America's Blood Centers
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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

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Transfusion-Related Alpha-Gal Syndrome Studied in *JAMA*

A paper published in *JAMA Internal Medicine* reported on the findings from an epidemiologic study that sought to, "investigate the possibility that severe allergic transfusion reactions (ATRs) to B or AB plasma or platelet units may reflect a manifestation of Alpha-gal syndrome (AGS)." The authors explained that, "AGS is an acquired food allergy transmitted by tick bites. Patients with AGS characteristically develop allergic reactions 2 to 6 hours after eating mammalian meat, with presentations ranging from mild urticaria or gastrointestinal symptoms to fatal anaphylaxis."

The researchers hypothesized that, "if transfusion-related AGS (TRAGS) is a true clinical entity, then in AGS high-prevalence regions-only (where many inhabitants have preformed alpha-gal IgE), we should observe excess ATRs among patients with blood type O receiving B antigen–containing units." The international, multicenter, retrospective cohort study took place from January 2020 through December 2024. "Study sites were academic medical centers in the U.S., Australia, Japan, Germany, and France. [Each site] extracted data from hospital records for its assigned study period on all platelet and plasma transfusions administered to consecutive patients with blood type O and reported ATRs. [At all sites,] clinical testing for serum alpha-gal IgE had been performed using the same commercial ImmunoCAP assay (Thermo Fisher/Phadia)." The study defined ATRs as, "a transfusion-associated adverse event reported by a clinician and documented as an ATR in the medical record by a transfusion medicine physician. Sites categorized all ATRs as mild or as moderate to severe."

The authors noted that, "[i]n total, 558,823 platelet and plasma transfusions at 40 sites in five countries were analyzed, among which ATRs occurred in 1,744 transfusions (0.3 percent). U.S. data were obtained from 26 sites. The AGS-high cluster had 9 sites (3 in U.S. counties with >87 suspected AGS cases/1M PPY and 6 in U.S. counties with 11-87 suspected cases/1M PPY). The AGS-low cluster had 15 sites (14 in U.S. counties with <11 suspected cases/1M PPY and 1 in a U.S. county with 0 suspected cases/1M PPY)." The researchers found that, "in the AGS-low cluster, there was no significant difference in ATR rates between patients with blood type O receiving B or AB units and patients with blood type O receiving O units. In the AGS-high cluster in contrast, ATR rates were significantly higher among patients with blood type O receiving B or AB units vs patients with blood type O receiving O units (overall risk ratio (RR), 3.93; 95 percent CI, 2.96-5.21; $P < .001$). Excess ATRs were not observed at AGS-high sites among patients with blood type B receiving B or AB units. [Additionally,] in the AGS-high cluster, group A plasma or platelet transfusions were not associated with excess risk for ATR. In contrast, AB plasma or platelet transfusions were associated with higher

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Transfusion-Related Alpha-Gal Syndrome Studied in *JAMA* (continued from page 1)

ATR risk vs the reference group of patients with blood type O receiving O units (overall RR, 2.53; 95 percent CI, 1.59-4.01; P < .001). B plasma or platelet transfusions were associated with an even higher ATR risk (RR, 4.48; 95 percent CI, 3.32-6.06; P < .001). In the AGS-low cluster, no significant overall differences in ATR rates were seen between patients with blood type O receiving B, AB, or A units vs those with blood type O receiving O units."

The authors also explained that, "[f]or patients with blood type O receiving A units in the AGS-low cluster, the overall RR for moderate to severe ATRs was 1.60 (95 percent CI, 1.09-2.36; P = .02). The overall RR in the AGS-high cluster was identical, although it showed no significant difference from the reference group. Among patients with blood type O receiving B units in the AGS-low cluster, the RR for moderate to severe ATRs was 2.15 (95 percent CI, 1.34-3.47; P = .002). Among patients with blood type O receiving B units in the AGS-high cluster, the RR for moderate to severe ATRs was 9.14 (95 percent CI, 5.39-15.52; P < .001). [Consistent with their observations, the researchers] would expect the ability of allergens to cross-link alpha-gal IgE to be greater for B than AB and much greater for AB than A (some alpha-gal antibodies can recognize A[6]). Finally, [the findings] suggest that TRAGS reactions tend to be moderate to severe more often than other ATRs, although [the study's] statistical power was constrained by low event rates."

Additionally, the paper noted that in, "U.S. sites in regions where AGS was highly prevalent, there were significantly more ATRs among patients with blood type O receiving B or AB platelets or plasma than among patients with blood type O receiving O platelets or plasma (the reference group). At these AGS-high sites, excess ATRs were not observed when patients with blood type B were transfused with B or AB units. Individuals with blood types B or AB are relatively protected from producing IgE to alpha-gal and developing AGS. [Recent case] reports, French hemovigilance data, and this study's results are consistent with a putative allergic reaction mechanism whereby transfused B carbohydrate antigens cross-link recipient alpha-gal IgE."

The researchers concluded that, "[t]his study provides provocative epidemiologic evidence consistent with TRAGS representing a newly recognized risk to recipients of blood transfusions. Case reports suggest that TRAGS can be lethal. Because there are important clinical implications, prospective validation of [the] results is warranted. Meanwhile, hospitals in AGS high-prevalence regions may wish to evaluate their local ATR rates by blood product and patient ABO group and consider practice changes to reduce risk. Blood collectors can consider curtailing the collection of plasma and platelets from donors of type B or redistributing B and AB units to AGS low-prevalence regions. Hemovigilance systems could track suspected TRAGS cases prospectively. Finally, further investigation is needed to better elucidate the mechanism of TRAGS, clarify the risk among patients with blood type A, and identify blood product modifications that could reduce risk to patients."

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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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Transfusion-Related Alpha-Gal Syndrome Studied in *JAMA* (continued from page 2)

Some limitations of the paper acknowledged by the authors included: "[g]iven that this was a retrospective study, it was not feasible to test patient sera for alpha-gal IgE to confirm the proposed association of ATRs with AGS; we cannot exclude the possibility that clinicians at AGS high-prevalence sites may have been more likely to investigate and report suspected ATRs to B or AB units; and [i]t is formally possible that geographic factors unrelated to AGS could explain the finding of excess ATRs to B or AB units."

An accompanying Invited Commentary titled "Ticks and Transfusion at the Crossroads—Alpha-Gal Syndrome" explained that, "Anti–alpha-Gal IgE has recently been implicated in allergic transfusion reactions. While traditional thinking has been that donor and recipient ABO blood groups are not relevant in considering risk for allergic transfusion reactions, investigators have recently hypothesized that some allergic reactions following transfusion of B antigen–containing products [to be] the result of recipient IgE antibodies related to AGS. [This study provides the strongest data to date supporting the existence of TRAGS. Strengths of the study included the large number of transfusions evaluated, [the] number and broad geographic distribution of study sites, and [the] study design that allowed evaluation of the association of O vs B recipient status and AGS prevalence with the incidence of allergic transfusion reactions." The authors of the commentary concluded by explaining that, "[the study] presented new findings that support the existence of allergic reactions associated with group B or AB products transfused to O recipients in regions of high prevalence of AGS. This report should motivate further studies of allergic transfusion reactions."

America's Blood Centers has developed an AGS resource that includes frequently asked questions (FAQs). Last month, the Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* published a paper titled "Alpha-gal Immunoglobulin E Seroprevalence Among Blood Donors—10 States, 2024–2025."

Citations: Kaufman, R.M., Hoen, A.G., Khan, J., *et al*. "Epidemiologic Study of Transfusion-Related Alpha-Gal Syndrome." *JAMA Internal Medicine*. 2026

Hollenhorst, M.A. Anderson, J.R., and Dzik, W. "Ticks and Transfusion at the Crossroads—Alpha-Gal Syndrome." *JAMA Internal Medicine*. 2026.

REGULATORY NEWS

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research, Office of Blood Research and Review (OBRR) has published the draft agenda on the agency website for the virtual FDA Roundtable: Strengthening the Supply Chain for Blood Manufacturing taking place September 29th. The draft agenda is currently divided into the following sections:

- "Welcome and Roundtable Objectives;
- Session I: Current State;
- Session II: Supply Chain Manufacturers;
- Session III: Department of Health and Human Services;
- Open Public Comments; [and]
- Concluding Remarks and Next Steps."

The website also provides a listing of the speakers and moderators who are scheduled to take part in the roundtable. Registration for this event is open.

(Source: FDA Announcement, 8/18/26)

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REGULATORY NEWS (continued from page 3)

The FDA recently announced the authorization of "a first-of its-kind robotic blood draw device." Specifically, the agency explained that, "[the device can] draw blood from a patient's arm without hands-on operator intervention. The device is authorized for use in adults in outpatient settings and must be operated under the oversight of a supervisor trained in phlebotomy. One phlebotomist can oversee up to three Aletta devices at the same time, which may help address the current phlebotomist shortage in the U.S." The FDA announcement also noted that, "Aletta autonomously handles each step of the blood draw, while a trained phlebotomist initiates each session and remains available to respond to any issues throughout. The device guides the patient to position their arm, after which the patient or supervisor presses a button to start the blood draw. The Aletta then uses near-infrared light and Doppler ultrasound to locate a suitable vein and tell it apart from arteries. If no appropriate vein is found, the device will not attempt the procedure. Once a vein is identified, the Aletta proceeds through the remaining steps on its own: applying a tourniquet, preparing the skin, inserting and disposing of the needle, changing collection tubes and placing a bandage. The supervising phlebotomist confirms that collection tubes are filled in the correct order and verifies that all tubes are adequately full following the procedure. The Aletta is designed with multiple layers of patient safety in mind. The device continuously applies disinfectant to the skin during the ultrasound scan. The device is also cleaned by a trained professional between patients. If a patient moves too much during the procedure, the needle automatically detaches and the draw stops; additional onboard sensors can pause the procedure and alert the supervisor if other unsafe conditions are detected."

(Source: FDA News Release, 8/19/26)

WORD IN WASHINGTON

President Trump has nominated Heidi Overton, MD, PhD to be the commissioner of the U.S. Food and Drug Administration (FDA)," reported the *Associated Press*. She is currently the deputy director of the White House Domestic Policy Council [and] has, "worked on several of President Trump's second-term health initiatives." According to her bio, she previously served as, "the chief policy officer at the America First Policy Institute, as well as the vice chair for the Center for a Healthy America. During [President' Trump's first term], she served as a White House Fellow in the Office of American Innovation and the Domestic Policy Council, advising senior Administration officials on healthcare policy and working with U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services to develop and execute major healthcare initiatives."

(Source: *Associated Press*, "Trump picks Dr. Heidi Overton, a top White House aide, to lead the Food and Drug Administration," 8/19/26)

The FDA has announced the publication of a discussion paper on considerations for the regulation of generative artificial intelligence (GenAI)-enabled medical devices, seeking feedback from interested parties on risk assessment, premarket evaluation, postmarket monitoring, and other topics relevant to the regulation of GenAI-enabled medical devices." The agency explained in a news release that the, "Digital Health Center of Excellence (DHCoE), within the FDA's Center for Devices and Radiological Health, is leading this discussion paper which supports the FDA's Public Health Pillar on Innovation and Global Leadership. This strategic pillar includes key priorities to advance regulatory frameworks for AI and digital health technologies. The discussion paper begins by outlining a possible two-axis framework for risk assessment that might be used to inform regulatory expectations. It then discusses a potential approach to premarket evaluation built on the concept of competency assessment, inspired at a high level by how physicians are trained and evaluated, consisting of non-clinical device benchmarking and clinical confirmation to evaluate whether a GenAI-enabled medical device performs as

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intended before reaching patients. The paper also describes several potential approaches to risk-proportionate postmarket monitoring and discusses considerations around foundation models and agentic AI systems. For each of these areas, the FDA poses targeted questions to inform the development of a regulatory framework that is scientifically rigorous, prioritizes patient safety, and aligns with the novel capabilities of GenAI-enabled medical devices." FDA is soliciting feedback on the discussion paper from, "device manufacturers, clinicians, consumers, researchers, the public, and other interested parties, to be submitted under the docket FDA-2026-N-7874 on www.regulations.gov by October 19th."

(Source: FDA News Release, 8/19/26)

INFECTIOUS DISEASES UPDATE

ARBOVIRUSES

A paper published in the Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* (*MMWR*) described the annual update, "on domestic arboviral disease case numbers and incidence to increase awareness of the occurrence and characteristics of arboviral diseases in the U.S." It explained that in the U.S., "humans typically acquire arboviral infections when they are bitten by an infected mosquito or tick and, although rare, through other routes such as blood transfusion and organ transplantation." The authors noted that the, "CDC received 1,955 reports of confirmed (594; 30 percent) and probable (1,361; 70 percent) arboviral disease cases with illness onset in 2024; 1,485 cases (76 percent) were neuroinvasive. Cases were reported from 647 (21 percent) of 3,143 U.S. counties and from 48 states and the District of Columbia (DC). West Nile virus (WNV) accounted for 1,808 (92 percent) cases, followed by Powassan (60; 3 percent), La Crosse (37; 2 percent), Jamestown Canyon (27; 1 percent), eastern equine encephalitis (19; 1 percent), St. Louis encephalitis (2; <1 percent), and unspecified California serogroup viruses (2; <1 percent). The specific virus was unknown for two cases with California serogroup virus; these cases were excluded from further description in this report. [In 2024,] a total of 1,808 WNV disease cases were reported. [WNV disease] cases were reported from 591 (19 percent) of 3,143 counties in 48 states and DC. Texas (363 cases), California (103), and New York (69) accounted for 40 percent of all U.S. WNV neuroinvasive disease cases. The national incidence of WNV neuroinvasive disease was 0.40 per 100,000 population, and incidence was highest in North Dakota (2.76), Nebraska (2.49), and Mississippi (1.43). Incidence was higher among males (0.52) than females (0.28) and among adults aged ≥70 years (1.30) than persons in other age groups. Incidence was lowest among children aged <10 years (0.02). The 1,808 reported WNV disease case count in 2024 is below the 10-year median of 2,162 cases (IQI = 1,132–2,628). The 456 cases reported in Texas are more than double the number reported in Texas in 2023 (163)." The authors noted that, "[h]igh-quality and timely surveillance is critical to understanding the epidemiology, seasonality, and geographic distribution of domestic arboviruses, which can facilitate clinical recognition, identification of outbreaks, messaging activities to the public and health care providers, and vector-control activities. WNV and other arboviral disease testing should be considered by clinicians for patients with acute febrile or neurologic illness, including recipients of organ transplants or blood transfusions, particularly during times when mosquitoes and ticks are active. Health care providers who order testing for a specific causative agent should take into consideration the timing of illness onset, type and location of exposures, patient age, and underlying health status."

Citation: Mace, K.E., Jacobs, D., Gould, C.V., *et al*. "West Nile Virus and Other Nationally Notifiable Arboviral Diseases — United States, 2024." *MMWR*. 2026.



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.

Registration Is Open for the Rise & Lead Workshop

Register for the ABC Women's Executive Leadership Community (WELC) Rise & Lead Workshop taking place in San Antonio, Texas November 5th-6th at The Westin Riverwalk, San Antonio. Join blood community professionals and industry partners for a dynamic leadership experience focused on Executive Presence and Personal Brand to develop the skills needed to increase your visibility, strengthen your influence, and confidently communicate your value while building meaningful connections with peers and industry leaders. For chief executive officers (CEOs) seeking a more intimate leadership experience, an optional CEO Retreat on November 4th offers a dedicated opportunity to connect with fellow executives, discuss shared challenges, and engage in meaningful peer-to-peer conversations before the workshop begins. WELC empowers leaders throughout the blood community through networking and professional development. Whether you are an emerging leader, experienced manager, or seasoned executive, the workshop creates space for meaningful conversations, shared learning, and the development of lasting professional relationships. Please contact us with any questions.

Nominations Are Open for the ABC Medical & Scientific Emerging Leader Award

America's Blood Centers (ABC) is encouraging member blood centers to recognize an early to mid-career medical and scientific professionals (individuals who are within 20 years of having completed their training) with the ABC Medical & Scientific Emerging Leader Award. The deadline to submit a nomination is September 30th. This award honors individuals who demonstrate leadership, innovation, and commitment to advancing blood banking and transfusion medicine. The award recipient will receive:

- complimentary meeting registration and travel support to the 2027 ABC Annual Meeting in Atlanta, Ga.;
- an opportunity to deliver a featured 60-minute lecture during the 2027 ABC Annual Meeting; and
- recognition as an emerging leader in the field.

Additional criteria details and more information are available on the ABC website. Please contact us with any questions.

ABC Releases New State Advocacy Toolkits

ABC has developed two new resources to help member blood centers with their ongoing state-based advocacy efforts. Members now have access to the State Advocacy Toolkit on Blood Donor Leave and the State Advocacy Toolkit on Blood Donation Education. Both are designed to move from awareness to action, giving you resources needed to open a conversation with a state legislator and see it through to enacted policy. Each toolkit includes:

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- an overview of the issue and why it matters;
- talking points members can customize for meetings with policymakers;
- a current-landscape review of where the states stand today; and
- model legislation members can adapt to their own state's law and political environment.

Specifically, the donor leave toolkit maps the six states that currently name whole blood donation as a covered leave reason and offers two model templates (a standalone policy and a lighter-lift amendment to existing sick leave law). The donor education toolkit covers the two states with enacted school-based education laws, tracks pending bills in several others, and pairs an "encouragement" model and a "curriculum mandate" model with ABC's *Vein to Vein: The Science of Blood Donation* curriculum as the ready-made pathway to compliance. Please contact us with any questions.

Economic Outlook Survey Report Available

America's Blood Centers (ABC) recently announced that the ABC Economic Outlook Survey Report has been released. The report is complimentary to participants and instructions on accessing it have been distributed to the designated contact. Non-participating ABC members may purchase the report. The ABC Economic Outlook Survey provides a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures. Please contact us with questions.

Schedule Released for the 2026 ADRP MasterClass

Join us for the 2026 ADRP MasterClass: "The Manager Magnet: Influence and Execution in the Most Complex Leadership Seat!" This virtual event will take place September 16th-17th. View the schedule and register now. In today's competitive market, businesses that prioritize both employee and customer experience gain a significant edge. Join us as we explore:

- "the connection between employee engagement and customer satisfaction;
- strategies for creating a positive workplace culture;
- how technology and data improve experiences for employees and customers; and
- real-world examples of companies excelling in both areas."

Whether you're in collections, recruitment, marketing, a customer experience professional, or business executive, this event will equip you with actionable insights to enhance both employee and customer journeys.

BRIEFLY NOTED

On August 18th, Kaufman Hall released its most recent National Hospital Flash Report containing June 2026 data. Key takeaways from the report included:

- "[u]ncompensated care pressures are intensifying. Hospital bad debt and charity care grew both in dollar terms and as a percentage of gross revenue year-to-date through June, accelerating financial pressure for health systems;
- emergency department (ED) demand is growing. ED visits rose in June as compared with last year. With broader payer landscape shifts, more patients may rely on EDs for care, potentially driving further volume increases;

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BRIEFLY NOTED (continued from page 7)

- [h]ospital performance varies widely in 2026 despite stable margins. While the median operating margin held steady year-to-date through June, performance continues to vary across hospitals, with smaller and rural facilities bearing the greatest strain on already thin cash reserves; [and]
- [e]xpense inflation remains a persistent drain on performance. Supply and drug expenses continued rising well above inflation year-to-date through June, reinforcing the need for targeted, disciplined spend management strategies across the system."

(Source: Kaufman Hall National Hospital Flash Report, 8/18/26)

MEMBER NEWS



Senator Dick Durbin (D-Ill.) recently visited **ImpactLife** to, "discuss the importance of addressing the nation's blood product supply shortage and thank the medical officials and donors who are working to maintain adequate supplies." A news release explained that he met with officials from the blood center and Memorial Health. Senator Durbin noted in the news release that, "[t]imely access to blood can be the difference between life and death, especially in a medical emergency. I want to thank the professionals at ImpactLife and other medical sites along with the countless donors who come forward to help those in need."

(Source: Sen. Dick Durbin News Release, 8/17/26)

Miller-Keystone Blood Center recently welcomed Rep. Ryan Mackenzie (R-Penn.) for a tour of its Bethlehem headquarters, donor room, and lab. An announcement by the blood center noted that, "[h]is visit offered a firsthand look at the vital work behind our community's blood supply, and the dedicated team members and generous donors who make that lifesaving work possible every day."



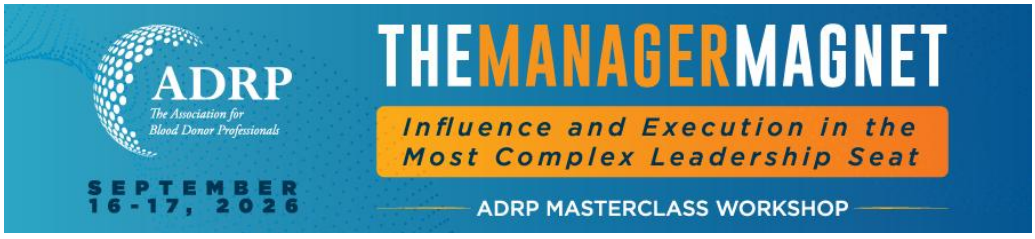
(Source: Miller-Keystone Blood Center Announcement, 8/5/26)



Rep. David Kustoff recently visited **LIFELINE Blood Services** where he honored the organization as a part of America's 250th birthday celebration and, "highlighted its role in supporting patients and medical facilities across the region." He also presented the blood center with a flag which had been flown over the U.S. Capitol in recognition of LIFELINE's lifesaving services to the Jackson, Tenn. area." Members of the congressman's staff also rolled up their sleeves to donate during the visit.

(Source: LIFELINE Blood Services Announcement, 7/21/26)

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Hoxworth Blood Center has partnered with Vitrafy to, "expand [the company's] next-generation cryopreservation ecosystem." According to a news release, "[u]nder the partnership, Vitrafy and Hoxworth will each contribute resources and in-kind support toward delivering a solution to this emerging threat [to existing red blood cell cryopreservation workflows created by the discontinuation of critical legacy technology.] The agreement is not expected to generate revenue for Vitrafy [who] will initially place one cryopreservation freezing and software package at Hoxworth. The Company expects the partnership to support broader engagement with market participants and government stakeholders toward a unified industry response to the red blood cell preservation issue, with a goal of converting into a longer-term commercial engagement across a wide range of blood centers."

(Source: Vitrafy News Release, 7/23/26)

ADVANCED THERAPIES NEWS

The U.S. Food and Drug Administration (FDA) has published a notice in the *Federal Register* titled "Frequently Asked Questions-Developing Potential Cellular and Gene Therapy Products; Final Guidance for Industry." The agency explained that the guidance document, "provides industry with answers to frequently asked questions (FAQs) and commonly faced issues that arise during the development of cellular and gene therapy (CGT) products. The FAQs represent common questions directed to the agency and span multiple disciplines, including regulatory review; chemistry, manufacturing, and controls (CMC); pharmacology/toxicology; clinical; and clinical pharmacology. This guidance [finalizes] the draft guidance of the same title issued [in] November 2024."

(Source: *Federal Register* Notice, 8/20/26)

The Blood & Cells Advocacy Roster (BCAR) recently announced that *BioProcess International* has published an article titled "Decentralized Apheresis: The Missing Link in Equitable Cell and Gene Therapy Access?" The authors of the article are Adrienne Mendoza, MHA, (BBG Advanced Therapies), Becky Cap, (Vitalant), and Liza Loidolt, Terumo Blood and Cell Technologies. The article highlights that, "[a]lthough cell and gene therapies are gaining traction commercially, the distance between patients and specialized collection centers threatens to exacerbate current problems with accessibility. The [authors] demonstrate how decentralized apheresis offers a practical path for addressing concerns with access and logistics." America's Blood Centers joined BCAR last year.

(Source: *BioProcess International*, "Decentralized Apheresis: The Missing Link in Equitable Cell and Gene Therapy Access?" 8/18/26)

The *Massachusetts Institute of Technology (MIT) News* recently published an article titled "Cell-preservation technique could make CAR-T cell therapy more accessible." The publication described how, "researchers at MIT have developed a new way to protect the cells from damage that can occur when they are frozen for storage and shipment. Their technique significantly reduces the use of a chemical preservative that is now used to protect the cells, which should make it easier for more hospitals to provide this treatment option to patients. Instead of treating the cells with a cryoprotective chemical that has to be removed before treatment, the researchers were able to preserve them using a nontoxic antifreeze sugar."

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ADVANCED THERAPIES NEWS (continued from page 9)

In a study featured in *Trends in Biotechnology*, the researchers, "showed that cells preserved using this process had higher survival rates and could be successfully used to treat lymphoma and glioblastoma in mice."

(Source: *MIT NEWS*, "Cell-preservation technique could make CAR-T cell therapy more accessible," 8/19/26)

Genetix Biotherapeutics Inc. and the National Football League (NFL) Alumni Association are partnering on an awareness campaign that aims to spotlight the, "difficulties of living with sickle cell disease, while helping individuals, families, and healthcare providers better understand available treatment options and support services." A news release describing the partnership also noted that, "[m]any families are unaware that U.S. Food and Drug Administration- (FDA) approved genetic medicines, including one-time transformative gene therapies, are available today and have proven to dramatically transform the lives of many people impacted by the disease." Genetix Biotherapeutics currently has, "received FDA-approved gene addition cell therapies for sickle cell disease, beta-thalassemia, and cerebral adrenoleukodystrophy, designed to treat the underlying cause of disease with a single dose and deliver durable clinical benefit."

(Source: Genetix Biotherapeutics Inc. News Release, 8/18/26)

GLOBAL NEWS

The National Institute for Public Health and Environment (RIVM) in the Netherlands has reported that, "[a] West Nile virus infection has been confirmed in a blood donor in the Netherlands. This occurred in August 2026 during a Sanquin study among blood donors from areas where the West Nile virus had previously been detected in humans, horses, birds, or mosquitoes. A laboratory test (PCR) detected the virus in the donor, who had no symptoms and is still not showing any." The agency further noted that, "[t]his is the first confirmed case of a human infection in 2026 that originated in the Netherlands. The last time people contracted a West Nile virus infection in the Netherlands was in 2020." West Nile virus is a mosquito-borne illness that is transfusion-transmissible. "The disease caused by the West Nile virus is called West Nile fever. 80 percent of people with West Nile fever have no symptoms, 19 percent have flu-like symptoms and 1 percent may develop neurological symptoms. People over 50 and people with weakened immune systems due to illness or medication have a higher risk of becoming very ill from West Nile fever."

(Source: RIVM Announcement, 8/17/26)

***CNN* recently published an article titled "U.S. Supplies Most of the World's Plasma. No Country Depends on It More Than China."** The pieced described how, "China is the world's biggest consumer of human albumin, the most abundant protein in plasma. But it's long suffered a domestic shortfall largely due to strict rules on plasma collection, a legacy of an HIV infection scandal in the 1990s, and it remains heavily reliant on plasma from its biggest geopolitical rival, the United States, for much of its human albumin supply." The news organization noted that the, "U.S. supplies about 70 percent of global plasma and is one of the few countries that pays donors. [More than 60 percent] of China's albumin market is supplied by foreign manufacturers and all of it is made from plasma collected in the U.S." The article highlighted that, "[r]esearchers told *CNN* that China's domestic plasma shortfall could leave patients vulnerable to drug shortages and price spikes if U.S.-dominated supply flows are disrupted by geopolitical tensions or global health emergencies, like the COVID-19 pandemic. [After opening] dozens of new licensed plasma [centers]

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in 2023, the country cleared its first rice-based albumin for market last July, as part of a broader push to reduce reliance on American plasma. Despite the efforts, China still faces an annual shortfall of around 6,000 tons of plasma, according to a *CNN* calculation based on industry data and estimation of domestic demand cited by Chinese state media."

(Source: *CNN*, "U.S. Supplies Most of the World's Plasma. No Country Depends on It More Than China," 8/23/26)

The *Times of Malta* recently reported that country's regulatory authority has, "lifted a ban on blood donations by people who lived in the United Kingdom (UK). The ban was introduced some 20 years ago and applied to anyone in Malta who had lived in the UK for a cumulative period of six months or more between 1980 and 1996. The decision was taken as a precaution against variant Creutzfeldt-Jakob disease (popularly called Mad Cow Disease) in the absence of a reliable screening test. Similar bans have been lifted by other countries over the past few years. [The Health Ministry told the publication that] scientific research and long-term monitoring had confirmed that there is no longer a risk of the disease being transmitted by blood donations."

(Source: *Times of Malta*, "Malta lifts ban on blood donations by former UK residents," 8/17/26)

COMPANY NEWS

Merck and **Moderna, Inc.** have recently shared topline results from phase III trial evaluating adjuvant treatment their novel investigational mRNA-based individualized neoantigen therapy (INT) "in patients with completely resected stage IIB-IV melanoma." A company news release noted that, "trial met its primary endpoint of recurrence-free survival (RFS) and a key secondary endpoint of distant metastasis-free survival (DMFS)." The investigational therapy (intismeran autogene) was used in combination with Keytruda (pembrolizumab), ananti-PD-1 therapy. The companies further explained that, "[a]t a pre-specified interim analysis, intismeran in combination with Keytruda as adjuvant therapy demonstrated statistically significant and clinically meaningful improvements in recurrence-free survival and distant metastasis-free survival compared to Keytruda alone for patients with completely resected stage IIB, IIC, III or IV cutaneous melanoma who had not undergone prior treatment with systemic therapy. In accordance with the trial protocol, the study will continue in order to evaluate other key secondary endpoints, including overall survival (OS). The safety profiles of intismeran and KEYTRUDA in this trial were consistent with those observed in previously reported studies for the combination, with no new safety signals observed."

(Source: Moderna, Inc. News Release, 8/19/26)

The **American Red Cross** has announced the creation of the LifeBlood Fund. The organization described the fund as a, "five-year, $300 million national effort to strengthen and modernize the nation's blood supply. [The campaign] aims to address these urgent challenges, including rising hospital demand, fewer donors, increasing costs, and aging infrastructure. Through expanded donor engagement, advanced technology and modernized facilities, the initiative will strengthen the Red Cross' capacity to collect and deliver lifesaving blood." The announcement stated that campaign co-chairs Teresa and Byron Pollitt, "are making an extraordinary investment of $15 million."

(Source: American Red Cross Announcement, 9/17/26)

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

September 16-17. **ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** Registration is open. More information is available here.

September 22. **NHTSA Office of EMS Working with a Blood Supplier in Your Prehospital Blood Program Webinar (Virtual).** Registration is open. More information is available here.

September 23. **FDA Scientific Public Workshop: Next-Generation Sequencing for Adventitious Agent Detection in Biologics (Virtual).** Registration is open. More information is available here.

September 29. **FDA Blood supply Chain Roundtable Webinar (Virtual).** Registration is open. More information is available here.

October 4-7. **Association for Advancing Tissue and Biologics (AATB) Congress 2026. San Francisco, Calf.** Registration is open. More information is available here.

October 5-7. **ARM Cell & Gene Meeting on the Mesa. Phoenix, Ariz.** More information is available here.

October 14-15. **Biomedical Excellence for Safer Transfusion (BEST) Collaborative Member Meeting. Atlanta, Ga.** More information is available here.

October 17-19. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Atlanta, Ga.** More information is available here.

November 3-4. **Plasma Protein Therapeutics Association (PPTA) Plasma Protein Forum Alexandria, Va.** Registration is open. More information is available here.

October 20. **NHTSA Office of EMS Paying for Your Prehospital Blood Program Webinar (Virtual).** Registration is open. More information is available here.

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

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Sign up for ABC's &ADRP's *Pulse of Leadership*



CALENDAR (continued from page 12)

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

2027

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.

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

Director of Quality Assurance. National Blood Testing Cooperative (NBTC) is seeking an experienced **Director of Quality Assurance** to lead the Quality Management System supporting testing services for more than 20 blood centers at **Stone Mountain, Georgia** laboratory. The Director of Quality Assurance is responsible for overseeing all quality management activities to ensure compliance with applicable FDA, CLIA, AABB, 21 CFR, OSHA, and other regulatory and accreditation requirements. This position provides strategic leadership for quality assurance, validation, auditing, document control, supplier qualification, occurrence management, CAPA, continuous process improvement, and inspection readiness. Working closely with onsite laboratory leadership, the Director develops, implements, and maintains quality policies and programs; supports operational excellence; and promotes a culture of quality and regulatory compliance. The position partners with laboratory managers on performance improvement, employee development, and strategic initiatives to ensure the laboratory consistently delivers safe, accurate, reliable, and timely testing services. **Qualifications:** Demonstrated experience in a blood center, blood banking, transfusion medicine, or related healthcare laboratory environment required. Bachelor's degree in science or an allied science discipline. Minimum five (5) years of Quality Assurance management experience. Medical Laboratory Scientist (MLS/ASCP) or Specialist in Blood Banking (SBB/ASCP) certification preferred. CMQ/OE or CQA certification through the American Society for Quality (ASQ) preferred. Strong leadership, communication, organizational, analytical, and problem-solving skills. Demonstrated ability to lead cross-functional quality initiatives and drive sustainable process improvement. This is an outstanding opportunity for a collaborative and strategic quality leader who is passionate about regulatory excellence, continuous improvement, and advancing the safety and reliability of the nation's blood supply. Click here to apply.

Community Operations Executive Director (Tulsa, OK). Our Blood Institute is looking for a Community Operations Executive Director. This position will lead local efforts to recruit blood donors, engage community sponsors and volunteers, and oversee the efficient collection, storage, and delivery of blood products. This highly visible leadership position combines community engagement with operational leadership in a dynamic environment where innovation, collaboration, and continuous improvement are at the heart of everything we do. This is more than a management position-it's a **leadership opportunity** to shape community engagement, drive strategic growth, and influence the future of blood services in the Tulsa region. We're seeking an experienced, relationship-focused leader to oversee our Tulsa operations and help advance our mission through strategic partnerships, operational excellence, exceptional team leadership, and **cross-functional**

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collaboration. 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 ($500 bonus after 6 months, $1,000 bonus after 1 year, and $1,500 bonus after 3 years). **How to apply:** https://ourbloodinstitute.org/about/careers/

Reference Lab Supervisor. OneBlood is currently recruiting for a Lab Supervisor in our AABB-accredited Immunohematology Reference Laboratory in Ft. Lauderdale, FL. This position provides leadership and technical expertise, coordinates workflow and staff scheduling, and performs training and quality activities for the staff responsible for performing basic through advanced testing procedures on patient and/or donor samples. Applicants must have a bachelor's degree in medical technology, biological science or related scientific field from an accredited college or university. Three or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training, and/or experience. Applicants must have a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Florida Supervisor license and SBB certification preferred. To apply and view a complete Job Description of this position, go to www.oneblood.org and click on the Careers tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Director of Operations (Lifeline Blood Services – Jackson, TN). Lifeline Blood Services is seeking an experienced **Director of Operations** to provide strategic leadership for Administrative Services, including Human Resources, Information Technology, Finance, Purchasing, and Fleet & Facilities. Working closely with the CEO, this executive leadership role ensures operational excellence, regulatory compliance, and organizational success. **Qualifications:** Bachelor's degree required; Master's preferred. Minimum of five (5) years of operations management experience. Strong leadership, financial, organizational, and communication skills. Experience with budgeting, contracts, vendor management, and regulatory compliance preferred. **Schedule:** Full-time, Monday-Friday, 8:00 a.m.-5:00 p.m., on-call as needed, with up to 25 percent travel. At Lifeline Blood Services, our mission is to serve our communities with the safest lifesaving transfusion medicine possible. If you are a collaborative leader who is passionate about operational excellence and making a meaningful impact, we encourage you to apply. **Click here to view the full job description and apply.**

Chief Operations Officer. We are hiring for Chief Operations Officer: Purpose: To effectively deploy and manage the operations resources (physical, human, and financial), drives oversight, compliance with all outside regulatory and accrediting services, and oversee operational performance of We Are Blood to achieve its mission and goals. **Responsibilities:** Oversee the operations processes of We Are Blood, including blood donor screening, collections, clinical services, components preparation, donor testing, reference laboratory, inventory management, distribution, and supply chain. Participate in developing and implementing the organization's strategic plan. Provide leadership in establishing and accomplishing operational goals and objectives. In conjunction with Executives and VPs, develop business plans and monitor the execution of each plan. Responsible for the oversight of the operational planning/budgeting and compliance for meeting budgets, goals, and objectives. Prepare and present operational reports and metrics as directed by the CEO. Provide leadership and direction for reporting staff in evaluating, coaching, and counseling employees. Ensure timely and effective training, feedback, and constructive guidance to improve employees' job performance and to expand their knowledge, skills, and techniques. **Skills, Education, & Experience:** College degree with RN, MT (ASCP), SBB, or related field preferred. Minimum of seven to10 years of leadership management and/or supervisory experience in a blood center required. Relevant experience in a highly regulated environment may substitute for formal education. Excellent communication skills, both verbal and written, as well as presentation skills. Must have the ability to handle difficult situations and deal with sensitive and highly confidential information. Requires strong interpersonal, organizational experience, and demonstrated success in project and time management. Prefer management-level budget experience. Apply here.

Hospital Services Director of Operations (LifeServe Blood Center). Lead a mission-driven team where your decisions directly support patients, donors, and clinical partners across the region. In this role, you'll oversee blood manufacturing, product management, distribution, and advanced immunohematology reference laboratory testing—critical operations that ensure safe, reliable blood products for more than 175 hospitals across Iowa, Nebraska, South Dakota, and Illinois. You'll guide daily operations, uphold rigorous regulatory and quality standards, manage financial performance, and develop leaders at every level. This position directs staffing, equipment allocation, laboratory procedures, and productivity outcomes while fostering a culture of continuous improvement and exceptional customer service. You'll supervise testing personnel, validate results, support policy development, and ensure compliance

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POSITIONS (continued from page 14)

with SOPs, quality programs, and federal regulations. Ideal candidates excel in complex operational environments, bring strong leadership experience, and thrive in roles where precision, accountability, and collaboration matter. Occasional evening or weekend availability may be required. Join one of the nation's largest community-based blood centers and make an impact that truly saves lives. Please click here to view the full job description and apply.

Transfusion Medicine Quality Program Manager. ARUP Laboratories is seeking a Transfusion Medicine Quality Program Manager to lead and support quality, regulatory, and continuous improvement initiatives across ARUP's transfusion medicine programs, including Blood Donor Services, the hospital-based blood bank, and the Immunohematology Reference Laboratory. In partnership with medical directors, laboratory leadership, and corporate quality teams, this role is responsible for developing and maintaining a comprehensive quality management framework aligned with ARUP's Quality Management System. The Manager will oversee regulatory compliance, audit readiness, risk management, CAPA processes, and data-driven quality improvement efforts in a highly regulated environment. This position serves as a key liaison between ARUP Laboratories and University of Utah Health clinical partners and provides expert guidance on transfusion medicine quality, regulatory interpretation, and best practices. The role also supports standardization, change management, training, and quality-related reporting to leadership. Qualified candidates will have a bachelor's degree in Medical Laboratory Science, Clinical Laboratory Science, or a related scientific field; at least seven years of experience in transfusion medicine, blood banking, and/or donor services; and at least five years of experience in quality systems, regulatory compliance, and audit management. Knowledge of FDA, AABB, CAP, CLIA, ISO, and related standards is required. A master's degree and relevant certifications are preferred. Please click here to review the full job description and apply.

Business Development Manager. Gulf Coast Blood is seeking a dynamic Business Development Manager to help expand our impact across advanced therapies, research programs, and clinical services. In this role, you will drive business growth by identifying new opportunities, building strategic partnerships, and expanding relationships with hospitals, pharmaceutical companies, biotech firms, and research organizations. You will manage the full business development lifecycle—from prospecting and solution development to deal closure and ongoing account growth—while supporting innovative programs that help save and sustain lives. **Qualifications:** We are looking for a results-driven professional with experience in business development, sales, account management, or healthcare-related industries. **Advanced therapies or biotechnology background are strongly preferred!** The ideal candidate will have strong relationship-building, communication, and strategic thinking skills, with the ability to navigate complex client environments and identify growth opportunities. **Why join us?** We offer competitive compensation and benefits, career growth opportunities, and the chance to contribute to innovative therapies and services that make a meaningful difference in patient care throughout our community. If you're passionate about building partnerships and driving innovation, apply today!

Blood Bank Medical Laboratory Specialist (MLS/MLT). Gulf Coast Blood is seeking a dedicated Blood Bank Medical Laboratory Specialist (MLS/MLT) to join our East Texas team and support our lifesaving mission. In this role, you will perform specialized immunohematology and transfusion medicine testing, ensure accurate blood product processing and distribution, maintain regulatory compliance, and contribute to providing safe, high-quality blood products to patients throughout the region. You will work collaboratively with healthcare professionals while upholding AABB, FDA, and internal quality standards. **Qualifications:** We are seeking candidates with a current **MLS or MLT certification (ASCP or equivalent)** and experience in a clinical laboratory setting. Blood banking experience is preferred but not required. Strong attention to detail, critical thinking skills, and a commitment to quality patient outcomes are essential. **Why join us?** We offer competitive compensation and benefits, opportunities for professional growth, and the chance to make a meaningful impact in the communities we serve. If you're passionate about laboratory science and helping save lives, we encourage you to apply today.

Medical Apheresis LVN. Gulf Coast Blood is seeking a dedicated **Medical Apheresis LVN** to support our mission of providing safe, high-quality blood components to hospitals and patients across the Texas Gulf Coast region. As an Apheresis Nurse, you will provide donor and patient care through apheresis and leukapheresis procedures. This role includes phlebotomy, peripheral IV and central line care, medication administration and monitoring the donors receiving mobilizing agents. The nurse will monitor patients throughout the procedure. The nurse ensures documentation meets regulatory standards and maintains compliance with AABB, FDA, FACT, and internal policies. **Qualifications:** We're looking for someone who has graduated from an accredited vocational or nursing program with a current LVN license. Request at least four (4) years of recent direct patient care experience, preferably in acute care with strong peripheral IV skills. Apheresis or dialysis experience is strongly preferred. Must hold BLS or

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ACLS certification and have reliable transportation for travel to donor and group sites. **Why join us?** We offer a **competitive compensation and benefits package**, free parking at the Texas Medical Center, opportunities for career growth, and a supportive workplace focused on excellence and mission. Apply Today!