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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #21 **June 21, 2024**

INSIDE:

Blood Advocacy Week 2024 Features BARDA, FDA, and HHS Meetings

America's Blood Centers (ABC) recently concluded Blood Advocacy Week 2024. This year's event featured more than 80 organizations, including member blood centers and partner organizations, united in the common goal of advancing policies that prioritize the blood supply, promote access to blood and blood products, and increase the blood donor base.

During the week of June 10th-14th, ABC and leaders from community blood centers conducted meetings with representatives from multiple federal agencies to encourage administrative action to support the blood supply. These in-person meetings included staff from the Biomedical Advanced Research and Development Authority (BARDA), the Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS), and the U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER).

The BARDA meeting included Mary Homer, PhD, chief of the Radiological and Nuclear Countermeasures Division of Chemical, Biological, Radiological and Nuclear Medical Countermeasures and other BARDA staff to discuss the state of the blood community, pre-hospital blood transfusions, and increasing surge capacity.

While at HHS, the meeting featured HHS Assistant Secretary for Health Admiral Rachel Levine, MD to discuss the implementation of individual donor assessments and the "Summer of Giving" campaign, blood product supply chain, the state of the blood community, and post-COVID-19 trends in donation.

The meeting with FDA included CBER Director Peter Marks, MD, PhD and CBER's Office of Blood Research and Review Director Anne Eder, MD, PhD to discuss several issues such as licensure challenges ABC members are facing when implementing apheresis product collections at new fixed site locations. ABC had the opportunity to share the results of ABC's member survey and feedback regarding streamlining product licensure with FDA and highlighted the need for the agency to clarify the licensure and submission processes.

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Blood Advocacy Week Features FDA, HHS, and BARDA Meetings (continued from page 1)

Other Blood Advocacy Week action included:

- a congressional briefing on Tuesday, June 11th on Capitol Hill regarding the status of the nation's blood supply and urging action on key priorities;
- a group letter from 80+ partners to members of Congress highlighting the need to make the blood supply a national priority; and
- encouraging public action through a weeklong *Axios* Politics and Policy takeover, press releases, letters to Congress, and social media campaigns.

ABC thanks all members, partners, and sponsors for their participation in Blood Advocacy Week and amplifying our advocacy efforts.

WORD IN WASHINGTON

The American Clinical Laboratory Association and HealthTrackRx, its member company, have filed a complaint in the Eastern District of Texas, stating that, "U.S. Food and Drug Administration (FDA) does not have authority to regulate professional laboratory-developed testing services as medical devices." The complaint explained that, "the development and performance of laboratory developed tests is regulated at the federal level under a separate statutory and regulatory framework, CLIA, that ensures the validity and reliability of laboratory tests and the training and qualifications of the skilled professionals who perform, supervise, and interpret those tests. Notably, when Congress enacted CLIA, it did not hint that it had already granted FDA authority to regulate laboratory testing services as medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). If Congress had wanted to expand FDA's authority so dramatically over an entire profession, it would have said so." ABC continues to engage in this issue on the Hill and will continue to monitor activity around the regulation of lab developed tests.

(Source: ACLA News Release, 5/29/24)

The U.S. Government Accountability Office (GAO) has sent a letter to U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra, JD regarding, "Priority Open Recommendations" for HHS. The letter aimed to serve as an update on, "the overall status of HHS' implementation of GAO's recommendations and to call your continued personal attention to areas where open recommendations should be given high priority. In November 2023, we reported that, on a government-wide basis, 75 percent of our recommendations made 4 years ago were implemented. HHS's recommendation implementation rate was about 68 percent. As of April 2024, HHS had 417 open recommendations. Implementing

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The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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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these recommendations could significantly improve HHS's operations. In our May 2023 letter, we designated 45 recommendations as priorities for HHS, and HHS has implemented seven of them." Included in the recommendations to HHS were:

- "**public health emergency preparedness, including the COVID-19 response.** The COVID-19 pandemic has highlighted the critical need for an effective national response to public health emergencies—an area for which HHS's leadership and coordination has been placed on GAO's High-Risk List. We have identified five priority recommendations in this area. These include a recommendation to develop an approach for managing risks associated with gaps between Strategic National Stockpile medical countermeasure inventory levels and recommended quantities. We also recommended that HHS develop a mechanism to routinely monitor, evaluate, and report on coordination efforts for infectious disease modeling across multiple agencies. If implemented, these recommendations will help improve HHS's preparedness for any future public health emergencies.
- **Food and Drug Administration (FDA) oversight.** FDA has a critical role in ensuring the safety, efficacy, and security of the millions of medical products used by Americans each day, as well as the safety of our nation's food supply. Both areas are on our High-Risk List. We have identified three priority recommendations in this area. For example, we recommended that FDA assess the effectiveness of the foreign offices' contributions to drug safety. If implemented, these recommendations would help FDA ensure that medical products and food imported into the United States are safe.
- **Health care infrastructure, information technology, and cybersecurity.** The federal government exchanges a large variety of sensitive information with states to implement key federal and state programs. Recent high-profile cyberattacks targeting the public and private sectors highlight the urgent need to address cybersecurity weaknesses. We have identified five priority recommendations in this area. For example, we recommended that CMS revise its policies to maximize coordination with other federal agencies on the assessment of state agencies' cybersecurity. In addition, as a co-sector risk management agency for the food and agriculture sector with the Department of Agriculture, we urge HHS to implement our priority recommendation related to critical infrastructure protection. We recommend HHS work within the food and agriculture sector to develop methods to determine the level and type of adoption of the National Institute of Standards and Technology's Framework for Improving Critical Infrastructure Cybersecurity. If implemented, these recommendations could help address current cybersecurity weaknesses."

(Source: GAO Letter, 5/28/24)

The HHS Health Sector Cybersecurity Coordination Center (HC3) has issued a June 13th alert of 14 cybersecurity vulnerabilities that have been added to the Department of Homeland Security's (DHS) Cybersecurity and Infrastructure Security Agency's (CISA) "Known Exploited Vulnerabilities Catalog." HC3 specified that these vulnerabilities may be of particular interest to the health sector. It noted that, "[v]ulnerabilities that are entered into this catalog are required to be patched by their associated deadline by all U.S. executive agencies. While these requirements do not extend to the private sector, HC3 recommends all healthcare entities review the vulnerabilities in this catalog and consider prioritizing them as part of their risk mitigation plan."

(Source: HC3: Monthly Cybersecurity Vulnerability Bulletin, 6/13/24)

The Administration for Strategic Preparedness & Response (ASPR) has published a blog post attributed to Dawn O'Connell, the assistant secretary for Preparedness and Response, detailing the agency's plans to transform the strategic national stockpile (SNS) and its request for federal funds in support of its mission. In the blog, she noted that, "to make certain the SNS has the infrastructure in place to support operations, I have prioritized ensuring that the SNS has the appropriate caliber workforce to

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WORD IN WASHINGTON (continued from page 3)

manage complex procurements, facilitate warehouse logistics and operations, communicate effectively with state and local partners, and manage strategic decision against an evolving threat landscape…I am seeking [the] ability to use the Commercial Solutions Opening (CSO) mechanism which is a merit-based source selection strategy used by the Department of Defense to acquire innovative commercial items, technologies, or services that directly fulfill requirements, close capability gaps, or provide potential technological advances. This acquisition tool would allow the SNS to purchase the supplies it needs quickly through a competitive process with a reduced risk of unwarranted, time-delaying protests. While I will continue to use all tools available to me to strengthen the SNS, I hope we can work together to secure the necessary authorities and funding to transform this important component of the public health infrastructure."

(Source: ASPR Blog, "ASPR Is Transforming the SNS," 5/30/24

BRIEFLY NOTED

The Biomedical Excellence for Safer Transfusion (BEST) Collaborative has issued a call for applications for the Scott Murphy Memorial Lecture, which was, "established in 2007 by the BEST Collaborative in recognition of the tremendous contribution of the late Dr. Scott Murphy, a past chair of the BEST Collaborative, [in] the field of transfusion medicine and to the science of platelet storage." The organization is, "encouraging junior faculty involved in the broadly understood field of transfusion medicine to apply for this unique award. The recipient of the next award will be invited to present during the BEST Meeting and to network with our members." A listing of previous winners is available. Applications with a letter of interest and C.V. can be submitted online. The submission deadline is Monday, August 5th at 12 p.m. PDT, and the decision will be announced by the end of August. The award recipient will present a lecture during [the] BEST Meeting to be held in Galveston, Texas October 16th-17th. The award[ee] will be invited to attend the entire BEST Meeting [and will be provided] a $500 honorarium and [a stipend] up to $1,000 toward travel expenses [by BEST to the meeting.]"

(Source: BEST Collaborative Announcement, 6/19/24)

The National Alliance of Sickle Cell Centers (NASCC) is hosting its Annual Meeting and Consensus Conference July 28th-August 1st in Minneapolis, Minn. According to the organization, this year's conference aims:

- "to work collaboratively to improve care in sickle cell disease by identifying and implementing best practices and care management for affected individuals. Our goal is to ensure everyone living with sickle cell disease in the U.S. has access to a sickle cell specialist to obtain the available treatment;
- to build consensus on optimal screening and treatment pathways for sickle cell centers;
- to identify and build consensus on measures of quality improvement in sickle cell disease; and
- to create a community and fellowship for people caring for those living with sickle cell disease.

NASCC strives to be the leading organization in clinical practice in sickle cell disease including recognizing and supporting sickle cell disease centers who deliver multi-disciplinary care for affected individuals."

(Source: NASCC Announcement, 6/18/24)

RESEARCH IN BRIEF

Autologous Donation Guidelines. The updated guidelines for predeposit autologous transfusions have been published in the *British Journal of Haematology*. The authors noted that, "[t]here remains a small group of patients who, despite clinicians utili[z]ing patient blood management techniques, may still require intraoperative or postoperative red cell transfusion and where the blood services cannot provide compatible allogeneic blood. It must, however, be borne in mind that the greatest risks of transfusion relate to administrative error." The paper explained that, "[o]ne infectious risk of blood component transfusion is bacterial contamination, which may also be paradoxically increased by a non-standard process and longer storage." The key recommendation is that "predeposit autologous donation (PAD) is only recommended for patients with rare blood groups or who have multiple blood group antibodies, which make compatible allogeneic (donor) blood difficult to obtain (Grade 1B)." The authors wrote that, "[t]here are no large, high-quality randomi[z]ed controlled trials, so it is impossible to judge whether the benefits of PAD outweigh the potential harm. Non-infectious transfusion risks are not mitigated by autologous donation, particularly transfusion-associated circulatory overload (TACO)." The paper also noted that, "iatrogenic an[e]mia post-PAD is a risk…PAD is no longer recommended in obstetric practice." Following donation, a patient's h[e]moglobin concentration (Hb) may not return to baseline before delivery, leading to a decrease in maternal iron stores and exacerbating an[e]mia." The authors explained that the, "Tissue Transplantation Services Professional Advisory Committee (JPAC) also offers the following advice: 'Patient Blood Management strategies should be discussed and considered as part of a wider blood conservation approach, tailored to the patient's status and the nature of any planned surgery.'" The paper described, "a study of 501 patients undergoing radical prostatectomy found that treating an[e]mic PAD donors with IV iron plus erythropoietin (EPO) in the context of an[e]mia reduces the requirements of allogeneic blood transfusion. Patients scheduled to undergo PAD who are iron deficient should have underlying causes investigated and treated so that patients are iron replete prior to collection and surgery." The also noted that, "[s]pecifically in the PAD setting, there is strong evidence to show that the use of erythropoietin can increase PAD yield and, in some cases, can also reduce the need for allogeneic transfusion in the perioperative and postoperative periods…The use of cell salvage and tranexamic acid in the perioperative phase, along with improved surgical techniques and the increased use of less invasive techniques, have contributed to the continued reduction in red cell use during surgical intervention."

Citation: McSporran, W., Anand, R., Bolton-Maggs, P., *et al.*; "The use of predeposit autologous donation: Guideline prepared by the BSH Blood Transfusion Task Force." *British Journal of Haematology*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

STATE ADVOCACY BRIEFS

A source plasma bill has been signed into law in Connecticut titled, "An Act Concerning Source Plasma Donation Centers." According to the legislation, "[t]his act eliminates prior law's requirement that the regulations require a registered nurse or advanced practice registered nurse to be on-site during these facilities' operating hours. It also requires the regulations to allow 'responsible physicians' [to be] directors of these facilities. (In doing so, it aligns with federal regulations)…Additionally, the act exempts someone who performs apheresis on a healthy donor to collect blood or its components from needing a nursing license. Under the act, a person may do this regardless of existing health care institution and nursing laws, so long as they follow federal and state regulations."

(Source: Public Act No. 24-7, 5/9/24)

House Resolution 262 has been introduced in Louisiana to, "request the Louisiana Department of Health to work with the Louisiana State Board of Medical Examiners to study and make recommendations to establish a more efficient process for licensing nondiagnostic technicians, which will benefit Louisiana residents who rely on plasma-derived therapies."

(Source: House Resolution 262, 5/21/24)

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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.

ADRP July Webinar Announced: Marketing Insights to Drive Change

Registration is open for the Wednesday July 24th ADRP Webinar: Marketing Insights to Drive Change. This event will highlight findings from the first-ever ADRP Marketing Survey, a tool designed to enhance marketing strategy at blood centers. During this webinar, attendees will receive key information from the ADRP Marketing Survey to help drive future decision-making, including aggregate data on:

- appointment acquisitions and donor retention;
- spend allocation through various marketing channels, and
- paid advertising, donor incentives, and social media activity.

The webinar's keynote speaker will be Riley T. Krotz, PhD, who will also share findings from his research in "Saving Lives in the Social Media Era: Increasing Blood Donations." Dr. Krotz is an award-winning marketing professor at Florida State University exploring blood donations, frontline employees, and public policy. His work has appeared in marketing and supply chain management's most prestigious academic journals and has received over $200,000 in grant funding from globally recognized organizations, including the American Marketing Association, the Academy of Marketing Science, the Association for Consumer Research, and the American Antitrust Institute. The will webinar will close by celebrating the 2024 ADRP Marketing Showcase winners.

MEMBER NEWS

Blood Bank of Alaska has opened a new location in Soldotna. According to *Homer News*, Blood Bank of Alaska Chief Executive Officer Robert Scanlon explained that, "restoring a permanent presence for the blood bank on the [Kenai] Peninsula is exciting because peninsula residents have historically been 'some of our strongest supporters.' He said mobile donation drives have seen great success on the peninsula, and that blood donated from the local communities has saved lives statewide…'Whenever we're down there, they always roll up their sleeve. We're making it easier for them to do it, and we owe that to them. They are just fantastic donors, and we're really honored to serve the community.'" A ribbon cutting ceremony at the new location will take place on June 22nd.

(Source: *Homer News*, "Blood Bank relaunches permanent center on Kenai Peninsula, 6/19/24)

Photo courtesy of Fort Bend Herald.

Gulf Coast Regional Blood Center recently announced the opening it Fulshear Donor Center. "Expanding our new blood donor center into northwestern Fort Bend County represents more than just growth for Gulf Coast Regional Blood Center," said Marc Lewis, vice president of Operations at Gulf Coast Regional Blood Center in a news release. "It signifies a commitment to saving lives and strengthening our bonds with our donors and patients of the Fulshear community. By welcoming new

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MEMBER NEWS (continued from page 6)

donors and engaging with the heart of Fulshear, we are creating a future where our mission can thrive."

(Source: Gulf Coast Regional Blood Center News Release, 6/12/24)

ImpactLife is celebrating its 50th anniversary throughout this year. Founded in 1974, "with the merger of the Scott County (Iowa) and Rock Island County (Illinois) blood banks [into] Mississippi Valley Regional Blood Center, which remained the blood center's name from 1974 to 2021, when leaders announced a new name for the organization: ImpactLife…Over the years, we've joined forces with other blood providers in our region, merging with Southeast Iowa Blood Center (2001), Central Illinois Community Blood Center (2010), and Community Blood Services of Illinois (2011). Our name reflects our history and the lifesaving mission we have always had while uniting our entire organization under a single, shared identity."

(Source: ImpactLife Announcement, 1/5/24)

GLOBAL NEWS

***Bloomberg News* and Airfinity have published a report that shows a surges in infectious diseases globally in the aftermath of the COVID-19 pandemic.** The report highlights, "data from over 60 organi[z]ations and public health agencies showing that the world is seeing a resurgence of at least 13 infectious diseases, with cases higher than before the pandemic in many regions. Over 40 countries or territories have reported at least one infectious disease resurgence that's 10-fold or more over their pre-pandemic baseline." It associates the rise in cases of infectious diseases to:

- decreasing vaccination rates;
- reduced population immunity during the COVID-19 pandemic; and
- climate change "enabling the spread of diseases."

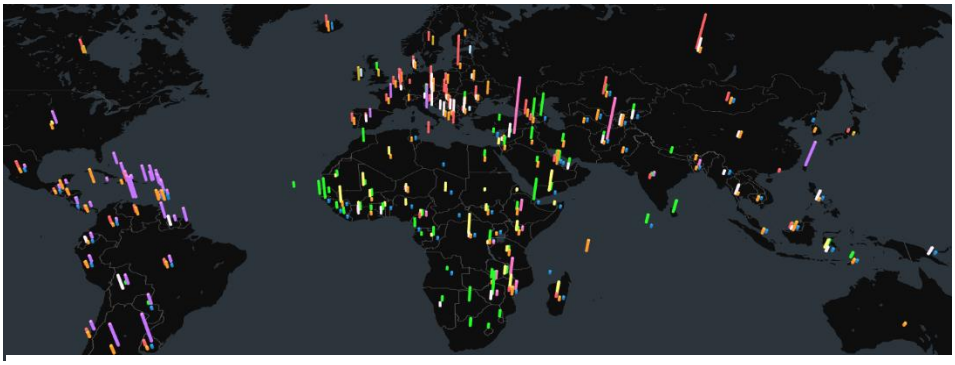

Photo courtesy of Airfinity: Spike map above showing fold changes in reported cases pre- and post-pandemic: all diseases.

Airfinity Biorisk Analyst Kristan Piroeva explained in an announcement unveiling the report, "[c]ases of dengue, which most people think of as a tropical disease, are growing in non-endemic countries. As temperatures continue to rise, we could see the disease becoming endemic in southern Europe. Airfinity's global overview of dengue incidence shows nearly half the world's population may now be at risk of dengue infection. An increase in surveillance and testing for disease also plays a significant role in today's analysis. By enhancing our monitoring capabilities, we can better track the spread of these diseases and implement timely interventions to mitigate their impact."

(Source: Airfinity, "Global surge in infectious diseases as over 40 countries report outbreaks 10-fold over pre-pandemic levels," 6/13/24)

COMPANY NEWS

Editas Medicine, Inc. has reported new safety and efficacy data from a phase I/II/III clinical trial of its investigational gene-editing therapy (Reni-cel) to treat individuals with severe sickle cell disease (SCD). According to a company news release, the one-time, investigational therapy, "was well-tolerated and continues to demonstrate a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all patients (N=18). Since treatment with reni-cel, patients have been free of vaso-occlusive events (VOEs) (N=18) for up to 22.8 months of follow-up. Patients had early normalization of total hemoglobin (Hb) with a mean within the normal range at >14 g/dL and rapid and sustained improvements in fetal hemoglobin (HbF) well above levels of >40 percent. Patients in the RUBY trial underwent a median of 2.0 apheresis and mobilization cycles (min: 1.0, max: 4.0)." Editas Medine also explained in the news release that, "[a]ll patients (N=18) are free of VOEs since reni-cel infusion with follow-up ranging from 2.4 to 22.8 months. Reni-cel treatment drives early, robust increases and sustained levels of total Hb and HbF. Across patients with ≥6 months follow-up, at month 6, the mean (standard deviation; SD) total Hb was 14.3 g/dL (2.1 g/dL) (n=9) with a mean (SD) HbF of 48.5 percent (3.7 percent) (n=10). The mean percentage of F-cells increased early and were sustained at >90 percent from month 4 through subsequent follow-ups for all patients with ≥4 months follow-up (n=12). Mean corpuscular fetal hemoglobin (MCH-F) of HbF-containing red cells (F-cells) was sustained above the anti-sickling threshold of 10 pg/F-cell by month three after reni-cel infusion for all patients with ≥3 months follow-up (n=14). Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all evaluated RUBY trial patients (N=18). After reni-cel infusion, all patients (N=18) demonstrated successful neutrophil and platelet engraftment. Neutrophil engraftment occurred at a median of 23 days (min: 15 days, max: 29 days), and platelet engraftment occurred at a median of 24 days (min: 18 days, max: 51 days). No serious adverse events (SAEs) related to reni-cel treatment in the RUBY trial have been reported."

(Source: Editas Medicines News Release, 6/14/24)

Vertex Pharmaceuticals Inc. has shared the latest data from a clinical trial of its therapy to treat severe SCD and transfusion-dependent beta thalassemia (TDT). In a June 14th news release, Vertex reported that, "[i]n SCD 36/39 (92.3 percent) evaluable patients (those with at least 16 months of follow-up) were free from vaso-occlusive crises (VOCs) for at least 12 consecutive months (VF12), consistent with the previously reported primary endpoint data. Mean duration of VOC-free was 27.9 months, with a maximum of 54.8 months. 38/39 (97.4 percent) patients with at least 16 months of follow-up were free from hospitalizations related to VOCs for at least 12 consecutive months (HF12), consistent with the previously reported key secondary endpoint data. In TDT 49/52 (94.2 percent) evaluable patients (those with at least 16 months of follow-up) were transfusion-independent for at least 12 consecutive months with a mean weighted hemoglobin of at least 9 g/dL (TI12), consistent with the previously reported primary endpoint data. Mean duration of transfusion independence was 31.0 months, with a maximum of 59.4 months. All TDT patients dosed with at least 16 months of follow up are transfusion free. Two of the three patients who did not achieve TI12 in CLIMB-111 achieved TI12 in the long-term follow-up study, CLIMB-131, and have been transfusion independent for over one year. The third has been transfusion free for 3.4 months. Both SCD and TDT patients reported sustained and clinically meaningful improvements in their quality of life, including physical, emotional, social/family and functional well-being, and overall health status. In both SCD and TDT patients, edited levels of *BCL11A* alleles were stable over time in bone marrow and peripheral blood indicating successful editing in the long-term hematopoietic stem cells. All patients engrafted neutrophils and platelets after exa-cel infusion. The safety profile of exa-cel was generally consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant." Casgevy™ is, "a non-viral *ex vivo* CRISPR/Cas9 gene-edited cell therapy for eligible patients with SCD or TDT, in which a patient's own hematopoietic stem and progenitor cells are edited at the erythroid specific enhancer region of the *BCL11A*

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COMPANY NEWS (continued from page 8)

gene through a precise double-strand break." The U.S. Food and Drug Administration approved Casgevy in December 2023.

(Source: Vertex Pharmaceuticals Inc. News Release, 6/14/24)

Bavarian Nordic has announced that it has completed submission of its biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) for its investigational chikungunya vaccine candidate. The news release specified that, "[t]he BLA submission includes results from two phase 3 clinical trials in more than 3,600 healthy individuals 12 years of age and older, demonstrating that the vaccine [candidate] was highly immunogenic, as demonstrated by the strong induction of chikungunya neutralizing antibodies against chikungunya 21 days after vaccination, with antibody titers equal to or above the threshold agreed with authorities as a marker of seroprotection. The [investigational vaccine candidate] was well-tolerated across both studies and vaccine-related adverse events were mainly mild or moderate in nature. [The company] also intends to submit a Marketing Authori[z]ation Application (MAA) with the European Medicines Agency (EMA) by the end of the first half 2024. The MAA has already been granted accelerated assessment, which means the [investigational vaccine candidate] could potentially obtain approval by the European Commission in the first half of 2025."

(Source: Bavarian Nordic News Release, 6/17/24)

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.)*

2024

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

June 27. **U.S. Food and Drug Administration (FDA) Webinar: Final Guidance: remanufacturing of Medical Devices.** More information available here.

July 24. **ADRP Webinar: Marketing Insights to Drive Change.** Registration is open. More information available here.

July 28-Aug. 1. **National Alliance of Sickle Cell Centers Annual Meeting and Consensus Conference.** More information available here.

Aug. 12-14. **National Institutes of Health (NIH) National Heart, Lung, and Blood Institute's (NHLBI) Annual Sickle Cell Disease Research Meeting. (Hybrid) Bethesda, Md.** More information available here.

Sept. 3-6. **American Society for Clinical Pathology (ASCP) Annual Metting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 18-19. **2024 ADRP Master Class: Bring in the Coach — The Path to Effective Leadership (Virtual).** Registration is open. More information available here.

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** More information is coming soon.

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CALENDAR (continued from page 9)

Oct. 16-17. **Biomedical Excellence for Safer Transfusion (BEST) Fall Meeting. Galveston, Texas.** More information available here.

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information available here.

Nov. 6-7. **ABC Women's Executive Leadership Community (WELC) Workshop. San Antonio, Texas.** More information is coming soon.

2025

Mar. 10-12. **ABC Annual Meeting. Arlington, Va.** More information is coming soon.

May 6-8. **2025 ADRP Annual Conference. Oklahoma City, O.K.** More information is coming soon.

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

Oct. 12-15. **AATB Annual Meeting. Atlanta, Ga.** More information is coming soon.

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

CLASSIFIED ADVERTISING

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

POSITIONS

Immunohematology Reference Laboratory Manager. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Immunohematology Reference Laboratory team in Atlanta, GA. This position is responsible for providing mentorship and leadership to laboratory staff. The IRL Manager is expected to provide onsite day-to-day supervision of testing personnel and reporting of test results under the direction of the Laboratory Director. This position is also responsible for performing laboratory procedures and reporting of test results, ensuring compliance with company policies and procedures, ensuring compliance with regulatory requirements from agencies such as CLIA, FDA, AABB, and HIPAA. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Birmingham, AL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Atlanta, GA. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure the blood is

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POSITIONS (continued from page 10)

there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Jacksonville, FL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Executive Director (Lawton, OK). Our Blood Institute is seeking a **"community spirited" professional to LEAD its Lawton/Wichita Falls team** in fulfilling the mission 1) to recruit blood donors, drive sponsors, and volunteers and 2) to store and deliver blood units for local hospitals. This public-facing, "visible" position not only requires an outgoing, bright, and energetic personality to foster relationships, but also demands detailed attention to planning, communication, regulations, finances, and personnel. Significant successes in project management and organizational expansion/entrepreneurship are desirable. Connectivity with regional leaders and access to key social networks would also be positives. The successful candidate will present and maintain a credible, positive image of Our Blood Institute in the local community. A bachelor's degree with at least three years of senior level operations and/or large project management experience is preferred. Community relations, marketing, sales, fundraising or blood banking experience is a plus. Candidates should have excellent written and verbal communications skills and proven abilities in managing multiple, complex projects and processes. Our Blood Institute provides a competitive salary and excellent benefits package including Health, Dental, Vision, Life, LTD, Flex Plan, 401(k), Paid Time Off, Tuition Reimbursement and holiday pay. **$500 bonus after 6 months and $1,000 bonus after 1 year!** How to apply: https://ourbloodinstitute.org/about/careers/

Director of Operations. Rock River Valley Blood Center, based in Rockford IL, is seeking a Director of Operations. Lead daily operations in recruitment, collections, and special services, ensuring organizational objectives are met, including collection and recruitment targets. Implement strategies for a balanced inventory aligned with organizational and hospital needs. Additionally, this position will oversee all aspects of Special Services, including cell therapy and therapeutic phlebotomy programs. This role requires strong leadership, operational expertise, and a commitment to quality and compliance. Qualifications include: Bachelor's degree in business administration or related field, seven plus years progressive management experience, proven track record of meeting production goals, and management experience in blood center operations or non-profit preferred. Please visit our careers site online to apply https://www.rrvbc.org/careers/.

Supervisor, Immunohematology Reference Lab (San Diego Blood Bank). The San Diego Blood Bank is currently seeking a motivated, knowledgeable professional to lead the Immunohematology Reference Lab. This person will oversee the daily operation of the department as well as support the greater Lab Management Team following safety, cGMP, and Quality Plan. Additionally, the ideal candidate will supervise the flow of samples, blood, and blood components through the department from satellite centers, mobile collection vehicles, hospitals, blood banks, and laboratories. **Qualifications** include a minimum of 2 years in blood bank related fields to include leadership experience and IRL experience. **Certification/Licensure** required include MLS(ASCP)CM/MT(ASCP) or equivalent experience and a California Clinical Laboratory Scientist License (CLS). Certification as a Specialist in Blood Bank (SBB) or equivalent is preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com)

Immunohematology Reference Laboratory CLS (San Diego Blood Bank). Under the direction of the department leadership, the Medical Laboratory Scientist I will assist the Immunohematology Reference Laboratory in daily operations according to cGMP compliant policies and Standard Operating Procedures implemented by the San Diego Blood Bank (SDBB). The ideal candidate will successfully complete/pass an initial training program resulting in the ability to provide guidance and expertise for the laboratory to meet the needs of SDBB customers, in accordance with accepted standards and regulations. **Requirements:** Bachelor's degree, MLS/MT (ASCP)CM or equivalent experience, Clinical Laboratory Scientist (CLS). Certification as a Specialist in Blood Banking (SBB) preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com)

Director, Donor Marketing. The Director, Donor Marketing is a pivotal leadership role within New York Blood Center Enterprises (NYBCe), overseeing a team of seasoned marketing professionals tasked with driving donor engagement and donor acquisition across various Blood

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Operations divisions. Working closely with divisional Donor Recruitment and Collections teams to ensure alignment with overarching marketing strategies. As the senior-most authority in donor marketing, the Director, Donor Marketing operationalizes Enterprise Donor Engagement strategies at the local level, guiding and empowering divisional marketing managers to execute targeted initiatives that meet product and service objectives across all divisions. Reporting directly to the Executive Director, Strategy and Planning, Donor Engagement, this role carries significant responsibility in steering local marketing efforts in line with enterprise goals. Candidates must be able to report into one of the following NYBCe locations: New York City, NY; Providence, RI and Newark, DE. Education: BA or master's degree in marketing, communications, or public relations. Experience: Minimum 10 years of demonstrated leadership experience in marketing and/or communications, including at least seven years of team management. Demonstrated experience managing budgets. Demonstrated experience evaluating media opportunities and buying. Licenses / Certifications: Valid driver's license. Click here to apply.

Director of Quality Assurance. Shepeard Community Blood Center in Augusta, Georgia, seeks an ambitious leader to promote product safety and compliance. A generous benefits package, including up to a 9 percent employer 401(k) contribution, relocation expenses, and ample PTO, are available for a successful candidate. Shepeard serves several communities in rapidly growing communities in Georgia and South Carolina. The ideal candidate will have at least six years of experience in blood banking, quality assurance, or compliance. Responsibilities include serving as the subject matter expert in regulatory compliance; working with operational leaders to help advance Shepeard's strategic plan; and overseeing the review and implementation of SOPs, validations, maintenance, reporting, and other related processes. The person selected for this role must see themselves as an integral member of the Shepeard leadership team and dedicated to furthering the organization's long-term goals. Those interested can apply at shepeardblood.org.

Operations Coordinator – Mobile Collections (Carter BloodCare). Principal Accountability: The Operations Coordinator-Mobile Collections position is crucial within the Collection Management team. Key responsibilities include ensuring daily production objectives and standards are met, maintaining high levels of compliance and customer service, and serving as the primary contact and acting manager in the manager's absence. Duties also involve hiring collection staff, conducting investigations, fostering employee development, and providing feedback on termination decisions. The role requires promoting team spirit within the department and collaborating with all CBC personnel to ensure maximum efficiency. Education: High School diploma or equivalent. College degree preferred. Bilingual skills are a plus. Special licensure such as CDL driver a plus. Experience: Two (2) years of supervisory/management experience. Background in a highly regulated field. Previous blood banking or apheresis experience required. Equal Opportunity Employer: Disability/Veteran. at www.carterbloodcare.org, click Careers & search for job **"Ops Coord Mobiles."**

Massachusetts General Hospital
Founding Member, Mass General Brigham

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital; Boston, Massachusetts). The Department of Pathology at the Massachusetts General Hospital (MGH), a founding hospital of Mass General Brigham, and a major teaching affiliate of the Harvard Medical School, seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology, or hemostasis. The Blood Transfusion Service at MGH encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. We collaborate closely with colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Our faculty also work closely with transfusion medicine faculty within the MGB network. Service and teaching responsibilities will be shared with two full- and several part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatric). Academic rank as Associate Professor, Assistant Professor or Instructor and salary will be commensurate with experience and accomplishments. Interested candidates should send a personal statement with research interest, three potential referees and Curriculum Vitae to: Dr. Robert Makar; Director, Blood Transfusion Service; Department of Pathology; Massachusetts General Hospital; 55 Fruit Street, GRJ 148; Boston, MA 02114. Email: rmakar@mgh.harvard.edu C/O Diane Savickas dsavickas@mgb.org. We are an equal opportunity employer, and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, gender identity, sexual orientation, pregnancy and pregnancy-related conditions or any other characteristic protected by law.

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

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Director, Division of Cellular Therapies (Hoxworth Blood Center, University of Cincinnati). Hoxworth Blood Center (HBC) is seeking a Stem Cell Transplant/Cellular Therapies Medical Director and Processing Facility Director. This is an open rank/track, faculty position, with opportunities for collaborative clinical and basic research, and an active clinical trials program in stem cell transplantation and immunotherapies, supporting four different stem cell transplantation programs in Ohio. Candidates with expertise in transfusion medicine, hematology, hematopoietic biology and therapy, immunology and/or immunotherapies could use this opportunity to build a translational/clinical research program. HBC has established connections with world-class research departments that offer access to a wide variety of shared facilities. Minimum Requirements: Applicants must have an MD or DO to be considered as the processing facility director and processing facility medical director, and licensed or eligible for unrestricted license in the State of Ohio. Applicants must have a PhD to be considered solely as the processing facility director. Position and track will depend on academic accomplishments and programmatic expectations. At least two years' relevant experience in the preparation and clinical use of cellular therapy products is required. For full description and to apply, visit https://bit.ly/3woC42L. The University of Cincinnati is an Equal Opportunity Employer.

Regulatory & Audit Compliance Specialist. Blood Bank of Delmarva is seeking a quality professional with experience in auditing and management of regulatory activities to join its Quality and Regulatory Affairs team. The department has responsibility for protecting the safety of the donors and patients we serve by ensuring that organizational policies, processes, and practices comply with quality system essentials and regulatory requirements of federal, state, local and industry-focused agencies. Key responsibilities include: managing the organization's internal audit program; serving as lead during external inspections; managing regulatory submissions, licenses, and registrations; serving as a liaison to regulatory agencies; and serving as a subject matter expert, advising divisional leadership of new or changed regulations and standards, and providing interpretation for successful implementation. Required education and experience: Bachelor's degree in life sciences, pharmaceutical, biotech or biologics manufacturing, quality management, or other related field. Minimum of 3 years' experience performing quality audits in a related, highly regulated environment, preferably in the blood, biologics, or pharmaceutical industries. Please click here to view the full job description and apply.

Director, Quality Assurance & Regulatory Affairs (Hoxworth Blood Center). The University of Cincinnati College of Medicine (COM) has a reputation for training best-in-class health care professionals and developing cutting-edge procedures and research that improves the health and clinical care of patients. Hoxworth Blood Center (HBC) is located within the College of Medicine and is the only Regional Blood Center owned and operated by a University in United States. The HBC is seeking a Director of Quality Assurance & Regulatory Affairs. This position will oversee and direct the coordination of quality assurance and regulatory compliance for the Cellular Therapy, Therapeutic Apheresis, and Transplantation Immunology divisions. Required Education & Experience: Bachelor's degree in medical technology, Biology, Chemistry, or related field. Seven (7) years of experience in a clinical laboratory, blood banking or other related experience. Additional Qualifications Considered: Previous experience in a FACT, AABB and HCT/P (21 CFR 1271) and GMP (21 CFR 211) for Phase I/II clinical manufacturing, Regenerative Medicines, Cleanrooms, and Aseptic Processing is ideal. Understanding of CAP requirements for histocompatibility (HLA) laboratories which includes disciplines of sequencing, molecular, serological, immunology, flow cytometry, and cellular analysis is preferred. For full description and to apply, visit https://bit.ly/489l7Gl. The University of Cincinnati is an Equal Opportunity Employer.