FDA Revises Zika Testing Guidance

The U. S. Food and Drug Administration (FDA) has revised the Zika testing guidance for reducing the risk of transmission of Zika virus by blood and blood components.

This guidance replaces the August 2016 guidance and implements the Blood Products Advisory Committee (BPAC) recommendation for converting to minipool (MP) from routine individual donation (ID) nucleic acid testing (NAT), a position that America’s Blood Centers has advocated for on behalf of its member blood centers, most recently in joint comments submitted with AABB and the American Red Cross to the FDA Zika blood donor screening docket.

“[W]e are announcing that we have revised our recommendations for testing blood donations for the Zika virus,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research in an agency statement. “When Zika virus first emerged, the unknown course of the epidemic and the observed severe effects from the disease indicated that individual donor testing was needed to ensure the continued safety of the blood supply.”

The guidance states that compliance can be achieved either by testing all donations collected in the U.S. and its territories with a licensed NAT for Zika virus “using either MP NAT or ID NAT,” or through the collection and preparation of blood components using pathogen reduction (PR) technology with an FDA-approved PR device, which is currently available for use with platelets and plasma.

Future flexibility is provided in the guidance if a PR device “becomes available for whole blood or red blood cells, you may implement pathogen reduction technology for such products rather than testing the donations as described in section IV.A.1. of the guidance (21 CFR 610.40(a)(3)(ii)(B)),” according to the guidance. At this time, two testing platforms have FDA approval, the Roche Cobas and Grifols Procleix Panther systems.

“Now, given the significant decrease in cases of Zika virus infection in the U.S. and its territories, we are moving away from testing each individual donation to testing pooled donations. This is usually more cost effective and less burdensome for blood establishments. However, the FDA will continue to monitor the situation closely, and as appropriate, reconsider what measures are needed to maintain the safety of the blood supply,” added Dr. Marks in the agency statement.

(Sources: FDA Guidance, 7/6/18; FDA Statement, 7/6/18) ✶
**DoD Granted Emergency Use Authorization for Freeze Dried Plasma**

The U. S. Food and Drug Administration (FDA) announced that it has given emergency use authorization to the U.S. Department of Defense (DoD) for pathogen reduced (PR) freeze dried plasma produced by Centre de Transfusion Sanguine des Armées (referred to as French FDP in the emergency use authorization). “Through our collaborative program with the DoD, they’ve made clear the importance of access to freeze-dried plasma in initial efforts to control hemorrhage from battlefield trauma,” said FDA Commissioner Scott Gottlieb, MD in an agency statement. “Granting this authorization will support access to this important product in the event it’s needed. The FDA remains deeply committed to implementing an enduring pathway to ensure that these potentially life-saving medical products are made available in the most expeditious, safe and effective manner possible.” The agreement permits the use of freeze dried plasma in the treatment of hemorrhage or coagulopathy for U.S. military members during emergency situations involving combat. The FDA and DoD collaborated on a work plan in January 2018 to lay the framework for the emergency use authorization.

(Source: FDA Statement, 7/10/18)

**ABC Submits Letter of Support for Replacement of High-risk Cesium Irradiators**

ABC voiced its support on behalf of member blood centers for language in the House fiscal year 2019 National Defense Authorization Act that extends the current program for replacing and eliminating high-risk cesium irradiators. In a letter to Senators John McCain (R-Ariz.), Jack Reed (D-R.I.), Deb Fischer (R-Neb.), and Joe Donnelly (D-Ind.) of the Senate Armed Services Committee, ABC asked that they accept the provision extending the replacement program currently within the National Regulatory Commission (NRC) Office of Radiological Security (ORS) to 2027. The current program is set to expire in 2020. ABC has actively collaborated with the NRC to reduce the risks posed by Cesium-137 in powder form, which exists in cesium irradiators used by blood centers to prevent graft versus host disease from blood product transfusions.

The letter notes the merits of cesium irradiators to blood centers due to their reliability and low maintenance requirements for 25–30-year periods. It also raises concerns of ABC member blood centers incurring significant additional costs to retire their current irradiators (on average ABC members have 12 years of life remaining in their cesium irradiators worth $3.5 million) while operating on small margins. The letter also acknowledges the need to replace these irradiators with either x-ray technology or potentially pathogen reduction technology moving forward. The benefits of continuing to fund the ORS replacement program are stated within the letter as, “[t]his program began in 2014 and since its inception, seven of our member blood centers have participated. ABC member surveys demonstrate a 30 percent reduction in cesium (continued on page 4)
2018 Summer Meeting

The 2018 Summer Meeting and Medical Directors Workshop will be held in Montreal, Québec hosted by ABC member Héma-Québec July 31st – August 2nd at the Hotel Omni Mont-Royal. Don’t miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Medical Directors Workshop, the Scientific, Medical, and Technical Forum, the Business Forum, and ABC Members Meeting. Additionally, Héma-Québec will host a networking event. Member and government registration rates are below:

- 3-Day Summer $760: MD Workshop, SMT Forum, Business Forum, Members Meeting
- 2-Day Summer $655: SMT Forum, Business Forum, Members Meeting
- 2-Day Medical $655: MD Workshop, SMT Forum, Business Forum
- 1-Day Medical $435: MD Workshop

You will need a U.S. Passport to enter Canada. Please be sure to check the expiration date.

Hospital, public, and emeritus registration rates are available here. Contact Leslie Maundy for available sponsorship opportunities. Click here for additional meeting information.

ABC Executive Compensation Survey Launched

ABC’s annual Executive Compensation Survey has launched. The survey is a benchmarking tool for executive leadership and human resources professionals at ABC member blood centers that features aggregate data on salaries and benefits for C-suite members—including chief executive officers, chief operating officers, chief financial officers and medical directors. Blood centers are grouped by center size and budgets.

As with all ABC surveys, data is strictly confidential and anonymized. With this information, ABC can provide a strategic overview of the industry and where blood organizations need to position themselves to compete in the future. All members are encouraged to participate in the survey and should have received the survey link via email. If you have not received the link or have any questions, please contact Sameer Ughade. The survey closes July 20th.

WEBINAR SAVE THE DATE

ABC SMT Journal Club Webinar

August 7, 2018 at 3 PM EDT

Additional information including login details available to ABC members in MCN 18-028.

ADRP Webinar

Register for the upcoming July 19th ADRP webinar entitled “Ferritin Deferrals A Global Blood Banking Issue” scheduled to take place at 2 p.m. EDT presented by OneBlood Chief Medical Officer Rita, Reik, MD. The webinar will explore the current deferral recommendations and provide attendees with insight into mitigation strategies used by OneBlood. To become an ADRP subscriber visit: https://www.adrp.org/Join-Now.
CESIUM IRRADIATOR LETTER (continued from page 2)

irradiator with a concurrent 220 percent increase in x-ray devices since 2008. This shift has taken place since the inception of the ORS program. The continued funding of this program is vital to ensure the complete phase-out of cesium irradiator. ABC fully supports extending the acceleration of replacement of cesium blood irradiation sources and respectfully requests that the Senate agree to the House language.”

(Source: ABC Letter, 7/11/18)

BRIEFLY NOTED

The *Los Angeles Times* and *Kansas Star* recently published stories concerning the blood donation policy of the U.S. for men who have sex with other men (MSM). The respective authors question the need for the current U.S. Food and Drug Administration (FDA) MSM guidance. The pieces suggest that the current 12-month deferral is medically unnecessary and discriminatory, while contributing to local blood shortages. Additionally, the authors present the case for deferrals based on individual behaviors similar to a blog post that appeared on the *Economist* website in April, “[g]ay men can donate blood in Argentina, Italy, Spain, Poland and even Russia, among others. Rather than screening out potential donors based on sexual orientation, countries like Italy engage in individual sexual risk assessment and evaluation (so-called “assess and test”), wrote Nicholas Cuneo, MD in the *Los Angeles Times* op-ed. Megan McSeveney from the FDA told the *Kansas Star* that FDA is “fully committed in its actions to facilitate change” as the agency.

(continued on page 5)
BRIEFLY NOTED (continued from page 4)

examines new donor evaluation methods. She added that “[d]eveloping the scientific information that is needed to further change blood donor policies will take time and effort.”

(Sources: Los Angeles Times, Rules for gay blood donors are based on outdated fear, not science, 7/5/18; Kansas City Star, ‘Completely unreasonable’: Gay men can donate blood — if they give up sex, 7/1/18)

The U.S. Department of Health and Human Services’ (HHS) Tick-borne Working Group will hold an online meeting on July 24th. This will be the group’s seventh meeting and will be a “review and vote on the content of the five chapters that will be submitted into the Working Group Congressional Report,” according to a meeting announcement in the Federal Register. The virtual meeting will be available via webcast. The interface of tick-borne infections and transfusion is not a primary focus of the group. Additional information is available on the HHS site. Individuals who would like a copy of the draft chapters may email their request.

(Source: Federal Register Meeting Notice, 6/27/18)

The World Health Organization (WHO), the World Bank, and the Organization for Economic Co-operation and Development (OECD) have published the findings of a joint report linking the trend of rising healthcare costs globally to low quality healthcare in the form of “inaccurate diagnosis, medication errors, inappropriate or unnecessary treatment, inadequate or unsafe clinical facilities or practices, or providers who lack adequate training and expertise.” According to the report, an estimated 15 percent of hospital expenditures in high-income countries is due to errors in care or patients contracting infections while hospitalized. “At WHO we are committed to ensuring that people everywhere can obtain health services when and where they need them,” said WHO Director General Tedros Adhanom Ghebreyesus, PhD in the news release. “We are equally committed to ensuring that those services are good quality. Quite honestly, there can be no universal health coverage without quality care.” Proposed solutions include strong national healthcare policies and strategies from governments, competent care from health providers with a focus on the patient experience, and informed and empowered citizens that are engaged in healthcare decisions. The full report is available on the WHO website. “Without quality health services, universal health coverage will remain an empty promise,” said OECD Secretary-General Ángel Gurría. “The economic and social benefits are clear and we need to see a much stronger focus on investing in and improving quality to create trust in health services and give everyone access to high-quality, people-centred health services.”

(Source: WHO New Release, 7/5/18)

The Sickle Cell Disease Association of America, Inc. launched “Get Connected” a patient powered registry for individuals with sickle cell disease. The registry will serve as a resource for anyone with sickle cell disease, their family members, individuals with sickle cell trait, healthcare organizations, and clinical researchers. “Get Connected” allows patients improved access to healthcare specifically targeted for sickle cell disease through research initiatives, health services, and medical information on diagnosis and treatment. “We are very excited to officially launch ‘Get Connected,’ the first patient powered registry for sickle cell disease,” said Sickle Cell Disease Association of America President and CEO Beverley Francis-Gibson. “This database provides a significant benefit for the sickle cell community and for our efforts to share information, resources, and to collect data that can be leveraged for advocacy, research and awareness efforts. We encourage individuals to register today.” Registration is available on the “Get Connected” website.

(Source: Sickle Cell Disease Association of America, Inc. News Release, 6/18/18)
REGULATORY NEWS

The U.S. Food and Drug Administration’s (FDA) Centers for Biologics Evaluation and Research (CBER) has released six gene therapy guidances according to an agency statement. Three are disease-specific including a draft guidance for therapies that treat hemophilia. “Once finalized, this new guidance will provide recommendations on the FDA’s current thinking on clinical trial design and preclinical considerations to support the development of these gene therapy products,” said FDA Commissioner Scott Gottlieb, MD. “Among other elements, the draft guidance provides recommendations regarding surrogate endpoints that could be used by sponsors pursuing accelerated approval of gene therapy products that are intended for treatment of hemophilia.” The two additional disease-specific guidances cover retinal disorders and rare diseases, while the other three preexisting guidances are related to manufacturing gene therapies. “In the past 12 months, we’ve seen three separate gene therapy products approved by the FDA. This reflects the rapid advancements in this field. In the future, we expect this field to continue to expand, with the potential approval of new treatments for many debilitating diseases. These therapies hold great promise. Our new steps are aimed at fostering developments in this innovative field,” added Commissioner Gottlieb.

(Source: FDA Statement, 7/11/18)

The Centers for Medicare and Medicaid Services (CMS) will exercise enforcement discretion for the laboratory date of service policy until January 2, 2019. This includes diagnostic laboratory tests and molecular pathology tests that are subject to the new date of service policy. Additional information is available on the CMS website.

Video recording from the CBER 2018 Science Symposium are available. The two-day symposium recordings are divided into six parts. Links to the recordings can be found on the FDA website for one year. Topics that may be of interest to the blood community are:

- Blood Safety and Availability: Regulatory and Scientific challenges for Emerging and Re-emerging Infectious Diseases (John Hobson, PhD, Deputy Director, Office of Blood Research & Review);
- Benefit–Risk Assessment to Support Management of Transfusion-Transmission Risk of Infectious Diseases (Hong Yang, PhD, Principal Investigator, Office of Biostatistics and Epidemiology);
- The Human Cell Atlas (Aviv Regev, PhD, Massachusetts Institute of Technology (MIT), Chair of the Faculty and Core Member, Broad Institute of MIT and Harvard);

(continued on page 7)
REGULATORY NEWS (continued from page 6)

- High-throughput Sequencing for Adventitious Virus Detection to Enhance Safety of Biologics (Arifa Khan, PhD, Principal Investigator, Office of Vaccines Research & Review);
- New Approaches to Improve Stored Cellular Blood Components (CD Atreya, PhD, Associate Director for Research, Office of Blood Research & Review); and
- Bioinformatics of Microbiome: Challenges and Solutions at FDA (Vahan Simonyan, PhD, Lead Scientist & Project Director, High-Performance Integrated Virtual Environment, CBER).

(Source: FDA Announcement, 6/29/18)

PEOPLE

Deanna Renaud has been named Executive Director of the Community Blood Bank of Northwest Pennsylvania & Western New York by the board of directors. She joined Community Blood Bank in 2006 and most recently served as the director of donor services leading the recruitment, collections, and communications/marketing departments. Ms. Renaud has also previously held the roles of mobile drive coordinator and manager of donor recruitment. She holds a bachelor’s degree in Communications and Media Studies from Penn State Behrend (Erie, Penn.).

(Source: Erie News Now, Community Blood Bank Appoints New Executive Director, 7/2/18)

STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Daily updates are available at:

www.AmericasBlood.org
COMPANY NEWS

Cerus has announced that U.S. Department of the Navy will begin using pathogen-reduction (PR) technology on apheresis platelets. “We are pleased that the U.S. Navy is expanding the use of pathogen-reduction technology to treat platelet components throughout its entire blood collection system,” said Cerus President and CEO William ‘Obi’ Greenman. “By fully adopting pathogen reduction, the U.S Navy Blood Program is providing our Nation’s Sailors, Marines, and their families around the globe access to platelets with reduced risk of transfusion transmitted infection (TTI) from known and emerging pathogens.” The Navy’s seven blood donor collection facilities are expected to fully implement PR technology for all apheresis platelet components by the end of this calendar year. The complete instruction from the Navy’s Bureau of Medicine and Surgery is available.

(Source: Cerus News Release, 7/10/18)

GLOBAL NEWS

The Dutch Ministry of Health recently published a report on the results from a survey designed to gain insights into the blood systems within western European countries. Twenty-two nations participated in the survey with most of the European respondents being blood systems run by government entities at the national or local level. The report, authored by Martin Gorham and Jim MacPherson, found that most of the responding countries have self-sufficiency models regarding the blood supply and blood components for transfusion. However, many of the nations surveyed lacked self-sufficiency for “plasma-derived medicinal products.” The report also contains descriptions of the demographics, economy, healthcare, and blood systems of the participating countries.

(Source: Dutch Ministry of Health Report, 2/1/18)

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!

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) 899-2621. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

2018

July 18-19. FDA Blood Products Advisory Committee Meeting, Silver Spring, MD. More details available here.


July 31-Aug. 2. Summer Meeting & MD Workshop, Montreal, Québec. Contact: ABC Meetings Dept. Phone: (202) 654-2917; e-mail: meetings@americasblood.org.

(continued on page 9)
CALENDAR (continued from page 8)

Sept. 5-7. 3rd European Conference on Donor Health and Management, Copenhagen, Denmark. More details available here.

Sept. 11. 37th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD. More details available here.


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. 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.

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

Senior Director of Blood Operations. LifeShare Blood Center is seeking a Senior Director of Blood Operations (SDBO). The SDBO is responsible for the management, organization, and leadership of LifeShare Donor Center locations. Regional Directors of each location report to this position. The SDBO is responsible for the oversight of reaching collection goals and ensuring community involvement of the Regional Directors. The SDBO must ensure that all personnel are following expected processes, policies, and SOPs. Responsible for team members to adhere to all cGMP, SOP, FDA, AABB, and other regulatory bodies, as well as departmental policies and procedures. Responsible for meeting quality standards while actively ensuring compliance. Requirements include bachelor’s degree in health or related field, four plus years’ blood banking experience or five years in progressively responsible management position and/or five years working in or leading sales team. Demonstrated experience in leading teams in a regulated environment preferred. Must have working knowledge and understanding of CLIA, FDA, OSHA and AABB regulations and statutes, as well as cGMP. Knowledge of strategic planning, budgeting, organizing and implementing required. To apply, please visit: www.lifeshare.org/careers.

Part Time MT/MLT/MLS (MedCity Dallas & JPS Hospital in Fort Worth, TX). The Medical Technologist will report to the Manager or designee of Reference & Transfusion Services. The incumbent will participate in all activities in the R&T Services to include but not limited to: 1. Support Carter BloodCare’s vision, mission and core values. 2. Maintain compliance with Carter BloodCare’s attendance policies. 3. Perform testing and services associated with assigned departmental duties. These duties are in the scope of complexity according to accrediting agencies. 4. Participation in competency, proficiency, and educational opportunities. By accomplishing these duties, the MT ensures that daily operations in the R&T laboratories meet and follow all established guidelines, provide excellence in service and meet the needs of all R&T customers. Shifts: Nights (MCD), weekends (JPS). Qualifications: Associates or bachelor’s degree in Biology/Chemistry/Laboratory Sciences or related field required. MLT (ASCP), MT (ASCP), BB (ASCP), MT (AMT) or equivalent required. Recent graduate from an accredited Clinical Laboratory

(continued on page 10)
POSITIONS (continued from page 9)

Sciences (CLS) program within the last five years and currently board eligible. Carter BloodCare is an EEO/Affirmative Action employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing. To apply go to http://www.carterbloodcare.org/, click on Careers.

Director of LifeCord. LifeSouth Community Blood Centers is currently seeking an individual to join our team as the Director of LifeCord in Gainesville, FL. This position is responsible for overseeing the cord blood collections and cellular therapy initiatives within the organization through the LifeCord program. LifeCord is a public, community-based cord blood bank that collects and stores umbilical cord blood for the purpose of clinical cures and basic research in the field of stem cell transplantation. LifeCord is a program of LifeSouth which performs community and donor education, cord blood collection and processing, distribution of cord blood units and evaluation of transplant outcomes. LifeCord also works to increase the diversity of donors from which cord blood is collected. Bachelor’s degree required. Concentration in healthcare or science-related field preferred. Two years of management or supervisory experience required. Valid driver's license required. Must meet and maintain LifeSouth driver's eligibility requirements. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Follow this link to apply: https://lifesouth.careerplug.com/jobs/789460/apps/new.

Medical Director. LifeSouth Community Blood Centers is currently seeking an individual to join our team as a Medical Director in Gainesville, FL. The selected candidate will be expected to contribute significantly to LifeSouth’s strategic goals and provide medical oversight for the company. M.D. or D.O. degree with post-graduate training in blood banking/transfusion medicine required. Must obtain and maintain an active medical license in Florida, Georgia and Alabama. Must be board certified or eligible in blood banking/transfusion medicine, pediatrics or clinical pathology. Valid driver’s license for state of residence is required. Must meet and maintain LifeSouth driver’s eligibility requirements. Must be willing to travel as necessary. Must be on call as necessary. Starting pay based on qualifications and relevant experience. Travel and relocation expenses are reimbursable. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Follow this link to apply: https://lifesouth.careerplug.com/jobs/789460/apps/new.

Division Director. Hoxworth Blood Center seeks a qualified, experienced Division Director to maximize the blood products collected and increase our ability to deliver existing and new products to customers. This Senior Level Director reports directly to the COO. Primary responsibilities: Eliminate inefficient processes, provide meaningful donor satisfaction data, collect new products for our donors, reduce products lost, ensure collection records are completed and issues are resolved within 24 hours, maximize donor operations so Hoxworth has a combination of blood products to resource share $650,000 in products by end of year one, increase recovered plasma sold and implement the collection of Source Plasma. Requirements: bachelor’s degree with nine (9) years of experience; or associate’s degree with at least eleven (11) years of experience. Degree must be in a related field and related experience requires at least five (5) years of direct supervision. Apply to http://www.uc.edu/hr/careers.html.