LANE MEMORIAL
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May 1, 2003

Jay E. Epstein, MD, Director
Office of Blood Research and Review
Center for Biologics Evaluation and Review
Food and Drug Administration, Mail Stop HFM-300
1401 Rockville Pike
Rockville MD 20852

Re: Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS

Dear Dr. Epstein:

We are writing to express our concerns about the SARS Guidance issued by the FDA on April 17, 2003, and its anticipated effect on nation's blood banks as we strive to maintain a safe and adequate blood supply.

Implementation of new guidelines requires extensive resources and adequate time to conduct research, produce materials and forms, revise SOPs, change software, train staff and validate processes. To put the changes recommended by the agency into operation in just 30 days is not feasible if our blood center is to adhere to current Good Manufacturing Practices, to which we are certainly committed. The abbreviated implementation timeline is insufficient and at this time seemingly unjustified by demonstrated risk of SARS to blood safety.

In light of the absence of more complete scientific understanding of the epidemiology of SARS and the current incidence rate of 1 per 8,000,000, the first and second questions recommended in the guidance (Have you had history of, treatment for, or suspected SARS? Have you had contact with someone who has had SARS?) seem non-productive. We believe it would be a waste of staff and donor resources to question all donors in this manner, especially those with no history of travel to the affected areas. Alternatively, donors who disclose travel to CDC-listed destinations could be deferred for the recommended 14 days from the date of their return, thereby capturing the at-risk donor population using screening questions that are already in place.

This Final Guidance was issued without input from the public, blood collection establishments, and industry trade organizations or, most importantly in this case, the Uniform Donor History Questionnaire task force. The FDA indicates that the Impact of Guidance on Blood Availability (section II D.) will be "no more than 0.4%". According to America's Blood Centers' estimates this could be equal to the number of current deferrals for travel to malarial areas--a loss of 56,000 units per year. This shortfall cannot be considered insignificant.

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While the FDA reacts to public perceptions and political pressures, the blood banking industry it regulates is left with the challenge of implementing required regulations while maintaining an adequate blood supply. Clearly the FDA should monitor the SARS threat and develop scientifically relevant recommendations commensurate with the evolving medical knowledge of this disease. Additionally, US Public Health authorities should act to advise travelers returning from affected areas not to donate blood for at least 14 days. In the meantime, the current SARS Guidance should be rescinded and blood collection facilities should be permitted to implement a 14-day deferral for donors who have traveled to affected areas.

In conclusion, we ask that the FDA consider the public health impact of the worsening blood shortages in this country as assiduously as it does the threat of transfusion transmissible disease. Thank you for your time and consideration of our comments.

Sincerely,

SARAH B. DAVIS
Administrative/Regulatory Coordinator

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Quality Assurance Coordinator

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