

2021 #7

February 26, 2021

INSIDE:

National Blood Community Issues Joint Statement Encouraging Blood Donation Following Weather Disruptions.....	2
REGULATORY NEWS.....	3
RESEARCH IN BRIEF	3
COVID-19 Convalescent Plasma Updates	4
24 th Annual Awards of Excellence Winners.....	5
Call for ABC Committee Nominations Deadline Approaches	5
Register Today for the ABC Annual Meeting	6
Upcoming ABC Webinars – Don't Miss Out!.....	6
PEOPLE.....	7
MEMBER NEWS.....	7
WORD IN WASHINGTON	7
GLOBAL NEWS	8
COMPANY NEWS	9
CALENDAR.....	10
POSITIONS.....	11

CBER Publishes 2020 Report from the Director

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) released its fiscal year 2020 year-end [report](#) from agency Director Peter Marks, MD, PhD. Among the accomplishments highlighted of interest to the blood community were:

- “the emergency use authorization (EUA) of COVID-19 Convalescent Plasma as part of the agency’s response to COVID-19 pandemic;
- facilitated a Mayo Clinic-led Expanded Access Program for convalescent plasma from April to August 2020 to fill an urgent need to provide patient access to convalescent plasma. FDA worked collaboratively with industry, academic, and government partners to implement the national expanded access treatment protocol (EAP). The program helped approximately 100,000 patients receive convalescent plasma as a treatment for COVID-19 and generated data regarding outcomes associated with its use;
- convened the Blood Products Advisory Committee to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, during storage and clinical indications for use; and
- the [Transfusion-Transmitted Infections Monitoring System](#) (TTIMS) collected and validated data for over 23 million donations at participating blood establishments as of December 31, 2018. Data analyses were approved for the following:
 - Donor and donation prevalence for HIV, HBV, and HCV.
 - Classical incidence analysis among repeat donors for the TTIMS study period for HIV, HBV, and HCV (September 2015 - December 2018).
 - [Incidence modeling](#) for first time TTIMS donors for HIV, based on 1) evaluation of donor HIV antibodies, using LAg avidity assays that characterize “recent” HIV infection; 2) viral load testing.”

The report also provided a complete listing of the guidances issued by the agency throughout the year. The full report is [available](#) on the FDA’s website. It summarizes “achievements, which reflect the [staff’s] continued dedication to CBER’s mission and [the agency’s] ongoing commitment to improve public health globally.”

(Source: CBER [Report](#), 2/4/21) ♦



National Blood Community Issues Joint Statement Encouraging Blood Donation Following Weather Disruptions

America's Blood Centers, AABB, and the American Red Cross issued a [joint statement](#) on February 18th urging eligible individuals to donate blood. The statement also notes that “weather-related challenges come at a time when the nation’s blood supply was already strained. Some blood centers are now reporting critically low inventories, and blood collection organizations across the country are working together to help meet the need as best they can. AABB, America’s Blood Centers and the American Red Cross are joining together to urge eligible, healthy individuals to make and keep an appointment to donate blood, when they are able to do so in their community. Eligible individuals who are able to donate are asked to give blood now to help support those in your community, as well as those throughout the country. Eligible individuals in affected areas are asked to make an appointment to donate when it is safe to do so.” America’s Blood Centers will continue to provide additional updates to member blood centers as they become available and regarding its efforts national outreach efforts with the blood community and external stakeholders to communicate the status of the U.S. blood supply and the importance of the need for blood donors to schedule and keep appointments to donate. Please contact [us](#) with any questions.

(Source: America’s Blood Centers, AABB, American Red Cross, [Joint Statement](#), 2/18/21) ♦

Get ready. Get set. Go. New Integrated Platelet Bacterial Samplers for LVDS

It's time to get ready for the new FDA guidelines* issued to control bacterial risk in platelets. The first step is creating SOPs that include your large-volume delayed sampling (LVDS) strategy.

Let us help you prepare with information on integrated sampling kits — available for use with the Trima Accel® Automated Blood Collection System Version 7 — as well as an example SOP.

The FDA deadline is almost here — so let's get started.
[Contact your Terumo Blood and Cell Technologies sales associate today.](#)

TERUMO BLOOD AND CELL TECHNOLOGIES

©2021 Terumo BCT, Inc. | BC-TRIM-00525
*Download the guidelines at [fda.gov/media/123448/download](https://www.fda.gov/media/123448/download)



The *ABC Newsletter* (ISSN #1092-0412) is published by America’s Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2021 by America’s Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher. (ABC members need not obtain prior permission if proper credit is given.)

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize 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 healthcare 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: Rita Reik
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: \$390

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



REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) [revised](#) the emergency use authorization (EUA) for COVID-19 convalescent plasma (CCP) on February 23rd. In the EUA letter, the agency authorizes an additional test for use in the manufacturing of high titer CCP. The Roche Elecsys Anti-SARS-CoV-2 (with qualifying result of COI \geq 109) can now be used bringing the total number of authorized tests for plasma donations for anti-SARS-CoV-2 antibodies as a manufacturing step to determine suitability before release to 10.

(FDA Announcement, 2/23/21)

On February 22nd, FDA [published](#) notice in the *Federal Register* seeking public comment on “Current Good Manufacturing Practices (CGMP) and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and ‘Lookback.’” According to the agency, the regulation “provide[s] FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections.” The notice specifies that the agency is looking for comments pertaining to:

- “[w]hether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;
- the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected; and
- ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The comment period ends on April 23rd, 2021.

(Source: *Federal Register* [Announcement](#), 2/22/21) ♦

RESEARCH IN BRIEF

Convalescent Plasma For Older Adults with COVID-19: The Earlier The Better. A study in *The New England Journal of Medicine* “evaluated whether convalescent plasma (CP) with high SARS-CoV-2 antibody titers, administered within 72 hours after the onset of mild symptoms, would be efficacious in preventing progression to severe disease in older patients with COVID-19.” This was “a randomized, double-blind, placebo-controlled trial [conducted] between June 4th, 2020, and October 25th, 2020, at clinical sites and geriatric units in Argentina...Patients who were 75 years of age or older, irrespective of current coexisting conditions, or between 65 and 74 years of age with at least one coexisting condition [were eligible].” The authors note that [p]atients “were randomly assigned to receive either 250 ml of CP with an IgG titer greater than 1:1,000 against SARS-CoV-2 spike (S) protein or 250 ml of placebo (0.9 percent normal saline)...[T]he infusions were concealed with opaque bags and tape...479 [p]otential donors were visited at home and screened for SARS-CoV-2 S IgG...Each of the 135 candidates (28 percent) with adequate titers [$>1:1,000$] donated 750 ml of plasma...The primary end point of the trial was the development of severe respiratory disease.” The researchers explained that “[p]atients were assessed for this between 12 hours after the infusion of CP or placebo and day 15...Due to decreasing cases the trial was stopped at “enrollment of 76 percent of the target population, [as] 160 patients with SARS-CoV-2 infection underwent randomization; 80 receive[d] CP and 80 receive[d] placebo.” They note that “the median time to the development of severe respiratory disease in the CP group (15 days; interquartile range, 15 to 15) was longer than that in the placebo group (15 days; interquartile range, 9 to 15) (P = 0.03)...The relative risk reduction

(continued on page 4)

RESEARCH IN BRIEF (continued from page 3)

with CP was 48 percent...Donor titers selected on the basis of a median titer of 1:3200 showed a relative risk reduction of 73.3 percent.” The study concluded that “[t]he administration of CP with high titers of antibodies against SARS-CoV-2 to infected patients within 72 hours after the onset of symptoms reduced the risk of progression to severe respiratory disease by 48 percent.”

Citation: Libster, R., Marc, G.P., Wappner, D., *et al.* Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults. *The New England Journal of Medicine*. 2021. Doi: [10.1056/NEJMoa2033700](https://doi.org/10.1056/NEJMoa2033700).

Contributed by Richard Gammon, MD, Medical Director at OneBlood ◆

COVID-19 Convalescent Plasma Updates

CCP Research. *The New England Journal of Medicine* published a [study](#) that reported “the administration of high-titer convalescent plasma against SARS-CoV-2 to infected older adults within 72 hours after the onset of mild symptoms reduced the progression of COVID-19 to severe illness.” More on this study can be found in the “Research In Brief” section of the *ABC Newsletter*.

The *Journal of Clinical Investigation* also recently published a [viewpoint](#) titled “SARS-Cov2 Variants and Convalescent Plasma: Reality, Fallacies, and Opportunities.” Its authors (Arturo Casadevall, Jeffrey Henderson, Michael Joyner, and Liise-anne Pirofski) state, “[a]lthough SARS CoV-2 variants may elude antibodies elicited by earlier, ancestral SARS-CoV-2 strains, people who recover from variant-COVID-19 are likely to generate [convalescent plasma] capable of neutralizing variants. Hence, variant [convalescent plasma] could be a potential antidote for variant-SARS-CoV-2. As variant SARS-CoV-2 strains spread in human populations, recently donated [convalescent plasma] units will be especially efficacious for variant COVID-19 patients.” A [study](#) also distributed by the *Journal of Clinical Investigation* earlier this month concluded that “the administration of high-titer donor plasma is safe and effectively transfers antiviral titers, while preserving the endogenous development of immunity.”

Convalescent Plasma: Industry Collections, Distributions & Inventory





America's Blood Centers®
It's About *Life.*

INSIDE ABC

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

24th Annual Awards of Excellence Winners

Recipients of America's Blood Centers' (ABC) 24th Annual Awards of Excellence will be honored during a virtual awards ceremony on Wednesday, March 10th during the 59th ABC Annual Meeting. ABC and its member blood centers will recognize individuals and organizations that have made outstanding contributions in promoting blood donation and improving transfusion medicine. This year's recipients include:

- **William Coenen President's Award** - *Jacquelyn Fredrick, MBA and Jay Menitove, MD*
- **Thomas F. Zuck Lifetime Achievement Award** - *Jerome L. Gottschall, MD (Versiti)*
- **Blood Community Advocate of the Year** - *VADM Jerome M. Adams, MD, MPH*
- **Corporation of the Year Award** - *Lodge Cast Iron (Blood Assurance) and Macerich (New York Blood Center Enterprises)*
- **Larry Frederick Award** – *Jan Moore (New York Blood Center Enterprises)*
- **ABC Outstanding Blood Drive of the Year** – *Seattle Mariners (Bloodworks Northwest)*
- **ABC Outstanding Public Relations Campaign** – *The Community Blood Center Save Someone's Summer (Community Blood Center Appleton, Wis.)*

Thank you to all blood centers that submitted nominations.

(Source: MCN 21-018, 2/12/21)

Call for ABC Committee Nominations Deadline Approaches

ABC is encouraging all individuals who work at member centers to consider volunteering to serve on an ABC Committee. Interested individuals are invited to submit their committee nominations by completing the online [sign-up form](#) by Tuesday, March 3rd. ABC relies on staff volunteers from member blood centers to do much of the great work that is accomplished by the association.

All current membership of the committees (listed below for your convenience) will sunset on March 31st.

Committees

- Bylaws Committee
- Membership Committee
- Leadership and Meetings Committee
- Public Policy Council
- Quality Committee
 - Quality Education Subcommittee
 - Regulatory Review Subcommittee – Blood
 - Regulatory Review Subcommittee - HCT/P
- Scientific, Medical, Technical Committee (SMT)
 - SMT Journal Club
 - SMT Publications Subcommittee (*Blood Bulletin*)

(continued on page 6)



INSIDE ABC (continued from page 5)

This is the call to continue the committees' work by volunteering to serve on a committee for a two-year term. We ask all Member Voting Representatives (MVRs) and their staff to review the listing of committees and their [descriptions](#) to determine interest in serving on a particular committee.

Thank you for your time, consideration, and commitment to helping ABC achieve excellence. Please feel free to contact [us](#) with any questions.

(Source: MCN 21-016, 2/11/21)

Register Today for the ABC Annual Meeting

[Registration](#) is now open for the 59th America's Blood Centers Annual Meeting, which will be a virtual event March 8th–12th. Last year's meeting demonstrated the power of coming together as an industry to collaborate on strategies for the future of the blood industry. It is essential now more than ever, to bring executive, operational, and medical leadership together to focus on key issues which will ultimately impact blood center bottom-lines. The meeting will also feature a virtual Advocacy Day as member blood centers will have the opportunity to let their voices be heard with Congress. The schedule is available [here](#). ♦



Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – March 31st from 1 – 2 p.m. (ET). Additional details coming soon.
- **Meeting the Challenges of Implementing the Bacterial Detection Guidance** – webinar recording now available. [Contact us](#) for a link to the recording or see MCN 21-021 for more information.





PEOPLE

Todd Abner has [joined](#) InVita Healthcare Technologies as the business development director for Blood and Plasma. In this role he will “support InVita’s blood and plasma product line that manages hospital order entry and inventory, donor recruitment and engagement, mobile drives and collections staffing, product quality control, and equipment maintenance,” according to a company news release. Mr. Abner has more than 30 years of experience in the blood industry including serving as the vice president of Donor Recruitment at Oklahoma Blood Institute and Versiti. He has also held director roles at Carter BloodCare, the American Red Cross, and BloodCenter of Wisconsin (now Versiti Blood Center of Wisconsin). Additionally, Mr. Abner served as the ADRP Board President in 2014-15. “Todd Abner brings a unique balance of donor recruitment expertise and strong business development track record to InVita,” said Todd Collins, president and chief executive officer of InVita Healthcare Technologies. “Todd Abner’s strong reputation in the industry and depth of knowledge in blood and plasma operations will enable us to more broadly meet the needs of blood centers and hospital blood banks across the country. We are excited to welcome Todd to our team.” Mr. Abner received his Bachelor of Arts degree in Management from the University of Mount Union and is currently working towards a master’s degree in Executive Leadership from Liberty University.

(Source: InVita Healthcare Technologies [News Release](#), 2/18/21) ◆

MEMBER NEWS

Blood Bank of Alaska will [begin](#) serving as a COVID-19 vaccination site as part of a partnership with the Municipality of Anchorage according to news release from the blood bank. The organizations’ warehouse will act as a vaccine site with an estimated capacity of 150-200 people per day. Last month (January), the blood bank “began providing freezer storage for the vaccine.”

(Source: Blood Bank of Alaska [News Release](#), 2/22/21) ◆

WORD IN WASHINGTON

The Administration announced this week that the COVID-19 pandemic will continue to be declared a national emergency. President Joe Biden made the announcement in a [letter](#) to Congress acknowledging that he is publishing a notice the *Federal Register* “stating that the national emergency declared in Proclamation 9994 of March 13th, 2020, beginning March 1st, 2020, concerning the coronavirus disease 2019 pandemic, is to continue in effect beyond March 1st, 2021. There remains a need to continue this national emergency. The COVID-19 pandemic continues to cause significant risk to the public health and safety of the Nation. More than 500,000 people in this Nation have perished from the disease, and it is essential to continue to combat and respond to COVID-19 with the full capacity and capability of the Federal Government. Therefore, I have determined that it is necessary to continue the national emergency declared in Proclamation 9994 concerning the COVID-19 pandemic.” The national emergency would have expired on March 1st, 2021 “unless, within 90 days prior to the anniversary date of its declaration, the President publishes in the *Federal Register* and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date.”

(Source: White House [Announcement](#), 2/24/21)

President Biden has [named](#) Chiquita Brooks-LaSure as the Administration’s nominee to serve as Centers for Medicare and Medicaid Services (CMS) Administrator. According to a new release from the Administration, “[Ms.] Brooks-LaSure is currently Managing Director at Manatt. [She] is a former policy official who played a key role in guiding the Affordable Care Act (ACA) through passage and implementation; she also provides policy analysis and strategic advice to healthcare stakeholders across the

(continued on page 8)

WORD IN WASHINGTON (continued from page 7)

private and public sectors. [Ms.] Brooks-LaSure has more than 20 years of experience in health policy. As deputy director for policy at the Center for Consumer Information and Insurance Oversight within [CMS], and earlier at the Department of Health & Human Services as director of coverage policy, she led the agency's implementation of ACA coverage and insurance reform policy provisions."

(Source: White House [News Release](#), 2/19/21)

The National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI) has paused a [pilot and feasibility study](#) of hematopoietic stem cell gene transfer for sickle cell disease sponsored by the agency at Boston Children's Hospital. The announcement comes in the wake of bluebird bio, Inc. suspending "its [clinical trial](#) external link exploring the curative potential of genetic therapy for sickle cell disease using its lentiviral vector (gene therapy delivery system), because two research participants in this trial developed myeloid neoplasms following gene therapy." The NHLBI stated that its decision to pause the trial is "out of an abundance of caution." The agency's statement continued, "Since this trial began in February 2018, nine individuals with sickle cell disease have been treated. The Boston Children's trial uses a different, yet related, vector, and targets a different gene than those used in the bluebird bio, Inc. trial. However, despite having no indications of such harm in the Boston Children's trial, NHLBI is taking this action following the announcement that bluebird bio, Inc. temporarily suspended its study. For more than a decade, gene therapy has been considered a promising approach to a cure for sickle cell disease. Lentiviral vectors have been a critical part of the process, as they are used to deliver a therapeutic gene into blood producing stem cells in the bone marrow. This therapy results in the production of healthy (or normal) hemoglobin in red blood cells. The Institute has requested that its Data and Safety Monitoring Board (DSMB) conduct an independent safety review of the NHLBI-funded Boston Children's Hospital. Patient volunteers and their safety are the highest priority in any research endeavor, and their participation is the foundation for scientific progress... NHLBI remains committed in its pursuit of a cure for sickle cell disease. The Institute will reassess this pause following a thorough review."

(Source: NHLBI [Statement](#), 2/16/21) 💧

GLOBAL NEWS

Health Canada has [approved](#) a therapy for treatment of "adult patients with transfusion-dependent anemia. Reblozyl® can be used on adult anemia patients who [require] at least two red blood cell (RBC) units over eight weeks resulting from very low-to intermediate-risk myelodysplastic syndromes (MDS) who have ring sideroblasts and who have failed or are not suitable for erythropoietin-based therapy." The approval was based on the "findings from the phase III, double-blind, randomized, placebo-controlled MEDALIST study...The patients were randomized 2:1 to Reblozyl® or placebo.1 In the trial, results demonstrated significantly greater percentage of patients treated with Reblozyl® achieving transfusion independence for eight weeks or longer during the first 24 weeks of the trial as compared to placebo (38 percent vs. 13 percent, P<0.001) at primary endpoint." The U.S. Food and Drug Administration [therapy](#) in 2019 to treat anemia in patients with beta thalassemia.

(Sources: Acceleron [News Release](#), 2/16/21; FDA [News Release](#) 11/8/19)

The World Health Organization (WHO) [announced](#) the agency has granted "Emergency Use Listing (EUL) to AstraZeneca/Oxford University COVID-19 vaccine. Two versions of the vaccine are approved for use through COVAX, the Vaccines Pillar of the Access to COVID-19 Tools (ACT) Accelerator, an international collaboration designed to provide global equitable access to vaccines. "Countries with no access to vaccines to date will finally be able to start vaccinating their health workers and populations at risk,

(continued on page 9)



GLOBAL NEWS (continued from page 8)

contributing to the COVAX Facility’s goal of equitable vaccine distribution,” said Dr. Mariângela Simão, WHO Assistant-Director General for Access to Medicines and Health Products, in a news release. “But we must keep up the pressure to meet the needs of priority populations everywhere and facilitate global access. To do that, we need two things – a scale-up of manufacturing capacity, and developers’ early submission of their vaccines for WHO review.” It becomes the second vaccine approved by the WHO authorized the Pfizer/BioNTech vaccine for emergency use in December 2020. According to a [news release](#) from AstraZeneca, the EUL allows for two doses of the vaccine to be administered at a four to 12-week interval. This regimen was shown in clinical trials to be safe and effective in preventing symptomatic COVID-19, with no severe cases and no hospitali[z]ations more than 14 days after the second dose. The WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) recommended a dosing interval of eight to 12 weeks. In addition, they also recommended use of the vaccine in countries where new variants, including the South African B.1.351 variant, are prevalent. [AstraZeneca] will now work with the COVAX Facility to begin supplying the vaccine around the world, with the majority going to low and middle-income countries as quickly as possible. In the first half of 2021, it is hoped that more than 300 million doses of the vaccine will be made available to 145 countries through COVAX, pending supply and operational challenges.”

(Sources: WHO [News Release](#), 2/15/21; AstraZeneca [News Release](#), 2/15/21) ♦

COMPANY NEWS

Cerus Corp. [announced](#) the formation of a joint venture, with Shandong Zhongbaokang Medical Implements Co. Ltd. (ZBK) aimed to “develop, obtain regulatory approval for, manufacture, and commercialize the Intercept Blood System for platelets and red blood cells in China.” The joint venture will be known as Cerus ZBK Biomedical and will have headquarters in China’s Zibo Shandong Province. Pascal Maillard, vice president of Commercial Operations for the Asia Pacific region of Cerus, stated in a news release, “We are honored to join forces with ZBK in China, furthering our mission to make INTERCEPT the standard of care for patients globally. We believe that ZBK’s experience with local clinical and regulatory requirements, ISO-certified manufacturing infrastructure, and existing sales channels will facilitate accelerated and broad access to Intercept across China’s transfusion medicine community.” ZBK’s Chief Executive Officer Xu Junfeng added, “[w]e are delighted to collaborate with Cerus to work to bring INTERCEPT to China as the market for platelets continues to grow rapidly. Intercept-treated platelets would address an unmet clinical need in the blood transfusion market in China and would offer an important new, prospective measure of safety against known and emerging pathogens during this new era of pandemic preparedness planning.

(Source: Cerus Corp. [News Release](#), 2/24/21)

Novartis and the **Bill & Melinda Gates Foundation** are [partnering](#) on the development of gene therapy to cure sickle cell disease (SCD). “Existing gene therapy approaches to sickle cell disease are difficult to deliver at scale and there are obstacles to reaching the vast majority of those affected by this debilitating disease,” said Jay Bradner, a hematologist and President of the Novartis Institutes for BioMedical Research (NIBR) in a [news release](#). “This is a challenge that calls for collective action, and we are thrilled to have the support of the Bill & Melinda Gates Foundation in addressing this global unmet medical need.” Trevor Mundel, president of Global Health at the Gates Foundation, added in the release, “gene therapies might help end the threat of diseases like sickle cell, but only if we can make them far more affordable and practical for low-resource settings What’s exciting about this project is that it brings ambitious science to bear on that challenge.” Novartis will attempt to develop a “a single-administration, *in vivo* gene therapy” for SCD that the will be funded by the Gates Foundation.

(Source: Novartis [News Release](#), 2/17/21)

(continued on page 10)

COMPANY NEWS (continued from page 9)

The SCD gene therapy trials being conducted by **bluebird bio, Inc.** have been [paused](#) temporarily due to reports of a “Suspected Unexpected Serious Adverse Reaction (SUSAR) of acute myeloid leukemia” in a trial participant treated with the therapy (HGB-206) and “a second SUSAR of myelodysplastic syndrome in a participant.” A statement issued by the company said the cases are being “investigated” and highlighted that no “hematologic malignancy have been reported in any patient who has received” the company’s gene therapy for the treatment of transfusion-dependent beta-thalassemia “(licensed as ZYNTEGLO™ in the European Union and the United Kingdom).” bluebird bio decided to “temporarily suspend marketing” of ZYNTEGLO™ as well “because it is manufactured using the same BB305 lentiviral vector used in the gene therapy for SCD.”

(Source: bluebird bio, Inc. [News Release](#), 2/16/21) ♦



CALENDAR

***Note to subscribers:** Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)*

2021

Mar 8-12. **ABC Annual Meeting (Virtual)**. Registration now [open](#).

April 15. **FDA Cellular, Tissue, and Gene Therapies Advisory Committee Meeting (Virtual)**. More details available [here](#).

May 4-6. **IPFA/PEI 27th International Workshop on Surveillance and Screening of Blood-borne Pathogens (Virtual)**. More details available [here](#).

May 12-13. **Elevate Your Donor Journey: ADRP Master Class in Finding Your XFactor (Virtual)**. More details available [here](#).

May 21-22. **64th Annual California Blood Bank Society Annual Meeting (Virtual)**. More details available [here](#).

Aug. 4. **ABC Medical Directors Workshop, Cleveland, Ohio**. More details coming [soon](#).

Aug. 5-6. **ABC Summer Summit, Cleveland, Ohio**. More details coming [soon](#).

Aug. 17-19. **2021 ADRP Conference, Kansas City, Mo.** More details coming [soon](#).

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany**. More details available [here](#).

Oct. 16-19. **AABB Annual Meeting**. More details available [here](#). ♦



CLASSIFIED ADVERTISING

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

POSITIONS

Medical Affairs Counselor (Scottsdale, AZ). Vitalant is a nonprofit organization that collects blood from volunteer donors and provides blood, blood products and services across the United States. Under minimal supervision, this position is responsible for verbally counseling donors, physicians, and customers on the medical significance of infectious disease markers and responding to questions and concerns. Bachelor's degree or equivalent combination of education and experience required. Extensive working knowledge of infectious diseases preferred. RN license or Certification as a Medical Technologist by a recognized certifying agency preferred. Three years' experience in a healthcare environment required. To include: Experience in patient and/or donor education/counseling/communication. Please apply [here](#). EOE

Phlebotomist/Collections Instructor. Carter BloodCare is hiring an Instructor to our team in Bedford, Texas. The Instructor position is responsible for the training and continuing education of the Collection Services staff in all procedures involved in the allogeneic and special donation collection process. This includes but is not limited to medical history, donor lookup, phlebotomy, quality control, CPR, basic apheresis and a minimum of one apheresis technology. This position is also responsible for ensuring that trainees receive adequate clinical experience, safely performing all required skills and successfully completing competency testing. They plan for and guide the learning process to help students achieve objectives required within the allotted time. They must have adequate transportation to travel. Please click [here](#) to apply. Carter BloodCare is an EEO/Affirmative Action employer. Carter BloodCare provides equal employment opportunities to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, sexual orientation, gender identity, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. Carter BloodCare is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing.

Clinical Apheresis Registered Nurse. The Clinical Apheresis Registered Nurse (CARN) collects leukocytes and performs therapeutic apheresis procedures for Carter BloodCare (CBC) clients in and around the Dallas/ Fort Worth area. The CARN follows CBC SOP's, assesses

and monitors patient/donor while receiving an apheresis treatment; contacts patient physicians or a CBC Medical Director as situation warrants consults or order clarification; transfusion reactions and/or emergency situations; and ensures that excellent customer service is provided to CBC customers. Education: RN with active unencumbered licensure in the State of Texas and CPR Certification. Experience: Minimum one (1) year nursing experience in a hospital setting, oncology unit, or clinic; Intensive care unit, dialysis, ER, oncology, and/or pediatric experience preferred; and Apheresis experience preferred. Please click [here](#) to apply. Carter BloodCare is an EEO/Affirmative Action employer. Carter BloodCare provides equal employment opportunities (EEO) to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, sexual orientation, gender identity, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. Carter BloodCare is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing.

Medical Laboratory Technician. The MLT 1 will report to the Medical City Dallas Heart & Spine Hospitals located in Dallas, TX. The incumbent will participate in all R&T Services activities including but not limited to: Perform testing/services associated with assigned departmental duties. By accomplishing these duties, the MLT 1 ensures daily operations in the R&T laboratories follow established guidelines, provide excellent service, and meet the needs of all R&T customers. Education: Associate Degree; and Medical Laboratory Technician, MLT (ASCP) certification or equivalent. Experience: Recent graduate from an accredited MLT program within last five years and currently board eligible. Must successfully obtain/maintain board certification (i.e., MLT (ASCP) or equivalent) and provided board certification documentation within 12 months of hire date. Please click [here](#) to apply. Carter BloodCare is an EEO/Affirmative Action employer. Carter BloodCare provides equal employment opportunities (EEO) to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, sexual orientation, gender identity, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies

(continued on page 12)

POSITIONS (continued from page 11)

with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. Carter BloodCare is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing.

Chief Clinical Officer (Central California Blood Center). Looking for a blood banking expert who can successfully navigate the ever-changing health care provider and blood industry landscapes to provide ever increasing value to our clients. The CCO will provide clinical, scientific, and technical leadership, along with our senior management team, for our innovative and independent community blood center to assure our expanding position as a national industry leader. The CCO will oversee blood component manufacturing, donor testing lab, R&D programs, IRL, donor services and IT departments. The position will be responsible for developing strategies to ensure blood manufacturing operations are running efficiently and growing effectively to meet the needs of our hospitals and clients, with a focus on excellence and compliance. The CCO will build and guide a team of highly competent, high-achieving department leaders who will consistently exceed standards and goals for cGMP, productivity, and customer service. MS, SBB, PhD or MD preferred. Strong and progressive blood industry leadership experience required. Please send inquiries to lchristiansen@donateblood.org.

Vice President of Finance and Business Development (SunCoast Blood Centers). Reports to the CEO. Is responsible for all financial and accounting functions for the organization including, but not limited to, oversight of Accounts Payable and Receivable, internal controls, period end financial statement preparation and analysis, cash and investment management, all auditing processes, contract management and annual budget development and analysis. Consults with the CEO to provide financial analysis and strategic direction on project/product development and growth opportunities. Bachelor's degree in accounting, business development or other relevant area. At least five years of progressively responsible finance and/or business development experience. Prefer CPA and blood center experience. Submit resumes to <https://scbb.org/careers.html>.

OneBlood has exciting career opportunities available in the incredible state of Florida! Join our life saving mission in one of the following roles: **Reference Lab Manager (Ft. Lauderdale, FL).** Valid and current Florida Clinical Laboratory Supervisor license in Immunohematology or Blood Banking and SBB certification required. Bachelor's degree in medical technology or related field with five (5) or more years' experience; prior management experience essential. **Compatibility**

Testing Lab Supervisor (Tallahassee, FL - \$5k Bonus Eligible). Bachelor's degree in medical technology, biological science, or related field and three plus years in a clinical laboratory, preferably in blood banking. Requires a current Florida Technologist license in Immunohematology or Blood Banking; FL Supervisor License preferred. **Medical Technologist (Tallahassee, FL - \$5k Bonus Eligible).** A valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking is required. Prior blood banking experience preferred. Multiple shifts available. **Therapeutics Apheresis RN (Ft. Lauderdale, FL - \$5k Bonus Eligible).** Current and valid Florida RN license, current BLS CPR certification, and a valid and clear driver's license is required. Flexibility in scheduling needed to meet the needs of the department; travel within the tri-county market in the South Florida area is required. OneBlood offers competitive benefits, including excellent shift differential pay for night and weekend schedules, Paid Time Off, Student Loan Repayment Program, a FREE medical coverage option, 403(b) Retirement Plan, company-paid annual CEU training & CE Broker account and MORE! To apply visit our OneBlood careers website at www.oneblood.org/careers.

Outside Sales Representative/Event Planner (Lawton, Okla.). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions, and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing, and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: <http://obi.org/careers/>.

(continued on page 13)

POSITIONS (continued from page 12)

Operations Coordinator of Mobile Staging. Carter BloodCare is hiring an Operations Coordinator of Mobile Staging to our team in Bedford, Texas. You will be responsible for overseeing all aspects of Bedford/Waco Mobile Staging and Centralized Scheduling. This includes development and implementation of all operational activities with emphasis on continuous process and improvement. Responsible for overseeing the preparation of payroll, supplies, equipment, vans, coaches, and finalization of mobile drive schedules needed for daily mobile operations. Responsible for overall management of mobile staging and scheduling technicians. If you have at least three years of Management experience and want to be a part of making a difference, please click [here](#) to apply on our company website! Carter BloodCare is an EEO/Affirmative Action employer. Carter BloodCare provides equal employment opportunities (EEO) to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, sexual orientation, gender identity, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. Carter BloodCare is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing.

Director of Technical Services (Morrisville, NC (Raleigh, NC Area)). At The Blood Connection, our mission is to support our healthcare partners with adequate, safe, cost-effective blood supplies and services. We desire to be the community blood provider of choice. Position Overview: The Director of Technical Services (ENC) is responsible for supervising and directing the daily operations of the Technical departments in the ENC division: Hospital Services, Component Manufacturing (Biologics Processing), Immunohematology Reference Laboratory, as well as the HS couriers. Duties include: Developing and maintaining procedures. Supervising Reference Laboratory staff. Supervising Hospital Services staff. Supervising Component Manufacturing/Biologics Processing staff. Performing bench work as needed. Interfacing with hospital customers. This position requires general laboratory knowledge and skills as well as specialty (SBB) skills and is expected to perform tasks and well as supervise the performance of laboratory and other staff. Education Requirements: MT (ASCP) or equivalent. SBB strongly preferred. Licensure/Certification Requirements: Valid Driver's License. Experience Requirements: Previous supervisory experience required. Complete applications on <https://thebloodconnection.org/about-us/careers/> for consideration. 💧