



PATIENT ALLIANCE FOR NEUROENDOCRINEIMMUNE DISORDERS
P-A-N-D-O-R-A
ORGANIZATION FOR RESEARCH AND ADVOCACY inc.

255 Alhambra Circle, Suite 715
Coral Gables, Florida 33134
Phone: 305-441-1591
www.pandoranet.info

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To Blood Products Advisory Committee members:

Preserving the safety of blood products is paramount to the public trust in government officials. As your website says, "The FDA is responsible for ensuring the safety of the nation's blood supply." A recent U.S. Food and Drug Administration and National Institutes of Health study¹ revealed that 6.7% of blood donor samples tested have infectious² MLV-related retroviruses that are linked to chronic fatigue syndrome and aggressive cancers. The study's results mandate that the FDA take action now. We urge the FDA to ban people with chronic fatigue syndrome, also known as myalgic encephalomyelitis (ME/CFS), from donating blood.

A "wait and see" approach is not in the best interests of public safety. A retrovirus does not disappear from a person's blood on days they "feel well." Would the FDA allow an HIV positive person to donate blood on a day that he/she was "feeling well"? Government officials don't want to see another retrovirus scandal similar to the one in the 1980s precipitated by HIV; another retrovirus. Banning ME/CFS patients from donating blood would show that the FDA is proactive on matters of public health.

While we appreciate the Dec. 3 announcement from the American Red Cross that they are deferring potential donors who reveal their ME/CFS diagnosis in an interview, more action is needed. This policy does nothing to protect blood transfusion recipients from the more than 80% of ME/CFS patients who have not been diagnosed; more than 800,000 Americans³. Since ME/CFS is a relapsing and remitting chronic illness, many patients may "feel well" on donation day yet have high blood titers of this and other viruses.

An announcement from the FDA banning ME/CFS patients from blood donation will amplify the safety of the blood supply and the well-being of the American population. The announcement will motivate researchers, physicians and the CDC to work together to develop better diagnostic criteria for ME/CFS. Better diagnostic criteria will reduce the number of non-diagnosed ME/CFS patients in the United States. Greater numbers of accurately diagnosed patients will further prevent infection of the blood supply and thereby reduce the number of newly-infected ME/CFS patients.

We depend on the FDA to make policies that will actually lead to a safer blood supply. Stimulating researchers and health agencies to create an accurate and universally-accepted diagnostic criteria for ME/CFS, or any disease, is good policy for patients and the population at large.

Now is the time to take action; to be safe rather than sorry. Ban all ME/CFS patients from donating blood.

P.A.N.D.O.R.A., Inc. welcomes working with your committee to protect more Americans from become disabled with a devastating NeuroEndocrinImmune disorder.

Sincerely yours,

Marly C. Silverman

Marly Silverman,
Founder
Patient Alliance for NeuroEndocrinImmune Disorders Organization for Research and Advocacy, Inc.
(P.A.N.D.O.R.A.)

Kenneth J. Friedman Ph. D.

Vice President & Secretary, Director of Public Policy
Patient Alliance for NeuroEndocrinImmune Disorders Organization for Research and Advocacy, Inc.
(P.A.N.D.O.R.A.)

1. Lo S, Pripuzova N, Li B, Komaroff AL, Hung G, Wang R, Alter H: Detection of MLV-related virus gene sequences in blood of patients with chronic fatigue syndrome and health blood donors, *Proc. of the National Academy of the USA*, August 23, 2010, doi:10.1073/pnas.1007944107
2. CDC website: "It is unclear whether certain individuals are more likely to be infected with XMRV and MLVs."
3. Jason J, Benton M, Valentine L, Johnson A, Torres-Harding S: The Economic impact of ME/CFS: Individual and societal costs, *Dynamic Medicine*, April 8, 2008, doi:10.1186/1476-5918-7-6

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