America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2012 #31 **August 24, 2012**

INSIDE:

The Basics of a Blood Center Merger and Acquisition

It is no secret that there has been much consolidation within the healthcare industry as hospitals struggle to keep costs down. Just among America's Blood Centers' members, there have been about ten major mergers, alliances, or acquisitions since 2010, and often the road to regulatory compliance when forming these partnerships is not simple.

At ABC's recent Interim Meeting in Buffalo, N.Y., Jennifer Jones, a consumer safety officer (CSO) for the Food and Drug Administration, shed light on the regulatory steps that blood centers need to take when going through an "establishment change," such as acquisitions, mergers, and facility moves. She highlighted the importance of contacting an FDA CSO early and creating a timeline to meet the regulatory deadlines for submitting various forms.

The first step when two blood centers (or more) are considering an establishment change is to determine exactly what type of partnership they will be forming by reviewing the relevant FDA guidance documents and the Standard Operating Procedures and Policies (SOPPs) found on the Center for Biologics Research and Review page on the FDA website. The two major FDA guidance documents on this topic can be found at http://1.usa.gov/QWsLph and http://1.usa.gov/NhWlVr; these will clarify what forms need to be submitted, important definitions, and important deadlines.

Two particular types of establishment changes that have become familiar in the blood community recently are mergers, the union of two or more licensed manufacturers to form a new legal entity, and acquisitions, when a manufacturer purchases some or all of the facilities that were previously operating under a different US license. In a merger situation, Ms. Jones recommends that the blood centers reach out to FDA about six months before submitting the application materials and determine a regulatory leader at the blood center who will be FDA's primary contact. FDA then has a 12-month review process for mergers.

The three Florida blood centers that recently merged to form OneBlood worked together for about a year before the formal merger documents were submitted to FDA and other regulatory agencies, Judith Smith, DM, MBA, MT(ASCP), SBB, the chief quality and regulatory officer of OneBlood, told the *ABC Newsletter*. She also noted that blood centers need to investigate state requirements for laboratory licenses and the timeframe to submit different forms, as well as requirements for blood irradiators, tissue licenses, biomedical waste permits, and accreditation

(continued on page 3)

OUR SPACE

ABC CEO Jim MacPherson

Waste

The basic principle of Lean Manufacturing is to create customer value (often by lowering costs) through eliminating waste. Sometimes this literally means reducing wasted product all along the supply chain, in our case from donor to recipient – sometimes this means eliminating wasted effort in our processes, also called process improvement.

The recent heavy adoption of lean tools by blood centers has been credited with allowing blood prices and margins to stabilize even as costs have increased during the flat market over the last four years. Some blood centers have told me that their internal efforts are beginning to see "diminishing returns" in new lean targets. But other indicators show there is much to be done.

For example, a recent, high level comparison between donor recruiting and screening strategies of the best European Union (EU) countries (as determined in the European Blood Alliance's Domaine project) and an average ABC center show that some European centers defer fewer donors, while also collecting from those with lower disease markers. It is too early to say whether relevant EU techniques can be adopted here, but it does show the potential value of international benchmarking.

On blood products, the growing ABC database of both hospital and blood center data indicates that the combined hospital/blood center wastage of red blood cells released for patient use is about two percent – a figure that has been consistent for over 30 years. Some say we probably can't do better than two percent, but nationwide that still represents about 350,000 donor gifts, worth nearly $74 million, that go unused. A big part of the problem is that even large hospitals (>300 beds) with high turnover maintain an 8-to-10 day supply of blood not matched to a specific patient. Should we need to reduce the shelf life of red cells to provide fresher blood to patients, that wastage number would easily rise if we don't put better blood management systems in place, such as ABC's AIM software.

For platelets, which have a five-day shelf life that makes the product hard to control, the combined wastage of the dominate pheresis product is nearly 25 percent according to recent AIM data. Nationally, that's potentially 550,000 gifts, worth more than $300 million, that go unused. While overuse of blood is the hot topic, such wastage is low hanging fruit.

Jmacpherson@americasblood.org *Visit Jim on Facebook: www.facebook.com/JimMacPhersonABC.*

The *ABC Newsletter* (ISSN #1092-0412) is published 46 times a year by America's Blood Centers® and distributed by e-mail.

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.

America's Blood Centers
President: Dan A. Waxman, MD
Chief Executive Officer: Jim MacPherson
ABC Publications Editor: Betty Klinck
Business Manager: Leslie Norwood
Annual Subscription Rate: $390

Send subscription queries to
mnorwood@americasblood.org.
America's Blood Centers
725 15th St. NW, Suite 700, Washington, DC 20005
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

Blood Center Mergers (continued from page 1)

organizations. For example, the State of Florida Agency for Healthcare Administration requires a 60-day advance submission for name-change and change of ownership.

Tracy Sipma, vice president of Quality at LifeServe Blood Center, added that when The Blood Center of Iowa and Siouxland Community Blood Bank began talking about a merger in 2009, the blood center leaders created a timeline that was divided into two sections – the business and regulatory aspects. After the two blood centers' boards of directors went through due diligence and decided that the centers would merge, the blood center leaders and Ms. Sipma talked with the FDA CSO to determine their next steps. She added that AABB's book, *Regulation and Licensure of Whole Blood and Blood Components*, was a useful tool in guiding the centers through the merger process.

Another early step in a merger or acquisition is to use the FDA guidance documents to identify any changes in "major equipment" and "core personnel." Major equipment includes items such as computer systems and associated software, apheresis equipment, blood irradiators, infectious disease instruments, and self-contained mobile collection units; core personnel includes center management, medical personnel, and staff responsible for quality oversight. In a merger, the new legal entity must apply for a new US biologics license under a new Biologics License Application (BLA), which must include any changes within these areas, including alterations to the blood center's standard operating procedures (SOPs).

"The organizations need to consider whether they will be using previously approved SOPs, writing new ones, or a combination of both," said Ms. Jones. When the two blood centers that formed LifeServe were working on their new SOPs, the centers formed teams with various stakeholders and subject-matter experts to ensure that the best practices from both centers were being implemented.

"You must allow for an ample amount of time when working on the SOPs and do a lot of communicating with employees about all the changes that are coming," said Ms. Sipma. "A good starting point is to establish the new entity's SOP for writing SOPs to ensure standardization to assist with procedure alignment. Having a well-understood plan for creating the new SOPs – whether it's blending them together or creating completely new ones – makes for a much smoother and more harmonious process," said Ms. Sipma.

Aligning the quality systems, change control procedures, and the validation procedure should be made a priority, said Ms. Sipma. For example, the centers worked together to align the deferral registries early on to ensure that quality measures would be in place throughout the merger. While aligning thousands of documents and numerous procedures can be difficult, communication was the key to a smooth merger, she added.

"We used lean manufacturing as our 'vehicle' to procedural alignment, which was very effective. Our lean teams had representatives from both organizations that worked through best practices and used lean tools. This resulted in the development of relationships, strong collaboration, and newly designed efficient processes," said Ms. Sipma.

"Change management, in general, is a challenge, especially in a merger when you have so many changes coming. You cannot communicate enough with the employees when aligning procedures and even when using process improvement techniques ... We were very transparent with our employees. If you're not going to be transparent, then you'll have problems with getting things aligned," said Ms. Sipma. "You're not just aligning procedures, you're aligning cultures, and these cultures are ingrained and have their own philosophical approaches. It's all about communicating and explaining the why."

(continued on page 4)

Blood Center Mergers (continued from page 3)

Open and frequent discussion with FDA and other regulatory agencies is also key to aligning processes of multiple blood centers, said Ms. Smith. She noted that OneBlood staff has been working together as a team to begin building a new set of SOPs established through collaborative efforts, involving quality staff to review for compliance.

After the merger that formed LifeServe, which FDA officially approved in Jan. 2011, the center has continued to conduct internal auditing. "Our focus over that last year has been about aligning and implementing changes. Now, it's all about the 'plan, do, check, act' cycle of process improvement," said Ms. Sipma. "We have to keep asking ourselves – 'Did our changes make sense? Has it been effective? Are we still compliant?'"

Ms. Jones reminded the audience at ABC's Interim Meeting that the CSOs are always willing to provide guidance in any way that they can when blood centers are considering or going through an establishment change. "There are resources out there, including the FDA guidance documents, but it never hurts to contact us with any questions. We're happy to answer whatever questions you may have," she said. ABC members can access Ms. Jones' presentation at http://members.americasblood.org/go.cfm?do=FileCenter.Get&fid=3792. ♦

Ortho ON DEMAND

LEARN. ENGAGE. TRANSFORM.

Your virtual experience is about to begin.

Ortho Clinical Diagnostics is bringing science-driven education to you. Industry thought leaders are now just a click away when you register for education that is online, on-demand and free.

Sessions begin in July 2012. CLICK HERE to register today.

America's Blood Centers®
It's About *Life.*

INSIDE ABC

Singer Jenni Alpert Offers Free Music Download for Blood Donors

Singer/songwriter, blood donation advocate, and *Conversations About Life* speakers bureau member Jenni Alpert is partnering with America's Blood Centers to offer blood donors a free music download in celebration of the release of her new album *Take It All*.

Take It All, a fresh sounding eclectic pop album produced by Mikal Blue, is about the process of discovering different definitions of love. As a special thank you to blood donors, who share the gift of life and love through blood donation, Ms. Alpert's song "Listen to your Heart" will be made available as a free download. Community blood centers can use this free download to promote blood donation within their local communities, free of cost, now through Dec. 31.

Download instructions can be found in MCN 12-118 at http://members.americasblood.org/go.cfm?do=FileCenter.List&srt=PublicationDate&srtdir=1. Please contact Ms. Alpert at jennialpertmusic1@yahoo.com with any questions or concerns.

Upcoming ABC Webinar to Focus on Succession Planning

As much of the "baby boomer" generation in the blood community plans to retire, preparing for the next generation of blood banking professionals has become a hot topic. America's Blood Centers' Member Employee Training and Development Committee recently announced an upcoming webinar called "Succession Planning – Best Practices," to be held on Sept. 12 from 1 to 2 p.m. EDT.

The webinar seeks to discuss the purposes and processes for succession planning. It will cover strategies and techniques used for the development of those identified as potential successors, especially high potentials. Don Colvin, MAOM, SPHR, MHCS, the organizational development manager of Blood Systems, will speak on these topics, and the webinar will then open up for a question and answer session with the audience. Login information can be found in MCN 12-119 at http://members.americasblood.org/go.cfm?do=FileCenter.List&category=MCNs. ♦

Sign up to Golf at *Links for Life* Event – Deadline is Approaching!

The deadline to register for the *Links for Life* Golf Tournament to be held on Monday, Oct. 22, is almost here! Next week is your last chance to sign up for this one-of-a-kind golfing experience at a top-rated golf course with the opportunity to meet PGA players and support a worthy cause. Those interested must register by **Sept. 4.** Please visit http://www.cvent.com/d/2cqpl5/1Q to register. Additional questions may be directed to Jodi Zand at (202) 654-2994 or jzand@americasblood.org

A Word From The FABC

Jodi Zand

Ain't Too Proud to Beg

It has been six months since I began working at the FABC. Part of me feels like I have worked here forever (in a good way!) and part of me still feels very much like the new kid in town. I remember sitting in the ABC offices during my interview, learning about the two main fundraising events – a gala with the Sickle Cell Disease Association of America (SCDAA) and a golf tournament. I then learned the dates of each. "Wow," I thought. "That's not too far away. This should be interesting."

I must have said all the right things about loving a challenge and how I jump right into things, (all true!) because here I am a little more than a month away from the first of these two huge events – the Unity Gala! Although I did come with some event planning/logistics background, it has been quite the learning experience – not to mention challenging, exciting, nerve wracking, terrifying, encouraging, moving, and every emotion in between.

I admit, I've had fleeting moments of sheer terror. I knew I was in it for the long haul when I started dreaming about the gala. You know, the "nobody shows up-I leave my dress at home-the food is missing" kind of dreams. But 99 percent of the time, I am just excited to be a part of this event.

Of all the things blood donation touches, sickle cell has always been the one that, without fail, moves me the most. Honestly, other than spokespeople I have met through the years, I don't actually know anyone in my personal life with sickle cell disease. But as a mother, it is enough to move me to action just knowing that there are thousands of children out there, who by no fault of their own, suffer with this debilitating condition and thousands of parents who watch in horror as their children are doubled over in pain, knowing that there is a chance they may be robbed of adulthood and of the chance to have children of their own – their dreams of the future being replaced by fears of the next episode. I can only imagine the pain these parents go through, and I am certain that every single one of them would do anything to relieve their children's suffering.

I know if that were my child, I wouldn't stop fighting for a cure. I would be dragging people in to donate blood. I wouldn't be able to live with myself if I gave any less than 110 percent to make him better. But, I am lucky. I have been blessed with a healthy child. So the best I can do is thank the powers that be for that blessing and channel my gratitude for my son's health into helping the parents and children that face the challenges of sickle cell disease every day. I am so lucky that those tough "toddler days," when a silly temper tantrum is the worst thing I have to face – not wondering if the right type of blood will be available at a moment's notice when he goes into crisis.

There is something we can all do though, whether we are affected by sickle cell disease or not. We can join the movement to cure it, and in the process support programs to ensure that we always have the exact right type of blood ready for that patient when they need it. We have made huge strides in blood banking and in sickle cell research, but we still have a long ways to go. I know you are constantly asked for money and time, and pulled in a million directions, by a million causes. I know how frustrating it is and how sometimes it all melts together and you don't know who to support. But, in the famous words of Motown legends The Temptations, "I ain't to proud to beg." So, today I am begging all of you to support our joint Unity Gala with the Sickle Cell Disease Association of America. It's not too late!

Jodi Zand is the Foundation for America's Blood Centers' director of Fund Development. You can reach her at jzand@americasblood.org. To learn more about the Unity Gala or to register for sponsorship, please visit http://thefabc.org/gala/. ♦

BRIEFLY NOTED

AABB and the Brazilian Association of Hematology, Hemotherapy, and Cellular Therapy (ABHH) announced last week that the groups plan to administer a Brazilian accreditation program for cellular therapies. Under this expansion of an existing agreement, which was signed at the Brazilian Bone Marrow Transplantation Society's meeting on Aug. 2, AABB and ABHH will jointly offer a Brazilian accreditation program based on AABB's cellular therapy standards. "This is an important step in the evolution of cellular therapy in Brazil," said ABHH Vice President Dimas Tadeu Covas. "[The partnership] will provide an accreditation program that has both international recognition by way of AABB and domestic recognition by way of ABHH." The original agreement between the two organizations was signed in November 2011 and focused on accreditation for blood banks and transfusion services. Acceptance of applications for accreditation under the expanded program will begin later this year. Those interested may contact AABB's Department of Accreditation and Quality at accreditation@aabb.org. "AABB is proud to partner with ABHH in developing an accreditation program for Brazil that will promote the highest level of quality in care and management of donors and patients in both transfusion medicine and cellular therapies," said AABB CEO Karen L. Shoos, JD.

A panel of external experts convened by the National Heart Lung and Blood Institute (NHLBI) recently released evidence-based guidelines for clinical management of sickle cell disease, NHLBI announced in a press release last week. The expert panel, which began its work in 2009, developed recommendations for the clinical management of sickle cell disease after identifying important clinical questions and conducting a systematic review of the relevant scientific evidence. The guidelines based on that evidence cover health maintenance, management of acute and chronic complications, hydroxyurea usage, and transfusion therapy. Sickle cell disease results from genetic mutations that produce an abnormal form of hemoglobin. Red blood cells (RBCs) that contain this abnormal hemoglobin develop a sticky sickle or crescent shape, which may block blood flow in small vessels and some larger vessels, leading to organ damage and painful episodes. RBC transfusions help to reduce the percentage of abnormal hemoglobin circulating in the person's body, making frequent transfusion a common therapy for sickle cell disease patients. The 250-page NHLBI guidelines include an entire section on blood transfusion in the management of sickle cell disease, with sub-sections on indications for transfusion, recommendations for acute and chronic transfusion therapy, appropriate management and monitoring, iron overload, and others important topics. NHLBI invites patients, healthcare providers, and others to review and comment on the draft of the panel's report until Aug. 31. Once the review period has closed, the panel will review the comments and submit the final guidelines in late 2012. To access the guidelines and leave comments, visit www.nhlbi.nih.gov/guidelines/scd/index.htm. (Source: NHLBI press release, 8/17/12)

A Federal appeals court reaffirmed last week the right of Myriad Genetics to patent two genes linked to breast and ovarian cancer, reported *The New York Times*. A panel of the US Court of Appeals for the Federal Circuit upheld Myriad's right to patent "isolated" genes known as $BRCA_1$ and $BRCA_2$, which account for most inherited forms of breast and ovarian cancer. However, the court denied the biotechnology company's effort to patent methods of "comparing" or "analyzing" DNA sequences, reported *The New York Times*. Women who test positive using Myriad's gene test, called BRACAnalysis, have an 82 percent higher risk of breast cancer and a 44 percent higher risk of ovarian cancer in their lifetimes. The lawsuit against Myriad and the University of Utah Research Foundation, which hold the patents on the genes, argued that the patents were illegal and restricted scientific research and patients' access to medical care. The American Civil Liberties Union, which brought the case, argued that patents on human genes violated the First Amendment and patent law because genes are "products of nature." However, Judge Alan Lourie, writing for the majority in the ruling, said "Everything and everyone comes

(continued on page 8)

BRIEFLY NOTED (continued from page 7)

from nature, following its laws, but the compositions here are not natural products. They are the products of man, albeit following, as all materials do, laws of nature." Thursday's decision was made five months after the Supreme Court, in a case involving a blood test developed by Prometheus Laboratories, unanimously ruled that companies were not permitted to patent observations about natural phenomena, reported *The New York Times*. Myriad's patenting effort has drawn opposition from groups including the American Medical Association, the March of Dimes, the American Society of Human Genetics, and the Association for Molecular Pathology. In a brief arguing against patenting genes, James Watson, MD, one of the discoverers of double helix structure DNA, said he feared the court had failed to appreciate the fundamentally unique nature of the human gene, which stores information necessary to create and propagate life. Nevertheless, the appeals court accepted the argument of Myriad's supporters that denying patent protection could stifle innovation by the company and others. *The New York Times* article is available at http://nyti.ms/PwYtgt. (Source: *The New York Times*, 8/16/12)

The *Pittsburgh Post-Gazette* recently highlighted Allegheny General Hospital's Center for Bloodless Medicine and Surgery, which is applying bloodless surgery techniques developed for Jehovah's Witnesses to the general public. Jehovah's Witnesses refuse blood transfusions based upon their religious beliefs, but the doctors at Allegheny Hospital have recognized the overall benefits of the bloodless surgery techniques originally developed to help Jehovah's Witnesses. "I would say that every week, we are doing two or three Jehovah's Witness surgeries of some kind of another," said Jan. C. Seski, the center's medical director and director of the hospital's division of gynecology/oncology. A recent study published in the *Archives of Internal Medicine* shows that Jehovah's Witness patients who refused blood transfusions during cardiac surgery were not at greater risk for surgical complications or long-term mortality when compared with cardiac patients who had blood transfusions (see *ABC Newsletter*, 7/13/12). "We've taken what we have learned in the management of Jehovah's Witnesses and are applying it to the general medical population as a whole," said Dr. Seski. "Blood in and of itself may be lifesaving. If you have a trauma patient that comes in after a motorcycle accident and they are bleeding to death, you need to use transfusions. But if you can avoid it, in some situations, you will get a better outcome." Dr. Seski notes that doctors need to take a patient-specific route when implementing bloodless surgery. There are several techniques that doctors use to increase blood counts and prevent blood loss before, during, and after surgery. For example, before surgery, doctors can provide iron and erythropoietin, which stimulate the bone marrow to produce red blood cells. Also, performing surgeries using smaller incisions help to reduce blood loss. The complete *Pittsburgh Post-Gazette* article is available at http://bit.ly/NBs8lA. (Source: *Pittsburgh Post-Gazette*, 8/22/12) ♦

Don't Miss Out on The Unity Gala – Last Week to Register!

The deadline is quickly approaching to show your support for sickle cell disease patients by sponsoring the Unity Gala on Thursday, Sept. 27, hosted by the Sickle Cell Disease Association of America (SCDAA) and the Foundation for America's Blood Centers (FABC). The event will be held in Baltimore, Md.'s lively Inner Harbor and will support the life-saving work that the FABC and the SCDAA do to help sickle cell disease patients and those in need of blood transfusions. In order to properly recognize the gala sponsors in the program, those interested must register for sponsorship by **Sept. 4**. Please visit www.thefabc.org/gala/unitygala_sponsorships.html to sign up for a sponsorship, to purchase an individual ticket, or for more details. More information about the Unity Gala is available at www.thefabc.org/gala/index.html.

REGULATORY NEWS

The Centers for Medicare and Medicaid Services (CMS) announced recently that it will cover autologous platelet-rich plasma (PRP) gel for patients with chronic wounds only in approved clinical trials, reported *MedPage Today*. The CMS decision applies to use of the gel for chronic diabetic and pressure wounds, as well as for venous ulcers. The ruling came after a request from Cytomedix to cover its PRP product AutoloGel. The gel, derived from a patient's own blood, is an extract that, in addition to platelets, contains a mix of growth factors, chemokines, and cytokines that some researchers believe can help regenerate damaged tissue, reported *MedPage Today*. Cytomedix and others will now have coverage while they conduct studies to examine the product's effectiveness in the Medicare population. Clinical study applications for coverage must be received by Aug. 2, 2014, CMS said. At the end of the studies, CMS will decide if the product will have full coverage based on the trial results. The agency outlined trial designs eligible for coverage and what outcomes and treatment methods studies must contain. Specifically, trials will examine if patients demonstrate complete wound healing, return to normal function, or reduction in wound size. This CMS decision reverses a nearly 20-year precedent of non-coverage for PRP products. Most recently, CMS reiterated this stance in 2008 when it issued another non-coverage determination for acute wounds where PRP is applied directly to the closed infection site. However, in October, Cytomedix requested that CMS reopen and revise coverage of autologous blood-derived products for chronic, non-healing wounds, claiming that PRP is prevalent in treating such conditions. Cytomedix submitted new study data for chronic diabetic and pressure wounds and venous ulcers. CMS began investigating coverage of the product in November 2011 and announced its intention to issue a decision in May. CMS issued approval under its Coverage with Evidence Development program, a process that allows it to ask for clinical trial evidence before approving coverage. (Source: *MedPage Today*, 8/4/12)

The Food and Drug Administration recently issued a draft guidance to revise its 510(k) application policy and issue a new basic administrative checklist to pre-assess submissions for a certain level of completeness before passing them on for agency review, reported *MassDevice* last week. With this new pre-review assessment, FDA could reject submissions dubbed incomplete. This draft guidance is one of FDA's attempts to make good on the promises it made to the medical device industry in the latest iteration of the Medical Device User Fee & Modernization Act. FDA vowed to streamline its application review process in exchange for doubling of fees that companies pay when submitting for review. The 510(k) application is used to approve devices which are based upon and otherwise substantially equivalent to medical devices already approved by FDA. Under the 510(k) process, devices are cleared by the agency if they can show substantial equivalence, and are mostly exempt from submitting clinical data in support of the application. This guidance clarifies the necessary elements and contents of a complete 510(k) submission. The guidance explains the procedures and criteria FDA intends to use in assessing whether a 510(k) submission is administratively complete and should be accepted for substantive review. The draft guidance is open for public comment until Sept. 27, and can be accessed at www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm315317.htm (Source: *MassDevice*, 8/10/12; FDA draft guidance, 8/13/12) ♦

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 Editor Betty Klinck at newsletter@americasblood.org. Authors will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

INFECTIOUS DISEASE UPDATES

WEST NILE VIRUS

The Centers for Disease Control and Prevention announced on Wednesday in a press conference that the recent West Nile virus (WNV) outbreak is the largest ever seen in the US. The number of cases so far this year is the highest recorded through August since the disease was first detected in the US in 1999, reported CDC. As of Aug. 21, 38 states had reported human infections, and the cases reported to CDC total 1,118, including 41 deaths. "The WNV epidemics usually peak in mid-August, but it takes a couple of weeks for people to get sick, go to the doctor, and get reported," said Lyle Peterson, MD, director of the CDC's Vector-Borne Infectious Disease Division. "Thus we expect many more cases to occur." About 75 percent of the cases have been reported in Texas, Mississippi, Louisiana, South Dakota, and Oklahoma. Texas has been the epicenter of the outbreak, with 586 confirmed cases and 21 deaths, according to the Texas Department of State Health Services. Just last week, the Dallas County Judge declared a state of emergency due to the large number of WNV cases in that region. WNV has caused 10 deaths and 200 illnesses just in the Dallas region. Several mayors in surrounding communities approved aerial spraying and Fort Worth initiated ground spraying for the first time in twenty years, to stop the spread of the virus, which is carried by mosquitoes. Carter BloodCare, an ABC member blood center that serves 58 counties in north, central, and east Texas, has reacted to the local WNV outbreak by activating individual donor nucleic acid testing (ID NAT) to screen for WNV in the most highly affected regions, said Laurie J. Sutor, MD, MBA, vice president of Medical and Technical Services at Carter BloodCare. Blood center officials recognized early in 2012 that WNV activity was much higher than the center has experienced in the past, said Dr. Sutor. The center detected no cases of WNV infection in donors at all in 2010 or 2011, but this year, the center had detected its first cases in early June and by late June had to trigger ID NAT more than once. The blood center monitors for WNV activity by geographic zip codes and uses an algorithm to determine if ID NAT for WNV should be implemented in each of these regions. By late July, the center had 38 positive donors, mostly centered in the Dallas Fort Worth Metroplex and had up to five zones of ID NAT testing activated at any one time. Due to other indicators, like the number of WNV cases reported to the health department, Carter BloodCare decided to forgo the usual algorithm to determine if ID NAT should be activated in each zip code region, and instead designated a larger area within the Dallas Fort Worth Metroplex as a permanent NAT ID testing zone for the rest of the summer, in agreement with the Creative Testing Solutions lab that conducts this screening. The rest of the blood center's collection area has remained under the usual algorithm of surveillance for WNV activity and ability to go to ID NAT if necessary. So far, Carter BloodCare has detected 66 positive donors (as of Aug. 22) and about 50 percent of those have occurred in the permanent NAT ID testing zone centered in the Dallas and Tarrant County areas. Blood center officials are hopeful that ground and aerial spraying for mosquitoes, personal precautions, and increased awareness among Texans will help to reduce the number of WNV cases, said Dr. Sutor. (Sources: CNN.com, 8/22/12; CBS news online, 8/17/12)

BABESIOSIS

The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) recently highlighted a study evaluating babesiosis in Medicare beneficiaries, which found that the disease is rising among the elderly in the US. Babesiosis is an infection spread by the parasite Babesia, which is closely related to the parasite that causes malaria. The disease can cause mild flu-like symptoms, but can also be severe, causing anemia, multi-organ failure, and death. It is transmitted by the parasite which is spread by tick bites and can also be spread from a blood transfusion from an infected person. The FDA conducted a study using the Centers for Medicare & Medicaid Services (CMS) database to study babesiosis

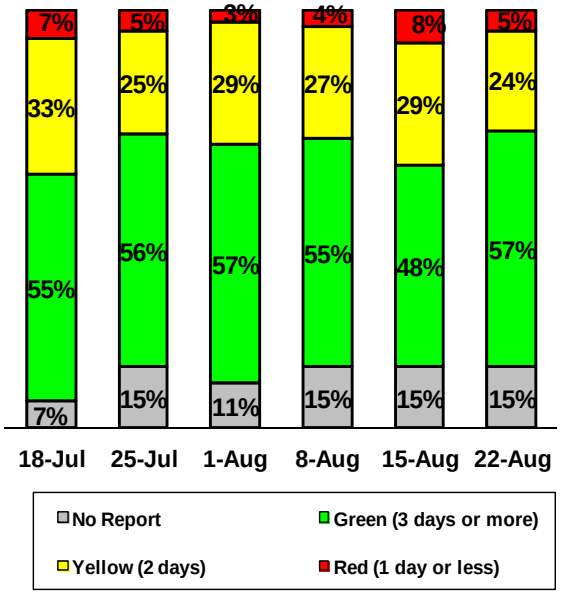
(continued on page 11)

INFECTIOUS DISEASE UPDATES (continued from page 10)

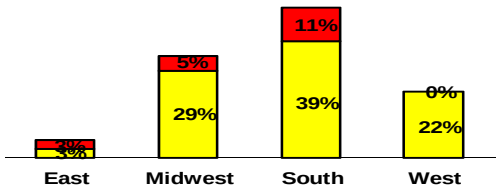
occurrence among elderly Medicare beneficiaries in the US during 2006 to 2009. Elderly people are known to be one of the most vulnerable at-risk populations for infection with the Babesia parasite. The researchers collected the babesiosis occurrence data among people 65 years or older and estimated the number of cases of babesiosis per each 100,000 Medicare beneficiaries each year from 2006 to 2008. They found 985 cases detected in 2006 with a rate of 3.6 cases per 100,000 Medicare beneficiaries; 851 cases in 2007 with a rate of 3.2 cases per 100,000; and 1,223 cases in 2008 with a rate of 4.7 cases per 100,000. The number of babesiosis cases and rates were highest during summer, with 41 percent of all cases being diagnosed during July and August, which coincides with the transmission season of the Babesia parasite and the life cycle of the tick that carries it. Babesiosis rates were highest in Connecticut, Rhode Island, New York, and Massachusetts. Currently, there are no FDA-approved lab tests to detect Babesia infections in blood donors, wrote CBER. However, blood center staff can use an FDA-approved current donor history questionnaire that specifically asks prospective donors if they have ever had babesiosis. CBER scientists are working to evaluate two types of lab tests that can differentiate between potential donors who are currently infected from those who were previously exposed to this parasite but are not infected. This Medicare study helps researchers to better understand babesiosis transmission patterns among the elderly, wrote CBER. Since the elderly are known to use the majority of transfused blood, studies are needed to evaluate transfusion-transmitted babesiosis in this group, wrote the authors. (Source: FDA CBER research review, 8/10/12) ♦

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, August 22, 2012



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

Blood Bank of Alaska (BBA) recently teamed up with local cartoonist Chad Carpenter of Tundra Comics to create artwork about "Donating Alaska Style," BBA announced in a press release on Tuesday. The print features two adventurers making their way through the wilderness – only to stumble upon what can only be described as a "suspicious" blood drive, said the release (see photo on right). Everyone who registers to donate blood during the Alaska State Fair Aug. 23 to Sept. 3 at BBA's mobile drives or Anchorage centers will receive a free T-shirt featuring the cartoon. "As a cartoonist, I myself have been the victim of many paper-cuts, and believe me, there's been a couple times where I thought a transfusion was in my future," Mr. Carpenter said jokingly. BBA has also featured Mr. Carpenter's cartoon in a coloring page, a print, and a poster. To see the color page online visit http://bit.ly/Nny3Jz. (Source: BBA press release, 8/21/12)

PEOPLE

Byron Selman was recently appointed as the president of the North America business operations for Haemonetics as of Aug. 22, announced Haemonetics President of Global Markets Michael P. Kelly in a letter to stakeholders. Mr. Selman has a long history in the blood industry and was with Pall Corporation for 21 years. He began his career with Pall in Engineering and took on progressively more responsible positions in Product Development and Project Management before assuming responsibility for a multi-disciplinary team charged with developing and commercializing a new line of bacterial detection products for blood. He became vice president of Global Blood Product Portfolio Management in 2002 and senior vice president of the transfusion medicine business in 2007. More recently, Mr. Selman served as president of the Pall Medical Division since 2010 and has played a role with Pall in the sale of the blood business to Haemonetics. Mr. Selman holds a Bachelor of Science in mechanical engineering from Case Western Reserve University and a Master of Business Administration from Hofstra University. In his new role, Mr. Selman will have overall responsibility for the Haemonetics North America business and will be a member of the Integration Steering Committee. (Source: Haemonetics letter, 8/17/12)

Col. Francisco Rentas announced on Tuesday that he plans to retire as the director of the Armed Services Blood Program Office (ASBPO) and from the US Army in September. "I have been honored to be entrusted with the mission of directing a program that has been part of my life for more than 25 years. Along the way, I have been blessed with some irreplaceable friends and memories," said Col. Rentas. In his 25 years of service, Col. Rentas has accomplished a multitude of achievements, including one that has made a lasting difference in the lives of the military family – the invention of the Golden Hour Human Blood Transport Carrier, reported ASBPO in its newsletter. The 10-inch square Golden Hour box is a device that carries blood far forward to the battlefield. It, or any other effective combat-environment thermal blood-carrying container, did not exist in 2002 as US troops were fighting in Afghanistan, far away from any fixed medical site. "The beauty of the Golden

(continued on page 13)

PEOPLE (continued from page 12)

Hour container is that it preserves red blood cells without the use of electricity, batteries, or even ice," said Victor Macdonald, MD, product manager and subject matter expert on blood products of the Pharmaceutical Systems Project Management Office at the US Army Material Development Activity at Fort Detrick, Md. Col. Rentas, Dr. Macdonald, and other members of the original invention team were recipients of the Army's 2003 Greatest Invention Award. Col. Rentas earned a bachelor's degree in biology from the University of Puerto Rico before joining the Army in 1982 as an enlisted clinical medical laboratory technician. He was enlisted for almost six years, attaining the rank of sergeant before earning a direct commission in 1987 as a second lieutenant in the Army's Medical Service Corps. Through his 30 years of service, Col. Rentas' achievements include: chief of military laboratories and blood donor centers, more than 20 medals, honors, and awards, close to 50 published presentations and publications, a master's degree, fellowship in blood banking, and doctorate in clinical laboratory science. It is being a part of military blood banking – the noble mission of saving lives – that has always inspired Col. Rentas, said the ASBPO article. "Our motivation is driven by the pictures of those returning in flag-draped caskets that could not be saved or those of a young wife with two children at her husband's funeral," said Col. Rentas, who plans to continue working in blood banking when he enters the civilian workforce. "From the dedicated staff here at home and around the world, to our donors and supporters, and those that we work with in the field of blood baking, I couldn't have asked for a more inspiring or more dedicated group of people to share my journey with," said Col. Rentas. (Source: ASBPO Focal Point newsletter, 8/21/12)

Leo J. McCarthy Lectureship in Transfusion Medicine

Jay Menitove, MD, president/CEO and medical director of Community Blood Center, Kansas City, shakes hands with Leo J. McCarthy, MD, after Dr. Menitove gave the Leo J. McCarthy Lectureship. Established in 1997, the Leo J. McCarthy Lectureship in Transfusion Medicine brings top physicians and scientists working in the critical and dynamic area of transfusion medicine to Indiana at the Riley Hospital for Children. Dr. Menitove's talk focused on "Keeping the Focus of Transfusion Medicine on Patient Care."

COMPANY NEWS

HemaTerra Technologies, a provider of end-to-end operational software products for blood centers, recently announced that it will work with Fenwal Inc. to develop a companion product to HemaConnect, a customer resource management system. The new product, HemaSource, will be designed to integrate with HemaConnect to create an end-to-end system from donor recruitment to order management, reported HemaTerra in a press release. Fenwal will provide technical and financial support to HemaTerra, and Fenwal Chief Technology Officer William Cork has agreed to serve on the

(continued on page 14)

COMPANY NEWS (continued from page 13)

HemaTerra's advisory board of directors. Using Smartphone and radio frequency identification (RFID) technology, HemaSource will provide inventory management and integration into HemaConnect. The companies hope that this product helps blood centers to lower their cost per unit collected. More information about this new system is available at http://yhoo.it/P4cUdn. (Source: HemaTerra press release, 8/6/12)

IN MEMORIAM – MICHAEL BEIRNE, MD

Michael Beirne, MD, a healthcare pioneer who established Blood Bank of Alaska (BBA), passed away at the age of 86 in his California home on July 30. Dr. Beirne was a major figure on the state's political and medical scene from the years leading up to statehood through the 1980s, reported the *Anchorage Daily News*. He served in the Alaska House of Representatives, spearheaded a movement to allow Alaskans to claim state land, and founded a number of important health facilities in Anchorage, including what became BBA. "Dr. Beirne was a major medical pioneer throughout Alaska's early years," said BBA CEO Bob Scanlon. Mr. Scanlon went on to explain that around the time that Alaska statehood was obtained in 1959, blood banking and transfusion medicine was far less advanced than it is now, with blood often being transfused from the donor to the recipient directly, with minimal testing. On July 26, 1962, Dr. Beirne of Alaska Medical Laboratories initiated the foundation of a not-for-profit blood bank designed to serve the blood needs of sick and injured Alaskans, said Mr. Scanlon. During the blood bank's first year of operation, there was one technician and one bed. "Thanks to the work of Dr. Beirne and his staff, BBA is helping Alaska patients in need each and every day. We are grateful for his contribution and are saddened to have lost a member of our life-saving team. This great man will truly be missed," said Mr. Scanlon. (Source: BBA press release, 8/23/12; *Anchorage Daily News*, 8/15/12)

MEETINGS

Sept. 29, or Nov. 3

Clinical and Laboratory Standards Institute Workshop, Houston and Boston.

The Clinical Laboratory Standards Institute (CLSI) will be holding a workshop titled "Tools for Tackling EP23: Laboratory Quality Control Based on Risk Management." The workshop will be held first on Sept. 29 at the Hyatt North Houston and will be held again at the Hilton Boston Back Bay on Nov. 3. This workshop will cover the EP23 document itself along with its companion products, EP23 Workbook and EP23 Worksheet. This one-day workshop will also include talks on the Centers for Medicare & Medicaid Services initial plans to incorporate key EP23 concepts into CLIA Interpretive Guidelines, assessing risk, as well as break-out sessions. More information about the September workshop is available at http://bit.ly/SsN8jJ and more about the November workshop is available at http://bit.ly/NjtG8m.

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 $390 for non-subscribers. 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:

Quality Control Technologist. LifeStream is searching for a Quality Control Technologist to perform quality control testing of apheresis and whole blood products; perform and review complete blood count testing on apheresis donors; perform tasks requiring a licensed Medical Technologist; perform quality control maintenance, and calibration on the BacT/Alert, Sysmex hematology analyzers, Flow cytometer, and other equipment used in component quality control and production. Collate, enter, and prepare quality control reports on apheresis and whole blood components;; maintains reagent inventories; files reports; enters test results into SafeTrace; and answers telephone, as well as other duties assigned. Education: Bachelor of Science Degree in Medical Technology or related field. One to two years experience in laboratory and hematology laboratory desired. California Clinical Laboratory Scientist License. Apply online: www.LStream.org. E-mail: employment@LStream.org. LifeStream is an Equal Opportunity Employer, M/F/D/V.

Chief Executive Officer (CEO), Western Lake Erie. The American Red Cross is seeking a Chief Executive Officer (CEO) in Toledo, OH. The CEO leads region wide activities to accomplish goals and objectives for the Blood Region; works in a collaborative fashion on project teams and leads change initiatives; develops and implements projects and plans to increase collection efficiency and collection totals and to identify and exceed hospital customer expectations; and insures that all region activities are carried out in compliance with Red Cross, FDA, and other applicable Fed, state, and local regulations. Additionally, the CEO monitors budgets, forecasts, and operational results and takes appropriate actions. Qualified candidates possess a bachelor's degree/equivalent experience and ten years' experience in a multi-task operational environment with budget responsibility or a profit/loss focus. Ideal candidate holds a master's degree and has health care experience. Occasional travel outside the region is required To apply, visit www.americanredcross.apply2jobs.com and search for requisition number NHQ24445. EOE, M/F/D/V

Chief Executive Officer (CEO), Great Lakes Region. The American Red Cross is seeking a Chief Executive Officer (CEO) in Lansing, MI. The CEO leads region wide activities to accomplish goals and objectives for the blood region; works in a collaborative fashion on project teams and leads change initiatives; develops and implements projects and plans to increase collection efficiency and collection totals and to identify and exceed hospital customer expectations; and insures that all region activities are carried out in compliance with Red Cross, FDA, and other applicable Fed, state, and local regulations. Additionally, the CEO monitors budgets, forecasts, and operational results and takes appropriate actions. Qualified candidates possess a bachelor's degree/equivalent experience and ten years' experience in a multi-task operational environment with budget responsibility or a profit/loss focus. Ideal candidate holds a master's degree and has health care experience. Occasional travel outside the region is required. To apply, visit www.americanredcross.apply2jobs.com and search for requisition number NHQ24425. EOE, M/F/D/V

Director, Finance. Blood Systems, a nationally known organization, is seeking a Director, Finance to work at our corporate office in Scottsdale, AZ. The ideal candidate will have treasury management, tax, internal audit and credit and collections experience. This top candidate will have good supervisory skills and strong organizational and analytical skills. Knowledge/Education: Bachelor's degree in related area required. Thorough knowledge of treasury management, finance, tax, investments and internal controls required. Master's degree in Business Administration or Finance preferred. Licenses/Certification: CPA certification preferred. Experience: Eight (8) years of related experience required. To include: five years supervisory experience. Experience in tax exempt municipal financing, taxes, internal audit and investment management preferred. Blood Systems offers an extensive benefits package! For consideration, please email your resume by **08/31/2012** to jobs@bloodsystems.org. ATTN: HR/2012/57. Please visit our website at www.bloodsystems.org. Pre-employment drug testing required. EOE M/F/D/V

Manager Donor Recruitment. Indiana Blood Center located in Indianapolis, Indiana seeks an experienced professional with three or more years of successful people management in a sales environment with proven sales accomplishments. The Manager provides direct

POSITIONS (continued on page 16)

POSITIONS (continued from page 15)

support and supervision to the representatives in the field and at fixed sites and manages the daily operations of all field and Donor Center donor recruitment. This person is responsible for establishing individual recruitment collection goals for his/her team members and assures that these goals are obtained in assigned regional territories. The Manager is also responsible for all fixed site and field recruitment activities including planning and follow-up of mobile blood drives. Requirements: Bachelor's Degree in marketing, sales or a related field required. Valid driver license, acceptable driving record and reliable transportation required. Must be proficient in all Microsoft Office products. Please apply online at www.indianablood.org.

Manager/Director, Quality Systems. Blood Bank of Delmarva (BBD) is a non-profit organization that provides blood and blood products to 16 hospitals on the Delmarva Peninsula. Reporting to the Executive Director of QCT, and an integral member of the Operations Management Team, the Manager/Director of Quality Systems is responsible for the organization's Quality Management Systems, including: the Quality Manual, Plan, and policies and procedures. This position is responsible for the planning, leading and directing of essential daily and project-oriented activities of the Quality, Compliance and Training (QCT) Department. The incumbent frequently provides transfer of knowledge and skills to the QCT staff that is responsible for daily activities that are essential to FDA regulatory compliance. Also, provides QCT content expertise including: Blood Product Deviation Reports, product quarantine determinations, donor suitability, Error Management activities, and internal/external Audit issues. This position makes critical decisions that impact FDA regulatory compliance. Please send resumes to Caroline Kelley: ckelley@bbd.org.

Clinical Specialist – Field-East Coast. Working without significant direction, the Field Based Clinical Specialist designs, develops, and delivers customer focused training and provides complex problem solving services in either a field or headquarters environment. Will provide pre-implementation and post-implementation support to Terumo BCT customers, and participate in product troubleshooting and optimization activities. Knowledge necessary to perform at this level is generally acquired through a bachelor's degree or equivalent experience in a medical, scientific, or clinical field of study. Minimum five years of relevant technical or clinical experience required. RN, MT(ASCP) or equivalent. Apply at www.terumobct.com, requisition #VG-1189.

Medical Director. Seeking a Medical Director for our Arizona Region. This position will be based out of our Tucson, AZ facility. The position will primarily be responsible for Arizona but will assist with coverage for Utah, Idaho, Montana, Nevada, Oregon, and Washington. This position will be responsible for medical coverage of the regional blood center, including a reference laboratory and an active Clinical Services program with therapeutic apheresis and peripheral blood stem cell collections. You will coordinate medical communications between the blood services region, the local and national medical community, and ARC National Headquarters; support the goals and objectives of the organization by providing accurate and timely medical and technical consultation in transfusion medicine to all operational areas of the region and as appropriate to its customers; and promote Red Cross products to the regional medical community. Apply online at www.americanredcross.apply2jobs.com requisition BIO24762. EOE M/F/D/V

Medical Technologist. LifeSouth is currently seeking to fill the Medical Technologist position in Palatka, FL. This position is qualified by training and licensure to process patient specimens for Transfusion services and laboratory analysis and is responsible for performing and interpreting tests that require the exercise of independent judgment, reporting results in the specialties for which they are licensed, and isolating and discarding blood unsuitable for transfusion. Other responsibilities include; ensure that test results and reports are legible, accurate, and precise as determined by the use of appropriate quality control; instrument maintenance, calibration, LifeSouth procedures, and reagent package inserts. Maintain CEU's for licensure as required by the State of Florida. Accurately record test results and QC. Maintain scientific and technical knowledge from current sources, such as AABB Technical Manual, AABB Quality Plan, and CFR Parts 211, 606, and 640. BS in Clinical Laboratory, Chemical or Biological Science required. Licensed as a Medical Technologist in the state of Florida with specialty in: Microbiology, Serology/Immunology, Clinical Chemistry, Hematology, Immunohematology, and/or Blood Banking (Transfusion services). Must be certified as: MT(ASCP), CLS(NCA), MT(AMT), MT(AAB), NRCC. This is a full-time position. Shifts may vary. Salary range $19.00 - $21.00 per hour. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Please click on the link to apply: https://home.eease.adp.com/recruit/?id=648481.