

December 1, 2000

Jane Henney, MD  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland  
20857

Dear Dr. Henney,

In papers filed on November 28<sup>th</sup> in the U.S. District Court for the District of Columbia, the FDA has documented long standing, widespread and dangerous practices by the American Red Cross (ARC) which have jeopardized the safety of the U.S. blood supply and which have violated a 1993 Consent Decree between the FDA and the ARC. [1] In its brief, the FDA stated that "ARC has been out of compliance with the statute and CGMP [current good manufacturing practices] since at least 1985...FDA believes that additional measures are essential to bring ARC into compliance with CGMP so that the public may be assured of safe blood and blood products." You are aware of many of these issues because of your attendance at an August 14<sup>th</sup> meeting at the FDA involving ARC President Dr. Bernadine Healy concerning these serious problems.

Based on the evidence presented by the FDA in the papers filed with the court, it appears that a strong case can be made by the FDA for requesting that the ARC be held in contempt of court for repeated violations of the 1993 Consent Decree extending through the present.[2] Unless the FDA exercises this legal responsibility, there is little evidence that the ARC will come into compliance with the terms of the 1993 Consent Decree or with U.S. laws and regulations concerning blood and blood products. As a result, these dangerous practices are likely to continue to the detriment of the public health.

**1993 Consent Decree:** Because of repeated instances of dangerous blood-handling practices by a number of U.S. ARC regional blood banks, and a failure by the ARC to abide by a voluntary 1988 agreement with the FDA to solve these problems, the 1993 Consent Decree was entered by U.S. Federal District Judge Stanley Sporkin. This Decree required the ARC to establish management control over blood service operations and to establish a quality control program.

Examples of problems which precipitated this Consent Decree included inspections following the 1988 voluntary agreement which found such serious violations of FDA laws and regulations that the FDA issued three Notices of Intent to Revoke.[3] for various ARC establishment licenses and actually revoked one license (the Albany Regional Blood Center). On September 10, 1990 FDA Acting Commissioner Benson wrote to the ARC citing "continuing release of unsuitable blood products and specified the corrective actions that ARC must take such as establishing control over regional operations..." [4]

**Serious Problems since 1993:** Since 1993, according to the FDA brief, "FDA has sent ten letters...advising ARC of significant areas of noncompliance.... At no time has ARC indicated that it disagreed with a letter."

One such letter followed an FDA inspection of ARC's Atlanta facility completed in July, 1999 which found: "failure to provide adequate space for the proper storage of blood components, resulting in blood products with positive test results being commingled with blood products that were acceptable for distribution; inadequate inventory management resulting in the inability to account for unsuitable blood products, including products with positive test results for infectious disease..."

In addition, an FDA inspection of ARC headquarters, completed in April, 2000, found among 63 observations, "a deficient quarantine system that does not prevent release of unsuitable products; improper release by ARC of cytomegalovirus (CMV)-positive blood products; donors being associated with incorrect histories; inadequate ARC oversight of system problems; failure to follow manufacturer's test kit instructions (for human immunodeficiency virus (HIV) p24 antigen neutralization ), resulting in the failure to perform look back investigations; lack of timeliness in addressing problems; inadequate assessment of problems."

An August, 14, 2000 meeting involving Dr. Bernadine Healy, current ARC President, you and other FDA and ARC personnel yielded some shocking statements from Dr. Healy. She said that the findings of the April, 2000 FDA inspection of ARC headquarters were "alarming" and that the "ARC headquarters was at fault regarding problems with its centralized computer system that had periodically "lost functionality". She also said that the "severity" of the issues held the potential for "grave impact" to patients. She stated, however, that ARC management had not been aware of the seriousness of these problems.[5]In a July 10, 2000 phone call from Dr. Healy to Robert Bowers, Director of the Baltimore FDA District office, Dr. Healy said she was "stunned" by the conditions found by the FDA at ARC Headquarters and said she was totally unaware of the number of problems and the period of time over which some problems had existed. She assured Mr. Bowers that her predecessor, Elizabeth Dole, had said she too was unaware of the deviations.[6]

Whether Dr. Healy or Elizabeth Dole personally knew of these serious ARC problems is not relevant. They, like all manufacturers of blood products, have a legal obligation to ensure that the necessary systems and controls are in place to make certain that their blood products are safe. Further, every ARC President has an obligation to know what is going on at the ARC. Ignorance is no excuse.

In summary, the ARC, including its regional blood centers, have for at least 15 years been consistently violating the laws and regulations governing the conduct of the blood industry. For the last eight years, there have been flagrant violations of the 1993 Consent Decree with never-ending promises that things will get better. It is time for the FDA to stop playing dangerous, cooperative, polite games with the ARC and ask that the organization be held in contempt of court for recklessly disregarding the 1993 Consent Decree. Otherwise, it will only be a matter of time before (if it has not happened already) patients receiving blood or blood products will become needlessly infected because of the sloppy procedures documented in many FDA inspections.

I look forward to a prompt response to this urgent request.

Sincerely,

Sidney M. Wolfe, M.D.  
Director of Public Citizen's Health Research Group

[1]The FDA court papers were filed in response to Red Cross allegations that the FDA was not abiding by the 1993 Consent Decree.

[2] In an affidavit from FDA Compliance Officer Nancy Rose accompanying the November 28<sup>th</sup> court filing, she stated that FDA officials could consider civil or criminal contempt against the ARC.

[3] Notice of Intent to Revoke means that a licensed blood manufacturing establishment has had continuing violations which are so significant that the FDA intends to withdraw authorization to ship blood products in interstate commerce.

[4] November 28<sup>th</sup> Declaration of Robert Bowers, FDA Baltimore District Director

[5] November 28<sup>th</sup> Declaration of FDA Policy Analyst, Dana Delman who wrote a memorandum of the August 14, 2000 meeting. This was included with the FDA court papers.

[6] November 28<sup>th</sup> Declaration of Robert Bowers, FDA Baltimore District Director