

January 24, 2002

Senator Thomas Daschle,  
Senate Majority Leader

Senator Ted Kennedy,  
Chairman, Health, Education, Labor and Pension Committee

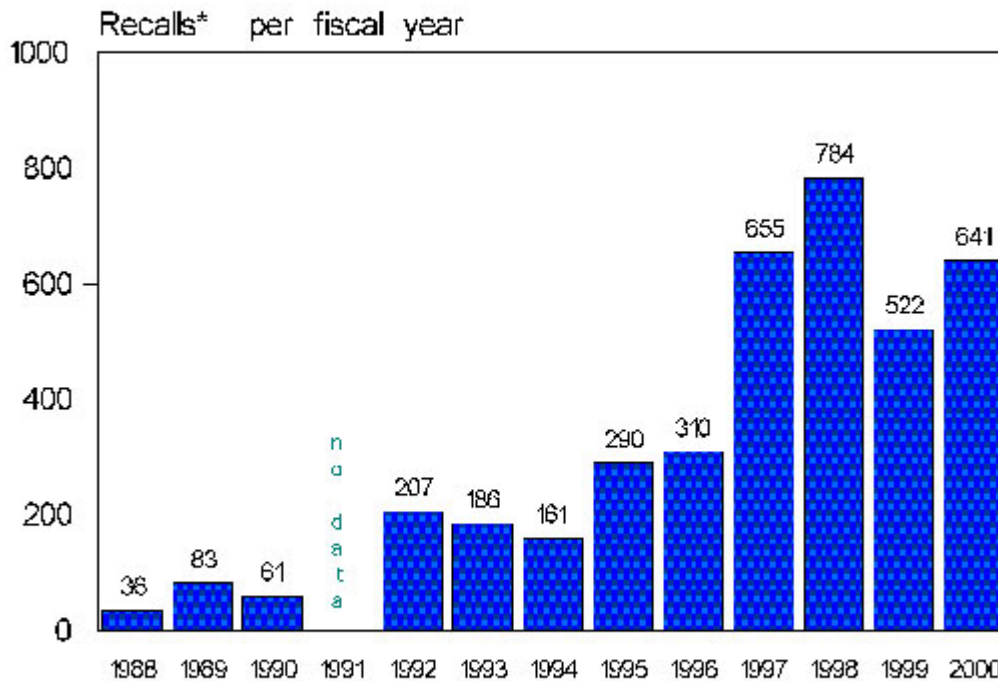
Dear Senators Daschle and Kennedy,

We have obtained, from the U.S. Federal District Court in Washington DC, declarations by top FDA officials which raise serious questions about the safety of the blood supply, specifically that major portion which that is collected, processed and distributed by the American Red Cross (ARC). These declarations were filed on December 13, 2001 in conjunction with the FDA's recent motion to hold the Red Cross in contempt of court for flagrant violations of a 1993 Consent Decree. We strongly urge you to launch an inquiry and/or a hearing into what else can be done to force the Red Cross to improve its public health-threatening record.

Among the findings of most concern were:

- A statement by Dr. Jay Epstein, Director of the Office of Blood Research and Review at the Center for Biologic Evaluation and Research of the FDA that the Red Cross has operated with "an attitude of disregard for the public's interest." He was also critical of the ARC's assertion that blood supply is safe because there has been no documentation of transfusion associated infections from unsuitable ARC blood products. He warned that this is "a notoriously dangerous assumption to make. Transfusion-transmitted infections may fail to be recognized and attributed to unsuitable blood for several reasons." These include the fact that many infections are dormant for long periods of time before causing an infection and that since all transfusion related infections can also be acquired in the community [from sources other than blood], this may cloud the attribution of blood as the source of contagion. Further, even if a doctor or a patient was able to link the disease to a blood transfusion, "the fact of a transfusion-acquired infection may not be reported since such reporting is not required of physicians".
- Data in the recent declaration of Robert Bowers, Director of the Baltimore FDA District Office in the same case showed a "dramatic increase in the number of unsuitable blood products released by ARC over the years". As seen in the figure below, the number of recalls of such unsuitable blood products increased from 36 recalls in fiscal year 1988 to 641 recalls in fiscal year 2000, an 18-fold increase in recalls during that interval. The FY 2000 recalls involved 12,701 units of blood products and 11,488 of these units "were determined to present Class II health hazards."<sup>4</sup>

## U.S. Red Cross "Unsuitable Blood Product" Recalls



Data compiled by Public Citizen Health Research Group was obtained from Declaration by Robert Bowers, Director, Baltimore FDA Office, December 7, 2001, filed with U.S. District Court, DC, with motion for Contempt of Court.

\* Recalls are actions taken to remove from commerce products FDA considers to be in violation of the law and against which FDA would initiate legal action.

- According to Dr. Epstein, The "FDA cannot be assured that ARC can effectively conduct product recalls, when they are necessary" even though the number of recalls has increased dramatically. This could mean that unsuitable blood products, which should be the subject of a recall, might not actually get recalled.

### History of Red Cross Failures

**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 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..."

**Serious Problems since 1993:** Since 1993, according to the FDA brief filed a year ago, "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 facilities to ensure the proper storage of blood products, resulting in commingling of acceptable blood products and blood products that

had positive test results for infectious diseases; inadequate inventory management, resulting in the inability to account for unsuitable blood products, including units that had positive test results for infectious diseases..."

In addition, an FDA inspection of ARC headquarters, completed in April, 2000, found among 63 observations, "a deficient quarantine system to 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 instruction (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."

Although we strongly support the FDA's efforts to hold the Red Cross in contempt of court for repeat violations of the 1993 consent decree, Congressional oversight of the Red Cross and this serious risk it presents to the public health is also necessary to better determine the full scope of the problem and to work with the FDA to more quickly find solutions. Dr.

Epstein's plea that "transfusion-acquired infection may not be reported since such reporting is not required of physicians" is an implicit message for congressional action to remedy this impairment of FDA's function. If we can be of help with this important effort, please contact us.

Sidney M. Wolfe, MD

Director

Public Citizen's Health Research Group

Amer K. Ardati

Research Associate

Public Citizen's Health Research Group