America's Blood Centers
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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

2026 Issue #32 November 4, 2026

INSIDE:

FDA Publishes Guidance for Reducing the Risk of Transfusion-Transmitted HBV....3
WORD IN WASHINGTON....4
INFECTIOUS DISEASES UPDATE....5
Nominations Are Open for the ABC Board of Directors....6
Register for the November ABC Webinar: "Risk Assessment for Blood Centers"....6
The Results are In: ABC Workforce Trends Survey....6
ABC Executive Fellows Program Call for Applicants Extended....7
ABC Executive Compensation Survey Is Open....7
September *Blood Bulletin* Is Available....7
MEMBER NEWS....8
ADVANCED THERAPIES NEWS....8
GLOBAL NEWS....9
COMPANY NEWS....10
CALENDAR....12
POSITIONS....13

Blood Community Submits Prehospital Blood Joint Comments in Response to NHTSA RFI

America's Blood Centers (ABC), the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross have submitted joint comments to the National Highway Traffic Safety Administration (NHTSA), on behalf of the Federal Interagency Committee on Emergency Medical Services (FICEMS), Request for Information regarding nationwide implementation of prehospital blood transfusion. An October 6th notice about the RFI in the *Federal Register* explained that the agency is, "solicit[ing] comments on strategies, barriers, and solutions to advance prehospital blood transfusion capabilities across state, local, tribal, and territorial emergency medical services (EMS) and 911 systems."

In the joint comments, the blood community cited, "current impediments to increasing the number of emergency medical services (EMS) agencies nationwide with active prehospital blood transfusion programs to 2,028 by the year 2028 including operational challenges that may limit the ability of blood collectors to meet increased demand for blood and blood components and flawed reimbursement policy." Recommendations proposed to the agency by the blood community were:

- "[d]evelop a federal grant program that provides funding for donor recruitment and public awareness efforts;
- [r]ecognize the blood supply as critical infrastructure in FICEMS and the U.S. Department of Health and Human Services' preparedness planning and include blood collectors and hospitals in FICEMS working groups on prehospital transfusion;
- [f]oster collaboration among blood collectors, hospitals, and EMS agencies, along with community engagement, so that prehospital programs expand without depleting hospital inventories;
- [s]upport product-flexible, regionally-tailored strategies and continued innovation to meet the diverse needs of EMS systems;
- [e]ncourage EMS agencies to adopt nationally recognized standards for prehospital transfusion, such as the *AABB Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions*, and to pursue independent accreditation. Accreditation gives blood collectors and hospitals objective evidence that an EMS agency's quality management system is adequate. Federal grants for prehospital transfusion programs should treat standards adoption and accreditation as allowable costs;

(continued on page 2)

Prehospital Blood Joint Comments in Response to NHTSA RFI (continued from page 1)

- encourag[e] the Centers for Medicare & Medicaid Services (CMS) to establish separate payment for blood products and transfusion services furnished by ambulance providers, such as a prehospital blood product add-on payment that incorporates the costs of manufacturing, procuring, storing, and administering blood, building on the TRICARE prehospital blood transfusion demonstration that takes effect January 1st, 2027;
- encourage[e] CMS to issue guidance urging state Medicaid programs to cover, and provide sufficient payment for, prehospital transfusion; [and]
- continu[e] to expand federal grant programs, including those offered by the [Defense Department] and NHTSA, that support establishing prehospital blood transfusion programs, and ensure that the funds cover all costs, including blood products and equipment."

Additionally, the blood community urged the agency to promote data integration and linkage across local, state, and national data systems by:

- "standardiz[ing] NEMSIS data elements related to prehospital blood transfusions;
- captur[ing] data that supports research; [and]
- preserv[ing] traceability and hemovigilance."

The joint comments also highlighted opportunities for improving military and civilian EMS integration to advance prehospital blood transfusion practices, logistics, cold-chain management, and clinical training. The blood community recommend that the, "civilian blood supply should be considered part of national security, and prehospital transfusion programs are part of this infrastructure. Closer integration of the military and civilian blood systems would support enhanced coordination and planning for surge capacity and response."

The blood community concluded the comments by proposing NHTSA and its federal partners prioritize:

- "assess[ing] the impact of expanded prehospital transfusion on the national blood supply and support donor recruitment and regional inventory stewardship;
- establish[ing] adequate reimbursement for blood products, transfusion services, and ongoing program readiness; [and]
- promot[ing] nationally recognized transfusion standards, training, traceability, and hemovigilance; and support[ing] flexible product strategies and continued innovation to meet the diverse needs of urban, rural, and pediatric EMS systems.

Thus, we urge FICEMS to work with the blood community to address the challenges that may create barriers to the adoption of prehospital transfusion programs."

ABC will continue to provide updates on our advocacy efforts to ensure both sufficient reimbursement for prehospital blood transfusions and broader adoption of blood transfusions in the prehospital setting. Please contact us with any questions or comments.

(Sources: Blood Community Joint Comments, 11/3/26; *Federal Register* Notice, 10/6/26)



FDA Publishes Guidance for Reducing the Risk of Transfusion-Transmitted HBV

The U.S. Food and Drug Administration (FDA) has published a final guidance titled "Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus." The agency noted that guidance provides, "blood establishments that collect blood and blood components, including Source Plasma, with recommendations for testing blood and blood components for hepatitis B virus (HBV) to reduce the risk of transfusion-transmitted HBV. [This guidance] consolidates FDA's current recommendations on HBV, as follows:

- "[f]inalizes the July 2025 Draft Guidance;
- [s]upersedes the recommendations specific to HBV contained in the July 1996 Memorandum; [and]
- [s]upersedes the December 1987 and September 1991 Memoranda, and the November 2007, May 2010, November 2011 and October 2012 Final Guidance documents."

FDA explained that the new recommendations, "introduced in this guidance relate to the finalization of the recommendations in the July 2025 draft guidance, specifically the recommendation for the discontinuation of testing certain donations for hepatitis B surface antigen (HBsAg) and conforming changes for donor requalification and labeling, found in section III of this guidance. Namely, we recommend that when donations of blood and blood components, excluding Source Plasma, are tested for HBV DNA by nucleic acid tests (NAT) and for antibody to hepatitis B core antigen (anti-HBc) using screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions, testing for HBsAg is not necessary to reduce adequately and appropriately the risk of transmission of HBV. For Source Plasma donations, we continue to recommend that testing for HBsAg and HBV DNA by NAT is necessary to reduce adequately and appropriately the risk of transmission of HBV."

The agency noted that, "we have revised some recommendations because of advances in the tests used to screen blood donations for HBV. We removed recommendations that blood establishments use HBsAg and HBV NAT tests with specific sensitivity levels, as described in the November 2007 and October 2012 Final Guidance documents. These recommendations are no longer relevant because all currently available FDA-licensed tests for HBsAg and HBV DNA meet the detection levels previously recommended and blood establishments must use FDA-licensed, approved or cleared screening tests in accordance with the manufacturer's instructions (see 21 CFR 610.40(b)). Further, we have made minor changes in recommendations for donor requalification and product management for consistency and alignment with current practice."

(continued on page 4)

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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FDA Publishes Guidance for Reducing the Risk of Transfusion-Transmitted HBV (continued from page 3)

America's Blood Centers (ABC) and its members have previously advocated for the removal of the requirement for testing blood donations for HBsAg as a part of the ABC Advocacy Agenda, and in an ABC letter to HHS regarding unnecessary, overly burdensome, and outdated regulations and guidance documents, and most recently in blood industry joint comments and ABC comments in support of the proposal to remove the HBsAg testing requirement. This marks a significant win for community blood centers as HBsAg testing costs an estimated $1.00 to $1.50 per test, saving blood centers a total of approximately $15 to $22.5 million annually. We thank members for their support on this issue and will continue to provide updates on our advocacy efforts.

(Source: FDA Final Guidance, 11/4/26)

WORD IN WASHINGTON

Rep. Paul D. Tonko (D-N.Y.), Sens. Chuck Schumer (D-N.Y.), and Kirsten Gillibrand (D-N.Y.) have announced that New York is being awarded more than $8 million in funding, "from the Bipartisan Infrastructure & Jobs Law in Safe Streets and Roads For All (SS4A) grant funding to improve safety at major roadways throughout the Capital Region [which includes prehospital blood delivery. Specifically, the lawmakers] explained that this grant will fund safety analyses and launch pilot programs for emergency vehicle alerts, prehospital blood delivery, and more to improve roadway safety outcomes in Albany, Columbia, Fulton, Greene, Montgomery, Rensselaer, Saratoga, Schenectady, and Schoharie counties. [The money will] will be divided between three projects serving nine counties including:

- $4 million for the Capital Region Integrated Roadway Safety and Post-Crash Care Initiative to develop a Supplemental Action Plan and conduct demonstration activities focused on post-crash care, emergency response coordination, and crash prevention across New York's Capital Region. Work includes safety analysis, partner coordination, protocol development, and pilots for emergency vehicle alerts, responder data interoperability, prehospital blood delivery, and responder protection to improve survivability, dispatch efficiency, and roadway safety outcomes; [and]
- $4 million for the Wilton Emergency Squad in Saratoga County to develop a Supplemental Action Plan and conduct demonstration activities focused on post-crash care, emergency response coordination, and roadway safety across its service area. Work includes safety analysis of high-risk corridors, stakeholder coordination, protocol development, and temporary pilots such as emergency vehicle transponder alerts, data interoperability tools, signal pre-emption, and prehospital blood delivery to inform future safety initiatives."

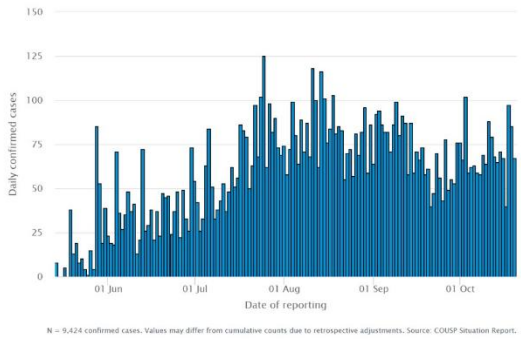
(Source: Rep. Paul D. Tonko News Release, 10/30/26)

The Centers for Medicare & Medicaid Services (CMS) Innovation Center recently announced that it is, "broadening the framework of the Cell and Gene Therapy (CGT) Access Model beyond sickle cell disease to invite manufacturers of other cell and gene therapies to apply to the model following positive initial results from the first model evaluation report." The agency announcement explained that, "[t]he broadened model would make life-changing therapies more affordable to state Medicaid programs, giving more patients access to treatments they need to live healthier lives. In the coming months, CMS will release a Request for Applications for manufacturers to allow for negotiations for outcomes-based agreements to start more quickly—whether right after FDA approval or licensure of a therapy or for therapies already approved—and to broaden the model's scope beyond sickle cell disease."

(Source: CMS Announcement, 10/27/26)

INFECTIOUS DISEASES UPDATE

EBOLA



On October 23rd, the World Health Organization (WHO) updated the status of the Ebola disease outbreak in the Democratic Republic of the Congo (DRC). As of October 20th, "the outbreak has expanded geographically in the DRC, as well as in the African Region, with Kenya and Nigeria reporting imported cases. Sustained, high-level transmission continues in the DRC." On October 20th, the WHO noted that, total of 9,704 confirmed cases, including 4,687 deaths (crude case fatality ratio: 48.3%), have been reported across 66 health zones in eight provinces. The high proportion of deaths occurring in communities continues to highlight challenges in early case detection and timely access to appropriate care. Of the 482 deaths reported since the previous update, 307 occurred in communities and 175 in treatment cent[ers]. On October 6th, the Ministry of Health of Kenya reported the first laboratory-confirmed imported case [in] Kenya in an individual who had traveled from the DRC to Kenya via Uganda. As of October 20th, a total of nine cases including one death, has been reported in Kenya. The eight additional cases are all known contacts of the first imported case. There is currently no evidence of wider community transmission. On October 20th, Nigeria confirmed an imported case in the Federal Capital Territory Abuja in a patient who had traveled from Uganda to the country. The patient is currently in isolation and receiving medical care. Further investigations are ongoing to better understand the complete travel history and the possible source of exposure. These developments underscore the need for sustained readiness in the region, including cross-border surveillance, points of entry monitoring, timely case detection and coordinated preparedness and response measures." In May, the WHO declared the Ebola disease outbreak in the DRC and Uganda caused by Bundibugyo virus a, "public health emergency of international concern (PHEIC), but [noted that it] does not meet the criteria of pandemic emergency, as defined in the International Health Regulations (2005) (IHR)." The U.S. Centers for Disease Control and Prevention (CDC) published an update on November 4th stating that the U.S. "is responding to an outbreak of Ebola disease in remote areas of the DRC. To date, no cases of Ebola disease have been confirmed in the United States because of this outbreak. The overall risk to the American public and travelers remains low." On May 18th, the CDC announced that it had, "enhanced travel screening, entry restrictions, and public health measures to prevent Ebola virus disease from entering the United States amid ongoing outbreaks in East and Central Africa." The CDC has not classified the affected region as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The Food and Drug Administration (FDA) updated its guidance document on June 29th and published a communication explaining that"[b]ecause of the severity of [Ebola disease] and the potential risk of transmission by blood and blood components, Ebola disease meets the definition of transfusion-transmitted infection 21 CFR 630.3(l); however, transmission of Ebola disease by blood transfusion has not been reported. Routine measures used to screen every blood donor effectively prevent individuals with symptomatic Ebola disease from donating blood. [Considering] the current Ebola disease outbreak in the DRC and Uganda, we refer blood establishments to the recommendations in our guidance document to update their donor eligibility processes accordingly, including asking donors about residency or travel to DRC and Uganda."

(Source: WHO Update, 10/23/26; CDC Update, 11/4/26)

INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

Nominations Are Open for the ABC Board of Directors

America's Blood Centers (ABC) is now accepting nominations for the ABC Board of Directors until Friday, November 13th. Individuals can self-nominate or nominate other ABC members. ABC is committed to an inclusive, transparent nominations process. Individuals may submit nominations here. Please contact us with any questions.

Register for the November ABC Webinar: "Risk Assessment for Blood Centers"

The ABC Educational Webinar Committee is hosting a November 17th webinar at 3 p.m. EST titled "Risk Assessment for Blood Centers." Registration is open and ABC members can find additional information including a link to register here. Featured speakers include:

- Loretta Olamigoke, PhD, CLS Quality Assurance Manager at Gulf Coast Blood; and
- Dana Knight, Director of Quality Assurance at Versiti.

The event will provide attendees with:

- valuable perspectives on the importance of having a robust risk assessment program;
- help exploring challenges and opportunities; and
- the opportunity to connect with subject-matter experts to ask questions and exchange ideas.

Please contact us with questions.

The Results are In: ABC Workforce Trends Survey

The results for this year's Workforce Trends Survey are now available. This valuable benchmarking survey is the most comprehensive source of information available on workforce trends at blood centers. The survey analyzes overall trends in compensation, benefits, and HR policies and provides specific data for 74 different blood center employee roles. The survey also provides insights into employee turnover and retention for the preceding calendar year, analyzing trends overall as well as by department and length of service. Those ABC member blood centers who participated in the Workforce Trends Survey can purchase the report at a discounted price (code required and has been emailed to authorized individuals) of $450 while non-participating blood centers can purchase the report at the full price of $900. Please contact us with any questions to access the results or to identify the authorized individual at your blood center who received the discount code.

(continued on page 7)

INSIDE ABC (continued from page 6)

ABC Executive Fellows Program Call for Applicants Extended

Apply to participate in the 2027-2028 America's Blood Centers (ABC) Executive Fellows Program (EFP) by December 14th. ABC is partnering with Vanderbilt University's Owen School of Management. This groundbreaking initiative offers industry-specific, best-in-class leadership training to blood community executives, elevating individuals, organizations, and the nation's blood supply. The program will accept an annual cohort of up to 25 fellows who will participate in:

- "a week-long leadership residency at Vanderbilt;
- three additional in-person learning immersions;
- virtual seminars taught by Vanderbilt faculty;
- a 360-leadership assessment;
- individual executive coaching; and
- a capstone project presented at the 2028 ABC Annual Meeting."

The EFP strives to accept participants from a wide variety of backgrounds and leadership roles. Final selections for the 2027-2028 cohort will occur by December 2026. An independent selection committee is responsible for choosing each year's cohort. Senior leaders from ABC member blood centers, hospital-associate members, affiliate organizations, and industry partners are encouraged to apply. The Foundation for America's Blood Centers (FABC) is pleased to announce a limited number of partial scholarships available for individuals employed by ABC active member blood centers. Additional information regarding tuition rates is available here.

ABC Executive Compensation Survey Is Open

ABC has launched the Executive Compensation Survey. Authorized individuals from ABC member blood centers have received an email with additional details and instructions for accessing the survey. The deadline to complete a submission is October 30th. The Executive Compensation Survey serves as a resource for blood center chief executive officers (CEOs) and their boards in setting executive salaries/benefits, as well as meeting the Internal Revenue Service (IRS) Form 990 requirements to demonstrate comparability of executive compensation. Please contact us with any questions.

September *Blood Bulletin* Is Available

The latest edition of *Blood Bulletin*, titled "Platelet Products in Clinical Practice: Manufacturing, Dose, and Safety Considerations" has been published. This issue of *Blood Bulletin* was written by: Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest; Kirsten Alcorn, MD, Co-Chief Medical Officer at Bloodworks Northwest; Roni J. Bollag, MD, PhD, Laboratory Medical Director, National Blood Testing Collaborative and Augusta University Blood Bank; Ruchika Goel, MD, MPH, CABP, Medical Director, Research, Carter BloodCare; Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Courtney Hopkins, DO, Vice President, Corporate Medical Director, Vitalant; Kathleen Hopping, MS, Senior Director Regulatory Affairs, Vitalant; Cyril Jacquot, MD, PhD, Medical Director, Children's National Hospital; and D. Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center. The authors of this publication disclosed no conflicts. *Blood Bulletin* is reviewed and edited by the ABC Scientific, Medical, and Technical Publications Committee.

MEMBER NEWS



We Are Blood recently celebrated its 75th anniversary with, "the inaugural Legacy of Life Benefit—an evening celebrating the people and partnerships that have shaped our past and will help carry our mission forward." An announcement from the blood center noted that, "[b]lood donors, recipients, healthcare professionals, first responders, volunteers, community partners, staff, and supporters gathered for an evening of celebration, connection, and community. Thanks to their generosity, the event raised nearly $115,000 to support We Are Blood's lifesaving mission and future initiatives. In 1951, a group of local physicians from the Travis County Medical Society recognized that a growing Central Texas needed a strong, stable community blood supply. What began as a blood bank serving four Austin hospitals and a handful of surrounding communities has grown alongside Central Texas. Today, We Are Blood serves a 10-county region through four donor centers and mobile blood drives seven days a week, providing lifesaving blood products to more than 50 hospitals, medical centers, and EMS agencies."

(Source: We Are Blood Announcement, 10/14/26)

ADVANCED THERAPIES NEWS

The U.S. Food and Drug Administration (FDA) has released a final guidance titled "Potency Assurance for Cellular and Gene Therapy (CGT) Products." According to the agency guidance, [d]eveloping assays that measure the potency of CGT products can be challenging. In this guidance document, we emphasize that potency assays and their corresponding acceptance criteria should be designed to make meaningful contributions to potency assurance by reducing risks to product potency. We provide illustrative examples of approaches to potency assay development that are grounded in quality risk management principles. Due to the diversity of CGT products and the product-specific nature of potency assays, the recommendations in this guidance document regarding the selection and design of potency assays are necessarily general. FDA has issued additional guidance documents that provide further advice about potency assays for specific classes of CGT products and intends to release additional guidance, as appropriate. [This] final guidance supersedes the document entitled 'Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products,' dated January 2011." A news release from the agency also noted that, "[t]he guidance provides flexible, risk-based recommendations for manufacturers on how to integrate potency considerations at every stage of development and commercialization—from early-phase investigational new drug (IND) submissions through biologics license application (BLA) approval and continued post-market verification. Key topics include controls for variability in raw materials, testing during manufacturing, and lab tests that confirm each batch is biologically active in a way that matches its intended therapeutic effect. The guidance also addresses specialized considerations for products with short shelf lives, viral vector gene therapies, and patient-specific therapies. [The FDA] will host a webinar on December 10th to help stakeholders understand and implement the guidance." Registration is open.

(Sources: FDA Guidance, 11/2/26; FDA News Release, 11/2/26)

FDA has published a draft guidance titled "Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management." The agency noted that the draft guidance, "is intended for sponsors and applicants developing individualized GE products. It addresses how an individualized GE product that includes multiple product variants can be submitted in a single Biologics

(continued on page 9)

ADVANCED THERAPIES NEWS (continued from page 8)

License Application (BLA) under section 351(a) of the PHS Act. It explains how to specify the extent of GE component variation in a BLA and how to add new product variants to the BLA after licensure. This guidance also addresses related topics, including in vitro safety and potency evaluation of product variants, manufacturing process validation, labeling and indication statements, and drug naming and identification. This guidance complements those previously issued guidances by providing advice on how to prepare and submit BLAs and BLA supplements for individualized GE products. This guidance will also be helpful to sponsors who intend to evaluate an individualized GE product that includes multiple product variants under a single IND. The scope of this guidance is limited to individualized GE products that meet all of the following criteria: (1) the product is intended to prevent, treat, or cure a monogenic disease or condition (e.g., autosomal dominant, recessive, or X-linked); (2) the disease or condition is caused by known pathogenic gene variants (e.g., single nucleotide variants, insertions, or deletions); and (3) all product variants in the BLA are designed to achieve the same editing outcome (e.g., correcting a pathogenic gene variant to the wild-type DNA sequence, or selectively inactivating a pathogenic gain-of-function allele). However, some principles in this guidance may be applicable to other individualized GE products. The scope of this guidance does not include the design or conduct of clinical studies (including postmarketing clinical studies) to generate evidence of safety and effectiveness that is adequate to support a BLA. However, FDA intends to issue further guidance on this topic. This guidance also does not address individualized products that are not GE products, GE products that are not individualized, or specific BLA approval pathways (accelerated vs. traditional)." The guidance also noted that, "[b]ecause a single product variant typically targets only one gene variant, a GE product intended to address a range of gene variants may include a set of modified GE components. The physical characteristics of these GE components that differ among product variants are termed variable features. A BLA for an individualized GE product may therefore contain many product variants, each sharing the same core design and differing only in the GE components used to address each patient's specific gene variant. Defining the allowable limits of feature variation in the BLA serves two purposes: establishing the boundaries of the product and facilitating the post-licensure addition of new product variants that fall within those boundaries. Importantly, this framework provides a way for applicants to add new product variants to a BLA based on *in vitro* data without additional clinical studies This guidance introduces the concept of the individualized feature space (IFS), which describes the allowable limits of variation for the GE components of an individualized GE product. [A new product] variant should be considered a manufacturing change for purposes of the BLA, rather than a new product, provided that: (1) the variable features of the product variant's GE components fall within the established IFS; and (2) the resulting product variant is predicted to have adequate safety and activity based on clinical and/or in vitro data. Section III describes the IFS in detail and provides additional examples of how it applies to individualized GE products."

(Source: FDA Guidance, 10/27/26) ♦

GLOBAL NEWS

***CBS News* reported that, "[a] cyberattack on several blood banks tried to raise temperatures to extremely high levels but was thwarted before it could do any damage to blood products or samples, French authorities said," according to the news organization.** The article noted that, "[i]n the most recent cyberattack, the French Blood Establishment, or EFS, said in a statement released late Tuesday 'temperature and defrosting thresholds were raised to extremely high levels' on Monday at three of its cold-storage sites for plasma. Monitoring systems quickly detected the problem, allowing staff to take action in time so that 'no blood products or samples were compromised.' French weekly newspaper *Le Canard Enchaîné*, which first reported the cyberattack, said that the attack had attempted to reset temperatures that normally are at -22 Fahrenheit (-30 Celsius) to as high as 230 F (110 C). The cyberattack hit a

(continued on page 10)

GLOBAL NEWS (continued from page 9)

supplier of refrigeration equipment at three EFS sites. The products stored were bags of plasma intended for transfusions and plasma used to manufacture medicines, and were either transferred or secured, the EFS statement said. [Blood collection] and distribution operations remain uninterrupted, ensuring continued services for patients at hospitals and other healthcare. The company supplying the refrigeration equipment, Coolworld, said in a statement it 'is aware' of the cybersecurity incident. 'The vulnerability currently being reported in the media relates to a component from a third-party supplier and was outside Coolworld's direct control,' the statement said. The company said only a limited number of units were affected, and it was taking 'appropriate measures.' This week's cyberattacks on refrigeration systems mirrored an episode in mid-October that targeted fridges and freezers at hundreds of supermarkets and independent stores across France, Belgium, and the Netherlands," reported *CBS News*.

(Source: *CBS News*, "Blood banks hit by cyberattack in France days after European freezer hacks," 11/4/26)

Researchers in Canada from the University of Alberta and Canadian Blood Services have received $24 million in federal government funding to, "make Canada's blood supply more resilient and equitable." Canadian Blood Services, chief executive officer, Graham D. Sher noted in the news release, "[t]he investment will help us better understand how to engage new and diverse communities of donors while advancing research aimed at developing the next generation of blood products, including innovative technologies that could make blood products universally compatible." Researchers from the team have already been successful in, "rejuvenating red blood cells to make them more universally acceptable, avoiding the need to match transfusions according to type [by coating them] with a biodegradable natural sugar that's already in our bodies, so the immune system can no longer see it. The idea is that you can then give blood from any person to any other person and there would no longer be a need for matching. The team will perform a safety trial to support advanced red blood cell and platelet technologies using improved enzymes that will also be important for nanomedicine and other cell-based therapies."

(Source: University of Alberta News Release, 10/23/26)

COMPANY NEWS

Cerus Corp. has announced, "positive topline results from the Phase 3 RedeS (NCT03037164) trial." According to a company news release, "[t]he primary efficacy endpoint was met, demonstrating non-inferiority for INTERCEPT red blood cells (RBCs) compared to conventional RBCs, as measured by adjusted hemoglobin increment, a commonly used measure of RBC transfusion effectiveness. On a modified intent to treat (mITT) basis:

- [a]djusted hemoglobin increment was 1.996 g/dL (N=195) in the INTERCEPT arm compared with 2.050 g/dL (N=199) in the control arm, for an estimated difference of -0.054 g/dL (95% CI, -0.210 to 0.103); [and]
- [t]he lower bound of the 95% confidence interval was above the prespecified non-inferiority margin of −0.32 g/dL, demonstrating non-inferiority (p=0.004)."

Additionally, the company explained that, "[t]he study was designed with two prespecified primary safety endpoints:

(continued on page 11)

COMPANY NEWS (continued from page 10)

- [t]he proportion of subjects with any TEAEs (possibly, probably or definitely) related to a study RBC transfusion was 3.4% (n=9) in the INTERCEPT arm (N=267) compared with 2.5% (n=7) in the control arm (N=276), with no statistically significant difference between treatment arms (p=0.634); [and]
- [a]s in Cerus' prior ReCePI study, treatment-emergent, low titer, transient INTERCEPT-specific antibodies were detected in RedeS without evidence of hemolysis or clinical impact. The proportion of subjects with INTERCEPT RBC-specific antibodies was 2.2% (n=6) in the INTERCEPT arm (N=267), compared with zero in the control arm (N=276) (p<0.013). The six INTERCEPT RBC-specific antibodies observed in the treatment arm were included in the TEAE safety endpoint.

Full study results, including secondary endpoints, are expected to be submitted to a peer-reviewed scientific journal as well as presented at upcoming scientific meetings."

(Source: Cerus Corp. News Release, 11/2/26)

Fresenius Kabi has unveiled the 2026 inductees into the Fresenius Kabi National Blood Donation Hall of Fame. According to a company news release, this year's inductees include 14 individuals nominated by, "blood centers across the U.S. [The] honorees have demonstrated extraordinary commitment to donating blood or encouraging blood donation. This year's inductees hail from Hawaii to Florida. Some have given blood for decades, breaking records in the process. Others have inspired and educated their colleagues and students on the importance of blood donation. The 2026 honorees join more than 350 others inducted into the Fresenius Kabi National Blood Donation Hall of Fame in the last 28 years." The 2026 Fresenius Kabi National Blood Donation Hall of Fame inductees nominated by members of America's Blood Centers are:

- Peggy Hopp (LifeServe Blood Center);
- Mitch Eiting (Versiti Blood Center);
- Amy Jo Wess (The Blood Connection);
- David Butt (ImpactLife);
- Dja Dugue-Wright (OneBlood);
- Lyman Koike (Blood Bank of Hawaii);
- Hubert Stalling (Versiti Blood Center of Illinois);
- Melissa Culpepper (OneBlood);
- Officer James "J.T." Taylor (Carter BloodCare); and
- Cherie Towers and Julie Ellis (LifeStream Blood Bank).

(Source: Fresenius Kabi News Release, 10/15/26)

Terumo Blood and Cell Technologies (Terumo BCT) has announced that Versiti has become the 10th blood center in the U.S. to, "adopt the Reveos™ Automated Blood Processing System." A company news release noted that, "Reveos is the only whole blood automation device available in the U.S. that separates whole blood into red blood cells, plasma, and platelets in a single, fully automated centrifugation cycle. Historically, separating platelets from whole blood donations has relied on manual, multi-step processes that require significant hands-on time and can introduce variability."

(Source: Terumo BCT News Release, 10/19/26)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2026

November 5-6. **2026 ABC Women's Executive Leadership Community (WELC) *Rise &* Lead Workshop. San Antonio, Texas.** Registration is open. More information is available here.

November 17. **ABC Educational Committee Webinar: Risk Assessment for Blood Centers (Virtual).** ABC members can contact us for more information including a link to registration.

November 17. **NHTSA Office of EMS Prehospital Blood Transfusion Policies, Protocols Guidelines & Training Webinar (Virtual).** Registration is open. More information is available here.

November. 17-20. **American Society for Clinical Pathology (ASCP) and Canadian Association of Pathologists- Association Canadienne des Pathologistes (CAP-ACP) Joint Annual Meeting. Montreal, QC.** Registration is open. More information available here.

December 10. **U.S. Food and Drug Administration (FDA) OTP Guidance Webinar: "Potency Assurance for Cellular and Gene Therapy Products" (Virtual).** Registration is open. More information is available here.

December 15. **NHTSA Office of EMS Prehospital Blood Transfusion: Tracking Success & Improvement Webinar (Virtual).** Registration is open. More information is available here.

2027

March 2-4. **Eugene Springfield Fire "Pacific Northwest Whole Blood Summit."** Eugene, Ore. Col. More information is available here.

March 8-11. **2027 ABC Annual Meeting. Atlanta, Ga.** More information is coming soon.

April 20-21. **PPTA International Plasma Protein Congress (IPPC). Barcelona, Spain.** More information is available here.

May 11-13. **2027 ADRP: The Association for Blood Donor Professionals Annual Conference. Columbus, Ohio.** More information is coming soon.

May 12-13. **The International Plasma and Fractionation (IPFA)/Paul-Ehrlich Institut[e] (PEI) 33rd International Workshop on Surveillance and Screening of Blood-borne Pathogens. Edinburgh, Scotland.** Registration is open. More information available here.

September 15-16. **2027 ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** More information is coming soon.

September 20-23. **Association for Advancing Tissue and Biologics (AATB) Congress 27. Montréal, Canada.** More information available here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Chief Donor and Growth Officer. Carter BloodCare (Bedford, TX) seeks a strategic, mission-driven **Chief Donor and Growth Officer** to lead donor growth, collection operations, marketing and communications, donor experience, and community engagement. As an executive leadership team member, you will guide the complete donor journey, strengthen partnerships, and align innovation, resources, and operations to sustain a reliable blood supply for patients. **Required qualifications: Education** - Bachelor's degree in business administration, healthcare administration, marketing, communications, public health, life sciences, or a related discipline; **Experience** - Seven years leading executive-level customer, patient, community, or donor acquisition, retention, engagement, and experience strategies; five years in executive or senior leadership overseeing multiple functions or complex operations; experience in a regulated industry or mission-driven environment. Competitive compensation and comprehensive benefits package. Apply Here.

Divisional Director (Suffolk/Norfolk, VA). The Blood Connection seeks an experienced and strategic Divisional Director to provide leadership, administrative guidance, and operational direction across key departments within the organization. This leader will oversee critical functions that may include donor recruitment, blood collection operations, facilities, fleet, procurement and materials management, hospital services, component manufacturing, and laboratory services. The Divisional Director will oversee departmental budgets, staffing, performance, quality, and operational planning while ensuring compliance with current good manufacturing practices. This leader will also drive process improvements, support strategic initiatives, and partner with executive leadership as The Blood Connection expands services and enters new regions. Candidates must have a bachelor's degree in a related field, five years of experience in a technical or laboratory setting, including at least five years of progressive management experience, and a background in blood banking or another regulated biologics manufacturing environment. Strong analytical, organizational, communication, and leadership skills are essential, along with the ability to effectively manage priorities and collaborate across all levels of the organization. This is an opportunity to lead mission-critical operations that directly support The Blood Connection's continued growth and lifesaving work throughout the communities we serve. Apply today: https://jobs.dayforcehcm.com/en-US/tbc/CANDIDATEPORTAL/jobs/19089.

Finance Manager. LifeSouth Community Blood Centers is seeking an experienced **Finance Manager** to lead our Business Office operations at our headquarters in Gainesville, Florida. This is an opportunity to put your financial expertise and leadership skills to work for a non-profit organization with a lifesaving mission. **Position Highlights:** Lead and develop a team supporting essential financial and accounting operations. Oversee functions including payroll, accounts payable, revenue cycle, fixed assets, and expense reporting. Promote accuracy, accountability, operational efficiency, and exceptional service across the organization. Identify opportunities for process improvement and strengthen financial operations. **What We're Looking For:** Progressive accounting or finance experience with demonstrated supervisory experience. Strong knowledge of accounting principles, financial controls, and business operations. Proven leadership, organizational, and communication skills. Bachelor's degree in Accounting, Finance, or a related field (equivalent education, training, and experience may be considered). **Location:** Gainesville, FL (fully on-site). Starting Salary: Negotiable based on relevant experience and qualifications. **Interested?** Learn more about the position and apply using the link below. **To be considered for this opportunity, candidates must submit an application through LifeSouth's official careers website.** APPLY HERE

Blood Services Medical Director (Milwaukee, WI - Hybrid). Versiti is seeking a physician leader to serve as **Blood Services Medical Director**, providing medical oversight and strategic leadership for blood collection, manufacturing, testing, distribution, and transfusion medicine services across Wisconsin and the broader Versiti network. This role offers the opportunity to influence patient care, donor safety, regulatory excellence, and innovation within one of the nation's leading blood health organizations. Working closely with physicians, laboratory teams, operational leaders, hospital partners, and community stakeholders, you will support quality systems, regulatory compliance, donor eligibility programs, adverse event management, investigations, product look-backs, and public health reporting. You will also provide transfusion medicine consultation to hospital clients, support Special Patient Services, participate in physician on call coverage, and collaborate across the organization to advance standardized practices, education, research, and continuous improvement initiatives. **Qualifications:** M.D. or D.O. degree. Board certified or board eligible in Blood Banking/Transfusion Medicine. Board certification or eligibility in Pathology, Internal Medicine, or Pediatrics with transfusion medicine specialization. Eligibility for Wisconsin medical licensure and multi-state licensure within Versiti's service area. Qualifications to serve as a CLIA Laboratory Director. Join Versiti's non-profit organization and help advance blood health through trusted medical leadership. This hybrid role requires onsite presence three days per week, **while supporting innovation, collaboration, and operational excellence**. Click here to apply.

(continued on page 14)

POSITIONS (continued from page 13)

Blood Center Executive Director (Amarillo, TX). Join **Coffee Memorial Blood Center**, an innovative, dynamic, and successful company that provides lifesaving and life improving blood products to hospitals and first responders throughout our region. We help build strong community partnerships by bringing together donors, volunteers, businesses, schools, healthcare organizations, civic leaders, and many others ensure that blood is available for patients in need. Ours is more than a management position – it's a **leadership opportunity** to shape community engagement, drive collections growth, and strengthen the fabric of giving across the Panhandle. We're seeking an experienced, relationship-focused, compassionate, disciplined, and insightful executive to oversee our Amarillo operations and to help advance our mission as the Donor to Patient Lifeline. In directing staff, strong aptitudes for motivating people and developing talent are required. Good communications and interpersonal skills are must haves, as are strong organizing skills, process orientation, project execution, and proactive energy. Impeccable character and uncompromising integrity are foundational. **Salary Range:** Competitive compensation and comprehensive benefits package, including Health, Dental and Vision insurance, Life Insurance, Long-Term Disability, Flexible Spending Plan, 401(k) retirement plan, Paid Time Off, Holiday Pay, and Tuition Reimbursement along with tenure bonuses. **How to apply:** https://ourbloodinstitute.org/about/careers/

Chief Operating Officer. National Blood Testing Cooperative (NBTC) is seeking a strategic **Chief Operating Officer (COO)** to lead and scale the operations of our blood testing laboratory services, located in Stone Mountain, Georgia. The COO is a senior executive responsible for overseeing laboratory operations and operational support functions, providing service to 20 blood centers. The COO ensures the organization consistently delivers accurate, timely, and reliable testing services while advancing NBTC's mission to provide exceptional value to its member blood centers. The COO partners with senior leadership to translate the organization's strategic goals into reliable, compliant, efficient, day-to-day execution across laboratory operations, quality systems, personnel, technology, client interactions, facilities, and financial performance. The COO is responsible for defining, monitoring, and reporting key performance indicators (KPIs) to drive accountability, operational efficiency, and continuous improvement across laboratory functions. **Qualifications:** Bachelor's degree in clinical laboratory science or related life science required. MLS/ASCP, MT/ASCP, or equivalent certification required. Minimum five years of senior management experience and 10 years of progressive leadership experience within clinical laboratory setting, transfusion medicine or diagnostic testing operations required. Must have demonstrated success leading complex, high-volume, regulated laboratory operations. Experience managing multiple operational departments and cross-functional teams. Proven record of driving operational excellence and organizational performance improvements. Strong capability to lead organizational change and with extensive knowledge of laboratory operations, quality systems, and regulatory compliance. Experience with FDA-regulated laboratory operations is required; CAP and CLIA expertise is preferred. Click here to apply.