Critical Resource Continuity Webinar Series (BLOOD MAY 4)

May 2026

FK Risk Mitigation (95% U.S. Market Share)

BPUs

- Horatev & San German – 2 FDA licensed manufacturing sites significantly reducing risk
- FK manufacturing capabilities:
  - San German, PR: 7M BPUs
  - Horatev, CZ: 9M BPUs – Shift ROW production to Brazil/China
  - FK global BCP production – Brazil, China, Horatev, PR
    - 4 BPU manufacturing plants
- HemaSource 3PL – 45 DIOH in Bioflex/CompoSelect

Filter Manufacturing

- Bologna, Italy – Primary manufacturing site (currently sole site)

- San German, PR – FK received CAPEX approval for newly automated San German plant to be secondary manufacturer by end of 2027

BCA WB Bag Strategy Continued

Alternate Blood Bag Supplier:

Approved Supplier Requirements/Risks

- Complete operational transition with all products off of allocation, 60DIOH, prehospital CPDA1 non-luecko WB blood bag
- Upon completion of successful audit – scheduled June 2026
    - Assessing product quality

US Manufacturing Opportunity: U.S. government sponsoring production of ~1M bags

- Initial/Primary focus is LTOWB BPU needs
- 2nd phase – potential production of primary LRS BPUs up to 1M

All BCA members to be validated in 2 primary BPUs

CMS Seeks Public Input for Strengthening Domestic Supply Chain

BCA Response Submitted 03/30/2026:

BCA's Proposed Solution: Phased approach to safeguard the Nation's blood supply from disruptions caused by vulnerabilities

Phase I: Immediate Risk Mitigation (First 90 Days Post-Funding)

- Identify and engage qualified manufacturing partners capable of producing up to 10M WB bags annually in the U.S.
- Create a contingency buffer by procuring an additional 90-day supply of WB bags stored in BCA's 3PL network

Phase II: This phase aims to achieve full vertical integration and domestic production capacity, significantly reducing reliance on foreign suppliers and enhancing national supply chain security.

- Partner with a manufacturing entity to establish U.S.-based (FDA-licensed facilities) capable of producing a minimum of 10M WB bags annually.
- Provide incentives to relocate operations to the U.S, as their costs of production are likely less expensive in their current manufacturing locations.
- Cost Considerations
  - Currently overseas production is more cost-effective.
  - U.S. relocation may require incentive packages and infrastructure support.

Potential Risks of Delaying Implementation:

- **Increased Vulnerability to Disruptions:** With little inventory buffer, blood centers remain susceptible to supply chain interruptions
- **Higher Costs:** Without establishing a U.S.-based supplier this will prolong reliance on a single manufacturer, resulting in continued lack of competition
- **Economic Impact:** Postponing local production could delay the creation of economic opportunities and jobs within the U.S., impacting the overall financial health of the industry

Supply Chain Considerations: Pre-Hospital/Other

LTOWB Current blood bags (BPU's)

Fresenius Kabi CPDA1 non-LRS WB BPU - LFK will discontinue all production of CPDA1 BPU's by end of CY26/Early CY27 due to shutting down of the Maricao PR plant

Terumo BCT Imuflex "Platelet sparing" LRS WB BPU - Limited production capacity out of Japan with a max production capability of 110-120K BPU's annually

BCA is currently working with a 3rd manufacturer; actual production timeline TBD

- CPDA1 non-LRS WB BPU with 35-day WB shelf life. 35-day, critical to support rural EMS programs due to logistics complexity

Component Therapy BPU's

Fresenius Kabi is primary U.S. BPU producer

- San German, PR - BioFlex II LRS WB BPU double, triple, quad bag configuration capable of producing packed LRS RBC's, Plasm Platelet units. BPU Annual production capacity 7M bags
- Horatev, CZ - CompoSelect II LRS WB PBU triple bag configuration capable of producing packed PRS RBC, plasma and platelet unit. BPU Annual production capacity 9M bags

Supply Chain Considerations: Rare Donor and Pre-Hospital

Fresenius Kabi/Baxter:

- Fresenius Kabi is the exclusive distributor and holds the IP on Gycerolyte (used for extending dating on RBC's up to 10 years). This product is being discontinued with the final production run in early June 2026. The global inventory of the 500 ml SKU will likely last another 12-18 months. Additionally, there will be no more production of the 400ml SKU
- This product is used extensively in the Blood Center Rare Donor program and also with the military/Armed Services Blood Program to extend dating on RBC's

Terumo BCT:

- TBCT sunsetting COBE2998 cell washing device 2030. Device required for the glycerolyzing cell washing of long term stored red cells
    - Competitive alternative product manufacturer has limitations

Opportunity:

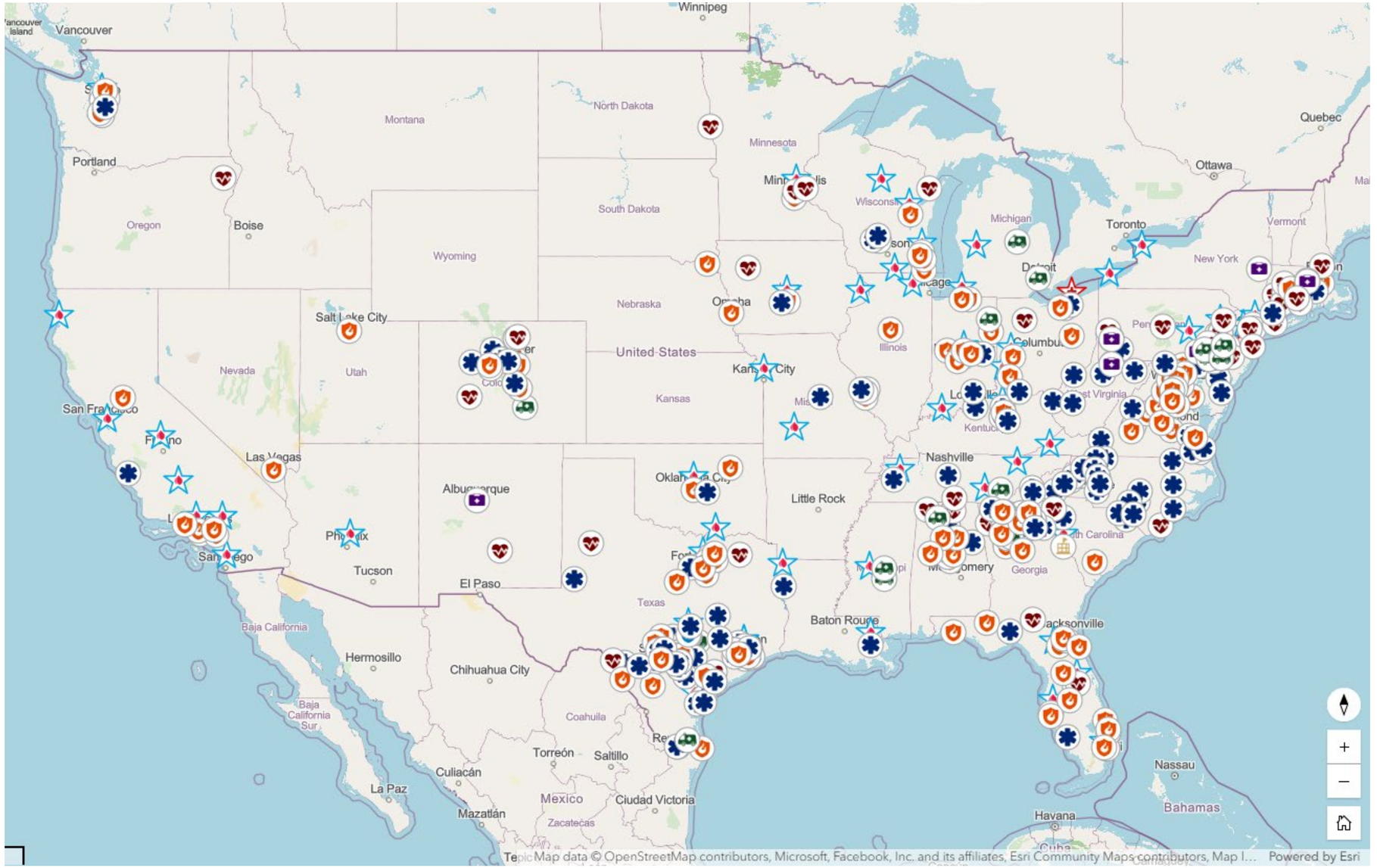
- BCA has been exploring alternative technologies with 2 U.S. based companies that have viable solutions but that are not yet commercially available:
    - Vitrafy – they have IP that is a next generation cryopreservation system enabling long term storage and no post thaw de-glycerization for packed red cells & no cell washing requirements
    - Evia Bio – Uses a Non-DMSO freezing methodology that again would allow for no de-glycerization or cell washing requirements

2025 Data

46,300,000 Patients were transported by EMS in 2025

- Blood was administered 22,500 times (0.05%)
- 300,000 patients had major trauma (0.65%)
- 1,200,000 patients had moderate trauma (2.7%)
- 8,331,062 patients had any type of traumatic injury (18%)

PHBTC Interactive EMS Map



375 Active agencies on the map as of April 2026

- Nationally a 126% increase since May 2024

Source https://prehospitaltransfusion.org/blood-program-interactive-map/

2025 Blood Donor Annual Report

Total Donors

3.21M

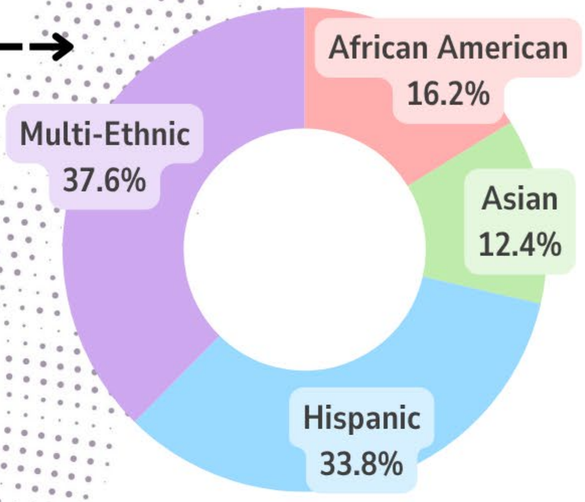
▼-0.71% from 2024

Total Donations

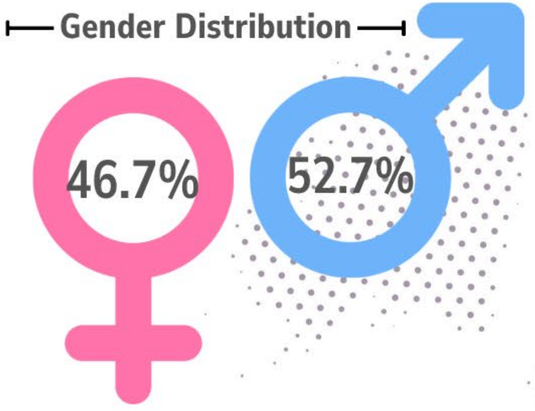
6.33M

▲+0.18% from 2024

Ethnic Diversity

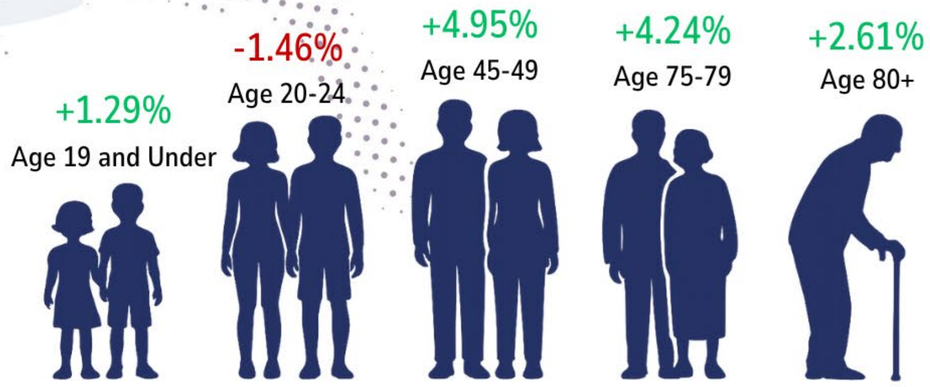


Gender Distribution



About 5 in every 10 donors are Type O

Aging Shift



BCA Donors by Age Group 2015-2025