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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #19 **June 16, 2025**

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ABC Letter to HHS Secretary Kennedy Addresses Prioritizing Nation's Blood Supply Amid HHS Reorganization

America's Blood Centers (ABC) has sent a letter to U.S. Department of Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. suggesting recommendations for prioritizing and maintaining the safety and availability of the U.S. blood supply following the reorganization of HHS. In the letter, ABC explained that, "blood is considered a national resource and designated an essential medicine but is largely supported by a network of not-for-profit blood centers who successfully manage the nation's blood supply in both routine and emergency circumstances. However, there are instances when government awareness and support is necessary to ensure continuity and rapid response." ABC urged Secretary Kennedy to:

- identify and designate a point person within HHS who is responsible for liaising with relevant agencies and the blood and hospital communities. "This individual should be familiar with the blood community and play a crucial role in engaging federal and state resources;"
- the letter further explained that, "[s]ince the inception of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (Disaster Task Force), HHS has consistently had a representative participating in these efforts, providing support as needed, ensuring the government is aware of the state of the blood supply during disasters. We urge you to ensure a government representative that communicates with the Blood, Organ, and Tissue Senior Executive Council (BOTSEC) is included in the Disaster Task Force moving forward;"
- finally, ABC asked Secretary Kennedy to, "ensure the full set of data already collected for the 2023 National Blood Collection and Utilization Survey (NBCUS) is released."

ABC will continue to provide updates as they become available. Please contact us with questions.

(Source: ABC HHS Letter, 6/4/25) ♦

Congressional Bills Introduced Regarding Prehospital & Hospice Care Blood Transfusions

Both expanding access to prehospital blood transfusions and to blood transfusions within the Medicare hospice program are priorities of America's Blood Centers' (ABC) advocacy efforts and Advocacy Agenda. Recently legislation has been introduced in Congress supporting each initiative.

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Legislation Introduced for Prehospital & Hospice Care Blood Transfusions (continued from page 1)

Representatives Richard Hudson (R-N.C.) and Debbie Dingell (D-Mich.) introduced a bipartisan bill named "The Modernizing EMS Delivery and Sustainability (MEDS) Act (H.R. 3443)." This bill includes a provision that creates a Centers for Medicare & Medicaid Innovation (CMMI) demonstration program to evaluate a separate payment model for blood products, potentially increasing their availability and use in EMS settings, particularly in rural areas. The bill aims to significantly increase the availability and use of blood products in trauma situations before a patient reaches the hospital. ABC strongly supports this bill. "ABC commends Representatives Hudson and Dingell for their leadership on this crucial issue. We urge members of the House to support this bill and members of the Senate to introduce companion legislation, which would save lives and improve patient outcomes nationwide," said Kate Fry, MBA, CAE, chief executive officer of ABC in a statement.

On June 5th, Senators Jacky Rosen (D-Nev.), Tammy Baldwin, (D-Wis.), and John Barrasso (R-Wyo.) announced that, "The Improving Access to Transfusion Care for Hospice Patients Act (S.1936)" has been introduced. This legislation would, "carve out payment for transfusion services within the Medicare hospice benefit, allowing for separate billing to Medicare for transfusions. This would improve access to hospice care for patients who rely on transfusion care to maintain quality of life," according to the news release. ABC CEO Kate Fry explained in the news release, "[b]lood transfusions are a proven palliative measure that can significantly enhance the quality of life for many patients. This legislation bridges a gap in care, ensuring patients can receive transfusions while also benefiting from the holistic support provided under the Medicare hospice benefit. It's a compassionate step forward in patient-centered care that recognizes the complex needs of those navigating serious illnesses." Belinda R. Avalos, MD, president of the American Society of Hematology, added in the news release, "[w]e commend Sens. Rosen, Barrasso, and Baldwin for the introduction of the Improving Access to Transfusion Care for Hospice Patients Act. This bill will support critical access to transfusions for patients with blood cancers in hospice and will make great strides in guaranteeing comprehensive palliative care."

ABC will provide updates as they become available on the bills and our advocacy efforts. Please contact us with any questions.

(Sources: Rep. Debbie Dingell News Release, 5/23/25; Sen. Jacky Rosen News Release, 6/9/25)

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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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REGULATORY NEWS

A "Viewpoint" published in *JAMA* by U.S. Food and Drug Administration (FDA) Commissioner Martin Makary, MD, MPH and FDA Center for Biologics Evaluation and Research Director (CBER) Vinay Prasad, MD, MPH outlines the agency's new priorities. Drs. Makary and Prasad explained in the article that FDA will, "transition from a purely reactionary health care system to one that is proactive, intellectually curious about underlying causes, and financially aligned to promote health — not just treat sickness. At the same time, the FDA must have the courage to create new pathways for therapeutic and device developers to respond to the current forest fire that is the worsening health of the U.S. population. We will rapidly usher to market new products with transformational potential." Drs. Makary and Prasad also noted that the FDA's two guiding principles will be, "gold-standard science and common sense." Other topics addressed in the publication include:

- accelerating cures;
- unleashing artificial intelligence;
- harnessing big data; and
- financial toxicity.

The article concluded by emphasizing that, "FDA will be focused on delivering faster cures and meaningful treatments for patients, especially those with neglected and rare diseases, healthier food for children, and common-sense approaches to rebuild the public trust. The FDA and our great medical profession should unite to consider fresh new approaches to the evolving health topics facing the US today."

Citation: Makary, M. and Prasad, V. "Priorities for a New FDA." *JAMA*. 2025

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) has announced the launch of a new generative artificial intelligence (AI) tool (Elsa). According to a news release from the agency, the AI tool aims to, "help employees — from scientific reviewers to investigators — work more efficiently. This innovative tool modernizes agency functions and leverages AI capabilities to better serve the American people." Elsa is described by FDA as a, "large language model–powered AI tool designed to assist with reading, writing, and summarizing. It can summarize adverse events to support safety profile assessments, perform faster label comparisons, and generate code to help develop databases for nonclinical applications. These are just a few examples of how Elsa will be used across the enterprise to improve operational efficiency. The introduction of Elsa is the initial step in the FDA's overall AI journey. As the tool matures, the agency has plans to integrate more AI in different processes, such as data processing and generative-AI functions to further support the FDA's mission." The news release further explained that FDA is, "already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets." FDA Commissioner Martin Makary, MD, MPH added, "[f]ollowing a very successful pilot program with FDA's scientific reviewers, I set an aggressive timeline to scale AI agency-wide by June 30th. Today's rollout of Elsa is ahead of schedule and under budget, thanks to the collaboration of our in-house experts across the centers."

(Source: FDA News Release, 6/2/25)

Jim O'Neill has been sworn in as Deputy Secretary of the U.S. Department of Health and Human Services (HHS). An agency announcement noted that Mr. O'Neill will help HHS Secretary Robert F. Kennedy, Jr., "oversee an agency that includes the National Institutes of Health, FDA, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Administration for Children and Families, and many others. [He previously worked at] HHS from 2002 to 2008. As the Principal Associate Deputy Secretary from 2007 to 2008 he led reforms at FDA to overhaul food and safety regulations

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WORD IN WASHINGTON (continued from page 3)

and implemented the FDA Amendments Act to improve drug and medical device safety. He helped design and launch HHS' Administration for Strategic Preparedness and Response to lead the health response to emergencies and disasters. [More recently,] Mr. O'Neill served as chief executive officer of SENS Research Foundation where he led efforts to research and develop regenerative medicine solutions for age-related diseases such as Alzheimer's, cancer, and heart disease. Under his leadership, SENS Research Foundation made progress toward rejuvenating the immune system, eliminating senescent cells, rejuvenating the neocortex, and obviating mitochondrial mutations."

(Source: HHS Announcement, 6/9/25)

On June 9th, HHS made an announcement that the agency had removed, "the 17 sitting members of the Advisory Committee for Immunization Practices (ACIP) and will replace them with new members." HHS Secretary Kennedy explained in the announcement, "[t]oday we are prioritizing the restoration of public trust above any specific pro- or anti-vaccine agenda. The public must know that unbiased science — evaluated through a transparent process and insulated from conflicts of interest — guides the recommendations of our health agencies." ACIP is responsible for making, "recommendations on the safety, efficacy, and clinical need of vaccines to the Centers for Disease Control and Prevention (CDC)." Secretary Kennedy revealed eight new members of ACIP in a post on X on June 11th.

(Source: HHS News Release, 6/9/25)

The U.S. Government Accountability Office (GAO) has published a report titled "Public Health Preparedness: HHS Needs a Coordinated National Approach for Diagnostic Testing for Pandemic Threats." Recommendation in the report for HHS include:

- "[t]he Secretary of Health and Human Services should develop a national diagnostic testing strategy for infectious diseases with pandemic potential that incorporates all six desirable characteristics of a national strategy;
- [t]he Secretary of Health and Human Services should periodically update the national diagnostic testing strategy to incorporate any future lessons learned from infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises;
- [t]he Secretary of Health and Human Services should establish a national diagnostic testing forum for infectious diseases with pandemic potential or expand an existing group. The forum should include a broad representation of knowledgeable testing stakeholders from HHS and its component agencies along with other relevant federal agencies, jurisdictions, the public and private sectors, academia, and nonprofits. This forum should include key decision makers and facilitate two-way discussion; [and]
- [t]he Secretary of Health and Human Services should ensure the national diagnostic testing forum meets regularly, including both before and during infectious disease threats with pandemic potential, other public health threats as deemed relevant, or any related preparedness exercises."

GAO conducted the study in the wake of the COVID-19 pandemic by convening, "a roundtable of 19 experts to discuss actions HHS should take to improve diagnostic testing. GAO contracted with the National Academies of Sciences, Engineering, and Medicine to help identify experts representing a range of perspectives. GAO also reviewed HHS documents and interviewed HHS officials."

(Source: GAO Announcement, 6/4/25)

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INSIDE ABC

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

Thanks For Making Blood Advocacy Week & the Advocacy Summit A Success!

America's Blood Centers (ABC) thanks all members, partners, sponsors, and participants in our most successful Blood Advocacy Week yet and the inaugural ABC Advocacy Summit. Your support and dedication played an integral part in making an impact, raising awareness, and advancing policies that support blood donation. We will provide more in-depth coverage on Blood Advocacy Week 2025 and the Advocacy Summit in the coming weeks. Stay tuned!

SAVE THE DATE: ABC WELC *Rise & Lead Workshop* November 13th-14th

Rise & Lead
A WOMEN'S LEADERSHIP WORKSHOP

ABC is excited to announce that the 2025 ABC Women's Executive Leadership Community (WELC) *Rise & Lead Workshop* will take place November 13th-14th in San Antonio, Texas at the Westin Riverwalk. Book now to secure the discounted rate. Registration will open in August. This workshop is designed for women in leadership positions, emerging leaders, and professionals seeking personal and professional growth. It also welcomes individuals who want to cultivate diverse perspectives. Attendees will engage in an intimate, engaging, and interactive environment focused on networking, mentorship, and meaningful discussions on leadership and growth. Please contact us with questions.

May *Blood Bulletin* Published

ABC has published the May 2025 edition of the *Blood Bulletin* titled "Neonatal Transfusion Support — Modifications and Preparations of Red Cell Transfusions — A Case Study." The issue was written by Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest; Ruchika Goel, MD, Senior Medical Director, Corporate Medical Affairs at Vitalant National Office; Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center; Nanci Fredrich, RN, BSN, MM, Transfusion Safety Officer at Versiti Blood Center of Wisconsin; Courtney Hopkins, DO, Vice President, Corporate Medical Director at Vitalant; Louis Katz, MD, Chief Medical Officer Emeritus at ImpactLife; Debra Smith, MD, PhD, MBA, Chief of Transfusion Medicine Services at Banner University Medical Center; Kirsten Alcorn, MD, Co-Chief Medical Officer at Bloodworks Northwest; Richard Gammon, MD, Medical Director, Blood Bank & Transfusion Services at Moffitt Cancer Center; and Jed Gorlin, MD, MBA, Chief Medical Officer at ABC. Contributors for this *Blood Bulletin* included: Amit M. Mathur MBBS, MD, MRCP (UK), Director, Division of Neonatal Perinatal Medicine, Department of Pediatrics, Saint Louis University School of Medicine and SLUCare Group at SSM Health; Edward F. Bell, MD, Professor of Pediatrics and Neonatologist, University of Iowa; and Nabiha Huq Saifee MD, PhD, Medical Director of Transfusion Service, Seattle Children's. *Blood Bulletin* is a quarterly publication reviewed and edited by ABC's Scientific, Medical, and Technical (SMT) Publications Committee.

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INSIDE ABC (continued from page 5)

Register for the June ADRP Webinar: "From Partnership to Purpose: Strengthening Hospital Relationships"

Registration is open for the Wednesday, June 25th ADRP Webinar: "From Partnership to Purpose: Strengthening Hospital Relationships." This event aims to, "help blood centers deepen their hospital partnerships and elevate the donor-to-patient journey." Hear speakers share programs and strategies to deliver value-added services that keep hospital clients engaged and loyal, while gaining practical ideas for successfully onboarding new hospital partners and ensuring long-term collaboration using ADRP's newest Hospital Partnership Idea Book. Whether you're strengthening existing connections or forging new ones, this session is packed with actionable takeaways to help. ♦

INFECTIOUS DISEASE UPDATES

CHIKUNGUNYA

The World Health Organization (WHO) has published a "Global Chikungunya Epidemiology Update". The document is meant to serve as a "comprehensive overview of reported data on chikungunya virus globally." According to the WHO, as of December 2024, "a total of 119 countries and territories have had documented evidence of autochthonous mosquito-borne transmission of chikungunya virus (CHIKV), distributed across all six WHO Regions. Reviews of global chikungunya epidemiology have been published, including a review of reported chikungunya outbreaks and seroprevalence data prior to 2020 (13). However, accurate and timely global chikungunya epidemiologic data are limited as many countries lack or have limited capacity for routine surveillance, case detection, access to diagnostic tests, and reporting of CHIKV disease cases. Lack of reporting of CHIKV cases, therefore, cannot necessarily be equated with evidence that transmission is not occurring. Globally, 27 countries and territories in six WHO regions have evidence of established and competent *Aedes aegypti* vector populations but have not yet documented autochthonous CHIKV transmission. In addition, other countries have established populations of *Aedes albopictus*, which are competent to transmit CHIKV, particularly lineages with the IOL mutation increasing transmission efficiency. The presence of either of these vector populations poses an ongoing risk for CHIKV introduction and spread to previously unaffected countries or subnational areas. It is also possible that CHIKV transmission occurs, or has occurred, in some of these countries without being detected or reported. All areas with prior reports of CHIKV transmission have the potential for re-emergence or re-introduction, especially in large countries and territories where pockets of non-immune individuals remain susceptible." Transfusion-transmission of chikungunya has not been documented and any risk to the blood supply is believed to be theoretical. Last month, the Centers for Disease Control and Prevention (CDC) has issued a Travel Health Notice for several countries in the Indian Ocean region regarding chikungunya virus.

(Source: WHO Global Chikungunya Epidemiology Update, 6/11/25) ♦

MEMBER NEWS

Gulf Coast Regional Blood Center is celebrating its 50th anniversary. The blood center was founded in 1975 and currently, "serves 170 hospitals and healthcare facilities in a 26-county area." Theresa Pina, chief growth officer at Gulf Coast Regional Blood Center, told *Community Impact*, "[We are] looking at the next 50 years and how it can expand the center, such as putting a greater focus on the contributions to research and opening a new building across the street from the center's headquarters to serve as their new donor room. [The] new donor building will open this year. 'We want to celebrate the 50 years of who we are

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MEMBER NEWS (continued from page 6)

going to be and how we can serve bigger and how we can save more lives, not only through saving people with transfusions, but also helping provide cures for medical mysteries that exist today.'"

(Source: *Community Impact*, Gulf Coast Regional Blood Center celebrates 50-year milestone, 6/11/25)

SunCoast Blood Centers has been awarded an $85,000 grant from the Barancik Foundation. According to a news release, the grant will provide, "support [for the] Resilient Incubator, office space housing nearly a dozen environmental nonprofit organizations on the second floor of its facility on Mound Street in Sarasota."

(Source: Barancik Foundation News Release, 5/12/25)

Carter BloodCare recently shared a behind the scenes look at the development of an awareness campaign to dispel myths about blood donation. "In a series of comedic public service announcements (PSAs), paranormal performers — including a vampire, a fairy, and Bigfoot — compete for spokesperson spots with the blood center. The cryptic cryptid auditions are overseen by Carter BloodCare's legendary resident hematologist, Dr. Chupacabras. The blood donation campaign — 'Don't believe the myths. Be a legend' — [began airing in early June.] The spots are also available here. The lighthearted PSAs have a serious goal: to shed light on myths that can discourage Texans from donating [blood.] These myth-understandings range from tattoos, piercings, dental visits, weight gain, fasting and vegan diets to availability of blood types, donation times and emergency needs."

(Source: Carter BloodCare Announcement, 6/2/25)

GLOBAL NEWS

The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe has announced the publication of the 22nd edition of the *Guide to the preparation, use and quality assurance of blood components (Blood Guide)*. A May 21st news release explained that the latest edition features, "an in-depth revision of the h[e]movigilance chapter and the addition of two new chapters, blood components for topical use or injection and blood supply contingency and emergency planning. Other significant changes relate to donor selection criteria (Creutzfeldt–Jakob disease, malaria, blood pressure and pulse, plasmapheresis, iron stores, donor age, and insulin), along with the standardi[z]ation of terminology." The *Blood Guide* is designed to, "serve as an essential technical reference for healthcare professionals, regulators, policy makers and all those involved in blood donation and transfusion." The Plasma Protein Therapeutics Association (PPTA) issued a statement regarding the publication of the updated *Blood Guide* noting, "[w]e commend EDQM's efforts to advance standards and align practices to enhance donor and patient safety. However, PPTA believes that greater clarity on source plasma donation for fractionation would be beneficial, especially where donor eligibility, testing and deferral criteria differ due to rigorous manufacturing protocols that ensure plasma-derived medicinal products (PDMP) safety and quality. PPTA also welcomes the EDQM's focus on increasing plasma collection in Europe to support PDMP supply through the introduction of two plasma collection approaches: the 'standard approach' and the 'individuali[z]ed donor assessment' approach. The latter, which includes IgG monitoring and adverse event tracking, aligns well with evidence-based programs like those in Germany. While EDQM's recommended seven-day donation interval marks an important step in balancing donor safety and collection

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targets, PPTA sees further opportunity to refine this approach by incorporating the growing body of evidence supporting shorter intervals with appropriate monitoring, as demonstrated in scientific studies and national practices across Europe. PPTA is committed to supporting EDQM in this important work and contributing evidence-based insights to the development of future *Blood Guide* editions."

(Source: EDQM News Release, 5/21/25; PPTA Statement, 5/26/25)

***Newsweek* is reporting that clinical trials are underway in Japan to, "explore the use of universal artificial blood."** The publication explained that, [t]he research, led by Professor Hiromi Sakai's laboratory [at Nara Medical University], plans to assess artificial blood, usable for all blood types and storable for up to two years, as a potential solution to critical shortages in blood supplies for emergency and chronic health care worldwide." The Nara University trial included, "100 to 400 milliliters of the artificial blood to 16 healthy adult volunteers in March, according to *Kyodo News*. The next stage would be to examine the treatment's efficacy and safety if no side effects were reported."

(Source: *Newsweek*, "Artificial Blood That Could Work for All Blood Types in Trials," 6/2/25)

The Pan American Health Organization (PAHO) and World Health Organization (WHO) have released new data regarding blood donation in the region of the Americas. The organizations stated that the, "preliminary report, Access to Blood for Transfusion in Latin American and Caribbean Countries 2023, shows that 23 countries — 17 in Latin America and 6 non-Spanish-speaking Caribbean nations — collected 9,212,861 units of blood in 2023, marking a 15.5 percent increase compared to the 7,776,198 units collected in 2020. Nearly 80 percent of countries reported significant increases thanks to post-pandemic recovery and new awareness strategies. [The region] averages 16 blood donations per 1,000 inhabitants, but disparities persist: 13 countries fall below this average, while 10 exceed it. Brazil, Mexico, Colombia, and Argentina account for 75 percent of total donations. In 2023, 56.8 percent of donated blood came from voluntary donors — a 6.7 percent increase compared to 2019 — resuming the pre-pandemic growth trend. This progress was driven by digital campaigns, mobile drives, and institutional partnerships. The remaining donations came from family members or close contacts responding to direct requests. No country reported paid donations, highlighting the region's commitment to altruistic giving." Additional highlights from the report include, "100 percent of donated units were screened for transfusion-transmissible infections, and 90 percent were fractionated into components such as red blood cells, plasma, and platelets, optimizing clinical use. However, national and regional blood systems continue to face structural challenges. Over 1,900 collection sites and 1,400 processing centers operate independently, limiting efficiency. Only four countries processed more than 10,000 units per year on average, with Paraguay leading at 20,706 units."

(Source: PAHO & WHO News Release, 6/12/25)

The European Blood Alliance (EBA) recently raised awareness of the "Commit to Plasma" campaign which aims to, "[call] on national and European authorities for increased political support and funding for public plasma collection program[s]. The new "Commit to Plasma" campaign has broad support from across the plasma supply chain and was developed together with patients, donors, physicians and other healthcare professionals, hospitals, healthcare services and public sector industry representatives." The organizations backing the campaign issued a call to action for the European Commission, the European Parliament, as well as other relevant institutions such as Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM) and national authorities to:

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GLOBAL NEWS (continued from page 8)

- "[p]ublish National Plasma Plans by the end of 2026, with ambitious and clear commitments for national plasma collection goals;
- [e]armark the resources required to achieve these goals;
- [e]stablish or intensify their cooperation with the national representatives of all stakeholders supporting this call to work together in reaching these goals;
- [e]nsure optimal use of all available plasma;
- [w]ork towards equipping Europe with a European Plasma Coordination Plan by 2027, building on the National Plasma plans and to be reviewed regularly.
- [u]rge national authorities to commit to increasing public plasma collection, as above, through all means at their disposal, be it through the future European Plasma Coordination Plan or more formal instruments at their disposal such as communications, reports, or hearings;
- [c]ollect and share national data and practices to accompany plasma-collection progress of Member States and Europe as a whole. Reliable, publicly accessible data is missing today; [and]
- [e]ngage with other regional and global organi[z]ations to exchange data, policies and establish a dialogue to address plasma shortages at a global level."

(Source: EBA News Release, 6/2/25)

COMPANY NEWS

Beam Therapeutics Inc. has shared new safety and efficacy data from an ongoing phase I/II clinical trial of its investigational advanced therapy (BEAM-101) to treat sickle cell disease (SCD) with severe vaso-occlusive crises (VOCs). According to a company news release, "17 patients with severe SCD were treated with BEAM-101 and included in the safety and efficacy analysis, with follow-up ranging from 0.2 to 15.1 months. [All] patients achieved endogenous HbF levels exceeding 60 percent and a durable reduction in corresponding HbS below 40 percent. A pancellular distribution of HbF-expressing cells, with HbF levels per cell above the sickling threshold, was maintained through follow-up. Total Hb levels increased rapidly with resolution of anemia in patients after elimination of the transfused blood. Increases in HbF, decreases in HbS and resolution of anemia were durable for up to 15 months. Patients required a median of one mobilization cycle (range: 1-3 cycles). The median time to neutrophil engraftment was 16.5 days (range: 12-30), with a median duration of severe neutropenia of 7.0 days (range: 4-17). The median time to platelet engraftment was 19.5 days (range: 11-34). Key markers of hemolysis, including indirect bilirubin, haptoglobin, lactate dehydrogenase and reticulocytes, normalized or improved in all patients following treatment. Erythropoietin levels also decreased to normal or near normal, indicating significant improvement in oxygen delivery to tissues. The safety profile of [the investigational therapy] was consistent with busulfan conditioning, autologous hematopoietic stem cell transplantation (HSCT) and underlying SCD. The most common treatment-emergent adverse events (TEAEs) were consistent with busulfan conditioning, including stomatitis, febrile neutropenia, and anemia. As previously reported, one patient died four months after BEAM-101 infusion due to respiratory failure that was determined by the investigator to be likely related to busulfan conditioning and deemed unrelated to [the investigational therapy]. No patients experienced any investigator-reported VOCs post-engraftment. Exploratory biomarker assessments of red blood cell (RBC) health and function demonstrated improvements compared to baseline across multiple parameters after BEAM-101 treatment, including in multiple RBC sickling kinetic measurements to levels comparable to sickle cell trait, decreased RBC adhesion and percent dense RBCs, along with reduction in systemic inflammation." The company further explained that, "[e]nrollment in the adult and adolescent cohorts of the BEACON trial is complete, and 26 patients were dosed with [the investigational therapy] as of June 13th. Beam expects to dose 30 patients by mid-2025 and share additional data from the trial by the end of 2025." The company also recently announced that the investigational advanced therapy has been granted

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COMPANY NEWS (continued from page 9)

the Orphan Drug designation by the U.S. Food and Drug Administration. This designation is, "designed to support the development and evaluation of treatments for rare diseases affecting fewer than 200,000 people in the U.S. The designation comes with potential benefits for the sponsor company, including tax credits for qualified clinical trials, exemption from user fees, and a potential seven years of market exclusivity after approval," a company news release noted.

(Sources: Beam Therapeutics Inc. News Release, 6/13/25, 6/3/25)

Editas Medicine, Inc. recently presented new *in vivo* data regarding its advanced therapy to treat SCD and beta thalassemia. During a poster presentation at The European Hematology Association 2025 Congress, the company shared that, "new *in vivo* data demonstrating therapeutically relevant levels of HBG1/2 promoter editing in hematopoietic stem cells (HSCs) with a single dose of proprietary targeted lipid nanoparticle (tLNP) in non-human primates (NHPs). This clinically validated approach targeting HBG1/2 promoters to upregulate fetal hemoglobin (HbF) is in pre-clinical development as a potential transformative *in vivo* gene editing medicine for the treatment of SCD and beta thalassemia. [The latest data] showed that at five months a single intravenous administration of Editas' tLNP resulted in mean on-target editing levels in the HBG1/2 promoter region of 58 percent in HSCs: well exceeding the predicted editing threshold of ≥25 percent required for therapeutic benefit. In addition to achieving therapeutically relevant editing levels, the biodistribution data in NHPs with Editas' tLNP continue to show significant de-targeting of the liver in contrast to standard LNPs. [The] *in vivo* HSC program targets HBG1/2 promoters to mimic naturally occurring mechanisms of hereditary persistence of fetal hemoglobin (HPFH) and utilizes proprietary AsCas12a to edit with high efficiency and minimize off-target editing. Editing the HBG1/2 promoters with AsCas12a with the investigational medicine reni-cel led to robust increases in HbF and total hemoglobin (Hb) in clinical trials."

(Source: Editas Medicine, Inc. News Release, 6/12/25) ♦

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.)*

2025

June 25. **ADRP Webinar: From Partnership to Purpose: Strengthening Hospital Relationships.** Registration is open. More information available here.

Sept. 10-12. **6th European Conference on Donor Health and Management (ECDHM). Wijk aan Zee, the Netherlands.** Registration is open. More information available here.

Sept. 24-25. **2025 ADRP Master Class: "Building Brighter Experiences: Empowering Customers, Engaging Employees (Virtual).** More information is coming soon.

Oct. 12-15. **American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 14-15. **International Protein Forum. Old Town Alexandria, Va.** Registration opens in July.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is coming soon.

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CALENDAR (continued from page 10)

Oct. 26-29. **Blood 2025 and the ISBT 36th Regional Congress. Perth, Australia.** More information available here.

Nov. 12. **2025 ADRP International Showcase.** More information coming soon.

Nov. 13-14. **2025 ABC Women's Executive Leadership Community (WELC) *Rise & Lead Workshop*.** More information coming soon.

Nov. 17-20. **American Society for Clinical Pathology (ASCP) Annual Meeting. Atlanta, Ga.** Registration is open. More information available here.

2026

Mar. 9-12. **2026 ABC Annual Meeting. Tucson, Ariz.** More information coming soon.

May 12-14. **2026 ADRP Annual Conference. Minneapolis, Minn.** More information 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

Medical Laboratory Scientist. LifeSouth Community Blood Centers is looking for experienced Medical Laboratory Scientists, with a passion for making a difference. Current openings are in Gainesville, Florida (Overnight) and Atlanta, Georgia (Multiple shifts available; rotating weekends required). **Legal authorization to work in the United States is required. We do not provide visa sponsorship for this position.** Shift differential applies to eligible evening and overnight hours; **sign-on and relocation bonuses** may also be offered to qualified candidates. Our Medical Laboratory Scientists work in a full-service, accredited immunohematology laboratory following established policies and procedures to resolve complex immunohematology and compatibility problems to provide the safest donor blood for patients in our community. Join us in our mission to make sure blood is available when it's needed most. Visit our careers page to learn more about this position and apply today!

Laboratory Supervisor (Evenings). LifeSouth Community Blood Centers is looking for an experienced **Laboratory Supervisor** with a passion for making a difference to lead our evening shift Immunohematology Reference Laboratory team, in Gainesville, FL. Shift differential applies to eligible evening and overnight hours; **sign-on and relocation bonuses** may also be offered to qualified candidates. **Legal authorization to work in the United States is required. We do not provide visa sponsorship for this position.** In this role, you'll oversee daily operations, ensure adherence to established policies and procedures, and support staff in resolving complex testing and compatibility challenges. You'll play a critical part in identifying and addressing issues that may impact test performance or result reporting, while mentoring and guiding team members to uphold the highest standards of quality and safety. Your leadership will help ensure the delivery of the safest donor blood for patients in our community. We are committed to excellence in customer service and patient care. Join us in our mission to make sure blood is available when it's needed most. Visit our careers page to learn more about this position and apply today!

Quality Assurance Manager. Kentucky Blood Center (KBC) is seeking a Quality Assurance Manager to guide and support organizational adherence to standards issued by regulatory agencies and accrediting organizations. The position is responsible for KBC's compliance with applicable AABB, FDA, CLIA, State, OSHA, EU, and short supply agreement requirements. Reports to the Vice President, Quality and Regulatory Affairs; supervises the QA team. Qualifications include a minimum of a 4-year medical technologist degree (MLS/CLS) with ASCP professional certification and appropriate combination of experience. Must be located in, or willing to relocate to,

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POSITIONS (continued from page 11)

the Lexington, Kentucky area (assistance provided). For more information or to apply, visit https://www.kybloodcenter.org/about-us/careers.

Associate Medical Director/Medical Director. Serve as the physician face of Versiti and Versiti Ohio, translating complex medical issues to educate other physicians, support staff and the public. Opportunities in educational initiatives and clinical/applied research are available within Versiti and with our affiliated health systems. As part of the Versiti physician team you will have the opportunity to participate in clinical research projects with investigators at our world-renowned diagnostic laboratory and blood re-search institute. Joining our Medical Science Institute transfusion medicine physician team will provide you with a uniquely diverse and collaborative experience. Requirements: MD or DO Degree. Board certified/eligible in Blood Banking/Transfusion Medicine. At least three years of experience in blood center/transfusion medicine practice preferred. Licensed or eligible for an Ohio and Indiana; other state licenses may be required. Driver's License in good standing. Please click here to read the full job description and apply.

Vice President, Quality and Regulatory Affairs. The Vice President, Quality and Regulatory Affairs leads enterprise-wide quality, compliance, and regulatory initiatives in support of NYBCe's GxP Business Units, including Blood and HCT/P manufacture, analytical laboratories, specialty pharmacy, therapeutics, and medical programs. Reporting to the SVP of Quality and Regulatory Affairs, the VP provides focused oversight of quality systems to ensure compliance with regulatory and corporate requirements. She/he oversees quality-related interactions with clients, including customer audits and the development of quality agreements. The VP establishes a regulatory strategy for product development projects, advises NYBCe leadership on regulatory issues, prepares regulatory submissions, and represents NYBCe to regulatory and accrediting agencies. The VP applies strong leadership skills to motivate, coach, develop, and retain high-performing Quality staff, and fosters a quality-oriented culture throughout the organization. Responsibilities: Lead improvement projects dealing with broad or complex issues, or with strategic impact. Participate in preparation of CMC submissions. **Locations:** Candidates must be able to report into one of the following NYBCe locations: Rye, New York; Kansas City, Missouri; St. Paul, Minnesota; Providence, Rhode Island, and Newark, Delaware. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $270,000.00p/yr. to $280,000.00p/yr. Click here to apply.

Donor Recruitment Manager. Blood Assurance is seeking an individual to lead field recruitment efforts that build new and existing business in and around our Nashville region. Primary responsibilities include direct leadership of Account Managers in expanding blood drive activity on mobiles primarily, and in facilities as needed, based on growth strategy in a specific type of blood product recruitment and collection. Assist in developing long-term community business partnerships, and coordinating internally with all leadership levels to support or expand Blood Assurance recruitment efforts. Work closely with Donor Services leadership to ensure recruitment and collection teams are working together toward meeting overall product collection goals. Qualified applicants will have: a bachelor's degree, preferably in business, marketing, or related field. Previous blood banking experience required. 7-10 years sales experience, preferably in blood banking. 3-5 years sales staff management. Advanced communication skills. Public presentation and networking skills. Advanced organizational, customer service and teamwork skills. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Paid Time Off, 401K, and Wellness Program. Qualified candidates are encouraged to email a resume to garryallison@bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Environment.

Medical Laboratory Scientist. LifeSouth Community Blood Centers is looking for experienced Medical Laboratory Scientists, with a passion for making a difference. Current openings: Gainesville, Florida (Overnight), Birmingham, Alabama (Multiple shifts available; weekend coverage required) and Atlanta, Georgia (Multiple shifts available; rotating weekends required). Legal authorization to work in the United States is required. We do not provide visa sponsorship for this position. Shift differential applies to eligible evening and overnight hours; sign-on and relocation bonuses may also be offered to qualified candidates. Our Medical Laboratory Scientists work in a full-service, accredited immunohematology laboratory following established policies and procedures to resolve complex immunohematology and compatibility problems to provide the safest donor blood for patients in our community. Join us in our mission to make sure blood is available when it's needed most. Visit our careers page to learn more about this position and apply today!

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POSITIONS (continued from page 12)

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