



December 22, 2023

James Berger
Designated Federal Officer for ACBTSA
Office of Infectious Disease and HIV/AIDS Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services
Tower Building
1101 Wootton Parkway
Rockville, MD 20852

Sent via email: ACBTSA@HHS.gov

Re: ACBTSA Public Comment

Dear Mr. Berger:

The Association for the Advancement of Blood & Biotherapies (AABB), America's Blood Centers (ABC), and the American Red Cross (ARC) appreciate the opportunity to submit comments in response to the U.S. Department of Health and Human Services' (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recommendations related to the sustainability of the blood supply during national emergencies.

While we generally support the recommendations of the Committee, we provide several recommendations and comments below. Please note that we have limited our comments to the recommendations and are not commenting on the findings of the ACBTSA (i.e., the introduction and the whereas clauses throughout the recommendations). Such silence does not imply consent, but instead a focus by our organizations on the actionable portions of the document. As such, our comments are confined to and address only the actual recommendations (Recommendation 1 - Recommendation VII).

Recommendation 1: The Committee therefore recommends that during national and regional emergencies, government resources are made available to assist blood collection centers with the transport of blood samples and other key supplies that may be needed in affected areas of the country. The Emergency Support Function (ESF) #8 planning document should specifically incorporate this provision into their planning function. This may be done with an annex to the ESF.

AABB, ABC and ARC support this recommendation.

Recommendation 2: The Committee further recommends an analysis of all required blood supply functions with cross-reference to the ESF #8 planning document to ensure that all functions are appropriately covered with an annex to the ESF.

AABB, ABC and ARC support this recommendation.

Recommendation 3: The Committee therefore recommends that the Zika payment model be used during long-term emergencies to support the collection and manufacture of blood components to allow for a minimum 10 percent increase over baseline usage during emergencies when surge capacity is required.

AABB, ABC and ARC support the Zika payment model but encourage expansion of the model to (1) ensure blood establishments are not collecting blood at risk and are receiving necessary financial support through cost recovery funding, similar to the collection and distribution of COVID convalescent plasma (CCP), and (2) establish funding for local public awareness about the need for blood donors.

Throughout 2020 and 2021, the Biomedical Advanced Research and Development Authority (BARDA), under the Administration for Strategic Preparedness and Response (ASPR), provided cost recovery funds for collection of CCP through contracts with ABC and ARC. A key element of the CCP model was the provision of cost recovery funding upon collection, not distribution. By providing cost recovery directly to blood collectors upon collection of units requested as part of the CCP surge, blood centers were able to invest in the collection of CCP even where the cost of collection would have been otherwise prohibitively expensive. The shift in the model to cost recovery funding upon collection resulted in significant increases in the level of surge witnessed throughout the country.

Another essential aspect of the CCP model was the provision of funding for local public awareness about the need for a surge in blood donations. Availability of donors will likely be the greatest threat to long-term surge capacity, and it is critical that message be tailored to local communities. During the COVID-19 pandemic, such funding for local awareness was distributed through an Other Transaction Authority (OTA) with ABC and resulted in a sustained 244% increase in collections compared to previous baselines.

Recommendation 4: The Committee therefore recommends that Secretary Becerra fund additional public awareness campaigns including funding for data analytics to increase the donor pool and determine effectiveness.

AABB, ABC and ARC commend HHS for their support of the blood community during the COVID-19 pandemic and for their efforts in carrying out the congressional requirement of a public awareness campaign for blood.

While we remain supportive of the campaign, we believe the best use of any future federal funding for public awareness for blood donation is best directed locally. As stated above, funding for local awareness distributed directly to blood centers as part of an Other Transaction Agreement between the US Government and ABC during COVID-19 resulted in a 244% increase in collections.

It is essential that the U.S. Government invest in local funding for blood establishments to use in

increasing awareness of blood donation, especially among diverse, young, and newly eligible individuals. AABB, ABC and ARC recommend that the Committee emphasize the need to provide funding for public awareness campaigns at the local level.

Recommendation I: The Committee recommends that an agency within HHS be charged with safeguarding the availability of blood.

- a. **This agency should work closely with FDA so that regulatory measures developed for blood safety are balanced by the need to maintain blood availability.**

Our organizations request ACBTSA revise this recommendation to read “The Committee recommends that the HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) create a publicly available action plan that (1) includes specific activities to safeguard the availability of blood and (2) indicates how the agency intends to implement coordination and collaboration with other federal entities, including the FDA.”

We believe that this revised recommendation would complement the implementation of an existing statutory requirement related to the safety and availability of the blood supply. Specifically, as a result of the advocacy efforts of the blood community, Section 2233 of the PREVENT Pandemics Act was incorporated into the Consolidated Appropriations Act of 2023 (P.L. 117-328). This section mandates the Secretary of HHS to facilitate coordination and collaboration among relevant federal departments and agencies concerning the safety and availability of the blood supply. The Secretary is also required to engage with private stakeholders, such as blood collection establishments, healthcare providers, accreditation organizations, researchers, and patients, to address issues pertaining to the safety and availability of the blood supply.¹

As explained in a related report from the Congressional Research Service, the OIDP currently oversees the coordination of blood safety and emergency preparedness and response activities.² Further, OIDP has demonstrated collaboration with other agencies through activities outlined in national action plans to prevent infectious disease. Therefore, we believe that ACBTSA’s recommendation can support the implementation of the provision from the PREVENT Pandemics Act and enhance coordination and collaboration throughout the Federal government.

Recommendation II: The Committee recommends that companies providing critical supplies for blood manufacturing and storage shall work with HHS funding agencies to develop and enact contingency plans to stabilize the blood supply chain.

While we support the essence of the recommendation, our organizations would like to propose a revision to further enhance its clarity and effectiveness. Specifically, we recommend that ACBTSA revise the language to explicitly identify the HHS funding agencies with which the

¹ 42 U.S.C. § 247d-12

² Sekar, Kavya. (2023, August 15). *PREVENT Pandemics Act (P.L. 117-328, Division FF, Title II)*. (CRS Report No. RL47649), <https://crsreports.congress.gov/product/pdf/R/R47649>.

companies should collaborate. This adjustment will provide a more precise and actionable directive for the entities involved.

Recommendation III: The Committee recommends that OASH or other HHS funding organization receive an enabling budget to be used for projects that stabilize the blood supply such as stockpile of key supplies and components.

We endorse this recommendation; however, as blood and blood components are a critical resource required during a range of disasters, activities to ensure this critical and lifesaving product is available during these emergencies, including the creation of a blood-related supply stockpile, would be within the purview of ASPR. As the federal agency overseeing the nation's medical and public health preparedness, response to, and recovery from disasters and public health emergencies, ASPR receives Congressional funding for these crucial activities, which include managing the Strategic National Stockpile (SNS).³

We request that the ACBTSA also recommend that “the Assistant Secretary of Health recommend that ASPR (1) elucidate its role in stabilizing the blood supply chain and (2) revise its policies pertaining to Medical Countermeasures (MCMs) to ensure the availability of essential items, including but not limited to, blood bags, saline, reagents, pipettes and other critical components necessary for maintaining a secure and adequate blood supply.”

Recommendation IV: The Committee recommends that an HHS funding organization offer grant or contract funding that enables the development of novel means for extending the outdate of perishable materials in the stockpile.

Our organizations respectfully request that ACBTSA revise the recommendation to request that HHS (1) identify the specific HHS funding organization entrusted with overseeing and implementing this endeavor, and (2) specify which agencies within HHS are responsible for advancing strategies to extend the shelf life of perishable materials.

Recommendation V: The Committee recommends that the ACBTSA convene a working group dedicated to developing a risk-gap analysis with associated business costs for the mitigations and contingencies associated with these temporary regulatory measures.

- b. The FDA should be engaged in this analysis to assess the risks.**
- c. This work should be completed by the end of calendar year 2024.**

AABB, ABC, and ARC recommend revising this recommendation to read, “The Committee recommends that HHS, including the FDA, work to convene a multiorganizational working group, including government agencies and national experts from leading blood associations and organizations, to identify potential opportunities to pre-establish additional regulatory flexibility that could be granted in case of short or long-term surge capacity needs to extend the U.S. blood

³ Administration for Strategic Preparedness & Response, About ASPR, <https://aspr.hhs.gov/AboutASPR/ProgramOffices/Pages/ProgramOffice.aspx>, Accessed on December 7, 2023.

supply without impacting the safety, purity, or potency of blood donation. This analysis shall include an assessment of risks and burden associated with the different temporary options.”

Furthermore, our organizations request that ACBTSA clearly delineate the actionable goals and anticipated outcomes of this analysis to facilitate a targeted and productive assessment.

Recommendation VI: The Committee recommends that a Memorandum of Understanding (MOU) be negotiated with Canada to allow their blood and blood products into the U.S. and utilization of their testing laboratories to relieve transient strains in the blood supply brought about by emergencies.

- a. **The MOU would be bi-directional.**
- b. **The FDA would participate in this work to assure the safety of the incoming blood from Canada or other countries.**

Our organizations support this recommendation.

Recommendation VII: The Committee recommends OASH contract a qualified organization to develop a risk-capability analysis with business case development informed by actuarial science.

- a. **This agency would be administered by ASPR and OASH.**
- b. **Representatives from blood centers, hospital transfusion services, blood system supply chain agents, and health economists would provide input.**

AABB, ABC and ARC do not understand this recommendation as written. We recommend that that ACBTSA clarify: (1) the problem that the risk analysis is intended to solve, (2) the specific objectives and goals envisioned for the risk analysis, and (3) the definition, objectives, and goals of “business case development informed by actuarial science.”

Additional Recommendations:

AABB, ABC and ARC recommend the inclusion of the following additional items related to surge capacity:

- 1. Establishment of a baseline inventory of blood.** AABB, ABC and ARC applaud previous ACBTSA recommendations related to the need for a real-time mechanism on blood collection and distribution. While mechanisms currently exist to report daily on blood center inventory levels, the existing blood inventory reports are flawed and there is no mechanism to understand blood availability at hospitals.⁴ This gap undermines effective national surge capacity planning and execution and must be addressed.

⁴ Statement of Leo Debandi, Vice Chair, AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, HHS Advisory Committee on Blood and Tissue Safety and Availability, August 18, 2021, available at https://www.aabb.org/docs/default-source/default-document-library/positions/statement-by-aabb-interorganizational-disaster-task-force-vice-chair-to-acbtsa-august-2021.pdf?sfvrsn=bdd801f2_4.

2. **Modeling of Unprecedented Emergency Scenarios.** The blood community has demonstrated its ability to effectively respond to the need for local surge because of man-made and natural disasters. However, coordinated planning is essential for understanding the levels of surge required for unprecedented events such as a nuclear detonation, biological warfare, or a blood-borne pathogen.
3. **Funding for a Sustained Increase in Blood Inventories.** Our organizations request that HHS dedicate funding to support increased local public awareness and blood collection capacity. Additionally, we recommend that HHS invest additional funding for social science research, which is essential to understanding donor motivation and increasing the percentage of Americans who donate blood each year.

It is often stated that blood on the shelf saves lives. Past disaster scenarios have demonstrated that the most critical need for blood during an emergency is within the first 24 hours. Since it takes between 24 and 36 hours to process and test blood once donated, it is essential that sufficient levels of blood already be on hand nationwide to respond to every day as well as emergency needs. We consider this the “insurance value” of blood.

Over the past several years, we have seen national inventory levels well below three days on hand. It is essential that blood donation be treated as a national resource and investments be made to increase the sustained level of blood nationwide to a 3–5-day inventory at minimum. We have heard that other countries have set much higher national goals of 8+ days on hand.

We appreciate the opportunity to comment on the ACBTSA recommendations. If you have any questions or require additional information, please contact Susan Leppke (301-547-3962, sleppke@aabb.org), Justine Coffey (202-654-2983, jcoffey@americasblood.org), or Julie Manes (202-417-5147, julie.manes@redcross.org).

Sincerely,

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