America's Blood Centers®
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June 28, 2023

James Berger
Designated Federal Officer for ACBTSA
Office of Infectious Disease and HIV/AIDS Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services
Tower Building
1101 Wootton Parkway
Rockville, MD 20852

Sent via email: ACBTSA@HHS.gov

Re: Public Comment Relating to the Fifty-Seventh ACBTSA Meeting: July 6-7, 2023

Dear Mr. Berger:

On behalf of America's Blood Centers (ABC) and our member blood centers, we appreciate the U.S. Department of Health and Human Services' (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) meeting to discuss and vote on recommendations related to surge capacity for blood and blood products.

The nation's blood supply stands ready to meet both regular demand for blood and blood products as well as surge to meet emergency need. We have consistently witnessed the blood community rise to this challenge, whether it be in response to natural or man-made disasters. The availability of a sufficient amount of blood already "on the shelf" in advance of an emergency is known as the "insurance value" of blood. In the event of a local or national emergency that cannot be met by an individual blood center, systems are in place within the blood community to evaluate and execute a coordinated effort among the more than 50 licensed blood establishments throughout the country, primarily through the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. Other industry organizations also play a key role in coordinating emergency reserves and addressing shortages of blood and key manufacturing supplies for community blood centers.

It is important that surge capacity recognizes the vein-to-vein nature of blood donation, including donors, key manufacturing supplies, and hospital utilization. The COVID-19 pandemic strained all three of these areas and highlighted the need for robust public-private planning for future disaster scenarios, as well as flexibility in regulatory authority.

Supporting a Robust Base of Donors

As blood is unique and cannot be manufactured, blood donors must be considered part of the blood supply chain. Today, the source of this raw material continues to decline, with only 3 percent of Americans donating blood each year. Specifically, donors under the age of 50 continue to rapidly decline and only 20 percent of all donations come from communities of color, threatening patient care, especially for frequently transfused populations. It is essential that the U.S. Government investment in local funding for blood establishments to use in increasing awareness of blood donation, especially among diverse, young, and newly eligible individuals. It is only with a robust base of regular blood donors that blood centers can provide both ongoing and emergency reserves of blood.

The significant impact of federal funding for local awareness activities is best illustrated through the COVID-19 Convalescent Plasma (CCP) program. Throughout 2020 and 2021, the Biomedical Advanced Research and Development Authority (BARDA), under the Administration for Strategic Preparedness and Response (ASPR), provided cost recovery funds for collection of CCP through contracts with America's Blood Centers and American Red Cross. Furthermore, support through an Other Transaction Authority (OTA) was provided to America's Blood Centers to disseminate to member centers in support of additional surge activities; resulting in a sustained 244 percent increase in collections compared to previous baselines. By providing cost recovery directly to blood collectors upon collection of units requested as part of the CCP surge, blood centers were able to invest in the collection of CCP even where the cost of collection would have been otherwise prohibitively expensive.

Lessons learned from this experience should be discussed and memorialized to help shape the government and blood community response to future emergencies where a national surge in collection of blood product(s) is warranted.

Key Manufacturing Supplies

Over the past few years, significant supply chain challenges have at times threatened the availability of a robust blood supply. The limited number of manufacturers of whole blood and apheresis collection sets licensed in the United States, the limited number of manufacturing sites for blood bags and collection kits they operate, and the location of these sites in geographically vulnerable areas combine to pose significant concerns to the entire blood community. In addition, throughout the pandemic, blood centers experienced supply chain shortages of blood tubes, pipette tips, and personal protective equipment necessary for collecting and manufacturing blood components.

Blood collectors took numerous steps to mitigate the impact of these shortages on patient care, including validating additional types of bags, adjusting manufacturing operations to accommodate collection set changes, modifying recruitment and collections activities based on available supplies, and increasing recruitment efforts to increase whole blood donations to supplement the lack of double red cell procedures (due to limited kit availability). These changes ensured continued availability of blood components to serve patients, however, they also resulted in increased costs, staff time, and increased complexity within blood center operations. While the tactics differed, ensuring a safe and adequate blood supply was always paramount.

Given the fragility of today's supply chain, it is imperative that strategic reserves of key supplies are supported by the federal government to ensure the safety and availability of blood products for hospitals and their patients moving forward. It is essential that the focus of ACBTSA action is on ensuring blood centers have the capacity to produce necessary blood products in the case of an emergency that justifies a surge in blood collection.

Policy Recommendations

ABC recommends the following actions by the U.S. government in support of increased surge capacity within the blood community:

1. **Establishment of a vendor-management stockpile for key manufacturing supplies.** A reserve of key manufacturing supplies for the collection of blood should be regionally decentralized at blood centers throughout the United States. While not every blood center may be able to house these supplies, the location of these stockpiles should be selected to ensure easy transport to all centers that may require access to these supplies during an emergency. This dispersed stockpile will allow centers to utilize these supplies on a rolling basis to avoid expiration and wastage of needed supplies, ensuring the supplies are available where and when they are needed.

   ACBTSA should convene a multi-agency, public-private working group to identify the key manufacturing supplies that will be kept in the vendor-managed stockpiles and establish a clear plan to identify the authority and process for accessing key manufacturing supplies during an emergency.

   Finally, a clear definition of a surge that would justify federal government intervention should be discussed as part of the working group, as well as ensuring the specific authority, such as OASH, that will trigger the need for a surge based on the specific emergency. Blood centers have a demonstrated track record of handling local surge capacity, with the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism established to support local and regional blood center needs. It is important that any actions for surge capacity do not duplicate existing infrastructure with a demonstrated ability to ensure a safe and available blood supply.

2. **Inclusion of blood collection and blood collectors as part of the conversation during emergencies to ensure, where appropriate, blood centers are included as part of any effort to prioritize resources during a disaster**. Under Section 319C-3 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, consultation with appropriate healthcare providers, including blood banks, is required. This priority should include the full scope of potential needs of blood collectors during an emergency, including supplies, access to transportation for blood components, key supplies, and blood samples, personnel that may be required to support a surge, and any other resources determined to be necessary by the blood collectors and U.S. Government.

3. **Utilization of FDA regulatory flexibility related to blood and blood products during emergencies to support a safe and available blood supply.** ABC applauds FDA for

allowing multiple flexibilities included in FDA's "Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency Guidance for Industry." We again urge FDA to finalize this document to allow changes safely made throughout the COVID Public Health Emergency to continue. At the start of the pandemic, ABC sent the attached document, *"Options for Extending the Blood Supply in the COVID-19 Pandemic FDA Action Required"* which also included additional recommendations. ABC urges ACBTSA to consider these recommendations related to surge capacity for blood and blood products.

Our recommendations included:

- Lowering the inter-donation interval for donation of whole blood and double RBC collections where donors meet all other criteria.
- Raising the total annual platelet donation during emergencies up to the 48 donations per year allowed when medically necessary for a single patient.
- Lowering donor hemoglobin during emergencies.
- Finalizing the guidance for industry "Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency."
- Allowing for interstate shipment of blood products without licensure for products that would be able to be utilized safely intrastate.

4. **Utilization of FDA regulatory flexibility related to reporting of supply chain challenges and licensure approvals during emergencies to support a safe and available blood supply.**

While FDA has demonstrated a willingness to exercise some regulatory flexibility related to key manufacturing supplies, ABC urges the following additional steps to support a safe and available blood supply:

- FDA should gather and disseminate information as appropriate to ensure blood collectors can make informed decisions about their collection strategies when facing a potential or actual shortage of supplies. FDA should facilitate and encourage early reporting of potential supply chain challenges and where feasible, share the information between stakeholders.
- FDA should reduce barriers for blood centers through expedited licensure approvals of equipment necessary for collecting and manufacturing blood components, such as blood bags, allowing blood centers to utilize resources where they are needed. Expedited approval and simplified validation of new devices will also reduce the impact of a shortage or collection surge.
- FDA should utilize periods of enforcement discretion to allow products to move across state lines, or the use of an unapproved product during the process of validation or licensure for equipment necessary for collecting and manufacturing blood components, to ensure patients are not negatively impacted by supply disruptions.
- FDA should work with U.S. Customs during a shortage to ensure critical supplies are expedited through customs to avoid delays in getting these supplies to blood collectors.

5. **A public-private working group should be established to evaluate disaster planning scenarios (eg. biological warfare, nuclear detonation, blood transmissible pandemic) and the associated operational response for both the donor and supply side.**

Thank you again for your collaborative work to ensure a safe, adequate, and available blood supply. Please contact Justine Coffey at jcoffey@americasblood.org with any questions concerning these comments.

Sincerely,

Kate Fry, MBA, CAE
Chief Executive Officer