



Committee of Ten Thousand

Advocates for Persons with HCV-HIV/AIDS

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Remarks before the
Transmissible Spongiform Encephalopathy Advisory Committee
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Today's discussion of prion reduction through fractionation brings little comfort to persons with hemophilia in the United Kingdom. Different interpretations of the findings of science show the US and the UK to be going down very different roads on this subject.

As long ago as 1999, when the FDA first announced that screening for classical CJD was no longer needed, the agency began distinctly identifying the greater perceived safety of plasma products:

"... experimental studies in animal models for CJD suggested that manufacturing procedures used for plasma derivatives could lower the amount of infectious material present in plasma derivatives compared with whatever levels may be present in blood."

In 2002, FDA moved further down this road:

"... we recommend that you defer donors of Whole Blood and blood components intended for transfusion, Source Leukocytes, and recovered plasma, but not donors of Source Plasma, who have resided in Europe for a cumulative period of 5 years or more, between 1980 and the present."

This exemption of plasma occurred when the whole blood geographic donor ban was first being expanded beyond the UK. Since that time there has been no retraction from this position by the agency. Thousands of units have been collected throughout Europe, pooled and fractionated to make Factor VIII, IVIG, albumin, and other products, which of course by now have all been consumed, largely by Americans.

It was in 2003 and 2004 that true cases of vCJD transmission by blood were reported in the literature. From that point on, all of the language of prior government and industry regarding "theoretical" risk of transmission became obsolete. It died hard: at least one industry representative gave a report indicating that since a given risk of exposure had happened in November 2003, prior to the *publication* date of the first of these cases (December 2003, though infection was surmised to have occurred years earlier), the risk of transmission therein was still only theoretical.

The UK, following a different timeline regarding discovery of the dangers of vCJD in blood, learned of the contamination of plasma pools years earlier, and declared the recipients of products from those pools to be at great risk. The now-famous 2004 letter from the Ministry of Health to 4,000 homes of persons with hemophilia instructed them not to donate blood, organs or tissue, and to inform medical, surgical and dental providers so that disposable instruments can be arranged for in advance of any procedures.

Two years have passed since this risk communication exercise in the UK; the stigma it brought to every family with hemophilia is somewhat dulled now, although it was unprecedented and disruptive for weeks at the time.

So which is it? Are we at great risk or is there no risk, or rather "undetected" risk, which is NOT the same thing? CBER Advisory Committees are often asked to decide on issues for which there is inadequate data to make sound judgment. COTT has watched this country's response to TSEs unfold, from the USDA's denial that there is any problem to the un-tracked venison eaters in areas of US CWD outbreaks. We ask that you do not give ground. Do not expand the exemption from geographic donor bans which plasma collection now enjoys. We further ask that you retract altogether this dangerous exemption of source plasma from geographic donor bans. Thank you.