

August 24, 1998

David Satcher, M.D.
Surgeon General
716 G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Satcher:

The Immune Deficiency Foundation is a national health agency representing individuals affected with primary immune deficiency diseases. Primary immunodeficiency diseases are characterized by inherited defects of the immune system; thus our members are extremely vulnerable to viral, bacterial or other contaminants in the blood supply. Most primary immune deficient patients require life long therapies, including regular (e.g., monthly infusions) of intravenous immune globulin (IGIV) to maintain their health. More than 20,000 immune deficient patients are currently on this plasma derivative.

In response to a request from the FDA, the Immune Deficiency Foundation's Advisory Committee on Blood Safety and Availability comprised of top clinical immunologists and consumers, reviewed the FDA CJD Withdrawal Options Paper several weeks ago. Based on their discussion the Immune Deficiency Foundation supports the liberalization of the current CJD withdrawal policy. However, IDF is deeply concerned about the potential elimination of all CJD related withdrawals, particularly those involving confirmed cases of CJD in the plasma pool. The Foundation's expert Committee believes that in the absence of definitive laboratory findings and adequate surveillance within the primary immunodeficient community it is undesirable at this time to eliminate some categories of withdrawal.

The Immune Deficiency Foundation continues to work closely with industry and government to balance issues of safety and availability affecting our consumers. As recently as last December, the Foundation endorsed the FDA, TSEAC recommendation that albumin used as an excipient be exempt from CJD withdrawal policy. We have enclosed for your review a copy of the letter addressed to Kathryn Zoon, Ph.D., Director, CBER.

The Foundation recognizes that as Surgeon General you must take into consideration broad public health concerns. The Foundation would like to explore with you means of liberalizing CJD withdrawal policies consistent with the best interests of our patient population. To this end, we would like to schedule a meeting with you at your earliest convenience. We would like to include Dr. Richard Stiehm, UCLA School of Medicine, Co-Chair of the IDF Advisory Committee. You may contact me directly at 1-800-296-4433, or contact our Washington representative; Dale Dirks, at 202-544-7499. We look forward to the opportunity to discuss ways in which we can support your efforts to improve public health in our country.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Moran', with a long horizontal flourish extending to the right.

Thomas L. Moran
President