September 22, 2010

Internal Revenue Service  
CC:PA:LPD:PR (Notice 2010-51), Room 5203  
P.O. Box 7604, Ben Franklin Station  
Washington, DC 20044

Michael F. Mundaca  
Assistant Secretary (Tax Policy)  
U.S. Department of the Treasury  
1500 Pennsylvania Avenue, NW, Room 3120  
Washington, DC 20220

Douglas H. Shulman  
Commissioner  
Internal Revenue Service  
1111 Constitution Avenue, NW  
Washington, DC 20224

William J. Wilkins  
Chief Counsel, Internal Revenue Service  
Assistant General Counsel, U.S. Department of the Treasury  
1111 Constitution Avenue, NW  
Washington, DC 20224

Re: Notice 2010-51—Implementation of § 9006 of the Patient Protection and Affordable Care Act (PPACA)

Dear Assistant Secretary Mundaca, Commissioner Shulman, and Chief Counsel Wilkins:

The Immune Deficiency Foundation (IDF) is the national patient organization dedicated to the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases (PIDD) through advocacy, education and research. There are more than 150 primary immunodeficiency diseases recognized by the National Institutes of Health and the World Health Organization. Patients with PIDD are part of the rare disease population that impacts the lives of 30 million men, women and children in the United States.
Patients with PIDD have a genetic malfunctioning or non-existent immune system that does not allow them to create the antibodies necessary to fight viruses, fungi and bacteria. For most patients with PIDD, immunoglobulin replacement therapy (IgG) allows patients to live relatively healthy, normal lives, including being productive tax payers. Once diagnosed, a patient with PIDD will need to be infused with immunoglobulin once a month for the rest of his/her life.

We are concerned about the implementation of section 9006 of the Patient Protection and Affordable Care Act (PPACA) and the potential problems this additional tax reporting requirement may have on plasma donations and subsequent patient access to vital immunoglobulin therapies. The IDF does not believe Congress intended these new additional tax reporting requirements to be applied in a manner that would have a negative effect on the public health, including people being treated for PIDD. Specifically, the IDF is concerned that if this provision is interpreted by the Department of the Treasury to include annual aggregate payments of $600 or more between plasma collection centers to individual donors, it will dissuade people from donating plasma, and therefore impede the ability of manufacturers to produce the medicines our community of patients need.

We believe that applying the new tax reporting requirements in section 6041 of the Internal Revenue Code (IRC) to payments for plasma donations could potentially create patient access problems to immunoglobulin products because manufacturers need plasma from healthy and committed repeat donors to produce this lifesaving medicine. Moreover, our community has experienced access issues in the recent past prompted by changes in Medicare reimbursement rates, in addition to product availability as documented in the 2007 report by the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation, entitled Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV) (available at http://aspe.hhs.gov/sp/reports/2007/IGIV/report.pdf).

Because immunoglobulin therapies are made from donated human plasma, patients with PIDD are completely reliant on the generous donations of committed individuals that make it possible for companies to manufacture the medicines for our community of patients. To this end, for patients with PIDD, the average infusion per treatment is about 35 grams of immunoglobulin, meaning that producing enough medicine for just one infusion requires about 12 donations of plasma. Patients with PIDD require regular infusions, often every 3 to 4 weeks. Thus, it takes about 190 donations of plasma to manufacture enough therapy to keep just one patient with PIDD healthy for one year. Any actions that could possibly discourage individuals from repeatedly donating plasma will impede the production of vital therapies such as immunoglobulin.
Lastly, for the reasons described above, we urge the Department of the Treasury to help protect access to immunoglobulin products and other medicines for people with rare disorders and diseases, by making clear that section 6041 of the IRC does not apply to plasma donations.

Sincerely,

[Signature]

Lawrence A. La Motte
Director, Public Policy
Immune Deficiency Foundation