OBRR Director Stepping Down

Jay Epstein, MD is leaving the position of director at the U.S. Food and Drug Administration’s (FDA) Office of Blood Research and Review (OBRR). His career at FDA spanned 36 years, including 22 years leading OBRR. Dr. Epstein will be assuming a new role as senior advisor for international blood regulatory affairs in the immediate office of the center director as of March 4th. Nicole Verdun, MD, deputy director at OBRR, will serve as acting director, during the search for Dr. Epstein’s successor.

“Jay has been the face of OBRR for more than two decades, not only to us in [Center for Biologics Evaluation and Research] (CBER), but to the blood banking community across the country and around the world,” said Peter Marks, MD, PhD, director of CBER in an email announcement on February 14th. “Jay’s leadership, dedication and commitment to promoting and protecting the public health are exemplary. His contributions to product and policy development in the blood area are too numerous to recount here. It is precisely because of his expertise and global standing that Jay is an ideal fit for this new position focusing on international blood regulatory affairs.”

Dr. Epstein’s new role will consist of “close interactions with the World Health Organization (WHO)” as CBER strives to enhance global public health. “His expertise will be critical in working with WHO on capacity building for blood regulatory systems in low-and-middle income countries, especially in Africa and Asia,” added Dr. Marks in the email announcement. “While I know this is a significant change for OBRR, we’re very fortunate that he will be continuing this work from within CBER.”

Dr. Epstein received an A.B. degree from Harvard and a medical degree from the State University of New York Downstate College of Medicine. He completed internal medicine and clinical infectious diseases training at The George Washington University Hospital in Washington, D.C. and is board certified in both internal medicine and infectious diseases. “Dr. Epstein, unsurprisingly trained in infectious diseases, is certainly the most articulate scientist and regulator with whom I have had the pleasure to work during my career in transfusion medicine,” said Louis Katz, MD, chief medical officer for America’s Blood Centers (ABC). “His bulldog-like commitment to the safety of blood and its recipients is a shining example of what makes public health and medicine noble callings. I am sure I speak for my colleagues when I thank him for his tenure at OBRR and wish him well moving forward.”

(Source: Email Announcement from CBER’s Peter Marks, 2/14/18)
Trump Administration Places Limits on Use of Guidance Documents

_The New York Times_ reported this week on President Trump’s administration approval of new limitations being placed on guidances issued by federal agencies, “an action that could have sweeping implications for the government’s ability to sue companies accused of violations.” Guidances act as an important tool particularly for government agencies in highly regulated industries such as health care and transfusion medicine and are often used to clarify or interpret regulations. These limitations were issued by Rachel Brand, the third highest ranking official within the U.S. Department of Justice (DOJ). She stated that the DOJ will not “use its enforcement authority to effectively convert agency guidance documents into binding rules…and may not use noncompliance with guidance documents as a basis for proving violations of applicable law,” according to the _New York Times_. The administration noted that the policy covers all civil lawsuits “filed on behalf of the federal government to impose penalties for violations of federal health, safety, civil rights or environmental laws,” and will be applied broadly. The policy was issued on January 25th. Inquiries from ABC to the Center for Biologics Evaluation and Research (CBER) on implication for the blood community await a more complete understanding by CBER.

(Source: _New York Times_, _Administration imposes sweeping limits on federal actions against companies_, 2/10/18) ♦

**Joint Comments on HES Removal**

ABC, AABB, the American Society for Apheresis (ASFA), and the American Red Cross (ARC) submitted joint comments of opposition regarding Requests that the FDA immediately require the removal from the market of [hydroxyethyl starch] (HES) [intravenous] (IV) solutions in a petition submitted by Public Citizen. The ABC _et al._ comments label the complete removal of HES as “unwarranted” and state, “the broad case made for removal of the product from the market ignores, and in fact does not even recognize, other uses for HES, where available data do not suggest problems like those seen associated with resuscitation.” The organizations believe “separate considerations” must apply for HES use in therapeutic and donor apheresis such as white blood cell reductions for the treatment of hyperleukocytosis and where HES is used for umbilical cord blood, bone marrow, and peripheral blood hematopoietic stem cell processing, storage and transplantation. The organizations acknowledge potential adverse reactions from HES during resuscitation, but feel appropriate mitigation short of de-licensure can be accomplished with clearer guidelines on disclosure of risks from HES to donors and guidelines for “maximum exposure” to HES over time. “We believe it is likely that the apparent safety of HES seen by the transfusion medicine and cellular therapies communities relates to the use of lower doses than in resuscitation and perhaps the presence of fewer severe contributory comorbidities in most of the donors and patients we expose to HES, compared to the resuscitation population.” The comments may be viewed in their entirety here.

(Source: ABC, ARC, AABB, ASFA _Joint Comments_, 2/6/18) ♦
56th ABC Annual Meeting Registration

Registration is open for America’s Blood Centers (ABC) 56th Annual Meeting in Scottsdale, Ariz. March 17th – 19th at the Scottsdale Plaza Resort. 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 Celso Bianco, MD Lectureship, the Scientific, Medical, Technical Forum, and the 21st Annual Awards of Excellence. Additionally, ABC member Blood Systems Inc. will host a networking event at the Musical Instrument Museum. Please make your hotel reservations by February 23rd to ensure best availability and the group rate. Click here for additional details. Contact Leslie Maundy for available sponsorship opportunities.

SAVE THE DATES

- Process Improvement Test Cases: Best Bang for Your Bucks Webinar
  February 20th at 3 PM EDT
  A registration link and additional details are available here.

- ABC SMT Journal Club Webinar
  March 29th at 2 PM EST
  Additional details coming soon!
RESEARCH IN BRIEF

Danish investigators report a trial of parenteral iron to address donor iron depletion. Oral iron replacement use is fraught with issues of adherence and dose-dependent tolerance that impacts adherence. Transfusion medicine specialists at Copenhagen University Hospital and Aalborg University in Denmark have reported a double blind, randomized, placebo (saline) controlled trial of iron isomaltoside as a single 1,000 mg infusion over 15 minutes after a baseline blood donation. Eighty-five female first time donors with hemoglobin levels of ≥12.5 g/dL and plasma ferritin levels below 60 ng/mL were randomized. Three donations, at baseline 12 and 24 weeks, were required to complete the trial. The hemoglobin in the iron group rose 0.35 grams more than the placebo at week 12 and 1.25 grams at week 24 in the full analysis set. Ferritin levels were significantly higher in the iron group as well. Treatment emergent adverse effects (TEAE) were reported in 68.3 percent of the treatment and 75.6 percent of the placebo recipients. There were two severe TEAE in the iron group (one spontaneous miscarriage and one pregnancy) and one in the placebo group (spontaneous miscarriage). All were assessed by blinded investigators as unrelated to the study infusion.


HIV test seeking correlates among European men who have sex with men (MSM) described. Epidemiologists at the European Centers for Disease Control, the Robert Koch Institute, and London School of Hygiene and Tropical Medicine report the results of a survey of MSM with regard to HIV testing and blood donation. Despite a variety of donor deferral policies for this group, some MSM continue to present to blood collection facilities. This behavior is statistically associated with being “less open” about their sexual preferences, and having more limited access to anonymous or confidential “MSM-friendly” health services in less densely populated venues. These associations may be useful both to inform strategies for the provision of services to MSM and to design improved approaches to the reduction of HIV risk in the blood supply.


(continued on page 5)
RESEARCH IN BRIEF (continued from page 4)

Should you ask your prospective donors “would you take a blood transfusion if you needed it?” The blood community has leaned strongly on altruism to motivate donors—the idea that when you donate you get that good feeling that comes with helping others. A United Kingdom report of two small studies suggests that there is a subset of donors motivated by the concept of “voluntary reciprocal altruism”—essentially a reciprocal fairness construct based on an understanding that if they would accept transfusion, then they should be willing to donate for others to ensure blood is available. The studies used a variety of methods to explore their hypotheses, but there have been no trials of applying this principle. They conclude “[w]e advocate a clinical trials model for behavioural interventions. This study shows why experiments are a valuable first step.” The report adds that “[t]he next step would be to conduct acceptability trials to develop the accumulated evidence before a full randomized controlled trial and ultimate deployment of a campaign.”

Citation: Ferguson, E. and Lawrence, C. It is only fair: blood donors are more sensitive to violations of fairness norms than nondonors — converging psychometric and ultimatum game evidence. Vox Sanguinis. 2018. doi: 10.1111/vox.12636.
for combinations of these approaches. The review is suitable to provide a non-physician/scientist an understanding of current and potential future directions in this field.


**BRIEFLY NOTED**

**New and improved 2017 National Blood Collection and Utilization Survey (NBCUS) to launch at the end of this month.** The Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) will launch the NBCUS on February 28th and are encouraging blood centers to participate. This survey seeks data on the collection and transfusion of blood for the 2017 calendar year. “The NBCUS is our premier recurring assessment of the status of blood collection by U.S. blood centers and blood use in hospitals,” said ABC Chief Medical Officer Louis Katz, MD. “It is an invaluable resource to many of us trying to understand where our advocacy efforts should be aimed and to identify and quantify, with minimal sampling bias, the trends that are so critical for both operational and strategic planning in the blood community. CDC has made improvements to the process that should result in easier participation and more timely reporting. The agency has reached out to ABC members individually to request participation. Virtually all ABC members have committed to responding, for that the ABC staff is most grateful.” All participants will receive e-mails from CDC with a secure web-link to complete the survey. Upon receipt of the launch notification e-mail from CDC, you may contact Jefferson Jones, MD, MPH in the CDC Office of Blood, Organ, and Other Tissue Safety with questions or issues.

**NHLBI workshop on tissue oxygenation announced.** The National Heart, Lung and Blood Institute (NHLBI) will sponsor the [Towards Minimally-invasive or Non-invasive Approaches to Assess Tissue Oxygenation Pre- and Post-Transfusion Workshop 2018](https://www.nih.gov/videoCast) in Bethesda, Md. April 23rd - 24th. This workshop will also be available via [NIH VideoCast](https://www.nih.gov/videoCast). Registration is free and seating is limited to the first 100 registrants. The deadline to register is April 13th. It will focus on potential next steps to facilitate the development of new technologies and/or biomarker panels to assess tissue oxygenation in a minimally to non-invasive fashion, pre- and post-transfusion of red blood cells (RBCs). These techniques are needed pre-transfusion to predict who would benefit from RBC transfusions, and post-transfusion to determine if the patient actually benefited (and to be able to test the differential effects of various RBC products with specific characteristics). This workshop will build on a previous initiative focused on assessment tools to evaluate the dynamic changes in microvascular blood flow and tissue oxygenation in clinical research applications. Subject matter experts in multiple disciplines relevant to tissue oxygenation (transfusion, critical care, cardiology, neurology, neonatal/pediatrics, bioengineering, biochemistry, and imaging) will generate recommendations on what the next research priorities would be to combine global “omics” signatures with additional measures to predict who needs RBC transfusion and evaluate RBC effectiveness. For questions about the workshop, contact Margaret Ochocinska, PhD or Simone Glynn, MD.

**The World Health Organization (WHO) plans to form a “health reserve army to tackle emergencies and newly emerging diseases” according to its director general Tedros Adhanom Ghebreyesus, PhD.**

This step is part of a renewed focus on quicker “emergency response” to battle potential pandemic threats. “If anything happens, no country can do it alone,” said Dr. Ghebreyesus. “So, we need to have a health reserve force, or, if you like, a health reserve army in different locations so countries who are better off can
BRIEFLY NOTED (continued from page 6)

help other countries.” His goal is to have 50 countries with “thousands” of “trained health workers” ready to respond to emergencies with their countries covering their expenses.

(Source: Voice of America, **WHO to set up health reserve Army to tackle emergencies**, 2/7/18) ✪

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**Shed Light on Your Future**

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**Effective Leadership: How Do You Rate?**

Check your leadership effectiveness by answering yes or no to the following questions:

- Do you know exactly what you want employees to understand, think, and do in response to your communications?
- Are trust and commitment part of your team’s DNA?
- Do you know what motivates your employees?

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**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) 393-1282. 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.
REGULATORY NEWS

bioMérieux has received 510(k) approval from the U. S. Food and Drug and Administration (FDA) expanding its quality control claims for testing platelets with its BacT/ALERT® BPA and BPN culture bottles. Early culture using these bottles can detect bacterial contamination of platelets. The new approval grants the culture bottles an indication for secondary use as a “safety measure.” Additional information on the approval and application is available on the FDA’s website. The safety measure claim is a prerequisite for 7-day platelet storage. (Source: FDA substantially equivalent 510(k) device information, 2/1/18) ♦

WORD IN WASHINGTON

The Department of Health and Human Services (HHS) Secretary Alex Azar made a whirlwind trip around Capitol Hill this week appearing before the House and Senate Health Committees to testify regarding his agency’s proposed Fiscal Year 2019 budget. A full transcript of both his House and Senate testimony is available, in which he referred to the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) as “crown jewels of American science.” Mr. Azar told the committee that he intends to “[implement] burden reduction measures to reduce costs for grant recipients” at NIH. He added that FDA “needs and priorities must change as the face of medical innovation changes, too. The Budget includes investments for FDA to speed the development and approval of new drugs and medical devices, and to increase the quality and safety of next generation manufacturing practices, including approximately $500 million to strengthen medical product safety development and access.” Mr. Azar also touted the budget’s allocation of $512 million to the Biomedical Advanced Research and Development Authority (BARDA) and $510 million for Project BioShield to address preparedness and biodefense countermeasures, “it also provides $575 million to maintain and replenish the stockpile, the nation’s largest supply of life-saving medical countermeasures that can be deployed in the event of a public health emergency.”

(Sources: House Video Recording & Testimony, 2/14/18; Senate Video Recording & Testimony, 2/15/18)

President Trump issued the administration’s 2019 proposed $4.4 trillion budget. It contained a $1.4 billion increase for NIH funding over last year’s proposal. FDA also would receive a $473 million increase over current spending levels, the largest increase ever proposed for FDA, including $45 million for the Center for Biologics Evaluation and Research (CBER). HHS overall would receive a total of $95.4 billion reported The Hill, with significant funds dedicated to opioid addiction. The Centers for Disease Control and Prevention had its budget reduced by $900 million. “The president’s budget makes investments and reforms that are vital to making our health and human services programs work for Americans and to sustaining them for future generations,” said HHS Secretary Alex Azar in a statement.

(Source: The Hill, Trump releases budget proposal for health department, 2/12/18)

(continued on page 9)
Rhode Island Blood Center recently announced Scott J. Asadorian, MBA as executive director. He previously served as vice president and chief operating officer since 1995. He follows Lawrence “Larry” Smith who held the role of CEO for the past 29 years. “It’s been a privilege leading the blood center for 29 years, and I’m looking forward to my new role developing growth opportunities for all blood center members of the New York Blood Center system, including the Rhode Island Blood Center,” said Mr. Smith. “I also have every confidence that [Rhode Island Blood Center] will continue to fulfill its life-saving mission under Scott’s experienced and capable leadership.” Mr. Asadorian has a degree in management and a master’s
PEOPLE (continued from page 9)

degree in business administration from the University of Rhode Island. During his tenure at the blood center, he has led donor recruitment efforts in addition to hospital-customer business development, blood center operations, and strategic planning.

(Source: North Kingstown Patch, NK Resident Tapped To Lead Blood Center, 2/14/18) ♠

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

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<th>Total ABC Red Cell Inventory</th>
<th>Percent of Regional Inventory at 2 Days Supply or Less, February 15, 2018</th>
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Daily updates are available at:
www.AmericasBlood.org

**IN MEMORIAM**

Jeffrey S. Edwards, the facilitator of ProGuide's Blood Operations Optimization Training Sessions (BOOTS) since its inception in 2010, passed away on January 5th in Jacksonville, Fla. He was a principal architect of early supply chain theory at Motorola and actively engaged with the Toyota Production System, both progenitors of most Lean Programs in practice today. Mr. Edwards began working in the blood banking industry with ProGuide nearly 20 years ago and consulted globally at more than 30 blood centers. After years of

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IN MEMORIAM (continued from page 10)

developing relevant materials, BOOTS was launched to wide acclaim in Orlando, Fla. with participation from a majority of ABC, Blood Centers of America, Inc., and HemeXcel member blood centers, in addition to international participation from Canadian Blood Services and NHS Blood and Transplant in the United Kingdom. The program featured a wide array of topics including process optimization, cost reduction, and best supply chain management practices, helping the employers of attendees save millions of dollars from the projects they developed at BOOTS. Mr. Edwards will be honored by having the program bear his name when it re-launches in 2020.

MEMBER NEWS

LifeShare Blood Center recently announced several additions to their leadership team. Carrie Hrisafi, CPA has been appointed chief financial officer. She joined LifeShare in 2014 and previously served as the organization’s director of financial services. A CPA in both Louisiana and Texas, Ms. Hrisafi graduated summa cum laude from the University of Texas at Arlington. Her prior work experience includes accounting firms such as Carr, Riggs & Ingram and PricewaterhouseCoopers. Monica Kalvelage, MSTM, MT(ASCP)MB, SBB has been named chief operations officer. In this role, she will oversee the long-term strategic operations of LifeShare and its immunohematology reference laboratory and scientific support services. Ms. Kalvelage most recently served as the executive director of Technical Operations. Her other previous roles at LifeShare include director of laboratory services and medical technologist. Ms. Kalvelage has a master’s of science degree in Transfusion Medicine from the University of Texas. Margaret Plunkett has been appointed chief administrative officer. She is responsible for overseeing human resources, quality and regulatory services, training, and the information technology departments. She is certified by the Human Resources Certification Institute and the Society for Human Resources Management (SHRM). Ms. Plunkett graduated from Louisiana Tech University with a degree in human resources. Prior roles include executive director of Human Resources at LifeShare and vice president of human resources at Goodwill Industries of Northwest Louisiana. Geri Venable has been named executive director of blood operations. She previously served as the executive director of donor operations. Her responsibilities now include overseeing the planning, organizing, recruitment, collection, processing, and distribution of blood products with teams in Arkansas, Louisiana, and Texas. Ms. Venable has a degree in business administration and currently serves on the AABB Abstract Selection Committee.

(Source: LifeShare Blood Center. Press Release, 2/13/18)

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!
CALANDER

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.)

2018

Feb. 21. General Topics for Blood Bankers in Clinical Laboratory Medicine, Orlando, Fla. For more information, contact Nancy Benitez.


May 8-10. ABC Human Resources & Training/Development Workshop, America’s Blood Centers, Dallas, Texas. More details available here.

May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available here.


Sept. 28. 36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD. 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Recruitment and Retention Manager (Charlotte, N.C.) Come apply your blood banking and recruitment management experience in one of the fastest growing and best cities to live in the country! Community Blood Center of the Carolinas is seeking an experienced and analytical professional for the Recruitment and Retention Manager position in Charlotte, NC. The position is responsible for the development and direction of programs related to recruitment and retention of blood drive sponsors and donors, in order to meet the needs of patients and hospitals in our region. This position works closely with the Director of Marketing, Recruitment and Collections to ensure efficient operation of both center and mobile

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POSITIONS (continued from page 12)

whole blood, red cell, plasma and platelet collection. Supervisory, sales and data analytic skills, as well as blood bank experience highly preferred. Essential functions include, 1) implementing departmental and organizational goals by using planning and strategic agility as the foundation for successful results in meeting objectives; 2) ensuring that qualified and adequately trained personnel are available, and that company personnel policies and standards are administered equitably and consistently; and 3) leading and managing group through further development and emphasis on team building concept. Incorporates integrity and trust within group through example of leadership. Applications should send a resume to Ben Pryor at bpryor@cbcc.us or apply online at www.cbcc.us/careers.