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James J. Berger Senior Advisor for Blood and Tissue Policy Office of Infectious Diseases and HIV/AIDS Policy U.S. Department of Health and Human Services Mary E. Switzer Building 330 C Street SW, Room L600 Washington, DC 20024

Re: RFI Response ACBTSA-PAHPAIA Section 209

Dear Mr. Berger:

America's Blood Centers (ABC) is providing feedback to the Solicitation for Public Comments on Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act. ABC thanks HHS for soliciting public comments on this important report and for providing the additional time needed to assemble invaluable lessons learned during the beginning of this current pandemic.

# (1) Challenges associated with the continuous recruitment of blood donors (including those newly eligible to donate)

Continuous recruitment of eligible donors is the number one challenge blood centers face today. The blood supply must meet the everyday needs of the health care system as well as provide sufficient blood to allow a community to know they can weather unexpected disasters. The ready availability of blood, also known as the "insurance value of blood", is essential to the prompt administration of health care. Because it takes time to process and test blood, it is the blood already collected and on the shelf that saves lives. The short shelf life of blood components, ranging from 5-42 days for platelets and red blood cells, just adds to the complexity of maintaining an adequate blood supply. The distance between the blood centers and the transfusion site also adds complexity and inventory challenges to the situation. To meet this ever-present need given these realities, more than 30,000 units of blood must be collected by community blood centers every day.

Blood donors must meet stringent health criteria to ensure their own safety and the overall safety of the blood supply and patient recipients. It is essential that the donor base is continually replenished and expanded. While only 63 percent of Americans are eligible to donate, only 4.8% do. <sup>i</sup>

Exacerbating recruitment challenges are generational differences in donation rates and patterns. Currently, about 60 percent of blood donations are made by people over 40 years old, and of these, three-quarters come from people over 50. <sup>ii</sup> Historically, blood donation was viewed as a civic duty, an opportunity to support the health care of your fellow citizens. However, donation rates for younger cohorts have not kept pace with previous generations. Blood donation is no longer a part of the public consciousness as it once was and overall, younger generations do not comprehend the scope of the need or their role in ensuring a robust blood supply.

Furthermore, diversity is essential in the blood supply, especially for frequently transfused patients that require precisely matched blood components because of rare blood types. One such disease requiring frequent transfusions is sickle cell anemia, a condition overwhelmingly impacting communities of color. These patients can require blood most common among donors of color making these donations an essential element of a robust blood supply.

A national dialogue around blood donation is necessary. The dialogue must go beyond simple sustainability and instead focus on ensuring the blood supply is robust and resilient enough to meet patients' needs during a disaster and recovery afterwards. National encouragement of blood donation as a necessary prosocial behavior must be advanced with a focus on ethnic diversity and, in particular, the ability to recruit group O Rh negative donors. To be successful, this message cannot only come from blood centers but must include government, the entire health care community, and the local communities themselves through civic organizations.

As the COVID-19 pandemic continues to linger, substantial changes to the way blood is collected and donors are recruited are going to be required. The sufficiency of the blood supply is a public health safety necessity and has relied heavily on donors recruited as a part of blood drives, especially those through high schools and workplaces. However, as society faces the ongoing challenges of social distancing to stop the spread of COVID-19, schools and workplaces are not expected to return to normal with students and employees full time on campus. Even where in person work and schooling are resuming, social distancing and attempts to reduce the number of people on campus mean that schools and workplaces will be less likely to schedule traditional blood drives. At the same time, blood centers are struggling to create sufficient capacity for donor appointments to meet the needs for a robust blood supply while also maintaining social distancing. Government messaging during this pandemic must expand beyond the simple need for donors, to include educational messaging about the change to the blood collection process while the need remains constant.

Promoting a robust donor base is a national imperative. A public-private partnership would amplify the reach of a public awareness campaign to expand the donor pool to ensure blood is available to patients in need, both now and in the future.

## (2) Ensuring the adequacy of the blood supply in the case of public health emergencies

Ensuring the adequacy of the blood supply in the case of a public health emergency first and foremost requires implementation of broad policies to remove obstacles that inhibit innovation, adopt evidence-based decision-making, and relieve the burden of unfunded government mandates and flawed funding models. Only a blood supply that is abundant during normal usage

can be robust enough to withstand the stressors of a public health emergency. ABC strongly supports the rules and regulations that ensure a safe blood supply; however, the requirements must change as technology changes. An important component of this commitment is ensuring that all testing requirements are evidence-based using up-to-date data and that a risk-based approach is utilized and frequently updated for the plethora of donor deferrals that limit the base of individuals eligible for donation.

#### National Blood Supply Data and Monitoring System:

Key to an adequate blood supply is a national data and monitoring system to track the collection and utilization of blood components. Understanding the current blood supply is always important to support evidence-based policy making, however, during a disaster a dynamic and near real time system is absolutely essential where both the local and national blood supply can wax and wane quickly as can the need for blood. Thus far during the COVID-19 pandemic, blood centers have reported major changes in both the supply and the demand for blood, yet no comprehensive near-real-time data source exists to quantitate nationally. Currently the national blood supply is assessed based on a patchwork of systems that provide accurate macro trend data; however, it lacks the specificity and detail necessary for agile response during a rapidly changing situation such as the current COVID-19 pandemic. Additionally, this system does not include an active monitoring of hospital on-the-shelf inventory, but an estimate based on historical demand data which is completely inadequate in a very dynamic environment such as a pandemic.

Lastly, there is no near-real-time measurement of blood component usage. During the COVID-19 pandemic, we have learned that blood centers need very granular data on hospital usage of blood components broken down for their various key blood using services (e.g. elective surgery, chemotherapy patients, etc.). When elective surgeries were suddenly cancelled, we had no way to know what impact this would have on the immediate blood supply and demand. In fact, it varied from region to region, ranging from 15 - 50 %. This whipsawed revenues in a way that raised severe financial challenge for blood centers. We rely on the biennial National Blood Collection and Utilization Survey (NBCUS) conducted by HHS which is already two years out of date when published. This was of no use to assess blood usage changes during the COVID-19 pandemic and could not be relied upon to inform resumption of routine services decisions such as elective surgeries and treatment of chronic conditions. In a disaster where the situation changes over time, data is essential to allowing blood centers and supporting public health policy to dynamically change health decisions and messaging with the evolving situation which can vary widely geographically.

## **Blood Center Disaster Planning and Response:**

Ongoing disaster planning and response is essential to ensure the adequacy of the blood supply. A pandemic is a very different type of disaster than blood centers regularly plan for as it lasts longer and follows a dynamic pattern as the infection rate rises and falls. Planning for something unprecedented is based on assumptions; your plan is only as good as those assumptions and your ability to predict worst case scenarios. For example, an initial planning assumption was COVID-19 would spread regionally with other areas able to assist those hit the hardest with blood inventory. However, while various regions were certainly affected differently, the impact of

social distancing was ultimately national with some regional variations that occurred nearly simultaneously. Social distancing also directly impacted donor availability by changing the way most blood centers conducted blood drives with a switch to appointment only systems and the loss of mobile blood drives, resulting in drastically reduced collections. Illness and quarantine of donors and blood center employees alike, as well as a lack of sites to conduct blood drives, impact negatively the ability of centers to maintain needed blood inventory. These types of scenarios must be a part of future pandemic planning for the blood industry and government partners.

ABC appreciates the coordination that occurred throughout the COVID-19 pandemic among the industry, between organizations, and with the Federal government. However, in order to improve blood center disaster planning and response, increased coordination is needed, especially with public health on the national, state, and local levels. Blood centers must also bolster this connection to their local public health through relationship building outside of times of crisis. This pandemic has only reinforced that all disasters are local.

Fortunately, COVID-19 was not a transfusion transmitted virus which would have exponentially complicated the blood industry's response. Additional blood center and government planning is required to prepare for a public health emergency where the disease is transfusion transmitted, or if there is a delay in determining if it is transfusion transmitted. While COVID-19 is a respiratory illness caused by a virus similar to influenza, MERS, and SARS, early indicators supported the presumption that SARS-CoV-2 was not transfusion transmitted and the blood supply could continue uninterrupted. However, if this determination could not be made quickly, or if there was evidence of transfusion transmission, rapid uniform guidance would be necessary to trigger changes in standards for collection and transfusion practices including developing recommendations for when non-essential transfusions should stop and then resume. Coordination would be essential between the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), U.S. Health and Human Services (HHS), hospitals, and blood centers. A clear, open pathway for rapid transmission of information and standards must be well thought out and established so that concise information is delivered as broadly as possible. The potential for a virus similar to SARS-CoV-2 but with transfusion transmission highlights the need for a more robust blood supply that could be extended while the transmissibility by transfusion is investigated. Section (4) below highlights the need for whole blood pathogen reduction as a tool to enhance the safety of the blood supply especially if we encounter a pathogen which is transfusion-transmitted.

## **Supply Chain:**

The supply chain is a lynch pin to an adequate blood supply as well as an important consideration during any sort of disaster, with greater potential for disruption during a national or global disaster than localized disasters. All sectors of the economy have been required to examine the need for supply chain diversification. As manufacturing and supply chains have moved to overseas sources and/or just in time and lean manufacturing, more items have a single supplier (or multiple suppliers in a single country or region). While some of these changes have lowered costs, they also decrease the robustness and readiness of the supply chain. Although blood centers have not yet been dramatically impacted by the potential disruption of single

source supplies, it must be examined as a potential weakness in the supply chain with alternatives identified. This is a particular risk for items where changing to another supplier would require modifications to blood center Standard Operating Procedures (SOPs), validation, training, and in some cases FDA license supplement submissions to comply with current Good Manufacturing Practices. In addition, considerations must be made for the potential of needing large quantities of supplies not normally used by blood centers (e.g. face masks). The utilization of the Defense Production Act during the pandemic highlights the need to consider not only direct competition for acquisition of supplies but also how the supply chain could change during a crisis. Examination of what suppliers could be diverted to producing, either by one of the mechanisms set out in the Defense Production Act or where greater profit is anticipated. For example, the supplier of needles for use in the blood collection process could be diverted for needles for blood draws for disease testing. Additionally, the need for additional complex equipment such as apheresis machines and kits should be considered, as the manufacturing of these may not be able to be quickly switched or ramped up. Such downstream impacts must be considered as part of pandemic planning, especially prior to the government utilizing the Defense Production Act to change production.

#### **Blood** as a Supply:

As blood centers are also a part of the supply chain for hospitals, it is also important to consider the blood center's role as essential suppliers as part of hospital pandemic planning. The blood supply chain is by its nature different from other supplies because at its heart is the individual donor willing to roll up their sleeve and give of themselves. It is essential that hospitals consider blood supplies and communicate closely with their blood centers in developing their pandemic plans, particularly understanding the changing need for donors during a pandemic and the lag time required for any changes to the blood collection process. Blood centers routinely operate in a lean, just-in-time manufacturing environment which requires that no excess staff be maintained in times of decreased demand. This was extremely problematic when surgeries were cancelled and demand dropped for weeks, prompting blood centers to furlough excess staff. This situation was followed by a rapid ramp up in demand as hospitals began elective surgeries again. Blood centers were not able to quickly rehire and retrain staff to meet the sudden increase in demand.

The blood supply considerations must take into account constraints and capacity limitation on collections as a result of on-going public health guidelines. Hospitals must include conversations with their blood center suppliers to ensure it is safe to resume elective surgeries and medical care. A limitation on the blood supply impacts patient care just as much as a limitation on PPE or any other medical supply. Furthermore, government recommendations, such as those from CMS, to re-open the health care system in areas with low incidence of COVID-19 must include urging hospitals to consult with blood centers on the timing of resuming elective procedures and medical treatments prior to making the decision and setting the timeline without knowledge of available blood supply. CMS needs to include consideration of the blood supply in their hospital disaster plans.

#### Stockpile Considerations

Blood center specific supplies must also be included in the discussion of the medical supply chain. Blood components are generally considered inappropriate for a traditional centralized national stockpile due to the short shelf life but could potentially be sourced in a virtual, vendor managed supply. Similarly, some of the necessary supplies for blood collection are inappropriate for long term storage, particularly red blood cell typing and infectious disease testing reagents which also have short shelf lives. Alternative methods of ensuring a stockpile including vendor managed inventories for items such as blood bags, reagents, arm scrub materials, and other required supplies should be further explored.

# Personal Protective Equipment (PPE):

Blood centers comply with blood borne pathogen safety requirements and thus utilize PPE while collecting and processing blood. Blood centers did not have the existing relationships to purchase the type and/or needed quantities of PPE normally used during a respiratory-transmitted pandemic such as COVID-19, in particular masks and gloves. Thus, blood centers found it necessary during the COVID-19 pandemic to purchase the PPE at a time of increased need for these supplies. The available supply and national stockpile were insufficient to meet the rapidly expanded need; clear guidance during a rationing situation was not forthcoming. Blood centers utilized provided guidance from the Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA), however, as knowledge of the method of transmission of SARS-CoV-2 expanded so too did the level of PPE recommended. Updated guidance is needed to ensure that good faith compliance shields entities using the best real time information, especially when there is a shortage of supplies needed by front line health care providers. It is essential, especially when there are shortages, that each individual job can be assigned the appropriate type of PPE. Blood centers must be included in estimations of PPE requirements for future pandemic planning models both from a policy and supply standpoint.

## **Financial Stability:**

Finally, the financial stability of blood centers must be considered in determining a blood center's ability to remain robust during a pandemic or other disaster. The current pandemic has stressed the whole economy and while some components of the economy have received relief, blood centers have largely not benefited from these programs. Prior to this pandemic, aggregate operating margins for blood centers were -0.9 percent. Blood centers were then faced with increased costs of public health measures such as social distancing, plus additional expenses to replace donors and locations for canceled drives due to business and school interruptions. At the same time, blood usage dropped dramatically decreasing revenues by an average of between 30-40 percent, about double original predictions. Financial health is an essential requirement for withstanding disasters, especially as predictions about the length of time of the pandemic stretch longer and a second wave is anticipated.

#### **Donor Messaging During the Pandemic:**

In the early days of implementation of social distancing policies, blood drives were rapidly cancelled bringing the U.S. blood supply swiftly to the verge of collapse. As policies were quickly being developed and communicated early on, it was evident that the impact on blood donation of pandemic health policies such as social distancing had not been considered. ABC appreciates the quick response from various government officials in messaging on the importance, safety, and continued need for blood donation during the pandemic with the considerable unknowns about how COVID-19 would impact the need for blood centers were taking to assure their continuing safety as they came in to donate to ensure blood supplies were sufficient to meet the needs of the health care system. As has occurred following other major mass casualty events, the public responded. We refer to these as "disaster donors". However, we must get the public to understand the continuous need for blood donation to truly have a sustainable blood supply and not just rely on "disaster donors".

Clear consistent messaging is key in any disaster. Additional coordination of potential impacts on various tangent health care support entities is essential to prevent unintended messaging from the government, regardless of the agency and level. Impacts on the blood supply must be considered as a part of the health care system messaging right from the start. During the pandemic, early information on social distancing did not consider the impact on blood donations nor provide guidance that blood donations must continue with appropriate safeguards. Availability of accurate near real time data, discussed previously in this response, will help ensure everyone has the same information on the status of the supply of donors and the need for blood. The lack of this information during the current pandemic hampered initial understanding of the impact and resulted in little insight into the level of demand, expected expirations, needs for rare donor type, as well as other important messaging.

Young and minority donor messaging is particularly important during a pandemic. "Disaster donors" have historically been disproportionately Caucasian, however, patients requiring precisely matched rare blood types generally continue to need transfusions as these patients tend to be chronically transfused. The supply of units of these rare types tend to be a tight supply and loss of any donors to a potential pandemic illness could negatively impact these patients needing frequent transfusion. Again, the lack of national data means only anecdotal information is available on this during the COVID-19 pandemic. We have seen a shortage of type B COVID-19 convalescent plasma (CCP), which is of particular concern since this blood type is more common in communities of color which have been impacted more by COVID-19.

## **Regulatory:**

## Alternative Collection Procedures:

ABC applauds the regulatory flexibility provided during the pandemic and encourages such flexibility to be included in any pandemic planning. Early on during the pandemic, ABC submitted a list of alternative procedure options to FDA to extend collections. This list in the FDA's Guidance for Industry "Alternative Procedures for Blood and Blood Components During

the COVID-19 Public Health Emergency" is widely supported by the blood community but will remain in effect only for the duration of the HHS public health emergency associated with COVID-19.

ABC urges FDA to pre-approve changes that would be acceptable during a declared pandemic emergency or other disaster so that blood centers can prepare provisional emergency SOPs and include these changes within their pandemic plan to make roll out easier as needed. For example as a precedent, FDA issued in 2010 Guidance for Industry "<u>Recommendations for Blood</u> <u>Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and</u> <u>Reporting Certain Changes to an Approved Application</u>" to assist blood centers with operations in times of disaster and pandemics. The need to change SOPs, blood establishment computer systems, validate, and train staff delayed implementation of the modifications approved by the FDA early in the pandemic further validated the need to have pre-planned for such contingencies prior to rather than in the middle of a pandemic. This process should be ongoing and include an up to date list of alternative procedures that can be implemented quickly once a pandemic or disaster is declared.

## Investigational Products:

The COVID-19 pandemic brought to light some limitations and difficulties in the various available pathways for investigational products, including funding difficulties where the investigational product does not adhere to the traditional drug pathway.

COVID-19 convalescent plasma (CCP) is one of the more promising therapeutic options for treating patients with COVID-19. The product is viewed by all as a bridge therapy to a hyperimmune globulin product. Unfortunately, the drug development regulatory process did not envision such a bridge product that must be accelerated quickly with costs incurred by a different entity than would ultimately benefit from the market for that class of therapeutic agents. Furthermore, while FDA acted quickly to establish a pathway for its clinical use, certain contours of the differences between the options were unclear and created uncertainties during the process. Additionally, establishing clear communication pathways and information for dissemination to clinicians about therapeutic options in the IND (Investigational New Drug) process could increase patient benefits while also potentially improving the information gathered as a result. While we recognize how quickly the product development was moving and the need to create and roll out the program simultaneously, we believe that a review of the process can provide actionable information to improve the pathway for any future pandemics. It is important these lessons be truly learned and integrated into agency pandemic planning to ensure that those facing future pandemics, who may not have the benefit of actual experience, will have a thorough record of improvements made as a result of this pandemic.

## (3) Implementation of the transfusion transmitted infections monitoring system

ABC applauds the creation of the transfusion transmitted infections monitoring system (TTIMS). It is a significant step forward in the active monitoring of transfusion transmitted diseases and while COVID-19 was not transmitted by blood, the next disease to emerge may be. During disaster response, TTIMS could be a key component of a total data monitoring system for blood

supply status and utilization as discussed earlier in Section (2) under **National Blood Supply Data and Monitoring System**. Currently about 75% of the U.S blood supply is monitored by TTIMS using a common data dictionary and standardized testing platforms. The blood data monitoring capability of this system could be expanded to include additional parameters identified herein, and additional segments of the U.S. blood supply.

# (4) Other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the blood supply.

The blood industry should continue to strive to develop and implement a whole blood pathogen reduction system that would better prepare the country for a future emerging infectious disease that is transfusion transmitted. The current patch work of pathogen reduction for some components, but not all, fails to achieve that goal.

Please contact Diane Calmus, Senior Director, Federal Government Affairs, America's Blood Centers, for any questions or further information at <u>dcalmus@americasblood.org</u>

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<sup>&</sup>lt;sup>i</sup> Lennie To, MS, Tyler Dunnington, MS, Christy Thomas, MS., et al. The United States' potential blood donor pool: updating the prevalence of donor-exclusion factors on the pool of potential donors. Transfusion. 2019. doi:10.1111/trf.15573

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