March 28, 2023

The Honorable Bernard Sanders
Chair
U.S. Senate Committee on
Health, Education, Labor and Pensions
Washington, DC 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on
Health, Education, Labor and Pensions
Washington, DC 20510

The Honorable Robert Casey, Jr.
Member
U.S. Senate Committee on
Health, Education, Labor and Pensions
Washington, DC 20510

The Honorable Mitt Romney
Member
U.S. Senate Committee on
Health, Education, Labor and Pensions
Washington, DC 20510

RE: Senate Health, Education, Labor, and Pensions (HELP) Committee Pandemic and All-Hazards Preparedness Act (PAHPA) Reauthorization Request for Comments

Dear Chairman Sanders, Ranking Member Cassidy, Member Casey and Member Romney:

The Association for the Advancement of Blood and Biotherapies (AABB), America's Blood Centers (ABC), and the American Red Cross (ARC) appreciate the opportunity to provide comments on policies for consideration during the PAHPA reauthorization process. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

Our nation's blood supply is a critical aspect of emergency preparedness and response systems. Unlike other pharmaceuticals and biologics, blood cannot be manufactured to meet demand. Instead, our health care system relies on the continuous availability of donors to meet the ever-present needs of acute care patients as well as those with ongoing chronic conditions. Blood must be available for both day-to-day needs as well as for emergency surge responses. The finite shelf-life of blood components, coupled with the 24-48 hours required for testing post-donation, demands that blood already be available when emergencies occur.

Program Effectiveness: What specific changes could Congress make to improve the efficiency and effectiveness of current HHS programs and activities?

Public Health Emergency Coordination and Policy

1. **The authorities, duties, and functions of the Assistant Secretary for Preparedness and Response (ASPR)**
    - AABB, ABC and ARC encourage Congress to ensure that ASPR considers the availability of a safe, adequate blood supply as an essential part of its programs, policies, and procedures. As a vital part of the U.S. health care system, the blood community must be considered as an integral part of emergency preparedness; the essential role of blood collectors must be considered right from the start by federal, state, and local officials during disasters, including public health emergencies.

- Congress should require ASPR to work with federal, state, and local agencies to ensure the continuity of blood collection establishments' operations during disasters and public health emergencies by: (1) updating policies to prioritize blood collectors' access to PPE, blood bags, saline, reagents, vaccines and other critical supplies; (2) ensuring that blood collectors have priority access to transportation so that blood continues to be available to patients during an emergency; and (3) providing expedited customs clearance for critical items, equipment and supplies needed to maintain a safe and adequate blood supply.

2. The National Health Security Strategy (NHSS)

- AABB, ABC and ARC encourage Congress to specify that the National Health Security Strategy consider strategies to ensure the safety and resilience of the blood supply. During disasters and emergencies, it is the blood on the shelf that saves lives. Thus, Congress should ensure that the National Health Security Strategy provides resources and support for: (1) a regular blood donor population to ensure the continuous availability of a stable blood supply, (2) ensuring the diversity of the blood donor population, (3) a sufficient laboratory workforce, which is needed to collect, process, distribute and transfuse blood, and (3) integration of considerations of the blood supply and the related supply chain into preparedness and response policies and practices. There are significant challenges with each of these priority areas that should be considered as part of the National Health Security Strategy**.**

Medical Countermeasures Development and Deployment

1. The Strategic National Stockpile (SNS)

- Congress should continuously evaluate the policies regarding medical countermeasures (MCMs), the supply chain, and the SNS to determine how they can support the availability of the blood supply, and include all items, supplies and equipment required to collect, test, store, transport, and transfuse blood. One designated medical countermeasure (MCM) that receives little attention is the nation's blood supply. Blood products have short shelf-lives; platelets can be stored for less than a week from the date they are donated, red blood cells can be stored for up to six weeks and plasma can be frozen and stored for up to one year. Due to the unique nature of blood, it is not included in the SNS. Rather, the nation relies on a completely volunteer donor pool of millions of Americans annually to maintain the stockpile of this precious national resource. However, during the past several years there have been shortages of critical supplies and equipment needed to support the blood supply. Congress should ensure that blood collection establishments are prioritized as a critical part of the healthcare system for the purposes of distributing items from the SNS. Additionally, Congress should ensure that all items, equipment and supplies required to maintain a safe and adequate blood supply are available at all times.

- Congress should require HHS to convene stakeholders, including hospitals, blood collection establishments, manufacturers, and suppliers that are part of the nation's blood supply, to develop recommendations on how to strengthen the resiliency of the blood supply chain.

2. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan

- Congress should ensure the continuity of blood collection establishments' operations during disasters and public health emergencies by: (1) updating policies to prioritize blood collectors' access to PPE, blood bags, saline, reagents, vaccines and other critical supplies; (2) ensuring that blood collectors have priority access to transportation so that blood continues to be available to patients during an emergency; and (3) providing expedited customs clearance for critical items, equipment and supplies needed to maintain a safe and adequate blood supply.

Support for Jurisdictional Preparedness and Response Capacity

2. The Public Health Emergency Preparedness (PHEP) Cooperative Agreements

- The PHEP cooperative-agreement program should include considerations related to ensuring the safety and adequacy of the blood supply, such as including but not limited to supporting manufacturing capacity for blood and blood components, supply chain redundancy and resilience, and the development of a timely regulatory pathway that enables access to products and technologies that are not currently available but that could be sourced during emergencies.

3. The Hospital Preparedness Program (HPP) Cooperative Agreements

- As part of the Hospital Preparedness Program, AABB, ABC and ARC request that Congress provide the Department of Health and Human Services with the explicit authority to fund activities that support access to pre-hospital blood transfusions. Despite evidence indicating that providing pre-hospital blood transfusions to patients significantly improves patients' outcomes and long-term survival,[1,2,3] access to this service is quite limited. Traumatic injury resulting from hemorrhage is a leading cause of preventable death in trauma care, and delays in providing blood products increases the risk of mortality in patients with severe traumatic bleeding.[4] Unfortunately, only 0.6% of prehospital patients in the United States who could benefit from blood products are currently transfused.[5] The use of pre-hospital blood products is widespread within the Department of Defense trauma system and civilian pilot projects have shown that pre-hospital transfusion programs can be successfully implemented. Early civilian EMS pilot projects have demonstrated success deploying pre-hospital blood products in both traumatic and other causes of hemorrhagic shock.

[1] Butler FK, Holcomb JB, Schreiber MA, et al. Fluid Resuscitation for Hemorrhagic Shock in Tactical Combat Casualty Care: TCCC Guidelines Change 14-01-2 June 2014. J Spec Oper Med. 2014 Fall;14(3):13-38.
[2] Sperry JL, Guyette FX, Brown JB, et al. Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock. N Engl J Med. 2018 Jul 26;379(4):315-326.
[3] Shackelford SA, del Junco DJ, Powell-Dunford N, et al. Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan With Acute and 30-Day Survival. JAMA. 2017;318(16):1581.
[4] Holcomb JB, Tilley BC, Baraniuk S, et al. Transfusion of Plasma, Platelets, and Red Blood Cells in a 1:1:1 vs a 1:1:2 Ratio and Mortality in Patients With Severe Trauma: The PROPPR Randomized Clinical Trial. *JAMA*. 2015;313(5):471–482.
[5] Hashmi ZG, Chehab M, Nathens AB, et al. Whole truths but half the blood: Addressing the gap between the evidence and practice of pre-hospital and in-hospital blood product use for trauma resuscitation. Transfusion, Accepted, 2021.

4. Other ASPR activities financed through the general HPP budget, such as the Regional Disaster Health Response System (RDHRS) demonstration projects.

- As part of the Hospital Preparedness Program, AABB, ABC and ARC request that Congress provide the Department of Health and Human Services with the explicit authority to fund activities that support access to pre-hospital blood transfusions. Despite evidence indicating that providing pre-hospital blood transfusions to patients significantly improves patients' outcomes and long-term survival,[6,7,8] access to this service is quite limited. Traumatic injury resulting from hemorrhage is a leading cause of preventable death in trauma care, and delays in providing blood products increases the risk of mortality in patients with severe traumatic bleeding.[9] Unfortunately, only 0.6% of prehospital patients in the United States who could benefit from blood products are currently transfused.[10] The use of pre-hospital blood products is widespread within the Department of Defense trauma system and civilian pilot projects have shown that pre-hospital transfusion programs can be successfully implemented. Early civilian EMS pilot projects have demonstrated success deploying pre-hospital blood products in both traumatic and other causes of hemorrhagic shock.

5. Biosurveillance and Public Health Situational Awareness

- AABB, ABC and ARC encourage Congress to explicitly recognize and dedicate resources to support the screening, testing and surveillance activities conducted by blood collection establishments, which possesses unique, well-established expertise that is critical to the nation's public health infrastructure. Blood collection establishments effectively recruited over 13 million healthy individuals who presented to donate in 2019,[11] and test blood donations for a variety of infectious disease pathogens, such as human immunodeficiency virus (HIV), hepatitis B and C, West Nile virus, Babesia and Chagas disease among others.[12] Many blood collectors implemented Biosurveillance for COVID-19, which enabled the government to understand the percentage of people in the United States who had antibodies against SARS-CoV-2 and to track how that percentage changed over time.[13] Similarly, the blood community was instrumental in surveillance related to Zika Virus, even though many significant activities were unfunded. These screening, testing and surveillance efforts are a critical part of the public health infrastructure, can benefit donors, patients, local communities, and the nation, and often support other non-health care sectors.

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[6] Butler FK, Holcomb JB, Schreiber MA, et al. Fluid Resuscitation for Hemorrhagic Shock in Tactical Combat Casualty Care: TCCC Guidelines Change 14-01-2 June 2014. J Spec Oper Med. 2014 Fall;14(3):13-38.
[7] Sperry JL, Guyette FX, Brown JB, et al. Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock. N Engl J Med. 2018 Jul 26;379(4):315-326.
[8] Shackelford SA, del Junco DJ, Powell-Dunford N, et al. Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan With Acute and 30-Day Survival. JAMA. 2017;318(16):1581.
[9] Holcomb JB, Tilley BC, Baraniuk S, et al. Transfusion of Plasma, Platelets, and Red Blood Cells in a 1:1:1 vs a 1:1:2 Ratio and Mortality in Patients With Severe Trauma: The PROPPR Randomized Clinical Trial. *JAMA*. 2015;313(5):471–482.
[10] Hashmi ZG, Chehab M, Nathens AB, et al. Whole truths but half the blood: Addressing the gap between the evidence and practice of pre-hospital and in-hospital blood product use for trauma resuscitation. Transfusion, Accepted, 2021.
[11] Mowla, SJ, Sapiano, MRP, Jones, JM, Berger, JJ, Basavaraju, SV. Supplemental findings of the 2019 National Blood Collection and Utilization Survey. Transfusion. 2021; 61: S11– S35. https://doi.org/10.1111/trf.16606.
[12] Centers for Disease Control and Prevention, Blood Safety Basics, *available at* https://www.cdc.gov/bloodsafety/basics.html (last visited October 13, 2022).
[13] Jones JM, Stone M, Sulaeman H, et al. Estimated US Infection- and Vaccine-Induced SARS-CoV-2 Seroprevalence Based on Blood Donations, July 2020-May 2021. *JAMA.* 2021;326(14):1400–1409. doi:10.1001/jama.2021.15161

Gaps in Current Activities & Capabilities

1. ***What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above, or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)***

    - To help address the gaps in the PAHPA framework, we encourage Congress to adopt and implement the recommendations that were included in the HHS Report to Congress: Adequacy of the National Blood Supply (2020),[14] which include opportunities to improve the nation's blood safety and availability during public health emergencies. The recommendations in the Report to Congress are complimented by recommendations made at the September 25, 2020 meeting of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA).

2. ***Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?***

    - We encourage Congress to include the laboratory workforce in all health care workforce solutions intended to address current shortages and strengthen the pipeline of skilled laboratory professionals for the future. For example, we encourage Congress to establish a program within the HHS Health Resources and Services Administration (HRSA) that is charged with addressing laboratory workforce challenges. Laboratory workforce shortages are pervasive and are impacting blood collectors, hospitals' transfusion medicine service laboratories, and biotherapies laboratories. 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.

Partnerships: What specific steps could Congress take to improve partnerships with states and localities, community-based organizations, and private sector and non-government stakeholders, such as hospitals and health care providers, on preparedness and response activities? For example:

1. ***How can these entities be better supported in appropriately engaging with the federal government to understand available resources, capabilities, and expectations prior to, during, and following a public health emergency?***

    - Congress should require HHS to convene stakeholders, including hospitals, blood collection establishments, manufacturers, and suppliers that are part of the nation's blood supply, to develop recommendations on how to strengthen the resiliency of the blood supply chain.

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[14] 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-congress2020.pdf.

Thank you for the opportunity to offer these comments on the PAHPA reauthorization process. We look forward to continuing to work with Congress on recommendations related to maintaining a safe and adequate national blood supply. If you have any questions or need additional information, please contact If you have any questions, please contact Susan Leppke (301-547-3962, sleppke@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org), or Julie Manes (202-417-5147, julie.manes@redcross.org).

Sincerely,

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