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Congress, OSHA finally join fight to mandate needle safety precautions

Legislation would implement a federal standard on needle safety

With legislation in the works in some 20 states to require health care providers to implement the use of needle safety devices, Congress and the Washington, DC-based Occupational Safety and Health Administration (OSHA) are jumping on the bandwagon with legislation and new regulations aimed at reducing the risk of bloodborne diseases such as HIV and hepatitis from accidental needlesticks.

In May, U.S. Representatives **Pete Stark** (D-CA) and **Marge Roukema** (R-NJ) introduced the Health Care Worker Needlestick Prevention Act of 1999 to combat the estimated 590,000 health care worker needlesticks from sharps products each year.

The legislation is modeled after a California law to protect health care workers from accidental needlestick injuries, which goes into effect on July 1. California was the first state to pass this type of law, although 20 other states are expected to adopt similar measures.

Frustrated by years of apparent foot-dragging on the part of OSHA and Congress, the Washington, DC-based Service Employees International Union (SEIU) recently launched a state-by-state grass-roots effort to implement needle safety legislation. "We totally agree that a federal standard is the ultimate solution," says **Andrew Stern**, SEIU president. "We have called upon the producers of needles and other members of the health care community to join with us both in either getting OSHA to establish a national standard or [to] pass federal legislation."

The proposed federal law would amend OSHA regulations to require that employers utilize needleless systems or other engineered safety mechanisms to prevent the spread of bloodborne pathogens. The bill also includes an exception process, because these products may not be appropriate for all medical care settings.

In other provisions, the bill enhances current needlestick reporting requirements and establishes a national clearinghouse to collect data on safe technologies.

"Health care workers shouldn't have to risk their lives while saving the lives of their patients," Stark says. "Safe needle devices are used in some facilities across the country, but our bill would make use of safe technology the norm rather than the exception."

Although HIV transmission from needlestick injuries is rare, better protective technologies could help eliminate the risk of HIV and other more easily transmitted infections such as hepatitis, according to **Daniel Zingale**, director of Washington, DC-based AIDS Action, which supports the measure. (See related story on HIV transmission, p. 74.)

“I think the Stark bill is primarily driven by the availability of technology that for the first time is recognized as foolproof,” Zingale says. “This bill can move us from where HIV infection in a medical setting is highly unlikely to where it’s not heard of.”

In the meantime, OSHA has announced its three-point plan to reduce the risk of occupational exposure to bloodborne diseases due to sharps injuries. Although the details have not yet been made available, OSHA will make the following general areas a priority:

- The agency has proposed a requirement in the revised Recordkeeping Rule that all injuries from contaminated needles and sharps be recorded on OSHA logs. Officials say they’ll take final action on this proposal in the fall.

- OSHA will revise the bloodborne pathogens compliance directive later this year, including newer and safer technologies in the standard.

- OSHA will amend the bloodborne pathogens standard and place needlestick and sharps injuries on the fall regulatory agenda.

OSHA has reviewed nearly 400 comments from hospitals and other providers about needlestick safety, and the agency’s decision to change standards is in response to these comments, says **Charles N. Jeffress**, OSHA administrator.

Jeffress says OSHA welcomes the Stark/Roukema legislation. “I share their goal of wanting to reduce these types of injuries, and welcome the opportunity to work with all members of Congress on how to better protect health care workers from these potentially deadly problems,” he adds.

OSHA’s report on its analysis of needlestick safety as practiced across the country discusses various devices and their costs to medical facilities. But Jeffress and other OSHA officials refuse to speculate on whether the new standards will list or require any specific types of devices.

Here are the devices mentioned in the report:

- **Vacuum tube phlebotomy needle for venous blood draw:** The conventional device costs 10 cents and the safer device costs 33 cents. OSHA estimates that switching to the safer device would

cost a 250- to 300-bed hospital an additional \$15,500 per year.

- **Butterfly needle for venous blood draw:** The conventional device costs 65 cents and the safer device costs 90 cents. A 250- to 300-bed hospital would pay an additional \$4,000 per year.

- **IV catheter for IV access:** The conventional unit costs 75 cents and the safer catheter costs \$1.75. This would result in a 250- to 300-bed hospital spending an extra \$33,500 a year.

- **Hypodermic needle/syringe:** The conventional item costs 5 cents, while the safer device costs 25 cents. A switch to the safer product could cost a 250- to 300-bed hospital \$67,000 more per year.

However, health care facilities are not uniformly sold on the idea of these safer devices, according to the OSHA report.

Hospitals responding to OSHA’s survey said they haven’t introduced these devices because of the increased cost and staff resistance to the changes. Plus, some hospitals cited problems with equipment incompatibility and contractual purchasing agreements in which they are limited in their choices of safer alternatives.

(Editor’s note: To review OSHA’s record summary of the agency’s request for information on needlestick injuries, visit the OSHA Web site at www.osha.gov and click on “Needlestick Safety.”) ■

Provider-to-patient HIV transmission remains rare

CDC to release needle safety guidelines as well

While legislative and regulatory bodies focus on transmission of HIV from patients to health care workers, the public and media often have paid more attention to cases in which health care professionals infected patients with HIV, such as the 1990 case when a Florida dentist with AIDS infected six of his patients with HIV.

Despite the flurry of media attention that results when such cases occur, they remain very rare. In fact, the Atlanta-based Centers for Disease Control and Prevention (CDC) acknowledges only two instances worldwide when this has happened: the Florida dentist, and an HIV-infected French surgeon who evidently infected a patient

during orthopedic surgery, according to a recent report in the *Annals of Internal Medicine*.¹

It's more common for patients to transmit the virus to providers. The CDC estimates that a health care worker's risk of contracting HIV from a needle that contains the blood of an infected person is one in 200.

The CDC plans to release guidelines this fall that focus on prevention of needlestick injuries. The guidelines won't offer advice about specific safety devices, but they will give providers some strategies to follow in developing their own prevention standards, says **Denise Cardo**, MD, chief of the CDC's HIV Infection Branch and Hospital Infections Program.

"We're trying to make a document to guide hospitals in how to select, implement, and evaluate prevention strategies," Cardo says. "We'll give them a comprehensive plan for how to do that, including eliminating unnecessary use of needles, using devices with safety features, and educating staff on work procedures and prevention practices."

The guidelines also will provide background information on needlestick injuries, and they will show providers how to use their own surveillance data to make decisions about safety devices and practices.

"There are a lot of injuries occurring that could be prevented," Cardo says. For example, one study found that health care workers sometimes don't know how to use new safety devices because hospitals haven't properly trained staff in how to use the safety equipment.

Cardo says providers who want more information before the CDC's guidelines are released can check with the Chicago-based American Hospital Association to see their guidelines, released in May, titled "Sharps Injury Prevention Program."

By focusing on preventing needlestick injuries, providers also will cut down on health care workers' exposures to hepatitis, which lately has caused clinicians great concern because that virus is easier to transmit than HIV, says **Julie Gerberding**, MD, MPH, director of the hospital infections program for the CDC.

CDC statistics confirm 1,000 health care worker hepatitis B infections resulting from needlestick injuries and 54 health care worker HIV infections through occupational exposure. According to Gerberding, there have been 53 HIV-infected U.S. health care providers evaluated in retrospective studies, and these providers treated 22,759 patients — none of whom were

determined to have acquired HIV from the infected provider.²

On the other hand, providers must protect themselves from needlestick injuries, which place them at risk of contracting HIV or other viruses, Gerberding says.

"I think the basic bullet message is this: Most exposures that lead to bloodborne pathogens are preventable, and the highest priority should be prevention," Gerberding says. "If the goal is to protect both patients and providers, the only situation [in which] the provider is likely to come into contact with the patient's blood is through a needlestick injury."

The CDC doesn't promote specific needle products, but safer needles clearly should play a role in preventing HIV transmission, Gerberding says.

Phlebotomist reused disposable needles

The possibility of providers transmitting HIV to patients has again jumped to the forefront of national concern because of an incident in which a phlebotomist at a SmithKline Beecham lab in Palo Alto, CA, admitted reusing disposable needles while working at the lab between June 1997 and March 1999. SmithKline Beecham officials sent letters to some 3,600 patients encouraging them to be tested for HIV and hepatitis. Patients already have begun filing lawsuits against the lab.³

The French case, by contrast, provided the first solid example of how a surgeon could transmit the virus during an operation. The French surgeon had apparently been infected with HIV from a needlestick injury while performing surgery in the early 1980s at a hospital in the Paris suburbs. His patient's HIV status was unknown, and the patient later died. But the physician suffered a febrile illness of fatigue, weight loss, and rash shortly after that event.

The surgeon learned he was HIV-positive in 1994 after he was found to have HIV encephalopathy. Then, in 1995 — at the surgeon's request — the French Ministry of Health offered HIV testing to patients on whom the surgeon had operated. Investigators used a CDC risk ascertainment questionnaire to interview the surgeon. They also reviewed the surgeon's operating room practices and compared them with his peers. The surgeon had never received specific training about universal precautions, and he reported frequent opportunities for blood exposures, such as tightening suture wires with his fingers and tying sutures with the needle still attached.

Investigators found one of the surgeon's former patients, a 70-year-old woman, who was HIV-positive. She had undergone a total hip prosthesis with bone graft in 1992. She tested negative for HIV prior to the surgery, and tested positive in 1994. There were no needlestick injuries or other potential exposures recorded in reports of her procedure. The woman's viral sequences were significantly similar to the surgeon's, and investigators concluded that she had been infected by the surgeon, probably due to some of his risky habits, including palpating sharp tips or pins.

[Editor's note: To obtain a copy of the American Hospital Association's 77-page book titled "Sharps Injury Prevention Program, a Step by Step Guide," contact AHA at P.O. Box 92683, Chicago, IL 60675; telephone: (800) 242-2626; fax: (312) 422-4505. The book costs \$25 for AHA members and \$75 for non-members.]

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Next HIV guidelines likely to include salvage therapy

Latest version touts abacavir as alternative

The federal HIV treatment guidelines, which give clinicians a national seal of approval for various drug regimen choices, soon will include recommendations about choosing salvage therapy, providing guidance in deciphering the increasingly complex science of cross-resistance and HIV mutations. Salvage therapy occurs after the failure of a protease inhibitor-based regimen.

"The [guidelines] panel is taking on salvage therapy, and hopefully when we have our next update to the guidelines, we'll have something useful to say," says **Oren Cohen**, MD, executive secretary for the Panel on Clinical Practices for

Treatment of HIV Infection convened by the Washington, DC-based Department of Health and Human Services (HHS) and the Henry J. Kaiser Family Foundation of Menlo Park, CA. Cohen also is the assistant director for science policy at the National Institute of Allergy and Infectious Diseases in Bethesda, MD.

"As increasing numbers of HIV drugs are licensed, salvage therapy becomes more and more of an issue, making choices harder," Cohen says. "It's good news that there are more options, but there's little data available to help you make the right decision."

The recently released update to the "Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents" is the fifth revision to appear on the AIDS Treatment Information Services Web site at www.hivatis.org. The guidelines have been printed twice.

The latest version upgrades the nucleoside analog reverse transcriptase inhibitor abacavir (Ziagen). Previously, abacavir was listed as an experimental drug available through treatment investigations. Now the guidelines recommend it as an alternative to the preferred list of regimens.

Hypersensitivity remains problematic

The guidelines caution clinicians to watch for signs of hypersensitivity in patients on an abacavir regimen. In fact, it was partly because of this problem, which occurs in 3% to 5% of cases, that the panel was leery of making the drug a preferred recommendation, according to **Eric P. Goosby**, MD, director of the office of HIV/AIDS Policy at HHS.

Goosby, along with **Paul Volberding**, MD, professor of medicine and director of the Positive Health Program at the University of California School of Medicine in San Francisco, spoke at a recent teleconference about the revised guidelines. Goosby and Volberding are members of the guidelines panel.

"The key feature of abacavir sensitivity is that it tends to happen early on in treatment, often in the first few days," Volberding said. "It includes a fever, rash, malaise, and other things, but typically it's quite noticeable, and it gets worse with each dose."

Clinicians who have patients experiencing these side effects should immediately stop the drug and not restart it. If the drug is restarted, the side effects could worsen and even progress to death. One patient involved in an abacavir study

Study: New drug doesn't display cross-resistance

Fewer side effects, easier dosage

Agenerase, the first of a new generation of protease inhibitors to make it to the finish line, holds promise for clinicians looking for a powerful drug to use in salvage therapy, as well as for use with treatment-naive patients, according to a researcher who has studied the drug for a year.

"Because we have so many resistant species of virus in the community, we're always looking for new drugs that may have a chance of getting around those resistance patterns," says **Jeff Goodgame**, MD, principal investigator of clinical trials for Agenerase. Goodgame is associated with the Central Florida Research Initiative in Altamonte Springs, FL.

Agenerase (amprenavir), manufactured by Glaxo Wellcome in Research Triangle Park, NC, is the first protease inhibitor to be approved by the Rockville, MD-based U.S. Food and Drug Administration in more than two years.

So far, researchers have published data based on 24-week clinical trials, although 48 weeks of trials have been completed. Those data will be published in September, Goodgame says. "We're seeing a high range of effectiveness with the 48-week data," he says.

The 24-week studies show that amprenavir brought viral loads down to 400 copies/mL in therapy-naive patients, as well as in non-nucleoside reverse transcriptase inhibitor-experienced and nucleoside analog reverse transcriptase inhibitor-experienced patients when the drug was administered in triple combination therapy.

"Used in a combination with various drugs, it's very synergistic," Goodgame says. Amprenavir appears to do well with AZT and abacavir, for example.

However, Goodgame says, the drug's most promising aspect is that patients who take it

do not exhibit the mutation pattern found in patients on other protease inhibitor therapies. This means clinicians could use amprenavir as a salvage therapy and probably not see a cross-resistance pattern develop.

The key mutation associated with resistance to amprenavir is 50V, which has not been observed in patients who've taken other protease inhibitor therapies.

The drug's second big benefit is that it doesn't elevate glucose levels or lipids/triglycerides as much as other protease inhibitors do. This means patients may not develop lipodystrophy as readily. While some clinicians may be skeptical that this pattern will continue beyond the study's 24-week period, Goodgame says researchers saw the same trend at 48 weeks, as well.

"Amprenavir is more convenient than other regimens, and you can allow patients to take it twice a day with or without food," Goodgame says. The recommended dosage is eight 150 mg capsules twice daily.

Clinicians should caution patients that if they eat a high-fat diet, there will be some reduction in the drug's levels. The majority of adverse events were nausea, diarrhea, vomiting, rash, and perioral paresthesia. In 1% of patients, there were severe and life-threatening skin reactions, including Stevens-Johnson syndrome. The drug also may be associated with acute hemolytic anemia, diabetes mellitus, and hyperglycemia, as are other protease inhibitors.

"With all the protease inhibitors, the side effects become the primary issue," Goodgame says. "But after one month, this drug becomes very tolerable, with a little nausea and very little diarrhea, and if a patient develops a rash it's usually limited."

Researchers studied the drug's safety in more than 1,400 patients. They found that the drug could cause life-threatening reactions in interaction with some drugs, so clinicians should review the full prescribing information.

Glaxo Wellcome's wholesale price for Agenerase is \$16.50 per day or \$6,132 yearly. ■

died from what appeared to be a circulatory collapse, Volberding said. "Patients could potentially go into shock."

The guidelines as they appear on the Internet include a hypertext link to background material

on hydroxyurea, and the tables on drug interactions are more user-friendly, Cohen says.

"We were unhappy with how the tables were growing and becoming difficult to use, so the panel put a lot of hard work into updating them,"

Cohen says. “So now it’s a very nice reference for clinicians.”

The updated guidelines also address the issue of whether women’s HIV disease progresses at the same rate as men’s disease. The panel’s conclusion is that there is too little evidence of any difference for the guidelines to recommend clinicians start treatment sooner with women.

“One study suggested women progress at the same rate as men with only half the viral load,” Cohen says. “So while it’s an argument that could be made in favor of treating women sooner than men, the differences are not that great, and the study was in a cohort of injection drug users, so it’s not clear the results can be applied generally.”

Plus, other studies have found no difference between men and women in the rate of HIV progression, he adds. “So the panel reviewed this data and found no compelling reason to recommend a different threshold for women than men.”

When the guideline’s panel members finally address salvage therapy or second-line regimens, they could best do so with principles and illustrations rather than recommendations about specific drugs, says **Daniel Kuritzkes**, MD, associate professor of medicine and microbiology at the University of Colorado Health Sciences Center in Denver.

“Every patient has a unique history, and precisely what you use in salvage therapy depends on what kind of patient you have seen before, the patient’s mutation resistance, and any susceptibility that may be present,” Kuritzkes says.

“Also, much of what you do in salvage therapy depends on the drugs that are approved and the drugs that may be available through expanded access, and that’s hard to codify because the guidelines by nature tend to be somewhat conservative,” Kuritzkes adds. “Drugs currently under study are going to be hard to put in the guidelines because there’s not an adequate data base.”

Salvage therapy will be a difficult topic to distill into a format suitable for the guidelines, Volberding says. “Most of us grapple with this every day, and we know it’s a big issue.”

Plus, the guidelines never were intended to be a clinical cookbook, Goosby says. “We felt it really was an organic, viable, living document that needed to be updated.”

Panel members know HIV is evolving, as are standard treatments for it, so the guidelines are updated at irregular intervals to reflect these changes.

“There’s now a doubling and tripling of protease inhibitors occurring regularly that have not been studied adequately enough for us to put them in the document with confidence — but they’re out there,” Goosby adds.

By the time the guidelines are updated, many clinicians already have been using the newest drugs on the list, says **Aaron E. Glatt**, MD, chief of the division of infectious diseases at the Catholic Medical Center of Brooklyn, NY.

For example, the next version of the guidelines will include recommendations for one of the newest protease inhibitors, amprenavir (Agenerase), Cohen says. Amprenavir, which received accelerated approval in April from the Rockville, MD-based Food and Drug Administration has been available since September 1998 to several thousand patients through three early access protocols. **(See story on FDA’s approval of amprenavir, p. 77.)**

“It’s an exciting time, but everything is in a flux,” Glatt says. “Everyone is doing all different sorts of regimens now, with some people using five drugs. I’m using four drugs for patients with very high viral loads, and we experiment depending on what their response is and based on their viral load and previous drug history.”

[Editor’s note: For a printed version of the “Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents,” call (800) 448-0440. For more information about salvage therapy, check the Medscape Web site at www.medscape.com and click on the link to “Salvage Therapy for the Treatment of HIV Infection.”] ■

Names reporting fallout continues in states’ battles

Heated debates rise in states considering new laws

Since the Centers for Disease Control and Prevention (CDC) in Atlanta released its guidelines recommending names reporting late last year, political battles have erupted in more than a dozen states where new confidentiality and names reporting laws have been introduced.

To stir things up even more, some states have introduced laws that would further erode the confidentiality of a person’s HIV status, including partner notification laws, reporting HIV test

results to emergency workers and police, and mandatory testing requirements.

These developments have led to grass-roots protests, such as the half-dozen AIDS activists who chained themselves to furniture in the office of New York AIDS Institute Director Guthrie Birkhead, MD, in late April. The activists issued a list of demands, including asking the New York legislature to repeal the state's new names reporting and partner notification law.¹

So far, 33 states require names-based HIV reporting. Ten states have non names-based HIV reporting systems: Georgia, Illinois, Kentucky, Maine, Maryland, Massachusetts, Montana, New Hampshire, Oregon, and Rhode Island. Connecticut and Vermont have passed legislation requiring unique-identifier systems, but the laws have not yet been implemented.

Will names reporting hamper testing?

Names reporting might have the support of AIDS epidemiologists — who view it as the most efficient way to collect data on HIV infection rates nationwide — but the very mention of the practice is enough to rile AIDS activists, clinicians, and others who fear it will cause a major setback in community HIV testing and counseling efforts.

One of the strongest opponents of names reporting, the New York-based Lambda Legal Defense and Education Fund, has launched campaigns against various state proposals.

“We are afraid that names reporting is going to dissuade people from being tested and keep people from getting the treatment they need for AIDS,” says **Rachel Tiven**, managing editor for *Lambda Update*.

“We think ultimately an accurate count of people who are willing to be tested with their names is not an accurate count at all,” Tiven says. “You may have a more accurate list, but you may have dissuaded more people from being tested at all.”

Lambda wrote a protest letter to health officials signed by more than 60 leading AIDS and civil rights organizations, stating that names reporting will engender fear that discourages testing and creates more barriers to health care. The letter says, in part: “The overwhelming weight of evidence shows that significant numbers of people avoid testing if their names will be reported. Even a CDC-sponsored study, cited to show otherwise, demonstrated that nearly 20% of people interviewed identify names reporting as a factor preventing people from getting HIV tests.”

Names reporting might especially dissuade minorities from being tested because they often tend to be distrustful of government, some opponents charge.

“In Michigan, when they moved to names reporting, the amount of HIV testing in the African-American community decreased 26%,” says **Heather Sawyer**, JD, staff attorney for Lambda in Chicago. Lambda's Chicago office last year successfully challenged Illinois' move to names reporting and convinced state officials to switch to a non-name-based system as an alternative. (See story on Illinois' reversal on names reporting, p. 82.)

“What Illinois is doing is they've created a non-name identifier that has a formula for determining how each person will be uniquely identified without using the person's name,” Sawyer says. “We're now entering a two-year test period, and the state is training health care providers on how to code test results.”

New York internist **Robert Cohen**, MD, opposes his state's new names reporting law because it infringes on the private relationship he shares with his patients, forcing him to report their names, addresses, demographic data, and any potential sexual or needle-sharing partners to the state. “The state could ask me who the significant contacts are of one of my patients, and because of this law, patients are deciding not to be tested,” says Cohen, who is the director of the AIDS Center at St. Vincent's Hospital in Greenwich Village.

Paying the price for anonymity

Although Cohen's patients have the option of being tested anonymously at certain clinics, they would lose emotionally because they wouldn't have the opportunity to receive the bad news from the doctor with whom they've already developed a trusting relationship.

“One of the hardest things I do is give people their test results,” Cohen says. “And it worries me about names reporting that my patients may have to find out about their HIV status in another setting instead of finding out from me.”

The CDC recommends names reporting because it's the best way for HIV surveillance programs to eliminate cases that are counted twice, says **Joe Posid**, MPH, deputy chief of the HIV/AIDS surveillance branch.

HIV-infected people go to a number of different providers, including laboratories and physicians, and each time they see a new provider they

are likely to be reported as a separate HIV case. So the CDC seeks to prevent this duplication through names reporting, Posid explains.

Lambda Legal Defense advocates that states adopt a unique identifier system, in which each HIV case would be assigned one number that could be used at all provider sites. It might work like a social security number.

However, the CDC doesn't believe this system will work. Currently, only Maryland has used a unique identifier in place of reporting names for any length of time, Posid says. "Texas evaluated it for several years and found it insufficient, and then adopted a names-based system," he notes.

New Jersey touted as success

CDC officials sometimes point to New Jersey's name-based reporting system as an example of one that has succeeded. Since 1991, New Jersey has offered people the option of being tested for HIV anonymously or having their names reported confidentially.

Between 1995 and 1998, state health department figures show that 229,913 people opted for HIV testing that would disclose their names on a confidential basis. Of those tested, 7,491 had HIV, about 3.26% of the total. Another 31,644 people opted for the anonymous test, and of that number, 699 had HIV, about 2.21% of the total tested.

These statistics indicate that people are comfortable with names reporting — even people at high risk for HIV infection, says **Sindy Paul**, MD, MPH, medical director of the Division of AIDS Prevention and Control at the New Jersey Department of Health and Senior Services in Trenton.

Paul also cites another statistic that lends support to the argument that names reporting does not deter people from seeking HIV testing and counseling. "One of the things we have looked at is whether people have been leaving New Jersey for counseling and testing in New York or Pennsylvania," Paul says.

Neither of the two neighboring states had names reporting prior to 1999. But New Jersey officials found no trend of increasing numbers of people crossing state lines to be tested elsewhere. In fact, they found that more New York and Pennsylvania residents were tested in New Jersey after names reporting began. Paul has no explanation for this counterintuitive trend except to say the number of people seeking testing rose everywhere after basketball star Magic Johnson announced his HIV status in 1991.

Still, states that have names reporting also should give people access to the option of anonymous testing, because the most important aspect of any testing system is making sure HIV-infected people receive counseling and treatment, Paul says.

About 30 states have a names reporting system, and many of the remaining states may implement one soon. That's what has pushed the issue into coast-to-coast headlines in recent months.

Here's a brief list of states where controversies have flared recently over names reporting, partner notification, or forced HIV testing bills:

- **California:** After continued pressure from AIDS activists opposing the measure, the California Senate Health and Human Services Committee defeated a bill in mid-May that would have required name-based reporting for HIV-positive individuals. The bill, which was sponsored by Sen. Ray Haynes (R-Riverside), would have required the state health department to develop and implement a names reporting system that included partner notification.²

- **Connecticut:** State health officials opposed a bill introduced that would require mandatory HIV testing for all pregnant women. Critics said the bill would scare women away from prenatal care, while supporters said it would result in reduced mother-to-child HIV transmission.³ All 50 states require pregnant women to receive HIV counseling from their health care providers, and four states — Michigan, Mississippi, Tennessee, and Texas — require providers to test every pregnant woman for HIV unless the woman refuses. Additionally, Indiana, Rhode Island, and New Jersey require providers to offer HIV testing to pregnant women.⁴

- **Kansas:** Gov. Bill Graves signed a bill on April 15, 1999, that will force physicians and laboratories to report to the state health department the names and addresses of all people who test positive for HIV. The secretary of the Kansas Department of Health and Environment will establish rules regarding the confidentiality of data about HIV-infected individuals. Previously, Kansas only required providers to report the names of people diagnosed with AIDS.⁵

- **Oregon:** AIDS activists encouraged state health officials to consider issues of confidentiality and discrimination as the Oregon Health Division considered expanding its AIDS database to include the name, address, age, gender, race, and risk behavior of HIV-infected people. Oregon

officials held public forums in April, seeking input and reassuring people that the state always would give people the option of anonymous testing. The state has been using non-name-based reporting except for children younger than six years of age and for special circumstances.⁶

- **Nevada:** The Nevada Senate and Assembly passed legislation that would allow emergency workers, firefighters, and police officers to force a person to be tested for HIV and hepatitis B if that person splashed blood or other bodily fluids on them. Gov. Kerry Guinn has signed the bill into law. Before being able to force an HIV test, they will have to convince a court that they have been exposed. The state's law enforcement officials strongly support the law.⁷

- **Ohio:** A bill that passed the state house but failed in the Senate would have required HIV-infected people to notify potential sexual partners of their infection. Ohio lawmakers would have made it a felony punishable by a prison sentence of two to eight years for an HIV-positive person to have sexual relations without first disclosing his or her HIV status. Critics charged that the state didn't regulate other diseases, such as hepatitis C, in the same manner.⁸

County defies state mandate

- **Washington:** The state Board of Health has proposed a unique identifier that has one county's health officials in an uproar. The state's unique identifier proposal, which is expected to be approved in July, will require local health departments to regularly purge the names of HIV patients from their files and send the codes to the state health department. However, Pierce County officials said they would continue their policy — which went into effect Jan. 1 — of keeping the names, because it's a successful way to track the spread of HIV. Pierce County's public defiance of the state's move to a unique identifier system has raised the ire of several AIDS advocacy groups, including the Northwest AIDS Foundation, Positive Voice Washington, and Resist the List.⁹

- **Vermont:** In May, Gov. Howard Dean signed a bill requiring the state health department to develop a unique identifier system to track HIV cases. Legislators said they were concerned that patients would lose their confidentiality if the state used a names-based system.¹⁰

- **New York:** The state legislature's program for mandatory names reporting of HIV-positive

patients drew much criticism from AIDS activists and physicians in early 1999 during the regulations' 45-day comment period, which ended May 1. The program requires health care workers to disclose the names of HIV-positive patients and their sex partners. Critics blasted the proposed regulations' unwieldy requirements of mandatory partner notification and that doctors and lab technicians report an HIV-positive individual's name to the state within 21 days of the person seeking treatment, even if the person had opted for anonymous testing.¹¹

Immigrants may fear name reporting

New York's bill has drawn the most fire, partly because the state has the most on the line, with 11,329 AIDS cases according to the latest CDC count — 5,000 more AIDS cases than any other state. Plus, New York City has a large minority and immigrant population, and names-reporting critics say immigrants — especially those who are there illegally — are unlikely to seek HIV testing and counseling if they believe their names will be reported to authorities.

“If you were an undocumented immigrant, and you knew your name would be reported to the state, you wouldn't be tested,” Tiven says. “The people who have the most reason to distrust the system would not be tested.”

For example, Tiven says, a 1997 study conducted by the Latino Commission on AIDS in New York showed that 72% of Latinos surveyed would not be tested for HIV if they knew their names would be reported to the health department. For the highest-risk group of Latinos, those between the ages of 16 and 25, the percentage was even higher (87%).

Then there's the question of whether a person's HIV status could be used against him or her in court. While New York's regulation should guarantee that data wouldn't be used in criminal proceedings, opponents are skeptical.

For instance, the state broke its own confidentiality laws to identify one HIV-positive man, Nushawn Williams, 22, who was sentenced to four to 12 years in prison for statutory rape and charges of reckless endangerment for having sex with a teenager who later became infected with HIV. He was accused of infecting 13 women with HIV.¹²

The names-reporting law will further strain confidentiality efforts. “The new bill allows corrections officers and emergency medical staff to find out the HIV status of someone when they've been

in contact with their body fluids, and that's not just for a needlestick injury," Cohen says. "That's a bad precedent of limiting the confidential relationship patients have with their physician."

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Names reporting in Illinois is successfully challenged

Here's why AIDS activists are angry over the issue

When the Illinois Department of Public Health in Springfield first proposed in early 1998 a regulatory change to require names reporting, Lambda Legal Defense and Education Fund in Chicago sprang into action.

The organization submitted an 11-page comment refuting claims that the names of HIV-infected individuals will remain confidential

and that names reporting will result in better surveillance of the disease.

Lambda's comment notes that when Illinois began requiring HIV tests as a prerequisite for marriage licenses, the number of marriages in the state decreased dramatically. The General Assembly subsequently repealed the law in response to public outrage and clear avoidance of the testing requirement. There is every reason to believe that the proposed rules also will result in avoidance of testing."

The AIDS Legal Council of Chicago also objected to the state's names reporting change, claiming that the collected names could be accidentally or intentionally disclosed, resulting in discrimination against people infected with HIV.

The groups' efforts paid off. Last fall, the Illinois legislature did an about-face and switched to a non-name identifier system. Lambda officials are assisting the state health department with a two-year study of the new non-name identifier system.

"We're working very hard with the health department to make sure everyone is making a good-faith effort to make it work, instead of setting something up to fail," says **Heather Sawyer, JD**, a staff attorney with Lambda Legal Defense.

So why were these groups so adamant that names reporting would lead to breaches in confidentiality and other evils?

Names reporting opponents say you only need to read the headlines to learn about the discrimination AIDS patients face when their disease status becomes known in their communities.

Lawsuit stems from confidentiality breach

For example, the family of an HIV-positive 15-year-old is suing their daughter's school over an allegation that school administrators forced the student to reveal her HIV status, according to a May 4 article in the *Miami Herald*.

State prosecutors declined to file criminal charges against school officials for breaking the

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state's confidentiality law because the student already had told at least four friends of her HIV status.

Such confidentiality breaches are common, experts say. **Ann Hilton Fisher**, executive director of the AIDS Legal Council of Chicago, wrote in a five-page letter to the Illinois health department that the organization already has handled a variety of HIV discrimination cases resulting from confidentiality issues, including the following:

- A clergyman's wife, who had found out from her husband that a parishioner was HIV-positive, told other people in the congregation.
- A pharmacy assistant discovered an acquaintance had HIV after looking up the person's prescription records, and then the pharmacy assistant told mutual friends.
- A policeman told colleagues that a fellow officer was infected with HIV.
- A participant in the Cook County Sheriff's work-release program was forced to wear an identification badge saying he was HIV-positive.
- A substance abuse treatment center employee gave a client's HIV records to another client.
- A Chicago Department of Health Infectious Disease Clinic nurse told a patient's landlord that the patient had HIV.

'Disclosures will occur'

"The department proposes to maintain anonymous testing sites, but anyone testing at these sites cannot maintain his or her anonymity for long. When that person presents to a doctor for medical care, then his or her name will be reported," Fisher wrote. "Creating a system in which 102 county health departments maintain lists of HIV-positive individuals will inevitably create situations in which unauthorized — and damaging — disclosures will occur. We already know that AIDS registries are not safe: in the notorious Florida case, 3,000 people with HIV lost their confidentiality in a single incident."

Ultimately, the Illinois health department agreed to form a group to study names reporting. The group met over the summer of 1998, and by the summer's end, the group was convinced that the state should fund a study to see if the health department could meet the same surveillance goals through a less intrusive method, Sawyer says.

So the state moved to a non-name identifier that doesn't identify people by name but allows health officials to determine how many people have HIV without getting double counts.

States and the Atlanta-based Centers for Disease Control and Prevention would obtain much better statistics of actual HIV infection rates if they abandoned the practice of counting every patient and instead relied on random blinded surveys, Sawyer says.

"We should not be adding additional deterrents to HIV testing," Sawyer says. "Until we figure out a way to assure people that it is in their best interest as well as for the public health status, then we shouldn't be sending messages that if you come in you will show up on some governmental list that we can't guarantee over time that we'll be able to keep confidential." ■

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Consumer hotline starts for HIV/AIDS patients

The Texas AIDS Health Fraud Information Network (TAHFIN) has opened a toll-free hotline that educates consumers on HIV/AIDS treatment fraud issues.

The hotline, which is available by calling (800) 758-5152, will focus on presenting information about potentially dangerous or fraudulent therapies.

TAHFIN is a task force sponsored by the U.S. Food and Drug Administration and composed of the Texas Department of Health, community-based organizations, the Federal Trade Commission, treatment advocates, health care providers, and other groups that include people who have HIV/AIDS.

TAHFIN also can be reached on the World Wide Web at www.tahfin.org. ▼

California passes needle-exchange bill, causing stir

The California Assembly passed a needle-exchange bill in May, permitting drug users to exchange used hypodermic needles for clean ones.

The measure still must be passed by the California Senate.

About a third of new AIDS cases in California are among injection drug users. While 17 clean-needle programs already operate in the state, California previously banned such exchanges because of a state law requiring a doctor's prescription to obtain or distribute needles and syringes.

The San Francisco AIDS Foundation praised the measure, which resulted in criticism from opponents who claim the law implies government sanctioning of drug use, according to the *Kaiser Daily HIV/AIDS Report* of May 13, 1999.

While awaiting the bill's final approval, San Francisco and 17 California counties launched needle-exchange programs under "emergency orders" issued by San Francisco Mayor Willie Brown and the counties, the *San Francisco Examiner Online* reported on May 14, 1999. ■

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CE objectives

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

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