Mail-Order AIDS Tests

FDA confronts the implications

By RICK WEISS

In January 1986, the Food and Drug Administration received an unprecedented request. A private company sought approval to sell a do-it-yourself blood collection kit that would allow people to get tested for AIDS antibodies without ever having to leave home.

The application was rejected, in part because the request carried with it so many unstudied legal, ethical and public health implications that the agency didn't know what to do about it. Today, more than three years later, the FDA remains stymied in its efforts to sort out the complex questions inherent in such requests. Its painstaking — some say foot-dragging — review of the issue has left would-be AIDS-antibody entrepreneurs angry and, in at least one case, bankrupt.

No company has requested FDA approval to sell a kit enabling people to test themselves for antibodies to the virus, known as HIV. But several have sought to sell kits that would allow users to draw a small blood sample and send it to a laboratory that would provide test results and counseling by telephone. Moreover, at least two companies have recently developed tests that detect AIDS antibodies in saliva, making home specimen collection simpler than ever.

One study indicates that 30 percent of people who want AIDS testing would do so only with a home collection kit. Yet the public health advantages of such a test remain unsettled, say FDA officials and others. The questions at issue include test reliability under home collection conditions; safety of postal, transportation and garbage disposal workers who may come in contact with contaminated specimens; adequacy of the kits' educational materials; and the effectiveness of telephone counseling versus face-to-face counseling when test results are given.

"The benefits derived from the expected increase in testing . . . must be weighed against the risks inherent in these testing modes," says Lauren Pierik of the FDA's Division of Blood and Blood Products in Bethesda, Md.

To others, the risks of home collection appear minuscule compared with the public health benefits of boosting individual awareness of AIDS antibody status. Kit proponents point to estimates that 90 percent of HIV-infected Americans remain unaware they carry the virus, thus increasing their chances of inadvertently passing the disease to others. Surveys suggest that each case of AIDS prevented in 1989 can prevent two to five cases by the year 2000.

"It's clear that the potential for home AIDS tests to save tens of thousands of people from becoming infected far outweighs the risks," says Eliott Millenson, whose now-defunct company sought FDA approval for an AIDS home collection kit last year. "People will die needlessly because FDA refuses to examine the facts," he said at a recent FDA-sponsored public hearing in Bethesda.

To date, the FDA has licensed home test kits for pregnancy, ovulation, fecal blood, blood sugar levels and a variety of less frequently used tests. But opponents of home collection kits for HIV antibodies say these would differ from existing tests in several ways. For one thing, positive results amount to "a virtual sentence of death," says Paul Bachner, chairman of the AIDS task force for the College of American Pathologists in Skokie, Ill. He and others argue that such emotionally charged tests should be left to medical professionals. "We cannot think of an area of testing that could be less appropriate for introduction into the home environment than HIV testing," he said at the hearing.

Mental health professionals question whether telephone counseling can provide adequate and confidential guidance regarding such sensitive test results — whether negative or positive. Registered nurse and AIDS counselor Margo Nason of the Irwin Memorial Blood Centers in San Francisco says she has reflected on the gradual erosion of personnel and equipment that exacerbated the recent oil spill in Alaska. Even if test companies at first hired highly trained telephone counselors, she says, "I would hate to see in three or five years the telephones manned by teenagers at low wages."

Proponents counter that licensed professionals would test home-collected specimens, using FDA-approved methods; that new collection methods allow use of a few drops of blood on a piece of filter paper, eliminating the possibility of breakage in transit; and that telephone counseling has a long history of success in suicide prevention and poison control.

Taking aim at contentions that blood collection cannot reliably be left to laypeople, two companies released information about newly developed tests that can detect HIV antibodies in saliva. Dennis Burger of the Beaverton, Ore.-based Epitope Inc. says his company's test may be more specific than some already-approved blood tests — perhaps because saliva, compared with blood, has fewer proteins capable of producing false positive results.

Virotechnology Inc. of Lodi, Calif., has a 10-minute saliva test for which it will soon seek FDA approval for home collection. In an attempt to avoid the controversy over telephone counseling for positive results, the company would report all results as either "negative" or "inconclusive," says company attorney Corey Garber. Counselors would instruct an individual receiving an inconclusive result to see a doctor for further testing.

"To continue to prohibit [home collection kits] is to condemn some Americans to death as a result of inadvertent transmission of the disease," says William Johnston, vice president of the Hudson Institute, a nonprofit public-policy research group in Alexandria, Va. "For many people the availability of a home test provides the only avenue of finding out their antibody status."

On the contrary, says Stephen Bowen, deputy director of the AIDS program at the Centers for Disease Control in Atlanta. "The CDC does not believe that there are substantial numbers of people who cannot gain access to counseling and testing services in either a public or private health care setting," he says. Bowen estimates more than 1.5 million people in the United States will receive AIDS counseling and testing in 1989 in the public sector. Many more may do so through private physicians.

With such polarized views and so few data regarding relative advantages and disadvantages, nobody expects home collection kits for HIV antibodies to appear on store shelves in the near future. The FDA will accept written public comments on the topic through May 5.

As research progresses, solutions to the potential pitfalls of AIDS home collection kits may emerge, says Charles McCarthy, director of the National Institutes of Health's Office for Protection from Research Risks. But resolving the issues will require "a very imaginative, collective effort," he adds.

For now, McCarthy told the FDA, "I think a heavy burden of proof rests on the providers of home test kits to make sure these concerns are appropriately addressed before [the kits] become publicly available." □