

The Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) Meets to Discuss Sustainability of Blood Supply

ACBTSA, a committee under the Department of Health and Human Services (HHS), met on November 28 and 29 to discuss the RAND study on the sustainability and safety of the U.S. blood supply and make recommendations going forward to the Assistant Secretary of Health Karen DeSalvo, MD, MPH, and her successor in the new administration. The committee and those in the audience noted the report had many flaws—the most glaring of which was the lack of an urgent need to change the structure of the blood supply system.

RAND Report

RAND representative and lead author of the report, Andrew Mulcahy, PhD, presented the findings in the report and discussed its seven recommendations, which were listed in [Newsletter #41](#).

RAND analysts did not investigate the possibility of a fundamental shift in the blood system's structure or management as "under status quo, it (the blood system) seems to operate, in almost all cases, effectively and efficiently, with little evidence of serious shortages, a robust price competition," Dr. Mulcahy said. The system is working how policy makers intended it to, he added. He also noted that, for the most part, "blood gets where it needs to be." The level of urgency he said he heard in last year's ACBTSA meeting was not present during interviews he conducted with stakeholders for this report.

Dr. Mulcahy stressed that the data RAND had to work with was very limited as they were not allowed to view the [National Blood Collection & Utilization Survey](#) (NBCUS) information. Committee members noted that while more data was certainly needed, the report lacked key elements. They also commented that the study was limited in the number of stakeholders providing input; that blood was treated as one product and not as separate



components; and that RAND did not take into account the effect that one major blood center or supplier leaving the marketplace would catastrophic for the nation's blood supply.

ABC President Susan Rossmann, MD, PhD, chief medical officer for Gulf Coast Regional Blood Center, read a prepared statement from the association echoing these concerns. Dr. Rossmann also added ABC's fears that the evolving demographics and limitations on the donor base are essentially ignored in the report; definitions of surge capacity and the "insurance value" of blood are ambiguous; in

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OUR SPACE

ABC President Susan Rossmann, MD, PhD
ABC Chief Medical Officer Louis Katz, MD

What Does it Take to Get Their Attention?

This week, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) met to consider the RAND report on the [sustainability of the blood supply](#). The committee made critical comments and recommendations to the Assistant Secretary for Health, whose office funded the report. ACBTSA established blood is explicitly seen as a public good and we hope rational policy decisions regarding the blood supply system will be forthcoming from the incoming administration.

The report itself is disappointing. This was clearly stated in our [comments to the committee](#) and reflected in the ACBTSA subcommittee presentation. Most crucially, the report does not convey the sense of *urgency* that many of us feel about the system's sustainability. We have appropriately reduced collections to respond to the decline in demand and competition has further reduced our margins. More than half of the nation's blood supply is now being collected by organizations operating at negative margins. Capacity beyond the immediate needs is not available. The committee discussed the declining ability to respond to a surge in demand, such as might occur in a disaster, and the need for a resilient supply to cover day-to-day variations. Collection figures this fall suggest reserves going into the holidays may not be robust, and challenges may lie ahead. However, RAND did not properly recognize nor make any recommendations regarding the "insurance value of blood" and did not use available financial data. This year, the U.S. supplied Puerto Rico's needs until they could address Zika, we are absorbing the impact of the donor final rule, and have emergently implemented mandated Zika testing, all without any significant infusion of "new money" while RAND really limited their conclusions to the apparent absence of widespread shortages that would require urgent action.

We are victims of our own excellent performance and are setting ourselves up for failure. If we only address the issue of crisis after it has occurred, patients will bear the consequences. Other payment approaches need to be developed that recognize the "public good" of the blood supply (think public utilities).

Yet, this has not been a worthless exercise. We in the blood community have come together to discuss this issue. It is eminently clear that we need better DATA to clarify the situation. We cannot rely on global surveys, like the National Blood Collection and Utilization Survey, which produce aggregate, but almost two-year-old data, without sufficiently graphic evidence of bad outcomes to impress RAND. We need a system to supply and demand with more granularity, with local effects, and a real definition of shortages so we will know what the scope of the problem is. Of course, it will be difficult to develop systems without new money. ♦

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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ACBTSA MEETING (continued from page 1)

many ways, the products available to collection facilities in the U.S., such as donor testing platforms, are years behind those marketed in Europe and elsewhere; and that while mergers and acquisitions are continuing, they do not provide financial stability for the system nor reward technological advancement in the field. ABC members can [read ABC's full statement on the Member Site](#).

“While much of the RAND report is accurate, the RAND narrative fails to convey the rapid pace of change in the blood community and the urgency with which solutions must be sought,” she said. “ABC will continue to take a proactive approach to achieve recognition of the high value of blood. We must address the financial crisis affecting the blood community with policy and reimbursement changes that mitigate the developing threat to a sufficient blood supply in the future,” said ABC CEO Christine Zambricki, DNAP, CRNA, FAAN.

AABB President Zbigniew M. Szczepiorkowski, MD, in his statement to the committee, noted the aforementioned shortcomings with the RAND report and included the report did not take into account the federal government's silo system and how that isolating structure contributes to weaknesses that threaten the sustainability of the blood system.

ABC made the following recommendations:

- Blood must be recognized and reimbursed as a “public good” and the destructive competition between blood operators that inhibits innovation and erodes capacity restrained. Antitrust exemption of the blood community and regional public utilities are among the models that may be informative.
- Authority for risk-based decision-making must be conferred on an appropriate body, outside of the Food and Drug Administration, which is explicitly granted the ability to tie safety and technology advances to reimbursement of blood establishments. Reimbursement calculations must be inclusive of safety and technology initiatives, maintenance of capital resources, the insurance value of blood, and explicit levels of surge capacity adequate to support foreseeable disasters.
- The long delays at FDA for product approvals and between identification of issues, draft guidance, final guidance or rule making must be reduced if incentives for innovation are to be preserved.
- Ongoing data collection to assess the status of the blood supply in many dimensions is necessary and appropriate. Systems to do so are being implemented in the ABC data warehouse and already exist within the American Red Cross, together representing more than 90 percent of the US blood collections. Information technology solutions exist to facilitate collection of hospital level data and the Department has the authority to require its provision.

Subcommittee on Blood System Sustainability Response

The ACBTSA subcommittee responsible for oversight of the study then presented their responses to the RAND recommendations.

The Subcommittee agreed with:

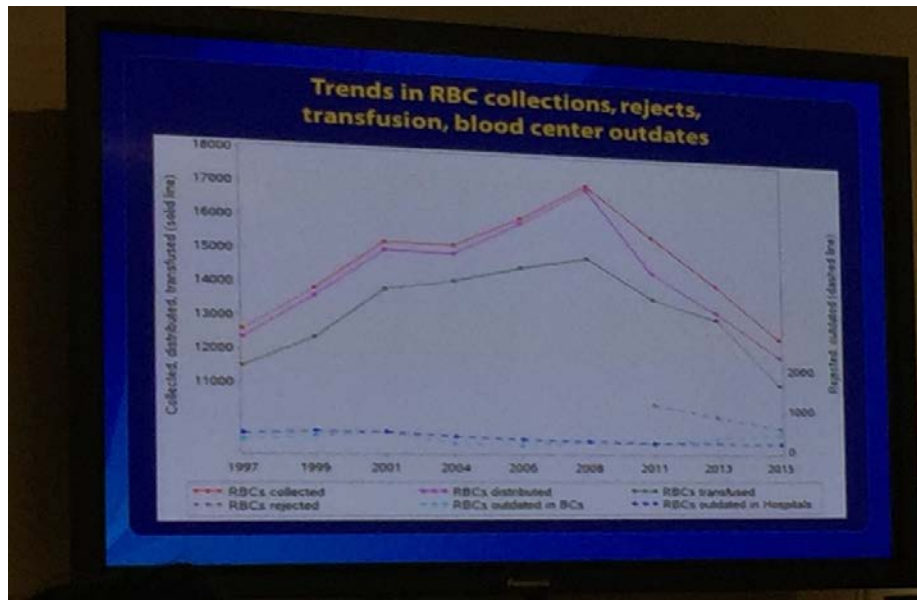
- The need for HHS to support more complete, validated, and long term data programs measuring collections, utilization, hemovigilance, insurance value, and financial relationships in the blood community.
- The need for consensus definitions of resilience and “surge capacity” based on empirical data, and
- Paying blood centers for the maintenance of such capacity and implementation of additional safety measures where the business case was not compelling.



ACBTSA MEETING (continued from page 3)

The subcommittee categorically disagreed that HHS should foster deeper relationships with brokers as a safety net precaution, nor did they agree with the recommendation that emergency use authorizations (EUAs) were an appropriate path to pursue toward helping mitigate revenue losses during recalls and other provider issues. They said more research is needed to determine how much society is willing to pay for the safety of the blood supply and innovative technologies that would help make that supply safer.

The Medical Officer and Deputy Director of the Office of Blood, Organ and Other Tissue Safety at the Centers for Disease Control and Prevention (CDC), Sridhar Basavaraju, MD, presented data, from the 2015 National Blood Collection and Utilization Survey. Dr. Basavaraju noted significant declines in the price and in demand for blood components between 2013 and 2015. For example, there was an 11.6 percent decline in whole blood and red blood cell collections, a 15.7 percent decline in total transfusions in the same two years, and the price of leukoreduced RBCs fell from median \$228 to \$211 per unit.



Before the full ACBTSA recommendations were discussed, members of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) said they would need more patient-centric data and evidence of the consequences to patient care to support the urgency with which the blood community sees the current status of the blood supply.

Moving Forward

“Although the blood system appears, from the outside, to be functioning today, we assess it as very fragile. Based on our experience, expertise and public comments received, the situation has worsened since the committee last addressed this topic,” noted the Committee’s findings to Dr. DeSalvo. Moving forward the committee recommended the items below.

Federal oversight should proactively address the competing forces within the blood system, this includes:

- Ensuring appropriate financial remuneration for infrastructural support to maintain a sustainable and resilient blood supply
- Collecting data in a timely manner to help to drive policy and resource utilization

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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 Seeking Nominations to Select Board Positions

The ABC Nominating Committee is seeking nominations from our member centers for the positions of officer and at-large director Fiscal Year 2018 ABC Board of Directors. Candidates should have a strong interest in conducting the affairs of the organization and advancing the interests of America's Blood Centers' members. Per ABC bylaws, from a slate of member nominees, the ABC Nominating Committee will prepare a ballot for the ABC President's consideration. The Nominating Committee's recommendations will then be submitted to the active membership in advance of the annual meeting. These nominees and any other persons nominated from the floor will be voted upon at the ABC Annual meeting in March in Washington, D.C.

1. A blood center may nominate an officer, director, trustee or employee from within their blood center or from another blood center. Individuals may self-nominate.
2. A blood center may submit more than one nominee for each position. A blood center may submit nominees for at-large director positions representing small, medium and large blood centers regardless of the size of the nominating center.
3. The ABC Nominating Committee is responsible for contacting the nominees and securing their agreement to serve.
4. Please submit your nominations via return email by completing the form on this [MCN](#).

Thank you for your help in selecting our next FY 2018 Board of Directors members! 📌

**ABC's
Got Talent**
.....
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ACBTSA MEETING (continued from page 4)

- Provision of sufficient support for technological innovation with respect to resource sharing and institution of new safety measures as appropriate.

With specific recommendations to:

- Prioritize a review of these findings and develop policies to address the listed vulnerabilities in a timely and expeditious manner
- Examine models of risk based decision making to inform future public policy to include all stakeholders in the vein to vein process from donor to patients and their families, and including all intermediaries, (e.g., blood centers, hospitals, clinicians, medical device developers)
- Develop mechanisms to encourage hospitals and blood centers to participate in data collection programs; this should include collection, utilization, and cost; the Secretary should convene a panel of stakeholders to suggest appropriate data elements
- Explore the potential for direct payment to blood centers to cover the costs of the infrastructure required to maintain adequate supplies for the public good
- Reduce regulatory uncertainty with respect to innovations to encourage investment in their development and implementation.

“I am struck that we are the only developed nation without some form of national blood policy,” said Karen Quillen, MD, MPH, medical director of the transfusion service at Boston University Medical Center, during discussion about the recommendations. “By size, we are bigger [than] every other country in how much blood we use, but we’re the only nation without national input.” ♦

SPECIAL NOTE

In this issue, we have several articles regarding the RAND report to ACBTSA, and have been covering this story for over a year. We at ABC would like to express our personal thanks to Jim Berger, MS, senior advisor for Blood and Tissue Policy under the Office of the Assistant Secretary for Health (OASH) at the Department of Health and Human Services (HHS), and Rich Henry, acting deputy director of the Office of HIV/AIDS and Infectious Disease Policy, for their vision in seeing the need for this work and their perseverance in pursuing it. Jay Menitove, MD, longtime friend of ABC and now chair of ACBTSA, has also been instrumental in supporting an analysis of the blood supply system and moving that effort forward. Much work remains to ensure a robust and sustainable blood supply for the U.S., but these individuals have allowed the discussion to begin. We thank them, and look forward to continuing to work with them in the future. With the changing of the guard as the new administration begins, we also wish to thank Assistant Secretary for Health Karen DeSalvo, MD, and Karen Scott, MD, chief medical officer at OASH, for their support and focus on the issues facing the blood community today and in the future. ♦

Christine S. Zambriski

Susan Postma

RESEARCH IN BRIEF

Hemoglobin-based oxygen carriers (HBOC) could improve survival rates for severely anemic patients for whom transfusion is not an option. In an update to a three-year old study on morbidity and mortality outcomes for the severely anemic who do not receive transfusion (mostly Jehovah Witnesses), researchers found three main outcomes: 1) the current mortality rate associated with severe life-threatening anemia for patients whom transfusion is not an option does not appear to have changed in the last 20 years; 2) mortality for these hospitalized patients appears to be greater than that of surgical populations of patients refusing transfusion; and 3) administering an HBOC to these severely anemic patients has the potential for

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RESEARCH IN BRIEF (continued from page 6)

reducing mortality. The update to a 2013 retrospective analysis on these patients used an additional three publications that examined databases with data on these patients, and found the survival of the 102 patients treated with HBOC-201 in the expanded access programs of Biopure/OPK/HbO2 Therapeutics was greater than those in Beliaev and Duke's studies (HR, 0.44; 95 percent confidence interval, 0.15-0.53).

Citation: Weiskopf R.B., Beliaev A.M., Shander A., *et al.* Addressing the unmet need of life-threatening anemia with hemoglobin-based oxygen carriers. *Transfusion*. November 18, 2016. DOI: 10.1111/trf.13923.

Unrelated donor (URD) HLA-matched bone marrow transplants (BMT) for severe sickle cell disease patients associated with a higher incidence of graft-versus-host disease (GVHD) than expected. In the six-year, phase two, Blood and Marrow Transplant Clinical Trials Network Sickle Cell Unrelated Donor Transplant Study (SCURT) 30 children between the ages of 4 and 19 with predefined severe sickle cell disease received URD HLA-matched BMTs. While the event-free survival after one year was 75 percent, the incidence for GVHD was higher than expected with the cumulative incidence on day 100 of grade II-IV acute GVHD being 28 percent (95 percent confidence interval [CI], 13-45), and 17 percent (95 percent CI, 6-33) for grade III-IV acute GVHD. The cumulative incidence of chronic GVHD at one year was 62 percent. Overall, the study had seven GVHD-associated deaths. GVHD prophylaxis in this study included calcineurin inhibitor, short-course methotrexate, and methylprednisolone and the authors concluded that “this regimen cannot be considered sufficiently safe for widespread adoption without modifications.” This new study from Shenoy *et al* was an important move forward as the first prospective multi-center study on these patients with no related donors—even if the results were not entirely desirable, noted an accompanying commentary to the study. SCURT highlights the importance of using new protocols in clinical trials of allogeneic transplantation is still the best option for cure and of arresting progressive organ damage, notes the commentary.

Citations: Shenoy S., Eapen M., Panepinto J.A., *et al.* A trial of unrelated donor marrow transplantation for children with severe sickle cell disease. *Blood*. November 24, 2016. DOI: <http://dx.doi.org/10.1182/blood-2016-05-715870>.

Roberts I. and de la Fuente J. Sickle cell disease: the price of cure. *Blood*. November 24, 2016. DOI: 10.1182/blood-2016-10-740969. ♦

BRIEFLY NOTED

Novel way to deliver blood. As we have reported in ABC newsletters [28](#) and [16](#), drone companies have been delivering blood in Rwanda and were looking to develop that technology to deliver blood to some remote parts of Maryland. To date, however, no study has been published on the impact on blood after drone transport. Such a study was published in *Transfusion* using six leukoreduced red blood cell units, six platelets units, and six frozen plasma units, placed in a cooler and attached to a drone. The drone was flown for 26.5 minutes and temperatures logged. There were no adverse effects on any of the units and drones appear to be a viable option for transporting blood products.

Citation: Amukele T., Ness P.M., Tobian A.R., *et al.* Drone transportation of blood products. *Transfusion*. November 11, 2016. DOI: 10.1111/trf.13900.

Sex and gender are not taken into account for most medical studies. While we know men and women metabolize medicines differently, the Sex and Gender Equity in Research (SAGER) guidelines were published in April calling for more sex and gender information in medical studies and urged journals to

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BRIEFLY NOTED (continued from page 7)

adopt the new standards. An article in the *Journal of the American Medical Association* (JAMA) called upon clinicians to take the patient's sex into consideration before choosing diagnostic tests, medications, and other treatments and highlighted the differences between in terms of drugs and cardiovascular diseases, separately. An accompanying commentary echoed the authors' concerns and said that considering sex and gender in studies may help eliminate the need for repeat trials and spotlighted important differences in clinical outcomes between the sexes.

Citations: Legato M.J., Johnson P.A., Manson J.E. Consideration of Sex Differences in Medicine to Improve Health Care and Patient Outcomes. *JAMA*. November 8, 2016. DOI: 10.1001/jama.2016.13995.

Clayton J.A. and Tannenbaum C. Reporting Sex, Gender, or Both in Clinical Research? *JAMA*. November 8, 2016. DOI:10.1001/jama.2016.16405.

A new online journal from the American Society of Hematology (ASH). ASH has published its first *Blood Advances*, a new peer-reviewed, open-access journal with Editor-In-Chief Robert Negrin, MD, at the helm. The first issue is live on their [website](#) and will debut in print at the 58th ASH Annual Meeting in San Diego, Calif. ♦

INFECTIOUS DISEASE UPDATES

Texas recognizes their first probable locally-transmitted, vector-borne Zika infection. The Texas Department of State Health Services (TDSHS) and Cameron County Department of Health and Human Services announced the case on Monday. A non-pregnant female Cameron County resident with no travel to Zika-endemic areas tested positive for the virus in her urine, but not in her blood. Through last week, TDSHS reported 257 confirmed cases of Zika, however, there are no other cases of suspected local transmission at this time. Spraying and other mosquito eradication techniques are being used in the area. "The finding of Zika here is not too surprising, as this is an area where dengue has been seen sporadically. The public health people have been anticipating that this might occur, and will be working to minimize local transmission," said ABC President Susan Rossmann, MD, PhD, chief medical officer for Gulf Coast Regional Blood Center in Houston, Texas. (Source: [TDSHS press release](#), November 28, 2016)

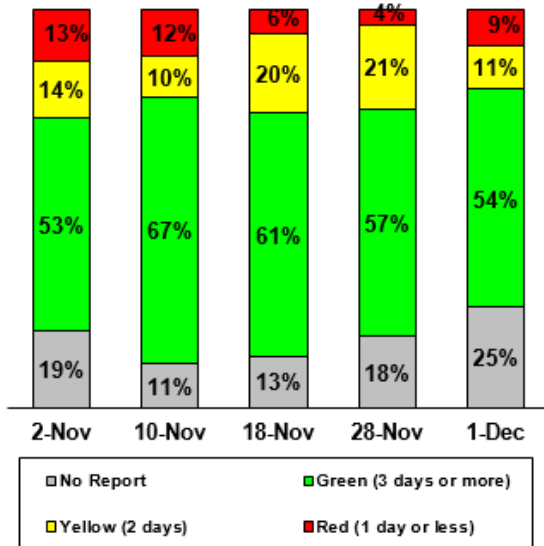
Florida Key residents approved the release of genetically modified mosquitoes. Residents of the Florida Keys voted for the release of *Aedes aegypti* mosquitoes engineered by the British company Oxitec with a self-limiting gene that, when passed to progeny, prevents them from maturing to their biting stage. The Food and Drug Administration (FDA) approved this trial in the Keys in August. The mosquitoes were released previously in Brazil and the Cayman Islands with reports of early steep declines in affected *Aedes* populations from Oxitec. (Source: *NPR*, [Florida Keys Approves Trial of Genetically Modified Mosquitoes to Fight Zika](#). November 20, 2016.)

The World Health Organization declared the end of the Zika world health emergency. At the fifth meeting of the Emergency Committee (EC) on Zika and microcephaly last week, the EC determined that while Zika is still "a significant enduring public health challenge requiring intense action" it no longer represents a Public Health Emergency of International Concern, as defined under the International Health Regulations. The EC determined more long-term mechanisms—and funding—are needed to manage the organization's response to the virus and toward containment. Some experts are worried that losing the sense of urgency will slow down research for a vaccine. There have been approximately 2,300 babies born around the world with microcephaly, mostly in Brazil, but that figure is most likely a "significant under-estimate," Dr. Peter Salama, executive director of WHO's Health Emergencies Programme, said during a press conference. (Sources: [WHO press release](#), November 18, 2016; *Huffington Post*, [WHO Declares End of International Zika Emergency](#). November 21, 2016) ♦

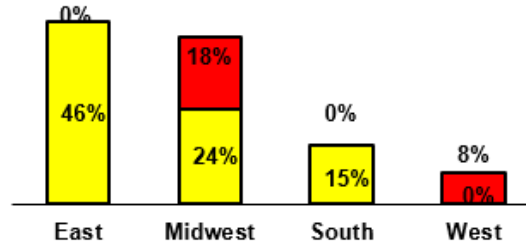


STOPLIGHT: Status of the ABC Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, December 1, 2016



Percent of Total ABC Blood Supply Contributed by Each Region
 East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:
www.AmericasBlood.org



AMERICA'S BLOOD CENTERS

55th ANNUAL MEETING



"The 2017 ABC Annual Meeting in Washington, DC is the premier place for industry leaders to experience peer-to-peer collaboration and networking, exclusive educational events and the opportunity to be an advocate for your blood center on Capitol Hill."
 —Christine Zambricki, Chief Executive Officer, America's Blood Centers

Meeting Schedule

<p>Friday, March 24 International Blood Safety Forum</p> <p>Saturday, March 25 Business Forum ABC Board Meeting</p> <p>Sunday, March 26 ABC Members Meeting SMT Forum & Celso Bianco Lectureship FABC Reception</p>	<p>Monday, March 27 Blood Center Leadership Forum 20th Annual <i>Awards of Excellence</i> ABC's Got Talent Season II</p> <p>Tuesday, March 28 Advocacy Forum Capitol Hill Visits</p>
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Hotel Information
 Ritz-Carlton (Pentagon City)
 Hotel room rate: \$249 + tax
[Reserve](#) hotel by March 3

March 24-28, 2017 – Washington, DC

Future Leader Scholarship Program (Funded by FABC)
 Details available upon registration.

Registration Fees (Member/Non-member)
 Annual Meeting: \$975 / \$1,605
 International Blood Safety Forum (Friday only): \$275 / \$275
 International Blood Safety Forum & Business Forum (Fri & Sat only): \$410 / \$410
 Business Forum through Advocacy Forum (Sat through Tue): \$760 / \$1,330
 Registration opens early December. For questions, contact [Lori Beaston](#).

Sponsorship Opportunities
 For questions or to learn more about sponsorship opportunities, contact [Jodi Zand](#).



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2017 ADRP Annual Conference

ADRP subscribers may now register for the 2017 ADRP Annual Conference in Chicago, Ill. The conference is a three-day event being held in the historic Chicago Hilton on Michigan Avenue. ABC has joined forces with ADRP to provide educational opportunities for blood donor recruitment, donor experience, management and collections professionals during this internationally-recognized conference. Some of the topics in next year's conference include: the international Missing Type campaign, engaging millennials in the workforce, and social media: how we communicate with donors continues to evolve.

Register before December 31, 2016, for only \$485 as a subscriber, non-subscribers pay \$650. Click [here](#) to register now. The subscription model for ADRP has changed slightly from years past due to the new partnership with ABC; click [here](#) to find out more on how that subscription model has changed and what the costs will be going forward.

We look forward to seeing you all in Chicago! 



REGULATORY NEWS

The International Council for Commonality in Blood Banking Automation (ICCBBA) announced many changes to the ISBT 128, the international identification, labeling, and information processing system for products of human origin. A new version of the Standard Technical Specification v 5.6.0 is now available. Some of the most significant changes noted in the announcement of the new release are: a greater flexibility in assigning identifiers for collection containers; a mechanism for encoding divisions (aliquots) for Solvent Detergent Pooled Plasma; a reduced bar code X dimension for some labels; added references to additional documents; and revised guidance on the printing of data content text associated with the bar codes. An updated [Implementation Guide: Use of the Manufacturers Data File v1.2.0](#) is also available and provides implementation guidance on the use of the Manufacturers Data File. A new release of the ISBT 128 Product Description Code Database v6.22.0 is also now available to licensed facilities and can be downloaded as a [Microsoft Access database](#). New medical products of human origin can be requested once request forms from the website have been submitted. An updated Product Lookup Program that is populated with the new codes is also available. The Standard Terminology for Medical Products of Human Origin v6.22 has also been [released](#). It provides definitions to all ISBT 128 terminology and should be used in conjunction with the ISBT 128 Product Description Code Database. (Source: ICCBBA, October 7, 2016.) ♦

PEOPLE



Dean Eller to retire. President and Chief Executive Officer of Central California Blood Center (CCBC) Dean Eller has advised the center's Board of Directors he intends to retire at the end of July, 2017. "Twenty-one years ago, an hour before she died, I promised my daughter I would carry on her work. I've kept that promise," said Eller in his announcement to the Board of Directors. Mr. Eller was referencing the promise he made to his late

daughter, Jennifer, to carry on her passion for blood donation as her four-year battle against an aggressive form of leukemia came to an end October 28, 1995. Following her death, Mr. Eller lived up to his promise to keep blood donation and the need for donors in front of people throughout the Central Valley and across the nation. He continued Jennifer's work as a blood donation advocate, and in 1999, Mr. Eller left a long and successful career in real estate and mortgage banking to become the President and Chief Executive Officer at the CCBC. Under his leadership, the blood center has thrived and grown. The cornerstone of Eller's work, in addition to motivating people to give and to be involved through his frequent presentations

WORD IN WASHINGTON



The House of Representatives overwhelmingly passed the "21st Century Cures Act" Wednesday, November 30. The \$6.3 billion dollar bill now heads to the Senate for approval the week of December 5. The bi-partisan 996-paged bill, which also received the endorsement of the White House, would help speed up the way in which drugs are approved, but some—including the Journal of American Medical Association Editor Rita Redberg—have argued that provisions within the bill weaken the Food and Drug Administration's regulatory authority and could potentially lead to unsafe drugs slipping through the speedier process. The package also includes \$1 billion to help fight the opioid crisis and \$1.8 billion to help fund Vice President Biden's "moonshot" project of curing cancer—though that money is not guaranteed in the bill. The legislation would also establish a new assistant secretary for mental health in the Department of Health and Human Services and Chief Medical Officer. ♦



PEOPLE (continued from page 11)

and writings, is the CCBC's headquarters, laboratories and the Jenny Eller Donor Center, named in tribute to his daughter, located in Northwest Fresno. "We are grateful to Dean for his passion, commitment and stewardship," said Valerie Vuicich, chairwoman of the CCBC Board of Directors. "Under his leadership, our organization is financially strong and well positioned to continue to serve area hospitals and their patients with safe and plentiful blood supplies and services." Mr. Eller and the CCBC are actively involved in various industry associations and trade groups, including America's Blood Centers, Blood Centers of America, and American Association of Blood Banks as well as California Blood Bank Society and Blood Centers of California. Mr. Eller served on various committees and boards, including president of Blood Centers of California in 2007-2008 and a six year member of the Board of Directors of The Foundation for America's Blood Centers. The CCBC's executive search committee will immediately reach within and outside the organization for Mr. Eller's replacement.

Rep. Tom Price (R-Ga.) was named as the next Department of Health and Human Services (HHS) Secretary. President-elect Trump named Rep. Price as the next HHS Secretary Tuesday, November 29. Known as an adamant opponent to the Affordable Care Act, Price has already drafted a full repeal and replacement proposal to the law. Trump also named Seema Verma, MPH, a health policy consultant known for spearheading changes to Indiana's Medicaid program, to run the Center for Medicare and Medicaid Services. Price, who is a member of the House GOP Doctors Caucus, has pushed to end entitlements that require Medicare and Medicaid to provide coverage to every person who qualifies and instead empower states to decide who receives assistance. (Source: *Washington Post*, [Trump names Rep. Tom Price as next HHS secretary](#). November 29, 2016)



Bloodworks Northwest is pleased to announce the appointment of Moritz Stolla, MD, as an assistant member of its Research Institute. Dr. Stolla joins the laboratory of Sherrill Slichter, MD, director of Platelet Transfusion Research at Bloodworks Northwest. "We are delighted to welcome Dr. Stolla to the Institute," said James Zimring, MD, PhD, chief scientific officer and director of the Bloodworks Research Institute. "His reputation as a creative, accomplished and recognized platelet biologist strengthens our capacity, and enhances the Northwest's vibrant medical research community." Stolla received his medical training at Ludwig-Maximilians-

University in Munich, Germany, and defended his doctoral thesis in vascular biology at the Technical University of Munich. He recently completed a transfusion medicine fellowship at the Harvard Joint Program at Brigham and Woman's Hospital in Boston. Previously he completed a clinical pathology residency in the Department of Pathology and Laboratory Medicine at the University of Rochester (where he was elected chief resident), and was a postdoctoral research fellow in platelet signaling and thrombosis at Thomas Jefferson University in Philadelphia. Prior to coming to the U.S., Dr. Stolla trained in cardiology at Klinikum Rechts der Isar at the Technical University in Munich. In addition to more than 30 published papers, abstracts and presentations, he received the AABB Top Abstract Award at the 2015 Annual Meeting, as well as similar awards from the American Society for Hematology (ASH) and the International Society on Thrombosis and Hematology (ISTH).

Yongming Zhu, former president of Shanghai Blood Center and director of the World Health Organization's Collaborating Center for Blood Transfusion Services, was elected to chairman of the board for the Chinese Society of Blood Transfusion (CBST). Mr. Zhu's appointment occurred at the 7th China Blood Transfusion Assembly on November 11. In this role, Mr. Zhu will be responsible for growth strategies and direction of the society. He will oversee committees and working parties to design transfusion services and transfusion



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PEOPLE (continued from page 14)

medicine, in professional education and improvement, in collaborative research and education, in finance and operation, and in quality improvement and regulatory compliance. Mr. Zhu obtained his bachelor and MBA degrees in Shanghai, and has been working in the industry for over 30 years. He also served as vice president for the International Society of Blood Transfusion (ISBT) from 2002 to 2006 and currently serves as one of the vice presidents for Asia Association of Transfusion Medicine (AATM). ♦

MEMBER NEWS



Blood Bank of Hawaii Celebrates 75 Years. One year and eight months before the attack on Pearl Harbor, Dr. Forest J. Pinkerton presented his plan to establish a community blood bank—one of the first in the nation—in Hawaii. As head of the Public Health Committee for the Chamber of Commerce, he was charged with planning medical facilities and care for any natural disasters or emergencies in the islands. As a member of the National Defense Council, he was also aware of the concern of the defense services in Washington, D.C. But Dr. Pinkerton was not taken seriously. He was called an “alarmist” and “war monger.” Several months later, he presented his plan for a second time and this time, it was better received. In February 1941, Honolulu Blood-Plasma Bank

was formed. The first blood donors were drawn later that summer on the grounds of The Queen’s Hospital. With radio silence and censorship, public interest waned for the blood collection defense/disaster program and exactly 22 days before the attack on Pearl Harbor, the blood bank ceased operations. On December 7, 1941, Dr. Pinkerton was called by an official from headquarters about the attack on Pearl Harbor and was asked to bring any blood available to Pearl Harbor immediately. Fortunately there were 253 units of plasma on the shelves. Before delivering the blood, Dr. Pinkerton called the radio stations to ask for doctors, volunteers and blood donors to report to The Queens Hospital. By 11:00 a.m., operations resumed drawing as many as 50 donors an hour, 10 hours a day, 7 days a week. For the next two years, BBH functioned as a wartime agency under the Office of Civilian Defense, Department of the Interior. In October 1943, BBH was chartered as a non-profit organization with the establishment of its own board of directors and staff. Now, 75 years later, BBH remains the steward of Hawaii’s blood supply. Thanks to Dr. Pinkerton’s vision and leadership, many lives in Hawaii were saved during the war and throughout the decades since. A true testament that it’s the blood on the shelves that saves lives.

Mississippi Valley Regional Blood Center (MVRBC) opens a new donor center. The new center was opened in West Davenport, Iowa, on November 1 with a ribbon-cutting ceremony on Tuesday, November 22. The new donor center, featuring additional space and improved access for donors, replaced MVRBC’s former location inside the Center for Active Seniors. (Source: QCOonline.com, [Mississippi Valley Regional Blood Center opens new donor center](#). November 21, 2016) ♦





GLOBAL NEWS

Hong Kong, the world's fourth most densely populated sovereign state or territory, has announced its eighth case of chikungunya. Seven of the cases were imported from India and one from the Philippines. No local vector-borne cases have been reported. (Source: OutbreakNews.com, [Hong Kong reports 8th imported chikungunya case](#). November 20, 2016.) ♦

CALENDAR

2017

Feb. 13-14: **AABB U.S. Hemovigilance Symposium, Atlanta, Ga.** To register and more information, click [here](#).

Mar. 2-3. [IPFA 2nd Asia Workshop on Plasma Quality and Supply, Yogyakarta, Indonesia](#). To register for the workshop, click [here](#).

Mar. 24-28. **Annual Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Department. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Mar. 25: **Board Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Department. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

May 1 -3. **2017 ADRP Annual Conference, Chicago, Ill.** More information is available on the [website](#).

May 16-17. [IPFA/PEI 24th International Workshop on "Surveillance and Screening of Blood-borne Pathogens"](#), Zagreb, Croatia. To register, click [here](#).

June 17-21: **27th Regional Congress of the ISBT, Copenhagen, Denmark.** [Click to register for the event](#).

Aug. 1-4. **Summer Meeting, MD Workshop & Golf Tournament, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 3. **Board Meeting, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 11-12. [IPFA/BCA 3rd Global Symposium on The Future for Blood and Plasma Donations, Atlanta, Ga.](#) ♦

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) 393-5527; e-mail: lmaundy@americasblood.org.

POSITIONS

Director of Technical Services. Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distribution annually), is seeking a strong leader to oversee all technical operations in the component manufacturing, quality control, and immunohematology reference laboratories and the 16-member team. Headquartered in Honolulu, we are the sole provider of blood to the state's hospitals. If you are a CLS and/or SBB with at least five years' technical and management experience in a blood bank setting, come join a dynamic, cohesive team that is effecting positive change. We offer a competitive salary and excellent benefits. Apply online now at www.BBH.org.

Director of Center Operations (DCO) (Shreveport, LA). LifeShare Blood Centers, a part of the community since 1942, is currently seeking to fill a key leadership position within our organization. The DCO is building a culture focused on Quality while ensuring all operational policies, procedures and SOPs meet the requirements of all regulatory bodies. Provides oversight for LifeShare Donor Centers (LDC) while working with peers to create departmental standards for Donor Services and Donor Recruitment. Direct oversight of Shreveport location. Works with ED-DO and other team members to develop collection plans to meet budgetary goals and operational performance trends to ensure the business viability. Bachelor's in health or related field. Four plus years' blood banking or five years in progressively responsible management positions or leading a Sales team. Demonstrated experience in leading teams in a regulated environment. Must have knowledge of strategic planning, budgeting, organizing and implementing initiatives. To apply, please visit: www.lifeshare.org under the careers tab. LifeShare Blood Centers is an EEO/AAP – M/F/D/V/Genetic Data employer maintaining a Tobacco and Drug Free Workplace. All qualified applicants will receive consideration without regards to race, color, ethnicity, religion, gender, national origin, disability, veteran status, genetic data or other legally protected status.

Director of Laboratory Services. SunCoast Blood Bank (SCBB) located on Florida's Gulf Coast, is seeking an experienced blood bank professional to direct and manage our transfusion service. SCBB provides services for an 800 bed hospital that also includes a trauma center, open heart unit and a neonatal intensive care. In addition, we provide reference laboratory services for other area hospitals. Ideal candidates will have increasing levels of responsibility in blood banking or clinical laboratory management including supervisory experience. Bachelor's degree in appropriate field, SBB preferred and Florida Supervisor license in all laboratory areas. Competitive compensation and benefits package. Pre-employment drug screening and background checks required. Interested candidates please apply [here](#).

Director Donor Recruitment & Client Services (8821-San Antonio, TX). Responsible for developing, leading,

and directing Donor Recruitment and Client Services. Will conduct customer service, sales, and marketing services on behalf of the South Texas Blood & Tissue Center's (STBTC) operational business units. Will develop, ensure, and maintain positive and lasting donor and customer relations, and serve as the liaison between internal and external customers. Will ensure the accomplishment of donor recruitment and marketing goals under the supervision of the Vice President, Blood Operations. Bachelor's degree in Business Administration or Marketing/Sales preferred or equivalent work related experience required. Seven years marketing or sales management experience required. Five years leadership experience required. Five years management experience required. Relevant computer software experience required. Three years driving experience with good driving record required. BioBridge Global and its subsidiaries are proud to be an EEO/AA-M/F/D/V/Genetic Data employer that maintains a Tobacco & Drug-Free Workplace. All qualified applicants will receive consideration for employment without regard to race, color, ethnicity, religion, sex, national origin, disability, veteran status, genetic data or other legally protected status. Apply online at <https://career4.successfactors.com/sfcareer/jobreqcareer?jobId=8821&company=biobridge&uname>.

Director, Donor Recruitment (Location: San Bernardino, CA). Responsible for managing/developing systems and internal resources necessary to retain current active blood donors, increase the number of first time donors, increase the number of career donors, and increase donation frequency. Responsible for directing the tactical aspects of both mobile and telephone recruitment, including the utilization strategy and selection process of new Area Representatives and Tele-recruiters. Works closely with Collections leadership to ensure donor satisfaction and effective production planning. Works closely with the Vice President of Marketing and Public Relations on developing recruitment materials and promotional campaigns. The ideal candidate will have a bachelor's degree (BA) in Business, Marketing, Public Relations, or related field. One to two years of experience managing a Recruiting, Sales and/or Community Development function is required because of the complexity and subtlety of issues required to lead the Department. Five or more years of direct experience in the Art of Communication with a strong background in Customer Service. Sales and Marketing experience preferred. Bilingual a plus. Current California Driver's License. For further information and to apply online please visit: www.LStream.org. Must pass pre-employment background check and drug screen. LifeStream is an Equal Opportunity Employer, M/F/D/V.

POSITIONS (continued from page 15)

Vice President, Corporate and Community Resources. Carter Bloodcare (CBC), is seeking a mission-focused, seasoned, strategic and process-minded leader with experience in leading a group of talented individuals. The candidate must be a leader who is able to help others deliver measurable, cost-effective results that drive performance. He/she oversees core operations for the blood program. This position reports to the CEO. Qualifications: Minimum five years senior level management experience; Advance degree; Experience in blood banking; Competency in strategic planning and business development; Working knowledge of data analysis; Energetic, flexible, collaborative, and proactive; Outstanding organizational and leadership abilities; Excellent interpersonal and public speaking skills; and aptitude in decision-making and problem solving. Carter Bloodcare is an EEO/Affirmative Action employer. CBC provides equal employment opportunities to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. CBC is a Pro Disabled & Veteran Employer. Please apply online at: www.carterblood-care.org. We maintain a drug-free workplace and perform pre-employment substance abuse testing.

Donor Services Supervisor (OneBlood Inc., Port Charlotte, FL). Supervises the phlebotomy of blood donors in a defined collection area. This position oversees the Port Charlotte Donor Center, North Port Donor Center, Venice Donor Center and two blood mobiles. The candidate for this position should be a proficient and knowledgeable operator of the apheresis technologies Alyx and Amicus. The candidate chosen for this position will be a trustworthy and proven leader, who embodies a fair and consistent leadership attitude. The candidate who is chosen for this role should be a capable multitasker and extremely detail oriented. The functions of this role will require the chosen candidate to work long hours, including early mornings, evenings, weekends and some specified holidays. This candidate should be a team player and fully embody the mission statement and vision of Oneblood Inc. Please apply [online](#). OneBlood is an Equal Opportunity Employer/Vet/Disability.

Quality Assurance Manager. The Community Blood Center, Appleton, WI is seeking a Quality Assurance Manager to lead our team of quality assurance professionals. This position develops, oversees, maintains and continually improves the organization's quality plan, ensures that cGMP requirements and quality standards are recognized, understood and maintained across the organization, and is responsible for maintaining the organizations deviation management systems. Candidates should be able to demonstrate strong leadership,

communication, and interpersonal skills. Requirements: Bachelor's degree or equivalent experience in medical technology or a clinical, allied health field. Certified Quality Auditor (CQA) and/or Specialist Blood Bank (SBB) desired. Previous experience required in a regulatory environment with a minimum of three years in a management position in quality/compliance/regulatory/audit department, preferably in lab, blood services or healthcare industry. Working knowledge of cGMP, AABB, CLIA and CFR blood banking requirements. To apply and view complete job description of this position, go to www.communityblood.org. The Community Blood Center is an Equal Opportunity Employer M/F/Disability/Veteran.

Manager, Donor Operations (Location: La Quinta, CA (Greater Palm Springs area)). Oversees donor operations including Manual, Special Services, and Automated Donation processes, and also advanced procedures where applicable. As needed, will be trained to perform Collections Technical Procedures. Responsible for overseeing, evaluating, making decisions regarding issues of customer service and compliance to cGMP Standards, equipment monitoring and Quality Control, staff training, assignments, scheduling daily breaks, and performance. Also, responsible for monitoring and trending Productivity and Facility/Equipment Management. Education and Experience: Bachelor's degree in Business Administration, Human Resources, Nursing or Medical Technology or RN with relevant supervisory/management experience. Or three to five years Supervisory experience in a Blood Bank setting. Experience with supervising people and processes; managing and prioritizing multiple assignments requiring a high level of problem-solving and organizational skills; possess excellent written and oral communication skills. Current CPR Certification. Current California Driver's License. For further information and to apply online please visit: www.LStream.org. Must pass pre-employment background check and drug screen. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal governments E-verify program to determine employment eligibility.

Associate Area Representative (Location: San Bernardino, CA; Schedule: Monday through Friday; 8:00 am to 4:30 pm). The essential element of the Associate Area Representative position is to assist Area Representatives through the development of specific territories with the community; maintain, and expand professional relationships with community businesses and organizations through quality customer service; contribute to departmental objectives with the goal of adding donations from new groups and increasing donations from existing groups. The Associate Area Representative will have access to all field territories for supplemental support. Under the direction of Management, the Associate Area Representative is responsible for all aspects of

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POSITIONS (continued from page 16)

the blood drive recruitment process within various territories in order to ensure successful drives and achieve the goals of the blood drive. The ideal candidate will have a bachelor's degree (BA) in Business, Marketing, Public Relations, or related field preferred. Three to four years of direct experience in the Art of Persuasive Communication, with a strong background in Customer Service. Sales and Marketing experience is strongly preferred. Current California driver's license. For further information and to apply online please visit: www.LStream.org. Must pass pre-employment background check, drug screen and physical exam. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility.

Area Representative (Location: San Bernardino, CA). The essential element of the Area Representative position is to develop, maintain, and expand professional relationships with community businesses. Provide quality customer service with the goal of adding donations from new groups and increasing donations from existing groups. The Area Representative is responsible for all aspects of the Blood Drive recruitment process within an assigned territory. This includes, but is not limited to booking the drive, education, management, and coordination of the drive in cooperation with the assigned Representative or Chairperson of the Business or Organization. The ideal candidate will have a bachelor's degree (BA) in Business, Marketing, Public Relations, or related field preferred. Three to four years of direct experience in the Art of Persuasive Communication, with a strong background in Customer Service. Sales and Marketing experience is strongly preferred. Current California driver's license. For further information and to apply online please visit: www.LStream.org. Must pass pre-employment background check and drug screen. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility.

Senior Collection Operations Director (Oklahoma Blood Institute; Oklahoma City, Oklahoma, USA). This position will provide leadership and direction over all aspects of the Donor Services collection team for both mobile and fixed site operations. It is responsible for assessing, developing and implementing strategic plans to achieve donor services objectives and goals. Create a friendly competitive environment to motivate staff to achieve high system wide standings on all key performance metrics (loss rates, errors, 2RBC conversion, Global Blood Fund, etc.). Conduct routine meetings to communicate organizational vision, updates, and changes and recognize outstanding staff performance keeping morale high. Maintain adequate staffing levels. Make frequent visits to both fixed and mobile collection sites. Actively participate in internal and external assessments/inspections including corrective action plans and

effectiveness checks as needed. Track and monitor inventory and collection goals, which include whole blood, automation rates, and WB conversion data. Analyze data and make adjustments to increase productivity. This includes working closely with recruitment to ensure projections are met. Prepare and manage department annual budgets. Qualifications: Bachelor's degree in management or medical field, Masters helpful. Minimum of five years' leadership/management experience, and valid driver's license. Salary: Competitive salary and excellent benefits package. How to apply: <http://obi.org/careers/>. 