FDA says tainted blood may have been released

Red Cross has failed to fix longtime safety violations, report states

Associated Press

WASHINGTON — The American Red Cross may have released tainted blood to hospitals, the government said Friday, reporting more than 200 violations of federal blood safety rules in its battle to get the Red Cross to improve the quality of its blood operation.

The Food and Drug Administration said it was investigating further to determine whether patients received bad blood.

"The blood supply is not as safe as it should be," said FDA Commissioner Mark McClellan. "I am troubled by apparent lapses in blood safety."

The Red Cross, which provides 45 percent of the nation's blood supply, said it is working hard to improve safety.

A year ago, the FDA went to court seeking contempt charges for 10 years of Red Cross safety violations. Friday's preliminary report on safety at the Red Cross biomedical headquarters says the problems have not been fixed, Mr. McClellan said, suggesting they point to a "culture willing to accept noncompliance."

The FDA alleges that some Red Cross employees were instructed to skip required safety steps and others altered records to allow release of blood that had failed safety testing.

In addition, the Red Cross failed to screen out some people who were not supposed to give blood, the FDA said. It was unclear what happened to the units these people donated, the agency said.

More than 1,000 units of blood were unaccounted for, it said.

The FDA emphasized that anyone who needs a blood transfusion should get one because the risk of forgoing a medical procedure is much higher than the risk of getting bad blood. The agency also noted that people who donate blood face no risk.

The Red Cross acknowledged the problems and promised to fix them.

"The Red Cross understands more work needs to be done to further strengthen our processes and procedures, and we are fully committed to working collaboratively with the FDA to enhance our systems," Remesh Thadani, who heads biomedical services, said a prepared statement Friday.

More than 200 individual violations were identified, the FDA said. Among them:

- Lack of management control and quality assurance oversight. Required testing steps were not always documented, and some employees reported being told to skip required steps.
- Data integrity. Employees were alleged to have changed records to indicate that flagged blood was safe.
- Failure to correct deviations from previous inspections, including failure to follow standard operating procedures.
- Release of unsuitable products. In some cases, the FDA does not know what happened to the blood from donors deemed unsuitable.

It was the first inspection of the Red Cross headquarters since last December, when the government asked a federal judge to hold the Red Cross in contempt for repeated violations of blood safety regulations, including shipment of contaminated blood.

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