

2014 #16

May 2, 2014

INSIDE:

Our Space: Don't Say I Haven't Said Anything Nice About FDA Recently2

IN MEMORIAM – Jerry Haarmann, 61.....4

IPFA, BCA to Hold Global Symposium on the Future of Blood, Plasma Donations5

ABC to Host Special Members Meeting Via Webinar to Vote on Bylaws Revision6

Hot on the Listservs: Can Donors and Staff Carry Weapons Into Blood Centers?.....7

Upcoming ABC Webinars – Don't Miss Out!.....7

RESEARCH IN BRIEF8

BRIEFLY NOTED.....9

REGULATORY NEWS..10

THE WORD IN WASHINGTON.....11

GLOBAL NEWS11

STOPLIGHT®: Status of America's Blood Centers' Blood Supply12

MEMBER NEWS.....13

PEOPLE13

MEETINGS14

POSITIONS AVAILABLE14

Blood Centers Help Camps for Kids with Bleeding Disorders

For more than 30 years, the National Hemophilia Foundation and its local chapters have been supporting summer camps for children with hemophilia and other bleeding disorders, offering these children the opportunity to experience fun outdoor activities in a safe environment. Prior to this summer, children with hemophilia in Wisconsin had to attend such camps in other states. But now, thanks to the BloodCenter of Wisconsin (BCW), in partnership with the Great Lakes Hemophilia Foundation (GLHF), Wisconsin children will be able to attend a new summer camp in their home state.

BCW and GLHF announced on April 24 that this summer they will open Camp Klotty Pine, the first summer camp in Wisconsin for children with hemophilia and other bleeding disorders. Through this partnership, BCW will provide medical staff at the camp and help with the creation of medical policies to improve the quality of life for these children and help them become more independent through self-care, said Tom Abshire, MD, chief medical officer at BCW.



Camp Lakotah in Wautoma, Wis., the future site of Camp Klotty Pine. (Photo Credit: Camp Lakotah)

While it may seem out of the ordinary for a blood center to run a summer camp, Dr. Abshire noted that establishing this camp was a natural extension of BCW's long-standing partnership with GLHF, as well as the center's role in providing clinical and pharmaceutical services to hemophilia patients, particularly through its Comprehensive Center for Bleeding Disorders. It became clear to BCW and GLHF that a need existed for a camp that Wisconsin children with bleeding disorders could attend within their home state.

"We believe that the camp experience is an extension of care for children so they can gain a sense of independence and socialize with other children who have hemophilia and other bleeding disorders," said Dr. Abshire. "We have been involved in providing clotting factors for these patients and running the clotting

(continued on page 3)



OUR SPACE

ABC Executive Vice President, SMT, Louis Katz, MD

Don't Say I Haven't Said Anything Nice About FDA Recently

The Food and Drug Administration's Center for Biologics Evaluation and Research and Center for Devices and Radiological Health has issued a draft guidance (available at <http://1.usa.gov/1nEBjUq>). It describes the statutory and regulatory foundations permitting the agency to approve "Premarket Approval" (PMA) applications for medical devices even when all of the data that FDA requires are not available at the time of approval. The lynchpin is that "FDA believes that applying postmarket controls in order to reduce premarket data collection, when appropriate, improves patient access to safe and effective medical devices that are important to the public health." The Food, Drug and Cosmetics Act requires that FDA use the "least burdensome" data requests to establish the effectiveness of a device and that "probable benefits" be weighed against "probable risks."

There is no new regulatory ground broken in this guidance, but it emphasizes the ability of the agency to be flexible. Current events in blood banking may provide an important example of that flexibility. I have argued that advisory committee discussion of the path to approval of pathogen reduction (PR) technologies was "hijacked" by attempts to apply rigid pharmaceutical principles to the evaluation of an extraordinarily complex biological product and its use – platelets and platelet transfusion. The agency has chosen to eschew the approach recommended by its Blood Products Advisory Committee that would have required large new clinical trials at great expense, entailing long delays, to evaluate what were – at best – controversial risks. Instead, FDA is considering using, in part, the postmarket experience in the European Union (EU) with a sponsor's pathogen-reduced platelets to evaluate a PMA. Assuming approval, FDA will require the sponsor to execute a substantial postmarket surveillance program to confirm what appears to be acceptable safety and effectiveness across the pond. The availability of PR holds promise to eliminate platelet-associated bacterial sepsis (the most common cause of infectious mortality from transfusion in the US), as well as the contortions we are considering for its mitigation. PR could alleviate our need to identify and provide to appropriate recipients with irradiated platelets and provide a layer of protection against a broad array of emerging pathogens.

The postmarket surveillance requirements under consideration will need an unprecedented level of cooperation from the sponsor, us, and our colleagues in hospitals to provide what I think the agency will request. Postmarket requirements will likely increase the cost of the technology to the collection facilities that will apply PR to blood products and to the providers that will use them – so we need to understand the cost-benefit proposition being considered. In the least, the approaches explained in this guidance and being applied in this example offer you an understanding what it will take to move forward.

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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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Hemophilia Summer Camp (continued from page 1)

program for Wisconsin for a number of years, and we feel that since we've been taking care of these children and adults, it is important that we contribute to improving their quality of life."

Physicians, nurses, and other staff from BCW's Comprehensive Center for Bleeding Disorders will assist in providing 24-hour care at the camp, along with medical staff from other Wisconsin hemophilia treatment centers. The children will enjoy all of the usual summer camp activities – swimming, canoeing, arts and crafts, and campfires – but will also be trained to self-infuse, helping them take control of their care.

"The children at this camp will get to experience the same kind of activities that happen at camps around the world, but we have to temper that with the fact that they have bleeding disorders. We want them to be safe, but also to feel as normal as possible," said Dr. Abshire.

To create a fun and safe environment for these children, Shawn M. Jobe, MD, PhD, medical director of BCW's Comprehensive Center for Bleeding Disorders, has been working closely with GLHF Executive Director Danielle Leitner Baxter to create appropriate medical policies. GLHF has visited several bleeding disorder camps around the country to learn from their policies. To allow the kids to participate safely in activities, the camp medical personnel may, for example, prophylactically administer clotting factors (with the parents' consent) to children who are highly likely to bleed, said Dr. Abshire.

"Providing a camp experience that is close to home reassures parents and prepares kids to manage their disease on a daily basis," said Ms. Baxter. "We are grateful that through this partnership with BloodCenter of Wisconsin, GLHF will be able to provide an experience that will open doors to improve the quality of life for these kids."

BCW is not the only center helping to run a camp for children with bleeding disorders, as a handful of other blood centers have become involved in supporting similar camps across the US. Nearly 40 years ago, Camp I-Vy was established, offering a weeklong summer camp for children with bleeding disorders and their families in Washington state. About 10 years ago, Puget Sound Blood Center (PSBC), headquartered in Seattle, Wash., partnered with the Bleeding Disorders Foundation of Washington to help facilitate and provide financial assistance for children to attend Camp I-Vy.

"Before Camp I-Vy was created, children with bleeding disorders often felt isolated, and their families often faced serious financial burdens arising from the cost of medical care, precluding them from enrolling their child in a medically-supervised camp," said Jim AuBuchon, MD, PSBC's president and CEO. Through annual joint fundraising events held with the Bleeding Disorders Foundation of Washington, PSBC has provided financial assistance to support the attendance of children and families at Camp I-Vy.

Camp I-Vy seeks to foster independence, build community, and empower children impacted by bleeding disorders in Washington state, said Dr. AuBuchon. "We support Camp I-Vy because it enables these children to experience firsthand the sensations of life in the outdoors – along with the camaraderie, teamwork, friendships, and lifelong memories that are part of a summer camp tradition. Without this active participation by PSBC, many of these children and families would not have the financial resources and could not otherwise share this camp experience," he added.

Dr. AuBuchon noted that participating in this camp is an extension of the center's hemophilia care program and its commitment to meeting the needs of patients, partly by identifying gaps in patient care and moving to close those gaps. (Source: BloodCenter of Wisconsin press release, 4/24/14) ♦

IN MEMORIAM – Jerry Haarmann, 61

Jerry Haarmann, who until recently served as president of Group Services for America's Blood Centers (GSABC) and president of the Blood Group Alliance (BGA), passed away on April 30 at the age of 61 due to a brain injury caused by a fall. With more than 20 years of executive leadership experience in blood banking and transfusion medicine, Mr. Haarmann was a widely respected authority in these industries and was well known for his financial acumen, leadership talents, and industry vision.



“Jerry always found the commonality and positive in people and situations. This was rare in an industry known for individualism,” said Linda Gerber, CEO of Rock River Valley Blood Center and immediate past board chair of GSABC. “He had the unique ability to put aside his personal feelings and find ways to unite. His leadership at GSABC was instrumental in its formation but demonstrated even more in the merger that was concluded this past month. He was a leader, mentor, and friend, and will be greatly missed by all who he touched.”

Mr. Haarmann was recruited by America's Blood Centers in 2004 to evaluate the ABC Group Services Committee and was instrumental to the initial start-up of GSABC as a new, forward thinking group purchasing organization (GPO) designed to be member-owned. Since 2005, he led the GPO to return over \$30 million in measurable value to members through rebates, patronage dividends, and additional revenue on other sales.

“Jerry was a great contributor to blood banking. As the president of GSABC, he brought innovation and cost savings to our community blood centers and led the way in finally bringing BCA and GSABC members together into one group,” said Jeanne Dariotis, senior vice president of Laboratories at OneBlood in Florida. “He was an active member of our professional community and a good personal friend to many of us. He will be deeply missed. Our thoughts are with his family in this difficult time.”

Prior to holding the presidency of GSABC and BGA, Mr. Haarmann served as CEO at Memorial Blood Centers in Minneapolis from 1990 to 2004, during which time he was instrumental to growing the organization into eight donor centers and expanding its range to include expert testing and laboratory services.

Before joining Memorial Blood Centers, Mr. Haarmann founded and served as president of Haarmann Business Services for eight years, providing financial advisory services to corporate clients in the retail, medical, manufacturing, and agricultural industries. From 1976 to 1982, Mr. Haarmann held a number of managerial and executive leadership roles at companies including Siemer, Inc., in Teutopolis, Ill. and Pillsbury in Olney, Ill.

“I know I will miss Jerry's friendship, his professionalism, and his dedication, but what I will miss most is his exceptional ability to see any obstacle, not so much as a restraint on progress, but rather as a stepping stone to a higher goal,” said Merlyn Sayers, MB, BCh, PhD, president and CEO of Carter BloodCare.

Mr. Haarmann had also served in several board and committee positions, including investor advisor for J.P. Morgan, board chair for Medical Alley, vice chair for the National Marrow Donor Program, and treasurer and board of directors member for ABC. He earned his Bachelor of Science degree from Western Illinois University in Macomb, Ill.

(continued on page 5)

IN MEMORIAM – Jerry Haarmann (continued from page 4)

“I had the pleasure of working with Jerry for many years, not only during his GSABC career, but also when he and I worked together on ABC’s finances during his term as ABC’s treasurer in the late 1990s,” said Bill Coenen, ABC’s vice president of Finance. “I will remember his ability to always get to the root cause of the problem. His friendship will be missed.”

Mr. Haarmann is survived by his loving wife of 39 years, Marjorie; daughter Jodi (Aaron) Lloyd; sons, Paul (Hillary) and John and his fiancée Renée; grandchildren, Lucy Haarmann and Harmon Lloyd; sisters, Madonna (Fred) Moffett, Sr. Patricia, Sr. Frances, Barbara (Don) Vahling, Rita (Larry) Habing, and Karen (Kevin) Niebrugge; and many other family and friends.

Mr. Haarmann’s family set up a CaringBridge website page for all who want to pay their respects; it can be accessed at <http://www.caringbridge.org/visit/jerryhaarmann>. There will be a visitation on Sunday, May 4 from 3 to 7 p.m. at Klecatsky & Sons Funeral Home, 1580 Century Point, Eagan, MN. The funeral will be held Monday, May 5 at 9:30 a.m. at the Church of St. Peter, 1405 Sibley Memorial Highway, Mendota, MN. The family has indicated memorials to Children’s Hospital of St. Paul are preferred. The address is Children’s Hospital, 2910 Centre Pointe Dr., Roseville, MN 55113.

The family is currently overwhelmed by the shock of this sudden tragedy and asks that those wishing to pay respects do so through the CaringBridge website rather than through contacting them directly. ♦

IPFA, BCA to Hold Global Symposium on the Future of Blood, Plasma Donations

The International Plasma Fractionation Association (IPFA) and Blood Centers of America (BCA) will hold the first-ever Global Symposium on the Future of Blood and Plasma Donations, hosted by BloodSource, at the Sheraton Grand in Sacramento, Calif. from Sept. 23 to 24. This inaugural conference seeks to raise awareness of and address the significant need for plasma to develop plasma-derived therapies.

“We are pleased to be partnering with BCA and BloodSource on this very important issue,” said Paul Strengers, MD, president of IPFA. “There is a growing need to collect plasma to help patients in need. Currently, there is a worldwide shortage of plasma and as we continue to see advancements in technology and plasma-derived medicines, the need will continue to grow. As a collective industry and on behalf of patients everywhere, we need to take action to address this growing concern.”

The two-day symposium will attract attendees from around the world including blood banking and plasma professionals, administrators and medical personnel, regulators, and patient advocacy groups. It will feature industry experts and international speakers who will discuss a broad range of topics including: Clinical developments and demand of plasma-derived medicines; quality management of plasma; donor recruitment and engagement; maintaining a safe and secure plasma supply; manufacturer highlights and information; and new developments and approaches to meet patient need (patient case studies).

The program has been developed by internationally recognized experts and will be of interest to colleagues from blood banking, patient and donor organizations, supporting industries, and regulatory authorities with an involvement in policies to meet patient needs for plasma derivatives.

Those interested in learning more about the meeting or in viewing the program may visit <http://bit.ly/1fDqJrX>. Online registration can be completed at <http://bit.ly/Sby25b>. Questions may be directed to Dr. Strengers at info@ipfa.nl. ♦



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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 to Host Special Members Meeting Via Webinar to Vote on Bylaws Revision

America's Blood Centers' board of directors requests that ABC members participate in a special members meeting via webinar on May 14 at 2 p.m. EDT to vote on an important revision to the ABC bylaws that will affect the ABC officers and board of directors. Prior to this meeting, ABC will also hold a webinar on May 6 at 4 p.m. EDT to brief members on the matter and allow for questions about the proposed changes.

As it currently stands, the ABC bylaws designate that an ABC board of directors member or officer who departs from the member blood center that he or she served at the time of election would become ineligible to continue serving in their current board or officer position. The bylaws also prohibit two board members currently employed at the same center from serving on the board. Therefore, if a board member changes jobs causing there to be two board members from the same center, he or she can no longer serve on the board.

The ABC Bylaws Committee recommended two changes that would:

- Allow an officer or board member to remain on the board if they change jobs, as long as they retain a significant leadership position with a member of ABC; and
- Allow an officer or board member to remain on the board until the conclusion of their current terms if a job change results in two board members being from the same blood center.

ABC's board voted unanimously that it is in the best interest of ABC members to bring these two recommendations for membership vote now, rather than waiting to include them in the comprehensive bylaw revision proposal to be presented at the Summer Meeting. If the ABC membership votes to approve these changes, the organization can assure continuity of board leadership going forward and maintain focus on important ABC initiatives.

ABC members can access a side-by-side comparison of the bylaws on the members website at <http://bit.ly/1hDpkmC>. ABC reminds members that the member voting representative (MVR) or alternate must be present on May 14 or complete a proxy ballot form prior to May 14 to vote. In order to conduct this meeting, ABC's bylaws require two-thirds of members to be present (45 members), and a three-fourths affirmative vote of those present is required to change the bylaws.

ABC members can access login details for the May 14 members meeting and the May 6 informational webinar, as well as the proxy ballot at <http://bit.ly/1u6028q>. Questions regarding MVRs or alternates can be directed to Lori Beaston at lbeaston@americasblood.org. ♦

INSIDE ABC (continued on page 7)

Hot on the Listservs: Can Donors and Staff Carry Weapons Into Blood Centers?

“Hot on the Listservs” is a series that appears in the Newsletter once a month, exploring a different topic that has generated discussion via America’s Blood Centers’ e-mail Listservs. These Listservs allow ABC blood center professionals to discuss issues, ask questions, and gain feedback from colleagues.

Lately, ABC member blood centers have been looking for information on the ABC Collections & Donor Services and Human Resources Listservs about policies regarding staff and donors carrying weapons on blood center premises. Issues have arisen at several ABC member centers regarding how to deal with concealed weapons.

While the Second Amendment gives US citizens the right to keep and bear arms, individual states develop their own laws on the execution of the Second Amendment. As states adopt laws making it easier for citizens to carry weapons, like Mississippi’s Open Carry and Georgia’s Safe Carry Protection Act, blood center staff have become concerned about blood center policies regarding weapons.

The majority of members responding in threads on the ABC Listservs indicated that they do not allow weapons or ammunition on the premises (while others exempt law enforcement personnel). Safety was the biggest reason cited for such policies, given the risk of donor adverse events involving altercations in consciousness and weapon control during the reaction. One center indicated that they had modified their policy for staff to comply with an amendment to Texas’s concealed carry permit, which allows holders to keep weapons and ammunition in their personal vehicles, even at work. Prior to the passage of that law, this was prohibited at the center.

None of the blood center staff indicated that they had encountered any problems with donors complying with policies, but some did say they had donors who discussed their Second Amendment rights. One center shared its policy on how to handle situations in which a donor is discovered to be carrying a concealed weapon. That policy reads:

“The reality is, the majority of donors will not see the sign and you would never know if they had a concealed weapon on them. But if you see one, the key is not to panic, but calmly explain to them our policy in private, as to not let other donors hear the conversation. When explaining the policy, you must inform them it is for safety reasons only. Please instruct them to place the weapon in their vehicle and come back to continue the donating process. If you notice a weapon while the needle is in their arm, you will continue the entire process and have the discussion with them once complete. Remember, the vast majority of the individuals are just exercising their right to carry and are dedicated to saving lives through blood donations.” ♦

Upcoming ABC Webinars – Don’t Miss Out!

- **“Bylaws Amendment Presentation and Discussion”** – May 6 at 4 p.m. EDT. More information: <http://bit.ly/1u6028q>.
- **“Special ABC Members Meeting – Bylaws Amendment Vote”** – May 14 at 2 p.m. EDT – More information: <http://bit.ly/1u6028q>.



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Scholarship opportunities available to ABC members to cover the cost of registration fees and help with travel expenses. Application form and details will be made available once registration opens.

“The Indiana Blood Center is looking forward to welcoming ABC members to Indianapolis for the Information Technology Workshop. We anticipate a vibrant dialogue, exchange of ideas and discussions on the time tested best practices used by our member centers. This will be an excellent opportunity to mingle with your peers, meet new people and prepare for the rigors of the changes bound to hit the information technology world. We look forward to seeing you in Indianapolis this Fall.”

– Byron Buhner
President and CEO, Indiana Blood Center

Sponsorship opportunities available. Contact Abbey Nunes at anunes@americasblood.org for details.



Indianapolis International Airport (IND) is served by most major US airlines and offers non-stop service to 34 destinations; check www.indianapolisairport.com for more information.

RESEARCH IN BRIEF

The authors of a recent Cochrane Review suggest that erythropoietin (EPO) should not be used routinely in preterm infants. Newborns can experience anemia after birth and this effect is exaggerated in preterm infants by frequent phlebotomy for blood tests. Therefore, preterm and low-birth-weight infants are more likely to receive red blood cell (RBC) transfusions. EPO, which stimulates RBC production, is often used in preterm infants and can be used “early” (before the infant is 8 days old) to prevent or decrease the use of RBC transfusions. Arne Ohlsson, of the University of Toronto, and colleagues conducted a review and analysis of randomized or quasi-randomized controlled trials of early (< 8 days old) initiation of EPO treatment vs. placebo or no intervention in preterm and/or low-birth-weight infants to assess its safety and effectiveness for reducing RBC transfusions in these patients. The authors analyzed the results of 2,209 preterm infants enrolled in 27 studies and found that early EPO treatment reduced the number of RBC transfusions and donor exposures following its use. They discounted the clinical significance of this decrease since many of these infants had been exposed to RBC transfusions prior to entry into clinical trials. Treatment with early EPO did not have any important effects on mortality or common complications of preterm birth with the exception that EPO may increase the risk for retinopathy of prematurity, a serious complication that can cause blindness. “Based on our findings EPO is not recommended for routine use in preterm infants,” write the authors.

Citation: Ohlsson A, Aher SM. Early erythropoietin for preventing red blood cell transfusion in preterm and/or low birth weight infants. *Cochrane Database Syst Rev.* 2014 Apr 26. [Epub ahead of print]

RESEARCH IN BRIEF (continued on page 9)

RESEARCH IN BRIEF (continued from page 8)

The results of a Phase II trial recently published in *BMC Medicine* found that higher-volume transfusions were safe and resulted in quicker hemoglobin recovery in Ugandan children with severe anemia. An accompanying commentary in *BMC Medicine* offered a risk-benefit analysis of transfusion for these children. Anemia is a leading cause of hospitalization for children in Africa, with an in-hospital mortality ranging from 6 to 16 percent and longer-term mortality of 13 to 20 percent. Blood transfusion increases short-term survival from severe anemia, but two-thirds of deaths occur before transfusion is administered. Furthermore, transfusion carries significant risks in Africa, such as transfusion-transmitted disease, and is a particularly scarce resource. Larger-volume initial transfusions may reduce these risks by reducing donor exposures and might conserve the resource. Peter Olupot-Olupot and colleagues evaluated the safety and efficacy of higher volume whole blood transfusion (30 ml/kg), as compared with the standard volume (20ml/kg) in Ugandan children with hemoglobin levels of <6 gm/dL for anemia correction at 24-hours and 28-day survival. The children in this study were very ill – half were in respiratory distress, one-third were prostrate, and one-third had a blood lactate level of ≥ 5 mmol/l. All received a bundle of standard care. The large volume transfusion group demonstrated more frequent correction and higher resultant hemoglobin than the 20 ml/kg group; an effect that was sustained at 48 hours, but not at 28 days. At 28 days, the overall mortality was 4 percent, which compares favorably with case fatality rates in other studies, thus supporting rapid access to transfusion and a standardized bundle of care for children with severe anemia in sub-Saharan Africa, wrote Thomas Brick and Mark J. Peters in the accompanying editorial. “We can, cautiously, hypothesize that the benefit of transfusion increases both as the child’s hemoglobin falls and when severe anemia is accompanied by severe physiological derangement. The risk-benefit relationship of transfusion is likely to be context specific, and will be influenced by region, etiology of severe anemia and accompanying disease,” they conclude. “The complexity of these factors is such that definite empirical data from large-scale phase III trial is the way forward. Olupot-Olupot and colleagues have moved this closer with their important study.”

Citations: Olupot-Olupot P, *et al.* Phase II trial of standard versus increased transfusion volume in Ugandan children with acute severe anemia. *BMC Med.* 2014 Apr 25;12(1):67.

Brick T, Peters MJ. Risks and benefits of transfusion for children with severe anemia in Africa. *BMC Med.* 2014 Apr 25;12(1):68. ♦

BRIEFLY NOTED

A biomedical engineer at the University of Houston is developing a microfluidic device to improve transfusion safety by separating the red blood cells (RBCs) from the substances accumulating during storage before transfusion, announced a university press release on April 23. Sergey Shevkopyas, PhD, a biomedical engineering professor at the University of Houston, has received a \$1.8 million grant from the National Institutes of Health to support this work. While RBC transfusions can be life-saving, patients are exposed to other materials with blood – including potentially bioactive substances that are altered or deformed related to storage. The clinical importance of these exposures is controversial. Dr. Shevkopyas, working under the NIH Director’s Transformative Research Award, is developing a simple device to separate healthy, well-preserved RBCs from these other materials just before transfusion. It consists of two tubes that feed a small microfluidic device that will wash the blood with a saline solution and then separate damaged RBCs from healthy ones. Dr. Shevkopyas emphasized that scaling up this microfluidic device, which normally handles just a few drops per hour, to process the

(continued on page 10)

BRIEFLY NOTED (continued from page 9)

larger volumes necessary for transfusion will be challenging. “Adapting our understanding of microfluidics to a high-throughput device is not very simple, though we do have some good data to show we can do it.” He notes that the materials he will use to build the device, like the saline solution, are already approved by the Food and Drug Administration, reducing the burden for regulatory approvals. (Source: University of Houston press release, 8/23/14)

AABB published the 2012 AABB Donor Hemovigilance report, prepared by the AABB US Donor Hemovigilance Working group, according to the April 25 AABB Weekly Report. This first annual report summarizes data from five blood centers – representing about 1.2 million donations – on adverse donor reactions. The overall reaction rate was 13.41 per 1,000 donation procedures. Participating blood centers used the Donor Hemovigilance and Analysis Reporting Tool (Donor HART) software to report collection sites, donor demographics, and adverse reactions. The report also describes the current capabilities and applications of the Donor HART software, as well as its potential for further development. The report can be accessed at <http://bit.ly/R3EMBK>. AABB encourages any blood centers or hospital blood banks interested in joining the AABB US Donor Hemovigilance Program to contact biovigilance@aabb.org for more information. (Source: AABB Weekly Report, 4/25/14) ♦

REGULATORY NEWS

The AABB Donor History Task Force (DHTF) resubmitted on April 18 revised flow charts to the Food and Drug Administration to comply with the agency’s malaria donor management recommendations. The flowcharts correspond to questions 28 and 39 on the full-length Donor History Questionnaire and question 12 on the abbreviated Donor History Questionnaire. The AABB DHTF, working with FDA liaisons, revised the flowcharts to reflect the recommendations made in the August 2013 guidance for industry “Recommendations for Donor Questioning, Deferral, Reentry, and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria” (available at <http://1.usa.gov/13P16yh>; see *ABC Newsletter*, 8/23/13). FDA will publish a separate guidance document to announce its official recognition of the revised flowcharts as an acceptable method for screening donors in compliance with the August 2013 recommendations. Blood centers that wish to implement the 2013 malaria guidance prior to publication of FDA approval of the revised flow charts must submit a Prior Approval Supplement (PAS) to their Biologics License Application to FDA. The *ABC Newsletter* will provide updated information when the separate guidance is published. (Source: AABB Weekly Report, 4/25/14) ♦

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer’s name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Betty Klinck at newsletter@americasblood.org. You will be sent a writer’s guide that provides information on style conventions, story structure, deadlines, etc.

THE WORD IN WASHINGTON

This week, America's Blood Centers sent a letter urging the US Senate to confirm the President's nominee, Sylvia Mathews Burwell, as secretary of the US Department of Health and Human Services (HHS), succeeding Kathleen Sebelius. In its letter, ABC cited the need for timeliness in the Food and Drug Administration's decision-making process and Ms. Burwell's public and private sector management experience. "Community blood centers rely on the FDA to make timely regulatory decisions based on scientific evidence. Ms. Burwell, an individual with outstanding private and public sector credentials, has demonstrated her ability to lead, build strong relationships, and deliver timely results," states the letter, signed by ABC President Dave Green and ABC CEO Christine Zambricki, DNAP, CRNA, FAAN. "Our organization has a particular interest in this appointment, as the FDA and the blood community collectively have an important role to play in balancing scientific evidence and risk management in order to assure the safety and availability of the US blood supply." The Senate Health, Education, Labor, and Pensions Committee has scheduled one confirmation hearing for Ms. Burwell on May 8. The full letter is available to ABC members at <http://bit.ly/1hhAhZY> (requires member login and password).

The House and Senate are back in Washington this week, with the Senate working on presidential nominations and minimum wage legislation. The House is taking up a bill exempting expatriates from the Affordable Care Act, and is starting to work on appropriations bills for fiscal year 2015.

Sen. John Boozman (R-AR), an optometrist knowledgeable about health policy issues, was admitted to an Arkansas hospital last week and diagnosed with acute aortic dissection. He underwent emergency surgery and is recovering. America's Blood Centers' members in Arkansas who would like to send their well-wishes may address get-well notes to Sen. John Boozman, 1401 W. Capitol Ave., Plaza F., Little Rock, AR 72201. More information about Sen. Boozman's condition can be found at *The Washington Post's* Post Politics blog at <http://wapo.st/1rJInIZ>. (Source: The Washington Post – Post Politics Blog, 4/23/14) ♦

GLOBAL NEWS

The World Health Organization (WHO) recently announced the theme for World Blood Donor Day, which will be celebrated on June 14. World Blood Donor Day is recognized by blood centers around the world each year in June to recognize regular blood donors and to raise the awareness of the need for voluntary donors. WHO announced on April 17 that this year's campaign is titled "Safe blood for saving mothers." It will focus on increasing the awareness about why timely access to safe blood and blood products is essential for all countries as part of a comprehensive approach to preventing maternal deaths. WHO encourages all countries and national and international partners working on blood transfusions and maternal health to develop an activity plan to highlight the need for timely access to safe blood and blood products in the prevention of maternal deaths. More information about the campaign and World Blood Donor Day resources can be accessed on the WHO website at <http://bit.ly/QAUd3w>. (Source: WHO World Blood Donor Day page, 4/17/14)



(continued on page 12)

GLOBAL NEWS (continued from page 11)

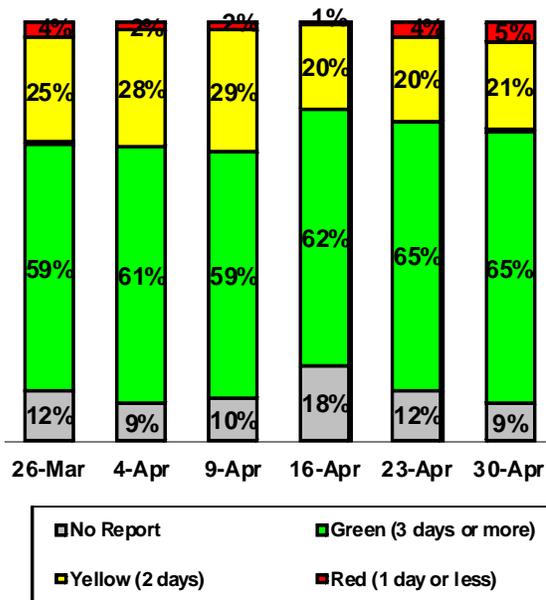
To celebrate Star Wars Day – celebrated on May 4 each year – the 501st Legion, the Star Wars fan club in Thailand, dressed as “Stormtroopers” and donated blood at the Thai Red Cross on April 26, according to several international news sources. The 501st Legion made the donations as part of a charity campaign, by which they will also raise funds for an orphanage house in Bangkok. Star Wars Day is now an international celebration with the movie’s fans all over the world being encouraged to use the greeting, “May the 4th Be With You,” while wearing their favorite Star Wars costumes and carrying Star Wars Props. Blood donors and staff gathered-round to watch the costumed Star Wars fans save lives through blood donation. Photos from the eventful donation were shared through online media all over the world. (Sources: Metro, 4/28/14; The Huffington Post, 4/28/14) ♦



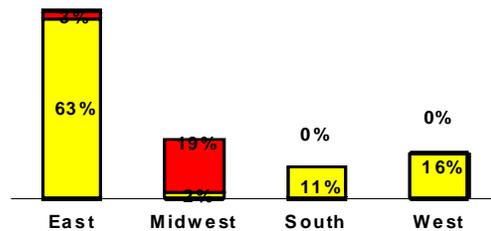
A Star Wars fan gives blood at the Thai Red Cross dressed in a Stormtrooper costume as part of a charity campaign.

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, April 30, 2014



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

MEMBER NEWS

Donors and blood center staff at LifeStream in San, Bernardino, Calif., cheered on Bob Hitchman III on April 23 when he became the second LifeStream donor in the 63-year history of the organization to reach 1,000 blood donations. “Bob’s dedication and commitment for saving lives has established him as a premier LifeStream blood donation ambassador for all blood donors to emulate,” said Rick Axelrod, MD, LifeStream’s president and CEO and ABC’s vice president. Mr. Hitchman recounted how his wife Jean Hitchman (now a 15-gallon donor herself) challenged him 35 years ago to donate blood. Once he did so, there was no stopping him. He first donated via apheresis in 1986 and converted to platelet donations full time in 1987. Since February, LifeStream has celebrated two, 1000-donor achievements and a 100-gallon milestone. “What a year this has been for LifeStream; or, more accurately, what a year for accomplishments at LifeStream that we’ve been privileged to witness,” said Piper Close, LifeStream’s vice president of marketing and public relations, at a post-donation ceremony commemorating the donation. Mr. and Mrs. Hitchman’s example have resonated with their sons, both of whom are first responders and blood donors. Mr. Hitchman has served local youth since 2000 as a volunteer high school coach. (Source: LifeStream submission, 4/30/14) 💧



PEOPLE

Donald “Joe” Chaffin, MD, recently joined LifeStream, San Bernardino, Calif., as the center’s vice president and chief medical officer. Dr. Chaffin will serve as a member of LifeStream’s executive team and be the medical leader for all LifeStream programs. Dr. Chaffin’s primary responsibilities include serving as LifeStream’s transfusion medicine resource for all hospital partners, including participation on transfusion committees, and as LifeStream’s medical expert for donor operations, medical surveillance, national marrow donor program, reference laboratory and quality assurance. Prior to coming to LifeStream, Dr. Chaffin served as director of clinical pathology services and senior consultant in transfusion medicine at Cedars-Sinai Medical Center in Los Angeles. Dr. Chaffin also served as medical director and vice president of medical affairs for Bonfils Blood Center in Denver, Colo., and blood services medical director for the Summit Pathology Group serving Banner Health and Poudre Valley Hospital Systems in Colorado. Dr. Chaffin is a graduate of the Loma Linda University School of Medicine. He completed his anatomic and clinical pathology residency at Walter Reed Army Medical Center, Washington, D.C. and was hired by the organization to serve as its medical director, blood services from 1995 to 1999. He was honorably discharged from the US Army at the rank of Major. Dr. Chaffin has a long history of innovative educational efforts, including his award-winning website, “Blood Bank Guy” (www.bbguv.org), visited more than 20,000 times per month by students around the world. He was honored as “Most Outstanding Teacher” by pathology residents at both Walter Reed and Cedars-Sinai, most recently in 2013. He is a member of AABB and a Fellow, American Society for Clinical Pathology and College of American Pathologists. (Source: LifeStream press release, 4/30/14)



PEOPLE (continued on page 14)

PEOPLE (continued from page 13)

Eric Blomfelt, JD, CPCU, was recently appointed the executive director of BCx, a community blood centers' exchange risk retention group. He will replace Kate Westover, who is retiring after serving as BCx's executive director for six years. Mr. Blomfelt received his law degree from the University of Wyoming and holds a Bachelor of Arts in Journalism from the same institution. He has extensive insurance and risk management experience including being the executive director of an association of risk managers and working with risk retention groups. Currently residing in Fort Collins, Colo., he has authored a number of articles on legal issues for risk managers, and teaches business courses in insurance and risk management. In his role as executive director, Mr. Blomfelt will be overseeing BCx's consulting team as they continue to implement the revised business plan developed during the BCx Board's 2013 strategic planning initiative. Mr. Blomfelt's contract will begin May 1 and he will work directly with Kate Westover thru August 31 to provide a smooth transition. BCx is a specialty insurance company owned by its insureds, which currently provides liability insurance to over 30 community blood centers. (Source: BCx press release, 4/30/14) ♦

**MEETINGS****June 4-6 68th Annual FABB Conference, Sarasota, Fla.**

SunCoast Blood Bank will host the 68th Annual Florida Association of Blood Banks (FABB) Conference. The conference will be held at the Sarasota Hyatt, June 4 to 6. Workshop topics will include leadership, education, medical and technical updates, recruitment and communications practices, and customer service training. The Southern Community Association of Blood Banks will also be in attendance, and will offer CEUs for nurses and medical technicians in medical, technical, and management and leadership tracks. More information and a link to register can be found at www.floridaabb.com. ♦

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 Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: mnorwood@americasblood.org.

POSITIONS AVAILABLE:

Associate Medical Directors (AD002- San Antonio, TX or AD003 – Norcross, GA). BioBridge Global (BBG) and its subsidiaries (South Texas Blood & Tissue Center, GenCure and QualTex) are seeking two Associate Medical Directors for locations in San Antonio, Texas (FT) or Norcross, Georgia (PT or FT). Reporting to the Medical Director, will establish medical procedures to ensure optimal care and regulatory compliance. This includes oversight of research, clinical consultation, client support, autologous/directed donations, cord blood collections and counseling. Will provide medical support to blood/components, laboratory testing, product

management, clinical diagnostics and QA. Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO) required. Must be licensed to practice medicine in the State of Texas, Georgia, and New York. Board certified in clinical pathology or hematology required. Blood banking, transfusion medicine, board

POSITIONS (continued on page 15)

POSITIONS (continued from page 14)

certification or board eligible. Visit our website at www.biobridgeglobal.org. E-mail résumé to hr_dept@bloodtissue.org or fax to (210) 731-5581. Call Human Resources @ (800) 292-5534, Ext.1559 for more information. 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.

VP, Quality & Regulatory Affairs. We are seeking a member of the San Diego Blood Bank Senior Operational team to ensure business objectives are aligned, quality is the foundation of operations and the company is performing to operational objectives. Responsible for company's quality to ensure compliance to regulatory requirements. Ensure cGMP, CLIA and quality systems compliance, as well as other applicable regulatory requirements in the US and from international bodies. BA/BS degree in a life science plus 15 plus years demonstrated expertise and success in regulatory and quality in a blood donor center or life sciences/clinical technology-driven company. Apply on-line at www.sandiegobloodbank.org.
EOE/Minority/Female/Disability/Vets

Hospital Services Laboratory Manager. LifeServe Blood Center is seeking candidates with senior-level experience to oversee daily operations of our Hospital

Services Department. This position will be responsible for the oversight, development and implementation of laboratory functions, such as donor testing, reference testing, components, and product management, in addition to direct management of a team focused on operational efficiencies, customer service, product testing and distribution. Primary responsibilities for this position include monitor collections and inventory to ensure capacity and utilization of resources; manage daily workflow and organizational processes; create, manage, and meet department budget; drive performance to ensure department metrics, efficiencies, and quality metrics are met; foster an environment that allows team members to work together to further the mission and vision of the organization; and ensure all team members comply with proper training and accreditation requirements. Education and/or Experience: Bachelor's degree in Business Administration, Biology or related field, MT, MLS or MLT preferred, two to three years of management experience required and management experience in blood banking industry or laboratory setting preferred. Offers of employment are contingent on the successful completion of pre-employment, post offer drug testing and background checks. EOE. Interested in joining our team? Submit resumes to

betsy.lambertsen@lifeservebloodcenter.org 