Advancing Transfusion and Cellular Therapies Worldwide

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Statement
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My name is Debra BenAvram and I am the Chief Executive Officer for AABB. I appreciate the opportunity to speak to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) about our experience with the COVID-19 pandemic. Our vantage point is that of AABB's vein-to-vein community of members, including transfusion medicine professionals, accredited blood collectors and the accredited hospitals that our association serves.

My reflections are shaped by the patients whose lives depend on the maintenance of a safe and adequate blood supply, such as Brittney Linder's four-year old son, Khalil. Khalil was diagnosed with sickle cell disease prenatally. He had a stroke when he was one day old, which was the first of many significant medical events he has had throughout his young life. Khalil and his mother have made several terrifying trips to the hospital; he has already had six blood transfusions.

Brittney cannot anticipate when Khalil will experience his next health emergency, but she knows that it is likely that Khalil will need more blood transfusions in the future. The continued resiliency of the blood system is critical to ensuring that the right blood will be available when he needs it. With Khalil and others like him in mind, I will focus on the patient to illustrate how the blood system can build on strengths and address weaknesses exposed during the COVID-19 pandemic. I will also offer several patient-centric recommendations intended to ensure that Khalil, and all patients requiring blood transfusions, continue to receive the right care and blood components at the right time.

1. **During COVID-19, what worked well and are strengths to build upon for future public health emergencies?**

I am extremely proud that despite significant challenges resulting from the COVID-19 pandemic, the blood community—including blood collectors, transfusion medicine specialists, device and testing manufacturers, government regulators and the public—is still able to care for patients such as Khalil. The blood system's resiliency has been augmented by three strengths that should be foundational for future public health emergencies.

Coordinated National Messaging on Need for Blood Donations

Coordinated national messaging on the need for blood donations was instrumental in securing the blood supply. At the beginning of the COVID-19 pandemic, the blood supply was precariously teetering on a fulcrum in which it experienced a sharp decline in blood donations. This was due to nationwide school closings, work from home policies and other social distancing efforts that resulted in cancelled blood drives, fewer donation appointments and a sharp and precipitous decline in our blood supply. The blood supply is critically dependent on donations through blood drives at schools and businesses, as well as the higher rates of donations from the senior citizen population.

The blood community immediately unified and collectively sought support from Congress, federal agencies and other policymakers to encourage blood donation. Simultaneously, individual blood centers engaged in significant local and regional outreach efforts, and the media emphasized the need for blood donation. As a result of these efforts, we were able to stabilize the supply and ensure patients like Khalil could still get blood when they needed it.

Collaboration Related to Changes in Blood Availability and Utilization

Blood centers and hospitals rapidly responded to changes in blood availability and utilization. Blood centers kept their hospital customers up to date on supply challenges and efforts to address those obstacles. AABB monitored its accredited hospital blood banks and provided resources and suggestions to help hospitals plan for a reduced blood supply, such as implementing best practices in blood management and keeping physicians and patients informed about the supply. The association's weekly survey of member accredited hospitals has been a strong monitoring tool during the COVID-19 response, providing insight into the blood supply, demand, wastage and utilization.

As the pandemic progressed, the blood supply again shifted; hospitals stopped performing non-emergent procedures, which resulted in a steep reduction of blood utilization. When hospitals eventually resumed performing non-emergent procedures, utilization quickly escalated, and the blood supply was once again imbalanced. Hospitals shared changes in utilization with their blood suppliers, which helped inform collection operations.

Balancing the blood supply requires the strategic use of data along with transparent, ongoing communications between hospitals and blood suppliers. Collaboration and continuous communication between hospitals and blood centers is essential to managing inventories and aligning hospitals' services and blood management activities with blood availability. It is especially critical in the absence of a data infrastructure that provides real-time information on blood availability and utilization.

Innovation Facilitated by Policymakers and a Unique Public-Private Partnership for COVID-19 Convalescent Plasma

The blood community quickly came together to manufacture, test and provide patients with access to an investigational blood product to treat patients with COVID-19 convalescent plasma (CCP). This investigational effort, rooted in past uses of convalescent plasma such as during the Ebola crisis, was facilitated by unique funding streams established by BARDA, strong support from FDA and an unprecedented multifaceted donor awareness campaign. AABB is proud of blood collection establishments throughout the nation for quickly developing and implementing new collection and distribution protocols for CCP. We also commend transfusion medicine specialists, researchers and clinicians for their integral role in driving ongoing research into the safety and efficacy of CCP. AABB appreciates how this community came together to address challenges, opportunities, the evolving regulatory framework and the emerging science related to CCP.

BARDA awarded grants to blood collection establishments for CCP, which removed potential barriers related to access and limited liability. Initially, the BARDA funding covered CCP distributed to patients receiving the therapy as part of a large, nationwide expanded access protocol. Subsequently, BARDA awarded funding to blood centers to cover a significant number of CCP collections, which limited blood centers' financial risk and encouraged them to continue collections. Hospitals do not need to pay for the CCP units reimbursed by BARDA.

FDA facilitated the availability of CCP by providing timely updates to guidance and information on its website. FDA approved several investigational pathways, including an expanded access protocol that made CCP widely available to patients throughout the country while it was being studied. AABB also appreciates FDA's support for the ongoing randomized clinical trials, which are critical to informing clinical practice.

Finally, the blood community received extraordinary support for CCP donor awareness and recruitment from private-sector companies, foundations, patient advocacy groups and the government. We saw first-hand the importance and impact of patient and community awareness as these groups pushed for CCP research and personally encouraged donations. Organizations that previously had not been connected to the blood community also became invested in raising awareness and recruiting CCP donors, and contributed significant in kind and financial support, leading to efforts such as "The Fight Is In Us" campaign. This unique public-private partnership supports the recruitment efforts spearheaded by individual blood collection establishments, and is reinforced by critical donor engagement activities such as targeted campaigns, grassroots efforts, community organizing, direct outreach by companies external to the blood centers and investment in technology infrastructure. This multi-industry alignment related to donor awareness and engagement is not only foundational for future public health emergencies but should be harnessed to raise awareness and engage blood donors overall.

To summarize, strengths including coordinated messaging, collaboration, innovative policies, and strong multidisciplinary efforts are key to the ongoing response to the current pandemic and lay the groundwork for how we respond to future public health emergencies. Any

pandemic, disaster or public health emergency has its unique challenges, but widespread coordination to secure an adequate blood supply is critical under all circumstances.

2. What weaknesses were identified that threatened or could threaten the safety and availability of the blood supply and patient care?

The pandemic response exposed three significant weaknesses that jeopardize the safety and availability of the blood supply and patient care.

Lack of Real-Time Data on the Blood Supply, Utilization and Hemovigilance

The lack of real-time, nationwide data on the blood supply, utilization and hemovigilance endangers patient care, and was particularly problematic due to the sharp changes in blood availability and utilization previously described. The blood system currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. While individual institutions and hospital systems have data on their own blood use, general changes in utilization are not monitored or shared in real-time.

In March, AABB began the weekly survey of its hospital members to capture near real-time trends on blood supply and utilization. While information was limited by the number of respondents, the snapshot proved helpful overall and continues to offer an important monitoring device during the COVID crisis. However, the absence of comprehensive national supply and utilization data continues to impede the ability of blood donor centers, hospitals, clinicians and policymakers to take data-driven actions to ensure that the blood supply is continuously sufficient to meet patients' needs.

While respiratory viruses such as COVID-19 are typically not transmitted by blood, it is possible that a future virus could be transfusion-transmitted. The threat of emerging and re-emerging infectious diseases is real to the safety of the blood supply. We do not have comprehensive, real-time data on hemovigilance to monitor the incidence and prevalence of transfusion transmitted diseases (TTDs) in current blood donations and can serve as an early warning system for policy failure or emerging infectious diseases. The lack of comprehensive hemovigilance data poses risks to patients' health since it prevents the implementation of policies and practices that reflect current data and limits the blood community's ability to track its impact.

Threats to the Blood System Supply Chain

The response to the COVID-19 pandemic exposed significant threats to the nation's blood system supply chain. The blood supply chain begins with donor recruitment and ends with a valuable therapeutic being transfused into a patient. Throughout the COVID-19 pandemic, each step of the vein-to-vein supply chain proved fragile. In addition to challenges already highlighted, the machines, kits and reagents used to manufacture blood components are developed outside the United States, which is a continuous threat to blood availability during public health emergencies. Access to personal protective equipment (PPE) was a significant concern for all health care workers, including at both hospitals and blood centers. Unlike

hospitals, many blood collectors did not have existing contracts for PPE and were constantly adjusting to ensure all staff who have contact with donors had the necessary PPE—which is also often manufactured outside the United States. Blood center and hospitals' staffs were lean before the pandemic, and staff quarantines resulting from COVID-19 exposures have exacerbated this. These vulnerabilities can be catastrophic if they interrupt the ability of the blood system to meet patients' needs.

Risks Related to Blood Collection Activities

The COVID-19 pandemic highlighted vulnerabilities in blood collection activities, including the blood community's longstanding practice of relying on mobile blood drives for donations. Due to social distancing and the closure of schools, workplaces and houses of worship, many blood collectors were forced to stop mobile blood drives and quickly convert to fixed-site blood drives. Fortunately, due to factors such as hospitals temporarily suspending non-emergent procedures and thus, reducing blood needs, this change did not result in patient harm during the pandemic. However, had blood utilization remained constant, the blood supply would not have been able to meet all patients' needs.

These three weaknesses threaten the lives and health outcomes of patients like Khalil since they each have the potential to interrupt the blood supply and impede blood availability. They are especially problematic for patients with sickle cell disease, who require chronic transfusions and need timely access to specialized blood components.

3. **What are the top three to five recommendations to achieve in the next 2-4 years to increase our preparedness and care for patients?**

It is incumbent that our community build upon the strengths and address the weaknesses of the blood system so that Khalil and other patients requiring blood transfusions continue to have access to blood when it is needed—even and especially during pandemic and other public health emergencies. The blood supply was fragile before the COVID-19 pandemic due to ongoing trends and challenges such as difficulties with blood donor recruitment, changing medical practices, reduced blood utilization, costs associated with implementing new safety measures and consolidation throughout the health care system. COVID-19 exacerbated existing challenges and has reinforced the need for the nation to invest in the security of the blood supply chain.

HHS should prioritize pursuing each of the following recommendations within the next few years through public-private partnerships. This will ensure that policy solutions support patients' needs while advancing the critical work done by organizations and individuals throughout the blood community.

Sustainable, Comprehensive Data Infrastructure

First, we urge HHS to work with Congress to establish, implement, and fund a sustainable infrastructure that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes and hemovigilance. Comprehensive data is critical to our nation's health care and preparedness infrastructure.

A comprehensive data infrastructure should be created and implemented in a cost-effective manner, and built on the following principles: protecting the confidential and proprietary nature of the data; imposing minimal new burdens on organizations and individuals; leveraging and coordinating with existing platforms, data systems and programs developed by public and private-sector organizations, such as TTIMS; and capturing information from the greatest number of blood donor centers and institutions possible.

Additionally, the data infrastructure should provide useful information to regulators, payers and other organizations and professionals throughout the blood community. For example, hemovigilance data, such as risks related to TTDs and emerging infectious diseases, TACO, TRALI and other transfusion-associated events, as well as the capabilities of novel processes and technologies, is critical for individuals and organizations throughout transfusion medicine.

The development of any new data infrastructure should be rooted in legislation. Statutorily mandated data systems for other areas of medicine, such as hematopoietic stem cell transplants and solid organ transplants, have been successful, especially when compared with participation in our nation's voluntary hemovigilance efforts. It is paramount that the federal government invest in the foundation of its blood system to improve the data used to inform policies, clinical practices and decisions that impact blood safety, blood availability and patient outcomes.

AABB recently submitted comments to HHS in response to a request for information on the long-term monitoring of health care system resilience that detailed recommendations for creating such a data system. We submitted similar comments to HHS in response to a request for information to inform the report to Congress on maintaining and adequate blood supply. In advance of this meeting, I provided the Committee with written versions of these comments to serve as an addendum to this statement.

Blood Donor Awareness and Engagement

Next, we encourage HHS to develop and implement effective donor awareness and engagement activities to strengthen the blood donor base, supplemented with other policies intended to increase the availability of blood components.

Congress recognized the value of the national message on blood donation by including in the Coronavirus Aid, Relief, and Economic Security (CARES) Act a requirement that HHS carry out a national blood donor awareness campaign. HHS should build on this CARES Act provision by requesting funding to carry it out with support from private sector partners.

A national awareness campaign is not a panacea. For instance, while coordinated national messaging by the U.S. Surgeon General, federal agencies and other policymakers at the beginning of the pandemic helped bolster the blood supply at the time, the long-term impact on donor behavior or engagement is unknown—and if history is any guide, it will not move the needle all that much. Additionally, broad messaging campaigns generally lack nuances aimed at increasing the diversity of blood donors, especially among people of color who are disproportionately impacted by conditions such as sickle cell disease. Targeted and nuanced awareness and engagement efforts are imperative to ensuring that patients like Khalil have access to matched blood components.

AABB is proud to be a founding partner in the "The Fight Is In Us" campaign – the unique, multi-industry partnership I previously discussed, which is focused on raising awareness of donations of CCP. The non-blood member organizations in this coalition now have firsthand experience with some of the challenges associated with donor recruitment that the blood community confronts daily. They recognize that a national awareness campaign cannot be successful on its own. Rather, it must be accompanied by other donor engagement activities, such as targeted campaigns, grassroots efforts, community-based activities, direct outreach by companies and investments in technology infrastructure.

We urge HHS to evaluate the efficacy of different awareness and engagement efforts, and to take a holistic, sustainable approach to blood donor awareness that can lead to a committed and engaged donor community over the long-term. We also encourage HHS to explore opportunities to leverage the commitment of the non-blood organizations when considering options aimed at increasing awareness and engagement of blood donors. Additionally, we recommend that HHS support the blood community as it considers novel efficient and donor-centric blood collection and recruitment models.

We further encourage HHS to supplement awareness with other policies intended to increase the availability of blood components. For instance, FDA should continually reassess and update donor deferral policies and testing requirements to minimize unnecessary costs and ensure that anyone who is able to donate blood can do so without unnecessary deferrals. We appreciate that during the pandemic, the Food and Drug Administration (FDA) released new guidances that reduced or eliminated certain donor deferral periods. These deferrals are significant and aligned with discussions that have occurred over the years.

As another example, HHS should consider establishing a national red blood cell antigen typing patient database, which would improve patient outcomes by expediting access to compatible units of blood for individuals with special transfusion requirements, such as individuals with sickle cell disease. This innovative resource would be augmented by funding to support widespread molecular testing, which would increase the number of potential donors for chronically transfused patients. Collectively, these measures could dramatically improve blood availability and decrease transfusion-associated morbidity and mortality for patients with unique transfusion needs.

Innovation

Finally, we recommend that HHS invest in working with the private sector to proactively explore and develop policy solutions intended to encourage innovation, promote quality and efficiencies, and advance the continued safety and availability of the blood supply. For several years, AABB has advocated that such a public-private collaborative forum would drive progress and advance policy solutions that address challenges that threaten the blood system. A few examples of potential activities involving multiple agencies and private-sector organizations may include:

A. Identifying regulatory and reimbursement barriers that limit innovation or interfere with patient care and exploring alternative policies that support the development and adoption of new blood products, technologies, processes and procedures;

B. Exploring patient-centric policy solutions that support better care for individuals, better health for populations and lower costs;

C. Proactively identifying efficiencies and opportunities to improve clinical trials conducted during public health emergencies;

D. Using information from the COVID-19 response to update preparedness plans for a future pandemic involving an emerging transfusion-transmissible virus.

Our nation's blood system is complex and must constantly evolve to ensure that it continues to meet patients' needs. These recommendations will provide a foundation that can build on existing strengths, address identified weaknesses and drive sustained progress. As outlined above, we encourage HHS to:

1. Work with Congress to establish, implement, and fund a sustainable infrastructure that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes and hemovigilance.
2. Develop and implement effective donor awareness and engagement activities to strengthen the blood donor base supplemented with other policies intended to increase the availability of blood components.
3. Invest in working with the private sector to proactively explore and develop policy solutions intended to encourage innovation, promote quality and efficiencies, and advance the continued safety and availability of the blood supply.

AABB is committed to working with HHS, patients, donors, organizations and individuals throughout the blood community to advance these solutions and strengthen the blood system. Together, we can ensure that Khalil and patients throughout the country can continue to rely on a safe, available blood supply.

Attachments

- Comments submitted in response to the HHS Request for Information on long-term monitoring of health care system resilience (July 8, 2020)
- Comments submitted in response to the HHS Request for Information to inform the report to Congress on maintaining the national blood supply (June 18, 2020)
- Statement submitted to the Assistant Secretary for Preparedness and Response on establishing a public-private partnership (January 10, 2018)

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July 8, 2020

Via Electronic Mail

The Honorable Admiral Brett Giroir, MD
Assistant Secretary for Health
Office of the Assistant Secretary for Health
U.S. Department of Health & Human Services
Mary E. Switzer Building
330 C Street SW, Room L600
Washington, DC 20024
Attn: OASH Comments
OASHcomments@hhs.gov

RE: RFI RESPONSE – LONG-TERM MONITORING OF HEALTH CARE SYSTEM RESILIENCE, 85 Fed. Reg 34,644 (June 5, 2020)

Dear Assistant Secretary Giroir,

AABB is submitting this letter in response to the "Request for Information - Long-Term Monitoring of Health Care System Resilience." We applaud the Department of Health and Human Services (HHS) for soliciting feedback on opportunities to strengthen the U.S. health care system and are especially pleased with HHS' focus on public-private partnerships in data sharing and comprehensive analytics. AABB recently submitted a letter to your office in response to a request for information to inform a report to Congress on the adequacy of the national blood supply. AABB believes that a safe, available blood supply is a critical component of health care system resilience and we encourage HHS to use the report to Congress to support this effort as well. We believe that the priority we set out in our previous letter – including the establishment of a national data infrastructure that monitors the blood supply chain from vein to vein – or from donor to patient – is critical to health system resiliency and preparedness in the United States and is essential to ensuring the adequacy of a safe blood supply before, during, and after public health emergencies.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to "improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide." AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

A safe and adequate blood supply is critical to medical practice, patient safety and the public's health. Blood transfusions make up roughly 15% of all hospitalizations, with blood products needed for major surgeries and trauma management. Blood is used to treat diseases such as sickle cell anemia and some cancers, and to treat victims who have injuries caused by accidents or natural disasters. Every day, the United States needs approximately 36,000 units of red blood cells, nearly 7,000 units of platelets, and 10,000 units of plasma. AABB is proud that despite significant challenges, the blood community - including blood donor centers, transfusion medicine services, device and testing manufacturers,

government regulators and the public - continues to ensure that patients have access to safe, available blood.

We urge HHS to work with Congress and private stakeholders to establish, implement and support a sustainable public-private system that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes and hemovigilance. A comprehensive data system is needed to reinforce and organize the blood supply chain and strengthen the U.S. healthcare system.

Barrier and Opportunities for Health System Resilience

1. ***What have been the most significant barriers to assessing, monitoring, and strengthening health system resilience in the U.S.?***

The lack of data has been a significant barrier to assessing, monitoring, and strengthening health system resilience. For example, the healthcare system does not have an infrastructure to monitor real-time data on blood availability and utilization, transfusion outcomes and hemovigilance.

The global COVID-19 pandemic has highlighted the fragility of the nation's blood supply chain. AABB is proud that despite significant challenges, the blood community - including blood donor centers, transfusion medicine services, device and testing manufacturers, government regulators and the public - continues to ensure that patients have access to safe, available blood. However, now more than ever we recognize that the absence of real-time data on the blood supply chain jeopardizes the public's health.

The availability of the blood supply and blood utilization are dynamic and must be continuously harmonized to ensure that blood is available to meet patients' needs. At the beginning of the COVID-19 pandemic, blood donation centers experienced a sharp decline in blood donation due to travel restrictions and social distancing efforts, such as remote working and school arrangements, which resulted in cancelled blood drives and fewer donation appointments. There was an urgent national effort to encourage blood donation to ensure that the blood supply remained adequate to meet patients' needs. As the pandemic progressed, hospitals stopped performing non-emergent procedures, which resulted in a steep reduction of blood utilization. Then, as the country resumed non-emergent and elective services amid prolonged social distancing practices, utilization quickly escalated, and the blood supply was once again strained.

The blood community currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. While individual institutions and hospital systems have data on their own blood use, general changes in utilization are not monitored or reported in real-time. The absence of comprehensive national data accounting for supply and utilization impedes the ability of blood donor centers, hospitals, clinicians, the broader health care community, and policymakers to take data-driven actions to ensure that the blood supply is continuously available to meet patients' needs. The lack of real-time data on fluctuations in supply and utilization is particularly challenging for the blood system since blood generally has a short shelf life of between days and weeks, depending on the specific blood component.

2. ***What policies and programs can be improved to mitigate the risk of COVID-19 and avoid negative impacts on patient outcomes?***

We recommend that HHS encourage Congress to use a legislative vehicle to establish, implement, and support a sustainable, public-private infrastructure that captures and makes accessible real-time data on blood availability and utilization, hemovigilance and transfusion outcomes. A comprehensive data system is critical to our nation's health care and preparedness infrastructure and is

essential to mitigating the risk of COVID-19, avoiding negative impacts on patient outcomes, and ensuring the adequacy of a safe blood supply.

Blood Availability and Utilization

We urge HHS to address the current lack of visibility into the health and status of the blood supply chain by recommending that Congress establish, implement and support a comprehensive, sustainable, minimally burdensome system that monitors and makes available data on the blood supply as well as utilization. Significantly, the system would need to be designed in a manner that accounts for the confidential and proprietary nature of the data. Real-time transparency into the status of the blood supply chain is the only way to ensure the adequacy of the blood supply, including during public health emergencies.

Such a system would be able to inform the health care community and policymakers about the availability and utilization of blood, including individual blood components. For instance, COVID-19 convalescent plasma (CCP) was identified as a first line investigational treatment for certain patients with COVID-19. Blood centers shifted their operations and worked tirelessly to build the national inventory of CCP without having a system capable of monitoring the constantly changing national demand. Likewise, clinicians seeking access to this investigational therapy were not able to clearly ascertain the evolving availability of the product.

Additionally, the data would enable blood donor centers, transfusion medicine services and policymakers to assess whether the available blood supply is able to meet the needs of specific patient populations, such as chronically transfused individuals with sickle cell disease who must have access to and receive antigen-matched or antigen-negative blood. Similarly, the data would clarify whether the current supply of specific blood components or blood types is adequate to satisfy patient needs. Blood donor centers could use the data to adjust their operations and transfusion medicine services could use the data to guide clinical practices.

We acknowledge that data can inform practices, but education, outreach, and resources are also needed to strengthen the donor base, which is essential to ensuring an adequate blood supply. We appreciate that Congress included in the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act requirements that HHS carry out a national blood donor awareness campaign and report back to Congress on the impact of that campaign. We encourage HHS to build upon this effort by requesting that policymakers appropriate funding to support this initiative as well as funding that can be awarded to blood centers to enable them to pilot novel approaches to donor recruitment, increasing awareness of blood donation and promoting diversity among blood donors.

Hemovigilance and Transfusion Outcomes Data

While COVID-19 is not transmitted by blood, it is possible that a future virus would be transfusion-transmitted. A system capturing comprehensive, real-time hemovigilance data and patient outcomes would advance safety and innovation by (1) promoting evidence-based policymaking, (2) informing the development and adoption of new blood safety technologies, and (3) enabling continuous practice and quality improvement by blood donation centers, hospital transfusion services, testing and device manufacturers and other organizations throughout the blood system.

For instance, thorough hemovigilance data would provide the blood community and regulators with a vehicle to monitor the incidence and prevalence of transfusion transmitted diseases (TTDs) in current blood donations as well as the potential risk of emerging infectious diseases, such as arboviral

infections. Thus, policymakers would be better equipped to continuously update policies, ensuring that they reflect current data on emerging infectious diseases, changes in the epidemiology of all TTDs, and the capabilities of novel processes and technologies. Additionally, hemovigilance data have the potential to help advance an individual risk assessment approach for blood donation, as policymakers and the blood community would have a tool to monitor the continued safety of the blood supply in real-time. Importantly, hemovigilance data would serve as an early warning system for policy failure or emerging infectious diseases.

As another example, policymakers, private-sector organizations and individuals could use hemovigilance and outcomes data, together with data on the blood supply and utilization, to determine whether new safety requirements or the implementation of novel processes or technologies successfully advance blood safety while ensuring that the blood supply continues to meet patients' needs. Hemovigilance and outcomes data can highlight continued challenges related to blood safety, which can help identify areas that would benefit from further innovation.

Outcomes data has the potential to improve patient safety and the quality of care since it can be used to update transfusion practices and policies. Similarly, comprehensive data on non-infectious complications, such as transfusion-associated circulatory overload (TACO), the transfusion-related acute lung injury (TRALI), and transfusion of an incompatible unit of blood, can inform policies and improve clinical practice.

3. ***What scientific advances are needed to assess and address vulnerabilities in the U.S. healthcare system during the COVID-19 response and in future disturbances to the healthcare system?***

While data is needed to support and monitor innovation, we also believe funds must be dedicated to supporting research and development related to innovative blood products, such as cold stored platelets, lyophilized plasma and thrombosomes, which are going to be important interventions to improve blood safety and accessibility. The COVID-19 pandemic has highlighted the vulnerability of the blood supply and supporting innovation around new product development could meaningfully alter the nation's susceptibility to situations where blood collection efforts are temporarily jeopardized.

<u>Key Indicators & Data Sources of Health System Resilience</u>

1. ***What is your definition of health system resilience within the context of your organization? Does the definition of resilience need to be defined differently based on geographic region and/or the domain of healthcare being assessed?***

A safe, available blood supply is a key component of health system resilience. The blood community's extraordinary efforts continue to ensure that patients benefit from a safe, available, accessible blood supply every day, even in the aftermath of severe hurricanes, mass casualty events and in the face of emerging infectious diseases and a worldwide pandemic. While there are regional and blood center-specific variations in blood availability, the nation has never faced widespread blood shortages.

However, we cannot assume that historical successes will translate into a stable, available blood system in the future. Prior to the COVID-19 pandemic, the blood supply was fragile due to historical trends and challenges, such as difficulties with blood donor recruitment, changing medical practices, reduced blood utilization, costs associated with implementing new safety measures, and consolidation throughout the health care system. COVID-19 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.

2. ***What key indicators or data sets are being used within your organization to assess health system resilience?***

As explained above, blood system resilience is assessed through indicators including blood availability, utilization, transfusion outcomes and hemovigilance.

There are several data systems, existing platforms and programs that different public and private stakeholders in the blood community use to evaluate blood availability and utilization, transfusion outcomes and hemovigilance. However, none of the data systems are comprehensive, many of them are manual and they often do not reflect real-time data. For instance, the blood community currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. While individual institutions and hospital systems have data on their own blood use, general changes in utilization are not monitored or reported in real-time.

As another example, participation in the hemovigilance module of the National Healthcare Safety Network (NHSN) is voluntary except if required by state law and is burdensome since the system is manual and staff must report adverse transfusion-related events. Thus, only some hospitals participate, which limits the utility of the data. The Transfusion-Transmitted Infections Monitoring System (TTIMS) captures the incidence and prevalence of infectious disease data, demographic variables and behavioral risk factors on approximately 60 percent of the blood supply. Additionally, the National Blood Collection and Utilization Survey (NBCUS) is retrospective and does not reflect real-time data.

3. ***What existing methods, data sources, and analytic approaches are being used to assess and monitor health system resilience in private healthcare systems?***

Private-sector organizations have developed and use a variety of programs, platforms and solutions to monitor blood availability and utilization, transfusion outcomes and hemovigilance.

4. ***What selected health conditions should be used as indicators of healthcare availability, access, timeliness, and quality, in terms of treatment and preventive services?***

The availability of blood to meet patients' needs should be an indicator of healthcare availability, access, timeliness, and quality.

<u>Public/Private Data Sources</u>

1. ***What data sources does your organization use to assess the resilience of the health system? What demographic populations are covered by these data systems? Do these data systems capture urban-rural and other geographic differences?***

AABB monitors changes in the blood supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. AABB also reviews manuscripts and data about the safety and availability of the blood system that is generated through a variety of private and public sources. Because the systems do not focus on inventory held by hospitals, they do not address urban-rural and other geographic differences.

2. ***How are you using these data sources to inform your public health response?***

The AABB Interorganizational Disaster Task Force (Task Force) brings together the private sector blood community and the government to support the nation and ensure the availability of the blood supply during disasters. AABB uses data to help inform the Task Force's activities. When acute

shortages with the potential to impact public health are reported, the Task Force may be convened to coordinate a community response. For example, throughout the COVID-19 pandemic, the Task Force has convened the blood community, worked to assess the status of the blood supply and coordinated public messaging about the need for blood donation.

Public-Private Partnerships

1. ***Provide ideas of the form and function of a public-private partnership model to continually assess and monitor health system resilience and individual as well as population health outcomes?***

A comprehensive data system for the blood supply chain must: (1) be created and implemented in a cost-effective manner; (2) be sustainable; (3) contain information from a maximum number of blood donor centers and institutions/individuals that utilize blood products; and (4) provide useful data to regulators, payers and other organizations and professionals throughout the blood community. For these reasons, we encourage HHS to recommend that Congress use its statutory authority to establish, maintain and fund a system that captures and make available data on the blood supply chain.

A comprehensive data infrastructure should be designed through a public-private partnership to ensure that the data supports the needs of blood donor centers, transfusion medicine services, testing and device manufacturers, accreditors, regulators, payers and other organizations throughout the blood community. It should protect the confidential and proprietary nature of the data, while imposing minimal new burdens on organizations and individuals.

One way to maximize efficiencies and minimize burdens is to leverage and coordinate any new data system with existing platforms, data systems and programs. For example, HHS may consider recommending that the Transfusion-Transmitted Infections Monitoring System (TTIMS) serve as the foundation for a hemovigilance system since it captures the incidence and prevalence of infectious disease data, demographic variables and behavioral risk factors on approximately 60 percent of the blood supply. Additionally, it is intended to provide data on the impact of shifts in the donor base, which can inform evidence-based policies. We recommend that HHS consider whether TTIMS can be expanded to cover all blood donations, and whether other data, such as supply data, can be incorporated into the system.

AABB encourages HHS to shape a comprehensive data system by working with the private sector to consider the successes and challenges of other existing platforms, data systems and programs, such as the hemovigilance module of the National Healthcare Safety Network (NHSN), the Biologics Effectiveness and Safety (BEST) Sentinel Initiative, the National Blood Collection and Utilization Survey (NBCUS), and other programs developed by public and private-sector organizations.

Similarly, public and private partners should evaluate challenges with the nation's hemovigilance efforts, which illustrate the benefit of having a comprehensive data effort rooted in statute. For example, participation in the hemovigilance module of the NHSN is voluntary except if required by state law and is burdensome since the system is manual and staff must report adverse transfusion-related events. Thus, only some hospitals participate, which limits the utility of the data. In contrast, policymakers have recognized the benefit of using legislation to establish mandatory data systems for other areas of medicine, such as hematopoietic cell transplants, solid organ transplants and end stage renal disease. It is paramount for the nation to make a similar investment in the foundation of its blood system to improve the data used to inform policies, clinical practices and decisions that impact blood safety, blood availability and patient outcomes.

2. What private and public sectors should HHS engage as part of such a collaborative effort?

HHS should engage with blood donor centers, transfusion medicine services, testing and device manufacturers, accreditors, regulators, payers and other organizations throughout the blood community as part of a collaborative effort to design a comprehensive data system that supports the resiliency of the nation's blood system.

* * * * *

Thank you for the opportunity to offer these comments on the RFI. We look forward to continuing to work with HHS on recommendations related to maintaining a safe and adequate national blood supply. If you have any questions or need additional information, please contact Leah Stone at lmstone@aabb.org or at 301-215-6554.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Advancing Transfusion and Cellular Therapies Worldwide

American Red Cross

June 18, 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 20024
Attn: ACBTSA-PAHPAIA Sec. 209

RE: RFI RESPONSE: ACBTSA – PAHPAIA Sec. 209

Dear Mr. Berger,

AABB and the American Red Cross commend the Department of Health and Human Services 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). We urge HHS to include in the report to Congress a request for policymakers to use a legislative vehicle to establish, implement, and support a sustainable, public-private system that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes, and hemovigilance.

A comprehensive data system is needed to reinforce and organize the blood supply chain and will address each of the challenges highlighted by Congress, including (1) ensuring the adequacy of the blood supply in the case of public health emergencies; (2) identifying challenges and opportunities to strengthen the donor pool; (3) promoting safety and innovation; and (4) building upon the implementation and intent of the Transfusion-Transmissible Infections Monitoring System (TTIMS).

1. **A national data system that monitors the blood supply chain from vein to vein – or from donor to patient – is critical to our nation's preparedness infrastructure and is essential to ensuring the adequacy of the blood supply in the case of public health emergencies.**

The global COVID-19 pandemic has highlighted the fragility of the nation's blood supply chain. AABB and the American Red Cross are proud that despite significant challenges, the blood community - including blood donor centers, transfusion medicine services, device and testing manufacturers, government regulators and the public - continues to ensure that patients have access to safe, available blood. However, now more than ever we recognize that the absence of real-time data on the blood supply chain jeopardizes the public's health.

The availability of the blood supply and blood utilization are dynamic and must be continuously harmonized to ensure that blood is available to meet patients' needs. For example, at the beginning of the COVID-19 pandemic, blood donation centers experienced a sharp decline in blood donation due to travel restrictions and social distancing efforts, such as remote working and school arrangements, which resulted in cancelled blood drives and fewer donation appointments. There was an urgent national effort to encourage blood donation to ensure that the blood supply remained adequate to meet patients' needs. As

the pandemic progressed, hospitals stopped performing non-emergent procedures, which resulted in a steep reduction of blood utilization. Then, as the country resumed non-emergent and elective services amid prolonged social distancing practices, utilization quickly escalated, and the blood supply was once again strained.

The blood community currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. While individual institutions and hospital systems have data on their own blood use, general changes in utilization are not monitored or reported in real-time. The absence of comprehensive national data accounting for supply and utilization impedes the ability of blood donor centers, hospitals, clinicians, the broader health care community, and policymakers to take data-driven actions to ensure that the blood supply is continuously available to meet patients' needs. The lack of real-time data on fluctuations in supply and utilization is particularly challenging for the blood system since blood generally has a short shelf life of between days and weeks, depending on the specific blood component.

Additionally, there is no current mechanism in place to inform the health care community and policymakers about the availability and utilization of individual blood components. For instance, COVID-19 convalescent plasma (CCP) was identified as a first line investigational treatment for certain patients with COVID-19. Blood centers shifted their operations and worked tirelessly to build the national inventory of CCP without having a system capable of monitoring the constantly changing national demand. Likewise, clinicians seeking access to this investigational therapy were not able to clearly ascertain the evolving availability of the product.

We urge HHS' report to Congress to address the current lack of visibility into the health and status of the blood supply chain by recommending that Congress establish, implement and support a comprehensive, sustainable, minimally burdensome system that monitors and makes available data on the blood supply as well as utilization. Significantly, the system would need to be designed in a manner that accounts for the confidential and proprietary nature of the data. Real-time transparency into the status of the blood supply chain is the only way to ensure the adequacy of the blood supply, including during public health emergencies.

2. A comprehensive data system that makes available data on the blood supply as well as changes in utilization would enable policymakers and organizations throughout the blood community identify challenges and opportunities to strengthen the blood donor pool.

As illustrated above, changes in the blood donor pool directly impact the ability of the blood supply to meet patients' needs. Thus, real-time data on the blood supply and utilization would enable policymakers and the blood community to immediately identify challenges and opportunities to strengthen the donor pool.

For example, the data would enable blood donor centers, transfusion medicine services and policymakers to assess whether the available blood supply is able to meet the needs of specific patient populations, such as chronically transfused individuals with sickle cell disease who must have access to and receive antigen-matched or antigen-negative blood. Similarly, the data would clarify whether the current supply of specific blood components or blood types is adequate to satisfy patient needs. Blood donor centers could use the data to adjust their operations and transfusion medicine services could use the data to guide clinical practices.

AABB and the American Red Cross acknowledge that data can inform practices, but education, outreach, and resources are also needed to strengthen the donor base. We appreciate that Congress

included in the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act requirements that HHS carry out a national blood donor awareness campaign and report back to Congress on the impact of that campaign. We encourage HHS to build upon this effort by including in its report to Congress a request for policymakers to appropriate funding to support this initiative as well as funding that can be awarded to blood centers to enable them to pilot novel approaches to donor recruitment, increasing awareness of blood donation and promoting diversity among blood donors.

3. A holistic data system that captures data on hemovigilance and patient outcomes would promote blood safety and innovation.

A national system capturing comprehensive, real-time hemovigilance data and patient outcomes would advance safety and innovation by (1) promoting evidence-based policymaking, (2) informing the development and adoption of new blood safety technologies, and (3) enabling continuous practice and quality improvement by blood donation centers, hospital transfusion services, testing and device manufacturers and other organizations throughout the blood system.

For instance, thorough hemovigilance data would provide the blood community and regulators with a vehicle to monitor the incidence and prevalence of transfusion transmitted diseases (TTDs) in current blood donations as well as the potential risk of emerging infectious diseases, such as arboviral infections. Thus, policymakers would be better equipped to continuously update policies, ensuring that they reflect current data on emerging infectious diseases, changes in the epidemiology of all TTDs, and the capabilities of novel processes and technologies. Additionally, hemovigilance data have the potential to help advance an individual risk assessment approach for blood donation, as policymakers and the blood community would have a tool to monitor the continued safety of the blood supply in real-time. Importantly, hemovigilance data would serve as an early warning system for policy failure or emerging infectious diseases.

As another example, policymakers, private-sector organizations and individuals could use hemovigilance and outcomes data, together with data on the blood supply and utilization, to determine whether new safety requirements or the implementation of novel processes or technologies successfully advance blood safety while ensuring that the blood supply continues to meet patients' needs. Hemovigilance and outcomes data can highlight continued challenges related to blood safety, which can help identify areas that would benefit from further innovation. While data is needed to support and monitor innovation, we also believe that HHS should recommend that Congress dedicate funds to support research and development related to innovative blood products, such as cold stored platelets, lyophilized plasma and thrombosomes, which are going to be important interventions to improve blood safety and accessibility. The COVID-19 pandemic has highlighted the vulnerability of the blood supply and supporting innovation around new product development could meaningfully alter the nation's susceptibility to situations where blood collection efforts are temporarily jeopardized.

Outcomes data has the potential to improve patient safety and the quality of care since it can be used to update transfusion practices and policies. Similarly, comprehensive data on non-infectious complications, such as transfusion-associated circulatory overload (TACO), the transfusion-related acute lung injury (TRALI), and transfusion of an incompatible unit of blood, can inform policies and improve clinical practice.

Clinical practice would also improve by establishing a national red blood cell antigen typing patient database, which would advance patient outcomes by expediting access to compatible units of blood for individuals with special transfusion requirements, such as individuals with sickle cell disease. This innovative resource would be augmented by funding to support widespread molecular testing, which

would increase the number of potential donors for chronically transfused patients. These measures have the potential to significantly decrease transfusion associated morbidity and mortality for patients with unique transfusion needs, thereby improving patient safety and health outcomes.

Finally, payers can use data on transfusion outcomes and hemovigilance to inform coverage and reimbursement policies that support safety and innovation. For instance, payers would be able to use such data to develop and revise coverage and payment policies so they better align with transfusion practices, blood safety requirements and promoting patients' access to new technologies. As another example, the data can be used to advance innovative care by supporting payment policies for blood transfusions furnished in the hospital as well as in out-of-hospital settings of care.

4. **A comprehensive data system would be a critical part of the public health infrastructure, should be supported by Federal funds through a public-private partnership and should leverage and build upon existing platforms, including TTIMS.**

A comprehensive data system for the blood supply chain must: (1) be created and implemented in a cost-effective manner; (2) be sustainable; (3) contain information from a maximum number of blood donor centers and institutions/individuals that utilize blood products; and (4) provide useful data to regulators, payers and other organizations and professionals throughout the blood community. For these reasons, we encourage HHS to include in the report to Congress a recommendation that policymakers use their statutory authority to establish, maintain and fund a system that captures and make available data on the blood supply chain.

A comprehensive data system should be designed through a public-private partnership to ensure that the data supports the needs of blood donor centers, transfusion medicine services, testing and device manufacturers, accreditors, regulators, payers and other organizations throughout the blood community. It should protect the confidential and proprietary nature of the data, while imposing minimal new burdens on organizations and individuals.

One way to maximize efficiencies and minimize burdens is to leverage and coordinate any new data system with existing platforms, data systems and programs. For example, HHS should consider recommending that the Transfusion-Transmitted Infections Monitoring System (TTIMS) serve as the foundation for a hemovigilance system since it captures the incidence and prevalence of infectious disease data, demographic variables and behavioral risk factors on approximately 60 percent of the blood supply. Additionally, it is intended to provide data on the impact of shifts in the donor base, which can inform evidence-based policies. We recommend that HHS consider whether TTIMS can be expanded to cover all blood donations, and whether other data, such as supply data, can be incorporated into the system.

AABB and the American Red Cross encourage HHS to shape a comprehensive data system by working with the private sector to consider the successes and challenges of other existing platforms, data systems and programs, including the hemovigilance module of the National Healthcare Safety Network (NHSN), the Biologics Effectiveness and Safety (BEST) Sentinel Initiative, the National Blood Collection and Utilization Survey (NBCUS), and other programs developed by public and private-sector organizations.

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recognized the benefit of using legislation to establish mandatory data systems for other areas of medicine, such as hematopoietic cell transplants, solid organ transplants and end stage renal disease. It is paramount for the nation to make a similar investment in the foundation of its blood system to improve the data used to inform policies, clinical practices and decisions that impact blood safety, blood availability and patient outcomes.

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Prior to the COVID-19 pandemic, the blood supply was fragile due to historical trends and challenges, such as difficulties with blood donor recruitment, changing medical practices, reduced blood utilization, costs associated with implementing new safety measures, and consolidation throughout the health care system. COVID-19 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. AABB and the American Red Cross commend HHS for its work in making recommendations to Congress to support the adequacy of the blood supply and believes that a comprehensive data system is an important step in ensuring the endurance of this critical public health resource.

If you have any questions or need additional information, please contact Leah Stone, Vice President, Public Policy and Advocacy at 301-215-6554 or lmstone@aabb.org.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

J. Chris Hrouda
President, Biomedical Services
American Red Cross

Advancing Transfusion and
Cellular Therapies Worldwide

Advancing the U.S. Blood System: A Community-Based Approach to Address the Challenges of Today and Opportunities of Tomorrow

Recommendation: Establish a pre-competitive public-private partnership to proactively explore and advance specific, innovative, workable policy solutions that address some of the unique challenges that threaten the U.S. blood system. This important public health security effort would promote quality and efficiencies, encourage innovation and advance the continued safety and availability of the blood supply.

Background

A safe, available blood supply is a public health priority, and is critical to all health systems. Blood and blood components are irreplaceable essential medicines and unique health care resources. Blood transfusions are routine medically necessary treatments for patients with certain chronic health conditions and are frequently required for patients who lose blood during surgery or because of injury. In addition to these predictable uses, blood components must be immediately available in emergent situations characterized by severe bleeding, such as resuscitation after traumatic injuries or severe burns.

The U.S. blood system – from donor to use or from vein to vein – is comprised of a complex web of public and private stakeholders. In contrast to most other life-sustaining medicines, blood and blood components originate from altruistic, volunteer donors. Blood collection establishments collect, test, process and distribute blood components to hospitals and other settings of care where blood is transfused to patients. Blood components have short shelf lives and must be administered to patients within days or weeks, depending on the specific blood component. Other key stakeholders include device manufacturers, testing laboratories, clinicians, private standard setting and accreditation organizations, payors, the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, the Office of the Assistant Secretary for Health and the Office of the Assistant Secretary for Preparedness and Response, as well as other federal, state and local governmental agencies.

The U.S. blood system successfully responded to several significant stressors over the past year and a half, including developing, universally adopting and implementing tests to screen blood donations for the Zika virus, ensuring that the blood supply was safe, available and accessible in the aftermath of hurricanes Harvey and Irma and having sufficient capacity to meet the needs of the victims of the June 2016 Orlando nightclub shooting and the October 2017 Las Vegas shooting. These herculean, life-saving efforts required coordination and participation by all private and public stakeholders throughout the system.

Problem

Historical resilience cannot be equated with stability or future capacity. A recent Sounding Board article in the *New England Journal of Medicine* issues a critical call to action, highlighting ongoing trends

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and existing challenges that threaten to disrupt the blood system.[1] Changing medical practices, reduced blood utilization, a shrinking donor pool and consolidation throughout the health care system have stressed the blood community. Additionally, the blood sector faces mounting economic pressures from existing and emerging voluntary and mandatory safety measures, which are intended to protect the health of patients and donors but are costly to implement. Existing challenges limit the ability of the blood system to invest in research and development and adopt innovative technologies to maintain and improve the safety of transfusions and ensure an adequate supply of blood. In addition, these stressors interfere with the ability of the blood system to maximize its potential for preparing for and responding to emerging infectious diseases and unprecedented disasters and emergencies.

Solution

The broad array of stakeholders comprising the U.S. blood system have diverse, and often competing interests; however, there is widespread agreement on the critical need to ensure that the blood supply is safe and available. An inclusive public-private partnership can drive progress guided by these important goals by:

- Advancing regulatory science, which is defined as "the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products."[2]
- Serving as a forum for collaborative efforts aimed at reducing existing regulatory and reimbursement barriers, exploring mechanisms to facilitate research and development, encouraging the adoption of innovative technologies, and coordinating strategic investments in research, programs and tools intended to strengthen the blood system.
- Developing workable, novel policy solutions that promote a robust, stable blood system capable of meeting both anticipated and unforeseeable needs.

The blood community may consider modeling a partnership after the Medical Device Innovation Consortium (MDIC), a unique partnership between government, nonprofits and industry committed to advancing regulatory science to improve patient access to medical devices. MDIC's projects are intended to make new technologies available to patients, expedite the regulatory process and development of medical devices, reduce the risk and expense of research, and lessen the time and cost of developing medical devices.[3]

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AABB is a not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. For additional information, please contact Leah Stone, Director of Public Policy & Advocacy at 301-215-6554 or lmstone@aabb.org.

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[1] Klein HG, Hrouda JC, Epstein JS. Crisis in the sustainability of the U.S. blood system. N Engl J Med 2017; 377:1485-1488.

[2] Advancing Regulatory Science at the FDA: A Strategic Plan, August 2011, *available at* https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf (last visited November 1, 2017).

[3] Medical Device Innovation Consortium, *available at* http://www.mdic.org (last visited January 5, 2018).