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# A B C N E W S L E T T E R

## URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #15

#### April 28, 2025

# UK "Engineering Biology Aspirations Report" Highlights Advancements & the Potential of Artificial Blood

The United Kingdom's (UK) Government Office for Science recently <u>published</u> an "Engineering Biology Aspirations Report" that highlights and explores, "engineering biology's (EngBio) transformative potential across sectors and its diverse applications, showcasing its societal impact."

The report features five papers demonstrating EngBio's ability to, "address realworld challenges effectively [with the stated goal] to inspire both government and the public by demonstrating the possibilities that can be realized through harnessing EngBio's opportunities."

One of the paper's is dedicated to labgrown blood and its potential to serve as a, "safe and unlimited source of blood for all."

The paper describes the ongoing challenges of recruiting enough donors to meet

the demand for blood. It highlights how, "NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the UK, and [its] partners are now conducting the RESTORE trial, a clinical assessment of minitransfusions of lab-grown red blood cells (RBCs) that should produce results by the end of 2025 or early 2026. Crucially, these cells come from volunteer donors, rather than the recipients themselves. Although groundbreaking, all these efforts have yet to achieve the scale and efficiency required for widespread clinical application." It explains that, "[1]ab-grown RBCs promise a safe, scalable, and sustainable solution that is free from infection, ensuring a resilient and equitable blood supply that meets the growing global demand. This has the potential to help save countless lives, particularly in emergency medicine and surgeries, while empowering healthcare systems, reducing [the] dependence on sourcing donors, and addressing inequalities in blood availability. Global beneficiaries include patients, healthcare providers, humanitarian organi[z]ations, and governments striving for healthcare resilience. Excitingly, a successful roll-out of lab-grown RBCs could lead to similar advances for other blood components, including engineered platelets or immune cells."

The paper emphasizes that now is the time to invest in artificial blood technologies describing a potential blueprint, "towards achieving the vision of widespread availability of lab-grown blood in the next 10 years:

#### INSIDE:

D.C. for Our First Annual Advocacy Summit2
BRIEFLY NOTED
WORD IN WASHINGTON
PEOPLE4
INFECTIOUS DISEASE UPDATES5
Nominations Are Open for HOSA Partnership
Recognition6
Deadline Approaching: Participate in the ABC Economic Outlook Survey
Still Time to Register for the 2025 ADRP Annual Conference
RESEARCH IN BRIEF7
GLOBAL NEWS7
COMPANY NEWS9
CALENDAR10
POSITIONS11



<u>UK "Engineering Biology Aspirations Report" Highlights Advancements & the Potential of Artificial Blood</u> (continued from page 1)

- "scaling production: develop scalable blood production processes and bioreactors capable of manufacturing lab-grown red blood cells in clinically relevant volumes;
- clinical validation: conduct phase I and phase II clinical trials to establish the safety and efficacy of lab-grown blood products from cell lines or other equivalent cellular sources; [and]
- regulatory frameworks: collaborate with regulatory bodies to create guidelines and standards for labgrown blood production, testing, and distribution."

The paper concludes by acknowledging the importance of, "engag[ing] with regulatory bodies, in order to ensure the correct processes are employed for use in humans and compliance with rigorous safety and efficacy standards. Engagement with the public will also be vital for offering reassurance on ethical concerns about lab-grown blood products and helping to foster public trust." It also describes an additional global benefit as, "the potential for this technology to drive a reduction in global healthcare disparities, particularly in rural or underserved regions across the globe. This will require careful consideration of processes to support technology transfer, but represents a transformative opportunity for national healthcare systems, contributing to UN Sustainable Development Goals (SDGs), such as health (SDG 3) and reduced inequalities (SDG 10)."

(Source: UK Government Office for Science Report, 4/25/25)

## Join ABC in Washington, D.C. for Our First Annual Advocacy Summit

America's Blood Centers (ABC) is excited to host our first annual <u>Advocacy Summit</u>. This event will take place at the Hamilton Hotel in downtown Washington D.C., from June 10-11<sup>th</sup> (<u>book your room</u> by May 15<sup>th</sup> to secure the discounted rate), as part of ABC's <u>Blood Advocacy Week</u>, and will provide a unique opportunity for both those new to advocacy and seasoned veterans to learn from experts and peers how to advocate at the federal level, build stronger connections with their congressional representatives, and meet with members of Congress and their staff to advance ABC's <u>Advocacy Agenda</u>. Register <u>here</u> to attend the Summit.

On <u>day one</u> of the Advocacy Summit, attendees will engage with a variety of speakers, learn ways to advance your center's advocacy efforts with government partners, and hear insights to developing relationships with elected officials to benefit your blood center and the entire blood community. Speakers will include ABC partners who are leading experts in healthcare policy and government affairs, former members of Congress, ABC members who have developed sustaining advocacy efforts year-round, and ABC staff members who are part of our government affairs team.

(continued on page 3)

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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.

#### America's Blood Centers

Chief Executive Officer: Kate Fry Chief Medical Officer: Jed Gorlin Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$420

Send subscription queries to <u>memberservices@americasblood.org</u> America's Blood Centers 1717 K St. NW, Suite 900, Washington, DC 20006 Phone: (202) 393-5725 Send news tips to <u>newsletter@americasblood.org</u>.

-2-



#### Join ABC in Washington, D.C. for Our First Annual Advocacy Summit (continued from page 2)

Panel discussions will cover best practices and strategies to advocate and articulate ABC member blood centers' priorities and allow participants to ask questions and discuss what has, and has not, worked at your center. Sessions will also include more fundamental elements, such as how not to get lost on Capitol Hill (it happens more often than you might think). Participants must attend the first day of the Summit if they wish to go to Capitol Hill the next day.

On day two of the Advocacy Summit, participants will head to Capitol Hill to meet with members of Congress and their staff. ABC will set up the meetings in advance for Summit attendees. During these meetings, attendees will have the opportunity to advocate for the policy priorities in ABC's <u>Advocacy Agenda</u>, discuss the importance of your blood center to your community, and thank members of Congress for their support of the U.S. blood supply. During the Hill meetings, attendees will also encourage Congressional offices to participate in a blood drive taking place on the Hill the following day, June 12<sup>th</sup>, as a part of ABC's <u>Blood Advocacy Week</u>. ABC and Inova Blood Donor Services will host the blood drive, which will provide an opportunity to remind past blood donors about the act of donating, as well as introduce new blood donors to the need for blood donations.

Additionally, we are asking you to <u>nominate</u> a member of the U.S. Congress who you believe is a strong champion for the U.S. blood supply. Members of Congress who are selected will receive the ABC Congressional Champion award during the Capitol Hill meetings. A Congressional Champion would be a Senator or House Representative who has demonstrated their support for the U.S. blood supply by, for example, supporting your blood center through an earmark request, helping reach out to an administrative agency, introducing legislation, or championing blood donation in your community or state.

After spending time on Capitol Hill, ABC will hold an evening reception back at the Hamilton Hotel for participants to share their experiences.

We hope you will take part in this unique opportunity to learn how to advocate at the federal level, build stronger connections with your congressional offices, and meet with members of Congress and their staff to advance ABC's <u>Advocacy Agenda</u> and your blood center's advocacy priorities.

If you have any questions, please do not hesitate to reach out to <u>Lorenzo Rodriguez</u>, manager of Government Affairs or <u>Leslie Maundy</u>, director, Membership Services.

## **BRIEFLY NOTED**

The Association for the Advancement of Blood & Biotherapies (AABB) has <u>announced</u> the <u>publica-</u> <u>tion</u> of the first edition of "Standards for Emergency Prehospital and Scheduled Out-of-Hospital **Transfusions.** The standards will, "maintain and enhance the quality and safety of services provided by prehospital transfusion services (EMS services) and out-of-hospital transfusion services (including infusion centers, nursing homes, long-term care facilities, hospice or home care settings), and provide the basis for accreditation by AABB."

(Source: AABB <u>Announcement</u>, 4/16/25)



-3-



# WORD IN WASHINGTON

**Centers for Medicare & Medicaid Services (CMS) Administrator Mehmet Oz, MD, MBA has <u>shared</u> <b>his vision and priorities for the agency.** Dr. Oz explained in an April 10<sup>th</sup> news release that, "CMS will work to modernize Medicare, the Marketplaces and Medicaid, so Americans get the care that they want, need, and deserve." This includes:

- "[e]mpowering the American People with personalized solutions they can better manage their health and navigate the complex health care system. As a first step, CMS will implement the President's Executive Order on Transparency to give Americans the information they need about costs;
- [e]quipping health care providers with better information about the patients they serve and holding them accountable for health outcomes, rather than unnecessary paperwork that distracts them from their mission. For example, CMS will work to streamline access to life saving treatments;
- [i]dentifying and eliminating fraud, waste, and abuse to stop unscrupulous people who are stealing from vulnerable patients and taxpayers; and
- [s]hifting the paradigm for health care from a system that focuses on sick care to one that fosters prevention, wellness, and chronic disease management. For example, CMS operates many programs that can be used to focused on improving holistic health outcomes."

(Source: CMS News Release, 4/10/25)

The U.S. Government Accountability Office (GAO) <u>published</u> an April 9<sup>th</sup> <u>report</u> making recommending that the U.S. Department of Health and Human Services (HHS), "should implement a mechanism to coordinate its activities" regarding drug shortages. The GAO report noted that, "[c]hallenges with the U.S. Food and Drug Administration's (FDA) oversight of medical products, including drug shortages, led to its inclusion on GAO's High-Risk List. As of July 2024, there were 102 drug shortages being tracked by FDA. Since the start of the COVID-19 pandemic in 2020, the number of new drug shortages reported each year has generally decreased, although drug shortages are lasting longer." The agency's recommendations to the HHS Secretary included:

- "identify and implement a mechanism to formally coordinate its drug shortage activities and collaborate with other federal stakeholders, and
- ensure this mechanism takes GAO leading practices for collaboration into consideration."

(Source: GAO <u>Announcement</u>, 4/9/25)

## PEOPLE



**Jesse McCool** has joined Our Blood Institute (OBI) as chief operating officer (COO), according to a report from *The Journal Record*. He is succeeding **Kim van Antwerpen**, "who is retiring after more than two

decades at the institute." Mr. McCool told *The Journal Record*, "I've got some big shoes to fill with Kim's 23 years at the blood bank, but it's an amazing team here, a really well-oiled machine and super mature organization, and I'm

looking forward to seeing what we can do for the next phase of growth through research and development (R&D)." Mr. McCool is the founder of Wheeler Bio and grew it to an \$80 million company. He hopes to, "advance R&D with a new clean room for CAR T-cell therapy and growth factor research [and] enhance donor col-



lections," according to the news outlet. Mr. McCool also explained in the article that he previously helped OBI, "capture a \$1.25 million federal funding allocation from the U.S. Government to help build a clean

PEOPLE (continued from page 4)

room that adheres to Good Manufacturing Practices, an industry standard. [The room] will boost [OBI's] ability to support the full ecosystem that's developing in Oklahoma, like at the Oklahoma University Health Stephenson Cancer Center, the home of a phase I trial center for conducting clinical development. [Mr. McCool told the publication that] Stephenson has the patients, and the institute has the blood bank, which provides services to the center already. All that's missing is the clean room to support CAR T-cell therapy at Stephenson across the street from the [OBI]."

(Source: *The Journal Record*, "<u>Wheeler Bio founder looks to boost R&D in new role with Our Blood In</u><u>stitute</u>," 4/25/25) ♦

# **INFECTIOUS DISEASE UPDATES**

### EBOLA

The World Health Organization (WHO) published April 26<sup>th</sup> communication providing an update of the Sudan virus disease (SVD) outbreak in Uganda. SVD is an Ebola disease. The agency reported that the Ministry of Health (MoH) of Uganda has declared the outbreak over following, "two consecutive incubation periods (a total of 42 days) since the last person confirmed with SVD tested negative for the virus on March 14<sup>th</sup>." This comes after the identification of, "12 confirmed and two probable cases with four deaths (two confirmed, two probable) during the outbreak." The WHO noted that, "[a]lthough the outbreak has been declared over, health authorities are maintaining surveillance to rapidly identify and respond to any re-emergence. Risk communication and community engagement will also continue to ensure the community stay informed and stigma to those who were affected is minimized." In February, the U.S. Centers for Disease Control and Prevention (CDC) published a Health Alert Network (HAN) Health Advisory regarding the outbreak of Ebola disease in Uganda reporting that, "[c]urrently no suspected, probable, or confirmed Ebola cases related to this outbreak have been reported in the U.S. [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 CDC did 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 (DHO), including your full-length and abbreviated DHO, 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: WHO <u>Communication</u>, 4/26/25)

#### Measles

The CDC has <u>published</u> an update regarding measles outbreaks. As of the April 24<sup>th</sup>, there have been 11 measles outbreaks (defined as three or more related cases) in the U.S. this year resulting in 884 confirmed cases, 94 hospitalizations (11 percent) and three confirmed deaths, the first in the U.S. since 2015. According to the agency the cases have been reported by 30 jurisdictions: Alaska, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, New Jersey, New Mexico, New York City, New York State, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington with 93 percent of cases (820 of 884) being outbreak-associated. In 2024, the U.S. reported 285 total cases. Transfusion-transmission of measles has never been demonstrated, and any risk to the blood supply is believed to be theoretical.



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

# Nominations Are Open for HOSA Partnership Recognition

ABC encourages member blood centers to submit nominations recognizing the HOSA-Future Health Professionals chapters that they are partnering with. The submission deadline is May 15th as the nominationbased categories highlight outstanding contributions from HOSA chapters and state associations in strengthening the nation's blood supply during times of critical need and/or through support of blood donation or a blood drive. The winning HOSA chapters will be honored at the HOSA International Leadership Conference in June. More information is available here. Also, please remind your HOSA student partners to upload their blood donation data for the 2024-25 school year by May 15<sup>th</sup>. The goal is to surpass last year's 33,000 donor record, and your support is crucial in achieving this. For more information on data submission and our HOSA partnership, please visit www.AmericasBlood.org/HOSA.

# Deadline Approaching: Participate in the ABC Economic Outlook Survey

The ABC Economic Outlook Survey deadline has been extended to May 2<sup>nd</sup>. This resource provides a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures. The aggregate data from this survey is important to both members and ABC as we advocate for fair and accurate reimbursement policies. Survey results are anonymized and aggregated, and all reporting complies with antitrust requirements. The ability to download final trend reports and create customized reports based on selected filters will be available to participants via ABC's benchmarking portal. Please contact us with questions.

## Still Time to 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. 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.



-6-

April 28, 2025



# **RESEARCH IN BRIEF**

**ABC** Newsletter

Association of High Mobility Group Box 1 (HMGB1) Levels in Apheresis Platelets. A study in Vox Sanguinis "hypothesized that [a] donor's age, sex or ABO blood group influences high mobility group box 1 (HMGB1) [protein] levels in single-donor apheresis platelet concentrates (SDA-PCs)." The authors of the paper found that, "HMGB1 levels were measured in 190 unpaired SDA-PC units obtained from 65 female donors and 125 male donors. The donors ranged in age from 21 to 65 years and were categorized into three age groups: young (21-35 years, n=44), intermediate (36-50 years, n=61) and elderly (51-65 years, n=85). Regarding ABO blood group distribution, 91 donors had blood group A, 15 had blood group B and 84 had blood group O." The researchers explained that, "SDA-PCs were stored for a maximum of five days, with storage durations grouped into short (0-1 day, n=65), intermediate (2-3 days, n=83) and long (4–5 days, n=42). No significant differences in HMGB1 levels were observed among the three age groups (21–35 years:  $2.57 \pm 3.42$  ng/mL; 36–50 years:  $2.28 \pm 2.54$  ng/mL; 51–65 years:  $3.30 \pm 4.28$  ng/mL). Furthermore, no significant correlation was identified between donor age and HMGB1 levels when analyzed as a continuous variable (p=0.63, r=0.04). PCs with high HMGB1 (>5 ng/mL) did not display abnormalities when compared to the entire population, while HMGB1 levels did not associate with the occurrence of severe adverse reactions. [N]o significant changes in HMGB1 concentrations in SDA-PCs across different storage durations were found. Plotting HMGB1 levels against storage time within each age group revealed no significant associations. [HMGB1 levels] were significantly higher in male donors compared to female donors (female:  $2.00 \pm 2.77$  ng/mL; male:  $3.23 \pm 3.93$  ng/mL). However, donor age did not appear to drive these differences, as no significant age-related differences in HMGB1 levels were detected within each sex." The authors also noted that, "[b]lood group was not associated with HMGB1 levels (A:  $2.80 \pm 3.69$  ng/mL; B:  $2.90 \pm 3.48$  ng/mL; O:  $2.57 \pm 3.42$  ng/mL)." They concluded that, "[t]hese findings reveal donor-specific variability in HMGB1 levels, particularly regarding donor sex, and underscore the need to systematically document donor demographic and biological characteristics during blood donation."

**Citation**: Heestermans, M., Arthaud, C-A., Prier, A., Eyraud, M-A., Hamzeh-Cognasse, H., Cognasse, F., *et al.* "Association of high mobility group box 1 (HMGB1) levels with donor's age, sex and ABO blood group in single-donor apheresis platelet concentrates." *Vox Sanguinis*. 2025

Contributed by Richard Gammon, MD

## **GLOBAL NEWS**

**The Taiwan Blood Services Foundation, the country's national blood provider, has <u>reported</u> declines in donation rate and young donors, according to** *Taiwan News***. The latest figures showed that, "the percentage of the population donating blood rose from 7.54 percent in 2015 to 8.13 percent in 2023, but dropped to 7.84 percent last year." It also noted that hospitals in Taiwan received, "2.43 million units of red blood cells last year, marking a 2.3 percent decrease from 2023. The [p]latelet supply fell by 1 percent, while plasma supply declined by 5.5 percent. [Additionally, eligible donors] gave blood an average of 1.82 times last year. Donors aged 21 to 30 averaged 1.49 donations, those aged 31 to 40 averaged 1.69, and donors aged 41 to 50 gave 1.89 times. The average rose to 2.06 for those aged 51 to 65, while donors over 65 had the highest average at 2.94 donations per person." The Taiwan Blood Services Foundation also reported that, "the blood donation rate among individuals aged 17 to 20 fell from 15.61 percent in 2013 to 11.19 percent in 2023, with the number of donors in that age group falling from 201,000 to 99,000," according to** *Taiwan News***.** 

(Source: Taiwan News, "Taiwan saw over 1.83 million blood donations last year,"4/21/25)



# GLOBAL NEWS (continued from page 7)

ABC Newsletter

The Canadian regulatory authority (Health Canada) is facing a legal challenge over the "constitutionality" of its organ and tissue donor eligibility policy. The report from CTV News explained that, "[t]he case was filed with the Ontario Superior Court on March 27<sup>th</sup>, and the legal team advancing the litigation is hoping to have a hearing on this constitutional challenge later this year." The current policy prevents, sexually active gay and bisexual men from organ and tissues donation, "irrespective of an individual donors' risk factors, or infectious disease testing results. It's a policy that stems from concerns over HIV transmission that date back to the 1980s and 1990s. Under the federal policy, sexually active gay and bisexual men are deemed 'unsuitable' donors, except for in 'exceptional' circumstances, where recipients can consent to accepting a 'higher risk' transplant if no other organ 'determined safe for transplantation' is available. These restrictions are based on the sex assigned at birth, so they also apply to transgender people." Michael Fazal is the 31-year-old Toronto resident who is challenging the policy and, "pushing for an end to what he calls a 'deeply hurtful, stigmatizing, and discriminatory' policy." His lawyers are arguing that, "the regulations violate their client's right to equality under the Charter of Rights and Freedoms [noting] that heterosexual donors don't face comparable limitations. All donors are tested, and donations are quarantined until deemed safe. And, while there are a few instances where living donations can occur - such as in donating a kidney, or part of a liver or lung — most organ donations occur after the donor has died, which [they say] adds another layer to this case. [Adding that it is exceedingly] difficult to bring a Charter challenge on behalf of someone who has passed away, because [you] don't actually know [and] can't ascertain their desires or wishes." Health Canada issued a statement to CTV News in response explaining that a review of the policy is taking place and that it has, "engaged' the Canadian Standards Association (CSA) in 2023 to 'review their donor screening criteria in response to concerns raised.' Health Canada said that it's the CSA that 'independently administers and maintains the standards,' and a committee focused on cell, tissue and organ donation is 'currently conducting a public review' until May 10<sup>th</sup>. That reassessment is focused on a proposal to shift from the current time-based screening criteria for [sexually active gay and bisexual men], to a 'gender-neutral, behave[o]r-based criteria.' If the proposed changes are adopted, the new standard would automatically become the regulatory requirement."

(Source: *CTV News*, "<u>Man taking Health Canada to court over 'stigmatizing</u>, and discriminatory' organ donation policy," 4/10/25)

The African nation of Eritrea recently announced that it is developing a national hemovigilance system during a launch event. Through the collaboration between the National Blood Transfusion Service (NBTS) and the National Medicines and Food Administration (NMFA), the country aims to be able to monitor the safety of the country's blood and blood products. According to the *AllAfrica*, the launch event's purpose was to, "foster a shared understanding among all involved parties regarding the critical role and purpose of a national haemovigilance system, [while] promoting the practical implementation of the system, laying out a clear roadmap for its rollout nationwide. A significant emphasis was placed on creating a culture of reporting, actively working to eliminate any hesitations, and encouraging transparency in documenting adverse transfusion events. Finally, the launch sought to foster seamless collaboration and communication between healthcare providers, hospital blood banks, and the national regulatory bodies."

(Source: AllAfrica, "Eritrea: Safer Blood for All - Eritrea Launches a National Haemovigilance System," 4/16/25) ♦



# **COMPANY NEWS**

Cellphire Therapeutics, Inc. has announced that a phase II/III multicenter, randomized, controlled trial of its investigational cryopreserved platelet product (CPP) is ending early after meeting its primary efficacy endpoint following a pre-planned interim analysis by an independent data monitoring committee (IDMC). According to a company news release, the "Cryopreserved Platelet Trial for Control of Bleeding in Surgery (CRYPTICS) clinical study (NCT04709705)" aimed to, "evaluat[e] the safety and efficacy of Cellphire's investigational CPP (CLPH-511) for the treatment of uncontrolled hemorrhage in patients undergoing cardiopulmonary bypass surgery. [The CRYPTICS study] met the primary efficacy endpoint of 24-hour chest tube drainage to demonstrate statistical non-inferiority of the cryopreserved CLPH-511 platelet product to the standard room temperature control platelet product (LSP) with a one-sided significance level less than p-value 0.00965." Cellphire also explained in the news release that it continues to progress, "toward its goal of providing a platelet alternative product with a significantly extended shelf life that may expand access to critical care for patients worldwide, earlier than anticipated." Congressman John "Judge" Carter (R-Texas) added in the news release, "[t]he early completion of this study is an important milestone in getting life-saving platelet treatments to treat traumatic injuries. I'm proud to see Cellphire making real progress on a product that can help our wounded warfighters and civilians alike — while also tackling nationwide platelet shortages and reducing waste in the system."

(Source: Cellphire Therapeutics, Inc. News Release, 4/22/25)

**Safi Biotherapeutics** has been <u>awarded</u> a Small Business Technology Transfer (STTR) grant from the National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI) to, "bulk manufacture Children's Hospital of Philadelphia's (CHOP) induced pluripotent stem cell- (iPSC) derived red blood cells (RBCs) with rare antigen profiles as diagnostic tools for alloimmunized patients." Specifically, the collaboration with CHOP will provide support for, "proof-of-principle studies for scaling the production of RBCs with rare, cell surface antigen profiles to use as novel blood banking reagents that allow identification of currently undetectable RBC antibodies in donor blood. A favorable outcome in these studies could lead to improved donor selection and safer transfusions, especially for those patients with sickle cell disease," according to a company news release. Stella T. Chou, MD, chief of the Division of Transfusion Medicine and attending physician in the Division of Hematology at CHOP will lead the research efforts. The news release also noted that, "[t]he Chou laboratory, focused on regenerative blood cellular therapy, has developed modified human iPSCs as a renewable source of RBCs with rare or uncommon cell surface antigen profiles to help ensure compatibility of donor blood used to transfuse alloimmunized patients, [individuals who form] antibodies to antigens on donor RBCs that the recipient lacks, [which] is particularly problematic for patients with sickle cell disease."

(Source: Safi Biotherapeutics <u>News Release</u>, 4/24/25)

**Valneva SE** recently <u>announced</u> that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), "updated its recommendation for use of Valneva's single-dose chikungunya vaccine Ixchiq® for the prevention of disease caused by the chikungunya virus (CHIKV)." According to the company, the CDC advisory committee, "maintained its current recommendation for IXCHIQ® for persons aged  $\geq 18$  years traveling to a country or territory where there is a chikungunya outbreak. Additionally, it may be considered for persons aged  $\geq 18$  years traveling or taking up residence in a country or territory without an outbreak but with elevated risk for U.S. travelers if planning travel for an extended period of time e.g., six months or more. The ACIP also voted to recommend a precaution related to the use of [the vaccine] in persons aged  $\geq 65$  years. This precaution is a response to an ongoing investigation by the CDC of six cases of serious adverse events (SAEs), including five hospitalizations, among persons aged 67-86 years after vaccination with Ixchiq®. These SAEs were reported through the Vaccine Adverse Event Reporting System (VAERS), which is intended to be an early warning



<u>COMPANY NEWS</u> (continued from page 9)

system to identify potential safety issues but generally cannot determine if adverse events are caused by a vaccine. All of the individuals who were hospitalized had pre-existing comorbidities, and ACIP concluded that while plausible, no causal association with [the vaccine] could be determined for all cases and that further investigation is warranted. ACIP also noted that for individuals aged  $\geq 65$  years, vaccination with Ixchiq® might be indicated in certain higher-risk settings (e.g., outbreak), given the known risks for severe chikungunya disease and hospitalization in this age group. [The ACIP recommendation] is pending final approval by the Director of the CDC and the U.S. Department of Health and Human Services."

(Source: Valneva SE <u>News Release</u>, 4/18/25) •

# CALENDAR

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

#### 2025

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

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

May 20-21. International Plasma Protein Congress. Warsaw, Poland. Registration is open.

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

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 is coming soon.

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

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

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

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

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

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

## **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: <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>

#### POSITIONS

Vice President of Technical Operations (Oklahoma City, OK). Our Blood Institute is looking for a VICE PRESIDENT OF TECHNICAL OPERATIONS who will provide strategic planning, operational management, budgeting, and leadership to the OBI and provide technical and leadership support to the Testing Lab, Quality Control Lab, Manufacturing Operations, Logistics/Inventory Management, and Technical Operations Systems departments. Overseeing the day-to-day operations, implementing business plans, managing the department's P&L, and fostering high performance, customer-oriented culture. Successful applicants must have a Bachelor of Science degree in Medical Technology and a Master's degree is strongly preferred. Position requires ASCP certification as a Medical Technologist and Specialist in Blood Banking is preferred. Position requires a minimum of ten years progressive management in a related medical industry. 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/

Director, Quality Assurance/Regulatory Affairs. 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 a full-time Director, to oversee and direct the coordination of quality assurance and regulatory compliance for the collection, manufacture, storage and distribution of licensed and unlicensed blood and blood components, and for the testing of donor and patient samples. Essential Functions: Direct the coordination of regulatory compliance with the Food & Drug Administration (FDA), e.g., review of changes to regulations & guidance documents, submission of biological product deviation reports & response to observations/findings from FDA inspections. Support the Division Director in the preparation of license applications, annual report of minor changes & correspondence with the FDA. Manage the quality programs for maintaining applicable licensure and accreditation, e.g. internal and external audits, supplier qualifications, change control, deviation management, document control and record retention. Minimum Requirements: Bachelor's Degree and seven (7) years' experience. Click HERE for the full job description and apply. EOE

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

