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January 15, 2001

Paul Brown, MD  
Chairperson,  
Transmissible Spongiform Encephalopathies Advisory Committee  
FDA/CBER

Dear Dr. Brown:

I write to you on behalf of the Council of Hospital Blood Bank Directors of the Greater New York Region. We are concerned that the Transmissible Spongiform Encephalopathies Advisory Committee, in its deliberations about the risks to patients posed by the TSE's, understands the risk to patients posed by policy recommendations which could markedly and abruptly diminish the blood supply to our region. Our region could be much more adversely affected than other regions in the country.

We share with you the concerns of potential transmission of this fatal disorder by blood transfusion and agree that emerging information must be carefully monitored on an ongoing basis. However, the risk to the nation's blood supply in terms of loss of donors must be equally regarded in order to maintain sufficiently safe levels of inventory. Particularly, we feel compelled to respectfully point out certain germane facts unique to the NY Metropolitan area blood supply. Specifically, 25% of the NY Metropolitan area blood supply is provided by continental European blood centers on a daily basis through the New York Blood Center's "Euroblood" program. Abrupt discontinuation of this supply due to donor deferral policy changes would have an obvious substantial adverse impact and threaten our ability to support a full range of medical care in our region from life threatening emergencies to comprehensive care for acute and chronic medical and surgical illnesses.

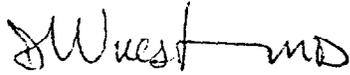
Currently, there is no other local or national source to replace this lost blood supply in the short term. Attempts to import blood from other regions of the country may not be possible due to the continuing national shortages we have been experiencing without compromising care in other geographic regions. A long term solution is to increase domestic collections. We propose that in the short term, a similar need exists.

Perhaps your Committee could find a way to recognize this potential calamity and suggest, for example, that there be a nationally funded initiative for an urgent campaign to increase the number of blood donors such as never has been seen in our country before.

We ask that during your deliberations you consider this clear and significant negative impact as a self-evident and major population risk with both local and national implications. As you evaluate the available information and decide whether or not to formulate recommendations that will necessarily result in such a major adverse effect on the national blood supply, please consider possible long and short term answers and solutions to be implemented to avoid these risks.

Thank you for your leadership and help in this matter of public safety.

Sincerely,

A handwritten signature in black ink that reads "D. Wuest MD". The signature is written in a cursive style with a horizontal line extending from the end.

David L. Wuest, MD