



April 21, 2020

The Honorable Andrew M. Cuomo  
Governor of New York State  
NYS State Capitol Building  
Albany, NY 12224

Dear Governor Cuomo:

The Plasma Protein Therapeutics Association (PPTA) thanks you for your recent executive orders and other actions recognizing that plasma donation is an essential function, both as a matter of healthcare access in general and as a mechanism for responding to the COVID-19 crisis in particular. We would like to share with you recommendations that will move New York forward to our shared goals of increasing plasma donation to make treatments for those with Covid-19 and treatments for patients with rare conditions, who are particularly vulnerable. The recommendations are for targeted regulatory and statutory changes that will increase plasma collection, help patients and spur investment in the economy.

PPTA represents the private sector manufacturers of plasma protein therapies, and the collectors of Source Plasma<sup>1</sup>. The first step in our members' manufacturing process is made when plasma donors visit plasma donation centers to donate Source Plasma. The donated plasma is used to create plasma protein therapies which treat a number of rare, chronic conditions including primary immunodeficiency diseases, chronic inflammatory demyelinating polyneuropathy; hereditary angioedema; and bleeding disorders, such as hemophilia.

In addition, a number of our members are working on a plasma protein therapy to treat individuals with COVID-19. The therapy, known as a hyperimmune globulin, will be a treatment made from convalescent plasma donated by individuals who have recovered from COVID-19. The collection of this plasma will need to follow state and federal law. In New York, the collection of plasma is made more difficult because of a number of the statutory and regulatory hurdles.

There are more than 800 plasma donation centers in the United States, yet only 12 are located in New York State. This is a direct result of the current state regulations governing plasma donation centers in New York, which even the State Department of Health acknowledges to be outdated. PPTA has been working for the last two years to improve plasma donation in the state by updating these regulations to make them more consistent with current technology, and best practices nationwide. We have met with the Department of Health (DOH), the State Education Department (SED) and Empire State Development (ESD) to address these concerns and thereby both improve access to life-saving treatments and create a robust new industry in New York State.

Our meetings with DOH focused on a specific regulation that governs the activities at source plasma donation centers. Our meeting with SED focused on the need to change scope of practice definitions in statutes to harmonize state law with the federal and state laws that govern plasma donation in the rest of the country. Our meetings with ESD have shared details concerning the

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<sup>1</sup> 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.



creation of jobs and the potential financial impact (more than \$4 million per center) that plasma donation centers bring to each community where they are located.

Given your great leadership during the current crisis, and your particular appreciation of the importance of plasma donation, we are hopeful that you will recognize the opportunity here, and take action to maximize plasma donation in the state and ensure that New York is prepared for the next crisis. As noted, some of this can be accomplished in the short term by regulatory action, but legislation is also required. We would therefore ask that any economic recovery package include language currently embodied in bill A.9915/S.7811, which would allow plasma donation centers in New York State to collect plasma pursuant to federal law. This would harmonize New York's regulatory landscape governing source plasma collection with the rest of the country.

Of course, relying solely on legislative and regulatory action will delay efforts to ameliorate this situation. Accordingly, we would also request that you execute an executive order that allows plasma collection in the state of New York pursuant to federal law. We would request that you include in the order that the state will recognize out-of-state licenses to assist in filling positions that are needed to perform plasma donations.

We are grateful for your leadership on plasma donation and your attention to our request. If you have any questions or comments, please Bill Speir at [bspeir@pptaglobal.org](mailto: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

cc: Estibaliz Alonso, New York State Department of Health  
Loretta Beine, New York State Empire State Development  
Jennifer Trowbridge, New York State Education Department