Date: September 20th, 2004. Embargoed until 2pm, September 21st.

Press Conference at Chief O' Neill's Hotel, Smithfield, Dublin 7

Date Tuesday, September 21st, at 2pm.

From: National Haemophilia Council

Subject: Possible risk of variant Creutzfeldt Jacob Syndrome (vCJD) from Plasma derived products used for treatment of Haemophilia

Two cases of vCJD were previously reported (December 2003 and July 2004) in the UK linked to blood transfusion.

To date there have been 147 cases of vCJD in the United Kingdom. These cases have been linked to the consumption of BSE infected beef from cattle ("mad cow disease"). It is now known that fifteen of those who have died of variant CJD were blood donors and their donations were linked to the two cases of vCJD which are thought to have been transmitted by blood transfusion.

In addition nine of these donors are known to have donated plasma on a number of occasions and this plasma was used in the United Kingdom to make various plasma components including Factor VIII and Factor IX concentrates. These concentrates were produced by the Blood Product Laboratory (BPL) in England and the Protein Fractionation Centre (PFC) in Scotland.

Health authorities in the UK have notified Haemophilia doctors that a significant amount of plasma derived products were manufactured from the plasma of these donors who subsequently developed vCJD. These batches include 16 batches of Factor VIII (used to treat Haemophilia A) and 9 batches of Factor IX (used to treat Haemophilia B) and a further 77 batches of Factor VIII where the risk is considered to be lower.

None of these batches have been imported into or used in Ireland. Furthermore, very few products produced from UK plasma for the treatment of Haemophilia and related bleeding disorders were used in Ireland between 1980 and 2001. If there are any further implicated batches in the UK in the future, their use in Ireland will be immediately checked and appropriate measures taken if any were imported here.

Because of the strong possibility that further batches may be implicated in the future the UK authorities are now designating any person with haemophilia who received any plasma derived concentrate manufacture from UK plasma between 1980 and 2001 (manufactured up the end of 1998) as at risk of vCJD for public health purposes. This means that additional precautions will be recommended in the UK for those persons with haemophilia to prevent possible transmission to other patients.

It is important to reiterate the following points.

- 1. None of the currently indicated batches of Factor VIII or Factor IX has been used in Ireland.
- 2. There has been no case of vCJD in a person with haemophilia anywhere in the world
- 3. Factor concentrates used for Haemophilia A and B in Ireland have been recombinant factor concentrates since 1997.

There may be some persons with haemophilia residing in Ireland who have received treatment in the United Kingdom between 1980 and 2001. This treatment may have been with United Kingdom sourced plasma derived concentrates.

For any person with Haemophilia who has received treatment in the UK with plasma derived concentrates from implicated or non-implicated batches, the standard recommendations from the National Disease Surveillance Centre (NDSC) will be implemented. These are limited to specific types of surgery including surgery on brain, eye or lymphoid tissue.

All people with Haemophilia in Ireland are being notified of this situation by the National Haemophilia Council (NHC), acting with the full participation of the National Centre for Hereditary Coagulation Disorders (NCHCD) and the Irish Haemophilia Society.

The NHC is the statutory body set up, following the Lindsay Tribunal of Inquiry, to advise the Minister of Health and Children and make recommendations on all aspects of treatment and care for persons with Haemophilia. The NHC includes representatives from the NCHCD, the Irish Haemophilia Society and the Department of Health and Children.

"It is important to note that no implicated batches were imported into Ireland. However, the National Centre has made arrangements to quickly see any person with Haemophilia who has used product in the UK or who has concerns in relation to this development." Stated Dr. Barry White, Medical Director of the NCHCD.

Information meetings for people with Haemophilia and their families have also been arranged in Cork on September 24th and in Dublin on September 25th.

"This is a further issue of concern for a community which in the past has been devastated by HIV and Hepatitis C. Fortunately, these specific products were not used in Ireland and we hope that the timely information and support available from the National Centre and the Irish Haemophilia Society will greatly assist any person with Haemophilia who received treatment in the UK" stated Brian O Mahony of the National Haemophilia Council.

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