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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #5 **February 10, 2025**

INSIDE:

Blood Community Comments on FDA HCT/P Guidances

America's Blood Centers, the Association for the Advancement of Blood & Biotherapies, and the American Red Cross (ARC) have submitted four joint comment letters to the U.S. Food and Drug Administration (FDA) regarding human cells, tissues, and cellular and tissue-based products (HCT/Ps) draft guidances. The February 5th comments addressed:

- Recommendations for Determining Eligibility of Donors of HCT/Ps;
- Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by HCT/Ps;
- Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by HCT/Ps; and
- Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by HCT/Ps.

The donor eligibility comments in response to the FDA draft guidance requested an extended implementation period of at least one year to, "allow facilities to focus on successful implementation of changes to highly complex systems which must be updated, tested, and validated for performance [including] changes to the establishment computer system, HCT/P Donor History Questionnaires, flowcharts, *Circular of Information*, policies and procedures, and extensive staff training and education."

While all four comment letters expressed support for the FDA draft guidance recommendations and updated guidance formats by the FDA, the blood community asked the agency in the comments on the HIV risk draft guidance, the HBV risk draft guidance, and the HCV risk draft guidance to provide clarification of the risk assessment timeframe for the secondary sexual partner through a, "timebound recommendation for the secondary sexual partner similar to the recommendations for blood donors in the May 2023 guidance."

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

The Potential of Artificial Blood Spotlighted

The New Yorker has published an article titled "The Long Quest for Artificial Blood." The story delves into the history of blood transfusions and describes current research efforts to develop alternative products to donated blood. The article references a clinical trial (called RESTORE) of "lab-grown red blood cells" being transfused into humans that is being funded by NHS Blood and Transplant

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The Potential of Artificial Spotlighted (continued from page 1)

(NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK). According to a NHSBT news release, the RESTORE trial, "is a first in human randomi[z]ed controlled trial in healthy volunteers to assess whether red blood cells that have been grown in the laboratory last longer in the circulation after transfusion and are safe."

The piece also mentions the work of, "Allan Doctor, MD the director of the Center for Blood Oxygen Transport and Hemostasis, at the University of Maryland School of Medicine, and the co-inventor of ErythroMer, a synthetic nanoparticle that mimics the oxygen-carrying role of red blood cells [who is leading an initiative to create] an artificial substitute that bleeds — or at least operates in the body — almost exactly like the real thing."

The reporter also addresses the challenges of blood shortages and an aging donor pool, while describing that, "although there is now evidence to show that giving whole, never-separated blood is more effective than red blood cells alone — or even recombined red cells, plasma, and platelets — blood banks on both sides of the Atlantic continue to break blood down into its components." Col. (Ret.) John B. Holcomb, MD, FACS stated to *The New Yorker* that, "[t]he problem here is that there's practically no reimbursement for prehospital blood by insurance and agencies. There's nothing that has a bigger impact on survival than prehospital blood. Nothing. And yet the major impediment is not logistics — we've worked through that. It's not how to store the blood. It's reimbursement. And, in our system, if you don't get reimbursed you don't do it."

(Sources: *The New Yorker*, "The Long Quest for Artificial Blood," 2/3/25; NHSBT News Release, 2/3/25)

New York Blood Center Enterprises Resumes All Blood Collection Activities After Cybersecurity Incident

America's Blood Centers (ABC) member New York Blood Center Enterprises (NYBCe) provided an update on February 3rd in the wake a January 26th cybersecurity incident that impacted all of their operating divisions:

- Blood Bank of Delmarva;
- Community Blood Center of Greater Kansas City;
- Connecticut Blood Center;
- Memorial Blood Centers;
- Nebraska Community Blood Bank;
- New Jersey Blood Services;
- New York Blood Center; [and]
- Rhode Island Blood Center.

As of February 3rd, NYBCe reported that, "at this time, all blood collection activities have resumed across our operating divisions. All donor center operations and community blood drives are currently moving forward as scheduled, and we are working to reschedule those that were cancelled. We are also making strides toward resuming normal distribution. We deeply appreciate your patience and support, and we will remain in touch with our partners as we continue to work through this incident. We would like to thank our greater blood and advanced therapy communities – who have stood shoulder to shoulder with us and provided thousands of units to support NYBCe over the past few days. By working together, we have been able to keep the utmost focus on the communities we serve. While our blood supply remains stable, sustained donor support is essential in the days and weeks ahead as we recover from this incident. We encourage all eligible donors to give as soon as possible and urge organizations and community groups to

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NYBCe Resumes All Blood Collection Activities After Cybersecurity Incident (continued from page 2)

host blood drives to help safeguard patient care. We continue to express our deepest gratitude to our entire community for the unwavering support during this time."

NYBCe previously announced that, "[o]n Sunday, January 26th, NYBCe and its operating divisions identified suspicious activity affecting our information technology systems. We immediately engaged third-party cybersecurity experts to investigate and confirmed that the suspicious activity is a result of a ransomware incident. We took immediate steps to help contain the threat and are working diligently with these experts to restore our systems as quickly and as safely as possible. Law enforcement has been notified."

The Association for the Advancement of Blood & Biotherapies (AABB) Interorganizational Task Force on Domestic Disasters and Acts of Terrorism "activated" in the wake of the cybersecurity incident and issued a January 30th Task Force statement.

ABC thanks its member blood centers and the blood community for assisting to ensure patient demand was met. We will continue to provide support through the Task Force and will pass along updates as they are made available.

(Source: New York Blood Centers Enterprises Statement, 2/3/25)

ABC Announces February Advocacy Forum Webinar on the Transition to the New Administration

America's Blood Centers (ABC) will host its next Advocacy Forum webinar on Tuesday, February 25th at 2 p.m. EST titled "What We Know about the Start of the Trump Administration." Join us as we share information and insights regarding the potential impact on community blood centers as the administration continues to transition.

A link to registration and additional information is available to ABC members here. This is your chance to learn more about the first weeks of the Trump Administration, discuss opportunities for ABC's advocacy priorities, and ask any questions that you or your blood center may have. Please contact us with questions.

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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

The U.S. Food and Drug Administration (FDA) published a notice in the *Federal Register* on February 3rd that revised, "the time by which FDA recommends implementation of the recommendations in [two final] guidances regarding Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." The final guidances are:

- "Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by HCT/Ps;" and
- "Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by HCT/Ps."

According to the notice, the final guidances now have a recommended implementation timeframe of May 4th. The agency explained in the *Federal Register* that, "[t]he revised implementation date will permit FDA to consider the comments received thus far prior to the implementation date. Permitting the Agency additional time to further review and consider the guidances, including comments received, as well as seek additional comments is consistent with the President's January 20, 2025, memorandum entitled, 'Regulatory Freeze Pending Review.'"

FDA previously published the guidances on January 7th and had recommended that establishments making donor eligibility determinations (establishments) implement the recommendations in the guidances 'as soon as feasible, but not later than 4 weeks after the guidance issue date.'"

(Source: *Federal Register* Notice, 2/3/25)

WORD IN WASHINGTON

The U.S. Food and Drug Administration's Center for Biologics Evaluation Research (CBER) has published Calendar Year 2024 Report from the Director. The publication attributed to CBER Director Peter Marks, MD, PhD includes highlights from the agency over the previous year including noting that, "[CBER has] advanced important public health priorities in blood and tissue safety and approved several important preventative vaccines." Of interest to the blood community, the report specifically references that, "CBER issued important safety communications to consumers, patients and healthcare providers including but not limited to the following topics: a required boxed warning for T cell malignancies following treatment with BCMA-Directed or CD19-Directed autologous chimeric antigen receptor (CAR) T cell immunotherapies; use of unapproved HIV blood sample self-collection kits; and modifications to the Risk Evaluation and Mitigation Strategy (REMS) for these CAR T cell immunotherapies to minimize the burden of complying with the REMS on the healthcare delivery system. Additionally, CBER provided information for blood establishments and tissue establishments regarding the Oropouche virus along with reminding the public that FDA has not approved 'young plasma' for any medical conditions or to provide other health and wellness benefits. Information for blood establishments and transfusion services for strengthening their cybersecurity practices to prevent and mitigate cybersecurity incidents that could affect the availability and safety of blood and blood components for transfusion or further manufacture was also made available on FDA's website. Guidance development and publication continues to offer CBER's current thinking on important product design, manufacturing and testing of many regulated products and in 2024, CBER published numerous draft and final guidance documents regarding blood and blood components, cellular and gene therapy, tissues, vaccines, and many other important regulatory topics. CBER's Office of Therapeutic Products (OTP) hosted eight events to share information about the review of regulated products and to bring together important stakeholders to discuss the development and advancement of products, including CAR-T cells, regenerative medicine, gene therapy, and provide a forum for clinical trial participants to learn about finding a support team as they take part in a study. OTP hosted two listening sessions for patients and their care partners perspectives on gene therapy for rare diseases."

(Source: CBER Report from the Director, 1/17/25)

PEOPLE

Wade Liu has been named president of the Human Biologics Division at InVita Healthcare Technologies. According to an InVita announcement, Mr. Liu has, "14 years of experience in leadership roles within the donation-transplant area and 25 years of experience in technology." He joined Transplant Connect, now InVita's donation and transplant division, in 2011 and has played an integral role in the company's product development, partner services, implementations, and organizational development. Mr. Liu previously worked at, "Northrop Grumman, Alpine Electronics of America, and PricewaterhouseCoopers Consulting. In these roles Wade was successful in wide-ranging initiatives, including establishing processes and calibrating operations to improve technology delivery for diverse client needs, designing and developing mission-critical software for spacecraft flight deployment, leading enterprise-wide process optimization and certification efforts (e.g., CMMI, ISO), administering large-scale program management offices, overseeing implementation and change management of new enterprise solutions, leading cross-functional teams and multi-national collaborations, and more."

(Source: InVita Healthcare Technologies Announcement, 1/28/25)

INFECTIOUS DISEASES UPDATE

EBOLA

The U.S. Centers for Disease Control and Prevention (CDC) has published a Health Alert Network (HAN) Health Advisory regarding a, "recently confirmed outbreak of Ebola disease in Uganda caused by the Sudan virus (species Orthoebolavirus sudanense)." The February 6th communication noted that, "[c]urrently no suspected, probable, or confirmed Ebola cases related to this outbreak have been reported in the U.S., or outside of Uganda. However, as a precaution and because there are other viral hemorrhagic fever (VHF) outbreaks in East Africa, CDC is sharing best practices for public health departments, public health and clinical laboratories, and healthcare workers in the United States to raise awareness about this outbreak." The agency has issued a, "Travel Health Notice Level 2: Practice Enhanced Precautions for people traveling to Uganda. Currently, CDC has not issued any interim recommendations to health departments for post-arrival risk assessment and management of travelers, including U.S.-based healthcare workers, arriving from Uganda. CDC recommends that travelers monitor themselves for symptoms of Sudan virus disease (SVD) while in the outbreak area and for 21 days after leaving. Travelers should also self-isolate and contact local health authorities or a clinician if they develop symptoms (early "dry" symptoms may include fever, aches, pains, and fatigue and later "wet" symptoms may include diarrhea, vomiting, and unexplained bleeding)."

The CDC has not classified the affected region as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that, "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2)."

(Source: CDC HAN Communication, 2/6/25)

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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.

Recording Available for ABC Stop the Bleed Partnership Webinar & Member Input Requested

A recording of the America's Blood Centers (ABC) Stop the Bleed webinar is now available to ABC member blood centers. The January 31st webinar discussed details of ABC's new national partnership with Stop the Bleed, a public-private initiative led by the Department of Defense and run by the American College of Surgeons. The collaboration aims to enhance emergency preparedness by training individuals to effectively stop severe bleeding in emergencies while promoting the importance of blood donation.

As the partnership prepares to launch in May in conjunction with National Trauma Awareness Month, ABC is asking member blood centers to share input regarding the partnership by taking a moment to complete a brief survey by Friday, February 14th. This initiative will make resources available to ABC members and feature a series of activities during National Trauma Awareness Month including:

- a customized partnership toolkit;
- the distribution of co-branded ABC/Stop the Bleed emergency kits to interested member centers; and
- the opportunity to host joint public events, such as Stop the Bleed training sessions and blood drives, to highlight the critical role of blood donation in emergency preparedness.

Please contact us with questions.

ABC Webinar: "An Overview of Whole Derived Platelets & Cold Stored Platelets Set for February 26th

The ABC Education Committee has announced that a webinar titled "An Overview of Whole Blood Derived Platelets & Cold Stored Platelets" will be held on February 26th at 3 p.m. EST. This event will feature South Texas Blood & Tissues' Senior Director of Systems Integration Jim Latimer and Carter BloodCare's Medical Director of Patient Services Frances Compton, MD sharing their experiences and insights from implementing whole blood-derived platelets and cold stored platelets at their blood centers. More information and a link to registration are available to ABC members here. Please contact us with questions.

ABC "Staying Ahead in the Digital Landscape" Webinar Taking Place February 27th

Registration is open for ABC's February webinar that aims to provide blood centers with valuable insights into today's search engine optimization (SEO) environment, upcoming trends, and proven strategies to elevate your digital communication efforts. During the "Staying Ahead in the Digital Landscape" Webinar, hear Tom Felgar, the head of Paid & Organic Search at 501SEM, share cutting-edge techniques and expert advice aimed at optimizing your blood center's online presence. Learn how to enhance your chances of being featured in Google's Artificial Intelligence (AI) summaries, drive organic traffic to your website, boost visibility, and effectively engage your blood center's audience. This webinar is open to all ABC members. More information and a link to registration are available here. Please contact us with questions.

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2025 ABC Annual Meeting Schedule Available

Join us for the 63rd ABC Annual Meeting in Arlington, Va. Registration is open and the schedule is available. Hear *POLITICO*'s Director of Regulatory Research Laura DiAngelo, MPH deliver the keynote as she addresses the impact of the 2024 Presidential and Congressional elections on the regulatory and congressional landscape. Meeting attendees will gain insights into how the administration's policy agenda and approach to regulation will impact the blood community, allowing your organization to stay ahead of the curve. This event will also explore the latest developments in advocacy, leadership, operations, science, and medicine, connecting and preparing your c-suite and senior leadership for the most critical topics facing your blood center. Following the success of last year's revamped format and expanded content offerings, we will continue this approach in 2025. Book your rooms by Friday, February 14th to secure the hotel group rate. Sponsorship opportunities are also available. Please contact us with any questions as we look forward to seeing you!

Executive Compensation Report Available

ABC has published the 2024 Executive Compensation Survey Report. This resource is available complimentary to participating ABC member blood centers. Non-participating member blood centers may purchase the report which is an important tool for blood center chief executive officers (CEOs) and their boards for setting executive salaries/benefits, as well as meeting the Internal Revenue Service Form 990 requirements to demonstrate comparability of CEO compensation. Please contact us with questions.

Register for the 2025 ADRP Annual Conference

Register now for the 2025 ADRP Annual Conference in Oklahoma City, Oklahoma, from May 6th to 8th at the Omni Oklahoma City Hotel. Remember to book your hotel room by April 11th for the discounted rate. This conference offers a chance to learn about industry trends, share ideas, and connect with other donor recruitment, donor services, collections, marketing, and communications professionals. Join more than 400 of your peers by participating in pre-conference workshops, attending compelling educational sessions, engaging in roundtable discussions, and exploring an expansive exhibit hall filled with innovative solutions. Seize this extraordinary opportunity to learn, share, and grow within the blood community.

2025 ADRP Call for Award Nominations Is Open for 1 More Week

ADRP encourages you to recognize the work of individuals on your staff, donors, and organizations who go above and beyond with their exceptional service and leadership in support of blood donation by submitting a nomination for the 2025 ADRP Awards before the February 14th deadline. This year's awards include:

- Franzmeier Lifetime Achievement Award;
- Ronald O. Gilcher, MD Award;
- Donor Experience Professional of the Year Award;
- Rolf Kovenetsky Leader of the Year Award;
- ADRP Volunteer of the Year Award;
- Media Partner Award;
- Blood Drive Partner of the Year Award; and
- School Partner of the Year Award.

Award winners will be honored during the 2025 ADRP Annual Conference in Oklahoma City, Oklahoma at the Omni Oklahoma City Hotel and receive a complimentary conference registration. You may view a description of each award here and a listing of the 2024 winners. Please contact us with questions.

RESEARCH IN BRIEF

The Effects of Air Pollution on Platelet Recovery and Function.– Authors of a study in the *Journal of Blood Medicine* "aim[ed] to address whether [a] platelet donor's exposure to high levels of PM2.5 (particles less than 2.5 micrometers in diameter) is associated with reduced platelet recovery in patients receiving prophylactic platelet transfusions." They explained that a, "cross-sectional study was conducted [in] adult patients with hematologic malignancies [in which] patients were eligible if they were 18 years or older, had chemotherapy resulting in thrombocytopenia (defined as platelet counts < 20,000/μL), and required at least one platelet transfusion." The paper noted that, "[t]he PM2.5 cut-off levels used in this study align with the World Health Organization Interim Target-3 for 24-hour PM2.5 exposure of 37.5 μg/ m^3…In this study, PM2.5 levels below 37.5 μg/m^3 were categorized as the control group, while levels equal to or exceeding 37.5 μg/m^3 were classified as the high pollution group." The researchers explained that, "[t]here were 66 patients: 28 (42.4 percent) were diagnosed with acute myeloid leukemia, 18 (27.3 percent) with acute lymphoblastic leukemia, 15 (22.7 percent) with lymphoma and 15 (22.7 percent) were undergoing stem cell transplantation [and a] total of 191 platelet transfusions were administered, ranging from one to nine per patient, with a median of five transfusions…The mean age of donors for transfusion performed during high PM2.5 concentrations was 35.9 ± 7.8 years, which was significantly younger than the mean age of donors for transfusion performed during normal conditions (39.9 ± 9.1 years, p = 0.046)." The paper noted that, "[a]dditionally, there was a higher proportion of donors with blood groups A and B during high PM2.5 period compared to normal conditions (p = 0.001)…The efficacy of platelet transfusions was assessed using platelet increment and corrected count increment (CCI)." The study found that, "[t]here was no statistically significant difference in platelet increment between the case group (30,395 ± 11,840 cells/μL) and the control group (27,081 ± 12,677 cells/μL) (p=0.128). [Also, a correlation] analyses revealed no significant association between PM2.5 levels and platelet increment (r=0.0565, p=0.437) or CCI (r=0.0370, p=0.614)." The paper concluded that, "[t]his study indicates that short-term exposure (one day prior to donation) to elevated PM2.5 levels is not significantly associated with platelet recovery in patients receiving prophylactic platelet transfusions...While these findings suggest limited immediate impact, further research is warranted to explore the potential long-term effects of environmental pollutants on transfusion outcomes, particularly in regions with persistently high air pollution levels."

Citation: Hantrakool, S., Sriwichai, M., Shaengkhamnang, B., *et al*. "The Effects of High Particulate Matter Levels on Platelet Recovery in Patients Receiving Prophylactic Platelet Transfusion." *Journal of Blood Medicine*. 2025.

Contributed by Richard Gammon, MD

GLOBAL NEWS

The regulatory authority in New Zealand (Medsafe) has approved an application from the country's national blood provider New Zealand Blood Services(NZBS) to shift to individual donor assessments. A statement from NBZS Chief Medical Officer Sarah Morley, MBBS, PhD explained, "I am pleased that Medsafe has now approved our application to shift towards an individuali[z]ed assessment when determining eligible blood and plasma donors. This evidence-based assessment will ask the same questions of every donor — irrespective of gender, sex, or sexual orientation — when assessing potential risk for sexually transmitted infections, while maintaining the highest level of blood safety. Achieving Medsafe approval means NZBS is one step closer to introducing individuali[z]ed donor assessments. However, before we

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GLOBAL NEWS (continued from page 8)

implement this change, our testing regime needs to be updated to align with global best practice. These additional testing requirements will complement the individuali[z]ed risk assessment change, and will help ensure the safety of our plasma products." NBZS expects to begin using individual donor assessments in early 2026. The organization previously announced that findings from the Sex and Prevention of Transmission Study (SPOTS) and peer-reviewed studies from other international blood organizations were used, "complete a detailed review and risk assessment of [NBZS'] approach to managing blood safety as it relates to sexual activity and sexually transmitted infections."

(Source: NBZS Statement, 1/30/25)

The National Blood Service Agency (NBSA) in Nigeria, Aminu Kano Teaching Hospital (AKTH), and the Universitätsmedizin Greifswald (UMG) in Germany have collaborated with the goal of improving transfusion safety in Nigeria. *Premium Times Nigeria* reported that the partnership, "aims to replicate the success of AKTH's transfusion medicine cent[er] across hospitals nationwide." The initiative known as "Towards Safe Blood in Nigeria" also seeks to, "enhance Nigeria's blood transfusion system by promoting best practices and standards in blood safety, testing, and transfusion management." Specifically, NBSA explained to the news organization that a, "key goal of the project is to address major challenges in Nigeria's blood transfusion system. These challenges include insufficient blood supply, safety risks such as the transmission of infectious diseases, and inadequate compatibility testing, which can lead to transfusion reactions. Additionally, the project aims to reduce operational errors caused by inadequate training and poor infrastructure. To address these issues, a national training cent[er] for transfusion medicine will be established at AKTH. The cent[er] will provide training for blood bank staff on hygiene protocols, donor screening, and compatibility testing, including for patients with sickle cell disease. NBSA added that a speciali[z]ed auditor training progra[m] will also strengthen its capacity to regulate blood banks nationwide."

(Source: *Premium Times Nigeria*, "Nigeria partners German hospital to enhance blood transfusion safety," 2/4/25)

The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) announced that its, "independent appraisal committee has approved the use of gene editing therapy exagamglogene autotemcel (exa-cel) for use in the NHS in England, providing a potential cure for some people with severe sickle cell disease (SCD)." According to the news release, "the treatment (also called Casgevy and made by Vertex) will be available to SCD patients 12 and over involves collecting the person's stem cells. These are then edited in a lab to produce non-sickling red blood cells. The edited cells are then infused back into the person. As exa-cel involves people receiving their own edited cells, they have no risk of their body rejecting them."

(Source: NICE News Release, 1/31/25)

COMPANY NEWS

Grifols recently announced the submission of a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) for an investigational fibrinogen treatment. The company previously announced that in February 2024 that, "the fibrinogen had achieved positive topline results in a phase 3 clinical trial. The study met its primary endpoint of being as effective as standard of care in reducing intraoperative blood loss in patients with acquired fibrinogen deficiency, while also maintaining an excellent safety profile." Grifols previously submitted a marketing authorization application (MAA) to multiple European

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COMPANY NEWS (continued from page 9)

nations in October 2024 and, "expects to begin treating patients in Europe starting in the second half of 2025, with rollout in the U.S. planned for the first part of 2026."

(Source; Grifols News Release, 1/9/25)

Star Therapeutics has been granted a "Fast Track" designation by the FDA for an investigational monoclonal antibody treatment for von Willebrand disease (VWD). According to the company, the investigational monoclonal antibody, "targets Protein S to restore balance in blood clotting, as a universal hemostatic therapy for numerous bleeding disorders. It is potentially the first subcutaneous therapy that addresses all types of VWD and has a convenient dosing regimen." The FDA Fast Track designation is designed to, "facilitate the development and expedite the review of medicines that demonstrate the potential to treat serious conditions and fill an unmet medical need. Programs with Fast Track designation can benefit from early and more frequent interactions with the FDA to discuss the product candidate's development plan in addition to a rolling submission of the marketing application. Product candidates with Fast Track designation may also be eligible for priority review and accelerated approval."

(Source: Star Therapeutics News Release, 1/6/25)

The **Advanced Medical Technology Association (AdvaMed)** published a statement requesting a medical technology exemption from all tariffs. Scott Whitaker, president and chief executive officer of AdvaMed, explained in the statement that, "[w]e have shared with the Administration our concerns about the potential impact tariffs could have on the medical technology (medtech) supply chain that American patients depend on for their care. In light of that risk, an exemption was provided for most medical devices during President Trump's first term with respect to the tariffs on China, and we are advocating for a similar approach this time. We will closely monitor for any effects the tariffs may have on this critical supply chain and share that information with the Administration. [Tariffs] impact American companies similarly to an excise tax, which would lead to less R&D/innovation, layoffs, higher prices for the above-mentioned payors and patients, or all of the above. Additionally, moving manufacturing from one facility to a different or new facility requires FDA approval, which makes it difficult in the short term to adjust production to the U.S. [During President Trump's] first term with respect to the tariffs on China, a carve-out was provided for much of the medtech sector, given the risks to the U.S. hospital supply chain. We maintain that the potential supply chain disruption and its downstream effects on patients remain a risk, should tariffs be implemented. Shortages of critical medical technologies are a real concern in our initial modeling."

(Source: AdvaMed Statement, 2/1/25) ♦

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

Feb. 20. **Terumo Blood and Cell Technology Launch in the Future of Whole Blood Revolutionary Reveos Webinar.** Registration is open.

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Feb. 26. **America's Blood Centers (ABC) Webinar: "An Overview of Whole Blood Derived Platelets & Cold Stored Platelets."** A link to registration and more information are available here.

Feb. 27. **ABC "Staying Ahead in the Digital Landscape" Webinar.** A link to registration and more information are available here.

Mar. 10-12. **ABC Annual Meeting. Arlington, Va.** Registration is open. More information available here.

May 6-8. **2025 ADRP Annual Conference. Oklahoma City, Okla.** Registration is open. More information available here.

May 14-15. **International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich Institut[e] (PEI) 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Heidelberg, Germany.** Registration is open. More information available here.

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

June 1-4. **International Society of Blood Transfusion (ISBT) 35th Regional Congress. Milan, Italy.** Registration is open. More information available here.

June 10-11. **ABC Advocacy Workshop. Washington, D.C.** More information is coming soon.

June 25-26. **HHS OIDP TBDAIC Community Engagement Meeting (Hybrid). Portland, Maine.** More information coming soon.

June 30-July 1. **HHS Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2025 (Hybrid). Washington, D.C.** More information available here.

Sept. 10. **FDA CBER Office of Blood Research and Review (OBRR) Public Webinar: FDA Review of Biologics License Applications for Blood and Source Plasma (Virtual).** More information coming soon.

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

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

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

CLASSIFIED ADVERTISING

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

POSITIONS

Director of Donor Services (Fixed and Mobile Collections). Shepeard Community Blood Center in Augusta, Georgia, seeks an ambitious leader to oversee the delivery of industry-leading customer service to its donors. This position is challenging, and the director of donor services must be willing to adapt to change, solve problems independently, and communicate effectively within their department and across the organization. The ideal candidate will be able to juggle multiple projects, hold others accountable, and manage their time efficiently. Shepeard has a fleet of ten collection vehicles, six fixed sites, and nearly 50 donor services staff, all reporting up to the

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POSITIONS (continued from page 11)

Director of Donor Services. The organization achieved record collection in 2024 and expects continued growth in the coming years. A generous benefits package, including up to a 7% employer 401(k) contribution, relocation expenses, and ample PTO, is available for a successful candidate. Shepeard also provides cost-of-living raises, merit raises, and annual bonuses. The ideal candidate will have at least five years of experience in blood banking, healthcare, or nursing. A bachelor's degree and five years of management experience is required. Those interested can learn more by going to shepeardblood.org and clicking "jobs" at the top of the home screen.

Medical Director/Associate Medical Director. Carter BloodCare seeks a passionate and dedicated **Medical Director/Associate Medical Director** to join our mission-driven team in North Texas. This role offers the opportunity to collaborate with a dynamic group of medical professionals and lead innovative initiatives that save lives every day. As Medical Director/Associate Medical Director, you'll play a pivotal role in the medical and technical oversight of blood centers, transfusion services, and advanced biotherapies. Working closely with the Chief Medical Officer and fellow directors, you will ensure our operations remain at the forefront of transfusion medicine. From providing consultative expertise to fostering relationships with healthcare providers, your work will directly influence patient care across the region. Carter BloodCare seeks candidates with an MD, DO, or equivalent degree, board certification/eligibility in Blood Banking/Transfusion Medicine, and qualified for an unrestricted medical license in Texas. The successful candidate will bring expertise, compassion, and a collaborative spirit to this vital role with strong knowledge and experience in blood banking and/or advanced biotherapies. This is a chance to join an organization dedicated to excellence and innovation in transfusion medicine. Apply at //www.carterbloodcare.org/careers. Carter BloodCare is an EEO/Affirmative Action employer.

Supply Chain Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Supply Chain Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all purchased materials, supplies, equipment, and services used by the company. The Supply Chain Manager is organized and decisive and can motivate the team to reach daily and long-range goals. Join our team and help us continue our dedication to making sure blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Cord Blood Program Supervisor. LifeSouth Community Blood Centers is looking for a bilingual (English and Spanish), highly skilled leader with proven supervisory experience and a passion for making a difference to join the team in the role of Cord Blood Program Supervisor in Miami, Fla. This position is responsible for educating the public about cord blood donation, recruiting new cord blood donors, and working closely with hospitals, while providing supervisory oversight of Cord Blood Donation Recruitment Specialists. LifeSouth Cord Blood Bank is a community-based public cord blood bank that collects and stores umbilical cord blood for the purpose of clinical cures and research in the field of stem cell transplantation. Visit our careers page to learn more about this position, and apply here!

Cord Blood Donor Recruitment Specialist – Miami. LifeSouth Community Blood Centers is looking for a bilingual (English and Spanish) candidate with strong interpersonal skills and a genuine passion for making a difference to fill the role of Cord Blood Donor Recruitment Specialist in Miami, Fla. In this position you will be responsible for tasks related to cord blood education, consent, and training. Must be comfortable interacting regularly with collection facilities staff, the general public, and donor mothers regarding cord blood collection and donations. LifeSouth Cord Blood Bank is a community-based public cord blood bank that collects and stores umbilical cord blood for the purpose of clinical cures and research in the field of stem cell transplantation. Visit our careers page to learn more about this position, and apply here!

Director, Blood Drive Partnerships. Be part of something bigger and change the world with us by joining **ImpactLife's** leadership team as a **Director, Blood Drive Partnerships**. The Director is responsible for the planning, development, organization, coordination, and management of the field recruitment team to secure organizational blood drive sponsors and volunteer blood drive coordinators. This role ensures adequate blood donations from mobile blood drives and center locations to meet patient needs and financial goals. Candidates must reside in and be able to travel within our territory footprint within Iowa, Illinois, Missouri, and Wisconsin; have a minimum of eight years' leadership experience working in business-to-business sales, partnership development and/or public relations; have a minimum of five years of multi-state or multi-community supervisory/management experience; and hold a bachelor's degree (preferred) with a concentration in business development, marketing, communications, or public relations. For more information including job details, benefits, and compensation click here: Join Us!

Chief Operations Officer (Oklahoma City, Oklahoma). Our Blood Institute (OBI), America's largest, self-sufficient blood center is seeking a seasoned, successful, and inspiring Chief Operations Officer (COO). The COO

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will provide leadership, guidance, and oversight for core blood center operations to include Donor Recruitment; Donor Services; Technical Operations; Client Relations/Contracting; 8 Subcenter, and 9 Satellite operations. This position will assure donor and product safety. He/She will recruit and foster the talent required to staff a dependable, high performance, engaged, and innovative team now and for the future. They will develop annual budgets at the organizational level (demand planning) and for supervised departments, with an eye to maximizing efficiencies and expanding revenue streams. They will also recommend new technologies and capital expenditures that are necessary to keep the organization's operations at the leading edge of performance. They will maintain productive industry collaborations and relationships via group purchasing organizations and professional/industry associations while working with executive leadership to shape strategic plans to benefit the organization's principle functions of blood product acquisition, processing, and distribution. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** https://obi.org/about/careers/

Operations Manager. Blood Assurance is seeking an **Operations Manager** to manage our collection efforts in the Georgia area. This position will be responsible for operational oversight of collection services for multiple collection teams in an assigned territory. Supervises staff in coordination with other department leaders and ensures compliance with all Standard Operating Procedures, FDA and AABB regulations. Monitors performance in the areas of productivity, proficiency and customer service. Operations Manager Requirements: A bachelor's degree with some prior supervisory/ management experience in blood banking is required. Advanced skills in leadership, teamwork, analytics, and communications are also required. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Generous Paid Time Off, 401K with company match and Wellness Program. Blood Assurance is a non-profit organization with a workforce of more than 300 employees. At Blood Assurance, our values are centered around LIFE: Laughter, Integrity, Family and Excellence. These values are embedded in our company culture. Come and join our team to be a part of this rewarding environment! Qualified candidates are encouraged to submit an online employment application for consideration at //bloodassurance.org/careers. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Assistant/Associate/Full Professor, Clinical Track (Hoxworth Blood Center). Hoxworth Blood Center (HBC) was founded in 1938 and serves more than 30 hospitals in 18 counties in Ohio, Kentucky, and Indiana. Annually, HBC collects more than 100,000 units of blood from local donors to help save the lives of patients in area hospitals. HBC is located within the University of Cincinnati (UC), College of Medicine, and is seeking an academic physician to advance clinical services and research in Blood Banking and Transfusion Medicine. The rank of the clinical track appointment is open and will be commensurate with the experience and professional accomplishments of the selected applicant. Essential Functions: Provide clinical blood banking/transfusion medicine coverage in an active academic transfusion service supporting a robust academic teaching hospital specializing in hematology/oncology, high risk obstetrics, organ transplantation and surgery; including a Level I Trauma Center. Provide medical coverage for a large regional independent blood collection center with an active apheresis program supporting cell therapy collections. Engage in the training of Transfusion Medicine fellows, pathology residents, and rotating fellows, residents, and medical students. Minimum Requirements: MD or MD/PhD; Board eligibility or Board certification in Blood Banking/Transfusion Medicine; and active or eligible for a State of Ohio Medical License. Click here to view the full job description and apply. EOE