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Statement before the Transmissible Spongiform Encephalopathies Advisory Committee
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I appreciate the opportunity to speak to this committee on behalf of the New York Blood Center. The New York blood Center is the largest independent blood center in the country. We collect over 450,000 units of whole blood and over 50, 000 apheresis platelet products annually, which is about 5% of the blood collected in the country.

For over 30 years the New York Blood Center imported blood from three European countries...Switzerland, Germany and The Netherlands, under the "Euroblood" program. This blood was collected entirely from volunteer donors under New York Blood Center's FDA license. During the period from 1980 until termination of the program in 2002 the New York Blood Center imported **4,469,950** units of red cells from these European blood centers (data from 1980-1984 are estimated).

In 2001 this committee recommended the extension of the prohibition of blood donation in the United States from those who had resided in the United Kingdom to other European countries. This resulted in the termination of the Euroblood program in New York. We are encouraged that, since 2001, the number of vCJD cases has remained small and the incidence of both BSE and vCJD has declined. There has not been a single case of vCJD identified within the three countries that participated in the Euroblood program...Germany, Switzerland and The Netherlands.

The consequences of the extension of these donation restrictions beyond the United Kingdom are as follows:

- Over 300 million Europeans and tens of thousands of Americans who have lived or traveled in Europe during the prescribed periods are now prohibited from blood donation in the United States. The Euroblood program was terminated, resulting in a major challenge to the New York blood supply.

- The viral disease marker rate (HIV, HCV and HBsAg) in 1999 for imported units from Switzerland was 0.15%, below similar marker rates for blood collected in the United States. It is not clear that replacing blood drawn from altruistic volunteer donors in Europe for blood drawn in the United States has added to blood safety.

- The percentage of group O positive and group O negative blood imported from Europe varied between 52 and 53%. The percentage of group O blood collected in New York was 46-47% at that time. With major recruiting efforts we have increased that percentage to closer to 50%. Approximately 51-52% of the blood we distribute is group O. We now have an imbalance between the blood groups collected and the blood groups transfused in New York, resulting in chronic shortages of group O red cells.

- The cost of collecting blood in New York is much higher that the blood collected and imported from Europe. These costs are passed on to our hospitals and, ultimately, to third party payers.

- Differences in applying vCJD deferrals among the major blood collection agencies have led to unusual differences in donation eligibility. For example, I lived in Geneva for one year in 1990-91 while on detail from NIH to the World Health Organization. I can donate in New York but not in Washington. I can donate in Seattle but not in Los Angeles. I can donate in Houston but not in Atlanta.

I raise these points as an illustration that extensions of the "precautionary principal," while made in good faith, may have far-reaching and unintended consequences.

Prohibiting blood donations from those who have received blood transfusions in Europe will, by extension, implicate recipients of European blood in the United States. If we assume a transfusion episode of four units, over 1,000,000 people were transfused with blood from European sources in the United States between 1980 and 2001, almost all in the New York metropolitan area. Most of these recipients are deceased. Living recipients are aware that they received life-sustaining transfusions. They do not know, as any blood recipient does not know, whether the donation came from an altruistic volunteer donor in Manhattan, New Jersey, Amsterdam or Geneva.

Identification and notification of the millions of units from European donors and subsequent requirement for hospitals to trace and notify these recipients is an exercise of mind-boggling complexity, scope and expense. This is in addition to the chilling message to these recipients that, while there is no established body of data to determine risk, they may be harboring a fatal neurological disease for which there is no cure. In addition, they are no longer eligible to be a blood

donor. Counseling these individuals would again fall to the hospitals, which are ill equipped to perform this task.

The "bright line" around the United Kingdom, where this unfortunate experiment of prion disease and transmission is unfolding, remains a reasonable basis for the application of the precautionary principal. Extension of these restrictions to donors and recipients from other countries opens a "slippery slope" of extensions to increasing numbers of countries, donors and recipients We must be mindful of evolving data, as well as the consequences of actions based on limited or absent data.

Blood safety remains a compelling priority for us all. We must consider, however, that not having enough blood, or burdening health organizations with unmanageable issues of notification and deferral, also has major and compelling implications for the safety of the American blood supply.

Thank you for the opportunity to speak before the committee.