



Advancing Transfusion and  
Cellular Therapies Worldwide

## **National Preparedness and Response Science Board (NPRSB) and National Advisory Committee on Children and Disasters (NACCD) Joint In-Person Public Meeting**

Dear Dr. Spires,

AABB urges the National Preparedness and Response Science Board (NPRSB) and the National Advisory Committee on Children and Disasters (NACCD) to consider the serious threats to the sustainability of the U.S. blood system as critical issues jeopardizing national health security, emergency preparedness efforts and the public's health.

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. AABB members include physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB is committed to advocating for policies that support two broad objectives: (1) ensuring that patients and healthcare providers have adequate, appropriate access to safe transfusion medicine and cellular therapies; and (2) promoting patient and donor care and safety in transfusion medicine and cellular therapies.

Blood components are unique and limited since they originate from volunteer donors, are perishable products and have short shelf lives. Additionally, blood components are essential medicines. They are used as routine treatments for patients with chronic health conditions, such as anemia, gastrointestinal bleeding, infection, liver failure, hematological disorders, cancer and other illnesses. They are also frequently necessary for patients who lose blood during surgery or because of injury. In addition to these predictable uses, blood components must be available in emergencies for immediate resuscitation, traumas, massive transfusion protocols and other critical treatments, such as for burn victims. Thus, any known threats to the availability of a safe blood supply are potentially catastrophic and are relevant to the nation's health security and emergency preparedness.

Despite being essential to emergency preparedness and healthcare generally, the sustainability of the blood system is in jeopardy. The blood system is facing challenges that limit the necessary flexibility of the blood system to respond in the event of disasters and emergencies and reduce access to new safety technologies. These obstacles were highlighted by the Advisory Committee for Blood and Tissue Safety and Availability (ACBTSA),<sup>1</sup> the ACBTSA

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<sup>1</sup> E.g. Meeting proceedings and recommendations from the forty-seventh ACBTSA meeting, November 9-10, 2015, available at <http://www.hhs.gov/ohaidp/initiatives/blood-tissue-safety/advisory-committee/recommendations/2015-11-09/index.html?language=en>, and meeting proceedings and recommendations from the forty-eighth ACBTSA meeting, November 28-29, 2016, available at <http://www.hhs.gov/ohaidp/initiatives/blood-tissue-safety/advisory-committee/meetings/2016-11-28/index.html>.



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Subcommittee on Blood System Sustainability, a report issued in November 2016 by the RAND corporation,<sup>2</sup> and stakeholders in the public and private sectors, and include:

- Reduced demand for blood due to medical advances and the successful implementation of patient blood management (PBM) programs;
- A contracting donor pool, resulting from aging donors, increases in exclusion criteria and deferrals and reduced investment in recruitment by blood centers;
- Consolidation throughout the health care system, including hospital consolidation and blood center mergers and alliances;
- Regulatory barriers;
- Flawed payment policies; and
- Vulnerabilities to public health emergencies and emerging infectious diseases, such as Zika virus.<sup>3</sup>

As a result of these pervasive challenges, non-profit blood centers and other providers in the United States have limited resources to invest in research and development, which is necessary for innovation and to continue to advance the safety and efficiency of blood and transfusion services. Furthermore, existing obstacles may result in fewer new technologies being introduced or adopted by the blood system, since there may be insufficient return on investment to work on products aimed at advancing blood safety and inadequate reimbursement to encourage adoption by blood centers and providers.<sup>4</sup>

The November 2016 report by the RAND corporation included recommendations related to data collection, surge capacity, and safety and innovation. For example, it is currently impossible to fully understand the real-time status of the blood supply or predict the needs of the country due to the absence of real-time data on blood utilization, frequency of regional blood shortages, lack of integrated health information technology and an insufficient understanding of what is needed to establish and maintain surge capacity. In addition, the nation does not have a strategy for ensuring that the blood system has sufficient surge capacity to be able to respond in disasters and emergencies.

AABB encourages NPRSB and NACCD to work with public and private stakeholders to ensure the sustainability of the U.S. blood system since the availability of blood components is vital to health security, emergency preparedness and public health activities. AABB appreciates the significant expertise and important role of government officials and staff who work in the offices and agencies that touch the blood system, such as the Food and Drug Administration, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the National Institutes of Health, the Department of Defense, the Department of Veterans' Affairs, the Office of the Assistant Secretary of Health, and the Office of the Assistant Secretary for

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<sup>2</sup> Mulcahy, Andrew W., Kandice Kapinos, Brian Briscoe, Lori Uscher-Pines, Ritika Chaturvedi, Spencer R. Case, Jakub Hlavka and Benjamin M. Miller. *Toward a Sustainable Blood Supply in the United States: An Analysis of the Current System and Alternatives for the Future*. Santa Monica, CA: RAND Corporation, 2016.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*



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Preparedness and Response. We support the ongoing work of the ACBTSA and the ACBTSA Subcommittee on Blood System Sustainability. In addition, AABB's unique mission and broad membership, which represents the U.S. blood system from "vein-to-vein," includes donors, patients, blood centers, hospitals, clinicians and suppliers, is committed to ensuring the sustainability of a safe, available blood system.

AABB would welcome the opportunity to work with NPRSB, NACCD and other public and private stakeholders to continue exploring workable solutions aimed at advancing the sustainability of a safe, available blood system. If you have any questions or need additional information, please contact Leah Stone, Director of Public Policy and Advocacy at [lmstone@aabb.org](mailto:lmstone@aabb.org) or 301-215-6554.

Sincerely,

Zbigniew M. Szczepiorkowski, MD, PhD, FCAP  
President  
AABB