

FDA fines Red Cross nearly \$9.6 million for blood safety lapses



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The American Red Cross is facing a new multi-million-dollar fine for problems with blood collection and distribution.

By JoNel Aleccia

Federal health officials have fined the American Red Cross nearly \$9.6 million for sloppy and unsafe blood management practices, the second multi-million-dollar penalty levied against the agency in the last two years.

The new Food and Drug Administration fine follows inspections at 16 Red Cross blood centers between April and October 2010 that revealed ongoing problems that appeared to endanger donors and to allow potentially contaminated blood into the nation's supply.

An FDA spokeswoman said the agency found no evidence of actual harm to blood recipients and that officials remain confident about sources of blood in the U.S.

But, spokeswoman Patricia El-Hinnawy added, problems at the Red Cross, which supplies 40 percent of the nation's blood, are worrisome.

"FDA cannot definitively say there was never any danger to the blood supply since the violations can create conditions that could lead to potential safety consequences," said El-Hinnawy.

The violations were outlined in a [32-page letter sent Jan. 13 to J. Chris Hrouda](#), executive vice president of Biomedical Services for the Red Cross. They describe a

blood collection system plagued with poorly trained staff and inadequate record-keeping where donated blood was mishandled or misplaced and, in some cases, potentially infected blood was transfused into patients.

“ARC has known of these continuing problems and has failed to take adequate steps to correct them,” wrote Evelyn Bonnin, director of FDA’s Baltimore District. But a Red Cross spokeswoman said in a statement that the problems primarily centered on an inspection at a Philadelphia site conducted 15 months ago and that the agency has since addressed many of the issues.

“We are disappointed that the FDA believed it necessary to impose a fine for an inspection conducted so long ago,” wrote Stephanie Millian, director of biomedical communications. “We are not aware of any adverse donor reactions or patient issues due to the problems in the FDA report.”

The latest fine, however, follows a \$16 million fine in June 2010 for similar failures and caps nearly two decades of trouble at the Red Cross.

About 17 million units of blood are donated each year and about 15 million units are transfused, according to a 2009 survey conducted by AABB, an international association of blood products groups.

The Red Cross has been operating under terms of a consent decree first issued in 1993 and then amended in 2003 to allow the FDA to impose stiff fines for ongoing failures to meet regulations and laws governing quality and safety of the nation’s blood supply. The problems detected then were the same ones that have not, apparently, been addressed now: overworked staff, sloppy clinical practices and inadequate record-keeping.

Despite repeated stiff fines and even the informal threat of criminal penalties from some FDA officials, the agency has not succeeded in improving its record, the latest sanctions demonstrate.

Problems outlined in the Jan. 13 letter include failure to process and review records of donor reactions and injuries, including a backlog of some 15,000 records in Charlotte, N.C.

Certain Red Cross sites have not been keeping an accurate list of deferred donors who should be barred from giving blood because of infections or other potential problems, the letter said.

Others weren't conducting "lookback" investigations to track down blood from donors who turned out to have infections and to notify patients who might have received potentially contaminated blood.

Still others didn't investigate complaints or other notices of problems, including a donor who was sprayed with blood during a mobile blood drive at the [Heart of America](#) regional center in Peoria, Ill., in 2009.

In Arizona in 2010, inspectors said a phlebotomist at a Red Cross center stuck herself with a needle and then stuck a patient with the same needle to draw a unit of blood, but no one reported the incident for a month.

FDA officials said that the Red Cross has taken steps to address previous violations, including new standardization of procedures, an upgrade and consolidation of national testing laboratories and increased oversight from biomedical headquarters.

El-Hinnawy stressed that donating blood is safe and that the risks of receiving a transfusion are far less than failing to receive blood when it's needed.

"FDA strongly encourages people who are in good health to donate blood and become regular blood donors," she said.