PPTA

Plasma Protein Therapeutics Association

2624 '01 NOV -5 P3:40

2629 '01 NOV -5 P3:40

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Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket Number 97D-0318
Comments on Draft Guidance entitled, "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Varian Creutzfeldt-Jakob Disease by Blood and Blood Products"

Dear Sir or Madam:

Thank you for the opportunity to comment on the published "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products" (hereinafter, the "CJD Guidance"). The Plasma Protein Therapeutics Association (PPTA) is the trade association and standards setting organization for the manufacturers of plasma protein therapeutics. PPTA member companies include eleven leading manufacturers of plasma protein therapeutics around the world. Collectively, the PPTA member companies represent over sixty percent of the critical, life-saving plasma protein therapeutics produced and administered to patients worldwide.

Data and information presented by PPTA member companies at meetings with European and US regulators support the conclusion that the manufacturing processes for plasma derivatives have the capacity to partition prion proteins. As such, PPTA member companies welcome the approach the Agency has taken in the CJD Guidance with respect to donor deferral and product recall and retrieval requirements.

In the past months, there have been a growing number of international developments with respect to the spread of bovine spongiform encephalopathy (BSE). Responses to these developments reflect increasing concerns throughout the world about the safety of European blood and plasma. Notwithstanding these events, currently there is no evidence that the blood of persons with pre-clinical or clinical vCJD carry infectious

97D-0318 C33

prions, the causative agents of the prion diseases that include BSE and vCJD. Neither is there evidence that vCJD has been contracted from blood or plasma products.

Furthermore, no verifiable evidence exists to demonstrate the transmission of BSE via transfusion in animal models. The experimental transmission of BSE by transfusion in a single sheep (Houston et al.) has neither been confirmed nor repeated. In fact, the European Commission Scientific Steering Committee considers the data as tentative evidence because the study is not complete. Indeed, to date, no other animals included in that study have become sick with BSE.

Moreover, it should be emphasized that whole blood, red blood cells, and platelets from UK donors are still used in transfusions in the UK (an estimated 30 to 40 million transfusions in the UK over the past ten years). Although several UK vCJD patients were blood donors none of the reported vCJD cases has been attributed to blood or plasma transfusion. Further, no single case of vCJD among the recipients of their blood has been reported nor has vCJD been reported in any recipient of plasma products. Consequently, the risk of vCJD infectivity in blood and/or plasma is considered purely theoretical by leading scientists worldwide.

It is also worth noting that many laboratories throughout the world are intensively working to develop highly sensitive assays to detect variant Creutzfeldt-Jakob disease in human tissue (Bruce et al., Wadsworth et al.). It can be expected that these tests will be commercially available in the near future and may add further assurance of the safety of blood and plasma.

In conclusion, we believe that the risk of vCJD infection through blood or plasma products remains purely theoretical. Therefore, the pragmatic measures related to the perceived risk should continue to be carefully balanced against the need to deliver blood, plasma and their derivatives to those whose lives depend on them.

Please feel free to contact us at the number below regarding these comments or for any further discussion of these important issues.

Yours sincerely,

/S/

Dr. Ilka von Hoegen
Director, Regulatory Affairs

References:

Houston F, JD Foster, A Chang, N Hunter, & CJ Bostock. 2000. Transmission of BSE by blood transfusion in sheep. Research letter. The Lancet 356:999-1000

Bruce ME, I McConnell, RG Will, & JW Ironside. 2001. Detection of variant Creutzfeldt-Jakob disease infectivity in extraneural tissues. The Lancet 358:208-209

Wadsworth JDF, S. Joiner, AF Hill, TA Campbell, M Desbruslais, PJ Luthert, & J Collinge. 2001. Tissue distribution of protease resistant prion protein in variant Creutzfeldt-Jakob disease using a highly sensitive immunoblotting assay. The Lancet 358:171-180