



# **Committee of Ten Thousand**

*Advocates for Persons with HCV/HIV/AIDS*

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## **Committee of Ten Thousand Statement FDA Workshop on Behavior-Based Blood Deferral**

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The Committee of Ten Thousand represents persons in the hemophilia community and beyond who were infected with the human immunodeficiency virus, the hepatitis C virus, or both, through the clinically proper use of their prescribed medication, FDA-licensed Anti-Hemophilic Factor (AHF). Historically, factor has been a blood-based product, manufactured from pools of plasma from 50,000 to 250,000 blood or plasma donors. Synthetically-produced 'recombinant' factor, which is not built from whole blood nor plasma, has become widely used in the past decade due to its safety from contamination. Until only two years ago, however, recombinant factor used some blood product in manufacture, even if only as an excipient.

The contamination of our community with two largely fatal diseases in addition to our original life-threatening condition occurred at a time when the country was just learning that HIV had entered the blood supply. The populations thought to be most infected and most susceptible had been addressed, albeit incompletely, with education and, in the case of immigration, interdiction. However the blood supply constituted a huge river of contamination to take the infection well beyond just these first-labeled risk populations.

While the supply is far safer now, thanks to manufacturing changes, donor deferrals, and testing improvements, our community remains somewhat shell-shocked – Post-Traumatic Stress Disorder has in fact been diagnosed in many – and rigorously watchful for subsequent, 'emerging' threats to the blood supply, upon which we so heavily depend. For example, we continue to be alarmed at the threat to the blood supply from blood donors who have unknowingly consumed beef from Bovine Spongiform Encephalopathy (BSE, or Mad Cow Disease) infected cattle. In the UK and here, authorities are quick to contact recipients of blood or plasma or blood products which include donations from persons who subsequently contract this disease – when they finally do, after years of incubation, meaning years that the recipient has been at risk ... and possibly also incubating. Other recent headlines have also underscored the need for vigilance: SARS, West Nile, Parvovirus, Avian Flu, and others. Hence it is understandable that a community like ours has as its number one priority guarding the safety of the blood supply from potentially infectious agents.

We have followed the FDA's presentations before its Advisory Committees from time to time regarding continuation of permanent MSM deferrals, and understand the logic used: adding this group, even if still rigorously screened, to the donor pool would increase the size of that pool only marginally, but can be expected to generate more positive test results, give the prevalence of the infection in the population in question. This in turn can lead to an increase in the *error rate* in inventory controls, such as retention for the supply of units that test positive. After all, Consent Decrees are still in place.

At the individual level, assurances of past safe behavior, although in concept not different from the many attestations of safety requested in the standard Donor Questionnaire, are accepted at face value only at the blood supply's risk. Accordingly, we concur with the continuation of current policy, despite NAT improvements.