



Advancing Transfusion and
Cellular Therapies Worldwide



May 4, 2018

The Honorable Lamar Alexander
U.S. Senate
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
U.S. Senate
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Richard Burr
U.S. Senate
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Robert P. Casey, Jr.
U.S. Senate
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Senators Alexander, Murray, Burr and Casey:

AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross commend the Senate Health, Education, Labor and Pensions (HELP) Committee's commitment to improving the nation's preparedness and response capabilities through the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) and appreciate the opportunity to comment on the discussion draft. Collectively, our organizations represent the nation's blood centers, hospital-based blood banks and transfusion services, and transfusion medicine professionals.

Our nation's blood supply is a unique, and often overlooked, aspect of emergency preparedness and response systems. Unlike other pharmaceuticals and biologics, blood cannot be manufactured to meet demand. Instead our healthcare system relies on the continuous availability of non-remunerated donors to meet the ever-present needs of acute care patients as well as those with ongoing chronic conditions. Independent, non-profit blood centers support this need by maintaining inventories sufficient to meet both day-to-day needs and acute surges, as well as preparedness for more extended 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.

Given the vital importance of a safe and robust blood supply, we urge the Committee to further recognize the role of blood centers in the final legislation. Specifically, we recommend amending the discussion draft to promote coordination among blood centers and other key stakeholders and to include blood centers in incentive programs intended to help implement emergency planning measures.

We would appreciate the opportunity to meet with Senate HELP Committee staff to further share our interest in prioritizing the safety and availability of the nation's blood supply when reauthorizing PAHPA. To that end, we offer the following suggestions to the discussion draft.

- We commend the Committee for specifically acknowledging that blood banks should be consulted when the Assistant Secretary for Preparedness and Response (ASPR) develops guidelines for regional public health emergency preparedness and response systems (Section

302 (42 U.S.C. §319C-3(c)(1)). Including blood centers in this process is paramount and consistent with the Department of Health and Human Services' (HHS) recognition of blood as one of the core functional areas in Emergency Support Function #8 of the National Response Framework.

- In addition to including blood centers in 42 U.S.C. §319C-3(c)(1), we believe it is important to include blood centers in subsection (c)(3) of that same section, which requires the ASPR to “consider financial requirements and potential incentives for facilities to prepare for and respond to public health emergencies.” Non-profit blood centers face significant financial challenges related to voluntary and mandated emergency functions for which they are expected to prepare. Given that blood is an essential part of the nation’s trauma system, emergency preparedness and response system and healthcare system generally, it is essential that financial barriers not impede the availability of safe blood ahead of and during response activities.
- The discussion draft includes several provisions related to medical countermeasures (MCMs) and the strategic national stockpile (SNS). However, one designated 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 up to one year. All of this must be done in precisely controlled environments. Due to the unique nature of blood and the financial cost of maintaining a constant supply, 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 in advance of need. We believe that policies that support the availability of the blood supply are needed. We welcome the opportunity to work with the Committee to envision a solution in this area.
- We appreciate the Committee’s commitment to advancing new technologies to prepare for emerging infectious diseases and other public health threats, and encourage the Committee to consider policies that facilitate the adoption of these important public health measures. The undersigned organizations are committed to protecting the U.S. blood supply from emerging infectious diseases, and the availability and accessibility of new technologies is critical to this goal. We commend the Biomedical Advanced Research and Development Authority (BARDA) for the critical support it has provided to advancing new technologies that protect the blood supply, such as two tests to screen blood donations for the Zika virus. Nevertheless, current policies do not provide similar support for the implementation of these safety technologies. For instance, while the screening tests were still under investigational new drug (IND) protocols, the Food and Drug Administration (FDA) required all blood collected throughout the United States to either be screened for Zika or treated with pathogen reduction technology. The blood community successfully met the challenge of implementing the FDA’s requirements within four weeks of an emergency FDA guidance for high-risk areas and 12 weeks for the rest of the country. HHS estimated in the attached June 2017 study that the universal adoption of these Zika screening

tests would cost the blood system approximately \$137 million annually.¹ We urge the Committee to consider policies that support and finance the implementation of new technologies that are required for blood safety.

Including the U.S. blood system in these provisions, as well as in several others throughout the discussion draft, would support recommendations included in a 2016 RAND report, commissioned by HHS, which assessed the sustainability of the U.S. blood system. The authors of the report made the following four recommendations related to surge capacity for the blood system: (1) develop and disseminate a vision for appropriate levels of surge capacity; (2) subsidize blood centers' ability to maintain surge capacity; (3) build relationships with brokers and other entities to form a blood safety net; and (4) implement emergency use authorization and contingency planning.² In addition, the authors of the report recommend that HHS "build a value framework for new technology and determine which technologies to encourage and pay for."³

AABB, America's Blood Centers and the American Red Cross welcome the opportunity to work with the Committee to ensure that the bill reauthorizing PAHPA continues to promote the safety and availability of the U.S. blood supply. Thank you for considering our comments. If you have any questions or need additional information, please contact AABB (Leah Stone, lmstone@aabb.org, 301-215-6554), America's Blood Centers (Kate Fry, kfry@americasblood.org, 202-654-2911) and American Red Cross (Dawn Latham, Dawn.Latham@redcross.org, 202-303-4219). We look forward to the possibility of discussing these and other issues with you.

Mary Beth Bassett
President
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

James C. Hrouda
President, Biomedical Services
American Red Cross

¹ Ellingson KD, Sapiano MRP, Haass KA, et. al. *Cost projections for implementation of safety interventions to prevent transfusion-transmitted Zika virus infection in the United States*. *Transfusion*. 2017 June; 57 (Suppl 2): 1625 – 1633.

² *Toward a Sustainable Blood Supply in the United States: An Analysis of the Current System and Alternatives for the Future*, by Andrew W. Mulcahy, Kandice Kapinos, Brian Briscoombe, Lori Uscher-Pines, Ritika Chaturvedi, Spencer Reynolds Case, Jakub Hlavka, and Benjamin M. Miller, RR-1575-DHHS, 2016 (available at rand.org/t/RR1575).

³ *Toward a Sustainable Blood Supply in the United States: An Analysis of the Current System and Alternatives for the Future*, by Andrew W. Mulcahy, Kandice Kapinos, Brian Briscoombe, Lori Uscher-Pines, Ritika Chaturvedi, Spencer Reynolds Case, Jakub Hlavka, and Benjamin M. Miller, RR-1575-DHHS, 2016 (available at rand.org/t/RR1575).