CJD INCIDENTS PANEL

7th September 2004

To Whom It May Concern:

Assessment of exposure to particular batches of variant Creutzfeldt-Jakob disease (vCJD) implicated plasma products

Recommendations of the CJD Incidents Panel

This letter sets out the recommendations of the CJD Incidents Panel (CJDIP)[1] for the tracing and assessment of patients exposed to plasma products manufactured in the UK using donations from individuals who subsequently developed vCJD.

The recommendations are based on a blood and blood products CJD Risk Assessment carried out by Det Norske Veritas Consulting [http://www.dnv.com/consulting/news_consulting/RiskofInfectionfromvariantCJDinBlood.asp] and accepted by the Spongiform Encephalopathy Advisory Committee (SEAC), the Committee on the Microbiological Safety of Blood and Tissue, and by the Committee on Safety of Medicines. Batch specific manufacturing data from the fractionators concerned has been used with the Risk Assessment to estimate the potential vCJD infectivity in each batch of implicated product. For each of the major assumptions underlying the Risk Assessment, the most precautionary option was chosen.

The CJDIP has defined an 'at-risk' threshold for public health purposes as the possibility of being exposed to a 1% or greater potential risk of infection, on top of the general risk to the UK population that is thought to have resulted from dietary exposure to the BSE agent. On this basis, three levels of likelihood of surpassing the threshold have been categorised as follows:

- **High:** the amount of potential vCJD infectivity is high enough for the threshold to be surpassed following the administration of a very small dose (e.g. one treatment with factor VIII, factor IX or antithrombin where one vial of product used has been implicated).

- **Medium:** the amount of potential vCJD infectivity is not low enough to be ignored but substantial quantities of the material in question would need to be administered before the threshold is surpassed (e.g. several infusions of intravenous immunoglobulin G, or large doses of albumin 4.5%).

- **Low:** the amount of potential vCJD infectivity is so low that the likelihood of surpassing the threshold can realistically be ignored (e.g. albumin 20%, factor VIII products where the albumin excipient used in

the manufacturing process, and not the plasma concentrate, has been implicated, intramuscular human normal immunoglobulin used for example for travel prophylaxis against hepatitis A, anti-D.)

The threshold is a guide for implementing special public health precautions to limit any possible human-to-human transmission of vCJD.

The uncertainties underlying the assessment of 'risk' are great, and several precautionary assumptions are involved. Therefore, the 'at-risk' threshold for public health purposes is not a precise guide for advising individuals about their potential additional risk of developing vCJD.

All batches of plasma products implicated to date have now been reviewed. This includes batches that were the subject of previous notifications. All the implicated products have passed their expiry date.

The CJDIP recommends the following action in relation to each implicated batch of plasma product, according to the likelihood that recipients will have surpassed the 'at-risk' threshold for public health purposes:

High: These batches should be traced and the individual recipients considered 'at-risk' of vCJD for public health purposes. The extent of individual exposure to these batches should be documented.

Medium: Efforts should be made to trace these batches and to assess the potential additional risk to individual recipients to determine if special precautions should be taken for public health purposes. The extent of individual exposure to these batches should be documented.

Low: These batches do **NOT** need to be traced and the individual recipients do not need to be informed. **The potential additional risk to recipients from particular implicated batches of albumin 20%, intramuscular human normal immunoglobulin, anti-D, and from factor VIII products manufactured using implicated albumin as an excipient, is considered negligible.**

For each of these categories a list of all batches of plasma products that have been implicated to the present time accompany this recommendation.

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Professor Don Jeffries
Acting Chairman
CJD Incidents Panel

[1] The CJD Incidents Panel [http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm.] is an expert committee established on behalf of the UK Chief Medical Officers in 2000. Its terms of reference include:

'To assist all those bodies responsible for the provision and delivery of healthcare to decide on the most appropriate action to take to handle incidents involving potential transmission of Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD) between patients through clinical interventions, including via surgical instruments, tissues, organs and blood and to keep the relevant devolved administrations informed.

To consider what information should be collected on patients who may have been exposed; advise on what studies or follow-up may be needed; advise Directors of Public Health on patient tracing and notification exercises where these are indicated; and advise on whether any other measures are needed to protect the wider public health.'