Plasma Protein Therapeutics Association

Oral Testimony of Amy C. Efantis, President & CEO, Plasma Protein Therapeutics Association
Hearing on *COVID-19 Related Goods: Conditions in the U.S. Industry and Key Supply Chains*
U.S. International Trade Commission
September 23, 2020

Allotted time: 10 minutes

Good morning and thank you, Chairman Kearns and Members of the Commission.

I am Amy Efantis, President & CEO of the Plasma Protein Therapeutics Association. We represent manufacturers of life-saving plasma protein therapies and more than 1,000 plasma collection centers, 880 of which are here in the US. Last year those U.S. centers collected over 50 million plasma donations, which were manufactured into therapies for many thousands of Americans. The total U.S. market for those therapies is around $12 billion. Our industry is a unique one, different from vaccines, from chemical pharmaceuticals, and even different from the blood sector. Our industry is also built on a complex, global supply chain that must be preserved to ensure access for the patients that depend on it.

The core business of PPTA member companies is the collection and manufacture of plasma into therapies to treat a range of rare, life threatening and frequently chronic conditions. The plasma collected contains many proteins, including clotting factors for those with bleeding disorders, albumin for those suffering from burns and trauma, and important antibodies for the immune compromised. Those antibodies are called immunoglobulins, or Ig, and are protective against a wide range of diseases. Ig has also shown to be an effective treatment for some complications of COVID-19, specifically Multisystem Inflammatory Syndrome in Children (MIS-C).

Plasma collected by PPTA member companies is collected from human donors through a process called plasmapheresis which collects plasma and leaves the other components of blood behind with the donor. This is called source plasma and is used as the starting material for these therapies; it is not used for transfusion. After collection, the plasma is frozen and then undergoes a months-long complex process called fractionation, which creates highly purified protein therapies.

Plasma collected specifically from donors who have recovered from a disease and thus containing antibodies to that disease is called convalescent plasma. In addition to the core business I noted, PPTA member companies use convalescent plasma for further manufacture into products called hyper immune globulins or hyperimmunes. Unlike regular Ig, which can be thought of as “broad spectrum,” these hyperimmunes are targeted toward specific diseases like tetanus and rabies. PPTA member companies are working hard to develop COVID-19 hyperimmunes, which is what brings me to this hearing today.

As I mentioned earlier, PPTA member companies occupy a unique space in the broader world of blood and plasma. Source plasma donation is different from blood donation because it *is* for further manufacture, unlike blood. Blood can be donated once every 8 weeks, it takes around 20 minutes and, in many cases, the equipment for transfusion travels to the donor. The donated blood is generally transfused into a local patient. Plasma collection is different. Donors can donate safely up to twice a week; the process takes closer to an hour and a half and must be done at fixed sites. Given this large

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commitment, source plasma donors in the US are recognized with compensation. The source plasma then goes through that complex, global manufacturing process. There is no way for plasma protein therapies to effectively remain community-based products.

Maintaining access to manufacturing capacity around the world is of critical importance. Broadly, around half of the manufacturing capacity used to manufacture therapies for use in the US is here in the US, and half is in Europe and elsewhere. Most PPTA member companies have facilities both here and abroad. I cannot stress enough how devastating to US patients and this industry it would be for companies to lose access to their overseas manufacturing facilities. For one, more plasma is collected in the US than can be processed here. Our members have made enormous investments in manufacturing facilities in the US – these are huge, expensive facilities that employ thousands of Americans in well-paying jobs. That capacity is growing all the time but a new facility can cost more than $1 billion and take more than 6 years from conception to opening.

Building on that, to achieve economies of scale, companies move plasma to the facility where it is most needed. Sometimes that means plasma will be partially fractionated and intermediates will be sent to another facility within that company, but not always one in the same country. In many cases, that plasma returns to the US in the form of a final therapy. Taking any sort of action that results in retaliatory measures could prevent the re-export of those final therapies back to the US. Currently, all of the plasma-derived therapies used to treat patients in the US are made from US-sourced plasma. The FDA has not licensed any product made from non-US plasma for use in the US.

In order to be most efficient, a liter of plasma needs to be made into as many products as possible, and those products all need to find a market. Countries demand different proteins in different volumes and cutting off access to plasma or final therapies in a particular country could cause ripple effects throughout the supply chain. The fragility of the market for plasma protein therapies has been widely reported over the last year or so, particularly for Ig. Clinical need for Ig has been rising and there is no alternative treatment for many of the diseases and conditions treated with Ig. The current supply chain is efficient and effective, but vulnerable to sudden policy changes.

I'm aware that a focus of this inquiry is to determine whether PPTA members would be able to serve existing patient populations and manufacture a COVID-19 therapy at scale. That is a question that only individual companies can answer. The supply chain vulnerability that I *can* speak to is the ongoing need for more plasma donations. Due to a variety of pandemic-related issues, plasma collections plummeted in March and April and have not yet returned to the levels seen in prior years. Some plasma centers have been periodically closed for cleaning, some employees have been unavailable to work due to quarantines or minor children not being in school, and capacity reductions due to social distancing requirements. At the same time, some donors have opted to remain "safer at home" or have been restricted in movement for the same reasons as center employees. Addressing the impact of the pandemic on plasma donations is currently the foremost concern of industry and patients.

This industry has reacted quickly to rapidly changing conditions, such as by developing remote inspections to assess compliance with industry standards and managing supply chain challenges of the soft goods and PPE required for the collection process. We appreciate the Administration's characterization of plasma collection as a national imperative, and we hope that those efforts will be continued. We also appreciate the jurisdictions, from the federal level to individual municipalities, that have prioritized plasma donors and employees by deeming both to be "essential." Any actions that can be taken as a result of this report to continue or increase that messaging will help to ensure access to

the core therapies that PPTA members produce and any COVID-19 -specific therapies licensed in the future.

I am before you today to stress the delicate, complex and global nature of the supply chain that serves and will continue to serve American patients in more ways than ever before. Any attempt to separate out any piece of this process or location in which it takes place could disrupt the process and have implications far beyond COVID-19. The patients who relied on these therapies to maintain healthy, productive lives before COVID-19 continue to rely on them now and will rely on them in the future. To preserve access for those patients and enable this industry to help the US fight its way out of this pandemic, we need to continue to be a global industry.

Signed,

Amy Efantis
President & CEO