Letters

FDA Action on Blood Poisoning

I have noted the article, "Food and Drug Administration: Is protecting lives the priority?" in your issue of 2 April (News and Comment, p. 41).

It is not true that in January 1971 the FDA knew that the bottled intravenous (I.V.) feeding solutions manufactured by Abbott Laboratories had somehow led to an outbreak of blood poisoning and several deaths.

It is true that in January the Center for Disease Control (CDC) in Atlanta, Georgia, was compiling data on the Abbott I.V. solutions. The data at this time were limited and inconclusive. CDC did not make a recommendation for action to the FDA at the time, and rightly so, because there was no basis for action. There was a clear need for further data and CDC proceeded to gather them in proper scientific fashion.

There was indeed a "suspicion" of the contamination problem in January. The matter was quite difficult to identify and assess. Not the least of the reasons for this were that the two bacteria involved in the infections associated with the Abbott products are plant pathogens rarely seen in clinical medicine. Most hospitals lack the technology necessary to identify them.

CDC presented its still incomplete Abbott data to FDA staff in Atlanta on 11 March. That same afternoon, I called David Sencer, director of the CDC, and arranged to meet with him and his staff in Washington the next day. In a meeting on 12 March, Sencer's staff presented the data to me and my top staff. Later that day, the data were also presented to representatives of Abbott Laboratories.

After consultation, my staff and I reached agreement with the tentative CDC conclusion that contamination could enter the fluid from the plastic cap liners after the caps were opened and then replaced while the bottle was held for later use. At this point, FDA and CDC jointly decided to issue a warning to all hospitals, nursing homes, and other health care facilities to reduce the risk of septicemia from the use of Abbott Laboratories intravenous infusion products.

Abbott officials were immediately told of our decision. They were also told what would be expected of them in making the precautions effective and in cooperating to identify the cause and end the problem. Action thus was taken by FDA and CDC within 2 days after minimum necessary data were accumulated and evaluated.

There was no question of banning the products on 12 March for two reasons. First, we concluded, on the basis of our knowledge at that time, that the precautionary action was prudent, reasonable, and adequate. Second, about 8 million bottles of I.V. solutions are used every month in the United States, and Abbott Laboratories supplies about 45 percent of this total. To have "banned" Abbott I.V. solutions, before replacement could be assured, could have led to life-threatening situations much more dangerous than the septicemia associated with the Abbott solutions.

Throughout the week following the 13 March warning, FDA and CDC were in daily consultation while additional studies were carried on. During this time surveys by both CDC and FDA showed sufficient potential production for a national supply of intravenous fluid from sources other than Abbott. Also, we continued to receive reports of Abbott-associated septicemia. Finally, we concluded that hospital personnel could not comply or were not complying fully with the precautionary instructions of the previous week. On the basis of these additional findings, FDA on 22 March recommended that all health care facilities cease using Abbott solutions as soon as possible.

The logistical problem that we anticipated on 22 March has continued to be a source of concern to FDA and to the nation's hospital system, and has, to this date, precluded a total temporary replacement of all lines of I.V. products provided by Abbott. Since 22 March FDA has coordinated a national emergency system to insure that no patient is denied I.V. fluid.

At this time, we are most hopeful that Abbott will solve its problems and return to I.V. production soon. This will not happen until we in FDA are convinced that the contamination problem has been solved. I am satisfied that the FDA and CDC acted responsibly in this matter. The record to this date clearly demonstrates in fact that the actions taken and being taken have been adequate to the situation and in full accord with FDA's obligations to consumer safety.

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Edwards essentially repeats what he said in an interview with *Science* prior to the publication of the article, and the points he raises were discussed in the article. It might be asked why a "suspicion" of contamination of a product is insufficient motivation for FDA to at least issue a warning and undertake an investigation of alternative suppliers, particularly when the problem potentially involved hundreds of deaths and thousands of illnesses.

Moreover, when FDA issued guidelines for the use of the Abbott products on 12 March, there was ample evidence that the precautions suggested by FDA would do little or nothing to reduce the incidence of infection from the I.V. solutions.

Early in January, CDC epidemiologists found a large percentage of the Abbott I.V. solutions in use at St. Anthony's Hospital in Denver to be contaminated. They then recommended that the hospital employ essentially the same set of precautions that FDA was later to recommend for every hospital in the country. And it was while the hospital was using the precautionary measures that 24 cases of septicemia, including one death, occurred as a result of the contaminated solutions. Officials at St. Anthony's Hospital decided, therefore, on 18 January to ban the Abbott I.V. products altogether, and the problem then disappeared.

That was 8 weeks before the FDA decision to suggest precautionary handling of the Abbott products and 9 weeks before the decision to ban them.

—R. J. BAZELL