



Advancing Transfusion and
Cellular Therapies Worldwide

**Advisory Committee on Blood and Tissue Safety and Availability
November 28 -29, 2016
AABB Public Comment**

My name is Dr. Zbigniew M. Szczepiorkowski and I am an associate professor of pathology and of medicine at Geisel School of Medicine at Dartmouth College. I am the president of AABB, and am offering these comments on behalf of AABB.

AABB is an international, 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 membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

AABB commends the Department of Health and Human Services for sponsoring the blood sustainability study conducted by the RAND Corporation and dedicating resources to analyze the current blood system. The RAND report accurately describes several widely recognized, significant stressors currently challenging all segments of the blood system. AABB urges the Advisory Committee to consider the following comments when developing recommendations for HHS to consider:

1. The RAND report fails to capture the urgency of the challenges facing the United States' fragile blood system;
2. The report is based on incomplete data and does not account for feedback from all key stakeholders in the current blood system; and
3. The report does not recognize that the government's siloed approach to overseeing the blood system limits communications and comprehensive analyses on how decisions will impact the blood system from "vein to vein."

I will now address each of these points in more detail.

Most significantly, the report does not reflect the immediate nature of the threats to the United States' fragile blood system.

Blood and blood products are unique and limited since they originate from volunteer donors, are perishable products and have short shelf lives. Despite these characteristics, blood and blood products are essential medicines. They are used as routine treatments for patients with chronic health conditions as well as life-saving therapies for patients who have experienced traumas, mass casualty events and other unforeseeable circumstances. Thus, known threats to the



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availability of a safe blood supply are potentially catastrophic and warrant immediate attention and action.

The RAND report highlights several significant challenges currently facing the blood system, including the shrinking donor pool, reduced demand for blood, consolidation throughout the health care system, reduced profits for blood centers and suppliers, workforce shortages, lack of integrated health information technology, barriers to innovation, declining investment in research and development, and vulnerabilities to emerging threats and public health emergencies. In spite of these threats, the report concludes that “the U.S. blood system under the *status quo* operates effectively and in many cases efficiently.” AABB believes that this conclusion is shortsighted, is not data-driven, and does not reflect a system which needs to proactively evolve *before* one of the many existing challenges results in reduced safety or availability of blood and blood products.

Although the RAND report specifically mentions the “vein to vein” process of the blood system, AABB does not believe that the report reflects experiences from all key stakeholders involved in the system.

AABB’s broad membership is uniquely aligned with the “vein to vein” approach to the blood system, and we appreciate the important role all stakeholders have in the blood system. AABB was surprised that RAND did not solicit feedback or engage with clinicians who routinely utilize blood as part of their medical practices. Similarly, the report barely acknowledges patients and does not account for their experiences with the blood system. The report discusses the shrinking donor pool, but there is no indication that RAND considered feedback from donors or prospective donors. AABB believes that feedback from these key stakeholders is essential to developing policies that ensure that patients have timely access to safe, medically necessary blood and blood products and that donors are safe.

AABB believes that the sample size of study participants was too small and is not reflective of the United States. We question whether eight hospitals, including one hospital with fewer than 500 beds representing the entire west coast and one hospital with fewer than 500 beds representing the south, accurately represents the experiences of all hospitals throughout the country. Similarly, only nine blood centers participated in the study, so feedback from that sector of the blood system is limited.

In addition, AABB believes that certain relevant government regulators and policymakers that were not included in the study could have provided helpful insight into different, important aspects of the current blood system. For example, although officials from the Food and Drug Administration’s Center for Biologics Evaluation and Research were interviewed, it does not appear that RAND interviewed other officials from other centers in FDA who touch on products used in the blood system. Similarly, it is unclear which officials at the Centers for Medicare & Medicaid Services participated in the study. We are uncertain whether RAND considered feedback from CMS officials who are responsible for inpatient hospital payment policy and outpatient hospital payment policy, which are both key to understanding the current blood



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system. Likewise, AABB is uncertain whether RAND engaged with CMS officials responsible for administering CLIA, which regulates several activities at blood centers and in transfusion services.

Also, it is striking that the Department of Defense was not interviewed for the study. As noted in the chapter providing an overview of the U.S. blood system, DOD has a separate blood collection system that is partially integrated with the broader U.S. blood system and funds a significant amount of blood-related research. DOD's feedback is especially relevant since the blood system is an integral part of emergency preparedness and in emergencies, the military is an instrumental partner in ensuring that blood is available to patients.

Despite discussing key private and governmental stakeholders, the report does not recognize how current silos contribute to weaknesses that threaten the sustainability of the blood system.

AABB appreciates the significant expertise of government officials and staff who work in the offices and agencies that touch the blood system, such as FDA, CDC, CMS, NIH, DOD, VA, the Office of the Assistant Secretary of Health, and the Office of the Assistant Secretary for Preparedness and Response. Importantly, each of these organizations has a unique mission, and the way they approach and regulate various aspects of the blood system is aligned with their independent missions. As a result, new policies or positions from one office may have significant operational or downstream effects that have not been considered, but which may threaten the availability of safe blood and blood products. There is no central body to manage efforts or to ensure that policies are coordinated or workable for the diverse array of stakeholders that are key for a sustainable blood system. Regular intra-agency and interagency communication, coordination, policymaking and analyses are especially important because of the unique nature of blood and blood products, and because blood system sustainability is key to emergency preparedness.

AABB believes that a sustainable blood system ensures that patients have timely access to safe, medically necessary blood and blood products, and that donors are safe. It is critical that HHS continue to work with stakeholders to address the current flaws in the blood system.

AABB believes that the publication of the RAND report and this ACBTSA meeting represent an important step in advancing the U.S. blood system. AABB will continue to provide ACBTSA and HHS with additional feedback as our members have an opportunity to digest the RAND report and its findings. We encourage ACBTSA to recommend that HHS continue engaging with all stakeholders involved in the blood system to explore policies that promote the sustainability of the blood system. To that end, AABB urges ACBTSA to recommend that HHS establish a working group comprised of representatives from all relevant government agencies, as well as hospitals, blood centers, private insurers, and other key stakeholders, to review and develop action plans to address key issues highlighted in the report. The working group's progress should



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be provided to ACBTSA on a regular basis, so that actions based on the feedback can be initiated in a timely manner.

Thank you for the opportunity to comment on the RAND report. AABB looks forward to continuing our work with ACBTSA, HHS and all stakeholders in the public and private sectors to advance the United States' blood system and work towards achieving a sustainable blood supply.