PLUS
AMERICAN PLASMA
USERS COALITION

February 2, 2018

Julie Birkofer
Senior Vice President, North America & Global Health Policy
Plasma Protein Therapeutics Association
147 Old Solomons Island Road, Ste. 100
Annapolis, MD 21401

Re: Patient Notification System

Dear Ms. Birkofer,

The American Plasma Users Coalition (APLUS) is a coalition of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. The organizations representing these patients share a common desire to ensure that the patient voice is heard when relevant public policies, regulations, directives, guidelines, and recommendations affecting access to safe and effective therapy and treatment are considered. Together, our coalition represents more than 125,000 Americans living with chronic disorders dependent upon plasma protein therapies for their daily living.

APLUS members are strong supporters of the Patient Notification System (PNS) and work to recruit our members to enroll in the PNS since it provides critical information to our patients about potential safety issues in our products. On a recent PNS Working Group call, the group discussed a few potential issues related to the system and we are writing today to formally ask PPTA to explore:

- **Providing data to each organization:** We would like to learn the number of people from our patient communities that have enrolled in the PNS so that we can better target our marketing and enrollment activities. We recognize that there are confidentiality concerns related to release of patient-level data and so we suggest that each organization work with Stericycle directly to receive only the aggregate number of patients who have signed up from their respective patient community.

- **Approaching new companies with treatments for our patient communities:** We encourage PPTA to explore extending the PNS to new companies and treatments being made available to our patient communities, even if they are not plasma-derived or recombinant technologies. Many of our patients have come to rely on the PNS, so it would be ideal for the group of products to be as robust as possible, particularly in cases where a patient may be taking a new treatment along with other products that are part of the system. Most immediately, we ask that PPTA be willing to include Genentech's new hemophilia product, Hemlibra, in the PNS.

We sincerely appreciate the work that PPTA, its member companies, and Stericycle do to ensure the ongoing work of the Patient Notification System. Our recommendation seeks to strengthen the system and make it more responsive to our patients' needs.

We thank you for your consideration. Should you have any questions or require additional information, please contact Johanna Gray at jgray@dc-crd.com or 202-484-1100 or Larry LaMotte, Vice President, Public Policy, Immune Deficiency Foundation, llamotte@primaryimmune.org or 443-632-2552.

Alpha-1 Foundation
GBS/CIDP Foundation International
Committee of Ten Thousand
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation

National Hemophilia Foundation
National Organization for Rare Disorders (NORD)
Patient Services Incorporated
Platelet Disorder Support Association
US Hereditary Angioedema Association