ADAP appropriation as we speak."

If California is in such bad shape, where does that leave Arkansas or South Carolina, he asks.

International HIV/AIDS funding, which has been the president's focus all along, has fared well, but only for money spent in the President's Emergency Plan for AIDS Relief (PEPFAR), Johnson notes.

"The president does not propose an increase in the Global Fund, but he proposes a $4.1 billion increase that would be for the focus countries within PEPFAR," Johnson says.

President Bush's budget is more generous to PEPFAR and international funding, but there are problems with those proposals as well, says **Kevin Frost**, chief executive officer of amfAR of New York, NY.

"There still are some problems with this administration's response to the epidemic," Frost says. "There's still an extraordinary emphasis on abstinence, and there's still an ideological focus on abstinence even though there is no scientific evidence that it works."

Studies continue to show that abstinence-only programs, which are the only kind receiving funding in the president's proposed budget, do not reduce sexual activity among youths.[1,2,3]

Federal money put into abstinence-only programs could be put to more effective use elsewhere, Clary says.

"There you have the Bush administration's legacy on the domestic HIV program," Clary says. "In his final year as president, the largest increase is for abstinence-based education instead of for care and treatment for the poor and uninsured or for research or for testing or for science-based prevention efforts." ■

References:

1. Ott MA, Santelli JS. Abstinence and abstinence-only education. *Curr Opin Obstet Gynecol*. 2007;19(5):446-452.

2. Underhill K,et al.. Abstinence-only programs for HIV infection prevention in high-income countries. *Cochrane Database Syst Rev*. 2007;17(4):CD005421.

3. Dworkin SL, Santelli J. Do abstinence-plus interventions reduce sexual risk behavior among youth? *PloS Med*. 2007;4(9):e276.

CDC and investigators find success with intervention in HIV clinics

"Positive Steps" works, study shows

The more scientists and public health officials learn about HIV prevention, the more they realize that targeting specific cultural and demographic groups of people who are not infected is a costly and labor-intensive venture.

With federal HIV prevention funding essentially flat-lined for seven years now, the CDC has shifted its focus to Prevention for Positives initiatives. And what better place to find positives and provide these prevention messages than the HIV clinic?

This was the genesis of the CDC's Positive Steps intervention that was implemented in seven HIV clinics in six states from New York City, NY, to Denver, CO.

"Patients are routinely coming to the clinic, so there's an opportunity that you will otherwise miss," says **Lytt Gardner**, PhD, an epidemiologist with the division of HIV/AIDS prevention at the CDC.

"The other reason for this type of intervention, and this wasn't touched on in our study, but some studies have shown that patients are very receptive when they hear a message from their main medical provider," Gardner says. "So those are two very important reasons for doing it in the clinic."

Investigators found that the intervention successfully reduced risk behavior among patients over a one year period, Gardner says.

"All of the risk behavior groups — men who have sex with men (MSM), heterosexual men and women — showed the same degree of declines in unprotected anal or vaginal intercourse," Gardner says. "We saw the same degree of decline in risk behavior subgroups."

The results were gratifying, he notes.

"We were very pleased to see how consistent the results were, and there was consistency on every dimension," Gardner says. "It was consistent across clinics and across risk groups, and it's a continuing process as it should be."

Here's how the intervention worked:

• **Use screening form:** Patients arriving at a clinic complete a screening form that asks them to list their recent sexual activity and drug use, Gardner says.

"The information they put on the form was used by the provider to initiate the discussion of risk behavior," he says. "That was how the conversation was started."

Most of the clinics in the study used paper screening forms, and one clinic used an electronic version. It typically was given out to patients while they were in a waiting room, and nurses were available to assist them in completing the form, Gardner says.

• **Develop risk reduction plan:** After the clinician and patient finish the three-to-four minute conversation about risk behaviors, the provider develops a risk reduction plan for the patient, Gardner says.

"This is given to the patient so that the patient has something to carry away," he says.

• **Offer counseling to those who need it:** "Some patients have many problems and those patients could receive additional counseling at the clinic," Gardner says.

The counseling session might provide more detailed descriptions of specific risk reduction practices, such as sexual negotiation with sex partners, he explains.

"This is something that takes a little more time and can't be crammed into three or four minutes," he adds. "People with master's degrees provided the counseling."

• **Providers gave tested prevention messages:** "The messages that the medical providers used were based on messages used for the Partnership for Health intervention, carried out on the West Coast," Gardner says. "So what the providers said to patients had some basis in previous successful interventions."

The Partnership for Health intervention is designed for outpatient clinic and healthcare providers. It has them provide brief, behavioral prevention messages through message framing, repetition, and reinforcement at each clinic visit.[1]

This clinic-based intervention can be implemented successfully with fairly modest amounts of training, Gardner says.

"That kind of training can be provided by the AIDS Education and Training Centers (AETC)," he says.

"We've received requests from other clinics for the materials, and although we — in our little research group — don't provide those materials, the materials that were used are available on an AETC Web site [www.aidsetc.org]," Gardner adds. "So that's one thing that we direct clinics to look at."

More information about the CDC's modified behavioral screener, which is titled, "Ask, Screen & Intervene," can be found on this AETC Web site: www.pamaaetc.org/events.asp.

"The part with the greatest correlation with Positive Steps is the screener," Gardner says. "That was the one thing unique about our study; we created a screener, and that's important when you're trying to figure out how to get conversation started with patients."

The CDC study did not contain a control group and was designed as a demonstration project, Gardner notes.

"So there is some caution that should be exercised when interpreting Positive Steps," he says. "However the previous clinical trials have provided the efficacy data that's needed to allow people to conclude that this type of activity is useful."

The value of Positive Steps is that it's a simple intervention that can be successfully implemented in multiple HIV clinics with a small investment of time and money, he says.

"We would certainly encourage clinics to adopt this because it is consistent with the recommendations that the CDC published in 2003 about incorporating HIV prevention into the medical care of people living with HIV," Gardner says. "What we're doing is a way clinics can implement most of those recommendations." ■

Reference:

1. Richardson JL, et al. Effect of brief safer-sex counseling by medical providers to HIV-1 seropositive patients: a multiclinic assessment. *AIDS*. 2004;18:1179-1186.

U.S. Virgin Islands and Caribbean HIV epidemic need more attention, researchers say

HIV infection rate is high among sex workers

The Caribbean receives scant attention from HIV researchers and public health officials, and this has resulted in an epidemic that is poorly understood, an investigator says.

"I sometimes feel the Caribbean is somewhat neglected as far as HIV research," says **Hilary Surratt**, PhD, scientist with the Center for Drug & Alcohol Studies of the University of Delaware in Coral Gables, FL.

This is especially true with the English-speaking Caribbean, which is very diverse culturally, Surratt says.

"Chiefly, the incidence of HIV/AIDS in the English-speaking Caribbean is very high, but there hasn't been a significant focus of research in the region," Surratt says.

Funding is the issue. HIV research funds are spent in areas where the HIV epidemic is greater in scope, she notes.

"That's understandable, but from a U.S. perspective, there should be greater focus in the area because that's our neighbor," Surratt says.

Surratt characterizes the Caribbean's HIV epidemic as primarily heterosexual in nature, although it's associated with non-injection substance use and men who have sex with men (MSM).

"Sometimes those [heterosexual transmission] features are not as exciting to people in terms of research dollars, and that's why there's not a history of research being done here," she says.

Surratt found in her own research that drug-using migrant sex workers are particularly vulnerable to HIV infection and transmission throughout the Caribbean.[1]

"The sex workers are servicing, to a great extent, tourists from the United States, Canada, and other parts of the world," Surratt says. "They work the cruise ship routes and bars, and that's their target much more heavily than the local population."

Lindsey Wolf, another investigator who has focused on the Caribbean, agrees that the region needs more research attention.

"A big challenge in the Caribbean is identifying all of those who actually need treatment, and that will involve HIV screening expansion," says Wolf, who is a medical student at the University of California in San Francisco, and who was working as a senior research analyst with the Cost Effectiveness of Preventing AIDS Complications Group at Massachusetts General Hospital in Boston, MA, when she conducted a study on HIV and the Caribbean.

The UNAIDS' 2007 AIDS Epidemic Update states that the primary mode of HIV transmission in the region is unprotected sex between sex workers and clients, the UNAIDS report says.[2]

HIV prevalence among female sex workers in Guyana is 31 percent; in Jamaica it's 9 percent, and in the Dominican Republic it's 3.5 percent.[2]

"Unsafe injecting drug use is responsible for a minority of HIV infections, and contributes significantly to the spread of HIV only in Bermuda and Puerto Rico," the report states.[2]

While men who have sex with men (MSM) transmission also is a significant factor, it is hidden because of stigma, the report adds.[2]

Stigma also plays a role in suppression of efforts to get sex workers and others to be tested for HIV, Surratt says.

"Honestly, the challenges are tremendous and not just with the sex workers," she says. "It goes back to a sense that this is a small, close-knit community, and HIV still carries a stigma in the community."

People are reluctant to be tested for HIV because they're afraid they'll be seen by someone they know, Surratt says.

"Going to the HIV clinic is something nobody wants to be involved with because within five minutes everybody on the island will know that so and so was going to this particular location," she explains. "There are tremendous barriers for people to talk about HIV, much less being tested for HIV."

Surratt did not provide HIV testing as part of her study, mostly for this reason.

Wolf saw the stigma first-hand when she worked on the English-speaking island of St. Lucia as a health educator for children at a boys' technical school.

"People who have an HIV diagnosis haven't told people about it, not even their families because they don't want the word to get out," Wolf says. "The number of identified HIV cases is very low compared with the World Health Organization's projection of how many people are infected in the region."

The stigma needs to be addressed, and health care professionals should come up with strategies for screening for HIV, Wolf says.

"Basically, everyone should be tested, and those who need treatment should get treatment," Wolf adds.

Universal testing might even be feasible since the island populations are small, she notes.

"We looked into what we could do to break down these barriers, to see what would make people more likely to be HIV tested," Surratt says. "People told us very often that if you want people to be HIV tested, make the location not identified with HIV testing."

For example, an HIV testing site should offer other health care screenings, such as blood pressure checks, and a variety of services.

"If we had a mobile unit with an array of services, that would be ideal," Surratt says. "But, honestly, the resources are not there to do something like that."

Even folding HIV testing into the existing medical clinics wouldn't be feasible because these established sites are resource-strapped, and the staff might worry about being associated with HIV testing, she adds.

Some of the other factors that increase risk of HIV transmission in the English-speaking Caribbean involve the tendency of island residents to have a young initiation of sexual intercourse and young women engaging in sexual activity with older men, Surratt says.

"There is really broad acceptance of alcohol consumption, which is endemic to many parts of the Caribbean," Surratt says. "There is a broad acceptance of men having many different female sexual partners, and many of these factors drive the heterosexual epidemic."

In Surratt's study, she found a strong relationship between the sex workers' use of illicit drugs and their engaging in riskier levels of HIV behaviors.[1]

"Among the non-substance-using sex workers, we found that protected sex was very common," Surratt adds. "So their HIV risk was significantly less if they were non-using women, but if they were drunk or high then they'd forget about using condoms or could be convinced not to use condoms." ■

References:

1. Surratt H. Sex work in the Caribbean Basin: patterns of substance use and HIV risk among migrant sex workers in the US Virgin Islands. *AIDS Care*. 2007;19(10):1274-1282.

2. UNAIDS/WHO. 2007 AIDS Epidemic Update. Dec. 2007: available online at www.unaids.org.

FDA issues warning for nonoxynol-9 products

By Rebecca Bowers
This article originally appeared in the March 2008 issue of Contraceptive Technology Update.

Over-the-counter contraceptive products that contain the spermicide nonoxynol-9 (N-9) now will carry a warning label to alert consumers that such products do not protect against sexually transmitted diseases (STDs) and HIV/AIDS, following a final ruling by the Food and Drug Administration (FDA).

The move comes after the agency's January 2003 proposal to issue new warning statements and other labeling information for such products. The agency says the rule is being finalized following a public comment period and a thorough analysis of information and views from consumers, health care providers, academicians, and industry representatives.

The ruling comes as no surprise to Contraceptive Technology Update readers. Clinicians have been counseling patients on the ineffectiveness of N-9 against HIV since 2000, based on the results of microbicide research.[1] This message was reinforced again in 2002, when further research indicated that N-9 failed to protect against such STDs as urogenital gonorrhea and chlamydia.[2] (Review the data in the article, "Nonoxynol-9 fails test as female microbicide," October 2000, p. 119, and "Nonoxynol-9 not protective against STDs," June 2002, p. 63. CTU reported on the FDA proposed labeling in the article "Labeling change: New warning proposed for nonoxynol-9 contraceptive drugs," March 2003, p. 25.)

"FDA is issuing this final rule to correct misconceptions that the chemical N-9 in these widely available stand-alone contraceptive products protects against sexually transmitted diseases, including HIV infection," said **Janet Woodcock**, MD, FDA's deputy commissioner for scientific and medical programs, chief medical officer, and acting director of the Center for Drug Evaluation and Research in an announcement on the final ruling. "Clinical research has shown that N-9 provides no protection against sexually transmitted diseases to the woman if her sexual partner is infected with an STD pathogen or HIV."

The guidance is specifically aimed at over-the-counter (OTC) stand-alone vaginal contraceptive and spermicidal products such as gels, foams, films, or inserts. The new warning information includes the following language:

- For vaginal use only.
- Not for rectal (anal) use.
- Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner.
- Do not use if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control.
- When using this product you may get vaginal irritation (burning, itching, or a rash). Stop use and ask a doctor if you or your partner get burning, itching, a rash, or other irritation of the vagina or penis.

Other information in the new labeling includes:

- Studies have raised safety concerns that products containing the spermicide nonoxynol 9 can irritate the vagina and rectum. Sometimes this irritation has no symptoms. This irritation may increase the risk of getting HIV/AIDS from an infected partner.
- You can use nonoxynol 9 for birth control with or without a diaphragm or condom if you have sex with only one partner who is not infected with HIV and who has no other sexual partners or HIV risk factors.
- When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate the risk of catching or spreading HIV, the virus that causes AIDS.
- Use a latex condom without nonoxynol 9 if you or your sex partner has HIV/AIDS, multiple sex partners, or other HIV risk factors.
- Ask a health professional if you have questions about your best birth control and STD prevention methods.[3]

While the news on N-9 may not be new, reports about the new label warning may be of concern to couples who rely on spermicides for contraception, advises Anita Nelson, MD, professor in the Obstetrics and Gynecology Department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance. Clinicians may wish to recap the follow-

ing message from Contraceptive Technology on spermicides: "Do not use spermicides to reduce risks of sexually transmitted diseases. Use male or female condoms for this purpose."[4]

How about condoms?

The final rule requiring warnings for all OTC vaginal contraceptives/spermicides containing N-9 applies to drug products, notes the FDA. It does not apply to condoms lubricated with N-9, which are primarily regulated as medical devices.

The agency issued draft guidance on condom labeling in 2005. Final ruling on the draft guidance has not been handed down yet. (CTU reported on the proposed labeling in the article, "Condoms protect against herpes, study shows, February 2006, p. 18.)

The draft guidance calls for retail packaging of latex condoms with N-9 to include a statement indicating "that the lubricant on the condom contains N-9, which kills sperm, but that the extent of pregnancy protection contributed by the N-9 has not been measured."[4] It also calls for packaging to include a statement that the N-9 in the product does not provide protection from HIV/AIDS or other sexually transmitted diseases.[5]

While some manufacturers have ceased manufacture of condoms of N-9, some brands continue to carry the spermicidal coating. A check of the retail web site www.condomania.com, yields eight choices: Beyond Seven, Life Styles Ultra Sensitive, Trojan Her Pleasure, Trojan Supra, Trojan Ultra Pleasure, Trojan Ultra Ribbed, Trojan Ultra Thin, and Trojan Very Sensitive.

Several organizations, including the Global Campaign for Microbicides and the San Francisco AIDS Foundation, have called for the removal of N-9 from condoms. If manufacturers will not remove N-9 from condoms, such groups are asking that the FDA require warning labels for condoms containing N-9. ■

References

1. Van Damme L, Ramjee G, Alary M, et al. Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: A randomised controlled trial. *Lancet* 2002; 360:971-977.

2. Roddy RE, Zekeng L, Ryan KA, et al. Effect of nonoxynol-9 gel on urogenital gonorrhea and chlamydial infection. *JAMA* 2002; 287:1,117-1,122.

3. 72 *Fed Reg* 71,769 (Dec. 19, 2007).

4. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*: 18th revised edition. New York City: Ardent Media; 2004.

5. Food and Drug Administration. Draft Guidance for Industry and FDA Staff. Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex. Accessed at www.fda.gov/cdrh/comp/guidance/1548.pdf. ■

Therapeutic trial of growth hormone releasing factor in HIV patients

By Dean L. Winslow, MD, FACP, FIDSA

Synopsis: *In this study, 412 HIV-infected patients with abdominal visceral fat accumulation as a major manifestation of lipodystrophy were randomized to tesamorelin 2 mg SQ daily or placebo for 26 weeks. Patients receiving tesamorelin decreased visceral fat and improved lipid profiles.*

Source: Falutz J, et al. Metabolic effects of a growth hormone-releasing factor in patients with HIV. *N Engl J Med*. 2007;357:2359-2370.

THIS MULTICENTER, RANDOMIZED, PLACEBO-CONtrolled trial of a synthetic GHRH analogue, tesamorelin (1-44 amino acids from the amino terminal of GHRH with a trans-3-hexenoyl group added to the amino terminal to increase the half-life over native GHRH), randomized 412 patients (86% male) to daily subcutaneous tesamorelin vs placebo for 26 weeks. Inclusion criteria included the receipt of at least 8 weeks prior antiretroviral (ARV) therapy and excessive abdominal visceral fat, as defined by various objective morphometric criteria. Use of stable lipid lowering regimen and testosterone replacement within 3 and 6 months of entry, respectively, was permitted.

The tesamorelin regimen was well-tolerated, with only a modest increase in treatment related side effects seen in the tesamorelin arm. Peripheral edema, myalgia, hypoesthesia, paresthesia, rash, and injection site reactions were the only remarkable events that seemed to be associated with active drug, but all of these were encountered in less than 10% of patients.

Bottom line results showed that tesamorelin therapy resulted in a 15.2% decrease in abdominal visceral fat vs an increase of 5% in the placebo group. Serum triglycerides decreased by 50 mg/dL in the tesamorelin group vs an increase of 9 mg/dL in the placebo group. Similarly, the total/HDL cholesterol ratio decreased by 0.31 in the treated vs increased by 0.21 in the placebo group. Levels of insulin-like

growth factor (IGF-I), which mediates the effect of hGH on tissue, increased by 81% in the tesamorelin group and decreased by 5% in the placebo group. No differences in glycemic measurements were observed between the groups.

■ **COMMENTARY**

Despite the use of newer antiretroviral agents (which are less likely to produce nucleoside analogue-related lipoatrophy and protease inhibitor-related fat accumulation), these dysmorphic changes, which were frequently induced by older agents, are distressing to patients and unfortunately persist following change to new ARV regimens. This study shows that a 26-week course of tesamorelin administered SQ daily can produce a reduction in visceral abdominal fat and is potentially a therapeutic option. However, caution is definitely warranted at this early date. It is known from experience with the therapeutic use of growth hormone in HIV patients that while use of hGH improved strength and lean body mass, side effects with prolonged use included salt and water retention, glucose intolerance, insulin resistance, and carpal tunnel syndrome. Longer-term studies of the safety and efficacy of GHRH analogue therapy will need to be conducted before this treatment modality should be considered standard of care. (It is intuitively evident to most internists that deliberately altering the hypothalamic-pituitary axis is not something to be done casually!) Even if shown to be well-tolerated in longer-term studies, use of daily milligram amount doses of a recombinant protein, such as tesamorelin, are likely to be quite expensive. ■

FDA Notifications

Generic stavudine and efavirenz are tentatively approved by FDA

On Feb. 29, 2008, the FDA granted tentative approval for two generic formulations of drugs used to treat HIV/AIDS. These are stavudine capsules, 15 mg, 20 mg, 30 mg, and 40 mg., and efavirenz tablets, 600 mg, all manufactured by Hetero Drugs Limited, Hyberdad, India.

They were tentatively approved for use in combination with other antiretrovirals in the treatment of HIV infection. The applications were reviewed under expedited review provisions for the President's Emergency Plan for AIDS Relief (PEPFAR)

"Tentative approval" means that FDA has concluded that a drug product has met all required quality, safety and efficacy standards, but is not eligible for marketing in the U.S. because of existing patents and/or exclusivity rights. Tentative approval, however, does make the product eligible for consideration for purchase under the PEPFAR program.

Effective patent dates can be found in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

These tentative approvals are generic versions of Zerit (stavudine) capsules, a Nucleoside Reverse Transcriptase Inhibitor (NRTI), 15 mg, 20 mg, 30 mg, and 40 mg, and Sustiva (efavirenz) tablets, a Nonnucleoside Reverse Transcriptase Inhibitor (NNRTI), 600 mg. Both Zerit and Sustiva are products of Bristol Myers Squibb.

As with all generic applications, FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval to these applications to evaluate the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application.

A list of all Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan (PEPFAR) is available on the FDA website at www.fda.gov.

Pediatric HIV infection guidelines for use of ARTs are revised

The Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection have been revised.

The new version includes updated information on:

- when to initiate therapy;
- change in treatment recommendations for

when to initiate therapy in HIV-infected children less than 12 months of age;

- reduction from 4 to 3 age bands for recommendations on when to initiate therapy (less than 12 months, 1 to less than 5 years, and 5 years and older);
- changes in immunologic thresholds for when to start in children 1 year or older;
- timing of diagnostic testing in HIV-exposed infants.
- the pediatric drug appendix and hyperlink on drug preparations, new dosage formulations, and pediatric studies;
- recently approved antiretrovirals: maraviroc (including a new coreceptor tropism assay section), raltegravir, and etravirine
- revised antiretroviral toxicity hyperlink with new tables detailing toxicity management;
- changes are highlighted in yellow throughout the text and tables.

The updated guidelines are available for download from the Pediatric Guidelines section of the AIDSinfo Web site at http://www.aidsinfo.nih.gov/. You can also request to receive them by mail or email from the AIDSinfo Order Publications section.

New 600 mg tablet strength for darunavir is approved by FDA

On Feb. 25, 2008, the FDA approved a new 600 mg tablet strength for darunavir (Prezista), manufactured by Tibotec, Inc., Yardley, PA. The new 600 mg tablet facilitates dosing by reducing pill burden.

The recommended oral dose of darunavir tablets is 600 mg (two 300 mg tablets or one 600 mg tablet) twice daily taken with ritonavir 100 mg twice daily and with food.

The 600 mg formulation will be available in bottles of 60 tablets.

The 300 mg tablet will continue to be available.

Darunavir is a protease inhibitor, which inhibits the formation of mature virus in HIV infected cells.

CE/CME *questions*

10. Recent studies now suggest that HIV infection among men who have sex with men, in the 33 states that have named-based HIV reporting, increased by what percentage from 2001 to 2005?
A. 5 percent
B. 13 percent
C. 18 percent
D. 29 percent

11. In President Bush's final proposed budget, for FY 2009, which of the following HIV/AIDS funding items received the largest (a $28 million) increase?
A. Abstinence-only program funding
B. Mental health services for HIV patients
C. AIDS Drug Assistance Program
D. Evidence-based HIV prevention programs for uninfected, at-risk populations

12. Researchers say too few at-risk people in the Caribbean are tested for HIV because of which barriers?
A. Funding is too limited to provide the kind of confidential testing sites that people would be comfortable in visiting
B. Stigma against HIV is so rampant that people who are infected won't discuss it with their families
C. Too little research has focused on this region and its HIV epidemic needs and epidemiology
D. All of the above

Answers: 10. (b); 11. (a); 12. (d)

COMING IN FUTURE MONTHS

- HIV organization provides a little TLC to HIV-infected women
- Use peer-based interventions in clinic setting
- Study suggests prevention messages be adjusted according to age range
- Psychosocial group support enhances HIV prevention, care, adherence

Tibotec issues Dear Health Care Professional letter

Tibotec Therapeutics, in cooperation with the U.S. Food and Drug Administration, issued a Dear Healthcare Professional letter to relay important, updated prescribing information for darunavir (Prezista) tablets that includes a warning about Hepatotoxicity.

The letter provides, in addition to other information, the following, which has been added to the WARNINGS section of the Prezista label:

• **Hepatotoxicity** —- Drug-induced hepatitis (e.g., acute hepatitis, cytolytic hepatitis) has been reported with darunavir (Prezista/rtv). During the clinical development program (N=3063), hepatitis has been reported in 0.5% of patients receiving combination therapy with darunavir (Prezista/rtv). Patients with preexisting liver dysfunction, including chronic active hepatitis B or C, have an increased risk for liver function abnormalities including severe hepatic adverse events.

Postmarketing cases of liver injury, including some fatalities, have been reported. These have generally occurred in patients with advanced HIV-1 disease taking multiple concomitant medications, having co-morbidities including hepatitis B or C co-infection, and/or developing immune reconstitution syndrome. A causal relationship with darunavir (Prezista/rtv) therapy has not been established.

Appropriate laboratory testing should be conducted prior to initiating therapy with darunavir (Prezista/rtv) and patients should be monitored during treatment. Increased AST/ALT monitoring should be considered in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pretreatment elevations of transaminases, especially during the first several months of darunavir (Prezista/rtv) treatment.

If there is evidence of new or worsening liver dysfunction (including clinically significant elevation of liver enzymes and/or symptoms such as fatigue, anorexia, nausea, jaundice, dark urine, liver tenderness, hepatomegaly) in patients on darunavir (Prezista/rtv), interruption or discontinuation of treatment must be considered."

In addition, the Adverse Reaction section of the darunavir (Prezista) label and the Patient Package Insert have been updated to include this new information.

The letter, and the new label are available in pdf format from the Tibotec web site. ■

CE/CME objectives

The CE/CME objectives for *AIDS Alert*, are to help physicians and nurses be able to:
• Identify the particular clinical, legal, or scientific issues related to AIDS patient care;
• Describe how those issues affect nurses, physicians, hospitals, and clinics;
• Cite practical solutions to the problems associated with those issues.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any question answered incorrectly, please consult the source material.

After competing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

AIDS ALERT®
INTERNATIONAL

International HIV/AIDS groups need to focus more on MSM, amFAR says

Prevention focus often overlooks group

HIV-infected men who have sex with men (MSM) in resource-limited countries, often are overlooked, underserved, and discriminated against, international HIV/AIDS advocates say.

"It's fair to say that for too long the important institutions that were mobilizing to fight AIDS overlooked the epidemic among men who have sex with men," says **Kevin Frost**, chief executive officer, amFAR of New York, NY.

"When people talk about HIV/AIDS in Africa, they are talking about a generalized epidemic," Frost says. "That generalized epidemic masked these concentrated parts of the epidemic, particularly among MSM in this case."

Without attention and support from the international world, HIV-infected MSM in resource-limited countries are subjected to local homophobia and stigma, Frost says.

"It's impossible to get around the fact that there's an extraordinary amount of institutionalized homophobia in African countries," Frost says. "Even countries with success stories like Uganda have the most institutionalized homophobia with the government."

As a result, MSM may avoid being tested, or band together as HIV/AIDS advocates, which further marginalizes their status and places them at risk.

This is why amFAR has begun to provide grants to community organizations that address the HIV prevention and services needs of MSM.

"Male-to-male sexual behavior exists in every culture and society around the world, and we know it puts men at risk for HIV," says **Sam Avrett**, MPH, consultant with the MSM Initiative of amFAR.

"Here we are 25 years into the epidemic and not enough is being done to address HIV among MSM," Avrett says. "HIV-positive MSM are not getting access to treatment and care."

While this is especially true in resource-limited countries, it's also true in affluent nations, Avrett says.

"Look at the infection rates among black gay men in the United States," he says. "It's a major problem, and certainly the HIV epidemics among black gay men in the United States are not new — they're a product of more than 20 years of neglect, and they need to be addressed."

Recent studies now suggest that HIV infection among MSM in the 33 states that have named-based HIV reporting increased by 13 percent from 2001 to 2005.[1]

"On a personal note, I came into the fight against AIDS, in New York City, as a gay man in the early years of epidemic," Frost says. "And my perception of the epidemic was shaped by that perspective."

Many of Frost's friends were infected with HIV, and all of them were affected by the epidemic, he says.

"You couldn't live in New York and be an innocent bystander," Frost adds.

"Interestingly though, as the disease and our work in the epidemic became more international and our perspective on the disease became more international, it became less about being gay," Frost explains. "I think that is because the size and the scope of the international epidemic in the developing world looks so heterosexual that whatever issues there are about men who have sex with men becomes lost in that."

Internationally, the little amount of information that is available about MSM and HIV paints a stark picture.

"In the places where we do have data on levels of HIV infection among MSM, the numbers are staggering," Frost says.

"In Bangkok, for instance, the sero-prevalence is 32 percent among MSM," he says. "So how in the world are these populations overlooked by [international] institutions? It's an enormous failure on part of our global response to the epidemic."

According to data collected by amFAR, fewer than 5 percent of men who have sex with men have access to HIV prevention, treatment, and care. In some places, such as the Asia-Pacific region, only 2 percent of MSM receive HIV prevention services.

"Male-to-male sexual activity is illegal in 85 countries around the world," Frost says. "The same stigma that allowed the epidemic to spin out of control in the United States is contributing to the epidemic in the developing world."

A recent study HIV risk and MSM in low and middle-income countries found that MSM are at greater risk of being infected with HIV when compared with the general population.[2]

In medium-high prevalence areas, the HIV risk for MSM is nine times higher than for the general population, suggesting an urgent need for prevention and care.[2]

It's in this environment of an underground MSM population that often is at high risk of HIV infection that amFAR began last year to offer small grants to community organizations that would provide MSM groups HIV education, prevention, outreach, and advocacy.

The MSM Initiative also is pushing for better data on MSM, their social and sexual networks, and their HIV-related needs, Avrett says.

The third part of the initiative is to help advocates hold their governments accountable to meeting the needs of at-risk MSM, he adds.

"That's one of the amazing things about all of this: there are men who have sex with men who are willing to stand up and speak out in most countries of the world, and they're doing amazing work in all of these countries," Avrett says.

So far, amFAR has funded 17 organizations with a total of $350,000 in grants. A second round of grants was recently announced for Latin America and Asia, and that will be about the same size, he says.

"We're trying to raise more money and are continuing to reach out to those foundations and individuals who have always supported amFAR," Avrett says. "AmFAR has a long history of responding to the epidemic in ways that try to reach the leading edge and push responses to the epidemic in ways that reflect the most current needs."

Fundraising for international efforts involving MSM populations has been a bit of a challenge, Frost notes.

"It's been a struggle to get people in the gay community to feel connected with MSM in the developing world," he says. "It's something we continue to work on."

The most surprising reaction to the amFAR grant announcements has been the large number of applications submitted, Avrett and Frost say.

"When we did a request for proposals for funding work related to MSM and HIV, we received 84 proposals from 25 countries — all in Africa," Avrett says. "It was more than $2 million in funding requests."

Seven of the 84 applicants are being funded, and amFAR is trying to raise money to fund an additional 10, he adds.

"And we did a similar process in the Caribbean where we're funding five organizations that are working in more than five countries," he says.

Although amFAR has been working on MSM issues domestically and internationally for some tie, even the organization's leaders were surprised at the level of response to their grants announcement, Frost says.

"There is an outpouring of support for this initiative that was surprising to us," he says. "This does speak to this overwhelming sense of need."

The other piece of good news is that the HIV prevention and care needs of MSM around the globe finally is starting to hit the radar of various nations and AIDS organizations, Avrett says.

"AmFAR is not the only organization working on this," Avrett says. "We're working in partnerships with other groups who see the same situation and are trying to recalibrate the global AIDS effort."

The attention has helped change some governmental policies, as well.

"China has changed where MSM are now part of their national HIV efforts," Avrett says.

Likewise, more attention is being paid to MSM and HIV in Eastern Europe and Central Asia. And the International AIDS Society's XVII International AIDS Conference, which will be held Aug. 3-8, 2008, in Mexico City, Mexico, will

feature plenary speakers, including Jorge Saavedra, MD, of Centro Nacional para la Prevención y el Control del VIH/SIDA (CENSIDA) of Mexico City discussing MSM and HIV.

"So the international AIDS conference will have a great deal of content and energy about this topic, and it's certainly a major issue across all of the Latin American countries," Avrett says. "There will world attention focused on this issue in August." ■

Reference:

1. Jaffe HW, et al. The reemerging HIV/AIDS epidemic in men who have sex with men. *JAMA*. 2007;298(20):2412-2414.

2. Baral S, et al. Elevated risk for HIV infection among men who have sex with men in low- and middle-income countries 2000-2006: a systematic review. *PloS Med.* 2007;4(12):e339.

Online, "live" educational conferences teach overseas doctors about HIV treatment

A hand icon lets them ask questions

When international funds first became readily available for treating HIV-infected patients in resource-challenged economies, it was clear that many regions lacked trained clinicians for administering HIV antiretroviral treatment.

HIV clinicians and researchers at Massachusetts General Hospital in Boston, MA, decided to address this need through an online teaching conference that could be accessed by any site that had a computer and Internet capability.

Physicians and nurses in sub-Saharan Africa and in other parts of the world have an incredible need for HIV treatment education, says **Rajesh Gandhi**, MD, director of HIV Clinical Services and Education at Mass General. Gandhi also is an assistant professor of medicine at Harvard Medical School in Boston, MA.

"There's a lot of expansion of treatment programs, but as drugs become available, it's just as important to have training for doctors, nurses, and community educators," Gandhi says. "To use the drugs properly you need to know the side effects, whether patients have used them correctly, whether resistance has developed or co-infections, etc."

Physicians rely on conferences and medical journals to keep them up to date on practices, but in many parts of the world, there are limited opportunities for continued education, Gandhi says.

A practical and relatively simple solution is the HIV Online Provider Education (HOPE), which was developed by Gandhi and co-investigators to provide educational conferences via the Internet. Professors and HIV clinicians in the United States can provide slides and an audio lecture to dozens of doctors across the globe. The virtual attendees can even ask questions in real time, and everyone can hear the answers.

Many HIV researchers visit Africa for their studies and often provide education when they're over there. But this is more sporadic than what is needed.

"We'll give a lecture or be in a conference, but if we have to go to Africa, it's not practical," Gandhi says. "But Internet technologies allow you to link up with up to 40 different sites."

Gandhi and other lecturers can sit at their desks, speak into a microphone that costs from $10 to $20, give their lecture with the visual aides of slides, and reach physicians in Africa, India, the Caribbean, and elsewhere.

"You can show an example of a skin rash or display a diagram of a particular educational point," Gandhi says. "It's a virtual lecture, and it allows us to record these presentations, so if a physician cannot attend one day, he or she can go to the site the next day."

The only requirements for the remote sites are that they have a computer, access to the Internet, speakers, and one of the inexpensive microphones if they wish to be able to ask audible questions.

"More and more places are getting computers," Gandhi notes. "Access is increasing, and even in remote settings they can work over the telephone wires."

Interestingly, technological changes have made it easier and less expensive to provide distance lectures than when these required specialized equipment like a video camera.

"Fifteen years ago, you had to go to a certain room for a telemedicine conference, and the audience needed to be in a certain room,"

Gandhi says. "In South Africa, India, Rwanda, there might not be an Internet and computer in every room, but there are in most clinics."

HOPE uses Centra, an Internet-conferencing technology, to provide VoIP interactive case conferences.[1]

When the program first began, clinicians across the globe had very basic HIV treatment educational needs. But as time has gone on, their knowledge has become sophisticated, and so the lectures now reflect that change, Gandhi says.

"Three years ago they had very limited experience in using these drugs in these settings," he explains. "Now in three short years, they're putting thousands of patients on drugs and they're getting much more experience with the basics."

Conferences typically begin with information on a certain subject that interests clinicians in resource-limited settings, such as TB/HIV co-infection, anemia and HIV, identifying a problem with limited available diagnostic tests, etc.[1]

Many of the current conferences provide in depth, challenging cases, with a dialogue between the lecturers and attendees, he adds.

Some of the lectures' most informative moments are when attendees ask questions, Gandhi says.

A doctor in South Africa or the Dominican Republic can virtually raise his or her hand by pressing on the hand-up icon. The lecturer's computer screen registers the hand-up and identifies the person who has a question by location, Gandhi explains.

"Usually the lecturer will finish his train of thought and say, 'There's a question in Durban, [South Africa],'" Gandhi says.

"Because of the voice and interactivity of the site, you're responding to them in a way that mimics the classroom," he says.

The lectures typically last about an hour and are held twice a month, on the second and fourth Tuesdays of every month, Gandhi says.

"We've been doing it for over three years on every topic from drug toxicity, psychiatric issues, HIV policies, such as HIV and circumcision, HIV prevention, and TB, which is so relevant," he explains.

Investigators plan to improve and expand HOPE to have more collaboration with local experts and faculty, who help to keep the content relevant. They also will be starting a pilot project of a nursing conference for nurses in resource-limited areas, he says.

The program is open to any site that's interested in hearing or teaching the lectures, and there are a number of universities in the United States and the United Kingdom that have joined, as well, Gandhi says.

In the twice-yearly surveys, the feedback about HOPE has been very positive with more than 95 percent of respondents saying that they find the educational content useful, he notes.

"The surveys are where we identified that many nurses were listening to the program and that it would be helpful to have a parallel series for nurses," Gandhi says.

There have been some technical challenges over the past few years, including one site that had such a tight firewall that the lecturers couldn't get through. But the remaining challenges involve language and time differences, he says.

"These lectures are done in English," Gandhi explains. "And if you do a lecture at 8 a.m. in Boston, then in China it's at 8 p.m." ■

Reference:

1. Kiviat AD, et al. HIV online provider education (HOPE): the Internet as a tool for training in HIV medicine. *JID*. 2007; 196(Suppl 3):S512-S515.