

buttressed by a 1979 report written by a blue-ribbon panel in Britain, which also advised a minimum of 400 samples. The proposed FDA restrictions would have required a lab to conduct only 50 tests weekly. The agency position now is that there is "no established relationship between volume of tests and proficiency." CDC is, however, developing some guidelines on quality control.

Macri is also concerned that, unless laboratory results are reliable, women will undergo amniocentesis unnecessarily. If too many women elect to have amniocentesis based on faulty data, the invasive procedure may do more harm to the mother and fetus than if the test were not performed, Macri argues.

FDA could learn from the experience with alpha-fetoprotein testing in Britain, he says. In that country, neural tube defects have caused considerable concern because the abnormalities occur in five out of 1000 children, a rate five times higher than in the United States. The 1979 study, headed by Sir Douglas Black, then president of the Royal College of Physicians, emphasized the need "to ensure that there were sufficient health professionals and facilities to perform followup testing and analysis" and called for extensive reporting to judge the program's effectiveness.

Some states, such as California and Maryland, are already establishing their own monitoring programs. Some observers predict that other states will follow suit, but to Macri and others a federal effort is needed.

FDA plans to issue formal approval of the alpha-fetoprotein tests in the near future and to announce exactly what kind of information it will require from doctors, manufacturers, and labs. Nichols of the obstetrics society and others seem pretty much resigned to the FDA's withdrawal of the proposed restrictions. When the official approval notice does appear, the Washington-based Health Research Group plans to file a petition for a hearing before Commissioner Hayes. If granted, supporters of the restrictions might get one more crack at persuading FDA to limit use of the tests.

Given the arguments and concerns of researchers and professional societies about quality control, it seems that Hayes had a reasonable basis to support temporary restrictions. If he had done so, he might have coincidentally allayed concerns by some antiabortionists. Instead, he has taken a very narrow view of FDA's role in judging safety and effectiveness of the tests. "I see lots of problems ahead," Macri says.

—MARJORIE SUN

Pesticide Office Demands New Safety Studies

Edwin Johnson, director of the Office of Pesticide Programs at the Environmental Protection Agency, called a news conference on 11 July to let reporters know that the gaps in health and safety data created by the Industrial Bio-Test (IBT) scandal are almost fully repaired. Earlier, his agency reported that IBT was responsible for submitting over 1200 invalid studies that were used to approve more than 200 pesticides. The laboratory's officials are now on trial in Chicago for committing wire and mail fraud (*Science*, 10 June, p. 1130). But Johnson said at the press conference that the "IBT situation has not proven to be the hidden public health disaster that some had feared."

Johnson released a summary of the IBT-related problems, announcing that the agency's review begun in 1977 is now complete. He also revealed a couple of new regulatory actions, the most important being that manufacturers of 35 compounds will be given 90 days to replace the IBT studies they relied on, commit themselves to filing new studies, or face suspension from the market.

Johnson emphasized that the actual number of problem chemicals is smaller than the early estimates suggested. He reported that there are only 140 compounds still in use which are supported in part by IBT data, and only five are supported wholly by IBT studies. Of these five, two are "major use" chemicals: prometon and dinoseb. The former is used for nonagricultural purposes and the latter is a food-related pesticide. Johnson's report notes that "A large majority (93 percent) of the pesticides tested by IBT also have non-IBT data available" to serve as a secondary assurance of safety.

However, at least one government expert told *Science* this report glosses over the problems that remain to be cleared up. For example, it does not indicate how many of the 140 compounds—some of which may be widely used—still depend heavily on IBT studies in the especially critical areas of carcinogenicity and chronic toxicity analysis. These are important for setting allowable human exposure levels.

An aide to Johnson says, "There are many ways to cut the data; we didn't do it that way." Nor is it clear when the invalid studies needing replacement will be fixed. Because it can take 4 years to run a carcinogenicity study, it is fair to assume that for some chemicals now in use, it will take until 1987—10 years after the IBT scandal broke—to learn whether or not they pose a health hazard.

Meanwhile, in Chicago, the judge hearing the IBT case granted a mistrial on 11 July to Joseph Calandra, the founder and former president of IBT. He was allowed to drop out to undergo open heart surgery. (The operation was a success.) Calandra is now separated from his three colleagues, whose trial for fraud is expected to continue until September. He will be tried later.—ELIOT MARSHALL

NRC Delays Pipe Inspections

The staff of the Nuclear Regulatory Commission (NRC) has been urging the temporary shutdown of five boiling water reactors so they could be inspected for cracks in the cooling pipes. However, after a meeting between the reactor owners and NRC commissioners on 15 July, the NRC agreed to postpone the order until the Electric Power Research Institute (EPRI) comes out with the results of ultrasonic studies on cooling pipes. Those are expected by 4 August.

Owners of the five plants had planned to inspect pipes in the fall or winter. The NRC staff wanted to accelerate this schedule so as to minimize the risk of an accident. But the industry argued successfully that the seriousness of the cracks could be overstated, a possibility that the EPRI tests could verify.

General Electric reactors manufactured in the late 1960's and early 1970's have been plagued by cracks in pipes. They have been detected in 13 reactors around the country and 7 are currently shut down because of the problem. Replacement of pipes with ones made of higher grade steel could cost between \$10 million and \$100 million per reactor, according to industry sources.

—CONSTANCE HOLDEN