

TESTIMONY OF NANCY NEWTON, PRESIDENT AFSCME LOCAL 3145
RAISED BILL 5732/ PUBLIC HEALTH COMMITTEE
FEB. 27, 2013

Good morning Chairman Gerratana, Chairman Johnson and members of the Public Health Committee. My name is Nancy Newtown. I am employed as a quality and labeling technician at the American Red Cross – Connecticut Blood Services Region in Farmington.

I also serve as President of AFSCME Local 3145, representing front line blood collection workers, including phlebotomists, technicians, driver-techs, RNs and LPNs. Just five years ago, our bargaining unit included more than 35 RNs and LPNs. **Today that number is ????**

We believe every Red Cross mobile blood drive should include a licensed professional who has been trained in assessing patients. A licensed nurse will be more adept at picking up on signs of early distress. And that's the whole point: Why wait for something serious or life threatening? Front line staff constantly sees adverse reactions on blood drives that require a nurse's professional opinion and intervention.

Rather than hiring RNs to oversee the safety of the blood collection process and Connecticut donors, the Red Cross has instead hired supervisors to be at blood drives. These supervisors are unlicensed, yet are put in the position of making decisions about the fitness of donor during the screening process.

The Red Cross sells the blood it collects from donors to health care institutions. Blood is a profitable product. The American Red Cross is under a 20-year-old Federal Consent Decree that orders improvements in its blood safety practices. Since 2003, the FDA has fined Red Cross more than \$46 million for safety compliance violations.

Let me be clear that the New England region has not experienced significant compliance violations. That's a tribute to our dedication and our skill. But how long can this continue with continued turnover and a reduction in medically licensed personnel?

In summary, we believe that one RN, and preferably a second licensed nurse should be present at mobile blood drive to ensure the outcome rightfully called for by the FDA. RNs have extensive medical training and greater experience to make medical assessments, and respond to donor reactions or injuries.

Thank you for your attention. Our union looks forward to working with you to ensure safe blood collection practices.

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

By JoNel Aleccia, Staff Writer, NBC News

February 27, 2013, 6:07 am

NBCNews.com

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.

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FDA fines Red Cross \$16 million after blood safety inspection

The federal agency said the charity failed to maintain quality controls in collecting and processing blood products in 2008 and 2009.

June 18, 2010 | By Andrew Zajac, Tribune Washington Bureau

Reporting from Washington —

The Food and Drug Administration on Thursday fined the American Red Cross \$16 million, alleging that the organization had been slipshod in the collection and manufacture of blood products. It was the latest in a string of multimillion-dollar penalties for failure to meet blood safety standards.

Despite the most recent violations, there is no indication that patients or the blood supply were endangered, "and the blood supply is believed to be safe," the FDA said in a statement.

The penalties resulted from FDA inspections of a dozen Red Cross facilities across the nation in 2008 and 2009 that identified multiple failures to investigate and correct sloppy processing of blood products and a failure to maintain quality controls.

The FDA said that it was encouraged by recent actions by the Red Cross' leadership to improve blood safety and that it was "hopeful these fines will encourage the Red Cross to act more quickly" to comply with safety regulations.

The fines bring to \$37 million the total penalties for substandard blood handling procedures levied against the Red Cross since 2003. In that year, a consent decree in place since 1993 was amended to let the FDA impose fines.

In a statement, the Red Cross said many of the incidents cited by the FDA took place before corrective action was taken.

The Washington-based charity said it was "fully committed to meeting all FDA standards" but was "disappointed that the FDA believed that it was necessary to fine us for prior violations dating back several years."

The Red Cross collects and processes about 43% of the nation's blood supply and produces blood products including red cells, plasma and platelets.

A Red Cross spokeswoman said fines were paid out of the agency's operating budget, which comes from fees paid by hospitals for blood services, and not from donations.

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