

Transmissible Spongiform Encephalopathies Advisory Committee
January 17, 2002
Statement from the New York Blood Center

With the release of final guidance on blood donor deferrals as a precaution for transfusion transmission of variant Creutzfeldt Jacob disease, we again assess the blood supply horizon through the phases of implementation of this new FDA policy. At the October meeting in the immediate wake of the disasters in New York and Washington, blood donations were at all time highs nationally and the supply was far overrunning our ability to distribute for medical need. At that time it was hard to remember blood shortages or imagine that we would have difficulty managing large dents in the donor base from the vCJD deferrals. Today, just four months after the largest surge of blood donations in history, we look at a depressing picture of blood donor apathy and rapidly dwindling supply that could soon impact the ability of our hospitals to deliver medical care.

The current picture goes beyond the usual pattern of soft donations and shortages that follow the holiday season or that accompany severe winter weather and seasonal illness. The compounding factors today include: 1) the poor economy resulting from 9/11 and preexisting conditions leading to corporate layoffs and low community morale; 2) a poorly defined general community malaise that is reflected in low charitable contributions as well as low blood donation rates; and 3) frustration with blood care organizations due to recent negative publicity as well as the attention on blood wastage after 9/11. There are regional variations in severity with the greatest intensity in New York and the Washington area but informal surveys on my part indicate a national phenomenon of disturbing instability in the national rates of blood donation and supply. For us, we now see donation rates dropping well below levels experienced before 9/11 and our December whole blood collections were below our previous year. See accompanying figure.

Prior to 9/11, we were very confident that with the agreements for US supply from ABC, BCA and ARC plus our own collections growth, we would have no supply problems for the New York area resulting from implementing the guidance released in draft last fall. As we project the new reality into our planning, we are now much less confident. Our latest understanding from our Euroblood partners is that the Swiss and Germans will cease their shipments at the end of March because of liability concerns and their inability to implement the questions around residence in France. What is most disturbing is the current instability and unpredictability of blood donations. We simply don't know whether our donation rates will return to previous levels and whether our existing agreements with other US providers will be fulfilled to fill this void. We are certainly doing everything we can to revive blood donations in our area. We assume all others are working similarly. However, we believe it is important for these committees to understand that there is some real danger that this situation could extend into the period of phase one implementation and that severe blood shortages could result, both nationally as well as in New York City.

Given this we urge the committee to consider the following:

- 1) Advise FDA that current uncertainty around blood donations nationally warrants delaying phase one implementation until at least the date for phase two. This would allow for a better understanding of how blood donation rates will stabilize.
- 2) Prospectively set specific triggers for modifying the guidance to in order to adapt meaningfully evolving events such as: 1) low blood supply related to the deferrals; 2) implementation of food controls assuring that the infectious agent is not entering the food chain; and 3) vCJD attack and prevalence rates that indicate that the precautions of blood donor deferrals that exclude so many willing donors world wide are no longer necessary.

We continue to fully support and participate in the agenda to make America's blood supply as safe as possible. We also believe that continuous assessment of the tradeoffs involved in this agenda is necessary to avoid causing patient harm in the name of blood safety.