

November 23, 2020

Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Mailstop A27
Atlanta, GA 30329-4027

ELECTRONIC DELIVERY

Re: Comments submitted to ACIP meeting on November 23, 2020 in lieu of oral remarks

PPTA represents manufacturers of plasma protein therapies and plasma collection centers. Last year, U.S. centers collected over 50 million plasma donations, which were manufactured into therapies for thousands of Americans and others with rare, life threatening and frequently chronic conditions. This industry is unique, different from vaccines, from chemical pharmaceuticals, and even different from the blood sector. It is built on a complex, global supply chain that must be preserved to ensure access for the patients that depend on it.

Plasma donation center employees, donors and production employees, all of whom are involved in the collection of plasma and the manufacturing of lifesaving plasma protein therapies in over 860 plasma donation centers and manufacturing facilities across the United States are at risk for contracting Covid-19. In March, CISA's Essential Critical Infrastructure document described "donors of plasma, and the workers of the organizations that operate and manage related activities" as "critical and essential." This is because more than 500,000 patients nationwide with rare diseases rely on plasma donors, donation center staff, and manufacturing facility staff as integrally important in helping them maintain access to the therapies that keep them healthy..

Plasma is collected from donors and is then manufactured through a 7-12 month long process called fractionation into highly purified non-interchangeable biologic therapies that treat a range of conditions, such as immune deficiencies and hemophilia. Plasma for further manufacture is essential to meet the clinical needs of patients, as therapies derived from plasma are often the only way to treat these life-long conditions.

Prior to the pandemic, plasma donation levels were struggling to meet clinical need, to the point where Asst. Secretary Brett Giroir asked to meet with PPTA last fall because of reported patient access problems for immunoglobulins. Adm Giroir has treated patients and knows how essential immunoglobulin availability is to these rare disease patients.

Plasma collections plummeted in March and April because of the pandemic and have not returned to levels seen in prior years. Donation center workers – phlebotomists, technicians, nurses, and doctors – are in constant contact with the many donors necessary to provide these medicines, and they need the protection a vaccine could offer. Donors should be prioritized for vaccines as their plasma is so urgently needed as the essential starting material for these medicines. And we should not forget the importance of the employees at the manufacturing plants, whose dedication is the final link in producing plasma protein medicines.

PPTA is doing all that it can to make donating plasma a national concern. We continue to work with Congress and HHS to raise awareness of the need to donate plasma. PPTA has issued a statement on the urgent need for plasma donations <https://www.pptaglobal.org/media-and-information/ppta-statements/1089-ppta-statement-on-the-urgent-need-for-plasma-donation> to keep these lifesaving medicines available during the pandemic.

So that patients do not lack access to plasma protein therapies we ask that you extend a high priority for Covid-19 vaccines to essential plasma donation centers, plasma donors and plasma production facilities.

Sincerely,

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