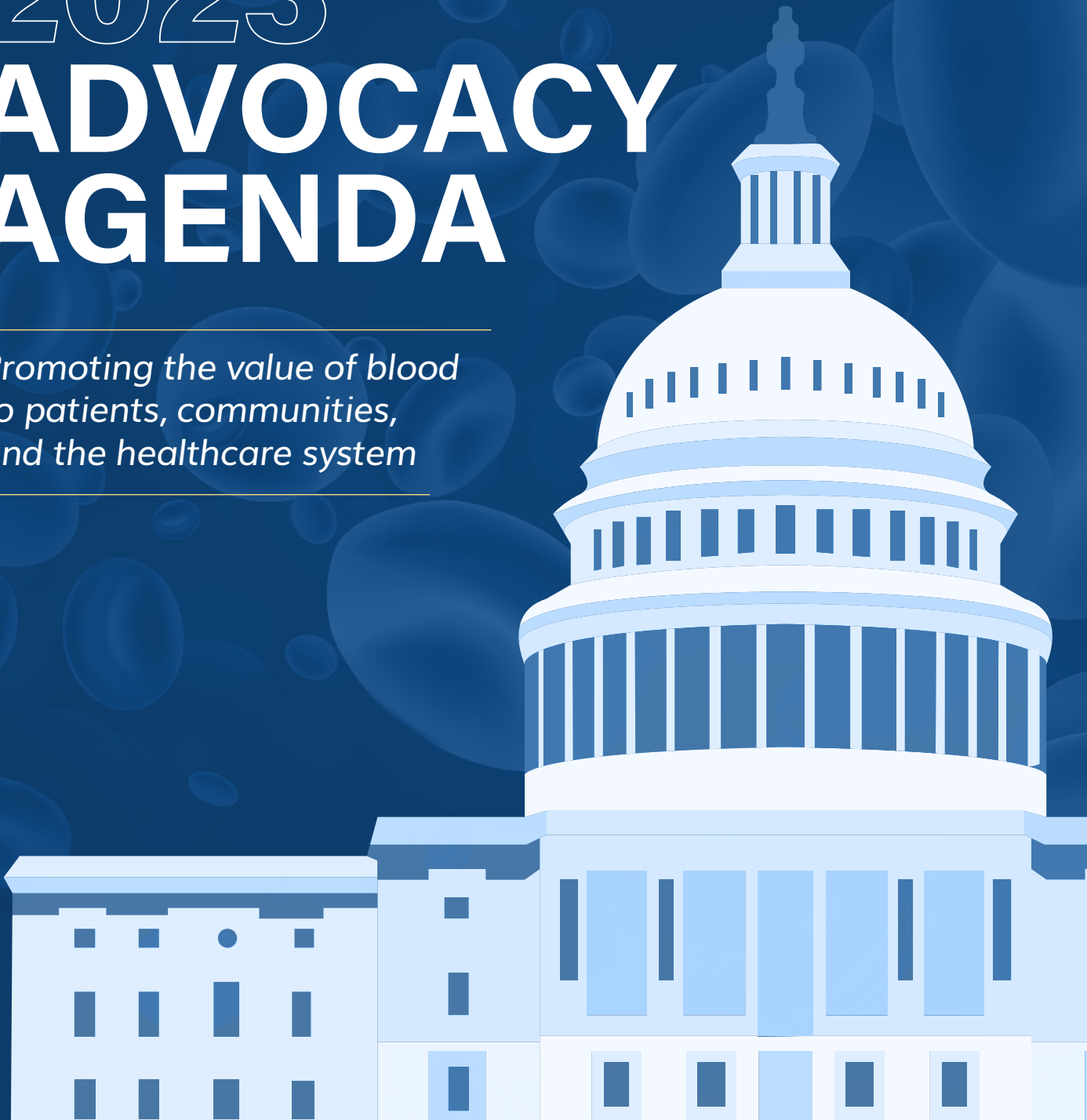


# 2023 ADVOCACY AGENDA

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

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[americasblood.org/advocacy](https://americasblood.org/advocacy)



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

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



### **Streamline product licensure to allow blood centers to adapt to changing donor needs.**

The pandemic has dramatically impacted the way blood is collected. As schools and workplaces moved virtual or limited who is allowed on site, blood drive cancellations threatened the stability of the blood supply. To meet the needs of donors, blood centers are now opening new locations to adapt to these enduring changes but face over a year wait while FDA reviews blood product licensure submissions and completes a site inspection. Until the new facility receives FDA approval, blood products manufactured (utilizing the same procedures already approved at other facilities operated by the same blood center) cannot be shipped across state lines, even though all products are already acceptable for distribution in the state of manufacture. To ensure a safe and available blood supply, blood centers need to quickly be able to fully utilize these new locations.



### **Expand the pool of blood donors and available blood by funding local awareness efforts to recruit new and previously deferred donors made eligible by recent FDA eligibility changes.**

Recent changes in deferral criteria made by the FDA will safely make many more Americans eligible to donate blood. These changes include the removal of indefinite deferral for geographic exposure to bovine spongiform encephalopathy, including those receiving blood donations in those locations and a proposal to move to a universal individual behavior assessment for all donors. These changes will allow more gay and bisexual men to donate blood and come at a critical time when only 3% of Americans donate blood. Congress should support local blood center efforts to recruit these potential donors and educate the public about these changes.



### **Ensure blood transfusions are available to patients when and where they need blood.**

Due to the work of blood centers throughout the U.S., blood has always been available to patients when they need it most. Unfortunately, due to some payment policies, blood transfusions are not equally available to all patients. As a result of bundled payments in the Medicare Hospice program and for care received in an ambulance, blood transfusions are not broadly available to patients in the hospice or pre-hospital setting. As a result, patients in need of palliative transfusions do not enroll in the hospice benefit resulting in greater Medicare expenditures with lower quality end of life care. And while extensive evidence shows benefits to receiving as soon as possible after a traumatic injury, the majority of patients do not receive their first transfusion until they arrive at a hospital, regardless of the amount of time required for transportation. By fairly reimbursing providers for the cost of providing this life preserving care, patients are assured the care they need when and where required.



In addition to the above priorities, ABC supports the following policy priorities:

## 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 including those with Sickle Cell Disease or Thalassemia.
- Establish funding for research on the predictive social and psychological factors in blood donor motivation to attract and retain donors and ensure long-term stability of the nation's blood supply.

## Commit federal resources in support of the vital role of blood in the healthcare system:

- Explore federal funding mechanisms to facilitate implementation of safety and technology measures when mandated by FDA or when market incentives otherwise do not exist.
- Increase federal resources for data gathering on the collection and utilization of blood components as needed to support evidence-based decision making in federal regulatory policy.

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

- 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.
- Encourage FDA to finalize the alternative procedures guidance before the expiration of the Public Health Emergency to ensure centers are able to continue these procedures demonstrated to safely expand the blood supply.
- Apply evidence-based decision making to FDA testing requirements to ensure testing burdens are justified by commensurate increases in safety, eliminating current FDA testing requirements without appropriate safety justifications (e.g. HBsAg).
- Advocate for FDA approval of extended shelf life for cold stored platelets for actively bleeding patients to expand platelet supply availability.
- Revisit FDA policy on the acceptance of international data for use in the approval of new products or technologies, and different policies and procedures.
- Lower the U.S. Platelet Content Requirement (PCR), the minimum number of platelets per unit, to expand platelet supply availability and in line with international standards.
- Implement a rational, flexible approach to the regulation of plasma products, advocating FDA licensure of recovered plasma to give blood centers the ability to convert plasma from transfusable to further manufacture without requiring expiration for more effective blood inventory management.

