

## FDA Blood Products Advisory Committee Meeting Testimony of K. Kimberly McCleary December 14, 2010

My name is Kim McCleary and I am president and CEO of the CFIDS Association of America. The CFIDS Association of America is the largest and most active organization working to make CFS widely understood, diagnosable, curable and preventable. For 23 years the Association has supported research through more than \$5 million in direct grants, sponsored scientific symposia and research think-tanks, sought to effect more responsive public policy and has widely informed the patient community, the media, the medical community and researchers about the severity of CFS and the individual and collective toll it exacts. I appreciate the opportunity to address BPAC on the topic of blood safety.

Earlier this year (prior to implementation of the AABB guidelines for CFS), we used a web-based survey tool to administer a 50-item questionnaire about possible risk factors for CFS. Questions were designed to correlate with larger national surveys like NHANES. Four items related to blood donation and transfusion experience.

1. Have you ever received a blood transfusion?
2. Have you ever donated blood or blood products?
3. How many times have you donated blood or blood products in the past 10 years?
4. How many times have you donated blood or blood products since being diagnosed with CFS?

1,747 individuals responded to the survey. 90% of respondents had been diagnosed with CFS by a physician. 86% were women and the average age was 57 years.

Of the 1,529 people who answered the question about blood transfusion, 124 (8%) indicated they had a blood transfusion prior to becoming ill with CFS and 50 (3%) reported that they received a transfusion after being diagnosed with CFS. The figure for blood transfusion prior to CFS (8%) is not significantly different from the general population as a whole, especially when adjusted for age and sex. However, retrospective donor-linked studies should investigate this issue with more rigor.

1,531 people answered the question about having ever donated blood. 42% reported ever having donated blood. Those who reported no history of blood donation were not asked to respond to additional questions about the timing or frequency of blood donations.

30 of 650 respondents indicated that they donated blood in the past 12 months and 225 responded that they had donated blood one or more times over the past 10 years. Of perhaps greatest interest to this committee is that 115 of 640 people indicated that they had donated blood **one or more times** since being diagnosed with CFS.

There are obvious limitations to web-based surveys but these results reinforce the need to expand efforts to educate potential blood donors about CFS. We commend the American Red Cross and independent centers that have already taken this step and now indefinitely defer individuals who indicate a past or present CFS diagnosis.

Many in the CFS community anticipated that the studies being led by the Blood XMRV Scientific Working Group by now would have yielded more definitive information about risks posed to the blood supply by MLVs and the feasibility of wide-scale testing of blood donations for MLVs. Today's presentations indicate that these issues cannot yet be resolved. However, the lack of conclusive data does not impede the FDA's opportunity to take action that will further safeguard health without an injurious impact on the availability of blood for those who need it.

According to the FDA web site, a person's suitability to donate blood depends on two general considerations: that the donation will not be injurious to the donor, and that the donated blood will not be unnecessarily hazardous to the recipient.

It has long been the Association's guidance to CFS patients that they not donate blood or organs out of concern for the safety of both the donor and the recipient. Research has demonstrated that orthostatic intolerance, low blood volume and infections with a variety of agents are common in CFS. While more information may be needed to assess the potential threat posed by MLVs and the prevalence of this family of viruses in CFS patients, there already exists sufficient evidence, in the 5,000 peer-reviewed articles about CFS, to support an FDA policy of indefinite deferral of individuals diagnosed with CFS. This policy would be consistent with the practice being followed by most of the blood collection centers in the U.S. Based on preliminary data on deferral rates, such a policy is "reasonably achievable without unduly decreasing the availability of this life saving resource," a policy requirement stated on the FDA web site.

The CFIDS Association of America urges the BPAC to respond affirmatively to the FDA's question about CFS and we restate our strong support of a policy to indefinitely defer individuals diagnosed with CFS.