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Statement of America's Blood Centers to the United States International Trade Commission

(September 23, 2020)

Thank you for the opportunity to present to this Commission on the experience of independent blood centers during the ongoing COVID-19 pandemic. I am Kate Fry, Chief Executive Officer at America's Blood Centers, the national trade association for independent, community blood centers in the U.S. and a portion of Canada. Our member centers collect nearly 60 percent of the U.S. blood supply and 80 percent of the convalescent plasma used so far to treat patients with COVID-19.

The U.S. blood supply is supported by a network of not-for-profit organizations that operate fixed and mobile operations in every state across the country. These organizations include approximately 50 independent blood collectors, the American Red Cross, and hospital-based blood collectors. These collectors are responsible for the recruitment of blood donors and collection of various blood components, manufacturing of various products, infectious disease testing, and distribution to hospitals. Blood components for transfusion are a unique element of our healthcare system in that they cannot be manufactured and must come from altruistic donors, necessitating unique considerations.

Through contractual agreements with hospitals and other points of patient care, blood components are provided for the nearly 17 million blood transfusions that occur in the U.S. each year, making blood transfusion one of the most common hospital procedures. The FDA Center for Biologics Evaluation and Research (CBER) regulates the collection of blood and blood components for transfusion; FDA does not recognize any regulatory approvals from other countries.

Blood Collection during COVID-19

The ongoing work of blood centers during COVID-19 reflects the blood community's commitment to meet any challenge. During the course of this pandemic, our member blood centers have assumed two critical missions: to rapidly mobilize the collection of COVID-19 Convalescent Plasma (CCP) and adapt operations to facilitate collections from volunteer donors, under new COVID safety protocols, in order to meet the constant need for blood components and services. The blood community continues to face challenges in charting this unprecedented situation.

Blood centers are actively engaged in supporting the needs of patients during COVID-19. A wide range of patients continue to need blood transfusions throughout the pandemic, including new mothers who may have experienced complications during delivery, patients with cancer who require blood as part of their regular treatment regimen, individuals with sickle cell disease who require ongoing blood transfusions to remain healthy, trauma victims who experience significant blood loss, patients who require surgery and need blood to ensure a healthy recovery, and many others.

The U.S. blood supply faces serious operational challenges as thousands of blood drives have been and continue to be canceled as organizations and businesses temporarily close, move to a virtual environment, or limit the number of people on site. As a result, blood centers

have had to quickly transition their operations to ensure a sufficient blood supply during the pandemic. While the need for blood remains, patient blood use temporarily decreased 30 to 40 percent on average while elective procedures were canceled due to the pandemic, with some communities experiencing far higher decreases. The result has been a devastating drop in revenue for centers that is unsustainable financially. As a result of the financial strain, many centers furloughed workers, leaving centers to figure out how to collect a sufficient blood supply while also creating a process for collecting CCP. Additionally, as blood usage increases again, blood centers face additional costs to recruit additional donors to compensate for delayed demand.

Protecting the health and safety of donors, patients, and blood center staff remains the top priority for the blood community. To ensure the safety of both staff and healthy blood donors, blood centers across the country are undertaking extraordinary public health measures such as social distancing, increased infection control procedures, acquisition of personal protection equipment (PPE) for staff, and more. These measures, in addition to the impact of cancelled drives, have added substantial costs to blood center operations, both directly and through decreased efficiency.

Prior to this pandemic, aggregate operating margins for blood centers were -0.9 percent. With increased expenditures relating to necessary public health measures such as social distancing, and significantly decreased revenues resulting from reductions in blood use due to elective surgery cancellations, many blood centers are now financially threatened at the very time they are stepping up to help the nation in the fight against COVID-19.

COVID-19 Convalescent Plasma

Early on during the pandemic, the idea of using COVID-19 Convalescent Plasma (CCP) was identified as a promising therapeutic option at a time when no other therapeutics existed. While CCP is a new product, the concept of using convalescent plasma dates back to 1892 for the treatment of diphtheria. More recently and relevantly, convalescent plasma was successfully used for SARS and MERS, as well as the 2009 H1N1 pandemic[1]. From that experience, it was postulated that convalescent plasma may be useful in the treatment of SARS-CoV-2. Across the country, approximately 70 different independent blood centers and hospital-based blood collectors have quickly ramped up CCP production, collecting nearly 200,000 doses of CCP and distributing over 160,000 doses to date, which has helped support patients fighting COVID-19. In addition 4,500 doses have been sent to support The Armed Services Blood Program and many more doses have been provided to support randomized clinical trials, INDs and research. Further, this amount only represents the nearly 80 percent of CCP collected by community-based or hospital-based blood centers. CCP collections are currently outpacing distributions, allowing blood centers to start building a national stockpile of 30,000 units and growing. As I will discuss shortly, additional convalescent plasma donors are needed.

Plasma is the liquid portion of blood and contains enzymes, antibodies, and other proteins. COVID-19 Convalescent Plasma comes from patients that have recovered from COVID-19 and contains antibodies to SARS-CoV-2 (the virus that causes COVID-19), allowing patients fighting COVID-19 to potentially benefit from the immunity built up by others that have already recovered. Plasma is collected either through a whole blood donation which is then split into component parts or through a process called apheresis, where an automated machine removes blood from the donor and separates it in real time, returning red and white blood cells and platelets to the donor and extracting only plasma. A whole blood donation results in a single dose of CCP whereas apheresis can result in up to 4 doses in a single session. The process takes between 15 minutes for a whole blood donation or about 45

[1] https://www.pnas.org/content/117/17/9490

minutes for apheresis, plus an additional 30 minutes or longer to screen donors.

COVID-19 Convalescent Plasma (CCP) is currently available under an Emergency Use Authorization (EUA) which was granted by the Food and Drug Administration on August 23, 2020. CCP also remains available through clinical trials and eIND. Previous to the EUA, the Mayo Clinic Expanded Access Program (EAP) was the main source of CCP for patients. The involvement of the Biomedical Advanced Research and Development Authority (BARDA) and subsequently Operation Warp Speed has been critical in establishing a central funding source for both the start-up costs involved in CCP and ongoing cost of providing product to hospitals across the country, as well as bringing national attention to CCP. The financial resources made available to blood centers to fully fund the activities necessary for the rapid production and distribution of this new and investigational product has been essential in identifying and recruiting potential donors and allowing blood centers to undertake operational changes such as staff and equipment redeployment, training, software modifications, re-engineering fixed site and mobile drives to accommodate appropriate social distancing, and expanded hours to enable collections from substantially increasing numbers of CCP donors.

The first step in the supply chain for any blood component is the donor who is willing to roll up their sleeve and literally give of themselves and CCP is not an exception. These donors are screened using the same Blood Donor History Questionnaire as any other blood donor to ensure the safety of the blood supply by assessing general health and high-risk behaviors that might preclude donation. Laboratory testing for transfusion transmissible diseases such as HIV and HCV are performed on all blood components, including CCP. Additionally, CCP donors must have evidence of prior COVID-19 infection (either through a positive diagnostic test result or two different positive antibody test results), must be symptom free for at least 14 days, and be HLA antibody negative (either by test result or being a male or never pregnant female).

These stringent donor eligibility criteria disqualify a large percentage of potential donors, making it critical that recruitment efforts identify a far larger pool of potential donors than is required for patient demand. For every 10,000 potential CCP donors recruited, it is estimated that fewer than 200 CCP doses are collected. Strategic partnerships are critical to achieving CCP collection goals in that they amplify existing blood center public relations and awareness activities. Through the assistance of Operation Warp Speed, efforts to date have solicited the involvement of outside stakeholder coalitions, national insurance plans, clinical testing laboratories, hospitals, and state and local public health in reaching out to potential donors. One early challenge in partnering with these groups was HIPAA concerns around the sharing of patient information. While there has been an attempt to remove regulatory barriers in this area, blood centers must currently rely on the third party to conduct outreach as the potential donor information still cannot be shared directly with the blood center. A far more effective system would allow partners to share the patient lists directly with the blood centers who are trained and prepared to recruit potential donors.

Additional Supply Chain Considerations

Donors are only one aspect of the supply chain. As with other areas of health care, blood centers rely on supplies from a decreasing number of suppliers. Leaning down of blood center operations in response to financial constraints has resulted in single supplier and just-in-time inventory models, which are not appropriate for disasters. Additionally, many of these suppliers are in the same geographic location, meaning a disaster could cause catastrophic impacts to multiple aspects of the blood supply and related services. Disaster planning requires advanced planning with multiple supplier backups and additional national attention is needed in this area throughout the remainder of the pandemic and for future planning efforts.

I would like to highlight just a few of the supply chain challenges faced by blood centers:

- First, as I previously mentioned, the number of available suppliers continues to dwindle for key supply chain areas utilized by blood centers. For example, there are only four primary medical plastic suppliers for U.S. blood centers with one of these supplier's supplying over 90% of this product category These suppliers have footprints in 10 different countries that produce 23 industry critical products. In some instances there is not an alternative supplier.

- Second, as the pandemic continues, various supplies are impacted as utilization increases for both blood centers and other healthcare providers. For example, as coronavirus testing has ramped up, it has utilized supplies needed by blood centers such as pipette tips, nasal swabs, blood collection tubes and various other products used for testing. Recently the assistance of the government has been needed to ensure blood centers are appropriately prioritized by private companies and distributors. While these efforts have been helpful, our future ability to access the national stockpile by prioritizing blood centers access to this inventory must be prioritized.

- Third, as hospitals and other health care providers scrambled to find the supplies they required, blood centers also fought to develop supply relationships to purchase these essential supplies. For example, early in the pandemic, blood centers struggled to find supply items outside their normal supply chain with new primary and secondary supplier relationships formed for essential personnel protection equipment (PPE) products such as mask, exam gloves, surface disinfectants, gowns, lab jackets, thermometers, saline, medical plastics, and reagents. Many of the PPE product category's such as mask, exam gloves and gowns are primarily manufactured outside of the US with varying degrees of quality control, especially during a pandemic with overwhelming supply request. Our dependency on foreign manufactured PPE items must be addressed by prioritizing manufacturing capabilities in the US before the next pandemic.

- Fourth, while the availability of COVID-19 testing was an issue for the public at large, the delays in testing and receiving results was particularly problematic for blood centers that required fast and accurate results to ensure staff and donor safety without resorting to long quarantine periods.

All these challenges and examples highlight the importance of accessing stockpiles of routine and non-routine supplies that could potentially be needed in a disaster and the identification of alternative suppliers to support market demands.

Conclusion

Thank you again for this opportunity to share America's Blood Centers experiences and the role of independent blood centers during the COVID-19 pandemic. We look forward to continuing to work with our federal government partners to examine this important area of our nation's healthcare system. I am happy to take any questions.