

2017 #44

December 15, 2017

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Gene Therapy Breakthrough in Treatment of Hemophilia A

Short-term success of gene therapy for individuals with the bleeding disorder hemophilia A has been described in the *New England Journal of Medicine*. Hemophilia A is caused by a genetic deficiency in coagulation factor VIII. One in 5,000 male births in the U.S. are affected. Those who suffer from the disorder are dependent upon regular infusions of factor VIII.

In the study, nine patients with severe hemophilia A were treated with a single dose of an adeno-associated virus (AAV) vector encoding a B-domain deleted human factor VIII gene with a liver-specific transcription promoter. This was a safety and dose ranging study. Low and intermediate doses were ineffective, but at higher doses, factor levels increased to “normal” in six patients, in whom they were maintained for 1 year of follow up.

Median annualized bleeding rates fell from 16 to 1 after gene transfer and factor use fell to zero in the high dose cohort by week 22. No factor VIII inhibitors developed. Serious toxicity was not seen.

In an editorial, the promise of this approach is recognized, but risks and limitations are described. These include the influence of immunity to AAV vectors, potential liver toxicity, risks of insertional oncogenesis with gene therapy and the limits on generalizability imposed by the necessary stringent inclusion and exclusion criteria for recipients in the paper. This study comes on the heels of a promising hemophilia B study that also utilized gene therapy supplying the factor IX gene via a viral vector as covered in *ABC Newsletter Issue # 43*.

Citations: Rangarajan S., Walsh, L., Lester, W. *et al.* AAV5-Factor VIII gene transfer in severe hemophilia A. *New England Journal of Medicine*. 2017. <http://www.nejm.org/doi/full/10.1056/NEJMoa1708483#t=article>

van den Berg, H.M. A cure for hemophilia within reach. *New England Journal of Medicine*. 2017. <http://www.nejm.org/doi/full/10.1056/NEJMe1713888>. ♦

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!



Hospitals Adjust to Changing Healthcare Landscape

For several years, blood centers have face increased economic pressure from the escalating costs of healthcare, decreased demand for blood products, and declining margins associated with increased consolidation across the blood community. Hospitals are experiencing consolidation of their own, which is said to be tied to mounting healthcare costs from regulations such as the Affordable Care Act and insufficient reimbursement from “insurance programs such as Medicare and Medicaid,” according to *Axios*, which [looked in-depth](#) at the financial statements of the nation’s largest non-profit hospital systems.

A recent Bloomberg report [noted](#) that, “[j]ust this month, health systems with at least 166 hospitals and \$39 billion in combined annual revenue have announced merger plans” with more expected. The *Wall Street Journal* [reported](#) Sunday that Ascension Health and Providence St. Joseph Health are working on a potential merger that would create “the largest hospital chain” with “191 hospitals and nearly \$45 billion in annual revenue.” The [analysis](#) by *Axios* found that the largest non-profit hospital systems in the U.S. are profitable due in large part to their “Wall Street investments, mergers, and other investment options” that resulted in a total of more than \$21 billion, describing their operating margins as “modest.” In response, the American Hospital Association stated that “[hospitals] need a positive margin to keep pace with advances in medicine and increasing health care needs.”

The 84 large hospital systems that were examined reported \$535.5 billion in annual revenue. However, the report did acknowledge that the economic realities differ drastically for smaller, rural, or publicly-owned hospitals “that are struggling more because of dwindling payments, fewer patients and an inability to compete against larger, better-funded systems when negotiating payment rates with commercial insurers.”

(Sources: *Wall Street Journal*, [Hospital giants in talks to merge to create nation’s largest operator](#), 12/10/17; *Bloomberg*, [Hospitals are merging to face off with insurers](#), 12/11/17; *Axios*, [Hospitals are making a fortune on Wall Street](#), 12/7/17) ◆

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.

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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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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.

56th ABC Annual Meeting Registration Open

[Registration](#) opened this week 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.

ADRP Registration & Call for Speaker Abstracts Open

Early bird registration for the ADRP, an international division of ABC, [2018 Conference and Expo](#) is open. [Register](#) by December 31st to take advantage of the discounted rate (\$525). ADRP also invites you to submit abstracts to speak at the conference in Dallas, Texas. All marketing and communications innovators, recruitment visionaries, and collections experts are invited to [submit](#) abstracts on topics including donor collections staffing, the impact of technology on donor flow, internal communications strategies for regulatory changes, reinventing your brand, fixed site recruitment, lead generation for new sponsor groups, first time donor retention programs, and emerging medical issues. Speakers who are chosen will receive a 30 percent discount off conference registration and a complimentary one-year subscription to ADRP. Interested individuals may submit abstracts [here](#).

Reminder: ADRP Award Nominations Open

Recognize a peer or outstanding donor group by nominating them for an [ADRP Award](#). Submissions are being accepted until December 31st via the online [nomination form](#). This year's categories include: Donor Recruiter of the Year, Donor Collections Team Member of the Year, Leader of the Year (Recruitment & Collections), Franzmeier Lifetime Achievement Award, Gilcher MD/CEO Award, Media Partner Award, Blood Drive Award (Creative & Most Productive), School Blood Drive Award, and the Humanitarian Service Award. 💧

RECENT REVIEWS

A revised platelet transfusion guideline has been published by the American Society of Clinical Oncology (ASCO). It replaces those from 2001. The new guidelines from ASCO for use of platelets in patients with malignancy are freely available online. They are based on review of more than 20 papers since the initial publication, including clinical studies, systematic reviews, and guidelines from other professional societies. "The most substantial change" makes a recommendation that recipients of autologous hematopoietic stem cell transplants can be transfused for signs of bleeding, rather than prophylactically at a trigger platelet count.

Citation: Schiffer, C.A., Bohlke, K., Delany, M. *et al.* Platelet Transfusion for Patients with Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update. *Journal of Clinical Oncology*. 2017. <http://ascopubs.org/doi/full/10.1200/JCO.2017.76.1734>.

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RECENT REVIEWS (continued from page 4)

Guidelines on triggering and stopping massive transfusion protocols (MTP) from The American Society of Anesthesiologists, the American College of Surgeons, and the task force of the European Society for Advanced Bleeding Care in Trauma (EU-ABC) are reviewed, with additional evidence sought from literature searches spanning December 2006 to January 2017. The review focuses on the EU-ABC guidance, and supporting literature, advocating for “prompt termination of the algorithm-based model of resuscitation” moving to one using laboratory-based resuscitation. Evidence contrasting the use of conventional coagulation assays and viscoelastic hemostatic assays is also a focus. The scoring systems available to drive this approach are critiqued. Massive transfusion in non-trauma patients and in the pre-hospital setting are addressed. The lack of evidence to support deciding when to terminate MTPs is noted.

Citation: Foster, J.C., Sappenfield, J.W., Smith, R.S. *et al.* Initiation and termination of massive transfusion protocols: current strategies and future prospects. *Anesthesia & Analgesia*. 2017. 125:2045-55. 💧



AMERICA'S BLOOD CENTERS' 56TH ANNUAL MEETING

March 17-19, 2018 | Scottsdale, AZ

2018 ANNUAL MEETING SCHEDULE

Saturday, March 17:	ABC Board Meeting Opening Session
Sunday, March 18:	ABC Members Meeting SMT Forum & Celso Bianco Lectureship Host Event by Blood Systems
Monday, March 19:	General Session 21st Annual Awards of Excellence

“ I look forward to welcoming America's Blood Centers back to Scottsdale, where the organization began more than 55 years ago. Along with opportunities to discuss emerging issues in our field, the Annual Meeting is a great forum for exchanging ideas and developing collaborations. The more who attend – the greater the value to all involved! ”



Blood Systems

— Dave Green, MSA, President and CEO
Blood Systems, Inc.



Hotel Information
Scottsdale Plaza Resort
Hotel room rate:
\$219 Single/Double



For registration information, visit http://bit.ly/abc_annual_meeting.

For sponsorship opportunities, please contact Leslie Maundy at lmaundy@americasblood.org.



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BRIEFLY NOTED

A free online resource is available for training on donation-associated syncope. The website developed by the Dutch with assistance from Peter Tomasulo, MD, Hany Kamel, MD, and Chris France, PhD is designed for medical students, internists, and blood bank physicians, and can be of use to any staff member who deals with donor vasovagal and syncopal events. It offers a nine-part free tutorial (in English) covering “all-

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BRIEFLY NOTED (continued from page 5)

things-syncope.” Included are detailed modules on the physiology of maintaining blood pressure; orthostatic dysregulation which leads to syncope; presyncopal signs and symptoms; syncopal reactions; prevention of syncope; and treatment of syncopal reactions. These modules incorporate useful graphics and videos to illustrate the learning objectives. Additionally, the site features tools for donors, including reasons to donate, management of fear of donation, and prevention of syncope using muscle tensing, distraction, and fluid intake. Collection facilities interested in this unique online training tool for medical, donor screening, and donor care staff, can learn more at Syncopedia.com. Access to the modules is available [here](#).

*Contributed by Mary Townsend MD
Senior Medical Director, Corporate, Blood Systems, Inc.*

The National Heart, Lung, and Blood Institute launched a newly designed [website](#) this week. The site contains a fresh look with “streamlined” content and a focus on the overall user experience including being optimized for mobile browsing. The blood disorders and blood safety landing page can be found [here](#).

(Source: National Heart, Lung, and Blood Institute Announcement, 12/6/17) 💧

INFECTIOUS DISEASE UPDATE

ZIKA

The association of Zika infection during pregnancy with microcephaly has been epidemiologically confirmed. In a final report of their case-control study at eight public maternity hospitals in Recife (Northeast Brazil), investigators have measured the strong association of congenital Zika infection, diagnosed using polymerase chain reaction and immunoglobulin M antibody assays, with microcephaly (defined as a head circumference at least 2 standard deviations below the mean). Further, they demonstrated no statistical association with other hypothesized potential causes. There were 91 cases of microcephaly and 173 unaffected, matched controls. The overall odds ratio for laboratory-confirmed Zika infection in the affected babies was 73.1 (95 percent confidence 13.0-infinity). Statistically insignificant odds ratios were found for maternal exposure to the larvacide pyriproxyfen (added to potable water supplies as a mosquito control strategy), and to a variety of vaccines, consistent with other studies. There was no evidence of Cytomegalovirus, Toxoplasma, or Rubella virus infection among cases. The rate of laboratory evidence of Zika infection in the control mothers was very high, 57 percent vs. 70 percent in mothers of affected infants ($p=.051$) attesting to a very high Zika attack rate that may provide a partial explanation for the extraordinary burden of congenital Zika in the region. Cases were more likely female, small for gestational age and premature.

Citation: de Araujo, T.V.B., de Alencar Ximenes, R.A., de Barros Miranda-Filho, D., *et al.* Association between microcephaly, Zika virus infection, and other risk factors in Brazil: final report of a case-control study. *Lancet Infectious Diseases*. [http://dx.doi.org/10.1016/S1473-3099\(17\)30727-2](http://dx.doi.org/10.1016/S1473-3099(17)30727-2).

CYTOMEGALOVIRUS

The results of questions added to the College of American Pathologists Transfusion Medicine Participant survey for 2015 concerning transfusion-transmitted Cytomegalovirus (TT-CMV) have been published in the *Archives of Pathology and Laboratory Medicine*. Historically, most institutions (2,712/3,032, 89.4 percent) rely on universally leukoreduced blood products, but then hedge their bets with the availability

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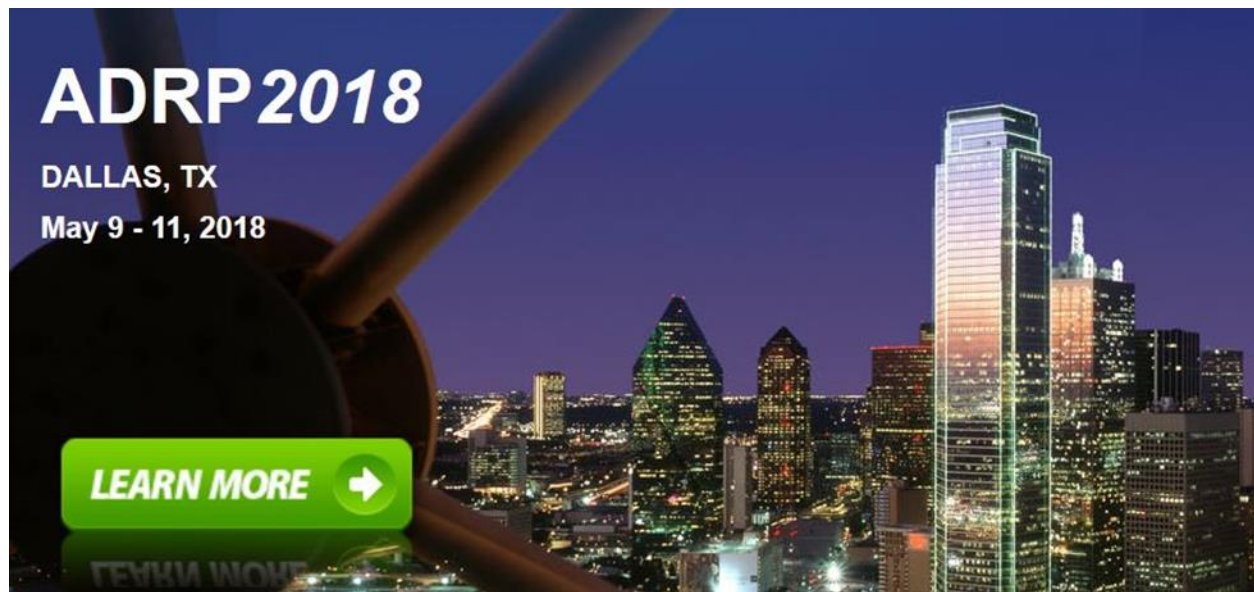
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INFECTIOUS DISEASE UPDATE (continued from page 6)

(2,481/3,004, 82.6 percent) of CMV-seronegative components for some circumstances. Data are also presented regarding patient monitoring and prophylaxis of CMV infection. The authors conclude that “[H]igh quality studies are needed to determine if CMV-seronegative and leukoreduced blood products are needed in high-risk patient populations.”

Citation: Weisberg, S.P., Staley, E.M., Williams, L.A., *et al.* Survey on transfusion-transmitted cytomegalovirus and cytomegalovirus disease mitigation. *Archives of Pathology & Laboratory Medicine*. 2017. 141:1706-11. 



WORD IN WASHINGTON

Leaders in the Senate and House announced that a tax bill agreement in principle has been reached. The agreement comes nearly one week after the Senate passed a tax bill that differed vastly from the House version. Reaching a compromise paves the way for votes next week with the goal of having the legislation ready for the President’s approval before the end of the year. This version of the consensus bill includes the Senate’s repeal of the Affordable Care Act’s individual mandate for health insurance and a slight increase of the corporate tax rate to 21 percent rather than the 20 percent in previous versions of both the House and Senate bills.

(Source: *New York Times*, [Republican tax bill in final sprint across finish line](#), 12/13/17)

President Trump signed the National Defense Authorization Act (NDAA) into law on Tuesday, approving both the NDAA Conference Report and a provision within the NDAA that allows the FDA the ability to authorize medical treatments that have not been approved by the agency for temporary use in emergencies and expedites product review. “This is an important day for our brave men and women in uniform, ensuring they get the timely care they need while protecting our country,” said House Energy and Commerce Committee Chairman Greg Walden (R-Ore.) and Health Subcommittee Chairman Michael Burgess, MD (R-Texas). “We commend all those at the committee and agency levels who came together to find a constructive compromise on an issue we all cared deeply about. Thanks to everyone’s willingness to have open,

(continued on page 10)



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WORD IN WASHINGTON (continued from page 8)

honest discussions, we were able to address a provision within the NDAA Conference Report that could have usurped FDA’s vital authority and long-standing process in reviewing and delivering cutting edge medicines and devices. Today we are well on our way to delivering the newest treatments and devices to our war fighters without forgoing important safety mechanisms.” [Previously](#) (page 3 of *ABC Newsletter* Issue #40), lawmakers vowed to delay passage of the NDAA without bipartisan support and agreement upon the language contained in the provision from both the Department of Defense and the Food and Drug Administration.

(Source: House Energy and Commerce Committee [News Release](#), 12/12/17)

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Members of the House Ways and Means Committee proposed five bills earlier this week “to deliver immediate targeted relief from Obamacare taxes that will be in effect in 2018,” according to a news release issued by the committee on Tuesday. Specifically, [H.R. 4617](#) provides “relief” for the medical device tax, opposed by ABC, suspending it for an additional five years. “Obamacare’s failures are continuing to hurt families across the country – and allowing burdensome health care taxes to continue or go back into effect would make these problems even more severe,” said Ways and Means Committee Chair Kevin Brady (R-Texas). “As we continue working toward a patient-centered health care system, Ways and Means Republicans are taking action to provide targeted relief from taxes that stand in the way of affordable health care, innovative treatments, access to medications, more jobs, and bigger paychecks for hardworking Americans. “I appreciate my colleagues for their work on commonsense proposals that will reduce health care costs for families, provide flexibility for employers to offer the plans that are right for their employees, and help American

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WORD IN WASHINGTON (continued from page 10)

businesses bring jobs back to the United States. I look forward to continuing this work and advancing legislation in the weeks ahead.”

(Source: House Ways and Means Committee [News Release](#), 12/12/17)

The House Appropriations Committee introduced a joint [resolution](#) aimed at extending both funding for the federal government through January 19th, and the Children’s Health Insurance Program (CHIP) for five more years. The short-term continuing resolution passed last week, to keep the government funded, expires on December 22nd. CHIP “provides health benefits to almost 9 million children whose families earn too much to be eligible for Medicaid but cannot afford private insurance, and has enjoyed bipartisan support since it was enacted in 1997.” Funding for the program expired on September 30th and remains a source of much debate amongst lawmakers who hoped to have an agreement on an extension in place by the end of the year.

(Source: *Reuters*, [With no deal on children’s health plan, U.S. states scramble for Plan B](#), 12/14/17) ♦

REGULATORY NEWS

The Food and Drug Administration issued a [guidance](#) on Thursday regarding the extension of container labeling referenced in the October 2017 [Circular of Information](#) for the Use of Human Blood and Blood Components. The guidance states that the October 2017 Circular is “acceptable for use in the labeling of blood and blood components intended for transfusion” in accordance with 21 CFR 606.122. These documents replace the 2014 guidance and the November 2013 Circular respectively.

(Source: AABB Announcement, 12/14/17) ♦

PEOPLE

Blood Systems, Inc. (BSI) announced **Charlie Wilcox** as president of its Northeast Division Blood Services. With more than 40 years of blood banking experience, Mr. Wilcox will lead a division, which collects approximately 300,000 units of red blood cells annually and consists of more than 45 donor centers. His initial aim will be growing “the donor base to approach self-sufficiency for the area’s blood supply,” according to a BSI news release. “At the same time, we have an ambitious timeline to fully integrate [the Institute for Transfusion Medicine] (ITxM) and LifeShare with Blood Systems’ operations, policies, programs and platforms,” Mr. Wilcox said. “Once we’re operating as one organization, we can bring Blood Systems’ offerings to interested hospitals and health systems in the northeast and mid-Atlantic region, and bring ITxM’s experience and expertise in centralized transfusion services, coagulation diagnostics and hemophilia patient services to Blood Systems’ customers around the country.”



(Source: Blood Systems, Inc. News Release, 12/12/17)

Ronald Sacher, MD, director at Hoxworth Blood Center, has been appointed as the 2018 president of the American Clinical and Climatological Association (ACCA). The organization is the oldest medical society in the U.S. Its active membership is limited at 250 physicians with members chosen for their leadership and

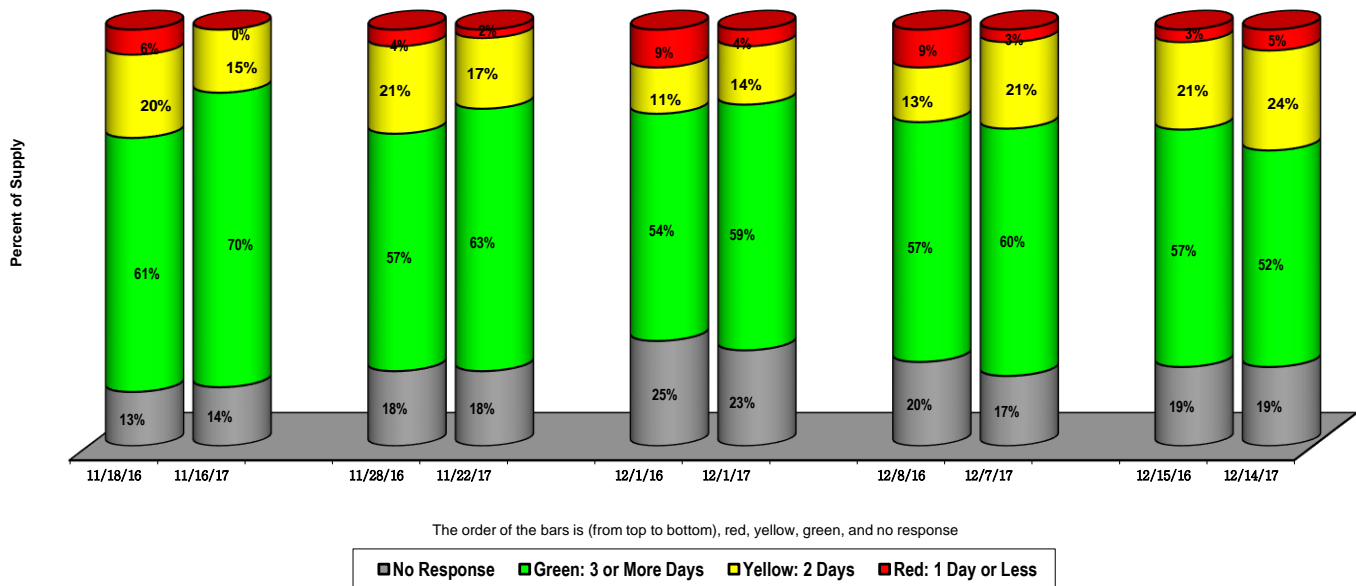
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PEOPLE (continued from page 11)

excellence in their field, while exhibiting integrity and professionalism. “The ACCA is a multidisciplinary organization of people who have leadership in American medicine,” said Dr. Sacher. “We have members who are presidents of universities, as well as leaders and deans of medical schools and department chairs. It’s a very prestigious organization. This is really one of the highlights of my career.” Dr. Sacher joined Hoxworth in 2000 and is the only the fourth director in Hoxworth’s 70-year history.

(Source: Hoxworth Blood Center News Release, 12/12/17) 💧

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



Daily updates are available at:
www.AmericasBlood.org

CALENDAR

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

2018

Feb. 5-7. **14th Annual FDA and the Changing Paradigm for HCT/P Regulation., Alexandria, Va.** Register [here](#).

Feb. 21. **SCABB Regional Symposium: General Topics for Blood Bankers in Clinical Laboratory Medicine, Orlando, Fla.** For more information, contact [Nancy Benitez](#).

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CALENDAR (continued from page 12)

Mar. 17-19. **ABC Annual Meeting, America's Blood Centers, Scottsdale, Ariz.** More details available [here](#).

Mar. 21-22. **IPFA 3rd Asia Workshop on Plasma Quality and Supply, Kuala Lumpur, Malaysia.** More details available [here](#).

May 8-10. **ABC Human Resources and Training/Development Workshop, Dallas, Texas.** More details available [here](#).

May 9-11. **ADRP Conference & Expo, Dallas, Texas.** More details available [here](#).

May 16-17. **IPFA/PEI 25th Workshop on "Surveillance and Screening of Blood-borne Pathogens," Athens, Greece.** More details available [here](#). ♦

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POSITIONS

Medical Technologist (MT). Blood Bank of Hawaii is seeking a Medical Technologist (MT) to join our Laboratory team!! The candidate is responsible for: Component antigen testing in the donor blood testing section of the laboratory; and patient testing in the Immunohematology Reference Lab, including but not limited to ABO grouping, Rh testing, antibody screening, and antibody identification to include complex work-ups. The ideal candidate will: Encompass a high standard for accuracy, follow-up and follow-through; thrive in an environment where problem solving is a necessity; work with team members ensuring compliance at all times; and serve as a technical resource to hospitals and other departments. Minimum qualifications include Baccalaureate degree in Medical Technology or in a related science from an accredited college or university; Certified Medical Technologist by the ASCP; eligible for Clinical Laboratory Technologist license by the Department of Health of the State of Hawaii. Previous work experience as an MT in hematology and immunohematology is preferred; certification as a Specialist in Blood Banking (SBB) highly desirable. Visit our website at www.BBH.org to complete an online application. 💧