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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #10 **March 22, 2024**

INSIDE:

NHLBI Report on Motivations and Barriers of African American Blood Donors

The National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI) has published a report that aims to provide insights into the motivations and barriers to blood donation for black donors. The resource titled "Blood Donation: Motivators and Barriers — Insights from Black or African American Donors and Non-Donors Report explains that, "NHLBI's Blood Diseases & Disorders Education Program conducted qualitative research on these topics. Initial conversations with blood donation subject matter experts (SMEs) identified Black or African American adults as an important audience for the focus of the research because of lower blood donation rates from this community. The SMEs suggested exploring the systemic and historical racism that has eroded trust in the medical system, including the racial segregation of blood donors and blood recipients. Additionally, common entry points for blood donations, such as college and workplace blood drives, have resulted in greater representation from white individuals and less representation from communities of color."

The report's findings are based on research from 12 focus groups, "conducted with Black or African American adults ages 18 to 50 for a total of 67 participants. Participants were segmented based on age and blood donation experience. Those with previous blood donation experience are referred to as Donor Experimenters, and those without blood donation experience are referred to as Susceptible Non-Donors. All participants expressed an interest in donating blood in the future."

Key insights included:

- "nearly all participants had been exposed to health information on social media, but most were not likely to trust that information. However, younger participants were more likely to seek health information, including information about blood donation, on social media;
- [m]ost previous blood donors did not donate again because the process took place at an inconvenient time or location, but participants stated they would be motivated to donate if donating blood was made more convenient for them, for example, located in their neighborhoods at less traditional locations, such as malls, community centers, barbershops, and salons;
- [t]he younger audience was more likely to outwardly recognize systemic barriers within the Black or African American community, such as mistrust of the medical system. The younger age group with blood donation experience was more likely to recognize word-of-mouth medical conspiracy theories shared by older generations;

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NHLBI Report on Motivations and Barriers of African American Blood Donors (continued from page 1)

- [m]ost participants did not regularly think about blood donation but expressed motivation when encountering a personal reason for donating, such as to help a friend, family, or a community member in need; [and]
- [p]articipants wanted messaging and materials to address barriers."

(Source: NHLBI Report, 3/15/24)

Update from House Hearing on LDTs

In response to the September 2023 U.S. Food and Drug Administration's (FDA) Laboratory Developed Tests (LDTs) proposed rule, Congress is again engaging on the issue. On March 21st, the House Committee on Energy and Commerce's Health Subcommittee held a hearing on, "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule." The witnesses and members of the committee focused on the need to ensure any regulation of LDTs should protect patients not only by ensuring tests are safe but by ensuring regulation is not overly burdensome such that it stifles innovation. Over the years, multiple bills have been introduced to address the regulation of LDTs including most recently the Verifying Accurate, Leading-edge, IVCT Development (VALID) Act. The VALID Act requires premarket review, with multiple exemptions, registration and listing, test design and quality requirements, labeling requirements, adverse event reporting, corrections, and removals. Grandfathered tests in use and meeting certain requirements are exempt from premarket review, labeling, test design, and quality requirements.

As reported last week, Sen. Bill Cassidy, MD (R-La.), ranking member of the Senate Health, Education, Labor, & Pensions (HELP) Committee, issued a request for information (RFI) on March 13th seeking ways to improve the regulation of clinical tests. Responses to this request are due April 3rd. America's Blood Centers (ABC) is developing comments and welcomes input from member blood centers. Please contact ABC Senior Director of Government Affairs Diane Calmus, JD if you have any questions or comments you would like included.

The "Medical Devices; Laboratory Developed Tests" final rule is currently being reviewed by the White House Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). The draft regulation explicitly stated that *in vitro* diagnostic products (IVDs) are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. In addition to this change, the agency proposed a policy under which the FDA intends to provide greater oversight of laboratory developed tests (LDTs), through a phaseout of its general enforcement discretion approach to LDTs, so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. America's Blood Centers responded to the proposed rule in comments submitted to the FDA in December 2023 that outlined four areas of concern. The rapid movement of the review process for the final rule is surprising considering the proposed rule received over 7,000 comments. FDA is required under the Administrative Procedures Act (APA) to respond to all substantive comments. If the proposed rule is finalized, litigation is anticipated that could impact implementation.

Agency IQ reported this week that ORIA, "appears to be holding regular meetings with stakeholders regarding FDA's pending final rule on LDTs. At least seven meetings have been scheduled to date, including with the American Clinical Laboratory Association, the Association for Diagnostics and Laboratory Medicine, the Association for Molecular Pathology, ARUP Laboratories, the American College of Medical Genetics and Genomics, the Center for Science in the Public Interest, and the Children's Hospital Association.

(Sources: House Committee on Energy and Commerce's Health subcommittee Hearing, 3/21/24; Agency IQ, *FDA Today*, 3/21/24; OIRA Announcement, 3/1/24; Sen. Bill Cassidy RFI, 3/13/24)

Contributed by Diane Calmus, JD, Senior Director of Government Affairs at ABC

Blood Center Input Requested: NBCUS Responses Due April 26th

The Centers for Disease Control and Prevention's (CDC) Office of Blood, Organ, and Other Tissue Safety is reminding blood centers to complete the 2023 National Blood Collection and Utilization Survey (NBCUS). Responses are due by Friday, April 26th. According to the agency, "[s]ince 1997, the NBCUS has been the primary method of gathering information on blood collection and use in the U.S. The survey results will give federal agencies and other organizations a better understanding of blood supply and demand, providing an accurate basis for identifying and planning regulations and strategies. To estimate blood collection and utilization, CDC has requested [participation from] all U.S. blood collection centers and acute care hospitals performing at least 100 inpatient surgical procedures per year. The NBCUS includes questions on:

- general facility information;
- blood collections, processing, and testing;
- blood and blood component transfusions;
- modification of components; [and]
- [p]rices paid by hospitals for blood components.

Results from the 2023 NBCUS will help the federal government continue to monitor trends in blood availability, which is critical to ensure an adequate supply of safe blood in the United States." Data is confidential and only reported in aggregate as part of the NBCUS Report. America's Blood Centers and ADRP, the Association for Blood Donor Professionals, rely on the NBCUS Survey Report to assist in the development of the "U.S. Blood Donation Statistics and Public Messaging Guide."

CDC is asking individuals to help spread the word:

- "[i]f you work in a blood center or large hospital, encourage your organization to submit their NBCUS input by the April 26th deadline;
- [i]f you have been asked to participate in the NBCUS, be sure to complete your survey response no later than the April 26th deadline;
- [h]elp build awareness of the importance of participating in the NBCUS within your organization;
- [s]hare CDC social media content on your platforms discussing the NBCUS; [and]
- [s]hare the results of the NBCUS with your colleagues upon its release later this year."

(Source: CDC Email Announcement, 3/21/24)

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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) recently published a draft guidance titled, "Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards." According to the agency, the draft guidance contains, "recommendations on provisions of the U.S. Department of Health and Human Services (HHS) regulations on the protection of human subjects as well as certain proposed revisions to FDA's current regulations for the protection of human subjects. Specifically, this guidance addresses the presentation of key information and includes recommendations for the content, organization, and presentation of informed consent information in FDA-regulated clinical investigations of drugs, devices, and biologics…and in HHS-supported or -conducted nonexempt human subjects research." FDA also explained in a blog post authored by Patrizia Cavazzoni, MD, director of the FDA's Center for Drug Research and Evaluation, and Hilary Marston, MD, MPH, chief medical officer of FDA, titled "FDA Works to Make Informed Consent Easier to Understand," that the draft guidance includes, "recommendations on how to implement two proposed requirements in the FDA proposed rule, "Protection of Human Subjects and Institutional Review Boards" and the corresponding current requirements under the revised Common Rule, including that:

- "[i]nformed consent begins with key information about the research presented in a clear and concise manner.
- [i]nformed consent as a whole be presented in a way that facilitates understanding of the reasons why someone might or might not want to participate in the research."

The FDA also intends for the proposed regulation to, "encourag[e] investigators to use key information as a guide to support the consent discussion between the investigator and potential participants. It allows for flexibility in implementing the key information requirement to ensure that the informed consent process makes information accessible for patients. The draft guidance also encourages sponsors, investigators, and institutional review boards (IRBs) to consider a variety of delivery methods for key information, such as written, oral, or media (illustrations or video) and electronic consent."

(Source: FDA Draft Guidance, 3/1/24; *FDA Voices*, "FDA Works to Make Informed Consent Easier to Understand," 3/1/24)

Contributed by Justine Coffey, JD, LLM, Director of Regulatory Affairs and Public Policy at ABC

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Adverse Reaction Time of Departure (ALL MEMBER FORUM)
- Abnormal Kleihauer Betke Staining (ALL MEMBER FORUM)
- Electronic Young Donor Parental Consent (MEMBER RESOURCES)
- Freeze Dried Plasma (MEDICAL ISSUES)
- Type A Liquid Plasma (MEDICAL ISSUES)
- Testosterone and Aromatase Inhibitors (MEDICAL ISSUES)
- Tracking Blood Center Equipment (QUALITY BYTES)
- New Hire Supports (EMPLOYEE TRAINING and DEVELOPMENT)

ABC members are encouraged to login and join the conversations today!

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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.

Meet Us in St. Louis for the ABC 2024 Quality and Technical Workshop!

Registration remains open and time is running out to book your room in the Live! by Loews Hotel for the 2024 America's Blood Centers (ABC) Quality and Technical Workshop. Check out our program as this year's workshop is centered around highlighting collaboration amongst blood banking professionals to allow for an exchange of innovative ideas and best practices. Sessions have been developed to emphasize the important topics that are affecting you and your blood center. The workshop will feature experts in their field presenting topics that include implementation of new devices and blood products, regulatory and licensure round tables, and peer to peer strategic discussions to name a few. Don't miss out on the opportunity to network with your peers and gain greater insights into the challenges that the blood industry is facing now.

ABC SMT Spring Journal Club Webinar Articles Announced

The next ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar will take place on March 29th from 12-1 p.m. EST. The webinar is free to all ABC members. The articles to be discussed during the webinar include:

- Reevaluation of the medical necessity of washed red blood cell transfusion in chronically transfused adults (*Transfusion*);
- Restrictive or liberal transfusion strategy in myocardial infarction and anemia (*NEJM*); and
- Patient and caregiver perceptions of the possibility of home transfusions (*Transfusion*).

A registration link is available to ABC members in MCN 24-016. A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars.

Webinar Recording Available: Developing Leaders for Tomorrow & Employee Conflict Resolution!

A recording of the February 20th "Developing Leaders for Tomorrow & Employee Conflict Resolution!" webinar is available to ABC members. Featured speakers included Maria Brcka of LifeServe Blood Center and Stephanie Rue of SunCoast Blood Centers. The webinar aimed to be a useful resource for developing staff and strengthening professional interpersonal skills. Please contact ABC Director of Scientific and Technical Operations Betzy Gonzalez, MS, BB(ASCP) with questions.

(Source: MCN 24-014, 2/26/24)

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INSIDE ABC (continued from page 5)

Schedule Available 2024 ADRP Annual Conference

The schedule is now available for the 2024 ADRP Annual Conference. Register today! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

WORD IN WASHINGTON

The U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) recently voted in favor of recommending approval for two supplemental biologics license applications (sBLAs) for earlier use of chimeric antigen receptor (CAR) T cell immunotherapies, Carvykti (cil-tacabtagene autoleucel) and Abecma (idecabtagene vicleucel), to treat multiple myeloma, according to a report from *MedPage Today*. "The favorable recommendations followed considerable discussion about an early mortality risk -- and the potential cause -- seen in pivotal trials of both therapies. In the end, the ODAC panel found that the benefits of earlier use of the therapies outweighed the risk." The ODAC recommendation also comes in the wake of a November 2023 agency communication notifying the public that the agency was investigating reports of, "T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies." FDA explained that, "[a]lthough the overall benefits of these products continue to outweigh their potential risks for their approved uses, FDA is investigating the identified risk of T cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action. As with all gene therapy products with integrating vectors (lentiviral or retroviral vectors), the potential risk of developing secondary malignancies is labeled as a class warning in the U.S. prescribing information for approved BCMA-directed and CD19-directed genetically modified autologous T cell immunotherapies…Patients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies." The agency announced in January 2024 that it had issued, "safety labeling change notification letters to all manufacturers of licensed BCMA-directed and CD19-directed genetically modified autologous CAR T cell immunotherapies requiring a revision to the package insert due to risk of T cell malignancies, with serious outcomes, including hospitalization and death." The January 23rd announcement explained that the agency, "considers the serious risk of T cell malignancy to be applicable to all BCMA- and CD19-directed genetically modified autologous T cell immuno-therapies. The letters notify manufacturers of each such licensed product to update the package insert to include available information related to the risks and to update the Medication Guide for these products to identify the possibility of the increased risk of getting cancers, including certain types of cancers of the immune system…The letters notify manufacturers of each such licensed product to update the package insert to include available information related to the risks and to update the Medication Guide for these products to identify the possibility of the increased risk of getting cancers, including certain types of cancers of the immune system."

(Sources: *MedPage Today*, "FDA panel gives thumbs up to earlier use of CAR T-cell therapy in multiple myeloma, 3/16/24; FDA Announcement, 1/23/24; FDA Safety Communication, 11/28/23)

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WORD IN WASHINGTON (continued from page 6)

The Centers for Medicare & Medicaid Services (CMS) recently released a "Request for Applications (RFA) from Applicable Manufacturers." Previously in January 2024, CMS announced that sickle cell disease (SCD) will be the initial focus of the Cell and Gene Therapy (CGT) Access Model. The RFA notice explained that, "[t]his RFA is for pharmaceutical manufacturers that participate in the Medicaid Drug Rebate Program (MDRP) and market FDA-approved gene therapies for the treatment of sickle cell disease (SCD) (hereinafter, 'Manufacturers') and outlines Model design elements, Model eligibility criteria, and additional Model details. Manufacturers who submit a timely and complete response to this RFA will be eligible to participate in negotiation under this Model with CMS, and may, upon conclusion of negotiation, be eligible to become a Model participant."

(Source: CMS RFA Announcement, 3/1/24)

The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) has published, "evidence-informed and actionable guide for the nation's hospital leaders to improve healthcare worker wellbeing [titled] Impact Wellbeing™ Guide: Taking Action to Improve Healthcare Worker Wellbeing." According to an agency news release, "[the] guide provides a step-by-step process for hospitals to start making organizational-level changes that will impact and improve the mental health of their employees…As highlighted in a recent CDC Vital Signs, health workers face a mental health crisis. The realities of our healthcare system are driving many health workers to burn out. They are at an increased risk for mental health challenges and choosing to leave the health workforce early. Leveraging CDC/NIOSH's expertise and leadership in Total Worker Health®, NIOSH and the Dr. Lorna Breen Heroes' Foundation developed the new, free, evidence-informed Guide to help executive-level hospital leaders make powerful workplace improvements quickly, while taking into account the realities that many hospital systems face when it comes to finding additional time, cost, and staff to implement this work."

(Source: NIOSH News Release, 3/18/24)

MEMBER NEWS

Illinois Governor J.B. Pritzker recently donated blood on March 21st at an **ImpactLife** blood drive hosted by Lieutenant Governor Juliana Stratton. "It's gratifying for us here in Springfield to have the opportunity to save lives and donate blood," said Gov. Pritzker in a news release. "Together, Lt. Gov. Stratton and I were able to join blood donors from all walks of life in our efforts to keep blood available to help save lives at hospitals across Illinois." Lt. Gov. Stratton added in the news release, "[b]lood [c]enters across the state are in constant demand for blood products year-round. Hosting a blood drive for state employees is a way to lead by example. I'm proud of every person who donated and changed a life today; the people of Illinois have each other's backs."

(Source: ImpactLife News Release, 3/21/24)

Versiti recently announced that expansion plans have been submitted to the city of Wauwatosa's Design Review Board for a "state-of-the-art" addition to the Versiti Blood Research Institute (VRBI). According to a company news release, "the expansion [would be a] 79,000 square-foot addition that will nearly double

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MEMBER NEWS (continued from page 7)

Rendering courtesy of HGA

VBRI's research capacity, add approximately 100 new jobs, and generate an estimated $19 million in additional tax revenue for the state of Wisconsin over 30 years. The project is expected to have a total economic impact for the state of more than half a billion dollars by 2050. Groundbreaking on the expansion project is scheduled to begin later this year with an estimated completion date in 2026. The new addition will expand the VBRI's research capacity and promote the discovery of novel, more effective, and less toxic therapies for a broad range of conditions that affect millions, positively impacting the health of residents across the state, nation, and international community…The expansion is a $79 million project that will include donations and private funding. A $10 million grant to support the project has been earmarked within Gov. Tony Evers' 2023-25 budget proposal, reaffirming the state's commitment to advancing blood health research." Chris Miskel, MBA, president and chief executive officer at Versiti, added in the news release, "[t]he expansion represents a crucial milestone for the Versiti Blood Research Institute. Renowned for our innovative and leading research and extensive knowledge of bleeding and clotting disorders, we are now broadening our focus to include blood cancers and immune system diseases. This initiative signifies a transformative phase where we can make a positive difference in the health and welfare of patients and families, both locally in Milwaukee and globally."

(Source: Versiti News Release, 3/18/24)

GLOBAL NEWS

Researchers in Australia recently shared data in a *Vox Sanguinis* "Short Report" that examined whether lifting the country's variant Creutzfeldt Jakob disease (vCJD) donor deferral impacted the, "availability of RhD-negative blood groups within" the country. The study included blood donor data from July 2022 through July 2023. "A total of 566,381 blood donors were included in our analysis. Of these, 114,619 were first-time blood donors; 34,560 were confirmed UK donors, [individuals who were affected by the change in deferral policy] of which 28,301 were first-time blood donors, and 531,821 were non-UK identifiable donors." The study found that, "[a]lthough the overall donor panel has increased in size, the potential for blood group provision remains similar to all previous reported Australian estimates, especially since blood group prevalence in blood donors is subject to selection bias based on clinical demand, such as O RhD-negative for RBC units and group AB blood for plasma, thus resulting in preferential recruitment of donors with these blood groups. Prevalence of other clinically significant blood groups may also have altered based on UK donor deferral being lifted. However, when compared with Australian Bureau of Statistics on country of birth, the removal of the UK donor deferral is unlikely to change the overall donor [population] phenotypes drastically…This data provides further information for evidence-based forecasting of supply and could be used to support removal of this deferral in other countries."

Citation: Hirani, R., Hoad, V.C., Gosbell, I. B., and Irving, D.O. "Has the frequency of ABO RhD blood groups in Australian blood donors changed as a result of the removal of the variant Creutzfeldt–Jakob disease-based deferral?" *Vox Sanguinis*. 2024.

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GLOBAL NEWS (continued from page 8)

The United Kingdom Health Security Agency (UKSHA) has published a report describing the number of cases and trends of travel -associated infections, including chikungunya, dengue, and Zika, in England, Wales, and Northern Ireland. Highlights from the report include:

- "there were 45 chikungunya cases reported in 2023, all of which were from England. Of these, 25 (56 percent) were confirmed cases and 20 (44 percent) were probable cases. This represents a 45 percent increase compared to 2022 (n=31);
- 634 dengue cases were reported in 2023 (603 in England, 23 in Wales and eight in Northern Ireland), of which 576 (91 percent) were confirmed cases and 58 (9 percent) were probable cases. This represents a 42 percent increase compared to 2022 (n=448);
- there were 8 Zika cases reported, all of these from England, consistent with number of cases reported in 2022…[A]mong these cases, one case of congenital Zika syndrome (CZS) was reported, which was linked to a travel history to Thailand. This was the first case of congenital Zika syndrome diagnosed antenatally in the UK."

(Source: UKSHA, "Travel-associated infections in England, Wales and Northern Ireland: 2023," 3/21/24

A report in *Reuters* described efforts underway in Brazil to combat increasing cases of dengue in the country using genetically modified mosquitoes developed by Oxitec. According to the publication, Oxitec created, "a version of the male *Aedes aegypti* mosquito which carries a gene that kills female offspring before they reach maturity, suppressing the population. Only female mosquitoes bite and transmit diseases. Eggs for the mosquitoes are placed inside a box and water is added to activate them. As the modified mosquitoes are released in a given region, they proliferate and the total population of the insect decreases."

(Source: *Reuters*, "Biotech company bets on GMO mosquitoes to fight dengue in Brazil as cases surge," 2/28/24)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) has approved the biologics license application for **Roche Molecular Systems, Inc.** cobas® Malaria, Nucleic Acid Test. According to the March 19th approval letter from the agency, "cobas® Malaria test for use on the cobas® 6800/8800 Systems (cobas® Malaria) is a qualitative in vitro nucleic acid screening test for the direct detection of *Plasmodium* (*P. falciparum*, *P. malariae*, *P. vivax*, *P. ovale*, and *P. knowlesi*) DNA and RNA in whole blood samples from individual human donors, including donors of whole blood and blood components, as well as other living donors. It is also intended for use in testing whole blood samples to screen organ and tissue donors when samples are obtained while the donor's heart is still beating." The agency also noted in the BLA approval letter that, "[w]hole blood samples from all donors are screened as individual samples."

(Source: FDA Letter, 3/19/24)

Cerus Corp. reported findings from a phase III clinical trial (ReCePI) of pathogen reduced Intercept Red Blood Cells (Intercept RBCs) transfused to complex cardiac surgery patients. In a company news release, the organization announced that, "the trial met its primary efficacy endpoint, demonstrating non-inferiority for Intercept RBCs compared to conventional RBCs as measured by the incidence of acute kidney injury (AKI) following transfusion of study RBCs. AKI is a sensitive transfusion efficacy indicator of RBC tissue oxygen delivery. In transfused subjects, by modified intent to treat (mITT pre-specified primary endpoint population) the incidence of AKI was 29.3 percent (46/157) for Intercept RBC recipients compared to 28.0 percent (45/161) for conventional RBC recipients, demonstrating non-inferiority of Intercept RBCs compared to conventional RBCs with an upper limit of the 95 percent confidence interval of 10.4 percent

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COMPANY NEWS (continued from page 9)

compared with a non-inferiority margin of 14.0 percent (p = 0.001)." Additionally, Cerus stated that, "[t]he safety endpoint of the proportion of patients with any related treatment-emergent adverse events (TEAEs) within 28 days of last transfusion was not significantly different for Intercept RBCs (2.5 percent) compared to conventional RBCs (0.6 percent) (p = 0.130). There was no clinical significance related to treatment-emergent RBC antibodies observed in five patients receiving Intercept RBCs. The trial's independent Data Safety and Monitoring Board (DSMB) evaluated these patients and was supportive of continued transfusion, having found no adverse health effects from trial transfusions. This safety endpoint is also being explored in the Company's ongoing RedeS Phase 3 clinical trial of Intercept RBCs. Cerus plans to include data from both the ReCePI and RedeS clinical trials in an integrated safety analysis as part of its planned modular premarket approval (PMA) submission. The ReCePI trial is, "[a] prospective, multicenter, randomized, double-blinded, controlled, non-inferiority design trial…Adult subjects at high risk of need for RBC transfusion received either conventional (control) or INTERCEPT RBCs during and for 7 days after complex cardiovascular surgery (CVS), including thoracic aorta surgery." Cerus also explained that the company, "anticipates initiating a modular PMA application to the U.S. Food and Drug Administration (FDA) in the second half of 2025, with the final PMA module submission planned for the second half of 2026, upon the anticipated completion of the RedeS clinical trial."

(Source: Cerus News Release, 3/19/24)

The FDA has cleared **Haemonetics Corp.**'s NexLynk DMS® Donor Management System 4.10.0. A March 15th letter from the agency explained that, "[t]he NexLynk DMS® Donor Management System is a record management software tool and database of information for use in source plasma establishments. The software assists in the manufacture of source plasma by performing the following functions:

- [d]etermine donor eligibility and component suitability for release;
- [m]anage component collection, processing, testing, labeling, and storage
- [c]rossmatch immunogens for immunizing specialty plasma donors; and
- [c]onduct unit inventory lookback.

The NexLynk DMS® Donor Management System is not indicated for patient management, treatment, or clinical care at a health care facility."

(Source: FDA Letter, 3/15/24 ♦

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

Mar. 29. **ABC Scientific, Medical, and Technical Journal Club Webinar.** More information available to ABC members in MCN 24-016 including a link to registration.

April 11-12. **International Haemoviglance Network Symposium. Athens, Greece.** Registration is open. More information available here.

April 12-13. **BEST Meeting. Amsterdam, Netherlands.** More information is coming soon.

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CALENDAR (continued from page 10)

April 16-17. **International Plasma Protein Congress. Athens, Greece.** Registration is open. More information available here.

April 17-18. **ABC Quality and Technical Workshop. St. Louis, Mo.** Registration is open. More information available here.

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting.** More information is coming soon.

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** More information is coming soon.

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

Sept. 4-6. **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.** More information is coming soon.

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

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

2025

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

Lab Technical Director. The Central California Blood Center (CCBC) is seeking a Laboratory Technical Director for our operations based out of Fresno, California. This position provides exceptional, mission-focused leadership to the blood component manufacturing, testing lab, research, and immunohematology reference laboratory and assures cost-effective, lean operations and compliance with all regulatory agencies and best practices as defined in AABB Standards and AABB Technical Manual. Assures that the department strives for optimal performance by providing the necessary resources and developing a highly competent team. This position works in close collaboration with CCBC senior leadership and the Medical Director, who holds the CLIA licensure for the organization. The ideal candidate must have a current California Clinical Laboratory Scientist (CLS) license or eligible, a minimum of six (6) years of experience working in a blood center, and a minimum of three (3) years of direct supervisory experience managing teams and assets. Certified as an SBB/BB or equivalent is preferred. We offer a generous benefits package including a great 401k matching program, PTO, paid sick leave, medical, dental, vision, electronic vehicle charging, wellness program, and employee assistance program (EAP). Prospective candidates may be eligible for relocation assistance. For full description and to apply visit: https://recruiting.paylocity.com/recruiting/jobs/Apply/2332121/CENTRAL-CALIFORNIA-BLOOD-CENTER/Lab-Technical-Director.The Central California Blood Center is an Equal Opportunity Employer.

Marketing Manager (Blood Centers of America). This position develops and executes a marketing strategy for BCA and for individual business units including budget planning and measurement of success. The position manages the social media accounts and website content and supports the needs of the Advanced Therapy Network including newsletter, search engine optimization, and maintaining a record of member capabilities. Other responsibilities include press releases, presentations with input from internal stakeholders and trade show participation. A bachelor's degree in business is required; major in marketing preferred. Requires three (3) or more years of marketing experience with a proven track record of success. Social media management experience required. Blood center or related industry experience preferred. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 10%-20% of overnight travel required. Apply at hrjobs@bca.coop.

Supply Chain Contract Manager (Blood Centers of America). This position is responsible for the day-to-day activities specific to BCA and national GPO supplier contract relationships. Position will identify, develop, coordinate and implement supplier contracts working with blood center Materials Directors and Purchasing Managers driving contract savings and increased revenue. A primary responsibility will be to oversee and manage the Third Party Logistics (3PL) operations, adding new product categories to be distributed in this program to increase overall program value and efficiency. A bachelor's degree in a related field is preferred. Requires 3-5 years of supply chain experience in a related industry. Ability to travel regularly throughout the year to meet member needs. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 20%-30% of overnight travel required. Apply at hrjobs@bca.coop.

Regulatory and Audit Compliance Specialist. The Regulatory and Audit Compliance Specialist ("Specialist") is responsible for developing and maintaining a risk-based quality auditing program for the New York Blood Center Enterprise division. The Specialist monitors and evaluates divisional compliance with regulatory requirements, professional accreditation standards and internal policies and procedures to ensure the ongoing quality and safety of products and services. Manages Audits: The Specialist manages the quality audit program for the division, including planning, risk assessment, scheduling, executing, and reporting on audits of the organization's facilities and operations. The auditor makes recommendations on areas of improvement based on audit observations and findings. Advises on Compliance: The Specialist represents the division as a direct liaison to regulators, managing communications, Biologics License Applications (BLA) submissions, regulatory reporting, and ongoing compliance matters, including the filing of Biological Product Deviation Reports (BPDRs). The incumbent serves as a subject matter expert, advising divisional leadership of new or changed regulations and standards, and providing interpretation for successful implementation. Please click here to view the full job description and apply.

Vice President, Quality & Regulatory Affairs (VPQRA). The Vice President, Quality & Regulatory Affairs (VPQRA) leads the Organization's adherence to regulations and standards established by governing agencies (AABB, FDA, CLIA, State, OSHA, NRC, EU, etc.). Kentucky Blood Center is seeking qualified candidates to fill this key executive leadership role which is responsible for our Quality Assurance (QA) program and regulatory compliance activities. The position has oversight of the QA department and team, and reports to the CEO. Qualifications include MLS/CLS (ASCP) with preference given to candidates with a graduate degree, and blood banking experience. Relocation to the Lexington, Kentucky area required (assistance provided). For more information or to apply, visit https://www.kybloodcenter.org/about-us/careers.

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POSITIONS (continued from page 12)

Quality and Regulatory Services Manager. The Quality and Regulatory Services Manager reports to the Director of QRS and is responsible for the quality and regulatory affairs, duties, and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, and validations, and assist with the development, as necessary. Reviews applicable regulations and standards from FDA, AABB, CLIA, OSHA, NRC, State of Tennessee, and manufacturers to ensure compliance. Personnel Training: Perform Good Manufacturing Practice (cGMP) and safety training and assist in inter-departmental training and competency evaluation. Maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports when required. Document Control: Maintain proficiency in Document Control within MediaLab. Able to revise and create SOPs, Forms, and Job Aids. Create, perform, and review validations. Manage the overall deviation management program to include investigation, root cause, analysis, corrective and preventative actions, and documentation. Responsible for developing, tracking, monitoring, and reporting quality indicators. Monitor and conduct trend analysis of quality indicators. Process improvement, including change control and corrective/preventative actions. Please click here to view the full job description and apply.

Cord Blood Operations Supervisor. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Cellular Therapies team at our headquarters in Gainesville, FL. This position is responsible for supporting and supervising the Cord Blood (CB) program's supply, records, logistics and communication activities. This position is also responsible for supervision and training of the cord blood logistics staff and for coordinating and managing all activities related to orders and shipments of biological products. 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!

Cellular Therapy Scientist. LifeSouth Community Blood Centers is looking for an experienced laboratory scientist, with a passion for making a difference, to join our Cellular Therapies team at our headquarters in Gainesville, FL. The Cellular Therapy Scientist is responsible for performing and developing testing, processes, troubleshooting, and investigation related to cellular therapy and manufactured biologics. Duties and projects may relate to products intended for research, commercial, and clinical use. 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!

District Director. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The District Director at our Jacksonville, FL location is responsible for managing and directing the operations within the assigned district to ensure blood donation goals are achieved. They will work closely with local hospitals to ensure blood products are available as needed and all service needs are met appropriately. The District Director also ensures local operations are managed appropriately, in accordance with all procedural requirements and are in line with organizational values. 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!

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Augusta, GA. This position will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources – Augusta, GA.

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Raleigh, NC and Rock Hill, SC. These positions will oversee donor collection operations within their assigned divisional territory. These positions provide leadership and discipline to direct reports, interviews, and hire staff, and ensure staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Services – Raleigh, NC. Manager of Donor Services – Rock Hill, SC.

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

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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.

Division Director, Core Operations (Hoxworth Blood Center). Hoxworth Blood Center is recruiting for Division Director, Core Operations, to provide leadership, vision, and oversight of programs related to donor center core operations, including Biomedical Engineering, Materials Management, Physical Operations, and computer software informational systems. Experience in daily production of cleanroom environments, as well as recruitment and training of new employees with knowledge in cleanroom environment and regulatory framework in accordance with cGMP, FDA, and ISO regulations pertinent to the environmental control in ISO7/8 facilities is crucial. Enforce current strategic planning initiatives; develop new activities and establish goals in support of blood center strategic plans. Direct and facilitate cross functional activities that support the interdepartmental communications, productivity, and quality between various operating units. Develop innovative processes for monitoring operations to ensure high quality customer service and successful delivery of outputs. Required Education and Experience: Bachelor's Degree in related field of healthcare, biological or computer sciences. Seven (7) years of relevant experience in equipment management, computer and software information systems, blood banking, biotherapies, transfusion medicine, or scientific research. Three (3) years of direct supervisory experience managing employees, teams, and assets. For full description and to apply, visit: https://bit.ly/3OHlZet. The University of Cincinnati is an Equal Opportunity Employer.