

March 12, 2020

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

ADM Brett P. Giroir, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

**RE: Protecting the Supply Chain for Critical Plasma Protein Therapies by
Maintaining the Essential Equipment and Materials for Plasma Collection**

Dear Secretary Azar and ADM Giroir:

This letter is intended to alert you to the fragile supply chain for certain critical biologic products that are derived from plasma separated from human blood. These plasma protein therapies, such as immune globulins (IVIG and SCIG), albumin, and coagulation factors, treat patients who are managing chronic life-threatening diseases due to their lack of protective antibodies. We, industry and the government must do our utmost to ensure these vulnerable patient populations have access to lifesaving plasma protein therapies. The Plasma Protein Therapeutics Association (PPTA) represents Source Plasma donation centers as well as the manufacturers of life-saving plasma protein therapies, including plasma-derived and recombinant analog therapies. Our membership accounts for approximately 80 percent of plasma therapies in the U.S.

The current outbreak of COVID-19 is already challenging the supply chain for medical products in various ways, and it is important to think proactively to help prevent further disruptions in access to plasma protein therapies. We would like to highlight the importance of maintaining the availability of certain essential materials and supplies, including donor screening assays, which are necessary to maintain the supply of plasma that is required to produce essential plasma protein therapies. Individuals who rely on plasma protein therapies may well be immunocompromised and cannot tolerate access issues that delay or deny these unique therapies.

The supply chain of plasma is vulnerable to many disruptions in the availability of basic medical supplies and personal protective equipment. It is also dependent on the availability of dedicated and timely transportation from the donation centers to the manufacturers.

A primary concern in the collection process of plasma is extensive testing, including testing to ensure that the blood and its components do not contain pathogens. Such testing must employ certain screening tests that have been licensed, approved, or cleared by the U.S. Food and Drug Administration (FDA); these donor screening assays are listed on FDA's website.¹ For certain pathogens, there are only a small number of suppliers that are authorized to produce the required screening tests. Accordingly, we want to be sure that HHS is aware of the importance of maintaining the supply of these screening tests. If there were a supply interruption associated with these tests, it would adversely affect plasma collections, which would raise significant access concerns for critical, life-saving plasma protein products.

Because there are relatively few companies that manufacture the tests that are necessary for plasma donor screening, it is important to recognize the potential unintended consequences that could occur if these companies, or the resources and materials on which they depend, are diverted to other priorities related to the COVID-19 outbreak. If satisfying the demand for COVID-19 diagnostic tests were to reduce the capacity to produce the test kits that are needed for blood/component screening, it could have significant unintended consequences, not only for the supply of plasma, but also for essential plasma protein therapies. For example, if there was a decision to employ authorities under the Defense Production Act of 1950² to reorient productions of in vitro diagnostic tests to address the COVID-19 outbreak, careful consideration would need to be given to the impact and unintended consequences of such a shift on the ability of manufacturers to maintain production of screening tests for the collection of plasma.

Accordingly, we are requesting that HHS remain cognizant of the fragile supply chain for plasma protein therapeutics and avoid taking any steps in the use of the government's procurement powers that would inadvertently interfere with plasma collection and have consequences for those with immune deficiency.

Sincerely,



Amy Efantis
President and CEO
Plasma Protein Therapeutics Association

¹ Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays, available at https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays#Zika_Nucleic_Acid_assay.

² 50 USC 4501 *et seq.*