



October 23, 2018

Dr. Robert Kadlec
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Dr. Kadlec,

AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross appreciate the opportunity to provide feedback regarding the Assistant Secretary for Preparedness and Response's (ASPR's) four pillars to achieving national health security. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

The safety and availability of the blood supply is critical to achieving national health security and sustaining public health security capabilities. Blood components are an essential treatment in trauma and are also medically necessary treatments for patients with certain chronic health conditions. Yet, our nation's blood supply is often an overlooked and misunderstood aspect of emergency preparedness and response systems. In the U.S., blood is typically collected, processed, and stored at regional non-profit blood centers and is distributed to hospitals on a daily or weekly basis. Unlike other pharmaceuticals and biologics, blood cannot be manufactured to meet demand. Instead, the blood supply relies on a volunteer donor pool of millions of Americans annually to maintain this precious national resource in advance of need. Blood components have a finite shelf-life and require 24-48 hours post-donation for testing and processing. Hence, blood must be collected from volunteer donors on an on-going basis.

During a time of crisis, patients' access to blood components is critical. The nation's blood supply is recognized as a medical countermeasure. However, due to the unique nature of blood and the financial cost of maintaining a constant supply, it is not included in the Strategic National Stockpile. Rather, 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. 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 challenges facing blood centers are augmented by financial constraints and dwindling inventories due to challenges including a shrinking donor pool and compliance with voluntary and mandatory safety requirements. In addition, current reimbursement mechanisms are not aligned with the blood community's role in protecting the public's health. For instance, in 2016 the Food and Drug Administration required that all blood collection establishments in the U.S. implement a requirement within 4 to 12 weeks that blood either be screened for Zika or treated with pathogen reduction technology. The Department of Health and Human Services (HHS) estimated in a June 2017 study that the universal adoption of these Zika screening tests would cost the blood system approximately \$137 million annually. A recent study published in the New England Journal of Medicine concluded that screening individual

blood donations for Zika not only had a high cost, but also had a low yield; out of 4 million blood donations screened, only nine were confirmed positive for Zika. Although the Biomedical Advanced Research and Development Authority (BARDA) provided critical financial support to advance new technologies that protect the blood supply, there have not been similar investments to encourage the implementation of these safety technologies. We believe that public policies need to support and finance the implementation of new technologies that are required for blood safety.

In addition, the nation's blood supply must be fully integrated into regional disaster health response systems. Our organizations support several provisions included in the House version of the Pandemic and All-Hazards Preparedness Act (PAHPA) that recognize the unique needs of the U.S. blood supply. First, the bill requires the ASPR to develop and update guidelines for regional health care emergency and response systems in consultation with blood banks and other key stakeholders, and to consider feedback related to potential financial implications for blood centers to implement and follow the guidelines. Second, within one year of enactment, HHS would be required to issue a report that contains "recommendations related to maintaining an adequate national blood supply, including challenges associated with the continuous recruitment of blood donors (including those newly eligible to donate); ensuring the adequacy of the blood supply in the case of public health emergencies; implementation of the transfusion transmission monitoring system; and other measures to promote safety and innovation, such as the development and use or implementation of new technologies, processes and procedures to improve the safety and reliability of the blood supply."

Including blood centers in establishing and updating guidelines for regional health care emergency and response systems is paramount and consistent with the HHS recognition of blood as one of the core functional areas in Emergency Support Function #8 of the National Response Framework. Under ESF#8, HHS monitors and coordinates the need for blood components and related medical supplies in coordination with the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (AABB Disaster Task Force). The AABB Disaster Task Force is comprised of representatives from U.S. blood services, associations and commercial entities, as well as liaisons from governmental agencies, who work together in an effort to ensure that safe and adequate blood product inventories are in place at all times in preparation for or response to disasters. While many blood centers have made inroads with their local emergency management agencies, they must be fully integrated into regional disaster health response systems to ensure a seamless transition. Our organizations, which are all members of the AABB Disaster Task Force, stand ready to assist ASPR in connecting regional disaster health response systems with blood collection establishments.

AABB, America's Blood Centers and the American Red Cross welcome the opportunity to work with the ASPR to implement these and other areas related to the safety and availability of the U.S. blood supply. We thank the ASPR for promoting interdisciplinary dialogue and transparency on the future of pandemic and all-hazards preparedness. 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 (Julie Manes, Julie.Manes@redcross.org, 202-303-4219).

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