

2020 ADVOCACY AGENDA

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



America's Blood Centers[®]
It's About *Life*.

OVERVIEW

ABC urges the Administration, Congress and industry stakeholders to promote the value of blood components to patients, communities, and the healthcare system through the following actions:

- **Elimination of Zika testing requirements.** ABC is committed to ensuring data support all of the FDA mandated testing in an overall commitment to evidence-based testing requirements.
- **Re-entry of previously deferred donors due to variant Creutzfeldt-Jakob Disease (vCJD).** This is one step in our ongoing efforts to maximize the eligible donor pool whenever scientifically and medically justified.
- A public-private partnership to **increase public awareness and education around blood donation** especially among younger 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.

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

ABC is committed to ensuring a safe and robust blood supply. One important component of this commitment is ensuring that **testing requirements are evidence-based** using up-to-date data. ABC believes this requires an updated view of ZIKV 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 ZIKV since 2017, with 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 ZIKV testing which transitioned to mini-pool testing in 2019 and inclusion of ZIKV testing on the agenda for the Blood Products Advisory Committee's (BPAC) April 2020 meeting.

Re-qualification of Eligible Donors Deferred for vCJD Will Safely Expand the Donor Base

Variant Creutzfeldt-Jakob disease (vCJD), the human form of "Mad Cow Disease" first identified in the United Kingdom (UK) in 1996, is **exceedingly rare** with only 231 people affected globally, with 88 percent of cases occurring in the UK and France. There have been only three cases of apparent transfusion transmission, all of which have occurred outside of the U.S.. The World Health Organization has listed the U.S. at negligible risk. ABC **encourages a risk-based approach** based on continued surveillance. This approach supports changes to the deferral policy including removal of the deferral for U.S. military personnel, DoD civilians and their families with six months or more than six at U.S. military installations in Europe outside of the UK from 1980-1996, removal of the deferral for injection of bovine insulin, and removal of human growth hormone from the medication deferral list. These changes are included in an ABC-supported FDA draft guidance from January 2020. ABC **encourages FDA to quickly finalize this guidance** to allow this cohort to make a valuable contribution to America's blood supply and become part of a larger commitment by ABC to expand the donor base to ensure a robust blood supply.

Prioritize Blood Donation as a National Imperative

Every two seconds in the U.S. someone 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 40 years old. Of those, three-quarters come from people over 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.

In addition to the 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 funding for social science research on donor and non-donor behavior and motivation.
- Establish targeted federal initiatives to support increased diversity in the donor base such as funding for increased molecular red blood cell typing for patients with Sickle Cell Disease receiving frequent donations.

Recognize the vital role of blood components to the healthcare 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

- Eliminate the need for blood centers to discard a safe blood donation if there is an error stemming from internal processes if the error has no influence on the safety, purity, or potency of the donation.
- Apply evidence-based decision making to FDA testing requirements to ensure testing burdens are justified by commensurate increases in safety.
- Revisit FDA policy on the acceptance of international data for use in the approval of new products or technologies, and different policies and procedures.
- 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.
- 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.
- Eliminate the need to submit a Blood Product Deviation Report generated because of post donation information that does not result in a recall.
- 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.