

March 31, 2021

The Honorable Adrin Nazarian
Capitol Office, Room 4146
Sacramento CA 94249

RE: Support for AB 392

Dear Assembly Member Nazarian :

The Plasma Protein Therapeutics Association (PPTA) would like to thank you for authoring Assembly Bill 392. As you know, this bill will remove the sunset and the pilot verification provisions from Section 1246.7 of the California Business and Professions Code. The passage of this bill should result in more plasma derived therapies for individuals with rare, chronic conditions and positive economic impacts in the communities where new plasma donation centers are opened.

In 2018, with your leadership, the California Legislature passed legislation to create a pilot to determine if a properly trained individual may satisfactorily perform a total protein test using a digital refractometer in a licensed plasma collection center. This is the federal standard followed in most of the 45 states where plasma is donated. The pilot was continued by the legislature in 2020.

The pilot has shown that the properly trained, but unlicensed individual, is able to satisfactorily perform the total protein test with no harm to the potential donor. These results are not surprising since properly trained but unlicensed individuals perform the total protein test using a digital refractometer in more than 900 source plasma donation centers in the United States.

The total protein test is one of six pre-donation screenings¹, such as blood pressure and pulse, that must meet federal regulatory requirements before a donor may donate plasma on a given day. The total protein test is non-diagnostic and easy to perform. The test may be seen at: <http://bit.ly/reichertdigital>. The test is done to monitor the protein levels of frequent plasma donors. Infrequent donors², individuals who donate less than once a month, do not need to have their protein levels checked prior to donating plasma³ because there is no risk in donating plasma with low protein levels.

¹ 21 CFR 630.10 and 630.15

² 21 CFR 630.3

³ 21 CFR 630.25

PPTA represents the private sector manufacturers of plasma protein therapies, and the collectors of Source Plasma⁴. The donated source plasma is used to create plasma protein therapies that 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.⁵

It is critical to increase plasma donation in California because there is an urgent need for source plasma donations. Reports vary, but plasma collectors 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.^{6 7} 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.^{8 9} This sharp decline in plasma collections could cause more significant challenges in the months to come.

This is where California may make a difference. California currently has 28 plasma donation centers collecting source plasma. This number is relatively low when compared to other states. For comparison, there are more than 100 source plasma donation centers in Texas, more than 60 in Florida, and more than 40 in Ohio. Passage of AB 392 will make permanent laws that harmonize California's laws with those in the rest of the country. This permanent change should result in more centers opening in the state.

Passage of AB 392 will ensure that licensed professionals are utilized to the highest level of their job skills resulting in more efficient source plasma donor screening. It will free up specialized staff to perform other essential functions in these source plasma donation centers, such as conducting new donor physical examinations. Before the pilot our members were struggling to find licensed personnel to work at plasma donation centers because of the shortage of nurses in California. The pandemic has only exacerbated this problem. The nurses who perform the total protein test question the utility of their skills in performing such an easy test that outside of California is routinely done by any trained employee.

⁴ 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.

⁵ <https://www.pptaglobal.org/media-and-information/ppta-statements/1081-ppta-repeats-appeals-for-plasma-donations>

⁶ Cherney, Mike. "Coronavirus Pandemic Slashes Donations of Lifesaving Plasma." Wall Street Journal, August 19, 2020.

⁷ 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.

⁸ 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.

⁹ 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

Passage of AB 392 should also improve the lives of people where source plasma donation centers will be located. Passage of this legislation will increase the number of source plasma donation centers in the state. 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.

PPTA appreciates your leadership in changing policies in California. We are available to assist in way to support this important legislation. If you have any question or comments, please contact me at 443-994-0900 or bspeir@pptaglobal.org.

We thank you for your leadership on this issue. If you have any questions or comments, please contact me at bspeir@pptaglobal.org or 443-994-0900.

Sincerely,



Bill Speir
Senior Director, Advocacy and Regulatory Policy