June 19, 2020

Mr. James Berger
Designated Federal Officer
Office of Infectious Disease and HIV/AIDS Policy
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW, Room L600
Washington, DC 20204

Attn: ACBTS-PAHPAIA Sec. 209

RE: RFI RESPONSE: Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (2020-06047)

Dear Mr. Berger,

The American Society of Hematology (ASH) appreciates the opportunity to submit comments to the United States Department of Health and Human Services (HHS) regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (2020-06047). ASH commends HHS for working with public and private-sector partners throughout the blood community to develop recommendations related to maintaining the national blood supply, which will be included in the report to Congress mandated by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI).

ASH represents over 18,000 physicians, scientists, and medical trainees committed to the study of blood and treatment of blood-related diseases. ASH members include clinicians who specialize in treating children and adults with hematologic disorders and researchers who investigate the causes of disease and potential new treatments and therapies. Maintaining a safe and sufficient blood supply is vital to supporting public health. ASH is especially concerned with ensuring an adequate supply of safe blood and blood products for individuals with hematologic conditions, including individuals with blood cancers, hemophilia, and sickle cell disease (SCD) for whom transfusions and plasma-derived therapies can prevent complications and be lifesaving. The Society is pleased to share the following information and recommendations for you to consider as HHS drafts the report to Congress.

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

   Life-saving blood is the most frequently prescribed intravenous therapy in hospitals. Despite its critical importance, the blood supply is fragile and the COVID-19 pandemic has exacerbated some of the existing challenges and has reinforced the need for the nation to invest in the security of the blood supply chain. ASH supports steps to ensure a safe and adequate blood supply and to further encourage donations during this critical period and beyond from all healthy people. Blood safety policies are complex, and many factors need to be considered when examining potential changes.
Therefore, it is important for all stakeholders to make the investment to explore potential solutions that are based on science and ensure patient safety.

One pressing challenge in recruiting new donors relates to the critical need to have a diverse blood supply. Unfortunately, recruitment of diverse donors is challenging. We are especially concerned about an adequate blood supply for individuals with SCD for whom transfusions are lifesaving and prevent complications. Since patients with SCD are at a very high risk of alloimmunization, providing prophylactic C, E, and K matched red cells must remain the standard of care, and this requires blood donors of African descent. This issue is incredibly critical now given the decline in donations among people of African descent during the pandemic. ASH encourages HHS to highlight the need to appropriate dedicated funding focused on minority donor recruitment in the report to Congress.

While blood donation recruitment efforts often aim at high schoolers who are newly eligible to donate, ASH supports broad-based recruitment strategies of all healthy people. ASH recently supported the U.S. Food & Drug Administration’s updated guidance to expand blood donor eligibility guidelines to address the pressing need for blood donations. We commend the FDA for its recent policy changes which are based on science and support donor and patient safety.

2. Ensuring the adequacy of the blood supply in the case of public health emergencies

There is a critical need in the United States to establish and maintain a comprehensive federally funded blood supply tracking and redistribution system. The ability to identify and move blood around the country quickly is paramount. This will help to guarantee an adequate blood supply is readily available during “normal” times and during public health emergencies.

During all times and especially in public health emergencies, it is important for policymakers to provide funding to pilot novel approaches to donor recruitment, increasing awareness of blood donation, and promoting diversity among blood donors. ASH was pleased that the United States Congress included in the Coronavirus Aid, Relief, and Economic Security Act (CARES) a requirement that HHS carry out a national blood donor awareness campaign and report back to Congress on the impact of that campaign. Additionally, encouragement for blood donation during public health emergencies needs support at a national level with constant messaging. In the current pandemic, there was initially a tremendous response from donors, but this has now waned, and we are, once again, experiencing blood shortages. Continuous, consistent and coordinated messages about the need for donations is important throughout a public health emergency and beyond.

The COVID-19 pandemic has also made clear that blood and plasma collection centers and strategies cannot function as usual during a public health emergency and there must be flexibility and creativity to respond to an evolving situation. For example, a large proportion of blood donations are done at churches and schools, as well as in office buildings. With schools, churches, and many offices closed, the ability to set up in spaces for students, congregants, and employees diminished. Blood donation centers redesigned their floor plans to allow for physical distancing, which reduced the number of available donation chairs. Clearly, this impacted the amount of blood that could be collected.

In addition, blood and plasma collection facilities implemented new safety protocols and required personal protective equipment for donors and staff. To ensure that blood and plasma collection can continue during a public health emergency, these activities must be designated as “essential,” and these facilities and providers must be prioritized as health care entities that should receive masks and other protective equipment.

Finally, the availability of platelets is generally one of the biggest challenges, since they must be used quickly because they cannot be preserved. Health care providers and hospitals should be educated and encouraged to formulate policies that result in fewer platelet transfusions. Utilization of smaller platelet doses created by splitting donations has been shown to be safe and effective in preventing bleeding in stem cell transplant and leukemia patients. In fact, ASH's Choosing Wisely List has several items that relate directly to blood and blood product
usage. The use of adjunctive therapies such as tranexamic acid may reduce the amount of blood and platelets needed by both patients with hematologic malignancies and those undergoing multiple types of surgeries.* Hospitals should strictly enforce accepted transfusion guidelines.

3. Implementation of the transfusion transmission infections monitoring system

National monitoring of transfusion-transmitted infectious diseases in the blood supply is important to continue. Implementation of a national system capturing comprehensive, real-time hemovigilance data and patient outcomes would advance safety and innovation by promoting evidence-based policymaking, informing the development and adoption of new blood safety technologies, and enabling continuous practice and quality improvement by all blood provision organizations. ASH encourages HHS to focus part of the report to Congress on the critical need for an expanded, comprehensive, well-funded and stable monitoring system that will help identify potential blood-borne threats quickly.

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.

ASH believes that complex blood safety policies should be based on science, and the Society supports the adoption of new technologies and/or revised donor eligibility criteria policies that can increase the potential pool of donors and improve the safety and reliability of the blood supply as long as the overall risk to end users is not increased. Continued funding of research in transfusion medicine is essential to advancing innovation and maintaining safety. The Society encourages HHS to include the need for sustained or expanded research funding as a central part of the report to Congress. This includes support for the national consortium performing the National Heart, Lung, and Blood Institute’s Recipient Epidemiology and Donor Evaluation Study (REDS-IV-P), individual investigators performing transfusion medicine research through R01 and PPG funding, and training new investigators in transfusion medicine research through K and T32 funding at the National Institutes of Health.

One of the challenges in the United States is that the blood industry is quite fragmented. This is a challenge even in the absence of COVID-19 as is often most apparent when seeking to procure compatible red blood cells for individuals with SCD who have many different alloantibodies against foreign antigens on transfused red blood cells. The fragmented nature of the industry can be challenging and often requires each donor center to work out independent solutions. This can result in a variety of innovative ways to accomplish common goals but can also reduce the efficiency of implementing key processes when time is critical.

To address these challenges, there is a critical need in the United States to establish, maintain and fund a system that captures and makes available data on the national blood supply chain. This type of data system needs be sustainable; contain information from a maximum number of blood donor centers and institutions/individuals that utilize blood products; and provide useful data to the entire blood transfusion community. Ideally, this system would also track adverse reactions and transfusion challenges patients face, which would enhance the safety and efficacy of transfusion medicine practices in the United States. The Centers for Disease Control and Prevention tracks immune responses that impact patients getting clotting factor replacement, such as hemophilia A. Other countries have an infrastructure in place to track transfusion challenges, which greatly enhances their ability to rapidly mobilize blood transfusion options to patients in a timely manner. Developing a system that requires blood donation centers to interface with a nationwide database would revolutionize the practice of transfusion medicine in this country.

Thank you for the opportunity to provide these comments. We welcome any discussion on this issue as you consider the Society’s input. If you have any questions or require further clarification, please contact Stephanie Kaplan, ASH Deputy Director of Government Relations and Public Health at skaplan@hematology.org or 202-292-0263.
We look forward to partnering with HHS, the ACBTS, FDA, blood organizations, and others to maintain a strong and safe blood supply and promote judicious use of blood and blood products while maintaining patient safety.

Sincerely,

Stephanie Lee, MD, MPH
President

*References*


