PLUS
AMERICAN PLASMA
USERS COALITION

March 24, 2020

APLUS Supports Plasma Donor Recognition & Home Infusion

The American Plasma Users Coalition (APLUS) appreciates the current efforts of your agency to protect public health and curb the spread of COVID-19. Today, we write to you to express concern regarding continued access to life-saving plasma-derived medicine products. In particular, we urge you to take action to (a) avoid disruptions in the supply of donated plasma, from which these medicines are made; and (b) ensure that vulnerable patients can receive their medication therapy in settings that do not expose them to undue risk of infection.

Plasma derived medicines are unique biologic medicines that treat diseases by replacing missing or dysfunctional proteins. These treatments are made from plasma that is donated by healthy volunteers. Plasma is collected from healthy volunteers at 780+ plasma donation centers in the US, then the plasma is frozen and shipped to a specialty facility where it is manufactured into plasma protein therapies. This manufacturing process takes 7- 12 months, and includes many processes that ensure the safety of the product. According to the Plasma Protein Therapeutics Association, which represents more than 750 human plasma collection centers in North America and Europe as well as the manufacturers of lifesaving plasma protein therapies, the current established processes of virus inactivation and removal during this manufacturing process ensure the safety of plasma derived medicines from the novel coronavirus known to cause COVID-19.

Plasma derived medicines are non-interchangeable, unique, and life-saving therapies that rely on the donations of plasma from healthy volunteers. Plasma donor centers have already gone to great lengths to ensure the safety of donors through a variety of innovative practices adapted to the current challenge of COVID-19 and consistent with social distancing and sanitization recommendations. On behalf of the patients who utilize these life-saving and life-sustaining therapies, we ask that agencies work collaboratively to recognize this unique challenge and propose that agencies consider acknowledging, thanking, and encouraging plasma donations from healthy volunteers across the United States knowing that every precaution is being taken to ensure the safety of plasma donors and plasma collection center staff.

Additionally, we encourage the public health system and policymakers to resolve known barriers to home and personal infusion of plasma-derived therapies as an additional step to protect vulnerable patients from ongoing COVID-19 challenges. A recent article in the New England Journal of Medicine written by a group of doctors from Italy highlighted the grave situation that hospitals face when their resources are required for serious COVID-19 treatment. The authors'

recommendation of social distancing techniques specifically included home care for patients as a way to relieve pressure from the hospitals and keep people away from contaminated infectious areas. APLUS hopes that Congress will recognize the value of home care, especially home infusion of immune globulin or similar products, and remove barriers within the Centers for Medicare and Medicaid Services (CMS) reimbursement process to facilitate home infusion under all public programs for all patients that require life sustaining infusions of plasma derived medicines.

APLUS is a coalition of national patient organizations created to address the unique needs of patients with rare diseases who 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. Safety is of utmost concern to APLUS: we believe that plasma collection regulations should always prioritize the safety of the donor and the safety of the eventual plasma user.

We appreciate the opportunity for further discussion in this regard and would like to serve as a resource during this challenging time. Please contact Lisa Butler, the current leader of APLUS, at Lisa.Butler@gbs-cidp.org to provide guidance on how the U.S Public Health System plans to protect patients in need of plasma-derived therapies as well as plasma donors essential to maintaining the supply of life-saving therapies.

Thank you for your time. Together, we can work together to protect public health from this emerging threat while ensuring that the supply of plasma derived medicines is not disrupted.

Sincerely,

APLUS Member Organizations

GBS|CIDP Foundation International

Jeffrey Modell Foundation

US Hereditary Angioedema Association

Immune Deficiency Foundation

The Alpha – 1 Foundation

Patient Services, Inc.

The Committee of Ten Thousand

Hemophilia Federation of America

Platelet Disorder Support Association

National Hemophilia Foundation