

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY**

**TESTIMONY OF THE
IMMUNE DEFICIENCY FOUNDATION**

REGARDING POLICY UNIVERSAL LEUKOREDUCTION

JANUARY 25, 2001

Good afternoon. My name is Jason Bablak and I am Vice President of the Immune Deficiency Foundation. I would like to briefly address the issue of Universal Leukocyte Reduction before the committee. IDF represents individuals affected with primary immune deficiency diseases, which are characterized by inherited defects of the immune system. There are about 50 of these diseases and many result in frequent and life-threatening infections. Due to these genetic defects, there are an estimated 20,000 people in the United States, including infants, children and an enlarging population of adults, who are not able to make antibodies, and who receive regular infusions of a plasma derivative, intravenous immune globulin. It is from this perspective that the Foundation is interested in the safety of the nation's blood supply.

While Universal Leukocyte Reduction (ULR) will not directly affect the treatment or health outcomes of individuals with primary immune deficiency, IDF supports the implementation ULR for the US blood supply for the following reasons.

- We agree with the 1995 Institute of Medicine report that called for instituting incremental blood safety steps as they become available. Leukocytes are known to cause transfusion reactions and removing them will result in a more pure and safer product.
- The Food and Drug Administration's Blood Products Advisory Committee unanimously voted to recommend that the FDA require ULR based on the benefits associated with this procedure. BPAC is the advisory committee charged with providing scientific and medical advice to the agency on blood-related issues, and a unanimous recommendation from this committee is a powerful endorsement of this technology.

IDF believes that the safety of the nation's blood supply is paramount importance, and we encourage this committee to recommend the taking of incremental steps to continue to improve the margin of safety in both blood and plasma products.

Thank you for your attention.