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March 21, 1971

Honorable Charles C. Edwards
Commissioner
Food and Drug Administration
Washington, D.C.

Dear Dr. Edwards:

This is an urgent plea for immediate preventive action by the FDA to save lives and injuries. This action is within the knowledge and under the authority of your Agency.

There are several thousand hospitals in the United States. In eight of these hospitals alone, between October 1970 and March 1971, there were 150 cases of blood infection and 9 deaths from a type of bacteria rarely found in humans. Recent investigations by the Center for Disease Control have directly traced the infections in these hospitals to bottle caps from intravenous fluids manufactured by Abbott Laboratories. According to information gathered by the C.D.C., one of the 8 hospitals, which had previously been plagued with these blood infections, stopped using Abbott products in January and has subsequently had no further cases.

On March 1st, this information was presented by the CDC to officials of the Food and Drug Administration at a meeting in Washington. Another week and a half went by before a joint report was issued March 13 by FDA and CDC which made these findings known. Although the report delineates the magnitude and severity of the crisis and identifies the contaminated lot numbers of Abbott Laboratories' bottles of intravenous fluids, its conclusions and solutions are shockingly irresponsible. It is as if the government's prime concern was Abbott Laboratories' sales image.

There is a clear mandate from the data the CDC has collected to order Abbott Intravenous products off the market and thereby insure the end of this epidemic of blood infections and deaths. Despite this, the FDA has suggested continued use of these contaminated products with several handling precautions whcih are of questionable efficacy or practicality (assuming that the hospital personnel know of them, which is uncertain).

One FDA recommendation is:

> "At the first suspicion of clinical septicemia (blood infection) or fever which might be associated with contaminated intravenous fluid, all existent IV apparatus should be removed . . ."

Such a position is totally inadequate. It is a form of malpractice to wait until a patient develops evidence of a blood infection before discontinuing the use of products known to have a high incidence of bacterial contaminants. It is a cowardly repudiation of the ethic of

preventive medicine. Although Abbott currently supplies about 45% of all IV fluids, CDC officials have stated that other companies could quickly increase production to replace the contaminated bottles.

On Saturday, March 20, we contacted 25 metropolitan Washington hospitals. Twelve of these hospitals which have used Abbott intravenous fluids are continuing to use them since they have not been ordered off the market by the FDA. Each day the FDA delays this action will bring new cases of entirely preventable blood infections and possible deaths. The FDA is in possession of clear, unequivocal, evidence and is not using its powers to get a documented, serious hazard out of hospitals and off the market. Anything less should incur administrative sanctions, as provided for in government regulations, against the officials responsible for such gross dereliction of duty.

Sincerely,

Ralph Nader

Dr. Sidney Wolfe
Internist, Washington, D.C.