

# 2021 ADVOCACY AGENDA



***Promoting the value of blood to  
patients, communities, and the  
healthcare system.***



**America's Blood Centers<sup>®</sup>**  
It's About *Life.*

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# OVERVIEW

America's Blood Centers (ABC) urges the Administration, Congress, and industry stakeholders to promote the value of blood to patients, communities, and the health care system through the following actions:

- **Include blood centers in nationwide emergency preparedness planning.** As a vital part of the U.S. health care system, the blood community must be considered as an integral part of emergency preparedness; the essential role of blood collectors must be considered right from the start by federal, state, and local officials during disasters, including public health emergencies.
- Prioritize blood donation as a national imperative by **increasing public awareness and education around blood donation through a public-private partnership**, especially for younger and diverse donors. This is one part of a broader effort to raise awareness of the need for blood donation and to ensure a robust and resilient donor base.
- **Eliminate Zika testing requirement.** ABC is committed to ensuring data support for U.S. Food and Drug Administration (FDA) mandated testing in an overall commitment to evidence-based testing requirements.

## Include Blood Centers in Nationwide Emergency Preparedness planning to Ensure a Safe and Robust Blood Supply is Available Through Any Disaster

In 2019, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) marked the first time-ever that the sweeping preparedness and response legislation specifically recognized the role of blood centers. This bill required the inclusion of blood centers as stakeholders which the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) must consult in disaster planning. While this is an important step, more is required to ensure blood center operations can continue during any disaster such as the COVID-19 pandemic. For example, stay-at-home orders often failed to mention the importance of blood center operations continuing unimpeded (or worse, indicated blood donation was not allowed) and when the pandemic stressed supply chains, blood centers were not initially considered in the prioritization plan. It is essential that blood centers' critical role in the healthcare system is recognized to ensure blood donors and staff can continue to maintain a safe and available blood supply.

## Prioritize Blood Donation as a National Imperative

Every two seconds, someone in the U.S. needs blood, with blood transfusion being one of the most common medical procedures performed in this country. However, demographic challenges threaten the U.S. donor base with approximately 60 percent of blood donations being made by individuals over the age of 40. Of those, three-quarters come from people over the age of 50 with **younger donors failing to donate at similar rates**. Additionally, a **diverse donor pool is essential** to provide for all patients needing transfusions, especially those requiring rare blood types. Promoting a robust donor base is a national imperative. A **public-private partnership will amplify the reach of a public awareness campaign** to expand the donor pool to ensure blood is available to patients in need, both now and in the future.

## Zika Testing Does Not Support the Safety and Sustainability of the U.S. Blood Supply

ABC is committed to a safe and robust blood supply. One important component of this commitment is ensuring that **testing requirements and donor deferrals are evidence-based** using current data. ABC believes this requires an updated view of Zika testing. Zika was initially identified as a potential risk in 2016 with FDA quickly providing guidance requiring screening for significant infectious risk. Current data shows no evidence of mosquitoes in the continental U.S. having transmitted Zika since 2017, with an extremely low threat for U.S.-based transfusion transmission. The required testing was initially estimated to cost \$137 million per year without commensurate benefit in increased safety of the blood supply. **ABC supports FDA's commitment to re-examine** the need for Zika testing. This issue is slated for future consideration by the FDA's Blood Products Advisory Committees (BPAC).

*In addition to the above priorities, ABC supports the following policy positions and urges the Administration, Congress and industry stakeholders to promote the value of blood components to patients, communities, and the healthcare system through the following:*

### ***Support a robust donor base by prioritizing blood donation as a national imperative***

- Establish targeted federal initiatives to support increased diversity in the donor base such as funding for increased molecular red blood cell typing for frequently transfused patients such as those with Sickle Cell Disease or thalassemia.
- Establish funding for social science research on donor and non-donor behavior and motivation.

### ***Commit federal resources in support of the vital role of blood in the health care system***

- Explore funding mechanisms to facilitate implementation of safety and technology measures when mandated by FDA, such as recent platelet bacterial detection guidance, or when market incentives otherwise do not exist.
- Increase federal resources for data on the collection and utilization of blood components as needed to support evidence-based decision making in federal policy.
- Expand availability of blood components to patients at the end of life by modifying hospice reimbursement rates to reflect the added cost of providing blood components.

### ***Reduce unnecessary and burdensome regulation to support innovation and blood product availability***

- Apply evidence-based decision making to FDA testing requirements to ensure testing burdens are justified by commensurate increases in safety.
- Advocate for FDA approval of extended shelf life for cold stored platelets; these products are particularly important for rural areas and in trauma with massive bleeding.
- Revise interstate transfer of products licensing regulations to reduce the time to process the application and allow interim licensure following a timely initial review, as these products are already acceptable for sale and use in the state of manufacture.
- Eliminate the need for blood centers to discard a safe blood donation if there is an error stemming from internal processes which has no influence on the safety, purity, or potency of the donation.
- Revisit FDA policy on the acceptance of international data for use in the approval of new products, technologies, and blood industry policies and procedures.
- Encourage FDA to establish donor policies which promote inclusivity with research-based donor-screening alternatives based on individual behavior, not sexual or gender identity, to provide equivalent or superior transfusion safety.
- Lower the U.S. Platelet Content Requirement (PCR), a minimum number of platelets per unit, in line with international standards.
- Implement a rational, flexible approach to the regulation of plasma products, advocating that the FDA license recovered plasma to give blood centers the ability to move plasma from transfusable to further manufacture as demanded by clinical need.