HIV-2 Case Found, AIDS Drug Tested

Recent reports of the first U.S. AIDS case caused by a second virus and results from human tests of a potential AIDS treatment illustrate how likely it is that 1988, like recent years, will be riddled with both optimism and pessimism in the now-global war against AIDS.

Physicians at the University of Medicine and Dentistry in Newark, N.J., said last week that they have diagnosed the first known U.S. case of AIDS caused by the virus called HIV-2. Although HIV-2 infection is frequently found in parts of West Africa, HIV-1 has been the cause of AIDS in the United States. Since HIV-2's discovery more than two years ago, scientists have debated whether this second virus actually causes full-blown cases of AIDS (SN: 3/7/87, p.151). Officials have been saying for months that it was inevitable that HIV-2-caused AIDS would be found in North America, with the virus already detected in Europe and Brazil.

Emphasizing that it is too early to assess the threat of HIV-2 in the United States, federal officials say there currently are no plans to specifically test the nation's blood supply for the virus. Peter J. Fischinger, AIDS coordinator for the U.S. Public Health Service, said last week at a Washington, D.C., briefing that existing HIV-1 screening tests cross-react with HIV-2 enough to handle the remote possibility of an HIV-2 blood donor. At the same briefing, Food and Drug Administration (FDA) Commissioner Frank E. Young said that prior screening of blood from more than 22,600 individuals in the United States had not detected infection with HIV-2. In anticipation of future HIV-2 spread, however, Young says the FDA is evaluating a rapid HIV-2 test in a "fast track" review process. He also says the FDA recommended last week that West Africans, like other high-risk groups, voluntarily exclude themselves from donating blood.

Young admits that potential treatments and tests for diseases other than AIDS have suffered under the FDA's concerted effort to rapidly review AIDS-related medical products. "We're running with bloody feet to try to keep up" with the many AIDS-related requests for FDA approval, he says.

Early last year, when zidovudine (AZT) became the first AIDS treatment approved by the FDA, human testing of other drugs was already underway. Among those candidate treatments was 2′,3′-dideoxycytidine (ddC), a more potent relative of AZT that inhibits HIV-1 infection of cells (SN: 3/28/87, p.198). Last month, researchers published the results from the phase I clinical trials of ddC, which were designed to evaluate the drug's toxicity and potential curative effects.

The multicenter study — led by scientists at the National Cancer Institute in Bethesda, Md. — included 20 AIDS or AIDS-related complex (ARC) patients given ddC, plus another six patients given zidovudine alternating with ddC. Length of treatment depended on the individual's response to the drugs.

Whether given intravenously or orally, ddC effectively crossed the blood-brain barrier, which is important because the virus can infect brain cells and cause dementia. Both sets of patients also showed an increase in the total number of certain immune cells called T4 lymphocytes, which can be drastically reduced during HIV infection. But like zidovudine, which has adverse effects on the bone marrow, ddC given alone is not without its problems. In addition to the rashes, mouth sores and fever of some ddC-treated patients, several patients developed reversible neurological symptoms, ranging from dizziness to dementia, after about three months of treatment.

More encouraging, say the scientists, are results from the smaller group of patients given ddC *and* zidovudine. At the time of the report, five of the six were without neurological symptoms after seven months of treatment.

Reporting in the Jan. 16 LANCET, the researchers note that "it is too early to say whether such a [combination] regimen will be better than AZT alone." But they conclude that the different toxicity profiles of ddC and zidovudine suggest that alternating the two therapies might help reduce adverse effects in patients.

— D.D. Edwards

Aspirin/heart issue, cont.

One day after last week's announcement by U.S. scientists that an aspirin every other day can reduce the risk of a first heart attack by 47 percent, British scientists reported that their study of 5,000 British physicians failed to find any similar benefits from daily aspirin intake. Published in the Jan. 30 BRITISH MEDICAL JOURNAL, the second study included data from a six-year study by researchers from Oxford University's Radcliffe Infirmary, who say the U.S. results are overly optimistic.

Both U.S. and British scientists involved in the conflicting research projects, however, agree that the British results do not entirely negate the positive findings of the Harvard Medical School/Brigham and Women's Hospital study (SN: 1/30/88, p.68). Authors of the British report point out that the U.S. study, with its larger numbers (more than 22,000 test subjects and three times as many heart attacks), is more statistically sound. It is because of these statistical differences, Harvard's Meir J. Stampfer said in an interview, that the Boston group feels the British study "is not especially informative. . . .Where they are is where we were in 1983 or so." Charles H. Hennekens, chairman of the U.S. study, also participated in the British project during a year-long appointment in London and is a coauthor of the report.

Despite the British study's smaller size, Stampfer acknowledges that its outcome could alter the final conclusions drawn from the larger study. He says the actual aspirin-related decrease in heart disease risk may not be "quite as extreme" as 47 percent. Authors of the British report suggest that the decrease in risk may be closer to 30 percent.

— D.D. Edwards

FDA to evaluate fat substitute

Two days after announcing its new fat substitute, the NutraSweet Co. agreed last week to file a petition with the Food and Drug Administration to seek "generally recognized as safe" (GRAS) status for the substance, which it calls Simplesse.

At first, company officials said at a news conference that they did not require FDA approval before giving GRAS status to Simplesse because it is made by merely changing the physical form of proteins from common foods.

But they agreed to file a petition after meeting with FDA Commissioner Frank E. Young, who said he was "perplexed" by their decision to announce the product without consulting FDA. Young, in a letter to NutraSweet Chairman Robert B. Shapiro, said the company had not provided "any information about the product to the FDA, leaving the agency unable to evaluate the company's unilateral judgment that the product is safe."

One of the key questions concerning Simplesse will be whether extracting the protein and altering it will change its toxicity and nutritional value, says Theodore Labuza, incoming president of the Institute of Food Technologists and professor of food science and technology at the University of Minnesota in St. Paul.

Labuza says NutraSweet was within legal limits when it commissioned an expert panel to determine whether Sim-