

April 9, 2020

Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Re: Provision of Masks to Source Plasma and Blood Collection Facilities to Ensure Supply of Life-Saving Treatments

Dear Secretary Azar,

Our organizations, which represent patients who are end users of blood, blood products and plasma-derived products and the medical providers who care for them, deeply appreciate your efforts to protect public health and curb the spread of COVID-19. We are writing today to ask for your assistance to ensure that life-saving source plasma and blood donation can continue in light of the COVID-19-related requirements for protective measures for center staff and donors.

Safety is of utmost concern to our organizations: we believe that plasma and blood collection regulations should always prioritize the safety of the donor and the safety of the eventual end user of the product. Accordingly, we agree with the recent recommendation by the Centers for Disease Control and Prevention (CDC) that all Americans wear masks when in close contact with others and understand that this would apply to blood and source plasma collection processes as well. We are concerned that this recommendation might have the unintended consequence of jeopardizing source plasma and blood donation, however, since collection facilities may not have a sufficient supply of masks to provide to staff and donors. **Therefore, we ask that you ensure that plasma and blood collection facilities are prioritized as health care entities that should receive masks and other protective equipment.**

Source plasma is plasma that is collected from healthy, voluntary donors through a process called plasmapheresis and is used exclusively for further manufacturing into final therapies (fractionation). It is vital that U.S. maintain a constant and robust flow of source plasma collection. To treat a single patient with Primary Immunodeficiency Disease 130 donations are needed per year; this number increases to 900 donations per year for Alpha-1 Antitrypsin Deficiency and 1200 per year for Hemophilia A. The U.S. collects the vast majority of plasma worldwide. Alternative sources for plasma collection on the scale needed are non-existent.

Source plasma and blood collection are vitally important and we agree with the U.S. Department of Homeland Security Cybersecurity & Infrastructure Security Agency, which designated these activities as essential ones that must continue during the crisis.¹ Plasma donors are vital to the health and wellbeing of Americans: for people who are severely ill from COVID-19 and for patients with rare diseases who require regular treatments of plasma-derived therapies. These critical donations not only help to save lives today but have a lasting effect over time. Plasma donations made today, for example, will be turned into life-saving therapies reaching patients in 7-12 months. We are very concerned that any disruptions in donations in the US will jeopardize this supply, harming American families in the future.

Plasma and blood donation from healthy donors is absolutely critical and we ask that you ensure that source plasma and blood collection facilities have the resources they need to ensure safety for their donors, staff and the end users of the blood, blood products, and plasma-derived products that result. We fear that without these resources,

¹ "Advisory Memorandum On Identification Of Essential Critical Infrastructure Workers During Covid-19 Response." Memo from Christopher Krebs, Director of Cybersecurity and Infrastructure Security Agency. Released March 28, 2020. Available at: https://www.cisa.gov/sites/default/files/publications/CISA_Guidance_on_the_Essential_Critical_Infrastructure_Workforce_Version_2.0_Updated.pdf.

the patients we serve will face shortages of life-saving products in the future, jeopardizing their health and well-being.

Thank you for your attention during this uncertain time. Together, we can work together to protect public health from this emerging threat while ensuring that the supply of critical treatments is not disrupted. Please contact Nathan Schaefer, Vice President for Public Policy with the National Hemophilia Foundation at NSchaefer@hemophilia.org, with any questions.

Sincerely,

Alpha-1 Foundation
Alpha-1 Global
Coalition for Hemophilia B
Committee Of Ten Thousand
Cooley's Anemia Foundation
European Haemophilia Consortium
GBS|CIDP Foundation International
Hemophilia Alliance
Hemophilia Federation of America
Immune Deficiency Foundation
International Patient Organisation for Primary Immunodeficiencies
Jeffrey Modell Foundation
National Hemophilia Foundation
Patient Services Incorporated
Platelet Disorders Support Association
Sick Cells
US Hereditary Angioedema Association
World Federation of Hemophilia

CC:

Admiral Brett P. Giroir, M.D., Assistant Secretary for Health

Vice Admiral Jerome M. Adams, M.D., M.P.H., Surgeon General

Tara J. Broido, MPH, Deputy Director of Communications, Office of the Assistant Secretary for Health

Jim Berger, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health