

Red Cross accepts threat of huge fines in pledge to fix blood safety violations

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Associated Press

WASHINGTON — The Red Cross, accused by the government of "persistent and serious violations" of blood safety rules, promised in a court settlement yesterday to meet all safety requirements and pay substantial fines if it fails to do so.

The Food and Drug Administration said the consent agreement settles concerns stemming from inspections going back 17 years.

Two years ago, the FDA went to court seeking a contempt citation against the Red Cross for not following a 1993 agreement to meet blood safety standards.

Under the new settlement, fines for various violations could total up to 1 percent of the Red Cross' \$1.9 billion in annual rev-

enues — or \$19 million — in the first year, increasing to a maximum of 4 percent by the fourth year, the FDA said.

"The new financial penalties in the consent decree create an important new incentive ... to improve the processes and controls necessary for making safer blood products," FDA Commissioner Dr. Mark B. McClellan said.

The Red Cross issued a statement saying it recognized the need to strengthen its procedures and was launching an aggressive quality program.

"The new consent decree provides greater specifics on how the Red Cross will manage, monitor and resolve problems if they arise," the statement said. The organization said that if it is forced to pay fines it will not use donations from the public to do so. The agreement will be sub-

mitted to the court for approval, McClellan said.

In its inspection of the charity last December, the FDA said it found "numerous and troubling problems in producing blood products — including a lack of management control and quality assurance oversight that could lead to a patient receiving potentially unsafe blood."

Potential financial penalties outlined in the decree include:

- Up to \$10,000 per event, and \$10,000 per day, for any violation of standard operating procedures, the law, or consent decree requirements and timeline for compliance.
- \$50,000 for the preventable release of each unit of blood for which the FDA determines that there is a reasonable probability that the product may cause serious health problems or death.

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