DHHS Advisory Committee of Blood Safety and Availability

The State of the US Blood Supply from a Health Activist Point of View

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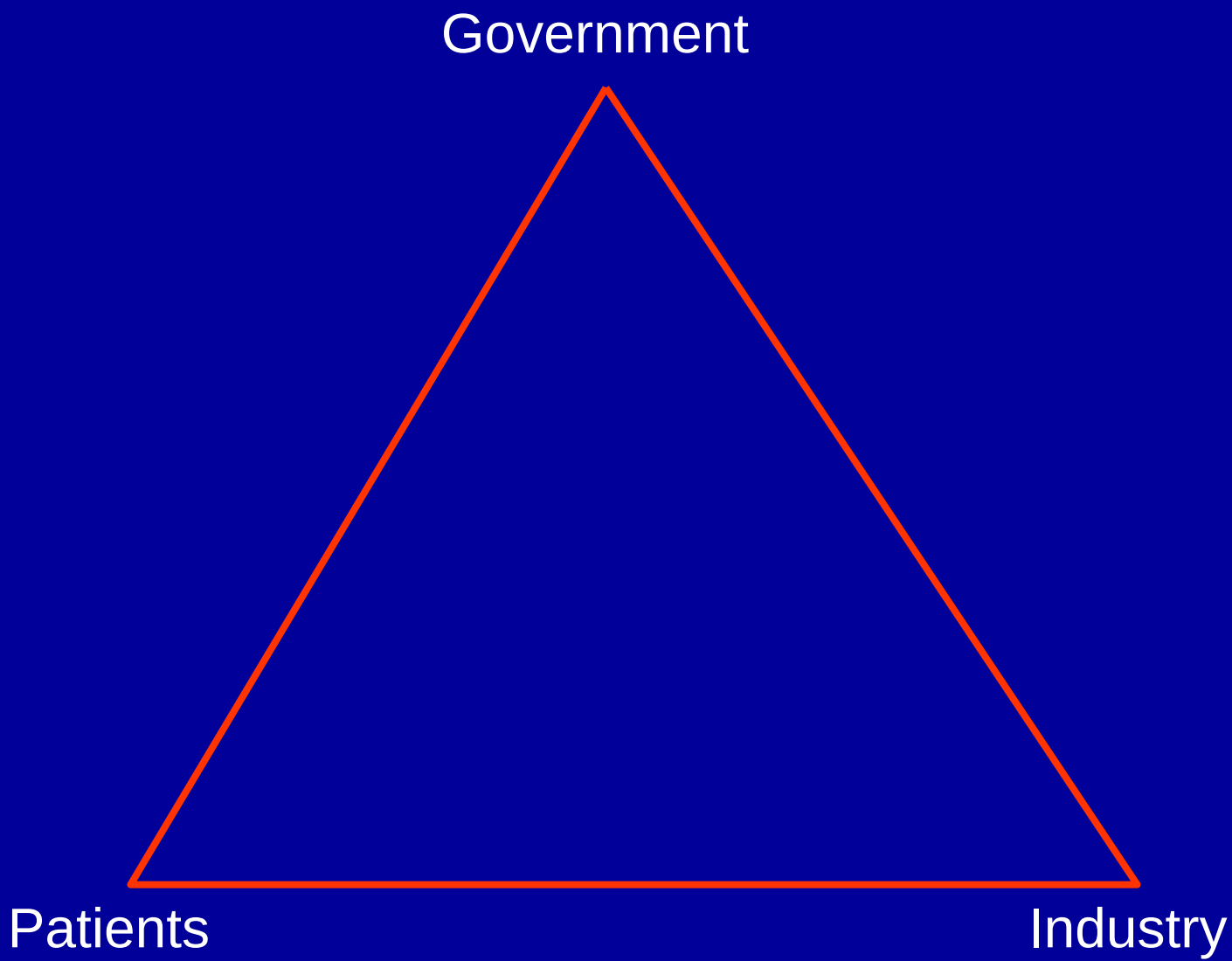
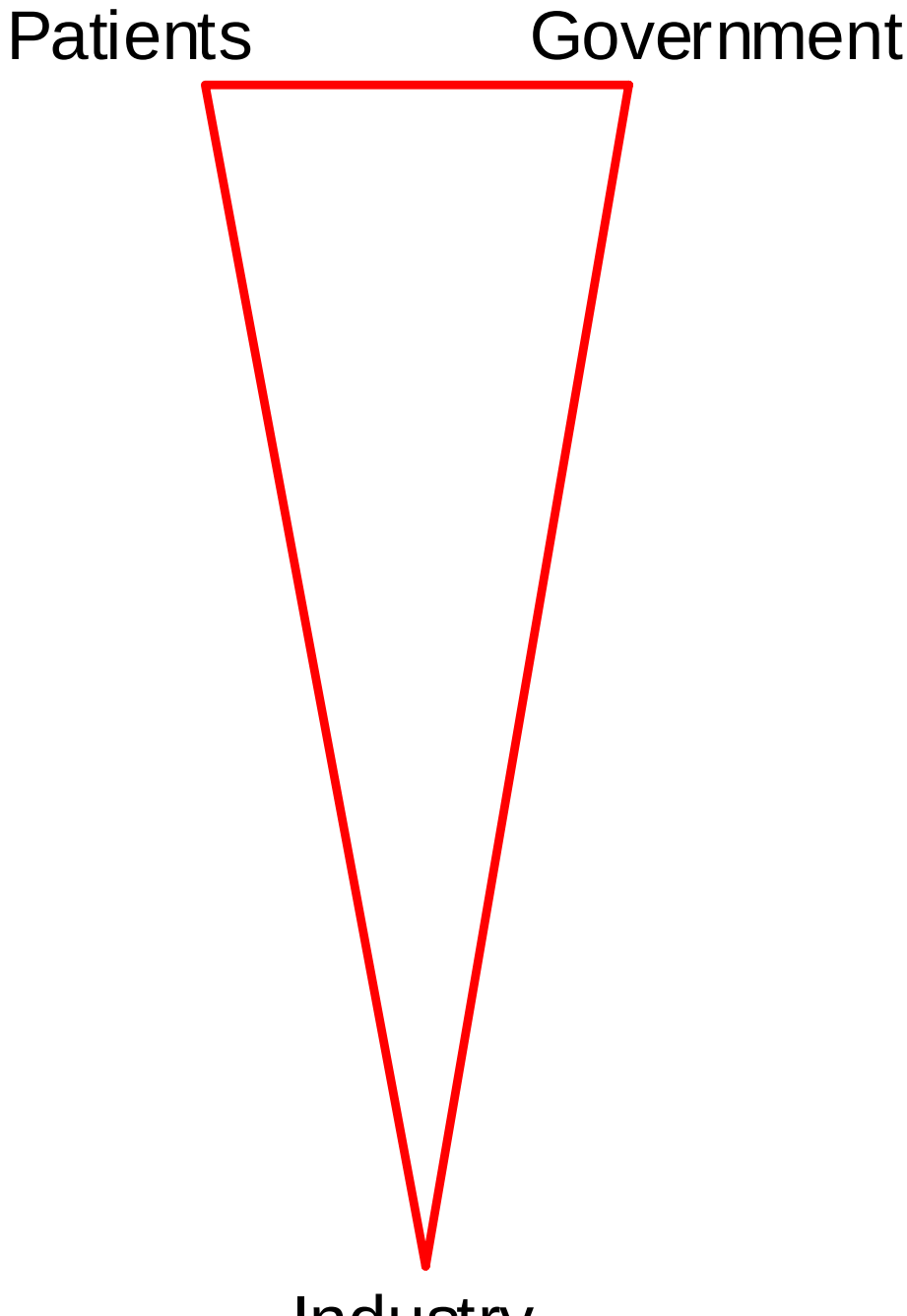
Risk Triangle: The Balance of Power




Patients
Government
Industry

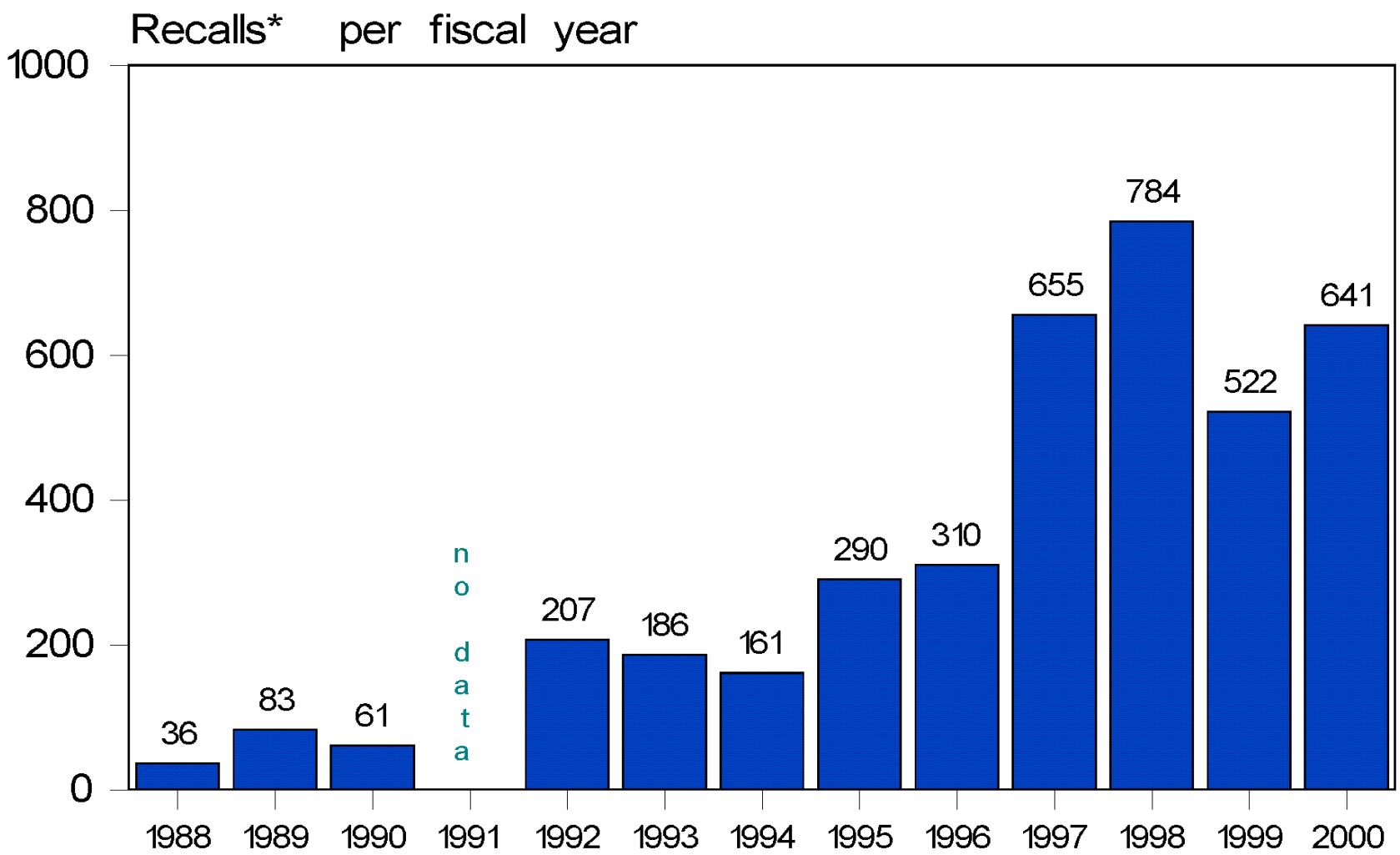
FDA Inspection of ARC Headquarters, Completed in April, 2000

- "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;"

April-December 2002 FDA Inspection of ARC Headquarters

- failed to do an adequate investigation following the death, from hepatitis B, of a patient who had received two units of red blood cells manufactured by the ARC
- 134 SPTHEP [suspected post transfusion hepatitis] cases across all 36 [Red Cross] regions for the period 1/1/00 through 6/30/00, were not investigated because the cases involve more than 10 donors
- the quality assurance officer in the NTL [national testing laboratory] stated there was a ‘culture to hide problems;’
- another employee “reported fearing retaliation if she was seen reporting a problem to the supervisor;”
- staff interviewed “verified they found documents which were changed and their initials had been forged in the changed documents

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.

Letter from Lee Bowers, Director, Baltimore District, FDA, to ARC CEO, Biomedical Services, Alan McCurry, September, 2003

"the consent decree requires that ARC investigate, correct, and prevent all problems; yet ARC's SOP clearly ignored that requirement, instead only requiring investigation of 'certain' problems." …….Because of this "egregious"… "failure to comply with the decree"… "FDA is assessing a $8500 per diem fine for the period June 6, 2003, through August 5, 2003.The total amount of the fine is $518,000."

$800,000 Jury Verdict for Admitted Negligence by Red Cross Involving a Blood Donor: October, 2003

- 32 year-old Virginia blood donor suffered an ulnar nerve injury and permanent pain because of negligence by a blood technician

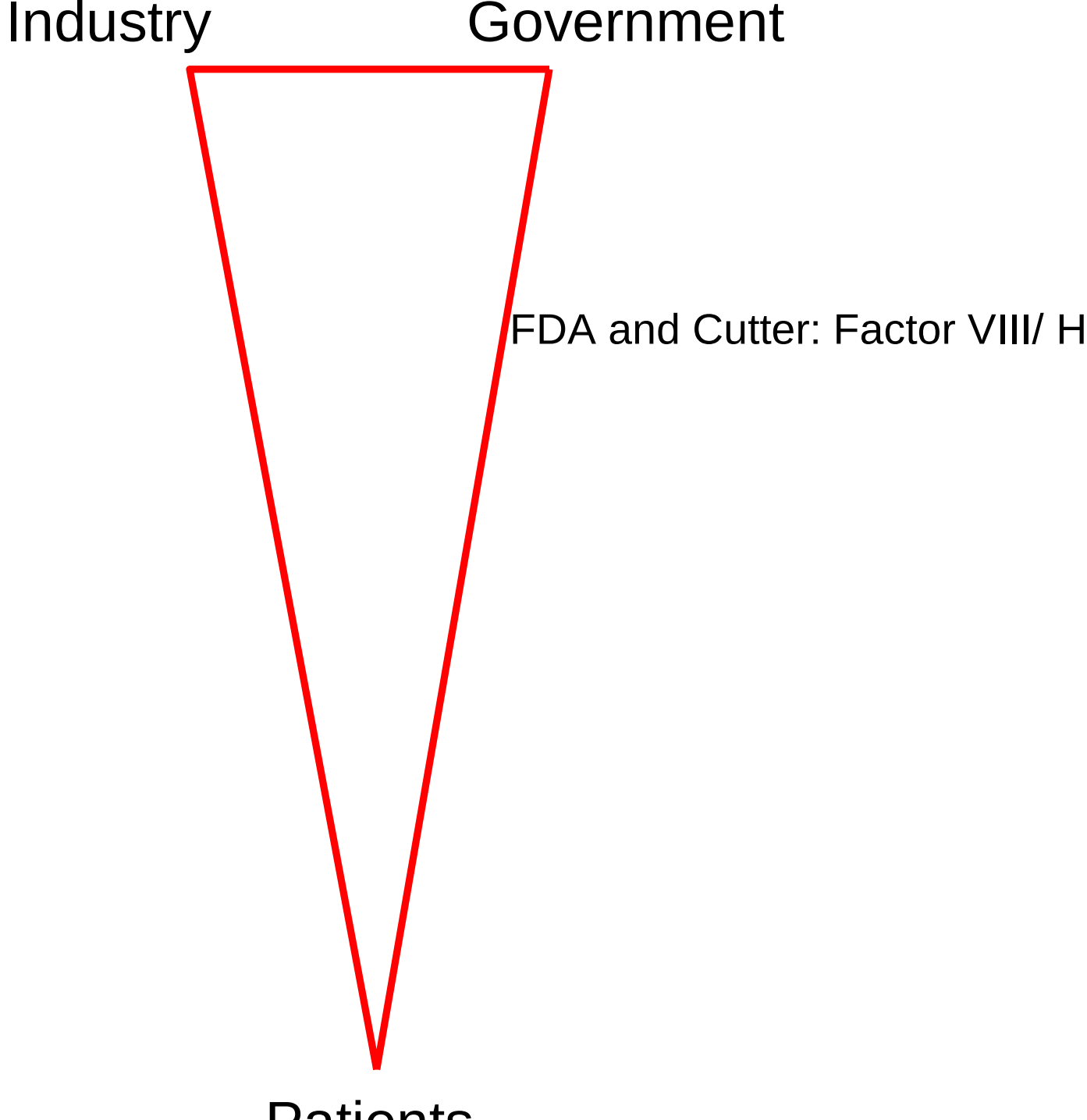
- Blood technician was recently hired and had been fired from a previous job that involved phlebotomy, because of inability to follow procedures

1999 FDA Consent Decree with Abbott

- Concerned 300 diagnostic products that Abbott manufactures - ranging from tests used to ensure the safety of donated blood to tests that detect heart attacks

- consent decree to settle the issue because Abbott did not correct the problems despite six years of government inspections and warnings

- $100 Million fine


Industry
Government
FDA and Cutter: Factor VIII/ H
Patients

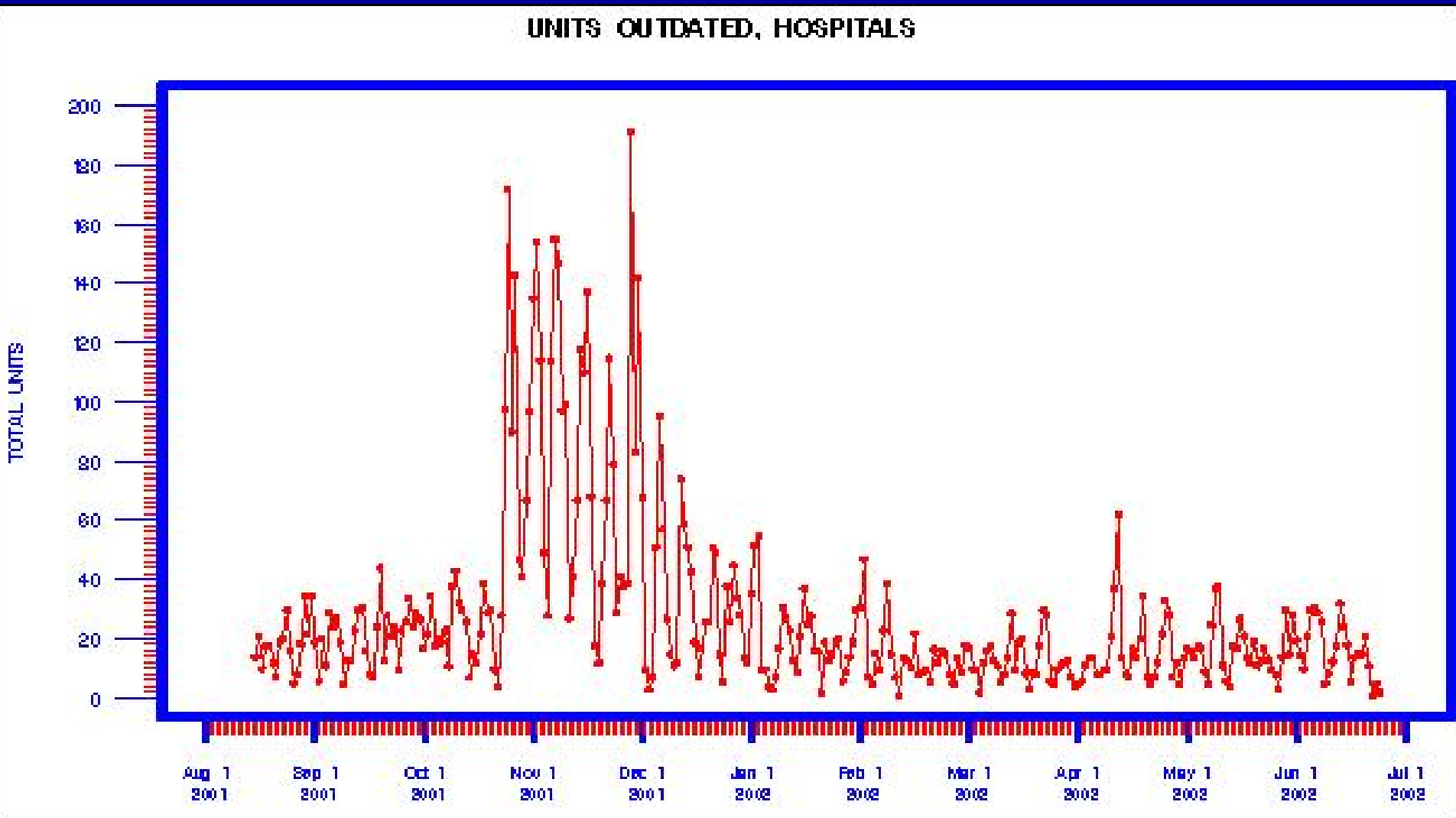
FDA and Cutter

statement attributed to former FDA official Dr. Harry Meyer, then Director of the Bureau of Biologics, 15 months after US approval of Cutter's safe heat-treated factor VIII: "although the FDA could revoke these [approval of non heat treated factor VIII] he [Meyer] did not want any attention paid to the fact that the FDA had allowed this situation to continue for so long,and would like the issue quietly solved without alerting the Congress, the medical community and the public"

Memo from FDA/Cutter meeting, May, 1985

Red Cross vs America's Blood Centers on 9/11/01

- The two blood suppliers took two radically different strategies to this phenomenon. Within one day of the attacks, ABC blood centers reported their coffers were full and urged volunteers to make an appointment for a later date.
- Red Cross centers refused to turn donors away, insisting whatever was not used would be frozen. Eventually, reports circulated that the Red Cross was forced to throw away some blood .


UNITS OUTDATED, HOSPITALS
TOTAL UNITS
200
180
160
140
120
100
80
60
40
20
0
Aug 1 2001
Sep 1 2001
Oct 1 2001
Nov 1 2001
Dec 1 2001
Jan 1 2002
Feb 1 2002
Mar 1 2002
Apr 1 2002
May 1 2002
Jun 1 2002
Jul 1 2002

Summary

- When anticipated and planned for, new donor deferral criteria can be accommodated by increased donor recruitment efforts
- After the increase in deferrals from a new measure, there is culling, and the deferral rate drops
- More regular volunteer blood donations continue to be needed to prevent seasonal shortages

Europe Bests U.S. in Blood Donations

"in Europe the number of volunteer whole blood donations per hundred thousand population is much higher than it is in the United States and that within the United States it's higher in rural areas than it is in urban."

Statement by Dr. Page, ARC, 6/27/02 at FDA TSE Advisory Committee

High Prevalence of Blood Donation Among Greek Citizens

- 809 residents 18-65 randomly selected from the Greater Athens area
- 40.8% of the study population had donated blood
- blood donation was correlated with gender, place of birth, occupation and knowledge about donation

Soc Sci Med. 1994 May; 38(10): 1461-7.

Modern Healthcare: Blood Rhetoric Exceeds Supply 7/8/02

- Bus crash east of Dallas, killing five and injuring 36 others.
- More than 100 people donated blood the next day and there was said to be a regional shortage necessitating the importation of 140 units of blood
- Dallas hospital spokeswoman states that although the crash was ``one of the worst accidents we have ever seen,'' it had a negligible effect on the hospital's blood supply.

Modern Healthcare: "Blood Rhetoric Exceeds Supply" 7/8/02

"Every summer as sure as there are mosquitoes at the New Jersey shore and long lines at Disneyland, blood banks throughout the country experience a severe, albeit predictable, downturn in inventories. The perfunctory pleas for more donors go out."

Modern Healthcare: “Blood Rhetoric Exceeds Supply” 7/8/02

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Recommendations

- The FDA must continue to lead the effort toward evidence-based trust in the collection, processing, storing and distribution of blood and blood components
- The need for government regulation over both the not-for-profit and for-profit sectors of this industry has never been greater
- I am unabashedly an optimist