March 9, 2022

Ms. Dawn O'Connell
Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Re: Request for Information: 2023 – 2026 National Health Security Strategy

Dear Ms. O'Connell,

The Association for the Advancement of Blood and Biotherapies (AABB), America's Blood Centers and the American Red Cross appreciate the opportunity to submit comments in response to the request for information to inform the 2023 – 2026 National Health Security Strategy. Collectively, our organizations represent blood collection establishments, transfusion services and transfusion medicine professionals.

Obstacles jeopardizing the resilience of the nation's blood supply are critical health security threats as well as public health and medical preparedness, response, and recovery challenges that warrant increased attention over the next five years. Blood transfusions are medically necessary treatments for patients with certain health conditions, such as sickle cell disease and cancer, and are essential treatments for patients experiencing blood loss during childbirth, because of trauma, or during surgeries. Unlike other essential medicines, blood must be constantly and regularly collected from donors in the community. Blood has a short shelf life, up to 42 days for red blood cells but only five days for platelets. Despite being an essential medicine for a wide variety of patients, the nation's blood supply is often an overlooked and misunderstood aspect of the healthcare system and the emergency preparedness and response infrastructure.

During disasters and emergencies, it is the blood on the shelf that saves lives. Thus, key components of our health security include: (1) a regular, diverse blood donor population able to ensure the continuous availability of a stable blood supply, (2) the workforce needed to collect, process, distribute and transfuse blood, and (3) integration of considerations of the blood supply into preparedness and response policies and practices. Each of these priority areas is challenged and warrants increased attention over the next five years.

Thus, the National Health Security Strategy should address current challenges that jeopardize the nation's blood supply by adopting and implementing the recommendations made at the September 25, 2020 meeting of the Advisory Committee on Blood and Tissue Safety and

Availability (ACBTSA), which identify opportunities to improve the nation's blood safety and availability during public health emergencies (Attachment 1).[1] The ACBTSA recommendations are complimented by recommendations that were included in the HHS Report to Congress: Adequacy of the National Blood Supply (2020).[2]

In addition to these recommendations, our organizations urge ASPR to consider the following policy solutions aimed at improving the blood donor pool, strengthening the workforce, and enhancing the preparedness and response infrastructure.

Blood Donor Engagement and Retention

Background: The blood donor base has been declining, which threatens the availability of the blood supply and health security. Many blood collectors experience challenges attracting first-time and lapsed donors as well as retaining donors. While a 2019 study found that approximately 62.6 percent of Americans are eligible to donate blood, less than 5 percent donated in 2018.[3] The blood donor base is aging; fewer younger individuals ages 16-24 are donating blood, while there is an increased reliance on donors ages 65 and older.[4] These trends have been exacerbated during the COVID-19 pandemic, as businesses and schools that were central to the blood donation ecosystem before the pandemic have not returned to hosting blood drives. The loss of school-based drives is particularly concerning as these drives are often how young donors are introduced to blood donation.

Additionally, the donor base must be increasingly diverse, which is essential to ensuring optimally matched units are available to patients in need. For example, some frequently transfused patients, such as patients with sickle cell disease, may develop antibodies that require advanced blood type matching to avoid negative health outcomes. Donors from communities of color are more likely to have blood that is a precise match for those patients with sickle cell disease and other blood disorders that disproportionately impact Black, Indigenous, and people of color populations.

Challenges with donor engagement and retention are complex; limited research into understanding donor motivation hinders the collective goal of fostering a committed, regular, diverse blood donor population.

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[1] See Recommendations of the 52nd ACBTSA Meeting, September 25, 2020, *available at* https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/recommendations/2020-09-25/index.html.

[2] U.S. Department of Health and Human Services: Adequacy of the National Blood Supply: Report to Congress (2020), *available at* https://www.hhs.gov/sites/default/files/hhs-adequacy-national-blood-supply-report-congress-2020.pdf.

[3] To, L., Dunnington, T., Thomas, C., Love, K., McCullough, J., & Riley, W. (2019). The United States' potential blood donor pool: Updating the prevalence of donor-exclusion factors on the pool of potential donors. Transfusion, 60(1), 206–215. https://doi.org/10.1111/trf.15573

[4] Sapiano, M. R. P., Jones, J. M., Savinkina, A. A., Haass, K. A., Berger, J. J., & Basavaraju, S. V. (2020). Supplemental findings of the 2017 National Blood Collection and Utilization Survey. Transfusion, 60(S2), S17–S37. https://doi. org/10.1111/trf.15715

Recommendations: We recommend that the Department of Health and Human Services take the following actions to help mitigate the challenges that jeopardize the blood supply:

- Work with the Departments of Labor and Education, the Small Business Administration, and other Federal agencies to adopt policies and promote practices that encourage businesses and schools to host blood drives and promote blood donation.

- Work with the Office of Minority Health to dedicate funding to improve the diversity of blood donors.

- Fund research related to donor motivation that generates efficient and effective strategies to engage and retain younger and more diverse blood donors.

Workforce Shortages

Background: Laboratory workforce shortages in blood collection establishments and blood banks are pervasive and are impacting the availability of a safe blood supply. Examples of impacted positions include phlebotomists, medical laboratory technologists (also referred to as medical laboratory scientists), medical laboratory technicians, and supervisory staff roles in blood banking. The workforce shortages of qualified personnel for blood banking and transfusion medicine present risks to patient safety and blood availability and reduce the nation's preparedness and response capabilities.[5,6]

Recommendation: We recommend that HHS strengthen the workforce needed to ensure a safe, available blood supply by working with Congress to establish within the Health Resources and Services Administration (HRSA) a program that provides funding to support recruiting, hiring, training, and retention of personnel that support the availability of a safe blood supply.

Preparedness and Response Infrastructure

Background: The blood community is a vital part of the U.S. health care system and integral to the emergency preparedness and response infrastructure; the essential role of blood collectors and the entire blood supply – from donor to patient - must be considered by federal, state, and local officials before, during and after disasters, including public health emergencies. In addition to ensuring that blood is available to meet patients' needs, the blood community is instrumental in surveillance, screening, and testing for multiple infectious agents.

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[5] The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs, April 2021, available at https://ascpcdn.s3.amazonaws.com/static/ISTP/Siemens_Clinical+Laboratory+Workforce_Brochure_042721.pdf.

[6] Edna Garcia, MPH, Iman Kundu, MPH, Melissa Kelly, PhD, Ryan Soles, MS, The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States, American Journal of Clinical Pathology, Volume 152, Issue 2, August 2019, Pages 155–168, https://doi.org/10.1093/ajcp/aqz046.

However, there are challenges that limit the nation's preparedness and response capabilities. Several federal agencies establish and implement policies impacting the safety and availability of the blood supply. However, the governance is uncoordinated, resulting in misaligned policies, such as new safety requirements being divorced from payment policies. It is unclear whether blood collectors have access to items maintained in the Strategic National Stockpile, and there is not a similar stockpile of critical supplies and devices needed to maintain a safe and available blood supply. Additionally, the absence of accurate, comprehensive, timely data on the blood supply limits the nation's ability to continually assess the status of the blood supply in real time.

Recommendations: We recommend that:

- Federal, state, local, tribal, and territorial governments include blood collection establishments and considerations related to the blood supply in all disaster, pandemic and emergency preparedness and response policies.

- HHS incorporate the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism into the National Health Security Strategy and other disaster, pandemic and emergency preparedness and response policies.

- HHS develop policies and invest resources to strengthen the resiliency of the entire blood supply chain. For example, HHS should ensure the continuity of blood collectors' operations during disasters and public health emergencies by clarifying their access to the Strategic National Stockpile and updating policies to prioritize their access to personal protective equipment, blood bags, saline, reagents, vaccines, and other critical supplies. Additionally, HHS should collaborate with blood collectors, device and testing manufacturers, and other private sector stakeholders to establish and maintain a 6-month distributed national stockpile of key supplies and devices that are essential to sustaining a safe and available blood supply, and should provide funding to support stockpile.

- HHS dedicate funding to modernize the infrastructure used to report the available blood supply and maintain an automated system that includes real-time, comprehensive, accurate data on blood inventories.

- HHS establish a defined, inclusive locus of national authority for blood policy inclusive of the Assistant Secretary for Health, the Assistant Secretary for Preparedness and Response, Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, the Health Resources and Services Administration, the Centers for Medicare and Medicaid Services, the Department of Defense, the Department of Veterans Affairs, and those non-government organizations that provide and transfuse blood products.

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If you have any questions or need additional information, please contact Leah Stone (lmstone@aabb.org, 301-215-6554), Diane Calmus (dcalmus@americasblood.org, 202-654-2988) or Julie Manes (Julie.manes@redcross.org, 202-417-5147).

Sincerely,

Debra BenAvram	Kate Fry	J. Chris Hrouda
Chief Executive Officer	Chief Executive Officer	President, Biomedical Services
AABB	America's Blood Centers	American Red Cross

Attachment: Recommendations of the 52nd ACBTSA Meeting, September 25, 2020

Recommendations of the 52nd ACBTSA Meeting, September 25, 2020

Dear Admiral Giroir:

The Advisory Committee on Blood and Tissue Safety and Availability met on August 26-27, 2020 to hear presentations and discuss strategies for improving the blood community's response to public health emergencies. The presenters shared their organizations' experiences of responding to public health emergencies, highlighted strengths that can be built upon for future emergencies, identified weaknesses that threaten the safety and availability of the blood supply, and recommended actions to ensure our nation's preparedness and patient care.

Challenges and Weaknesses to Be Addressed

The Committee learned that while previous threats from transfusion-transmitted bacterial, viral, and parasitic agents affected blood *safety*, the COVID-19 pandemic disrupted blood *availability* because of widespread cancellations of blood donations. Blood centers and hospitals highlighted that a lack of accurate, real-time information on blood supply and utilization affected informed decision making and patient care, particularly for patients who need surgical procedures that require large volumes of transfusion (for example, liver transplantation) and people who need regular transfusion (for example, people with sickle cell disease and cancer).

Additional challenges and weaknesses identified by the presenters include the following.

- Lack of coordination in national and local public messaging efforts about the status of blood supply and donation
- Significant concerns from blood donors and staff about the safety of the work environment
- Lack of existing stockpiles of critical blood supplies
- Lack of plans for addressing transportation logistics
- Significant financial impact of the pandemic on blood center operations

Strengths to Build Upon

Despite the challenges, the blood centers, in collaboration with government and industry, successfully managed the collection of regular blood products and COVID convalescent plasma (CCP) from recovered patients and began to create a CCP national stockpile. Tens of thousands of patients were treated with CCP resulting in reduced illness and prevention of deaths. The blood community attributed multiple factors as strengths in achieving the success, including

- National public awareness campaigns about blood shortage
- Collaboration between blood centers, hospitals, government agencies, and industry with defined outcomes
- Changes to regulatory requirements such as donor deferrals
- Blood centers' rapid adjustments to their operations

The current COVID-19 pandemic presents an opportunity for informing future decisions about our nation's blood safety and availability during public health emergencies. The presenters and the public proposed many recommendations covering the entire blood supply chain. To fully digest the information shared by the presenters and to make actionable recommendations, the Committee decided to form work groups to develop prioritized recommendations within 30-45 days.

Recommendations

On September 25, 2020, ACBTSA members met virtually to review, discuss, and fine-tune the recommendations developed by the work groups. After thorough discussion, the Committee members unanimously voted yes to approve the following recommendations.

Focus Area 1: Governance/Locus of Authority
Recommendation: Establish a defined locus of authority for national blood and plasma policy, the Assistant Secretary for Health, coordinating with FDA, CDC, NIH, HRSA, ASPR, CMS, DoD, VA, and those non-government organizations that provide and transfuse blood and plasma products, and develop and implement a National Blood Policy inclusive of all blood and plasma products.

Focus Area 2: National Disaster Planning/Business Community

Recommendation: Develop and fund a comprehensive national disaster plan for the blood and plasma supply and include in National Recovery Framework to assure coordination between private and government sectors at the Federal and State levels.

Some key issues concerning this recommendation include:

- Convene stakeholders from federal agencies, industry, and healthcare experts to develop plan, including what Congressional funding may be required to implement and support the plan.

- Ensure that blood and plasma donation, processing and product distribution are designated as critical infrastructure and essential services.
- Perform an independent after-action review of blood/plasma community and HHS response to pandemic, focusing on blood supply adequacy.
- Define role, gaps and needs in disaster response of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, and provide funding, as needed, to fill gaps.
- Examine adequacy of current agreements that support disaster response activities between the private and government sectors, such as with HHS, DOD

Focus Area 3: Supply Chain to Produce Blood Products

Recommendation: Develop policies and provide funding to strengthen the resiliency of the blood and plasma supply chain in order to ensure product availability to hospitals during national emergencies, to include:

- Ensure blood and plasma center employees are considered essential personnel and are federally recognized with the same designation as critical healthcare workers during national emergencies and have priority access to vaccines and to supplies that are critical for blood collection and manufacturing, including personal protection equipment (PPE).
- Appoint a representative from the blood and plasma industry to federal committees or task forces responsible for allocation of critical supplies and transportation and logistics resources during national emergencies and give priority access to transportation and delivery systems for blood and plasma centers to assure continued operations in situations where infrastructure is disrupted.
- Provide funding and assign a task force to establish a 6-month distributed national stockpile of key supplies and devices that are essential to maintain a safe and available blood supply. The storage process and resource sharing of the stockpile will be managed and coordinated by blood and plasma industry representatives, thereby ensuring currently in-use and in-dated supplies.
- Work with manufacturers of plastics, testing reagents and ancillary supplies to identify specific U.S. product codes that could be manufactured in alternative manufacturing plants and proactively work with the FDA on functional flexibility resulting in FDA approval to continue to supply products that are critical to the U.S. blood supply chain from these alternative manufacturing plants.

Focus Area 4: Blood and Plasma Donor Engagement, Growth, and Research

Recommendation 4.1: Fund social science research to generate efficient and effective strategies to engage and retain younger and more diverse blood and plasma donors.

- Support public awareness and sustainable donor engagement studies including implementation and translational science.
- Evaluate the effectiveness of monetary and non-monetary incentives.
- Evaluate the implementation of evidence-based interventions designed to engage and retain blood and plasma donors.

Recommendation 4.2: In partnership with FDA, examine and revise policies that could increase the availability of blood and plasma donors and products

Focus Area 5: Data Infrastructure Solutions

Recommendation: Establish, implement, and fund comprehensive, sustainable, minimally burdensome infrastructure that monitors and makes available real-time data on blood availability and utilization,

Building on current infrastructure and gap analysis, develop a plan for a hemovigilance and transfusion outcomes system and determine funding mechanism.

Key attributes of such an infrastructure include:

- Being rooted in legislation and/or regulation
- Promotes improved patient outcomes
- Ensures data confidentiality
- Minimizes reporting burden by key stakeholders
- Leverages existing electronic reporting platforms
- Captures data from the maximum number of blood centers and hospitals

Focus Area 6: Innovation

Recommendation 6.1: Establish a public-private partnership 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.

The goals of such a partnership applied to blood products could provide for the following:

- Utilize regulatory science in the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated blood products.

- Benefit patients by speeding the rate of important new products reaching the market by developing sound scientific and policy approaches to reduce the size and duration of pre-market clinical trials.
- Reduce time and resources needed for product development, assessment, and review. Utilize methods to allow rapid implementation of alternative approaches to supply blood product needs as exemplified in the response to past emergency situations such as hurricane Maria, other natural disaster scenarios, or situations involving specific military product needs.
- Establish early dialogue and coordination of clinical and development efforts with CMS and other government agencies regarding reimbursement policies and decision making to speed reimbursement programs and align with real costs as exemplified in the convalescent plasma program and funding of new screening tests for emerging pathogens at blood centers.
- Increase early discussion and collaboration between product developers and providers, regulatory scientists and decision makers as exemplified in the INTERACT program approach used by FDA for medical products.

Recommendation 6.2: Establish training and education workshops to instruct the general healthcare community on appropriate approaches and processes to use for regulatory approvals for the use of blood products (existing and new) under EUA, EAP and other appropriate approval mechanisms.

Focus Area 7: Finance

Recommendation: Identify and secure stable funding sources and mechanisms to support the national blood system in order to cover (but not be limited to) the following initiatives:

- Innovation that has the potential to improve the safety, efficacy, or reliability of the blood supply.
- Creation of redundant capacity in the blood system to reduce risk of blood product or critical supply shortages.
- Implementation of new mandated regulatory requirements that improve blood safety.
- Urgent financial needs of blood centers during national emergencies (e.g., the CARES Act).

OIDP Headquarters

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