
Hepatitis Control Report

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Hepatitis C called “tipping point” in marriage of STD/HIV and viral hepatitis programs

Two years ago, Dr. T. Stephen Jones, Associate Director of Science at CDC’s Center for HIV, STD, and TB Prevention, went to Tucson, Arizona to attend his first hepatitis coordinator’s conference (see the *Hepatitis Control Report [HCR]*, Spring 1999 issue). Jones had worked in HIV control since 1987. He had never worked in hepatitis. Now, here he was, standing in front of 300 hepatitis control people from all over the U.S.

“I come to you as an ambassador from the Kingdom of HIV,” Jones proclaimed, smiling. He was one of a small group of senior epidemiologists at CDC who had recently become convinced that HIV and hepatitis programs needed to get married, and he had come to propose. “What we are doing separately is too narrow,” he told the group. “The goal should be to bring viral hepatitis prevention into the existing HIV counseling and testing system.”

In 1999, Jones’ proposal was a bit of an oddity. Although hepatitis, HIV, and STD programs had worked with the same high-risk populations for years, the idea of integrating their services had not progressed much beyond the brainstorming stage.

Today, it looks as if the wedding is on. Driven by a mandate to expand its efforts against hepatitis C, CDC has begun to integrate viral hepatitis programs into existing programs against HIV and STDs. Now, ten years after CDC’s Advisory Committee on Immunization Practices (ACIP) recommended that all persons with STDs be vaccinated against hepatitis B, it is actually starting to happen. In a few places, HIV patients with intravenous drug abuse (IDU) histories are being routinely offered screening for hepatitis C, and counseling for HIV and hepatitis B risks are beginning to merge.

The road to integration

The road to integrating hepatitis services with HIV and STD programs has been closely tied to CDC’s hepatitis C effort. In recent presentations, Dr. Harold S. Margolis, chief of CDC’s hepatitis unit, has called hepatitis C “the tipping point for a new prevention direction.” Margolis believes that the current national interest in controlling hepatitis C will make integration happen.

The integration story goes back to 1996, when Dr. Miriam Alter, the well-known hepatitis C epidemiologist, walked into Margolis’ office and showed him her latest calculations for the prevalence of hepatitis C virus (HCV) infection in the U.S. “We all said, ‘Wow!’” Margolis recalled.

The new calculations, based on results of the NHANES III national serosurvey, showed that 2.7 million Americans were infected with HCV. That was over three

times higher than the number of Americans infected with HIV, by CDC estimates. “That really got everybody’s attention,” Margolis said.

Those 2.7 million Americans were largely unaware of their HCV infections and could transmit the virus to others. Many of them, perhaps 70%, had chronic liver disease and could benefit immediately from simple measures such as abstinence from alcohol and vaccination against hepatitis A and B. Thousands could benefit from treatment with antiviral agents.

In 1996, Dr. Miriam Alter walked into the office of her CDC boss, Dr. Harold Margolis, and showed him her latest calculation for the number of Americans chronically infected with HCV, 2.7 million. “We all said, ‘Wow!’” Margolis recalled.

Margolis and his staff began to sketch a national strategy for addressing what they saw as an emerging scourge. They needed a plan to manage the growing number of infected patients who would develop symptomatic disease in the next several years, and a plan to reduce the rate of transmission, estimated at about 36,000 new cases annually.

At about the same time, Margolis and his staff had become increasingly disappointed by the failure of hepatitis B prevention efforts in high-risk adults. CDC’s strategy to fight hepatitis B in infants and children had been an astonishing success. In just one decade, the agency, working with the states, advocacy groups, and the vaccine manufacturers, had dropped the rate of acute hepatitis B from almost 70 per 100,000 to less than 20 per 100,000. The coverage rate for hepatitis B vaccination in two-year-old children had climbed rapidly, soon to reach 88% in the 1999 National Immunization Survey. But nobody at CDC was happy with the uptake of the vaccine in high-risk adults, such as men who have sex with men, heterosexuals with multiple sexual partners, and intravenous drug abusers.

At the same 1999 Tucson conference attended by Stephen Jones, Margolis complained that the vaccination of high-risk adults had “basically gone nowhere.” Since 1990, ACIP had recommended that all persons with STDs be vaccinated against hepatitis B. But a 1997 survey of 59 STD projects, representing 1,510 STD clinics nationwide, showed that only 24% offered hepatitis B vaccination to clients. This was a huge missed opportunity. At the Tucson conference, Margolis pointed out that 36% of persons with acute hepatitis B had been treated previously for an STD.

Since 1990, ACIP had recommended that all persons with STDs be vaccinated against hepatitis B. But, at the 1999 Tucson hepatitis coordinators conference, Margolis complained that the vaccination of these and other high-risk adults had “basically gone nowhere.”

Job compartmentalization was surely part of the problem. For years, CDC had funded a corps of hepatitis B coordinators in every U.S. state health department. But their mandate was to promote hepatitis B vaccination in infants and children (and, later, adolescents). Most coordinators had offices in the immunization part of state health departments, where child immunization was the principal focus, and they were not well positioned to push vaccination in adults. A survey of hepatitis B coordinators showed that 70% did not collaborate with their own state’s HIV program staff.

Meanwhile, pressure was building from Washington to do more about hepatitis C. In 1997, a congressional committee held a series of hearings on the safety of the nation’s blood supply. The hearings triggered the formation of a new committee at the U.S. Department of Health and Human Services (DHHS), which, in 1998, decided to notify hundreds of thousands of persons who received blood transfusions from potentially

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HCV-infected donors before 1992 (see *HCR* Summer 2000 issue). DHHS Secretary Donna Shalala personally approved the committee's notification plan, but she also made clear that merely contacting transfusion recipients was not enough. She wanted a larger, more comprehensive strategy against hepatitis C, designed to let all Americans at risk, for any reason, know they needed to be tested.

In 1998, the total CDC funding available for hepatitis C control was under \$5 million, while the agency's HIV budget was about \$625 million. The funding advantage was obvious, but it also made programmatic sense to combine hepatitis services with HIV and STD whenever possible, since these programs aimed services at overlapping target populations.

Margolis figured he needed over \$40 million annually for a big national effort, including a national media campaign to build awareness and stimulate more screening and counseling. But, Shalala's desires did not translate into congressional funding. During 1997 and 1998, advocacy groups tried to secure dedicated congressional funds for a national hepatitis C control project, but they were not successful.

Fortunately, hepatitis C had been included in CDC's Emerging Infectious Disease (EID) Initiative from its inception. Launched in 1994 as CDC's effort to protect the nation from new and resurging infectious diseases, EID had been well funded by Congress. Using funds from EID, Margolis was able to get hepatitis C prevention activities started, including CDC's participation in an important NIH consensus conference, a state-of-the-art review of the disease and its control (*MMWR* 1998;47 [No. RR-19]), physician education meetings and mailings, and public messages from the Surgeon General.

Even with EID funding, however, it became clear to Margolis and his colleagues that, with no congressional funding in sight, to make CDC's hepatitis C initiative truly effective, they would need to join forces with the agency's HIV and STD programs. In 1998, the total CDC funding available for hepatitis C control was under \$5 million, while the agency's HIV budget was about \$625 million. The funding advantage was obvious, but it also made programmatic sense to combine hepatitis services with HIV and STD whenever possible, since these programs aimed services at overlapping target populations. Two years ago, the hepatitis staff began to push the messages, "let's get together" and, more recently, "one-stop shopping."

Margolis may be right when he says hepatitis C could be the tipping point that brings hepatitis, STD, and HIV services together. One sign is the agency's rapidly rising financial commitment to integration. This fiscal year, CDC awarded 15 grants, averaging \$112,000 each, to help states and counties integrate viral hepatitis prevention into HIV and STD programs, up from just four grants two years ago (see figure on page 7). These relatively small grants are not meant to fully fund integration, but will be used mainly for planning activities, according to Dr. Joanna Buffington, who heads the Viral Hepatitis Integration Projects for CDC. "The need to address hepatitis C is driving it, but the intent is to get hepatitis B and A prevention into appropriate settings as well."

Buffington has been impressed with what grantees have done with the limited grant funds. "Many were already doing integration activities, and several states have found their own funds for integration activities," she said.

San Diego

Dr. Robert A. Gunn, CDC's assignee to the STD program at the San Diego County (California) health department, had realized for a long time that STD patients were not going to get vaccinated against hepatitis B without a change in the day-to-day routine inside STD clinics. As part of a demonstration project under Gunn's direction, all clients at San Diego's clinics are now offered hepatitis B vaccination, and those in relevant high-risk groups are offered HCV screening, HIV counseling and testing, and hepatitis A vaccination.

In a recent review of San Diego STD clients, Gunn and his colleagues found that the overall rate of anti-hepatitis B core antibody, indicating past infection with hepatitis B

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virus, was 16%. The rate in men who have sex with men was 50%, and in IDUs, 37%. The anti-HCV rate in IDUs was 38%.

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*Dr. Robert A. Gunn
STD Control Program
San Diego County, CA*

“The hepatitis B vaccination project is going well. It’s really an integral part of the program now,” Gunn said. The hepatitis B vaccine acceptance rate among clients is 72%, and the three-dose completion rate is 25%. Gunn learned that the best way to get clients to accept the vaccine is to keep their waiting time down. “We are able to offer and give the first dose of hepatitis B vaccine to an STD patient in 12 minutes,” he said. “The subsequent doses are given even faster,” he said.

The county’s STD clinics use a standardized questionnaire to determine whether patients fit into high-risk groups. A similar questionnaire is used at San Diego’s alternative HIV counseling and testing sites, where every patient is now screened for hepatitis B and C risks. Gunn and his colleagues have worked out a way to keep HIV testing anonymous while maintaining hepatitis serology results as confidential. He hopes to expand the hepatitis services to other clinics that serve IDUs. “To be successful, we need to go where the IDUs go,” Gunn said.

Paula J. Murray, MPH, the coordinator of the integration project in San Diego, said the biggest obstacle has been persuading the STD and HIV clinic, nursing, and counseling staff to get interested in hepatitis control. The HIV counselors and staff were “somewhat resistant” to changing policies, she said. Murray thinks this is because HIV workers see their program as truly distinct, with its own culture and values. “Initially, both the STD and HIV people just saw it as just more work on top of their already heavy workload. We had to overcome that.” HIV workers were also worried about maintaining the anonymity of their clients’ tests, Murray said.

Another challenge has been persuading health care providers to offer the vaccine, Murray said. Even when the vaccine is free (as it has been in San Diego for the duration of the project), health care providers have not always offered it to their high-risk clients.

New York City

The New York City Department of Health used a CDC integration grant to fold hepatitis services into a busy STD clinic on the Upper West Side. The clinic had already been offering hepatitis B vaccine, but the grant funds allowed it to expand free vaccination to all patients and add counseling and testing for hepatitis C.

“Most of the funds were used for HCV testing,” said Dr. Isaac Weisfuse, director of communicable disease control for the New York City Department of Health. “The anti-HCV (ELISA) tests are not very expensive, but the confirmatory tests are, \$70 a pop.” The other main cost in the program was the purchase of hepatitis B vaccine, he said.

Like San Diego, the clinic uses a questionnaire to screen clients for risk factors. The provider reviews the completed questionnaire with each client and decides what hepatitis services are appropriate. Weisfuse said the City plans to evaluate the program by calculating how many at-risk clients accepted services, how many hepatitis B vaccine recipients came back for second and third doses, and how many HCV referrals initiated were actually completed. He said the City hopes to expand the program to all its STD clinics.

Can integration survive in a compartmentalized world?

At CDC, integrating hepatitis with HIV and STD services is now a continuing management challenge. It is always difficult, and sometimes impossible (even illegal), to tear down the walls between categorical programs. But integration is now a fact of life, and it has many advocates inside and outside the agency. The Association of State and

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Territorial Health Officers said recently, “States should consider integrating viral hepatitis into existing HIV/AIDS prevention, screening, treatment and programs.... Similar efforts should be integrated into family planning and STD clinics.” ■

In Florida, a brave new world of hepatitis C surveillance and prevention

Like most other states in the mid-1990s, Florida was not doing much about hepatitis C. The state received passive reports of acute cases, but did little in the way of follow-up. Because only about 30%–40% of acute HCV infections produce hepatitis symptoms, Florida’s surveillance data provided only the sketchiest view of the disease burden in the state.

In 1998, Dr. Steven T. Wiersma, Florida’s Deputy State Epidemiologist, and his boss, Dr. Richard Hopkins, decided they needed a more comprehensive approach to hepatitis C. “We thought our focus shouldn’t just be on acute hepatitis C. We thought we had a lot of opportunity for controlling the disease,” Wiersma said.

“We didn’t have a great case definition. We had no consistency in the way we handled cases. From national surveys, we estimated there were 270,000 chronic cases in Florida. But, we had no idea what the disease was doing in our state,” according to Dr. Steven T. Wiersma, Florida’s Deputy State Epidemiologist. “We were only getting about 100 case reports every year statewide. Sometimes physicians would call us and say they were following more than 100 cases in their own practices.”

Florida now has one of the nation’s most aggressive hepatitis C control programs, with a rebuilt surveillance system, a raft of community hepatitis C coalitions, and six state-funded county programs aimed at increasing hepatitis C awareness, surveillance, screening, and referral. Aided by a new hepatitis C coordinator from CDC, the state is now a leader in hepatitis C prevention.

In 1998, Wiersma and his boss, Dr. Richard Hopkins, Florida’s state epidemiologist, decided they needed a more comprehensive approach to hepatitis C. “We thought our focus shouldn’t just be on acute hepatitis C. We thought we had a lot of opportunity for controlling the disease.”

After consulting with CDC and other states, their first move was to draft a plan that included all the classical elements of hepatitis C control — preventing HCV infection, detecting and controlling chronic liver disease caused by the virus, and doing better surveillance, notification, and referral. They took the plan on the road to a series of “hepatitis summit meetings” around the state. The big turnouts surprised Wiersma. “Amazingly, we got 150 people at some of the meetings. And we got a lot of encouragement from physicians, other providers, academics, the American Liver Foundation. They told us to proceed.”

Schering-Plough, a manufacturer of hepatitis C treatment products, helped stimulate a grass roots movement in Florida by organizing community coalitions. The drug maker was criticized last year for its role in such campaigns (see *Washington Post*, Sept. 12, 2000), but Wiersma said, “Very honestly, Schering-Plough acted responsibly and just pushed awareness of the problem. They helped initiate the grass roots initiative in Florida, but the efforts proceeded later without the company’s help.”

Florida is one of only a few U.S. states that have been able to obtain state funds for hepatitis C initiatives. The state’s initial budget was \$2.5 million. Recently, the legislature increased it to \$3.5 million. “That’s a very healthy start,” Wiersma said.

“Our number one goal was always enhanced surveillance, and to form a registry,” Wiersma said. Even with the new funding, however, enhancing surveillance in Florida has been difficult, because Florida’s old, paper-based communicable disease reporting

Florida is one of only a few U.S. states that have been able to obtain state funds for hepatitis C initiatives. The state’s initial budget was \$2.5 million. Recently, the legislature increased it to \$3.5 million.

system could not handle many new reports. The hepatitis C initiative forced the state to re-evaluate its whole disease reporting system, and Florida now has a new system that is completely web-based. The goal is to reduce the state's reliance on reports from physicians and base surveillance on reports from laboratories. Wiersma sees this as dramatically more sensitive and reliable. "We want to respond to markers, not to case reports," he said.

By expanding surveillance to include cases of chronic infection, the state has triggered an avalanche of reports that some counties are finding difficult to handle. Dade County, Florida's largest, was one of six chosen to spearhead the state's new hepatitis C initiative. The county's task was to upgrade hepatitis C surveillance, and new case-finding efforts there have produced a flood of reports.

"Hepatitis C is a monster."

*Sterling Whisenhunt
Hepatitis Program
Coordinator
Miami-Dade County, FL*

"Hepatitis C is a monster," said Sterling Whisenhunt, Miami-Dade County's hepatitis program coordinator. "The amount of new information is overwhelming. We are scrambling for a good way to capture it and get it into our database."

The county stimulated more reporting by working with laboratories, hospitals, clinics, and physician practices, and by making the reporting requirements more clear. "We improved our relationships with them. They know that, when they report a case, we won't just let it sit. We'll follow up," Whisenhunt said. Because of staff limitations, the county has so far been able to follow up only on acute cases of hepatitis, he said.

In Dade County, each newly identified acute case is assigned to one of four investigators, who contacts the patient's physician, gets more information about the case using a questionnaire, and offers educational services, support groups, and other help. "It's a huge load on our resources. We're spread thin," Whisenhunt said.

"One problem is finding the dollars to care for people who have hepatitis C.... A lot of people don't have access to treatment because they don't have health insurance," Whisenhunt said. "We try to link people with resources available in the community."

Miami-Dade hopes to arm its disease intervention specialists, the people who track contacts of HIV and STD cases, with free home test kits for hepatitis C. While working in the field, they will offer the kits to people in high-risk categories.

Miami-Dade has put up billboards around the city that ask in huge lettering, "Are you at risk for hepatitis C?" The signs provide a toll-free hotline to call for further information. As an interesting innovation, the county hopes to arm its disease intervention specialists, the people who track contacts of HIV and STD cases, with free home test kits for hepatitis C. While working in the field, they will offer the kits to people in high-risk categories. The kits will give instructions on how to provide a finger stick blood sample and mail the specimen to a commercial laboratory, which will report the results back to the sender. The lab will also report results to the county, stripped of personal identifiers.

Florida is one of 16 states that now have a full-time hepatitis C coordinator provided through CDC grant funds (see figure). The Florida coordinator, Sandra Roush, MT, MPH, arrived in Tallahassee in September. "My title is hepatitis C coordinator, but my job is to coordinate hepatitis A, B, and C and make sure they are integrated with HIV and STD services," she said recently. Roush supervises Florida's six county hepatitis C projects. She also coordinates a telephone hotline with a self-administered risk assessment, a statewide outdoor advertising campaign (billboards, placards), and large direct mailings.

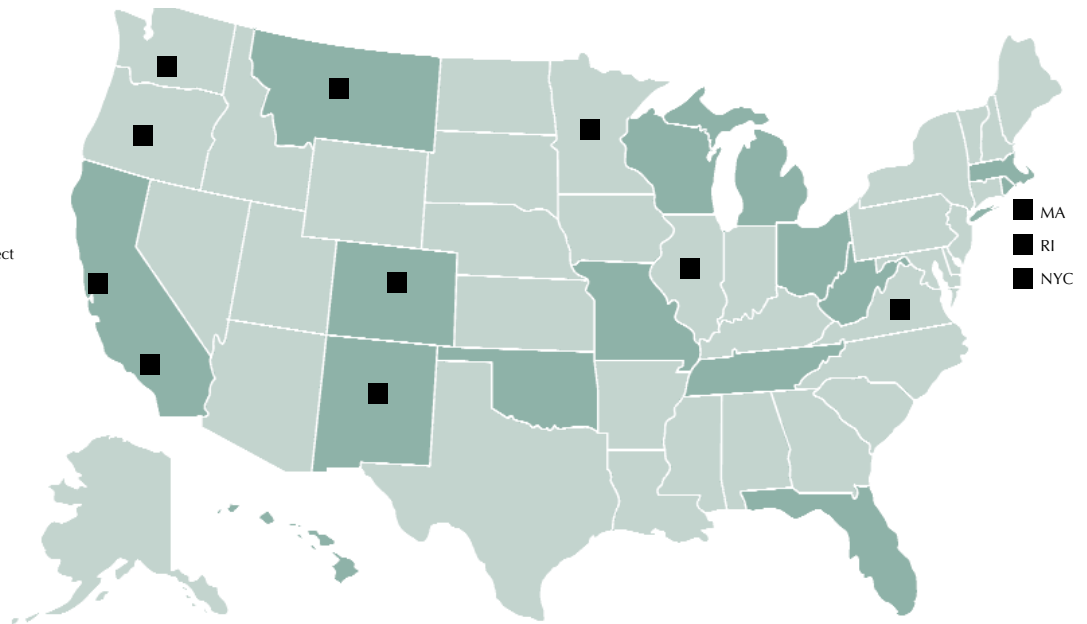
Florida is also planning a statewide population-based seroprevalence study. It will be tied to the state's annual behavioral risk factor survey. Interviewers will ask survey participants to take a free home HCV test. Through a contractor, the state will mail participants a home test kit, run the test, report results to the participants, and analyze the results. Wiersma said he expects to collect about 2,000 samples per month for about a year. In last year's behavioral risk factor survey, 40% of subjects said they would be willing to participate in a home HCV test.

**Location of CDC-Funded
Viral Hepatitis
Integration Projects and
State Hepatitis C
Coordinators, March 2001**

Source: CDC

■
CDC Viral Hepatitis Integration Project
(State or City/County)

■
CDC-Funded State Hepatitis C
Coordinator



Wiersma says Florida's hepatitis C effort is still young, but it is beginning to produce results. "Until recently," he said, "it was common for people to have a positive anti-HCV test and never be confirmed with supplementary tests, never be referred for evaluation, possibly never even be informed that their test was positive. We're changing that." ■

Hepatitis control notes

MS and vCJD are not hepatitis vaccine risks, say experts

Are multiple sclerosis (MS) or variant Creutzfeldt-Jakob disease, the human disease associated with bovine spongiform encephalopathy (BSE, popularly known as mad cow disease), risks associated with hepatitis vaccination? The answer is no, according to experts.

In a report published in the February 1, 2001 issue of the *New England Journal of Medicine*, Ascherio and colleagues from Harvard and Merck (a sponsor of this publication) confirmed that there is no association between hepatitis B vaccination and multiple sclerosis. The result came from a nested case-control study conducted as part of the Nurses' Health Study. The relative risk of MS associated with exposure to hepatitis B vaccination was 0.9 (95% CI 0.5 – 1.6). In an accompanying editorial, Drs. Bruce Gellin and William Schaffner (the latter is an advisor to this publication) said, "The results of these studies should provide reassurance to recipients of those vaccines... and to their physicians."

In 1998, the French government temporarily suspended hepatitis B vaccination in schools based on fears that hepatitis B vaccination might be associated with MS, but no study ever established such an association. Several studies have shown no relationship between hepatitis B vaccination and demyelinating diseases (see *HCR*, Winter 1998–99 issue).

Variant Creutzfeldt-Jakob disease (vCJD) is also not a risk of vaccination, at least beyond the theoretical level. In December, the U.S. Public Health Service (PHS) published a statement in the *MMWR* (December 22, 2000 issue) saying, "No evidence exists that cases of vCJD are related to the use of vaccines...." The topic carries theoretical interest

In a report published in the February 1, 2001 issue of the *New England Journal of Medicine*, Ascherio and colleagues from Harvard and Merck confirmed that there is no association between hepatitis B vaccination and multiple sclerosis.

The estimated risk of vCJD for viral vaccines is approximately 1 in 40 billion vaccine doses, or one transmission every 5,000 years in the U.S. But even this is an overestimate of the true risk, according to FDA.

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because some vaccines are made from processes that use bovine materials obtained from countries where BSE may exist.

FDA has been aware of the issue since the early 1990s. It convened an advisory committee meeting on it last July. The subject attracted little attention until February 8, 2001, when the *New York Times* ran a story listing nine vaccines, produced by five manufacturers, that use bovine-derived materials from countries where BSE may exist. Only one of the vaccines is a hepatitis virus vaccine, Havrix®, GlaxoSmithKline's hepatitis A preparation.

The FDA advisory committee concluded that the risk for vCJD posed by these vaccines is "theoretical and remote." According to Dr. Ira Berkower, a scientist at FDA, the risk of vCJD for viral vaccines is approximately 1 in 40 billion vaccine doses. "This level of risk would correspond to one case of vCJD arising every 5,000 years (assuming two doses per child) when vaccinating the entire birth cohort of the United States (four million children). Because of the assumptions that were used, this is an overestimate of the risk, and the true risk is likely to be significantly less," according to Berkower (see www.fda.gov/cber/bse/risk.htm).

The PHS has recommended that all persons continue to be vaccinated according to current schedules and that there is no preference for using one licensed vaccine product over another based on the source of bovine-derived materials used in vaccine production. FDA has recommended that manufacturers replace bovine-derived materials obtained from countries where BSE may exist with materials from countries where BSE does not exist, and all affected vaccine manufacturers have done so or agreed to do so. At the July advisory committee meeting, a representative from GlaxoSmithKline, Dr. Ray Bradley, said the company's policy has been "to move away from any risk or perception of risk." He said the company had made a concerted decision as early as 1990 to change routine manufacturing steps so that materials were sourced from countries with no BSE. ■

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