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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2019 #35 **October 11, 2019**

INSIDE:

Executive Orders Place Limitations on Agency Guidance

President Trump signed two Executive Orders this week entitled "Promoting the Rule of Law Through Improved Agency Guidance Documents" and "Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication" with the goal of bringing more transparency to the guidance process and ensuring that guidances issued by government agencies are truly non-binding recommendations on compliance with existing regulations and laws. "For many decades, federal agencies have been issuing thousands of pages of so-called guidance documents—a pernicious kind of regulation imposed by unaccountable bureaucrats in the form of commentary on how rules should be interpreted," said the President Trump during the signing ceremony, according to *Bloomberg*. "All too often guidance documents are a back door for regulators to effectively change the laws and vastly expand their scope and reach."

Additionally, the "Promoting the Rule of Law Through Improved Agency Guidance Documents" executive order states that federal regulators should "treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract, take public input into account when appropriate in formulating guidance documents, and make guidance documents readily available to the public. Agencies may impose legally binding requirements on the public only through regulations and on parties on a case-by-case basis through adjudications, and only after appropriate process, except as authorized by law or as incorporated into a contract." Clarifying that enforcement action of agencies should be based on legally binding regulations and statutes. The order also states that regulators must post guidance documents on a searchable website to prevent them from being rescinded.

The "Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication" executive order requires that "[a]gencies shall act transparently and fairly with respect to all affected parties, as outlined in this order, when engaged in civil administrative enforcement or adjudication. No person should be subjected to a civil administrative enforcement action or adjudication absent prior public notice of both the enforcing agency's jurisdiction over particular conduct and the legal standards applicable to that conduct… The agency may not treat noncompliance with a standard of conduct announced solely in a guidance document as itself a violation of applicable statutes or regulations." Guidance documents have always contained language that highlight their non-binding nature. It is unclear at this time how this will impact the FDA's use of regulatory guidance documents to clarify the agency's "current thinking" on topics important to the blood banking community. Both executive orders are effective immediately.

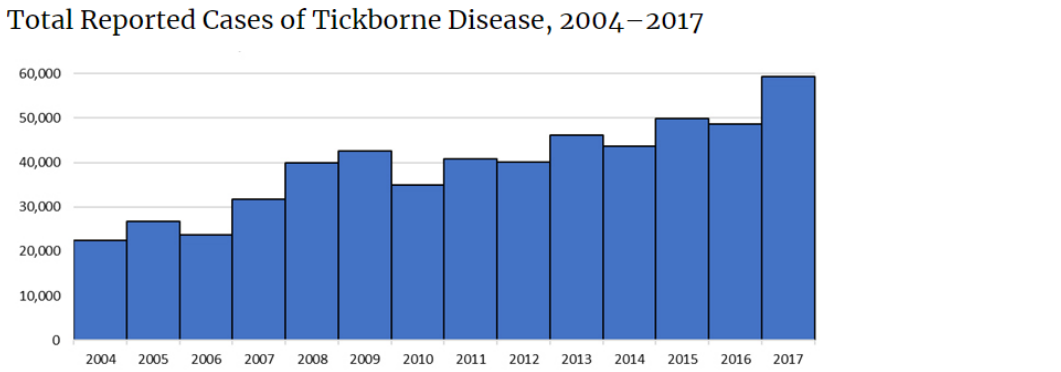
(Source: *Bloomberg*, Trump orders limit effect of agency guidance on industry, 10/9/19)

REGULATORY NEWS

The National Institutes of Health (NIH) announced the publication of a new strategic research plan to combat the growing threat of tickborne diseases (TBDs) such as babesiosis. The plan is part of a recommendation from the U.S. Department of Health and Human Services (HHS)Tick-Borne Disease Working Group. It acknowledges that the number of reported cases of TBDs more than doubled from 2004 to 2016 with 2017 reaching close to 60,000 cases, an all-time high. The plan identifies five strategic priorities:

- Improve fundamental knowledge of TBDs to understand the host, vector, and pathogen factors that drive TBD pathogenesis and transmission. Elucidate the host immune mechanisms in response to and exploited by TBD pathogens;
- Advance research to improve the diagnosis of TBDs using both host- and pathogen-targeted approaches, including research for rapid diagnostics and multiplex platform approaches that detect multiple tickborne pathogens;
- Accelerate research to improve TBD prevention by supporting science to design, develop, and evaluate vaccines, vector control strategies, and other prevention approaches;
- Promote research to improve treatment for all forms of TBDs, including studies to develop effective therapies to treat symptoms that persist after TBD treatment, therapies for non-infectious TBDs, and new antimicrobials; and
- Support tools and resources to advance research in understanding, preventing, diagnosing, and treating TBDs, including repositories, genomic resources, animal models, and preclinical services to aid the development and assessment of diagnostic, vaccine, and therapeutic candidates.

The complete report is available on the NIH website.



Reported cases of confirmed and probable Lyme disease, anaplasmosis/ehrlichiosis, spotted fever rickettsiosis (including Rocky Mountain spotted fever), babesiosis, tularemia, and Powassan virus disease all increased between 2016 and 2017.

Centers for Disease Control and Prevention's Tickborne Disease Surveillance Data Summary

(Source: NIH News Release, 10/10/19)

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REGULATORY NEWS (continued from page 2)

The U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) will be holding their next public meeting on November 22nd. The meeting will take place at the Tommy Douglas Conference Center in Silver Spring, Md from 8:30 a.m. to 4:45 p.m. eastern. It will include discussions and scientific considerations for the transfusion of cold stored platelets products including:

- product characterization;
- duration of storage; and
- clinical indications for use.

The official meeting notice and additional information are available here. Meeting materials will be posted at a later date including a link to the webcast for those unable to attend.

(Source: Blood Products Advisory Committee Meeting Notice, 10/2/19)

INFECTIOUS DISEASE UPDATES

MEASLES

The U.S. Department of Health and Human Services (HHS) announced that the U.S. has maintained its measles elimination status. The announcement follows the New York State Health Department declaring that their year-long outbreak is over. In the October 4th news release, HHS Secretary Alex Azar states, "We are very pleased that the measles outbreak has ended in New York and that measles is still considered eliminated in the United States. This result is a credit to the cooperative work by local and state health departments, community and religious leaders, other partners, and the CDC. But this past year's outbreak was an alarming reminder about the dangers of vaccine hesitancy and misinformation. That is why the Trump Administration will continue making it a priority to work with communities and promote vaccination as one of the easiest things you can do to keep you and your family healthy and safe." The Centers for Disease Control and Prevention (CDC) confirmed 1,249 cases of measles since January 1st with 75 percent of the cases connected to outbreaks in New York. "Our Nation's successful public health response to this recent measles outbreak is a testament to the commitment and effectiveness of state and local health departments, and engaged communities across the country," added CDC Director Robert R. Redfield, MD in the news release. "CDC encourages Americans to embrace vaccination with confidence for themselves and their families. We want to emphasize that vaccines are safe. They remain the most powerful tool to preserve health and to save lives. The prevalence of measles is a global challenge, and the best way to stop this and other vaccine preventable diseases from gaining a foothold in the U.S. is to accept vaccines."

(Source: HHS News, Release, 10/4/19)

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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 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.

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Do Patients Receiving Pathogen Reduced Platelets Have Fewer Transfusion Reactions?

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing an article for potential publication please contact us here.

Changes in platelet and red blood cell (RBC) transfusion requirements in patients receiving pathogen-reduced (PR) platelets when compared to standard platelets (CONV) have been reported in some studies, though there is limited availability of data regarding the safety and efficacy of PR platelets as currently manufactured in the U.S. A retrospective study published in the *British Journal of Haematology* analyzed platelet utilization, red blood cell (RBC) transfusion trends, and transfusion reaction rates data from all adult patients that received a transfusion at a single institution over a 28-month period.

During the study, a dual inventory was maintained with patients either receiving CONV products: leukoreduced single donor apheresis platelets or whole-blood derived platelet pools; or PR treated single donor apheresis platelets in PAS-C additive solution or plasma. "As an additional safety measure, on storage day four or five, CONV platelets were analyzed with a bacterial mitigation assay (PLT PGD test, Verax Biomedical, Marlborough, Mass.). All CONV platelets were gamma-irradiated; PR platelets were not irradiated." Following the index transfusion of CONV or PR platelets, the number of RBC and platelet components administered from 2 to 24, 48, 72 or 96 hours was calculated.

A total of 3,767 patients received 21,907 platelet components (CONV = 8,912; PR = 12,995); 1,087 patients received only CONV platelets (1,578 components) and 1,466 patients received only PR platelets (2,604 components). "There was a slightly higher number of platelet transfusions per patient for patients who received only PR platelet products (1.78 platelet components/patient) versus those who received only CONV platelet products (1.45 platelet components/patient) ($P < 0.001$)." The number of subsequently transfused platelet components was slightly higher following PR platelet components ($P < 0.05$); however, fewer RBCs were transfused following PR platelet administration ($P < 0.05$). The study also "assessed the mean time to the next platelet transfusion for those who received a second platelet transfusion between 2 and 48 hours after each index transfusion. This interval was slightly shorter following PR platelet transfusion (20.3 + 13.5 hours) compared to CONV platelet transfusion (21.2 + 14.2 hours) ($P = 0.002$)." The rate of non-septic transfusion reactions did not differ (all $P > 0.05$). Importantly, septic transfusion reactions were noted in five patients after receiving CONV platelets while no septic transfusion reactions were seen following PR platelet transfusion ($P = 0.011$). "Two septic reactions were due to *Acinetobacter calcoaceticus-baumanni* complex (ACBC) and *Staphylococcus saprophyticus*, and three septic reactions were due to *Streptococcus gallolyticus (bovis)*, with the five units coming from two donors…None of the five contaminated units had bacteria detected by routine culture pretransfusion."

Evidence of comparable clinical efficacy of PR and CONV platelets exists in these results. "PR platelets eliminated septic transfusion reactions without increased risk of other types of transfusions with only a slight increase in platelet utilization." For the CONV platelets, these septic reactions occurred despite the use of point-of-release testing for two of the units due to false negative results. The median cost to treat hospital-based sepsis is reported as $32,421 according to a 2017 review, the authors felt that "costs associated with sepsis probably could be decreased if the use of PR platelets was more widely implemented."

Citation: Bahar, B., Schulz, W.L., Gokhale, A., *et al*. Blood utilization and transfusion reactions in adult patients transfused with conventional or pathogen-reduced platelets. *British Journal of Haematology*. 2019. Doi: 10.1111/bjh.16187.

BRIEFLY NOTED

***ProPublica* published an investigative report looking at the plasma industry in the U.S and the nation's role as a supplier for other countries around the world**. It questions whether additional federal oversight is needed to prioritize the health and safety of donors, while exploring the donor recruitment practices of U.S. plasma donation centers, particularly those that border Mexico. "Unlike other nations that limit or forbid paid plasma donations at a high frequency out of concern for donor health and quality control, the U.S. allows companies to pay donors and has comparatively loose standards for monitoring their health," according to *ProPublica*. The article also examines the culture of paid plasma donation in America and the ability of individuals that reside in Mexico to cross the border in order to donate for renumeration under the guise of visiting family or shopping. It chronicles the experiences of a 21-year-old Mexican female donor who says she continues to come to the U.S. on temporary visas to donate plasma for the financial incentive. The article includes written statements from the U.S. Food and Drug Administration, the Plasma Protein Therapeutics Association, and multiple plasma centers.

(Source: *ProPublica*, Pharmaceutical companies are luring Mexicans across the U.S. border to donate blood plasma, 10/4/19)

The U.S. Department of Health and Human Services (HHS) through the Centers for Disease Control and Prevention has awarded $13.5 million in funding to support the Administration's commitment to reduce HIV infections in the U.S. by 90 percent by 2030 in accordance with the "Ending the HIV Epidemic: A Plan for America." The funds will assist both state and local efforts based on strategies from a national framework of the highest-impact prevention, care, treatment, and outbreak. "From the very beginning of President Trump's Ending the HIV Epidemic initiative, we have been clear: Defeating this epidemic will only be possible if we listen to the perspectives of people living with HIV and the communities in which they live and work," said HHS Secretary Alex Azar. "With these new planning grants, we are excited to support local communities in identifying the stakeholders and steps necessary to halt the spread of HIV, starting in the places where we can make the greatest impact." HHS Assistant Secretary for Health Admiral Brett Giroir, MD added, "[f]or decades, local community plans have been pivotal to HIV prevention, treatment, and care. "And locally designed plans in each jurisdiction are also essential to the success of the Ending the HIV Epidemic initiative. We are committed to enabling communities to best use the resources they need to plan and engage stakeholders."

(Source HHS News Release, 10/2/19)

PEOPLE

Cliff Numark, JD has been named chief marketing officer at Vitalant. He joins the organization having most recently served as senior vice president at the American Red Cross within the Biomedical Services Division. "Vitalant is poised to be the most significant transfusion medicine organization in the nation," said Mr. Numark in a news release. "Vitalant excels at transformational research, innovation and creating moments of impact for the lives it touches. I'm excited to step into this role to accelerate changes to achieve the organization's mission and purpose." He brings many years of blood banking leadership to the role with expertise in a variety of disciplines including marketing, recruitment, operations, and public affairs. "We exist to provide seamless and meaningful experiences for our donors and patients and are therefore always looking for ways to inspire and transform how we connect with them," said Vitalant's President of the Blood Services Division Rob Van Tuyle in the news release. "Cliff's experience in digital outreach, product innovation, omnichannel marketing, brand development and operational improvements support our strategic vision to be the continued, trusted leader in transfusion medicine." Mr. Numark holds a JD from the

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PEOPLE (continued from page 5)

University of California Berkley, a master's degree in public affairs from Princeton, and a master's degree from the University of Sussex School of Engineering.

(Source: Vitalant News Release, 10/9/19)

Mark Edmunds, MD has been announced as San Diego Blood Bank's new Chief Medical Officer. He received his medical doctorate from the University of New Mexico and completed his residency in Laboratory Medicine and fellowship in Blood Transfusion Medicine at Cedars-Sinai. Dr. Edmunds has previously served as associate medical director of Blood Centers of the Pacific and North American medical director for Grifols Transfusion Medicine.

(Source: San Diego Blood Bank Announcement, 10/8/19)

MEMBER NEWS

South Texas Blood and Tissue Center recently teamed up with the Victoria Fire Department (VFD) to launch the Brothers in Arms, which will allow VFD medical personnel to treat trauma patients and accident victims with whole blood transfusion in the pre-hospital setting. "The use of whole-blood transfusion prior to arrival at the hospital is saving lives and has already shown at least a 25 percent decline in trauma deaths for those requiring emergency transfusion," said South Texas Blood and Tissue Center Executive Director Linda Rapp in a news release. "In addition to the community and cities in the region, the program also supports workplace safety initiatives in industrial settings." The program is modeled after U.S. military battlefield transfusion practices that have also been used by the Mayo Clinic Trauma Center. "The Victoria Fire Department is proud and honored to be one of the first cities in the United States to offer this level of service to our community," added VFD Fire Chief Robert Fox in the new release. "Our mission is to preserve life and property with dedicated and caring service and this program enhances our ability to achieve our mission."

(Source: South Texas Blood and Tissue Center News Release, 10/2/19)

GLOBAL NEWS

The Canadian Human Rights Commission (CHRC) has referred a complaint, originally filed in 2016 by Christopher Karas claiming the country's blood donor deferral policy for men who have sex with other men is discriminatory, to the Canadian Human Rights Tribunal. According to a report from *CBC News*, the CHRC recommended the tribunal as the appropriate entity to begin an inquiry as it is can "examine and weigh the extensive and highly technical evidence submitted by the parties in support of their respective positions." Earlier this year, the country's public health regulatory body, Health Canada, approved an MSM policy change supported by the nation's blood collection organizations, Canadian Blood Services and America's Blood Center member Héma-Québec, that reduced the MSM deferral from one year to three months.

(Source: *CBC News*, LGBT activist's complaint over wait period for blood donation referred to human rights tribunal, 10/8/19)

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GLOBAL NEWS (continued from page 6)

The Irish Blood Transfusion Service's joint procurement arrangement with United Kingdom (UK) blood donation services will come to an end when the UK leaves the European Union (EU), or Brexit as it has been named, according to a report from *The Irish Times*. The Irish Blood Transfusion Service has been stockpiling blood bags and testing kits in preparation for the UK's departure from the EU. In the annual report, according to the article, Irish Blood Transfusion Services Chief Executive Andrew Kelly wrote, "[a]s we entered 2019 and the possibility of a no-deal exit from the EU the [Irish Blood Transfusion Service] had to engage more with our suppliers and look to having a contingency stock of our critical supplies on site." Earlier this year, the organization acknowledged ramping up its inventory supplies used in the collection of blood and blood products given the uncertainty surrounding an EU withdrawal agreement being reached by members of Parliament in UK.

(Source: *The Irish Times*, Brexit to end procurement arrangement of Irish and UK blood donation services, 10/7/19)

A 35-year-old Singaporean male has been sentenced to four months in prison and fined S$10,000 for lying on his donor health assessment questionnaire. He falsely indicated that he never engaged in sexual activity with another male nor had he had engaged in sexual activity with any individual in the past year that he had known for fewer than six months. The unit of blood that he donated tested positive for HIV. Upon being interviewed by Ministry of Health (MOH) authorities in Singapore to assess if had any HIV risk factors, the individual admitted to having sexual intercourse with other males on two separate occasions in addition to multiple sexual encounters with strangers. This was the sixth time that he donated, as his previous five donations were negative for HIV. In the article, the Singapore MOH said that "the donated blood was immediately isolated and destroyed. None of the donated blood was transfused."

(Source: *TODAY*, Man lied about sex history before donating HIV-contaminated blood, 10/3/19) ♦

COMPANY NEWS

Blood Bank Computer Systems (BBCS) recently announced a new partnership with Degree 37, a technology company that specializes in blood donor engagement and management. The companies plan to integrate BBCS' blood establishment computer software (BECS) solution, ABO Suite™, and Degree 37's donor engagement platform, which includes a blood donor mobile app and customer relationship management system. "We have been searching for a partner who understands donor engagement and who shares the drive and values of BBCS" said BBCS CEO Brian Forbis in a news release. "In [Degree 37], we have found a partner who can complement our offerings. They are committed to working with us and the greater BBCS community to rethink the possible in engaging donors for their life saving support." A rollout of the new integrated solution is expected to be available early next year. "We are excited about the opportunity to partner with BBCS as they bring a wealth of knowledge and experience in the blood collection industry," added Degree 37, LLC Managing Partner Mark Gilman in the news release. "In all industries we have entered, we always look for the most efficient means for our customers to adopt and leverage the technologies we develop. The partnership we have entered into with BBCS will allow us to quickly and efficiently bring our technologies to other blood centers throughout the country."

(BBCS News & Degree 37 Joint News Release, 10/7/19) ♦

Upcoming ABC Webinars – Don't Miss Out!

- **Staffing Success & Challengers at Blood Centers Webinar** – November 19th from 3 - 4:30 p.m. (ET). Additional details coming soon!
- **SMT Journal Club Webinar** – December 5th from 12 – 1 p.m.(ET). Additional details coming soon!
- **Irradiator Replacement at Blood Centers Webinar** – January 21st from 3 – 4:30 p.m. (ET). Additional details coming soon!

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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 staff only, unless otherwise specified.

ABC Seeks Member Participation in 2019 Service Fee Survey

America's Blood Centers is encouraging members blood centers to participate in the annual survey of member service fees by completing the online survey available in MCN 19-065 by Friday, October 25th. The results from this survey are important in assisting ABC in its advocacy efforts on behalf of member blood centers for better reimbursement for blood products. Only aggregate data will be reported and no individual data or identifiable information from any center will be shared. A copy of the survey questions is also available in the MCN.

(Source: MCN 19-065, 9/19/19)

Facebook Prepares for National Rollout of Blood Donation Tool

As previously announced, Facebook launched a pilot of their blood donation tool in June of this year. America's Blood Centers (ABC) has been informed that Facebook will now begin the process of expanding nationwide and expects all blood centers that are interested to be live on the tool over the course of the next six to eight weeks. Several ABC members have volunteered to participate in the testing phase of a self-service feature that will allow blood centers to manage the onboarding of their fixed facilities into the blood donation tool.

Assuming no setbacks or major issues, all non-testing centers will be able to start using the tool at the end of October/early November. Additional information will be made available as it is obtained. Facebook will be able to share instructions on how to use the tool with a wider audience and anticipates having the training materials uploaded and made available publicly to empower centers with the ability to onboard themselves. Please feel free to reach out with any questions or concerns.

(Source: MCN 19-070, 10/3/19)

ABC 2020 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9th-11th	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19th-21st	Phoenix, Ariz.	Hyatt Regency	More details coming soon!

Notes:

For the most up-to-date information on all events, members of ABC may check the calendar on ABC's Member Site.

Non-members may attend all events; information will be updated on ABC's Public Site.

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2019

Oct. 15-16. **Biomedical Advanced Research and Development Authority Industry Day 2019, Washington, D.C.** More details available here.

Oct. 19-22. **2019 AABB Annual Meeting, San Antonio Texas.** More information available here.

Nov. 12-14. **U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md.** More details available here.

Nov. 22. **U.S. Food and Drug Administration Blood Product Advisory Committee Meeting, Silver Spring, Md.** More details available here.

2020

Jan. 14-15. **IPFA/EBA Workshop on Plasma Collection, Location to be announced.** More details available here.

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** More details coming soon.

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Thailand.** More details available here.

April 14-15. **16th Annual U.S. Food and Drug Administration and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available here.

May 13-14. **IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available here.

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon.

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Clinical Lab Specialist (Med Tech) (San Francisco, CA). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Requirements: Bachelor's degree required. Must satisfy CLIA requirements for High Complexity Testing required. Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency required. Valid CA CLS license required. Five years clinical laboratory testing experience required. One-year IRL experience preferred. Please apply here. EOE

Clinical Lab Supervisor (San Francisco, CA; Req: 190704). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Requirements: Bachelor's degree required. Must satisfy CLIA requirements for High Complexity Testing required. Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency required. Seven years clinical laboratory testing experience required. To include: Two years supervisor experience required. Two years IRL experience preferred. Apply here. EOE

Medical Technologist II (San Francisco, CA; Req:191052). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Bachelor's degree in a chemical, physical, biological, medical technology or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. CA Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure (as required by regulations). Three years' experience in a clinical laboratory setting required or SBB. Experience in developing and conducting formal training preferred. Apply here. EOE

Assistant Lab Supervisor (San Francisco, CA; Req: 191123). Since 1941, Vitalant (formerly known as Blood Centers of the Pacific) has proudly served as a leader in the blood banking industry. Requirements: High School graduate or GED required. CLIA equivalent for moderate complexity testing required. Medical Laboratory Technician (MLT) or Clinical Laboratory Scientist (CLS) certification/licensed required. One-year laboratory experience required. Please apply here. EOE

Laboratory Operations Supervisor. Cascade Regional Blood Services in Tacoma, Washington is looking for a Laboratory Operations Supervisor. The Laboratory Operations Supervisor will be responsible for all operational oversight of the laboratory, including Hospital Services, Components Laboratory, and QC Testing. Supervise staff, in coordination with Technical Director, to ensure compliance with all SOP, FDA, and AABB regulations. Monitors performance in the areas of productivity, proficiency, and customer service. Ensures blood bank maintains adequate inventory and imports or exports as necessary. Education/Certification: Baccalaureate degree in medical technology or biological science, with a minimum of five years' experience in blood center, transfusion medicine, cellular therapy, clinical laboratory or related field. MT/MLS/SBB (ASCP) strongly preferred. MLT may be considered with relevant experience. Experience Required: Demonstrated familiarity with quality assurance requirements, blood banking, cell processing and cryopreservation, sterile technique and safe handling of potentially infectious human blood/tissues. Demonstrated knowledge of cGMPs, cGTPs and principles of QA/QC. Working knowledge of AABB and related FDA regulations. Minimum of three years of relevant supervisory experience. Team or project leadership experience preferred. Apply at: www.crbs.net/job-opportunities.

Physician/Chief, Infectious Diseases Section. The Department of Transfusion Medicine in the Clinical Center, National Institutes of Health is recruiting a physician faculty member to oversee the Infectious Disease Section, provide medical support for Clinical Center patients and perform subspecialty consultation related to infection transmission through blood, blood components, and cellular therapies. The successful candidate will oversee a section of 14 staff including a CLIA-approved testing laboratory. Additional functions include research related to transfusion-transmitted infections, and teaching in an ACGME-accredited training fellowship in Transfusion Medicine. The Department of Transfusion Medicine is a full-service collector and provider of blood, blood components and cellular therapies. The position requires detailed knowledge of molecular, genetic testing for transfusion-transmitted agents. Candidates must be board certified or eligible in Blood Banking / Transfusion Medicine, Hematology, Infectious Disease, appropriate subspecialty certification(s) must have an M.D. or equivalent degree and must possess an active, current, full, and unrestricted license or registration as a physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. Salary commensurate with training and experience. Please submit your curriculum vitae and a letter describing your skills and experience by Nov. 4, 2019 to: Lacey Gholson, Administrative Officer, NIH/CC/DTM, 10 Center Drive, Building 10/Room 1C711 (MSC 1184), Bethesda, Maryland 20892-1184. DHHS AND NIH ARE EQUAL OPPORTUNITY EMPLOYERS.

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POSITIONS (continued from page 10)

Senior Regulatory Affairs Officer (Macopharma USA). Responsibilities include: Develops appropriate regulatory strategy for bringing Macopharma Transfusion and Biotherapy products (Medical Devices and Drugs to the US). Identifies the status of the product according to the country (Medical Device, medicine). Sets the elements necessary for the compilation of files according to the regulations and regulatory guidelines. Collects data to assess compliance with the expectations of the authorities. Edits and submits the registration file to the competent authorities or notified bodies. Develop good relationships with the authorities. Keeps abreast of regulatory changes and analyze whether these changes have an impact on our business. Exchange with the service Materio/Pharmaco/ Biovigilance as part of risk management plans, the submission of periodic reports vigilance and change requests for medical information. Skills and requirements: Education and experience with FDA submissions/registrations for medical devices and drugs. Four years degree required in scientific field. Ability to multi-task effectively under tight deadlines. Expertise with Microsoft Package. Excellent organization and follow-up skills. High level accuracy and attention to detail. High level of discretion and confidentiality. Ability to communicate in a clear and articulate manner. By interest please forward your application to stephanie.ehrenberg@macopharma.de.

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Director of Collections (Full Time). We are looking for inspirational leader, customer-focused individuals who value integrity, accountability, collaboration and communication, to join our team as the Director of Collections. We are the sole blood bank for the State of Hawaii. We need people who are dependable, detail-oriented and comfortable following established procedures. For more information about us, visit our website at https://www.bbh.org/. This position reports directly to the Chief Operating Officer and the ideal Director of Collections candidate is a highly motivated individual with exceptional customer service skills who is able to work independently while managing multiple priorities and provides effective leadership, supervision and direction to ensure excellent services and an adequate, safe, pure and potent blood supply for the operations of Collections. Must possess excellent written and verbal communication skills, be organized and creative, and have the ability to effectively evaluate and solve critical problems. Minimum of eight years' progressively responsible experience in a blood center, healthcare or other relevant environment with a minimum of five years' proven experience in positive management of multiple direct reports and budget experience. For complete job description and to apply, send resumes to hr@bbh.org.

Reference Laboratory Supervisor (Full Time). Blood Bank of Hawaii (BBH) is seeking a successful leader to oversee and coordinate all reference lab work and product quality control testing services. We are a nonprofit, community-based organization that provides blood components and clinical/technical services to hospitals, and patients throughout Hawaii. The ideal candidate will encompass a high standard for accuracy, follow-up and follow-through, and thrive in an environment where problem solving is a necessity. Will work with team members ensuring compliance at all times, and will also be responsible for the supervisory functions offering support and guidance to personnel. The incumbent will also serve as a technical resource to hospitals and other departments outside their primary responsibility. Minimum qualifications include baccalaureate degree in Medical Technology or in a related science from an accredited college or university; certified Medical Technologist by the ASCP. Previous work experience as an MT in hematology and immunohematology preferred. To apply, please submit a resume and cover letter to HR@bbh.org. BBH is an equal opportunity employer. We do not discriminate on the basis of age, race, sex, religion, color, national origin, ancestry, marital status, disability, sexual orientation, arrest and court record or any other protected category recognized by state and federal laws.

Assistant Manager of Component Laboratory. Innovative Blood Resources is seeking an Assistant Manager of Component Laboratory. Responsibilities: Supervise personnel and coordinate operations with the component evening lab. Ensure the lab's compliance and help with process improvement. Provide manufacturing support to staff when needed. Qualifications: Bachelor's degree: in

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Chemical, Physical, Biological Science, or Medical Technology. Two years component laboratory experience and one year supervisory. Experience with data management systems and Microsoft Suite. Apply today! View full job descriptions on www.innovativebloodresources.org/careers/. Applicants must apply and submit a resume online to be considered.

Clinical Lab Manager (San Francisco, CA; Req: 191475). Since 1941, Vitalant (formerly known as Blood Centers of the Pacific) has proudly served as a leader in the blood banking industry. We are a globally-recognized leader in blood transfusion medicine. Requirements: Bachelor's degree required. Master's degree preferred. Must satisfy CLIA requirements for High Complexity Testing required. Immunohematology Reference Laboratory (IRL). Specialist in Blood Banking (SBB) certification required. CA CLS/MT required. Seven years clinical laboratory experience required. To include: three years supervisory experience. Previous supervisory experience and experience in molecular techniques, immunohematology/ IRL techniques, automated testing preferred. Please click here to apply. EOE

Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a **Medical Director**. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefits package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our ***Careers*** page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.