IMMUNE DEFICIENCY FOUNDATION

The National Organization Dedicated to Research, Education and Advocacy for the Primary Immune Deficiency Diseases.

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IDF Medical Advisory Committee Working Group Statement on variant Creutzfeldt-Jakob Disease (vCJD)

United Kingdom (UK) Department of Health authorities have released information about potential vCJD exposure with the use of plasma derivatives such as IGIV. The authorities have determined that prior to 1999, recovered plasma donations from British individuals who later developed vCJD were used for the manufacture of immune globulin for the treatment of primary immune deficiency and clotting factors for hemophilia. Since 1999, only plasma from United States donors has been used for the manufacture of plasma derivatives in the UK.

Using statistical models and the most conservative risk assessment exercise possible, the Health authorities have concluded that up to 6000 people with hemophilia, 50 people with primary immune deficiency, and some others with secondary immune abnormalities should be advised that they could be at a small increased risk of carrying the vCJD agent.

By warning these individuals, the UK Health authorities hope to reduce the risk of possible further transmission of the agent of vCJD patient to patient by blood or organ donation or through use of resterilizable surgical instruments.

In the United States there are several safeguards in place to reduce the risk to those who receive Immune Globulin manufactured from US plasma as a life saving medicine.

1. Individuals who resided in the United Kingdom for three or more months from 1980 through 1996 are not allowed to donate blood or plasma in the US. 1996 was the date of implementation of the food chain controls to remove potentially infected beef from distribution and consumption.
2. Individuals who received transfusions in the United Kingdom after 1980 are permanently barred from blood or plasma donation in the US.
3. Immune Globulin licensed and distributed in the United States is manufactured only from qualified US donors.

4. There are steps in the manufacturing process of Immune Globulin that could reduce a potential load of vCJD agents.
5. There is only a single reported human case of vCJD in the US that occurred in a previously long term UK resident. The infection was acquired through consumption of British beef.

The vCJD Working Group of the IDF Medical Advisory Committee has reviewed this information with representatives of CBER/FDA and the IGIV manufacturers and has suggested these additional recommendations.

1. There should be a minimum documented level of prion protein removal from all IGIV manufacturing processes.
2. Manufacturers should investigate additional methods to reduce potentially contaminating prion proteins.

Please share this information with your health care provider and seek their evaluation and opinions regarding your therapeutic regimen.