

2014 #7

February 21, 2014

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ABC Annual Meeting to Explore Blood Banking Trends, Cooperating to Compete, Affordable Care Act

America's Blood Centers' members, along with regulatory, government, and healthcare professionals, will convene at the scenic Omni Rancho Las Palmas Resort & Spa in sunny Palm Springs, Calif. for the ABC Annual Meeting from March 22 to 25. This year's meeting, co-hosted by Blood Systems and LifeStream, will be held in conjunction with the Foundation for America's Blood Centers (FABC) 4th Annual Links for Life Golf Tournament and will feature the inaugural lecture of the Celso Bianco Lectureship Series, funded by the FABC.

ABC's Annual Meeting provides ABC members and industry professionals with opportunities to learn about blood banking and transfusion medicine, share best practices, and solve challenges facing blood centers together. The Annual Meeting will feature presentations from leading blood bankers and researchers at the Scientific, Medical, and Technical (SMT) Forum, while the Blood Center Leadership Forum will explore the evolving healthcare environment and the future of blood banking.



A nighttime view of the Omni Rancho Las Palmas Resort & Spa in Palm Springs, Calif.

Hot Topics at the 2014 Annual Meeting. Whether it's on the news, in the hospital board room, or at the local community blood center, everyone is asking the same question – How will healthcare reform ushered in by the Affordable Care Act (ACA) impact me and my organization? Barbara McAneny, MD, chair-elect of the American Medical Association (AMA) in Albuquerque, N.M., will discuss this topic in her talk during the Blood Center Leadership Forum on March 24. The Blood Center Leadership Forum will also explore what the future may hold for blood centers by examining blood usage, donor trends, and other relevant trends observed at Héma-Québec in Canada.

(continued on page 3)



OUR SPACE

Matt Granato, ABC's Executive Vice President, Operations

Reconnecting Value to Satisfaction

Last week, the ABC board of directors, executive staff, and a handful of ABC committee chairs participated in the strategic “thinking” retreat in Dallas to develop the next strategic plan for your association (see page 6). You will have an opportunity to review the draft plan in the coming weeks, prior to the Annual Meeting in Palm Springs, Calif., but before we get to that, I wanted to reflect on a point that was discussed at the retreat.

ABC has discovered through SEQuALS (ABC's membership satisfaction survey), that our members are satisfied with ABC's overall performance (see latest report at <http://bit.ly/2012sequals>). However, we have had trouble linking higher levels of satisfaction with the value of ABC membership. Certainly, it is not an easy task to monetize every win, every accomplishment, and every “near miss.” It is even more difficult to track and assign value to every interaction that ABC member employees have with ABC. At least, we thought so until recently.

Once the strategic plan started to take shape, and the goals began to align with ABC's core values (Advocacy, Data, Education, and Innovation), assigning value to our activities did not seem like such a daunting task. Each strategic goal will be complemented with a series of tactics, which will lead to a defined outcome with – you guessed it – an assigned value for the membership. Every member center will receive an annual “Membership Value Report Card,” customized to each blood center, detailing the work that ABC has done for them, whether on the Hill, before regulators or vendors, or assisting their staff with routine and day-to-day requests. “Value” may not always be monetary; it may take the shape of number of interactions between ABC staff and blood center staff, types of activities undertaken on behalf of a particular member, topics discussed with key legislators, or media mentions.

In the end, members will have a summary of the activities done on their behalf, and most importantly, the outcome and impact on their bottom lines. By demonstrating the value of our work, we hope to reconnect value to satisfaction and be able to authoritatively say that “a satisfied member is one that finds the value in our work.”

mgranato@americasblood.org ♦

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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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ABC Annual Meeting 2014 (continued from page 1)

Cooperate to Compete. To help prepare blood centers for the challenges that lie ahead and position them for future success, the Blood Center Leadership Forum will continue the “Cooperate to Compete” discussions that began at the 2012 ABC Annual Meeting. These talks will highlight how blood centers can work together to achieve collective goals and how blood center executives can lead their centers through change. William Rice, MS, DBA, a professor of marketing and agriculture economics at California State University, will give a talk titled “F.I.G.H.T – How to Conquer Phantom Problems.” Dr. Rice, who has consulted for more than 300 different firms, will draw parallels between the regulation of dairy and blood products based on his work with the U.S. Department of Agriculture and dairy regulation. His talk will include discussion of the gaps that exist between buyers and sellers, government and producers, and management and employees. Dr. Rice will walk through the realities of value creation and protocol fulfillment, opportunities and presumptions, research and guess-timation

Will Marré, CEO of REALeadership Alliance, Inc., headquartered in Encinitas, Calif., will talk about “Leading to Win,” including the three proven essentials of 21st century leadership and how to create a unique value advantage for an enterprise. The REALeadership Alliance conducts ongoing research on business innovation of today’s most admired leaders. Mr. Marré’s primary focus is coaching and partnering with CEOs to thaw frozen bureaucracies and heat up agile cultures to win in a fiercely competitive marketplace.

SMT Forum. Prior to the Blood Center Leadership Forum, ABC Annual Meeting attendees will hear updates on blood banking and transfusion medicine during the SMT Forum on Sunday, March 23. The speakers will discuss a wide array of topics including extracorporeal membrane oxygenation, the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III), and improving platelet safety. Discussions will also cover transfusion related acute lung injury (TRALI) and the efficacy of whole blood derived-vs.-apheresis platelets. The ABC Members Meeting will be held following the SMT Forum.

Networking Events. For the first time, the annual FABC Links for Life Golf Tournament will be held in conjunction with the ABC Annual Meeting. Golfers will head to the beautiful Desert Willow Golf Resort in Palm Springs, Calif. on March 22 to network and golf for a good cause. Every ABC member CEO or designee receives a free registration. To learn more or register to golf, visit http://bit.ly/L4L_2014.

Annual meeting attendees will also be treated to a reception on March 23 hosted by Blood Systems and LifeStream at the Palm Springs Art Museum, located in the heart of downtown Palm Springs at the base of the San Jacinto mountains. The museum spans over 150,000 square feet with two outdoor sculpture gardens and major collections of modern and contemporary art. Guests will enjoy heavy hors d’ouvres and docent-staffed galleries, highlighting the museum’s permanent collection and special exhibits.

Don’t Miss the Inaugural Celso Bianco Lectureship Series Presentation!

Merlyn Sayers, MBBCh, PhD, president and CEO of Carter BloodCare, headquartered in Bedford, Texas, will give the inaugural presentation of the Celso Bianco Lectureship Series during the Blood Center Lectureship Forum on March 24.

The Celso Bianco Lectureship Series, funded by the FABC, was established in August 2013 to honor the outstanding 40-year career of Celso Bianco, MD, ABC’s previous executive vice president. His contributions to transfusion research and blood safety have impacted countless donors, patients, and blood center staff.

Dr. Sayers’ talk will describe Dr. Bianco’s contributions to transfusion medicine and review the changes in blood banking during his period of influence. To contribute to the Celso Bianco Lecture Series Endowment, visit <http://bit.ly/1mbghMw>.

ABC Annual Meeting 2014 (continued from page 3)

The 17th Annual *Awards of Excellence* banquet and reception will held on March 24 following the Blood Center Leadership Forum. This annual awards program recognizes organizations and individuals that have demonstrated extraordinary dedication to community blood centers.

Pre- and Post-Annual Meeting Events. Other meetings (by additional invitation only) include board meetings of ABC, BCx, the FABC, and AIMCo.

Attendees must register and reserve a hotel room by Feb. 28. More information about the meeting and the agenda can be viewed at <http://members.americasblood.org/go.cfm?do=Page.View&pid=32>. A link to register can be found in the event invitations e-mailed by ABC. If you did not receive an invitation or have other questions, please contact Lori Beaston at lbeaston@americasblood.org. Vendors interested in attending may contact Abbey Nunes at anunes@americasblood.org to learn about sponsorship opportunities. ♠

Letters from ABC Specialty Workshop Scholarship Recipients

In 2013, America's Blood Centers launched the ABC Specialty Workshop Scholarships Program, made possible by a grant from the Foundation for America's Blood Centers. This program provides 28 scholarships to professionals from ABC's member blood centers to supplement the costs for attendance at an ABC Specialty Workshop during this fiscal year.

ABC held the Medical Device Data Systems (MDDS) Workshop in Silver Spring, Md. from Jan. 15 to 16. Below are excerpts from letters to the editor from ABC members who received an ABC Specialty Workshop Scholarship to attend the MDDS Workshop.

"I would like to thank ABC and the FABC for the scholarship and opportunity to attend the MDDS workshop in January ... The speakers chosen were dynamic, the view points were varied, and the dialogue was great. We were very fortunate to have such a good attendance from FDA, who presented very good information and at the same time were candid and interactive with the audience. The breakout session design maximized the time spent discussing the topics ..."

As a result of the MDDS workshop, I am starting the dialogue within our blood center and with our blood establishment computer system (BECS) provider to understand how we are affected by this regulation. I feel that I went home from the conference with a game plan ... Attending the MDDS workshop not only allowed me to gain knowledge to take back to our center, but almost as importantly, I was able to meet many new people in similar positions. After the conference, I have already made contact with several attendees who I would not otherwise have known ..." – **Lindsay Mancini, Quality Support Services, Project Manager, Mississippi Valley Regional Blood Center.**

"I recently attended the MDDS Workshop in Silver Spring and wanted to express my gratitude to the planners and presenters of the workshop. The topic of MDDS regulations and their impact to the blood industry has been confusing at best and an area of increasing concern. I appreciated hearing from the Food and Drug Administration, as well as those dealing with these regulations on the frontline. It was helpful to be presented with an approach for evaluating systems to determine whether they met the

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Letters to the Editor (continued from page 4)

criteria for a MDDS. The information on BECS and BECS accessories was also of value in understanding their role in this discussion ...

Most facilities are finding themselves having to deal with fewer funds available for travel to workshops and conferences, so the scholarships are a wonderful opportunity for those who might otherwise not be able to attend.” – Liz DeAngelo, Quality Assurance Manager, Institute for Transfusion Medicine/Central Blood Bank.

“Thank you to the FABC for the scholarship to attend the MDDS Workshop in January ... The workshop was timely for my center, because in early 2013, staff from Community Blood Center, Appleton, Wis., attended a workshop where MDDS was on the agenda. The concept was new to us and generated many questions. We are thankful ABC collaborated with FDA to put on this workshop and that I was able to attend. The decision flow charts that were presented to help identify MDDS are invaluable ...

I now have the knowledge and tools necessary to move forward with an assessment of our current state, and can more confidently assess new processes being planned with respect to the MDDS regulation. In addition to the great presentations, I met some new people that I will be able to network with in the future ..” – Kathy Procknow, Manager of Quality Assurance, Community Blood Center, Appleton, Wis.

“Thanks to an ABC Specialty Workshop Scholarship, I had the pleasure of attending my first ABC professional meeting – ABC’s MDDS Workshop held in January. It was an extremely valuable opportunity to learn more about MDDS, as well as meet up with fellow professionals in our industry, including FDA ...

It became clear to me that, although we don’t currently use MDDS, we undoubtedly will in the future, as they are becoming more and more important to the business of blood centers. Therefore, it was very helpful to get some guidance on what systems might qualify as an MDDS so that we can ensure we stay in compliance with FDA if and when we implement those. I also enjoyed hearing presentations from FDA staff, having the opportunity for Q&A with FDA staff, and participating with FDA staff in small group discussions ... Last but not least, I enjoyed meeting and talking with the ABC staff who were present and felt they did an excellent job of putting on a very useful workshop.” – Jeff Cook, IT Manager, Lane Blood Center. ♦

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.



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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 Leaders Work on Redesigning ABC

The America's Blood Centers board of directors, committee chairs, and executive staff braved ice and snow to come together on Feb. 11 to 12 for a strategic thinking retreat at Carter BloodCare. During the two days, participants actively engaged to confirm ABC member value shifts, challenge core business assumptions, explore new partnerships, and project the lifecycles of products, services, and the ABC organizational model.

At the conclusion of the two days, the group had crafted a draft strategic plan that leverages leading marketplace and business models. Participants relied on ABC membership survey results and enviro-scanning intelligence on paradigm shifts in the blood world at large to inform their work.

"I felt honored to be part of thoughtful discussions that emerged from our board members who clearly want to do what is best for the industry in general, and specifically to position ABC to deliver value to independent blood centers in transition," said ABC Board Member Doug Engel, CEO of Lane Blood Center. "I observed the best crystal ball surrogate you can hope for – serious thinking about the future!"

Key elements of the draft plan include:

1. **Data Driven Excellence:** Evolve the ABC "Data Warehouse" to 100 percent member use with advanced big data applications each member may customize for their center;
2. **Advocacy Excellence:** Make 360 end-to-end enhancement of ABC's Advocacy program to raise ABC brand recognition with elected and appointed officials and strengthen assertive advocacy around regulation in all our fields of endeavor;
3. **ABC Association Model Redesign:** Initiate a top to bottom look at ABC operations, priorities, services, and products to identify opportunities for applying contemporary association management models to leverage ABC success;



(From left to right) Jennifer Feeney, vice president of Human Resources at Mississippi Valley Regional Blood Center; Louis Katz, MD, executive vice president, SMT; and Nelson Hellwig, president and CEO of The Blood Center (New Orleans) collaborate at last week's strategic thinking retreat.

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INSIDE ABC (continued from page 6)

4. **Education/Competency Development:** Develop a robust blended learning model aligned with members' needs to drive blood center managerial effectiveness, leadership development, succession preparation, and staff talent development; and
5. **Governance Excellence:** Assess the ABC governing model for opportunities to enhance governance leadership effectiveness and efficiency.

"I was impressed by the robust process the facilitator brought as well as the candid and insightful dialogue we had," said ABC President Dave Green, president and CEO of Mississippi Valley Regional Blood Center. "What struck me most, however, was the difference having seasoned association expertise at the table made in the way we saw ABC's value and its true potential for member service."

With ABC board guidance and prioritization, ABC staff is now leading the development of tactics and timelines necessary for accountability and resource allocation. When this work is complete, the draft plan will be available to ABC members on the ABC Member Website. The strategic plan will be presented to ABC members at the ABC Annual Meeting in Palm Springs, Calif., where members will have an opportunity to provide their feedback.

ABC Comments on FDA Draft Guidance on Syphilis Testing for HCT/P Donors

America's Blood Centers recently submitted comments on a Food and Drug Administration draft guidance titled "Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) for Infection with *Treponema Pallidum* (*T. pallidum*, Syphilis)."

Current regulations require that HCT/P establishments test donor specimens for evidence of *T. pallidum* infection using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exemption to this requirement applies. This draft guidance, issued in November 2013, clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor testing for *T. pallidum* infection under the criteria specified in the federal regulations (see *ABC Newsletter*, 11/8/13).

ABC stated in comments to FDA that the ABC Scientific, Medical, and Technical Steering Committee reviewed the recommendations in the draft guidance and agrees with them. The draft guidance can be viewed at <http://1.usa.gov/1fmwV8E>. ♦

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 ABC Publications Editor Betty Klinck 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.



REGISTRATION NOW OPEN

Human Resources & Employee Training/Development Workshop

Houston, TX – April 29 - May 1, 2014

Hosted By:  Gulf Coast Regional Blood Center

Negotiated hotel room rate: \$169 + tax
www.hotelderek.com

2014 Workshop Schedule

Human Resources topics: April 29
 Joint HR & Employee Training/Development topics: April 30
 Employee Training/Development topics: May 1

2014 Workshop Fees (early bird/regular)

2-day registration: \$390/\$445
 3-day registration: \$460/\$515

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

“Gulf Coast Regional Blood Center is excited to host ABC members in Houston for the 2014 Human Resources & Employee Training/Development Workshop. We look forward to a dynamic exchange of new ideas and best practices from across the country. I hope to see you in Houston in April!”

- Brian G. Gannon
 President and CEO
 Gulf Coast Regional Blood Center

There are eight (8) \$1,000 scholarships available to ABC members to cover the cost of registration fees and help with travel expenses. Application link and additional details included in registration.

For additional registration details, contact Lori Beaston at lbeaston@americasblood.org.



George Bush Intercontinental Airport (IAH) is served by most major US airlines. It offers non-stop service to nearly 200 domestic and international destinations; check www.fly2houston.com for more information on this airport, as well as Hobby International Airport (HOU).

RESEARCH IN BRIEF

A study reported in the Feb. 7 ABC Newsletter reporting that Japanese researchers had found a way to reprogram mature mice cells into an embryonic state is under investigation following allegations of irregularities, reported *Nature* on Feb. 17. Haruko Obokata, PhD, and colleagues of the RIKEN Center for Developmental Biology in Kobe, Japan, reported on Jan. 30 in *Nature* that they could reprogram mature mice cells into an embryonic state by applying stress, such as exposure to acid or physical pressure on the membranes. The research was lauded as potentially offering a simpler way to replace damaged cells or grow new organs. The RIKEN Center announced on Feb. 14 that it is looking into irregularities alleged through blog sites about the use of images in Dr. Obokata's papers, and failed attempts to replicate her results. Skepticism arose last week when blogs, such as PubPeer, started noting what seemed to be problems with the two *Nature* papers and in an earlier paper from 2011. In the 2011 paper, on which Dr. Obokata is the first author, a figure showing bars meant to prove the presence of a certain stem cell marker appears to have been inverted and then used to show the presence of a different stem cell marker. A part of that same image appears in a different figure indicating yet another stem cell marker. The paper contains another apparently unrelated duplication. The problems in the two recent *Nature* papers, on both of which Dr. Obokata is the corresponding author, also relate to images. In one paper, one of the sections in a genomic analysis in the first figure appears to be spliced in. In the other paper, images of two placentas meant to be from different experiments look strikingly similar. The skepticism has been inflamed by reports of difficulty reproducing Dr. Obokata's results, reported *Nature*. The

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RESEARCH IN BRIEF (continued from page 8)

authors have not responded to requests for more details on the protocol, and Dr. Obokata did not respond to inquiries from *Nature's* news team. A spokesperson for the Nature Publishing Group said "The matter has been brought to *Nature's* attention and we are investigating it."

Citations: Obokata H, *et al.* Stimulus-triggered fate conversion of somatic cells into pluripotency. *Nature*. 2014 Jan 30;505(7485):641-7.

Obokata H, *et al.* Bidirectional development potential in reprogrammed cells with acquired pluripotency. *Nature*. 2014 Jan 30;505(7485):676-80.

Obokata H, *et al.* The potential of stem cells in adult tissues representative of the three germ layers. *Tissue Eng Part A*. 2011 March;17(5-6):607-15.

A review published in the *Journal of Palliative Medicine* suggests that despite transfusion being common in the treatment of palliative cancer patients (PCPs), there is a serious lack of published research on the subject. Palliative care is provided to people with serious illnesses, focused on providing relief of symptoms, pain, and stress of the illness. Often times palliative care is used to describe end-of-life care. María Elena Uceda Torres, MD and colleagues of UGC Health Centre in Huelva, Spain, reviewed literature in the PubMed and EMBASE databases to find information available on transfusion in PCPs. Publications were classified according to the main topic discussed – either clinical, infrastructure, and ethics – and the information included in each article was critically assessed. The researchers found 335 articles but only 43 were considered useful for the study. Of these 43 articles, 21 dealt with clinical topics while 12 covered infrastructure, and 10 with ethical issues. They found that "there is an absolute lack of randomized controlled trials or clinical guidelines" for transfusion in PCPs, and transfusion triggers are not established. Contrary to expectations, the review demonstrated that PCPs are rarely transfused (incidence: 5 to 17 percent), and usually in less than two sessions and most of them receive less than three units. A higher frequency of transfusion has been observed in patients with hematologic malignancies or bleeding solid tumors; those in conventional hospital care (vs. hospices and home care); and those treated by oncology units compared with palliative units. Almost 50 percent of transfused patients are given blood in their last five weeks of life, and 13.7 percent in their last week. Transfusion has been considered a negative predictive parameter for survival in solid tumors when practiced in the last 15 days of life. "So, the usefulness of red blood cell transfusion in the last month of life should be considered with caution," write the authors. For most authors of the reviewed studies, home transfusions are desirable for the patient and family's comfort, as the displacement to hospitals for transfusion is disturbing. Moreover, it has been published that 40 percent of unnecessary hospital admissions are due to transfusions, so this is a potential way to reduce hospitalization costs, write the authors. Other authors, however, believe that home management of patients with high transfusion needs is difficult and should be avoided. Different cultures, cases, and realities illustrate the diversity of the ethical management of transfusion in PCPs, write the authors. "As transfusion products and financial and human resources are finite, it would be desirable to establish clear research lines on the different aspects considered (clinical, infrastructure, and ethical) that can help clinicians, nurses, patients, and caretakers to make a decision," conclude the authors.

Citation: Torres ME, *et al.* Transfusion in palliative cancer patients: a review of the literature. *J Palliat Med*. 2014 Jan;17(1):88-104. 💧

REGULATORY NEWS

The Food and Drug Administration published a guidance on Feb. 18 for industry and FDA staff titled “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff.” This document finalizes the draft guidance published on July 13, 2012, and supersedes “Pre-IDE Program: Issues and Answers – Blue Book Memo D99-1” dated March 25, 1999. The guidance provides an overview of the mechanisms available to applicants through which they can request feedback from FDA regarding potential or planned medical device Investigational Device Exemptions applications or other premarket submissions including Premarket Approval (PMA) applications; Humanitarian Device Exemptions applications; Evaluation of Automatic Class III Designations; Premarket Notification [510(k)] Submissions; and Clinical Laboratory Amendments (CLIA) Waiver by Application. The guidance also addresses certain Investigational New Drug Applications and Biologics License Applications. FDA provides information regarding logistics for submission, receipt, tracking, and review of/response to these requests. The guidance addresses feedback mechanisms that include pre-submissions, informational meetings, study risk determinations, formal early collaboration meetings, submission issue meetings, and PMA “day 100 meetings.” The document largely refers to existing guidance, but also establishes the procedures FDA intends to follow when providing feedback. However, all of these feedback requests will fall within the same organizational structure for tracking purposes, notes FDA in the guidance. These requests for feedback will now collectively be referred to as “Q-Submissions” or “Q-Subs.” “FDA believes the Q-Sub structure will provide a convenient and effective way to track these requests,” states the guidance. The guidance document can be accessed at <http://1.usa.gov/1ebgM2S>. (Source: FDA guidance, 2/18/14)

The Food and Drug Administration recently published the tentative 2014 advisory committee meetings schedule. The advisory meetings will provide advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA’s upcoming advisory committee meetings, said FDA. This schedule includes meetings for advisory committees in the Center for Biologics Evaluation and Research. The Blood Products Advisory Committee is tentatively scheduled to meet on March 8-19, July 31-Aug. 1, and Dec. 2-3. The Cellular, Tissue, and Gene Therapies Advisory Committee is tentatively scheduled to meet Feb. 25-26, July 29-30, Nov. 5-6. The schedule can be viewed at <http://1.usa.gov/NeQc2O>. FDA updates Advisory Committee Calendar webpage with information about upcoming meetings at <http://1.usa.gov/19T6frG>. (Source: FDA website, 2/11/14) ♦

THE WORD IN WASHINGTON

The Advanced Medical Technology Society (AdvaMed) recently reported the result of a showing that the medical device tax has led to a significant reduction in jobs, research and development (R&D), and US investment. Under the 2.3 medical device tax, mandated by the Affordable Care Act, device manufacturers are required to pay an estimated average of \$194 million per month in medical device payments. To provide information on the real-world impact of the tax in its first full year of implementation, AdvaMed conducted an online survey of its member companies between Nov. 14 and Dec. 9, 2013. Thirty-eight companies responded, accounting for approximately 40 percent of the domestic sales revenues of AdvaMed members and approximately 15 percent of member companies. The survey responses were generalized to the industry as a whole based on the ratio of revenues of responding companies to revenues of the overall industry. According to the report, the tax has led to employment reductions of about 14,000 industry workers and foregone hiring of more than 19,000 workers. The total job impact of the tax on industry employment was about 33,000. Independent estimates of the relationship between direct employment in the industry and indirect employment among suppliers and in the

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THE WORD IN WASHINGTON (continued from page 10)

general economy found a ratio of four indirect jobs for each direct job. Applying this ratio to jobs lost or foregone suggests that the impact of the tax on indirect employment would be about 132,000 jobs, for a total job loss due to the tax of as many as 165,000 jobs. The survey results also show that almost one-third of respondents said they had reduced R&D as a result of the tax. Almost ten percent of respondents said they had relocated manufacturing outside of the US or expanded manufacturing abroad because of the tax. In terms of investment dollars, three-quarters of respondents said they had taken one or more of the following actions in response to the tax: deferred or cancelled capital investments; deferred or cancelled plans to open new facilities; reduced investment in start-up companies; found it more difficult to raise capital; and reduced or deferred increases in employee compensation. “During a time when there is bipartisan support for growing high-technology manufacturing jobs, these results should serve as a wakeup call. As a result of the medical device tax, we have seen an unprecedented impact on jobs and key investments in R&D,” Stephen J. Ubl, president and CEO of AdvaMed, said in a press release. “These findings of the report underscore the need to repeal this tax.” The survey results can be found at <http://advamed.org/res/417/impact-of-the-medical-device-excise-tax>. (Source: AdvaMed press release, 2/18/14; AdvaMed Impact of the Medical Device Excise Tax survey results, 2/19/14)

Despite efforts by the Obama administration to ease shortages of critical drugs, shortfalls have persisted, reported the US Government Accountability Office. In 2011, GAO recommended that the Food and Drug Administration should enhance its ability to respond to drug shortages. The Food and Drug Administration Safety and Innovation Act, passed into law in 2012, gave FDA new authorities to address drug shortages and mandated GAO to study drug shortages. The GAO report found that while reports of new drug shortages declined in 2012, the total number of shortages active during a given year – including both new shortages reported and ongoing shortages that began in a prior year – has increased since 2007. Many of the reported shortages were of generic sterile injection drugs. Healthcare providers indicated that drug shortages may force clinicians to ration care or face difficulties finding alternative drugs. Shortages are generally caused by a manufacturer halting or slowing production to address quality problems, triggering a supply disruption, according to the GAO report. While FDA has initiated steps to improve its response to shortages, there are still shortcomings in its management of shortages, including lack of policies or procedures governing the management of data, stated GAO. FDA has also not created policies or procedures governing the management of data and has not conducted routine analyses using this data. GAO recommends that FDA strengthen internal controls over drug shortage data and conduct periodic analyses to routinely and systematically assess drug shortage information, using this information to proactively identify drug shortage risk factors. The report can be accessed at www.gao.gov/products/GAO-14-339T. (Source: GAO report, 2/10/14) ♦

GLOBAL NEWS

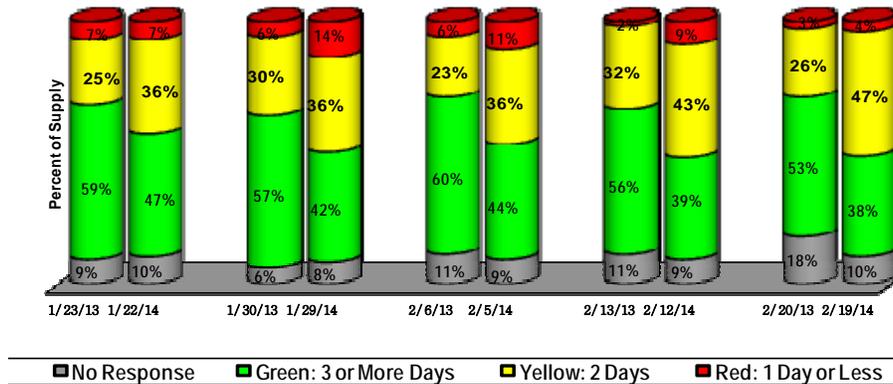
The Alliance of Blood Operators (ABO), a network of seven non-profit blood services from across the globe, has made significant progress in its project to develop an international framework to enhance blood safety decision-making. ABO’s Risk Based Decision Making (RBDM) Project will provide an overall risk-based decision-making framework that will include health economics and outcomes tools specially designed for blood safety; stakeholder engagement guidelines; and a collaborative web portal to provide information about the framework. The RBDM project was born out of discussions at a three-day ABO International Consensus Conference held in Toronto Canada, at which participants agreed that achieving zero risk in transfusion medicine is not possible and the well-being of transfusion recipients is central to any recommendations to improve blood safety decision-making. Further, the participants recommended developing an integrated risk framework to improve consistency in blood safety

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GLOBAL NEWS (continued from page 11)

decision-making, ensure that decisions are based on evidence, and increase confidence in investment decisions. “A consistent international approach will carry more weight than an isolated effort,” explained Sheila Ward, who is managing the project. Designed specifically for blood safety risk assessment, the framework will gauge quantitative and qualitative risk and overall risk tolerance in the context of patient and donor safety. It will also contain guidance regarding the use of health economic and outcomes assessments in the evaluation of risk and mitigation options. The framework will include guidelines to enable stakeholder engagement. ABO is nearly completed with phase I of this two-phase project, and constructed the overall risk framework, gained feedback, and refined it based upon the feedback. ABO has also developed the stakeholder engagement guideline principles and step-by-step guidelines; selected the health and assessment tools most appropriate for blood safety decisions; and completed designing the web portal for the ABO website. The organization is on track to begin phase II of the project in April 2014, which includes feasibility testing and stakeholder consultations. ABO plans to release this tool in 2015. ABC Executive Vice President of Operations, Matt Granato, chairs the web portal committee and ABC Executive Vice President, SMT, Louis Katz, MD, is a member of the project steering and risk framework committees. “The most critical element for success of this decision-making process in the real world will be the ability of stakeholders (e.g., blood establishments, regulators, patients, and/or donors and others) to reach agreement when tolerable risks are being defined and non-zero risk is to be apportioned,” said Dr. Katz. Continue checking the *ABC Newsletter* for updates on this project. (Sources: ABO RBDM Communiqués 1, 2, 3, and 4, 2/14/14; Blood Service in Brief, 2/14/14) ♦

STOPLIGHT®: Status of the ABC Blood Supply, 2013 vs. 2014



The order of the bars is (from top to bottom), red, yellow, green, and no response

We Welcome Meeting Notices

Do you have an symposium, conference, workshop, or annual meeting that you would like to publicize in the *ABC Newsletter*? If so, please send a meeting notice or press release to the editor, Betty Klinck at newsletter@americasblood.org. Notices should contain the following information: the exact date(s) of the meeting; the formal title of the meeting; the sponsoring organization or agency; the location of the meeting; a short (fewer than 35 words) description of the curriculum, agenda, or topics to be covered; a contact person or a website address with more information. Notices will be published in the Meetings section at the discretion of the editor.

MEMBER NEWS

LifeStream, headquartered in San Bernardino, Calif., recently celebrated Larry Bloemsma's 1,000th blood donation, reported the center in a Feb. 10 press release. LifeStream staff and fellow donors gathered on Feb. 6 to help celebrate LifeStream's most prolific donor as he made his 1,000th donation – a first in the center's 63-year history.

Local and regional broadcast and print media were on-hand to profile Mr. Bloemsma's 50-year (and counting) blood donation career. After more than 20 years of regularly donating whole blood, he made his first platelet donation in 1986 and made the switch full-time from whole blood to platelets in 1993. "Today is an opportunity very few blood banks have, to honor a donor who has made 1,000 blood donations," said LifeStream President and CEO Rick Axelrod, MD. LifeStream and representatives of elected officials made post-donation presentations to Mr. Bloemsma following his 15-minute break in the canteen. Since 1996 when LifeStream began keeping computer records, Mr. Bloemsma has made about 550 visits to donate blood. His service to others also includes volunteering with his church to visit local jails and rest homes. He credited his faith and wife, Lil, for maintaining the desire and continued good health required to reach the 1,000-donation milestone, said the press release. (Source: LifeStream press release, 2/10/14)



Larry Bloemsma, 79, makes his 1,000th blood donation at LifeStream.

Lifeblood, headquartered in Memphis, Tenn., recognized organizations, corporations, and individuals for their voluntary efforts in 2013 to promote and support blood donation in the community at its 5th Annual Awards Luncheon on Feb. 7. "Our volunteers are vital to ensuring a stable blood supply is available at all times for trauma centers, hospitals, and individuals in need," said Susan Berry-Buckley, Lifeblood CEO. "And so, we celebrate them today for their efforts to support Lifeblood and their fellow community members." The awards luncheon kicked off with a keynote address by Vickie Peal, the daughter of a blood, platelet, and plasma recipient whose life was forever changed when her father, an employee of the Shelby County District Attorney's Criminal Investigations Division, was diagnosed with pancreatitis and relied on volunteer blood donations to survive. The luncheon was emceed by WREG Channel 3 weatherman and blood donation advocate, Todd Demers, and included an invocation by Pastor Bartholomew Orr of Brown Missionary Baptist Church. (Source: Lifeblood press release, 2/7/14)



St. George's Independent School senior Ethan Cohen, and Lifeblood's Volunteer of the Year, is joined by program emcee, Todd Demers from WREG Channel 3.

South Texas Blood & Tissue Center (STBTC) celebrated Gerald Perkins donating his 110th gallon of blood on Feb. 10 after a lifetime of donating blood.

Mr. Perkins, 82, an outspoken advocate for blood donation, has worked to schedule blood drives and even recalls his first donation in 1951. Mr. Perkins retired from the US Army after 30 years of service in 1982. He then went on to work for the US Postal Service for another 26 years until his retirement in 2006. STBTC honored Mr. Perkins with a plaque alongside family, friends, and fellow donors at its donor center in San Antonio, Texas. (Source: STBTC press release, 2/10/14) 💧



Gerald Perkins, 82, donates his 110th gallon of blood.

PEOPLE

Joseph A. Yelo, MBA, MT(ASCP) SBB, will be joining Blood Bank of Delmarva (BBD), headquartered in Newark, Del., on March 10 as the lead executive for Business and Community Development, announced the center in a Feb. 17 press release. Mr. Yelo, most recently the vice president of Administration and Risk at Miller-Keystone Blood Center in Bethlehem, Pa., has more than 30 years of experience in blood banking and transfusion medicine. During his long tenure at Miller-Keystone, Mr. Yelo was responsible for the operations of a community blood service program that included 325 employees, 500 volunteers, apheresis and whole blood operations, technical services, nursing services, and donor recruitment. “Joe’s industry expertise and experience is a solid complement to BBD’s overall strategy and commitment to serve our community and patients, while also contributing to the broader success of our organization,” said Roy Roper, BBD president and CEO. Mr. Yelo holds a MBA in management/healthcare administration from LaSalle University, a bachelor’s degree in biology from LaSalle University, and a bachelor’s degree in medical technology from Pennsylvania State University. He also acts as an advisory member of the Transfusion Medicine National Institutes of Health Grant Award Panel at Temple University Hospital and Medical School. He is a former member of the board of directors at AABB, America’s Blood Centers, Community Blood Center’s Exchange, and the New Jersey Society of Blood Bank Professionals, among others. He has served as a past president and treasurer of the Rotary Club of Allentown, Pa. and is an active volunteer with the Pennsylvania Masonic Organization, March of Dimes, American Heart Association, and United Way. (Source: Blood Bank of Delmarva, 2/17/14) ♠

MEETINGS

March 20-21 **FTC Public Workshop: Examining Health Care Competition, Washington, D.C.**

The Federal Trade Commission (FTC) will hold a public workshop titled “Examining Health Care Competition” from March 20 to 21 at the FTC Conference Center in Washington, D.C. This workshop will study certain activities and trends that may affect competition in the evolving healthcare industry. The workshop will explore current developments related to professional regulation of healthcare providers; innovations in healthcare delivery; advancements in healthcare technology; measuring and assessing healthcare quality; and price transparency of healthcare services. More information and registration details can be found at <http://1.usa.gov/1kHU4Yd>.

March 31 **FDA Public Workshop: Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products, Silver Spring, Md.**

The Food and Drug Administration will hold a public workshop titled “Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products.” on March 31 from 8:30 a.m. to 4:30 p.m. at the FDA White Oak Campus in Silver Spring, Md. More information is available at <http://1.usa.gov/1hBEXzw>.

Contact: Sherri Revell, Center for Biologics Evaluation and Research. E-mail: CBERPublicEvents@fda.hhs.gov; Phone: (301) 827-2000. ♠

Correction

Last week’s *ABC Newsletter* included a guest Our Space column on page 2 by ABC Board Member Robert Scanlon, CEO of Blood Bank of Alaska. We accidentally included an incorrect e-mail address for Mr. Scanlon. The proper e-mail address is rscanlon@bbak.org. We apologize for any confusion caused by this error.

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: lnorwood@americasblood.org.

POSITIONS AVAILABLE:

Region Recruitment Manager. Puget Sound Blood Center is seeking a strategic leader to manage the departments responsible for donor group and volunteer recruitment goals. Responsibilities include: providing leadership and motivation to staff teams; developing systems and program analysis tools; improving communications enhancing community relationships to encourage donor and volunteer participation; positioning the Blood Program as a volunteer supported organization. Ideal candidates will have over eight years' direct experience in recruitment, marketing, customer relationship management, or volunteer management experience, and five years in a supervisory capacity. Requirements also include demonstrated familiarity with marketing and planning systems; strong data analysis skills; demonstrated written, verbal and interpersonal communication skills; and proficiency with Windows PC software. Bachelor's degree in a related field or equivalent work experience. Blood recruitment industry experience preferred. This exempt, full-time position is based in Bellevue, WA. Submit resume to Puget Sound Blood Center via email at humanresources@psbc.org; fax: 1-866-286-8495; USPS: Human Resources, Puget Sound Blood Center, 921 Terry Avenue, Seattle, WA 98104-1256. Reference Job #7032. Open until filled. For disability/accommodation assistance with the application process contact HR at humanresources@psbc.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104. AA.EOE.

Cord Blood Manager, Processing and Distribution. LifeSouth Community Blood Centers is currently seeking an experienced professional for the Cord Blood Manager, Processing and Distribution position in Gainesville, Florida. This position manages Cord Blood processing, storage and distribution. Responsibilities include, but are not limited to: manage the cord blood processing area, processing activities and record review process to ensure functionality and timely record turnaround; assist and manage the initiation of new cord blood collecting sites; oversee hiring Cord Blood processing staff; plan, assign and direct work of Cord Blood processing staff and routinely appraise performance; respond to audit/inspection findings; and represent and communicate LifeCord and LifeSouth favorably to the public and to the participating institutions. Bachelor's degree in science related field required. Four to 10 years related experience and/or

training may replace education requirements. Willingness and ability to travel is required. This is a full-time position. Starting salary range is \$50,000 - \$55,000 annually. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Click on the link to apply: <https://lifesouth.csod.com/ats/careersite/JobDetails.aspx?id=28>.

Hospital Services Manager. The Blood & Tissue Center of Central Texas in Austin is seeking a Manager for the Hospital Services Inventory Management department who has solid knowledge in blood product management and inventory control. This position will oversee department operations and staff, ensure compliance with applicable regulations, as well as serve as a subject matter expert; evaluate inventory and projections daily to ensure sufficient quantity and variety of products; maintain adequate operational supply levels; project production usage/needs and establish daily and long-range product levels for service area; maintain inventory expirations; and manage resource sharing of blood products to meet goals. At least four years production and process control experience in a biologic or GMP environment is required, preferably in a blood center, with a minimum of four years of supervisory experience. College degree in Clinical Laboratory Science is required. At least two years of inventory control experience in a hospital blood bank/center setting preferred. Must have knowledge of cGMP requirements and FDA regulations. Must be at least 21 years old, hold a valid driver's license, be able to provide a copy of an acceptable driving record and proof of liability insurance. Please visit www.inyourhands.org to apply.

IRL Clinical Lab Manager. Blood Systems Laboratories is searching for a Clinical Lab Manager to assist its busy Immunohematology Reference laboratory (IRL) in Phoenix, AZ! The successful candidate must be highly organized, able to multi-task in a busy office environment, as well as work successfully in a team environment. Responsibilities will include managing the overall activities and providing skilled technical oversight in the laboratory. This position will work with

(continued on age 16)

POSITIONS (continued from page 15)

other team members to ensure timely, quality, test results. Requires: Bachelor's degree, must satisfy CLIA requirements for High Complexity Testing, SBB or CHS certification, seven years clinical laboratory experience to include three years supervisory experience. For consideration, please submit resume via e-mail by **03/07/2014** to: jobs@bloodsystems.org ATTN: HR/2014/12. BSI offers a competitive benefits package including: affordable medical/vision/dental coverage, matched 401(k), education assistance, relocation and much more! Pre-employment background check and drug screen is required. For more information about this position, please visit our website at: www.bloodsystems.org. EOE M/F/D/V. *Find the Hero In You. Give Blood Three Times a Year!*💧