

PPTA Written Testimony for SB 1083 and HB 6666

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to share our support of Senate Bill 1083 and House Bill 6666, and the expected amendment to update plasma donation laws in Connecticut. The laws governing plasma donation in Connecticut were written in 1989, and no longer reflect current practices. It is very important to update these laws because there is a growing clinical need for plasma-derived therapies which are made from donated plasma.

PPTA represents the private sector manufacturers of plasma-derived and recombinant analog therapies, collectively known as plasma protein therapies and the collectors of source plasma¹. Plasma-derived therapies treat rare, chronic conditions including primary immunodeficiency diseases, chronic inflammatory demyelinating polyneuropathy; hereditary angioedema; and bleeding disorders, such as hemophilia. Most of our members are working on plasma protein therapies to treat individuals with COVID-19. The therapies, known as hyperimmune globulins, would be a treatment made from convalescent source plasma donated by individuals who have recovered from COVID-19. Our membership accounts for approximately 90 percent of plasma-derived therapies in the United States. There is concern that not enough source plasma is being collected to provide patients with their life-saving therapies in the future.²

It is critical to create a regulatory environment that supports plasma donation in Connecticut because there is an urgent need for source plasma donations. Reports vary, but plasma donation centers have experienced significant declines in collections due, in part, to the impacts of social distancing measures and other mobility restrictions caused by the COVID-19 pandemic.^{3 4} Considering the complex manufacturing of plasma-derived therapies can take 7-12 months, any decline in plasma donations could impact patients' ability to access their lifesaving therapies.^{5 6} This sharp decline in plasma donations could cause more significant challenges in the months to come.

This is where Connecticut may make a difference. There are more than 930 source plasma donation centers in the United States, yet none of them are located in Connecticut. This is a direct result of the current state regulations governing plasma donation centers in Connecticut which are severely outdated since they were enacted in 1989. If the Connecticut Legislature would create laws harmonizing Connecticut law with federal law, then they would provide PPTA members with the regulatory environment necessary to provide therapies to those in need of plasma protein therapies. This would certainly benefit everyone since everyone benefits from plasma donation.

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.

² <https://www.pptaglobal.org/media-and-information/ppta-statements/1081-ppta-repeats-appeals-for-plasma-donations>

³ Cherney, Mike. "Coronavirus Pandemic Slashes Donations of Lifesaving Plasma." Wall Street Journal, August 19, 2020.

⁴ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. (2020, April). Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency; Guidance for Industry.

⁵ Hartmann J, Klein HG, "Supply and demand for plasma-derived medicinal products - A critical reassessment amid the COVID-19 pandemic." Transfusion. 2020 Aug 28;10.1111/trf.16078. doi: 10.1111/trf.16078.

⁶ Prevot J, Jolles S, "Global immunoglobulin supply: steaming toward the iceberg?" Curr Opin Allergy Clin Immunol. 2020, 20:000-000 DOI:10.1097/ACI.0000000000000696



Plasma donation benefits thousands of Connecticut citizens with rare, chronic conditions that rely on plasma protein therapies for regular treatments. Plasma donation also benefits the general public since the donated plasma is also used to manufacture albumin which is used to treat individuals in emergency-room settings, and Rho(D) immune globulin which used to treat Rh incompatibility during pregnancy.

Plasma donation centers benefit the communities they are in by providing good jobs to more than 50 employees per center and an economic impact of more than \$4 million annually. This does not include the millions of dollars in start-up costs that companies need to put into the economy to create the plasma donation centers.

PPTA appreciates your attention to these comments and would welcome an opportunity to discuss this matter with you in the future. If you have any questions or comments, please contact me at bspeir@pptaglobal.org or 443-994-0900.

Sincerely,

A handwritten signature in black ink that reads "Bill Speir". The signature is written in a cursive, flowing style.

Bill Speir
Senior Director, Advocacy and Regulatory Policy