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IN THIS ISSUE

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Yes we can? Obama's win brings hope to HIV/AIDS groups

Election raises optimism for more funding

Next month a new administration will usher in great expectations with regard to how President-elect Barack Obama will fund a variety of domestic programs, including HIV/AIDS prevention and medical care.

But the big question is whether even a Democratic administration and Congress can satisfy eight years of pent-up needs when there also loom two costly wars and the biggest economic meltdown since the Great Depression.

"We are optimistic that with the new president and new Congress that the kinds of flat funding and reductions in funding that we've experienced will be reversed," says **Ronald Johnson**, deputy director of AIDS Action in Washington, DC.

"We are confident that the new Congress and president will have a leadership that is much more mindful of the crisis of HIV/AIDS that we still face in this country," Johnson says.

"President-elect Obama, as a candidate, has fully endorsed a national AIDS strategy that calls for resources that are targeted and designed to end this epidemic," he adds.

Obama's stated national strategy toward the HIV/AIDS epidemic are better than those that were proposed by his opponent Sen. John McCain, so his presidency is seen as possibly bringing a major change to funding for HIV/AIDS programs, AIDS advocates say. **(See Obama's HIV/AIDS strategy summary, p. 135.)**

"The democratic Congress will certainly try to make up for some of the funding shortfalls that we've had to deal with," says Bill Arnold, director of the ADAP Working Group in Washington, DC.

This is particularly true because the Hispanic caucus and Congressional black caucus are expected to make the HIV/AIDS epidemic a more visible priority, Arnold adds.

Still, there will be major challenges: "The fiscal constraints are going to be very difficult, anyway," Arnold says.

Any hope HIV/AIDS advocates feel is tempered by nearly a decade of disappointments.

"It's been a rough eight years," says **Marie Saint Cyr**, executive director of the New York AIDS Coalition in New York, NY.

HIV/AIDS programs essentially have been flat-funded because even when the government dollars rise a little, they are off-set by the increasing number of people living with HIV/AIDS, Cyr says.

"We also are dealing with increases in [HIV infection among] communities of color, and we're seeing a wide range of ages," she says.

"We've been really disappointed in the lack of funding increases in all parts of the domestic portfolio," says **Carl Schmid**, director of federal affairs for The AIDS Institute in Washington, DC.

"We thought with the democrats coming in two years ago we would have seen some major increases in the domestic portfolio," Schmid notes. "But we've really been disappointed in the area of prevention spending, which has gone down."

This year, the final bill for Ryan White appears to contain a $100 million increase on the House side and a paltry $6.5 million on the Senate side, Schmid says.

Demand expected by many groups

So even with more democrats in Congress and an Obama administration, AIDS groups will have to fight for increases because there will be so many other federal funding demands, Schmid predicts.

The current global economic crisis is propelling the nation into a recession that will increase public assistance needs among people living with HIV/AIDS, Cyr notes.

"Unless we see a major turnaround [financially], we're looking at more gaps and more cuts in the future," Cyr says.

AIDS organizations already are dealing with dwindling resources, so any further cuts will be hard to take, Cyr and others say.

"It's all a matter of priority," Schmid says.

So far, domestic AIDS programs have not been a political priority, he adds.

"Is this going to be a priority for president-elect Obama?" Schmid says. "We hope it will be."

An Obama administration probably will provide a national AIDS plan fairly quickly, Arnold says.

"At least in terms of what people say and reading between the lines, I think it's highly likely we'll be in better shape, and we will get steps in the right direction," Arnold adds. "We may even get the Ryan White Care Act extended three, maybe four years with very minor changes."

Arnold says the advocacy community would prefer an extension to having to undergo a full-

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scale reauthorization process.

Directors of HIV/AIDS service organizations say any positive funding change will be a welcome change.

AIDS service organizations (ASOs) across the nation have dealt with funding cuts and fiscal constraints for years, and this year's budget was no improvement.

For instance, the city and state of New York are under such budget constraints that there will be $5 million in cuts to services impacting people living with HIV/AIDS, Cyr says.

The HIV programs slated for cuts include programs for education and prevention for older HIV patients, programs targeting communities of color and HIV-positive persons who use crystal methamphetamine, a hepatitis C public education campaign, and housing for people living with HIV/AIDS, Cyr says.

"We see this is an extremely urgent situation, and we are meeting with the governor's office and will meet with the mayor's office," Cyr says. "In many ways, these cuts will have a long-term impact in the city."

All of these cuts could lead to increased infection rates, she notes.

"If you lose programs that help prevent infection and which educate people and pull them into services, then you will end up having a greater number of at-risk people and a greater number of HIV infections," Cyr says.

Even though the United States has made some major strides in combating the epidemic, challenges remain, Cyr says.

"We have major issues down the road," she explains. "We have a new Ryan White Care Act, which needs to be revised, and we have Medicaid policies that have been in moratorium, and so we're looking for a new administration to hopefully prioritize health and HIV as an epidemic."

Time to just say no to abstinence funding

One of the campaign promises Obama has made is that he will eliminate government programs that do not work and improve funding for those that have long-term consequences.

AIDS advocates suggest that abstinence-only funding programs should be cut given that criteria.

"I venture to say that the current presidential administration has done damage to HIV prevention in terms of values-based, rather than evidenced-based, programs," Cyr says. "It's a contradiction that we're promoting evidenced-based strategies when we're promoting abstinence-only."

President-elect Barack Obama's HIV priorities

The Obama/Biden presidential campaign created a six-page list of HIV/AIDS priorities prior to the election.

Here is a summary of the domestic priority list, which can be viewed in full at www.barackobama.com/pdf/issues/FactSheetAIDS.pdf:

• National HIV/AIDS Strategy: Obama pledged that in his first year of presidency he would develop and begin to implement a comprehensive national HIV/AIDS strategy encompassing all federal agencies. It would be designed to do the following:
— reduce HIV infections;
— increase access to care and reduce HIV-related health disparities;
— provide measurable goals;
— list timelines and accountability mechanisms.

• Fix the nation's health care system: Obama said his goal is to sign universal health care legislation by the end of his first term in office. This program would ensure that people living with HIV have access to lifesaving treatment and care.

• Bring Medicaid to low-income, HIV-positive Americans: Obama is a co-sponsor of the Early Treatment for HIV Act, which would help provide Medicaid coverage to more low-income Americans living with the disease.

• Fight HIV health disparities: Obama stated a desire to fight homelessness and poverty, which he calls a key driver of the epidemic, and to address health insurance access disparities.

• Promote AIDS prevention: Obama said he'd focus on preventing new infections with a strategy that relies on sound science and includes comprehensive sex education that is age-appropriate. He also said he'd support increasing federal money for science-based HIV programs, and he'd lift the ban on federal funding for needle exchange as a strategy to reduce HIV transmission among injection drug users and their partners.

• Expand research funding: Obama stated a desire to expand research funding, especially for prevention options, such as a vaccine and microbicides.

The Obama administration should cut all of the discretionary funds for abstinence-only education, which has been the centerpiece of the Bush administration, Schmid says.

Some of the abstinence-only program funding is mandatory as part of Medicaid legislation, but the discretionary funding easily could be cut, he adds.

"Abstinence-only is purely ideological and is playing to Bush's base," Schmid says. "Right now the discretionary part is $113 million, and it could be put right into HIV prevention."

To fully fund HIV prevention, according to recent research numbers supplied by the Centers for Disease Control and Prevention in Atlanta, GA, would cost $4.8 billion more than currently is being spent, Schmid notes.

"We need more money," he says. "It's difficult, but it's all priorities, and it's our job to make HIV funding a priority since there will be more people out there needing our services, especially in an economic downturn."

Despite the challenges ahead, these are the days for some glimmer of hope, AIDS advocates say.

"We're optimistic and hopeful, as so many people in the country are, as we're on the door of what may well be a new day in this country — not only for HIV/AIDS, but in general," Johnson says. ■

Making grant $ stretch through networking

HIV clients become peers, peers become staff

A New York City AIDS organization has demonstrated for years how to stretch funding and make programs more effective through a combination of collaborative meetings, networking, and volunteers.

"What has been really helpful to us as a collaborative is we have a very large network of women who work within other nonprofit organizations and who volunteer with us," says **Claire Simon**, executive director of The Women's HIV Collaborative of New York in New York, NY.

The network has stretched dollars and its small staff of two fulltime and one part-time employees by giving the organization access to researchers who volunteer time for projects, and it's helped with policy relations and advocacy work, Simon says.

The collaborative's work involves connecting HIV-positive women and girls to services throughout New York City.

For example, the organization publishes a pocket guide to HIV/AIDS services. It's 52-page booklet that is designed to fit in a woman's purse. Soon, it will also be available on the organization's Web site, Simon says.

"We've committed to having this document in as many organizations as possible and at the department of health testing sites," Simon says. "We particularly want it available at places where women can get tested, and if they are diagnosed as HIV positive, we want it to be something they can walk out the door with."

Another strategy involves the organization's community roundtable meetings in which leaders from a wide variety of groups and government entities gather to discuss their roles in helping women.

The roundtable meetings typically focus on a theme, such as women and the criminal justice system, which had about 75 attendees, representing 20-25 different groups, Simon explains.

At this roundtable meeting, attendees discussed how women in the criminal justice system learn of their HIV status and what happens with them when they have children who are taken away from them or when they have a partner who also is incarcerated, Simon says.

"We provide a space where partners can come together and build up relationships," Simon says. "It's a relationship-building tool."

The meetings usually are held on the second Thursday of the month, from 9 a.m. to 11 a.m. The panel consists of people with a range of views from direct service to research to advocacy and policy work, Simon says.

Panel moderators typically provide background information and statistics, and then each panelist discusses his or her own interest in the topic being discussed, she adds.

"They talk about what's happening with the population, what they're seeing, and what are the gaps in services," Simon says. "Then we generally try to get a person directly involved, like a woman who had been incarcerated, to speak about her experiences."

As the panelists and audience raise various issues and challenges, someone else attending the meeting might speak up with a potential solution.

"Everyone can ask questions and make comments, and this is where the networking comes in," Simon explains. "One goal of the collaboration is to create innovative solutions and strategies around these issues."

Often, attendees will raise questions, and then someone there will offer a creative solution and expertise to making the solution happen.

"Someone could say they'd write a grant or develop a plan for a solution," Simon says.

For example, one researcher who attended the collaborative meetings has since helped the organization with a research and meta-analysis project, Simon says.

"It saves us money," Simon says. "Having that level of expertise at the table is really informative to the work we're doing."

In another example, the organization's HIV/AIDS pocket guide was the result of a roundtable meeting.

"Time and again at these meetings people would ask, 'Where do I send this woman for this or that?'" Simon says. "We created this document with the help of our colleagues to say, 'Here's something that you can have in your waiting room, in your office, and if you're testing a woman and she's HIV positive, she can use the guide.'"

Another example of a collaborative effort resulted from a youth in foster care forum about young women of color, she notes.

"We partnered with an organization called Young Women of Color HIV/AIDS Coalition, and they work with young women and service providers who do not do HIV prevention," Simon says. "They share information about HIV and its impact on young women."

So someone who has a literacy program that reaches a large population of young women of color could help provide HIV prevention education to the literacy clients, Simon explains.

"We wanted to target folks who weren't doing HIV prevention and have them see it as a youth model," Simon says. "They have the opportunity to share information with the young women they work with."

A job placement and readiness forum resulted in providing networking for HIV-positive women and at-risk women who had an interest in various professional career areas.

At a forum on youth in foster care, a couple of attendees discovered that they could collaborate on services, a discovery that would never have happened if it weren't for the forum, Simon says. ■

ADHERENCE STRATEGIES

ASO's collaborate with medical providers

Services help patients improve adherence

With HIV/AIDS medical providers and AIDS service organizations (ASOs) all making do with less federal money these days, there is a new model for how the two groups can help more HIV patients with medical treatment adherence through collaboration.

"We understand the relationship between programs with different expertise and similar consumers, and we want to ensure a full access to our range of services," says **Sharen Duke**, MPH, chief executive officer of AIDS Service Center New York City (ASC) in New York, NY.

"So ASC has numerous partners with medical providers, homeless shelters, drug treatment programs, parent-teacher associations (PTAs), and other community organizations," Duke says. **(See brief story about collaboration with homeless shelters, p. 138.)**

ASC's collaborations with medical providers enables health care organizations to preserve their resources and expand access to services for their HIV/AIDS patients, Duke explains.

Some of these collaborations already help patients with medication and treatment adherence, although that soon will become a bigger priority, Duke notes.

"Medication adherence is the next level for us to incorporate into these collaborative models," Duke says. "Right now we're focused on case management."

For example, ASC works with New York Presbyterian Hospital in a way that includes having ASC's case managers involved with the hospital's discharge planning process, Duke says.

"This is unprecedented for an outside entity to be part of the inpatient discharge planning process," she adds.

"When patients are admitted as inpatients from the emergency room, and when they're identified as not connected to outside medical programs, ASC is called in," Duke explains. "We go into the hospital and, with the client's permission, we conduct an intake at the bedside."

On the day of discharge, an ASC professional will be present to escort the client home.

"Then we will pick the client up from his home and bring him to his first outpatient medical appointment post-discharge," Duke says.

"It's a phenomenal service for medical providers," she says. "And for people who are at risk of falling out of care, it's the additional support and social connection that is the difference between getting the continued medical care and falling out of medical care."

While the collaboration with New York Presbyterian Hospital works very well for ASC, patients, and the hospital, it's not a one-size-fits-all type of model, Duke notes.

ASC works with eight or nine hospitals and health centers, and each collaboration is adapted to fit well for that particular medical provider.

"The collaborations are the results of several months of meetings, identifying mutual benefits, designing service models tailored to each site's specific patient needs and administrative needs," Duke says. "Each hospital and health center is different, so the way we work with each of them has to be tailored to fit their culture, structure, and patients."

For example, on Manhattan's Lower East Side, there is a primarily Hispanic population. So ASC provides bilingual staff to support the medical providers there, she says.

In another unique model, ASC works with Harlem East Life Plan (HELP) in East Harlem at HELP's methadone maintenance clinic, Duke says.

Working with homeless shelters to expand reach

Model works in other settings, as well

The AIDS Service Center New York City (ASC) in New York, NY, teams up with the city's homeless shelters to expand its reach into high-risk communities.

"People residing in homeless shelters are marginalized and are often outside the health care delivery system, and they often have issues of mental illness and drug addiction," says Sharen Duke, MPH, chief executive officer of ASC.

"So all of those behaviors place them at very high risk for HIV," Duke says.

Since homeless shelters typically do not have services related to HIV prevention, ASC has targeted the shelters for collaborative educational services.

ASC sends peer educators, who have had similar life experiences as the people found in homeless shelters, to the shelters to talk about HIV testing, Duke says.

The peer educators often have been homeless and have pasts that include drug abuse and prostitution, Duke notes.

"They can say, 'I've walked your walk, and you can do something different,'" Duke says.

This program is a good example of how ASC targets organizations that cater to high-risk populations, but which do not directly provide HIV services, she notes.

"We also go into PTAs in East and Central Harlem in collaboration with public schools, and we target women through coffee klatches and do educational workshops on HIV prevention, women's anatomy, reproductive health, and how to talk with your children and disclosure issues," Duke explains. "It's taking the model of HIV prevention and bringing it to people who don't have the expertise, but who would benefit from it."

ASC provides HIV testing and counseling to those people in homeless shelters, and provides wrap-around support that connects homeless clients to medical care and treatment when they are diagnosed as HIV positive, Duke adds.

"The beauty of this collaboration is that everyone wins," she says. "And this is consistent with the New York City Health Department's goals of identifying people who are living with the virus but are unaware of their HIV status."

Unfortunately, the city's funding shortfalls have forced it to cut some services that needed by HIV clients, including discontinuing harm reduction outreach in homeless shelters, Duke notes.

"This program is ending in June, and it's been successful for about 10 years," she says.

The health department has made it a priority to identify people unaware of their serostatus, Duke says.

"They say there are 4,800 New Yorkers who are HIV positive and don't know it," Duke says. "And this is a program that identifies them and connects them with care, so it's my hope they'll find other resources to sustain this kind of service because it's certainly needed." ■

ASC has a case management team who works at the site from 7 a.m. to 3 p.m., which are the hours that work best for HELP, she notes.

"We catch folks who are coming in for their methadone appointments, and if someone misses a methadone appointment, we are notified and will go out and find them and bring them in," Duke says. "At HELP, our case managers have expertise in addiction issues because the work there is centered around the methadone clinic."

Another model is one employed in the collaboration with Beth Israel Medical Center.

ASC pays rent to locate case managers in the Beth Israel AIDS clinic, where they work with HIV clients when the clinic's HIV services identify people who would benefit from additional support, Duke says.

Also, the case managers are part of the hospital's social work team.

"While patients are at the AIDS clinic for medical visits, they meet with ASC case managers, who help them identify their needs related to taking their medication," Duke explains. "We do case conferencing and function as a part of the social work team within the medical clinic, and we can provide wrap-around support at our agency."

In yet another example of the collaborations, ASC has a partnership with St. Vincent's Hospital in which the hospital initially had posted an HIV counselor to ASC for the purpose of conducting HIV testing, Duke says.

"When we identify someone as HIV positive, we bring the person back to St. Vincent's Hospital for medical care," Duke says. "This partnership has increased ASC's capacity and taught us how to do HIV testing, so we now have our own HIV testing program."

St. Vincent's still does the confirmatory testing for clients who are identified as HIV positive through ASC's program, she adds.

From the medical providers' perspective, these collaborations enable them to extend their social work departments through ASC's outpatient staff, saving providers hundreds of thousands of dollars in staff time, Duke says.

"We provide home-based services and escort patients to entitlements advocacy and housing assistance," she explains. "The health systems' staff cannot meet the full demand [on their own] because of their limited resources."

"Health systems can't do everything on their own," Duke notes. "The collaboration with a community-based agency that has expertise in providing services within the community and within patients' homes adds value and consistency to sustaining patients in their care." ■

Research focuses on rapid HIV testing

Is rapid HIV testing in use in your local family planning facility? Findings from a 2007 survey conducted by the National Alliance of State and Territorial AIDS Directors Rapid point to "yes"; 94% of health departments indicated they use rapid HIV testing as part of health department-supported HIV testing programs.[1]

Results from a recently released study indicate that the OraQuick Advance test (OraSure Technologies, Bethlehem, PA), when conducted on oral fluid in a low-prevalence emergency department population, might lead to a high rate of false-positive results.[2]

In the study, researchers at Brigham and Women's Hospital (BWH) in Boston report that out of 849 adults tested with the oral rapid HIV test, 31 had reactive results. Five patients were truly HIV-infected upon confirmation. Investigators found 84% of positive rapid screening tests turned out to be false when further testing documented that the patient did not have HIV infection.[2]

The news follows recent reports regarding similar false-positive readings from the New York City Department of Health and Mental Hygiene. Between October 2007 and April 2008, the agency documented a higher-than-usual percentage of false-positive oral HIV tests in its sexually transmitted disease (STD) clinics, with the false-positive rate reaching 1.1% in some months.[3] While the rate is below the Food and Drug Administration (FDA) threshold of 2%, it is higher than expected.

In a statement, OraSure officials say that test accuracy rates remain within the FDA-approved and expected range of performance, based on monthly data from "hundreds of thousands of tests" conducted annually in New York and around the nation.[4] However, the company states it takes every customer inquiry or discordant situation very seriously and is working closely with BWH and the New York City health department to resolve any concerns about the performance of the test.

Review the study

To perform the current study, BWH researchers recruited adults without known HIV disease who were patients at the hospital emergency department. Investigators collected oral samples from the patients and processed them in the emergency department laboratory, where they were read within 20-40 minutes. If results were negative, patients received no further testing for HIV; if results were reactive, patients had a blood test to confirm HIV infection. Confirmatory tests included a serum enzyme-linked immunoassay, a Western blot test, CD4 (cluster of differentiation 4) count, and plasma HIV-1 RNA (ribonucleic acid) level.

Researchers then examined the number of patients who had both reactive results and confirmed HIV infection. Of the 849 adults included in the study, 39 had a reactive rapid oral HIV test. Confirmatory tests showed that five of the 39 patients were HIV-infected, which yielded a 0.6% prevalence rate of HIV infection in the study population. Specificity of the oral test in this setting was 96.9% (95% confidence interval, 95.7% to 98.1%).

Tests key in HIV fight

In 2006, the Centers for Disease Control and Prevention (CDC) called for voluntary HIV screening among all patients ages 13-64.[5]

Does the CDC still recommend oral fluid rapid HIV tests? Yes, according to information released following the New York report.[6] The agency says it continues to encourage the use of oral fluid rapid HIV tests "not only because they allow for testing to be done in many more settings than before, particularly non-clinical settings, but also because they offer the potential to increase the number of persons who are tested and who receive their test results."[6]

"It is important to note, however, that users need to be aware of the potential for unexplained variability in the rate of false-positive test results and the need to follow a reactive (positive) oral fluid rapid test with a confirmatory test," states the CDC guidance. "Finally, before using any rapid HIV test, patients should be informed that reactive rapid HIV test results are preliminary and require confirmation."

In the United States, there are six FDA-approved rapid HIV tests: OraQuick Advance, Clearview Stat-Pak, Clearview Complete (both from Inverness Medical Professional Diagnostics, Waltham, MA), Trinity Uni-Gold (Trinity Biotech, Bray, Ireland), Reveal G-3 Rapid HIV-1 Antibody Test (MedMira, Halifax, Nova Scotia, Canada), and MultiSpot HIV-1/HIV-2 Rapid Test (BioRad Laboratories, Hercules, CA). Such tests have been in use for many years in international markets; sensitivity data provided in support of licensure indicate such tests are at least as sensitive as traditional enzyme immunoassay tests.[7]

Rapid HIV testing represents an expanding field of knowledge; the more providers use these tests in different settings, the more is learned, states **Rochelle Walensky**, MD, MPH, associate professor at Harvard Medical School and an infectious disease physician at BWH. "We continue to use the OraSure test in the emergency department," says Walensky, who served as lead author of the current study.

With rapid testing, providers need to keep in mind two important points, says Walensky. First, all results should be considered preliminary until they are confirmed, and second, patients should be encouraged to follow up on test results, with providers responsible for facilitating that follow-up, she states. "We offer confirmation testing onsite, and we stay in close contact with the patient so that we can facilitate linkage of care for them," states Walensky.

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Time to step up HIV testing in women

Review the last three patient charts: a 19-year-old college student, a 26-year-old mother of two, and a 43-year-old woman who is newly divorced. Which women were offered screening for HIV?

All of them, according to new guidance issued by the American College of Obstetricians and Gynecologists (ACOG).[1] The ACOG recommendations fall in line with those issued in 2006 by the Centers for Disease Control and Prevention (CDC) calling for voluntary HIV screening among all patients ages 13-64.[2]

The ACOG recommendations call for routinely screening all women between ages 19 and 64 for HIV. Targeted screening should be performed in women outside the age range who are at high risk, such as sexually active teens under age 19 and women older than 64 who have had multiple partners in recent years, the ACOG guidance advises.[1]

HIV testing rates have remained fairly stable from 2001 through 2006. While 10% of adults ages 18-64 report getting tested each year, the percentage of people who report ever being tested in their lifetimes has not increased, according to new surveillance from the Centers for Disease Control and Prevention (CDC).[3]

HIV testing is the essential first step in linking people with HIV to medical care and ongoing support to help them maintain safer behaviors, says **Melissa Shepherd**, acting chief of the CDC's Division of HIV/AIDS Prevention's Technical Information and Communications Branch. Most new infections are believed to be transmitted by individuals who are unaware of their infection, says Shepherd. Studies show that once individuals learn they are HIV-infected, most will take steps to protect their partners, she notes.

Women of color at risk

While all women should be screened for HIV, providers and their patients must be aware that women of color are disproportionately affected by the disease, advises a second committee opinion issued by ACOG.[4]

The CDC estimates 56,300 HIV infections occurred in the United States in 2006. According to the CDC analysis, infection rates among blacks were seven times as high as whites (83.7/100,000 people versus 11.5/100,000) and almost three times as high as Hispanics (29.3/100,000 people).[5]

Women of color are acquiring HIV at higher rates compared with other groups, says **Maureen Phipps**, MD, MPH, director of the research division of the obstetrics and gynecology department and associate professor in the departments of obstetrics and gynecology and community health at the Warren Alpert Medical School of Brown University in Providence, RI. "Being able to diagnose a person with HIV early on is important because they need to receive appropriate medications and on-going health care," says Phipps, who served as a co-author of the ACOG committee opinion. "Early diagnosis is also important for the person to become well-educated about how to prevent transmitting the disease to others."

The CDC is working to fight HIV among African Americans through the Heightened National Response, a partnership of CDC, public health partners, and African American community leaders. The partnership is designed to build upon progress in four key areas: expanding prevention services, increasing testing, developing new interventions, and mobilizing broader community action. One such initiative is "Take Charge. Take the Test," a one-year HIV testing social marketing campaign for African-American women in Cleveland and Philadelphia. The campaign, held October 2006 to 2007, promoted local toll-free HIV testing hotlines through radio, print, and billboard advertisements. Preliminary findings indicate that the campaign exposure led to increases in information-seeking behavior.[6]

Shepherd says, "Social marketing campaigns such as 'Take Charge, Take the Test' about HIV testing are designed to increase knowledge of HIV status and to promote HIV risk reduction."These campaigns are important components of the CDC's comprehensive program for HIV prevention."

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FDA Notifications

FDA approves generic lamivudine: On Oct. 7, 2008, the FDA granted tentative approval for a generic formulation of lamivudine 150 mg and 300 mg tablets, manufactured by Macleods Pharmaceuticals Limited of Daman, India, indicated for use in combination with other anti-retroviral drugs for the treatment of HIV-1 infection.

"Tentative approval" means that FDA has concluded that a drug product meets 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 outside the United States under the President's Emergency Plan for AIDS Relief (PEPFAR). This product is a generic version of Epivir, manufactured by GlaxoSmithKline, which is still under patent protection.

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."

This application was reviewed under expedited review provisions developed by FDA for the PEPFAR program.

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

A list of all Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan is available on the FDA website. ■

Darunavir label has these changes

This FDA message describes the following important changes affecting darunavir (Prezista):

- Traditional approval of Prezista;
- New dosing regimen for treatment-naïve patients;
- New 400 mg tablets;
- Revised Pregnancy Category.

On Oct. 21, 2008, the FDA granted traditional approval to darunavir 600 mg, co-administered with 100 mg ritonavir and with other antiretroviral agents, for the treatment of HIV-1 infection in treatment-experienced adult patients. Darunavir was granted accelerated approval on June 23, 2006, based on analysis of plasma HIV-1 RNA levels in two controlled studies of 24 weeks duration. The traditional approval is based on a 48 week phase 3 study (TMC114-C214) in treatment-experienced patients and continuation of two controlled trials of 96 weeks duration in clinically advanced, treatment-experienced patients, confirming durability of the virologic response.

In addition to the traditional approval, a new dosing regimen for treatment-naïve patients was approved. The recommended dose for treatment-naïve adult patients is darunavir 800 mg (two 400 mg tablets) taken with ritonavir 100 mg once daily, with food. The type of food does not affect exposure to darunavir.

The dosing regimen for treatment-experienced patients remains unchanged as darunavir 600 mg taken with ritonavir 100 mg twice daily, with food.

The dosing regimen in treatment-naïve patients was based on a randomized, controlled, open-label Phase 3 study (Study TMC114-C211) comparing darunavir/ritonavir 800/100 mg once daily versus lopinavir/ritonavir (Kaletra) 800/200 mg per day (given as twice daily or as once daily regimen). Both arms used a fixed background regimen consisting of tenofovir and emtricitabine. The proportion of patients who were virologic responders (HIV RNA < 50 copies/mL) was 84% for darunavir/ritonavir and 78% for lopinavir/ritonavir.

Additionally, the pregnancy category was changed from B to C (section 8.1). Additional details regarding the supportive animal data for the reproduction studies and juvenile toxicity studies are included. The section now reads:

Pregnancy Category C: Prezista should be used during pregnancy only if the potential benefit justifies the potential risk.

No adequate and well-controlled studies have been conducted in pregnant women. Reproduction studies conducted with darunavir showed no embryotoxicity or teratogenicity in mice, rats and rabbits. However, due to limited bioavailability and/or dosing limitations, animal exposures (based on AUC) were only 50% (mice and rats) and 5% (rabbit) of those obtained in humans at the recommended clinical dose boosted with ritonavir.

In the rat pre- and postnatal development study, a reduction in pup body weight gain was observed with darunavir alone or in combination with ritonavir during lactation. This was due to exposure of pups to drug substances via the milk. Sexual development, fertility and mating performance of offspring were not affected by maternal treatment with darunavir alone or in combination with ritonavir. The maximal plasma exposures achieved in rats were approximately 50% of those obtained in humans at the recommended clinical dose boosted with ritonavir.

In the juvenile toxicity study where rats were directly dosed with darunavir, deaths occurred from post-natal day 5 through 11 at plasma exposure levels ranging from 0.1 to 1.0 of the human exposure levels. In a 4-week rat toxicology study,

CE/CME *questions*

4. Which of the following is a priority for HIV/AIDS spending by President-elect Barack Obama?
   A. Bring Medicaid to low-income, HIV-positive Americans
   B. Fight HIV health disparities
   C. Promote AIDS prevention
   D. All of the above

5. An AIDS advocacy group holds collaborative panel meetings for the purpose of making HIV funding services and dollars stretch through which of the following?
   A. Raising funding for seed grants and pilot projects
   B. Networking and volunteer efforts
   C. Both A and B
   D. None of the above

6. AIDS Service Center New York City forms partnerships with health care facilities across the city to expand services to HIV clients. Which of the following is not an example of one of these partnerships?
   A. ASC works with a hospital to be a part of discharge planning and helping patients return for post-discharge visits
   B. ASC rents an office in a hospital for the organization's case managers to work with HIV patients and provide expanded services
   C. ASC uses a hospital's HIV patient database to target HIV positive prevention education
   D. ASC works with a hospital to provide and confirm HIV testing results

Answers: 4. A; 5. B; 6. C.

COMING IN FUTURE MONTHS

- Rapid testing is underutilized, study shows
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- Peer education and skills training program has right mix for success
- Here's latest from IDSA/CROI

when dosing initiated on post-natal day 23 (the human equivalent of 2 to 3 years of age), no deaths were observed with a plasma exposure (in combination with ritonavir) of 0.1 of the human plasma exposure levels.

Several other changes were made to the package insert and include the following major revisions. Additionally, the label was converted to Physician Labeling Rule (PLR) format to make product labeling more informative and applicable to clinicians.

Section 6: Adverse Reactions was updated to include safety data from studies TMC114-C211 and TMC114-C214. Additionally serious adverse drug reactions of at least moderate intensity during the Phase 2B and 3 studies were added to section 6.3.

Section 6.6 Postmarketing Experience includes rare events of hypersensitivity including facial edema and rhabdomyolysis associated with coadministration with HMG-CoA reductase inhibitors.

Section 7, Drug Interactions, Table 6: Established and Other Potentially Significant Drug Interactions was updated to include appropriate dosing of carbamazepine and rifabutin in combination with Prezista/ritonavir. ■

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.

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2008 Index

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