

March 20, 2020

Governor Greg Abbott
1100 San Jacinto Boulevard
Suite 151-B State Insurance Building
Austin, TX 78701

RE: Essential Activities of Critical Infrastructure Industries

Dear Governor Abbott,

The Plasma Protein Therapeutics Association (PPTA) would like to take this opportunity to request the inclusion of plasma donation centers and the other supply chain activities of our members in any action your administration develops to classify essential critical infrastructure workers during the response to mitigate the spread of Novel Coronavirus 2019 (COVID-19). If our members' activities, including plasma donation center activities, are excluded, there will be a negative effect on patient access to plasma protein therapies.

PPTA is the standards-setting and global advocacy organization that represents the private sector manufacturers of plasma-derived and recombinant analog therapies, collectively known as plasma protein therapies, and the collectors of Source Plasma¹ used for manufacturing of plasma protein therapies. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies. Our membership accounts for approximately 80 percent of plasma protein therapies in the United States.

Plasma protein therapies are primarily used in the treatment of genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. These therapies include blood clotting factors for individuals with bleeding disorders, immunoglobulins (Ig) to treat a complex of diseases in persons with antibody deficiencies and severe autoimmune disorders, and albumin, which is used to treat individuals with severe liver diseases and, in emergency-room settings, shock, trauma, burns, and other conditions.

Leaders around the country like yourself are taking the prudent move to limit population activity to slow the spread of COVID-19, often through Executive Order. These orders can list essential activities that should continue despite restrictions on normal activities. As you consider limits on mass gatherings and restrictions on non-essential services, we urge you to exempt plasma donation centers and related supply chain activities.

The activities of our members are essential to the creation of pharmaceuticals known as plasma protein therapies. The first step in our members' manufacturing process is made when plasma donors visit our members' plasma donation centers to donate Source Plasma used to manufacture lifesaving pharmaceuticals. For this reason, these centers are within the category of essential, critical infrastructure (health care and pharmaceutical supply) that is recommended to be exempted from general lockdown or closure.

¹ 21 CFR 640.60 defines Source plasma as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use.

This exemption was noted in the President's Coronavirus Guidelines for America: "If you work in a critical infrastructure industry, as defined by the Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule." On March 19, the Cybersecurity and Infrastructure Security Agency issued the "[Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response](#)" to help state and local authorities determine which critical functions should continue normal operations amid COVID-19 related restrictions. Within the Healthcare / Public Health sector, plasma operations are specifically noted:

"Blood and plasma donors and the employees of the organizations that operate and manage related activities"

Without the continued Source Plasma donations, thousands of individuals who rely on plasma protein therapies may have difficulty accessing their life-saving pharmaceuticals. Clinical need for plasma protein therapies has been steadily increasing for many years². This need, which necessitates a high level of Source Plasma collections, has not gone away or diminished due to the COVID-19 situation. Patients reported serious Ig access issues as recently as Summer 2019. These issues were in the absence of travel restrictions, government ordered closures, widespread concern about the safety of public spaces, and other conditions that could severely impact plasma collections. Our members anticipate a drop in Source Plasma collections due to the fact that plasma donors, like everyone else, are likely to limit non-essential trips and errands outside the home. State-ordered closures of plasma donation centers on top of these likely actions risk turning an already challenging situation into a crisis.

We ask that you explicitly exclude plasma operations from COVID-19 related restrictions by referencing the CISA Guidance in any Executive action that classifies critical infrastructure workers. It is critical that we protect and maintain the supply of plasma protein therapies, starting with Source Plasma donations to the delivery of the finished products to patients. We also ask that as you coordinate with County, City, and Municipal health officials, you bring to their attention and reinforce the critical role of plasma donation centers in the development of essential medicines. Plasma donation centers in their jurisdictions are essential businesses.

We are grateful for your attention to the delicate supply chain for plasma protein therapies and appreciate your consideration to include plasma donation centers and the other supply chain activities of our members in any executive action you take in response to COVID-19. Please contact Josh Penrod at jpenrod@pptaglobal.org (202-557-0319), or Bill Speir at bspeir@pptaglobal.org (443-994-0900), if you have any questions or comments.

Thank you,



Joshua Penrod, JD, PhD
Senior Vice President, PPTA Source and International Affairs

cc: *State Department of Health*

² Grabowski, H., & Manning, R. (2018). *Key economic and value considerations in the U.S. market for plasma protein therapies*. Washington, DC: Bates White at 31.