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# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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**2012 #17** **May 4, 2012**

**INSIDE:**



## Low HCV Risk From Tattoos Given in Professional Parlors

A recent literature review and meta-analysis showed no definitive evidence of increased risk of acquiring hepatitis C virus (HCV) from receiving a tattoo or piercing in a professional parlor. However, the risk of HCV infection was higher when tattoos were applied by friends in a non-sterile setting, such as a home or prison.

Many of the studies included in the meta-analysis did not find any association at all between HCV and receiving a piercing or tattoo. This evidence is vital to the blood banking community, because blood centers are permitted to waive an AABB requirement to defer donors for 12 months after receiving a tattoo or piercing if the tattoo or piercing was given in a state licensed and regulated institution. This waiver has allowed blood centers in many states to gain a large number of donors who would normally be deferred, as the number of people with tattoos and piercings is growing.

The meta-analysis of studies was conducted by Rania A. Tohme and Scott D. Holmberg of the Centers for Disease Control and Prevention's Division of Viral Hepatitis at the National Center for HIV/AIDS, STD, and TB Prevention in Atlanta. The results were published on April 15 in the journal, *Clinical Infections Diseases.*

**Why Tattoos Matter to Blood Centers.** In recent years, several blood centers have worked to support state laws to regulate tattoo and piercing parlors. A 2004 survey among 18- to- 50-year-olds in the US shows that 24 percent of respondents had at least one tattoo and 14 percent had ever had body piercings. A growing population of people with tattoos or piercings means a growing number of deferrals for blood centers without state regulated facilities.

Young people account for a large majority of those with new tattoos or piercings, which has heavily impacted some blood centers, as high school and college aged donors provide about 20 percent of the US blood supply. In 2009, the Illinois Coalition of Community Blood Centers reported that about 150 donors were being deferred per day in Illinois due to the AABB tattoo/piercing requirement. The state has since passed legislation to regulate tattoo and piercing parlors.

In recent years, several states have passed such legislation, with America's Blood Centers members from 27 states reporting in a 2010 survey that their state regulates tattoo and piercing establishments. At that time, 48 of 82 survey respondents

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## OUR SPACE

ABC CEO Jim MacPherson

### Ethics in Blood Banking

In church this past Sunday I listened to an oncologist friend lament daily having to juggle shortages of generic chemotherapeutic drugs and antibiotics. "Which patients do I save and which might die?" he asked no one in particular. "There are no shortages of drugs that cost $30,000 a month!" he bellowed.

A thoughtful guy, Steve blames the increasing commercialization in science and medicine, as well as declining ethics among his fellow practitioners. He notes that as the US continues to decline in both disciplines, society encourages getting ahead at all costs. In a 2005 study published in *Nature*, over one-third of medical researchers receiving National Institutes of Health grants admitted to cheating on their clinical results. ONE-THIRD! The most common reason was pressure from their major source of funding, usually a drug or medical device company. Steve's suggestion is to assure that as we emphasize teaching science in schools, we sprinkle our kids with a heavy dose of ethics in science.

I began to think, "What about us? Are we also on an ethical decline?" Sadly, the answer is yes. Twenty years ago, an investigative reporter for the *Philadelphia Inquirer* noted blood bankers were the "last of the pure white hats" in healthcare who were slowly getting sucked into shadowy practices, both in donor recruitment and retaining and obtaining hospital clients. Many find themselves now in a downward spiral, offering more and more incentives to donors, who hold out for even better incentives, recent studies have shown. Our hospitals (mostly not-for-profits themselves) ignore the donor's gift and demand price concessions for our services. In response, some spin who they are and what they can provide, then slash their prices and staff, hoping for a better day.

It's hard to stay pure amid the corruption that surrounds us. My mentor in blood banking in the 1970s said, "Blood centers must operate efficiently like businesses, but must never become businesses." Prescient then, those are tough words in these tough times. Yet, if we are to remain, in the moral sense, the stewards of the donor's gift to another we should redouble our efforts to retain more than a patina of nonprofit ethics and values.

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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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HCV From Tattooing (continued from page 1)

reported that their state would waive the standard 12-month deferral due to state regulation of tattoo/piercing facilities.

**Study Method.** Although sharing needles through intravenous drug use (IDU) is the most common method of transmitting HCV, the virus can also be passed through re-used or improperly sterilized needles used in tattooing. There has been conflicting evidence regarding the risk of acquiring HCV through tattooing or piercing, leading the researchers to evaluate this risk using a process called the Meta-analysis of Observational Studies in Epidemiology guidelines.

The authors used PubMed and Medline to search the literature regarding HCV infection from tattooing or piercing and rated the strength of the studies' evidence using the following criteria: study design, representatives of the study population, adjustment for other HCV infection risk factors, and use of adequate laboratory methods for ascertainment of HCV infection. Cohort and case-control studies were given the highest rating, followed by cross-section studies, and then by case reports or case series.

**Results.** The researchers retrieved 293 studies from the literature and included a total of 62 studies in their analysis. Some studies were excluded if they were review papers or editorials, did not measure the risk of HCV infection through tattooing or piercing, did not control for any HCV risk factor, or relied on self-reported HCV infection. Only five of 23 studies reported an increased risk of HCV infection among persons with a piercing. The researchers assessed association between HCV infection and tattooing in three groups: the general population, blood donors, and the high-risk population (IV drug users, prisoners, etc.).

In the general population, of 10 case-control studies, six reported no increased risk of HCV infection from tattooing when they controlled for IDU and other risk behaviors, and two studies reported a 2-3 times higher risk for HCV infection when the tattoo was received in a nonprofessional setting. Receiving tattoos in a non-professional or non-sterile setting was a common risk-factor for acquiring HCV.

Among blood donors, almost all of these low-risk individuals who were controlled for major HCV infection factors have not reported increased risk for HCV infection from tattooing. Case-controlled studies conducted in large samples of US blood donors did not show an increased risk of HCV transmission from tattooing, but did report significant associations between tattooing and IDU.

In the high-risk population, two Australian cohort studies conducted among prisoners reported discrepant findings, with the larger study showing a significant association between tattooing and HCV infection and the smaller study finding no association. Cross-sectional studies involving incarcerated individuals have been inconsistent, with two studies of US incarcerated youths showing no increased HCV risk associated with tattooing. However, several studies from other countries found two to three times higher likelihood of HCV infection among prisoners with tattoos. Studies that recruited more than 1,000 US Army veterans found almost a three times higher risk of HCV infection among those with a tattoo.

**Conclusions.** The authors conclude that to date, there is no definitive evidence that HCV infections occur when tattoos and piercings are given in sterilized or regulated facilities. The authors note that although professional or licensed tattoo parlors have not been implicated in HCV transmission, it could occur due to errors such as improperly sterilizing equipment or failure to use disposable ink. The authors suggest that studies on preventing the spread of blood-borne pathogens in prisons should be conducted.

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HCV From Tattooing (continued from page 3)

Some limitations noted that were common to all studies were: reliance on self-reports about IDU, not including patients with incident cases of HCV infection and asking about ever having a tattoo or piercing, and not including venue of receipt of the tattoo or piercing. The authors suggest that publicity campaigns should reach out to youths and prisoners to highlight the danger of receiving tattoos and piercings in un-regulated and non-sterile facilities.

**Citation:** Thome, RA, Holmberg, SD. Transmission of hepatitis C virus infection through tattooing and piercing: a critical review. Clin Inf Dis. 2012 Apr; 54(8): 1167-78.



## International Forum Sheds Light on TRALI Prevention Methods

The journal *Vox Sanguinis* recently published online an international forum on measures to prevent transfusion-related (TRALI), showing that most participating countries have successfully implemented interventions to help prevent TRALI. It is one of the most serious transfusion adverse reactions and is the main cause of transfusion-related deaths in the US and in many other countries.

In a previous international forum published by *Vox Sanguinis*, two main interventions were suggested: the exclusive use of plasma from non-transfused male donors and screening donors with a history of blood transfusion and/or pregnancy for HNA and HLA antibodies before they are accepted as donors. These interventions were suggested because a significant percentage of TRALI cases are caused by antibodies against HNA and/or HLA class I or class II antibodies in the donor blood, and women are known to be more likely to present such antibodies, especially if they have been pregnant.

The authors of the international forum therefore sought to analyze whether these measures have been implemented successfully by asking representatives from various blood services and healthcare facilities in different countries six questions. The questions relate to transfusing fresh frozen plasma (FFP) only

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TRALI Forum (continued from page 4)

from male donors, use of additive solutions, transfusing only platelets from male donors, screening donors for HLA and HNA antibodies, any other TRALI prevention methods (such as pathogen inactivation), and techniques for HLA and HNA antibody screening. Overall, only two of the countries that participated in the forum have no preventive measures in place.

Different measures are taken with regard to plasma. In some countries, only non-transfused male donors are used, but other countries have adopted more complex measures. Some use only male donors for plasma collections and disregard transfusion history. In France and Germany, all previously transfused donors are excluded, but women are accepted if they do not have HLA antibodies (in France) or if they have not been pregnant (in Germany). In countries where only male donors are used, women may donate AB plasma. The use of additive solutions to decrease the amount of plasma in platelet concentrates is increasing.

In some countries only male donors are accepted for platelet apheresis collections. When female donors are accepted, they are screened for HLA and HNA antibodies if they have been pregnant. In most countries, some categories of donors are screened for HLA antibodies and in some for HNA antibodies as well; screening for HNA antibodies is seen as less important since they are rare.

Pathogen inactivation of plasma and/or platelet concentrates is applied in some countries, but it is not viewed as a TRALI prevention method. In Rochester N.Y., younger adults and some children with acute leukemia, and all neonates and infants undergoing cardiac surgery receive washed and pre-storage leukocyte-reduced red cell and platelet concentrates in order to decrease the inflammatory effects of stored components and transfusion-related immune modulation. In the 15 years since this policy has been implemented, no cases of TRALI have been diagnosed in these patients.

Detection of HLA antibodies is made in some countries by, the lymphocyte/cytoxicity and the lymphocyte immunofluorescence test, but in several countries these tests have been replaced by the Luminex System. For detecting HNA antibodies, the granulocyte agglutination test and the granulocyte immunofluorescence test are still generally used, the results being verified by a monoclonal antibody immobilization of granulocyte antigens assay in some centers. A combined Luminex test kit capable of detecting both HLA and HNA antibodies has been developed.

In all countries where FFP donations have been restricted to males, hardly any TRALI cases of been diagnosed in FFP recipients. In countries where TRALI cases have been serologically investigated, HLA and/or HNA antibodies were detected in one or more of the donors in 28 percent to 78 percent of cases.

The forum editors also note that the previously described two-event mechanism may be important in non-antibody mediated TRALI cases and may require additional mitigation strategies, among them avoidance of transfusion of components with elevated levels of bioactive lipids and proteins that may accumulate in stored cellular products, including the use of fresher or washed concentrates for seriously ill patients.

**Citation:** Reesink HW, *et al*. Measures to prevent transfusion-related acute lung injury. Vox Sang. 2012 Apr 20. [Epub ahead of print]

## Study Shows Wide Variability in Blood Use Among Surgeons

Blood transfusion is not an uncommon medical treatment – about one in every seven patients entering a hospital will need blood. However, a recent study shows there is vast variability in blood use and the point at which physicians decide that it is necessary to transfuse a patient.

In the blood banking and transfusion community, this is not a new finding but rather adds evidence to an already familiar concept: blood is often overused due to a lack of uniformity in transfusion practices. Experts in the field have become focused in recent years on how to ensure that blood is used appropriately and only when necessary, a practice called "blood management."

At a 2011 meeting of the Health and Human Services' Advisory Committee on Blood Safety and Availability, attendees stressed the need cut down on blood wastage and overuse, and organizations, such as America's Blood Centers and AABB, have become committed to improving blood management. Blood is an expensive product as it must be properly collected, stored, and tested to ensure its safety, making blood management a worthwhile task for hospitals. Appropriate blood use also protects patients, as transfusion has risks like any other medical treatment, such as adverse transfusion reactions.

Researchers, led by Steven Frank, MD, of Johns Hopkins University in Baltimore, observed transfusion data for surgery patients collected in an automated anesthesia recordkeeping system. They found that surgeons and aestheticians varied widely in the hemoglobin level that they used to indicate the need for transfusion, called a transfusion hemoglobin trigger. There was also variability in the hemoglobin level set as the goal of transfusion, called the transfusion hemoglobin target. These results were published online in *Anesthesiology* on April 23.

**Study Method and Results.** The researchers used transfusion data collected at Johns Hopkins Hospital in the Metavision anesthesia information management system from February 2010 to August 2011. They focused on surgical patients, analyzing the last and lowest hemoglobin level before transfusion of red blood cells (RBCs), defined as the transfusion trigger, as well as the last intraoperative hemoglobin value, defined as the transfusion target. Blood use and hemoglobin triggers and targets were compared among individual surgeons and anesthesiologists as well as among specialties and types of surgery. The researchers also observed fresh frozen plasma (FFP) and platelet usage, as well as RBC salvage.

Over the 18-month period, 48,086 surgical patients were entered into the automated anesthesia recordkeeping system, and 2,981 (6.2 percent) were transfused with RBCs. A total of 9,440 RBC units and 4,769 FFP units were used. The authors evaluated hemoglobin transfusion triggers and targets by using the time stamp from the data system. The lowest hemoglobin value defined the trigger if it occurred before the beginning of the first RBC transfusion. The transfusion target was defined as the last intraoperative hemoglobin value if it occurred after the last RBC transfusion was completed.

The timing of hemoglobin concentration measurements allowed for evaluation of the trigger in 69 percent and target in 73 percent of transfused patients. The five surgical services with the greatest amount of blood used were: adult cardiac patients (45.3 percent transfused), orthopedic-spine (33.3 percent); transplant (18.5 percent), pancreatic-biliary (17.5 percent), and vascular (14.9 percent).

The mean hemoglobin trigger for all patients was 8.4 ± 1.5 g/dl and the mean target being 10.2 ± 1.5 g/dl. There was significant variation in hemoglobin triggers and targets between services, with cardiac having the lowest hemoglobin trigger at 7.5 ± 1.2 g/dl, and orthopedic-spine having the highest hemoglobin trigger at 9.5 ± 1.1 g/dl. The service with the lowest hemoglobin target was adult cardiac at 9.1 ± 1.2 g/dl

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and the service with the highest hemoglobin target was pancreatic-biliary at 11.3 ± 1.4 g/dl.

The researchers also found variability between individual surgeons performing the same surgery. For example, among surgeons performing the Whipple procedure, a complicated surgery used to treat pancreatic cancer, there was a 1.8 g/dl difference between the lowest and highest hemoglobin triggers and a 1.9 g/dl difference between the lowest and highest hemoglobin targets. The hemoglobin trigger also varied among surgeons performing posterior lumbar fusion, with a 1.6 g/dl difference between the highest and lowest trigger.

Among all surgeons, the mean hemoglobin trigger range was 7.2 to 9.8 g/dl and the hemoglobin target range was 8.8 to 11.8 g/dl. For anesthesiologists, the mean hemoglobin trigger range was 8.8 to 11.8 g/dl and the hemoglobin target range was 9.0 to 11 g/dl. The use of RBC salvage, FFP, and platelets varied threefold to fourfold among individual surgeons compared with their peers performing the same procedure.

**Conclusions.** These findings highlight the importance of aggregating relevant and accurate transfusion data to improve patient blood management. "As part of a blood management program, these methods of assessing blood and blood component transfusion provide accurate and targeted information that has the potential for improving the utilization of blood products," write the authors. They suggest using data aggregation programs to find discrepancies in blood use and to create more uniform transfusion standards.

The authors note that many healthcare organizations have recognized that blood is overused, and that adherence to evidence-based guidelines has been lacking. The authors emphasize that physicians should take into account all of the risks and benefits of transfusion for each individual patient and that collecting transfusion data can help healthcare facilities to better predict the blood needs of a patient.

The authors note some limitations of this study, including that data was entered manually and some patients did not have the proper lab work to indicate hemoglobin levels before or after the transfusion. Also some providers had smaller numbers of transfused patients, creating a smaller sample size, and surgical patients with ongoing bleeding may have continued bleeding in the postoperative room.

The authors conclude that these findings provide the opportunity to improve patient care and reduce costs related to blood. Even a 10 percent reduction in RBC transfusion at Johns Hopkins Hospital would save more than $1,000,000 per year in blood acquisition costs. "If the methods we describe can be successfully incorporated into a blood management program, the potential exists to enhance patient safety, reduce costs, and conserve blood, a valuable and scarce resource," write the authors.

**Citation:** Frank SM, *et al*. Variability in blood and blood component utilization as assessed by an anesthesia information management system. Anesthesiology. 2012 Apr 23. [Epub ahead of print]

## BPAC Releases Background Material for May Meeting

The Food and Drug Administration's Blood Products Advisory Committee (BPAC) has released background materials for the May 16 meeting to be held at the Hilton Washington D.C. in Gaithersburg, Md. The topic to be discussed that day is the evaluation of potential new plasma products manufactured following storage at room temperature for up to 24 hours. These materials can be found at: http://1.usa.gov/IJoXdv. More information about the meeting can be found at: http://1.usa.gov/HybqmJ. (Source: FDA CBER What's New e-mail alert, 5/3/12)

# A Word From The FABC

Jodi Zand

## May Days

May has always been my favorite month. My husband, David, has jokingly dubbed it my trifecta month. For the first couple decades of my life, my May bias revolved solely around the fact that I celebrate my birthday in May. I was always that kid who would start the countdown weeks before, making sure everyone knew it was coming. However, as I inch closer to the next milestone birthday, I have drastically reduced the advertising campaign. May also happens to be the month in which David and I got married five years ago. Then there is the day that trumps all other days, Mother's Day. Not only for the mimosa that will likely be served to me in bed that morning, or the sweet handmade card I will be given with my son Oliver's handprints on it that I will keep forever, but because nothing has changed my life so profoundly as becoming a mother.

While I was pregnant, I never understood why so many people offered advice and clichés such as "They grow so fast – enjoy every minute" and "You will never believe the capacity to which you will love you children." Of course I was going to love my child. And in the first few sleepless weeks, I was certain the people who said they would grow up fast were evil liars and my life was going to be an eternity of feedings and diapers and sleep deprivation. Now I know they were all right. I still can't fully grasp how much I love my son. And I really don't know when that little baby turned into a hilarious 2-and-a-half-year old who just the other night finished half the lines to his favorite "Llama Llama" book.

Despite the joy my son brings, I find that raising a child in this world can be terrifying. Random acts of violence and hate crimes happen way too often. Kids are being bullied, simply for being themselves, to the point of feeling that suicide is the only way out. Way too many mothers and children are suffering from conditions like preeclampsia, cancer, and sickle cell disease for which we have no cures. It can be tempting to act in a way that makes those hovering "helicopter parents" seem relaxed.

But because I am lucky to have a mother who defines the word optimism and who always views her glass as not just half full, but overflowing, and who is impossibly cheerful at 6:00 a.m., I have inherited a knack for finding the good in people. Thanks to my mom, I hold the unwavering belief that although not always obvious, good will always triumph over evil. (The cheerful at 6 a.m. trait, however, is all hers).

This trait of my mother's reminds me of why I love blood banking. It is full of good. Thousands of people each and every day roll up their sleeves and donate a pint of blood to someone they will more than likely never meet. Thousands more will come to work at a blood center in some capacity to ensure the blood is collected safely and comfortably for the donors. People like Lauren Ward Larsen will tirelessly relive their traumatic stories day after day to motivate people to donate.

These are the good people. These are the people who deserve to be in the news every day. These are the people I am going to teach my son about so he grows up wanting to do his part in moving the needle on the world's scale towards good. And because of all these good people, countless blood recipients will be able to celebrate another birthday, another wedding anniversary, and another Mother's Day. Now that is a winning trifecta.

*Jodi Zand is the Foundation for America's Blood Centers' director of Fund Development. She can be reached at:* jzand@americasblood.org. ♦

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# INSIDE ABC

## ABC Webinar to Focus on Payment Decisions by Government and Others for CT

America's Blood Centers has announced a free Cellular Therapy Alliance (CTA) webinar scheduled for May 14 at 11 a.m. EDT that will focus on payment decisions by government and private sector payers for cellular therapies. Cliff Goodman, MD, SVP and principal at The Lewin Group will be presenting on this topic.

The environment for coverage decision-making by government and private sector payers in the US and abroad is changing in ways that are influencing the adoption and diffusion of advanced health technologies, including pharmaceuticals, biological, medical devices, and medical and surgical procedures. This changing environment includes more prominent roles of health technology assessment, comparative effectiveness research, and health economic analyses, as well as heightened interest in personalized medicine and patient-centered outcomes research.

Dr. Goodman will present an overview of these and related aspects of this changing environment, especially related to coverage decisions by Medicare and other government payers, with implications for such interventions as stem cell transplantation and cell therapies.

To join the webinar online go to: http://bit.ly/K4sC30 , enter your name and e-mail address, and click "Join Now." The meeting number is 590 078 532 and there is no password. To view the meeting in other time zones visit: http://bit.ly/Ip9xFu. For audio (in the US and Canada), dial the toll-free number: 1-888-625-8629. The conference code is 202 654 2902. Global numbers can be viewed at: http://bit.ly/AhgWXe.

## ABC Supports Government Employees' Ability to Attend Educational Meetings

America's Blood Centers has joined some 800 other organizations across the nation in signing a letter urging Congress to revise legislative language in bills passed by the House and Senate that would severely restrict government employees' ability to attend educational meetings and conferences. The restrictions were contained in amendment language in the Digital Accountability and Transparency Act (H.R. 2146) in the House and in the 21st Century Postal Service Act (S. 1789) in the Senate.

The letter was drafted by the American Society of Association Executives (ASAE), which represents executives from more than 12,000 organizations. Among the healthcare association signatories are the American Medical Association, the American Association of Orthopedic Surgeons, and AdvaMed, the trade association of the medical device industry.

"There is little defense for exorbitant or wasteful spending of taxpayer dollars," says the letter, which ASAE plans to send to Congress next week. "However, while the amendments are designed to limit spending on government-sponsored conferences and travel expenses for federal employees, the actual language would have a chilling effect on government employees' participation in non-governmental meetings and conferences as well. The dialogue that takes place at these meetings between government

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and the private sector is essential to the development of informed policymaking that facilitates economic growth and job creation."

Section 1(D) of the amendments defines "conference" as a meeting "sponsored by one or more agencies, one or more organizations that are not agencies, or a combination of such agencies or organizations." According to the letter, "This definition would encompass every conference held by an association, corporation, or virtually any other non-governmental organization. Our recommendation is to revise this definition to a meeting "sponsored by one or more agencies."

Section 4 "limits any agency from expending funds on "more than a single conference sponsored or organized by an organization during any fiscal year, unless the agency is the primary sponsor and organizer of the conference,'" the letter notes. "This provision is highly problematic for agency employees seeking education from non-governmental sources and for the associations and other private sector organizations that invite government employees to conferences. A reasonable reading of this provision would mean that if employees of the National Institutes of Health (NIH) attended a scientific conference sponsored by a medical association, no other employees of the Department of Health and Human Services could attend any other conference held by that same association for the remainder of the fiscal year. Our recommendation would be to strike this final provision from the amendment." To sign onto the letter on behalf of your organization, go to: www.asaecenter.org/Advocacy/fedsignon.cfm .

## BRIEFLY NOTED

**AABB recently released the "Hematopoietic Progenitor Cell (HPC), Cord Blood Donor History Questionnaire (DHQ), now available on its website.** The material was designed by an interorganizational task force, led by AABB, to provide establishments with a standardized tool to screen allogeneic and related cord blood donors for communicable disease risk factors in accordance with requirements of the Food and Drug Administration, AABB, the Foundation for the Accreditation of Cellular Therapy, and the National Marrow Donor Program. FDA has not indicated any intention to endorse through regulations or guidance the use of any particular screening tool to fulfill requirements for screening donors for communicable disease risk. The DHQ is available at: http://bit.ly/ImmdwO. (Source: AABB Weekly Report, 3/27/12)

**More than 900 million Facebook users can now post their status as an organ donor on the social networking website, announced Facebook Founder and CEO Mark Zuckerberg on ABC's "Good Morning America" on Tuesday.** "Facebook is really about communicating and telling stories ... We think that people can really help spread awareness of organ donation and that they want to participate in this to their friends. And that can be a big part of helping solve the crisis that's out there," said Mr. Zuckerberg during his ABC interview. Beginning last Tuesday, users in the US and the UK can now add that they are organ donors to their Facebook Timelines, and if they're not organ donors, they can find links to organ donation registries to instantly enroll. More than 112,000 Americans are awaiting organs, and 18 people die every day from lack of available organs, according to Donate Life America, which is partnering with Facebook to help inform users about organ donation. This launching of the Facebook organ donation status comes just after National Donate Life Month in April, which was a month-long celebration honoring the generosity of organ, eye, and tissue donors, and their families while also commemorating transplant recipients in the US. Donate Life America has also embarked on a campaign called 20 Million in 2012, an effort to register 20 million more organ donors in 2012; recently the transplant community celebrated reaching 100 million registered organ, eye, and tissue donors. Mr. Zuckerberg said that his friendship with recently deceased Apple founder Steve Jobs, whose life was extended by years following a liver transplant, spurred him to initiate an organ donation effort through Facebook. However, the idea all started when Mr. Zuckerberg's med-student girlfriend began talking about the critical need for organs. All that Facebook users have to do is go to the "health and wellness" section of their Timeline and list their status as an organ donor; they can also explain to family and friends why they chose to become an organ donor. Parts of the ABC interview with Mr. Zuckerberg are available at: http://abcn.ws/Ks4fd5.

## LEGISLATIVE NEWS

**The Kubuki theater that is the current US Congress has a new play to add to the "message vote" drama series dominating this election year.** Rep. Paul Ryan (R-Wisc.), chair of the House Budget Committee, has submitted a budget reconciliation bill for fiscal year 2013 that will likely die before it ever hits the floor of the Democrat-controlled Senate. A House budget resolution adopted in March directed the chamber's five major committees to submit budget-cutting recommendations by April 27. For its part, the Energy & Commerce (E&C) Committee was asked to come up with just shy of $97 billion worth of cuts. To help the House beat the deficit and thereby avoid sequestration, Mr. Ryan's bill adopts two of the five recommendations made by E&C. These include a recommendation that would essentially codify most, if not all, of the provisions of H.R. 5, the Protecting Access to Healthcare Act, a medical-malpractice reform bill that was passed by the House in April. Provisions include a cap on noneconomic damages of $250,000, limits on attorneys' fees, modifications of the statute of limitations, and the

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elimination of joint and several liability. The Ryan bill, however, does not contain a number of E&C recommendations to gut the Patient Protection and Affordable Care Act (ACA), including a repeal of the funding authority of Health and Human Services to provide grants to states to set up health insurance exchanges; repeal the Prevention and Public Health Fund set up by the ACA; and the rescinding of funds for the loans under the Consumer Operated and Oriented Plan (CO-OP) program. Repeal of the Independent Advisory Payment Board was already contained in the House-passed version of H.R. 5. Mr. Ryan's bill does include E&C recommendations to cut the Children's Health Insurance Program (CHIP) by limiting states' ability to tax health care providers; reduce Medicaid payments to states for hospitals that serve a disproportionate share of poor and uninsured patients; relax rules that require states to maintain Medicaid and CHIP eligibility rules and procedures; and repeal performances bonuses under CHIP. According to the E&C, the Congressional Budget Office and staff of the Joint Committee on Taxation say that enacting these recommendations would reduce the deficit by $113.4 billion over the years 2012-2022. All of this maneuvering seems intended to portray GOP House members as fiscally responsible and put Senate Democrats on the defensive to come up with their own budget slicing proposals before the general election in November. (Source: *CQ Today*, 3/28/12)

– Robert Kapler, rkapler@americasblood.org

## REGULATORY NEWS

**The Centers for Disease Control and Prevention recently updated its malaria recommendations for Bangladesh in an e-mail alert last week.** Previously, CDC provided district-level malaria risk and recommendations for Bangladesh, but it discovered that currently only the city of Dhaka remains free of malaria transmission. Anti-malarial drugs are now recommended for all areas except the city of Dhaka. Atovaquone-proguanil, doxycycline, or melofoquine can be used when visiting Bangladesh. In the US, blood donors who have visited an area with malaria are deferred for one year after their return. CDC's malaria recommendations can be accessed at: http://1.usa.gov/IEPwB0. (Source: CDC Malaria Information and Prophylaxis, 5/2/12)

**The adoption of electronic health records (EHR) among US hospitals is lagging far behind the timeline set out by the Centers for Medicare & Medicaid Services (CMS), the American Hospital Association (AHA) said in comments submitted to CMS last Monday (4/30/12).** The comments were in response to a notice of proposed rulemaking for Stage 2 of "meaningful use" under the Medicare and Medicaid EHR incentive programs published March 7 in the *Federal Register*. "The AHA shares the goal of the EHR incentive programs … to improve health care providing needed financial support," Rick Pollack executive vice president said in a cover letter to Marilyn Tavenner, acting administrator of CMS. "However, the vast majority of hospitals – more than 80 percent – have not yet met Stage 1 [deadlines], due to both the high bar set and market factors, such as accelerating costs and limited vendor capacity. Evidence also suggests that the digital divide is widening, with large and urban hospitals reaching much higher rates of adoption than smaller and rural facilities." AHA says its "major concerns and recommendations pertain to the implementation of the Medicare penalty phase, the proposed timing and staging of meaningful use Stage 2, the specific objections and measures for Stage 2, and the reporting of clinical quality measures through EHRs." (Writer's note: The federal initiative to encourage the use of EHRs so far has focused only on Medicare and Medicaid billers such as hospitals and physician practices, not suppliers such as blood centers.) AHA also plans to file comments on a proposed rule from the Office of the National Coordinator for Health Information Technology that outlines standards and certification

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**REGULATORY NEWS** (continued from page 12)

requirements to support Stage 2. The full comment document is available at: http://www.aha.org/advocacy-issues/letter/2012/120430-cl-cms0044p.pdf (Source: *AHA News Now*, 4/30/12)

## INFECTIOUS DISEASE UPDATES

### BOVINE SPONGIFORM ENCEPHALOPATHY

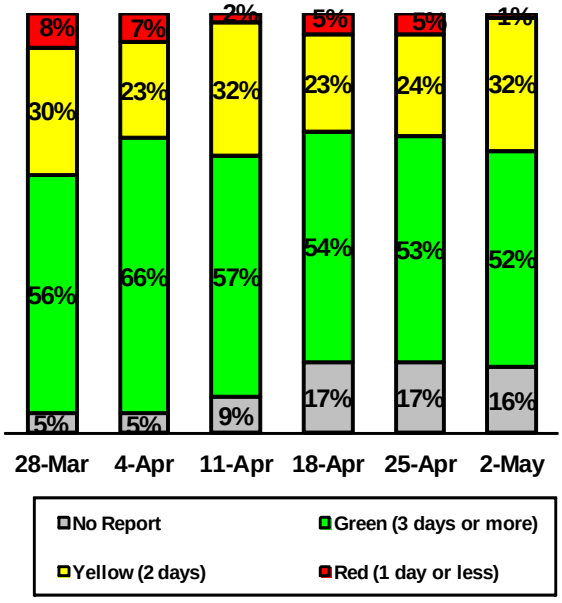
US Department of Agriculture Chief Veterinary Officer John Clifford, released a statement on April 24 with more information regarding the bovine spongiform encephalopathy (BSE) or "mad cow" disease case detected in a California dairy cow last week (see *ABC Newsletter*, 4/27/12). This was the first case confirmed since 2006 of BSE, and only the fourth case ever detected in the US. Last week, Mr. Clifford assured Americans that this is no cause for concern as the cow was never presented to be slaughtered for human consumption and thus never posed a threat to the food supply; he also noted that BSE cannot be transmitted through the cow's milk. Mad cow disease is a prion disease, which is part of a family of rare progressive neurodegenerative disorders known as transmissible spongiform encephalopathies; they affect both humans and animals. These diseases are fatal and their causes are not fully understood. Prion protein molecules are present in many normal cells; these proteins sometimes fold in abnormal ways and gather in clusters that are enzyme resistant and precipitate, causing tissue damage and sponge-like holes in the brain. The human form of "mad cow disease" is called variant Creutzfeldt-Jakob disease (vCJD), which is believed to be transmitted through eating meat from cattle infected with BSE or a blood transfusion from an infected donor. Mr. Clifford said in his most recent statement that scientists at the USDA's Veterinary Research Laboratories have identified this BSE case as a very rare, atypical form of BSE, not usually associated with eating infected food. This particular type of BSE is known as "L-type" due to the L-type prions found in this BSE strain, reported *Nature News Blog*. In the past, L-type BSE has not been found in cow feed tested for BSE contamination. It is unclear whether this particular strain is more contagious than the others or whether it can jump species from cows to humans without being directly injected into the brain. The USDA statement is available at: http://1.usa.gov/IC8LqA. (Source: USDA statement, 4/24/12; *Nature News Blog*, 4/24/12)

### FLAVIVIRUS

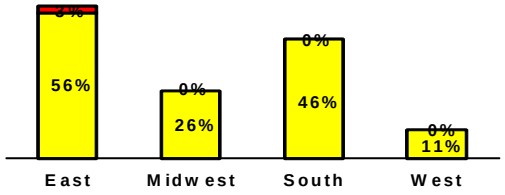
Scientists in Germany have detected the deadly Usutu virus in mosquitoes, which can infect blackbirds and humans, reported ProMed on April 20. Usutu virus is an arbovirus of the Flavivirus genus, closely related to important human pathogens like West Nile virus that may cause viral encephalitis. This virus was blamed for the death of many blackbirds last year, although only 72 bird cadavers tested positive. In rare cases, the virus can be spread to humans, in whom it causes fever, rashes and headaches, and in the worst cases, can lead to encephalitis. Experts are concerned that blackbirds in Germany are at risk for acquiring the virus this summer from the infected mosquitoes. The Bernhard Nocht Institute for Tropical Medicine in Hamburg called on April 19 for members of the public to keep their eyes open for dead blackbirds over the months to come and to report or even collect them. Living birds infected with the virus will display ruffled plumage and abnormal behavior. So far, 25 dead birds found this spring have been cleared as not having the virus. Anyone collecting dead birds should wear gloves or plastic bags over their hands and wash them thoroughly after. Birds should be sent to the Bernhard Nocht Institute for Tropical Medicine or to the Community for Action Against Mosquito-Borne Diseases. (Source: ProMed alert, 4/20/12)

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

**Total ABC Red Cell Inventory**




**Percent of Regional Inventory at 2 Days Supply or Less, May 2, 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

**Puget Sound Blood Center (PSBC) and LifeNet Health (LNH) announced in a press release on April 26 an agreement for Northwest Tissue Services (NWTS) to join and become a part of LNH Northwest.** NWTS was established by PSBC in 1988 as the region's first center to meet community needs for both bone and tissue grafts, providing tissue to surgeons, patients, and hospitals in the Pacific region. Once the agreement is complete, NWTS will become part of LNH, a global bio-implant provider with access to technologies that enable additional opportunities for tissue donation and recovery. LNH also has an extensive network of recovery partners, offering physicians, surgeons, and hospitals a wide range of services. "This agreement positions NWTS for future growth and continued success," said PSBC President and CEO James P. AuBuchon, MD. "As part of LNH, these talented employees will continue to use their expertise and local knowledge to serve communities in the Pacific Northwest."

Puget Sound Blood Center

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**MEMBER NEWS** (continued from page 14)

Dr. AuBuchon and Rony Thomas, president and CEO of LNH noted that there will be a continuing relationship between their two organizations. "We look forward to welcoming NWTS employees to LifeNet Health, and to building strong relationships with donor families, recovery partners, surgeons, and hospitals," said Mr. Thomas. "Hospitals will have single-point access to a larger array of products and services – including musculoskeletal and cardiovascular tissue," he said. "We look forward to becoming partners with them in delivering the highest quality of health care to families and communities in the region." LNH is in the process of opening a new scientific institute, The Institute of Regenerative Medicine, and PSBC will have an open partnership with the institute to research and develop collaborative biologic and cellular therapy products, said Mr. Thomas. (Source: PSBC press release, 4/26/12)

**Puget Sound Blood Center (PSBC) and Creative Testing Solutions (CTS) announced on May 1 an agreement-in-principle that will result in PSBC's Donor Testing operations becoming part of CTS by early 2013.** In return, PSBC will take an equity position in CTS and will be represented on its Board of Directors, reported the press release. "By becoming part of CTS, the Renton donor blood testing facility will benefit from being part of a large scale, specialized testing organization with strong purchasing power," said James P. AuBuchon, MD, president and CEO of PSBC. "Our mission to provide comprehensive collection, testing and distribution of blood components to hospitals in the region – backed up by our expertise in transfusion medicine – is fully supported by this change." PSBC currently tests about 550,000 samples per year, while CTS tests a total of 4.5 million donor samples at high volume labs collected in Dallas, Phoenix, and Tampa, Fla. The added testing volume will increase sample testing performed by CTS to almost 30 percent of the US blood supply. "We look forward to partnering with PSBC and other blood centers to provide high quality, cost-competitive testing services – backed up by the scale, resources, testing expertise and technologies that CTS provides," said Sally Caglioti, president and CEO of CTS. "We are a mission-driven, non-profit organization strongly committed to quality patient care, maximizing the value from health care dollars, and innovative research in sample testing." The months ahead will include a period of due diligence review, with the signing a final agreement anticipated in mid-summer. Closing and implementation is expected to be complete on or before Jan. 1, 2013. During this period, the Renton testing lab will operate on a business as usual basis, and employees will continue to be part of PSBC. "We look forward to welcoming the PSBC donor testing group to CTS once the transition process is complete, and to building strong relationships with other blood centers," said Ms. Caglioti. Both CEOs cite the agreement as the kind of innovative strategy to compete effectively in the dynamically-changing healthcare environment and to control healthcare expenses. (Source: PSBC and CTS joint press release, 5/1/12)

**South Texas Blood & Tissue Center (STBTC) has recently served as a model for success in the regenerative medicine field as STBTC President and CEO Mary Beth Fisk spoke at two national conferences last week, reported STBTC in a press release on April 26.** Ms. Fisk showcased STBTC's success in leveraging its core competencies in tissue and cellular therapies into an important role in the field of regenerative medicine, said the release. Ms. Fisk was a keynote speaker on April 23 in Washington D.C. at the National Blood Foundation Leadership Forum, a venue for discussing the future of transfusion and cellular therapies. She also presented at the Seventh Symposium on Biologic Scaffolds for Regenerative Medicine in Napa Valley, Calif. At the National Blood Foundation Leadership Forum, Ms. Fisk was invited to share the model that STBTC has developed to meet the demands of the growing field of regenerative medicine. A critical piece to that model

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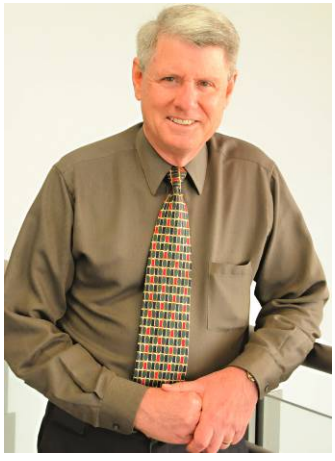
**MEMBER NEWS** (continued from page 15)

was the formation of GenCure, an arm of STBTC that provides cell and tissue services for regenerative medicine therapy and clinical research. "We are one of the only organizations in the US that has brought a unique set of competencies together in one place to create the ideal fit for this new generation of science," Ms. Fisk said. "Those competencies encompass peripheral blood and cord blood cellular therapy programs, tissue services and bone marrow donor registration, not only serving hospitals and clinics providing direct patient treatment, but also partnering with and providing products for researchers involved in regenerative medicine nationally and internationally." At the Symposium on Biologic Scaffolds for Regenerative Medicine, Ms. Fisk discussed the design and regulatory challenges in developing new products used in transplantation, clinical therapy, and clinical research. A recent example includes a bone tissue allograph component that is completed and now on the market for use in cervical fusion, said the release. (Source: STBTC press release, 4/26/12)

## PEOPLE

**Joe Chaffin, MD,** is resigning as the vice president of Medical Affairs at Bonfils Blood Center, and **Tuan Le, MD,** will temporarily fill this role as of June, announced Bonfils President and CEO Thomas C. Puckett in a letter. Dr. Chaffin will join Cedars-Sinai Medical Center in Los Angeles, Calif. on July 1 as the medical director of Clinical Pathology Services and the senior consultant of Transfusion Medicine. "This is a wonderful and well-deserved honor for Dr. Chaffin," said Mr. Puckett in his letter. In early June, Dr. Le, currently Bonfils' director of Clinical Services, will become the interim medical director and regulatory head of the organization until a successor has been named. Dr. Le will also take Dr. Chaffin's place on America's Blood Centers' Science, Medical, and Technology (SMT) Steering Committee. "Dr. Chaffin has been a key member of Bonfils' senior management team and has made numerous contributions since he joined the organization in 2010. We are grateful for his expertise, leadership, and dedication to transfusion medicine," wrote Mr. Puckett. Dr. Chaffin said, "My respect and admiration for the staff and leadership of Bonfils Blood Center have grown continually over my 13 years practicing in Colorado. I have been greatly honored to serve as Bonfils' medical director, and I look forward to hearing about all the great things that this company and all of the Colorado medical community will accomplish in the future." (Source: Bonfils Blood Center letter, 4/13/12)

**Joe Ridley** retired last month from his position as senior director of Strategic Diversified Services at Carter BloodCare and recently received the Cornerstone Award from the South Central Association of Blood Banks (SCABB), reported Carter BloodCare in an *ABC Newsletter* submission. Mr. Ridley began working for Carter BloodCare in 1998 and has worked in the blood banking industry for 46 years. He received the SCABB Cornerstone Award at the organization's annual meeting in Austin, Texas on April 20. The Cornerstone Award is presented to an individual who has contributed in an extraordinary way to the success of SCABB. During his more than 25 years of active involvement within the organization, Mr. Ridley served as both president of the association and the president of the foundation. "We congratulate Joe for his major contributions to SCABB, to the transfusion medicine profession, and for exemplifying Carter BloodCare's commitment to excellence," said Bobby Grigsby, executive vice president of Strategic Alliance for Carter BloodCare. (Source: Carter BloodCare submission, 5/1/12)



## IN MEMORIAM – Irving Millman, 88

**Irving Millman, MD,** a microbiologist whose work led to the creation of a vaccine against hepatitis B, died of internal bleeding on April 17 in Washington, DC, at age 88, reported *The New York Times* on April 26. Dr. Millman also helped create a test used to screen donated blood for hepatitis B. The hepatitis B vaccine, which Dr. Millman worked with the future Nobel laureate Brauch S. Blumberg to develop, is typically the first one given to babies, because the virus can spread easily from mother to child during birth. It is also considered one of the first entrants in the growing group of vaccines against cancer, since hepatitis B can lead to cancer. In the 1960s, Dr. Millman was the immunologist on a team at the Institute for Cancer Research (now the Fox Chase Cancer Center) in Philadelphia, studying the many causes of hepatitis. The team developed the hepatitis B vaccine, and was led by Dr. Blumberg who received the Nobel Prize in Medicine in 1976. After developing the vaccine in 1969, Dr. Millman and Dr. Blumberg struggled to find a pharmaceutical company to produce it, but eventually signed an agreement with Merck. Dr. Millman's blood screening test for hepatitis B became common in blood banks by the early 1970s, and infections through transfusion fell by about 25 percent, according to the Inventors Hall of Fame, which inducted Dr. Millman in 1993. Dr. Millman earned graduate degrees in virology and microbiology from the University of Kentucky and Northwestern University's medical school. Before joining Dr. Blumberg's team, he worked at Armour, New York City's public health department and the research arm of Merck. In World War II, he served in the Eighth Armored Division and earned a Bronze Star. Dr. Millman was an assistant professor at Northwestern University Medical School and an adjunct professor of biology at Hahnemann University in Philadelphia. Dr. Millman is survived by his daughter, Diane S. Millman, his son, Steven, and five grandchildren. (Source: *The New York Times*, 4/26/12)

## COMPANY NEWS

**Pall Corp. has agreed to sell certain operations and equipment used in blood transfusions to Haemonetics Corp. for about $550 million, reported the Associated Press on April 29.** The deal calls for Haemonetics to receive blood collection, filtration, and processing systems and equipment**,** along with manufacturing facilities in California, Mexico, and Italy from Pall. Some of Pall's assets in Puerto Rico are also included, and about 1,300 Pall employees will also be transferred to Haemonetics as part of the deal. Pall President and CEO Larry Kingsley said the asset sales will enhance the company's ability to grow in the long term. Haemonetics, based in Braintree, Mass., said the actuation will help boost its ability to serve the $1.2 billion global manual whole blood collection market. "The addition of Pall's whole blood collection and filtration products accelerates Haemonetics' entry into the whole blood collection market and provides resources to facilitate the development of new products in a competitive and highly regulated market," Brian Concannon, Haemonetics' president and CEO, said in a statement. The deal is expected close at the start of Pall's 2013 fiscal year; the current fiscal year ends July 30. The Haemonetics press release is available at: http://bit.ly/IxBPl9. (Source: Associated Press, 4/29/12)

**Hologic Inc., a company focusing on women's health, is set to acquire Gen-Probe by the second half of 2012, the two companies announced in a joint press release on April 30.** Gen-Probe produces

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**COMPANY NEWS** (continued from page 17)

molecular diagnostic products, including blood screening nucleic acid tests (NAT) and equipment, which are sold by Novartis. This includes Gen-Probe's TIGRIS platform and its PROCLEIX line of HIV, hepatitis C virus, hepatitis B virus, and West Nile Virus blood screening products sold by Novartis. Hologic will acquire all of the outstanding shares of Gen-Probe for $82.7 per-share in cash, or a total enterprise value of about $3.7 billion. Rob Cascella, president and CEO of Hologic, said, "Gen-Probe is an ideal partner and strategic fit to Hologic's existing diagnostics business and complements our focus on scaling and diversifying our diagnostics franchise. Gen-Probe is a unique player in molecular diagnostics, with best-in-class technology, including the differentiating automation capabilities of TIGRIS and PANTHER, a broad menu of tests, such as the recently approved APTIMA HPV and Trichomonas assays, and a leading blood screening business. This transaction establishes Hologic as a premier company in STD diagnostics and advances our core focus on women's health. With unique capabilities and an impressive new product pipeline, our combined company will be well positioned globally to capitalize on the fast-growing molecular diagnostics market with an established global infrastructure." Carl Hull, chairman and CEO of Gen-Probe said, "This transaction provides compelling cash value for our shareholders and represents an outstanding opportunity for our business. Together, Gen-Probe and Hologic will be very well-positioned to pursue a complete range of diagnostic opportunities in women's health, with a stronger focus on the dynamic molecular diagnostics market ... Our employees will benefit as part of a larger diversified organization with the necessary scale and resources to be a leader in today's rapidly evolving global healthcare marketplace." The press release is available at: http://bit.ly/KrgUNu. (Source: Hologic and Gen-Probe joint press release, 4/30/12) ♦

## MEETINGS

May 22-23 **Medical Device Workshop on FDA Inspections, Warning Letters, & CAPA. Crystal City, Va.**

Food and Drug Administration investigators are being more forceful when inspecting institutions, increasing the number of 483 observations resulting in more warning letters. CAPA system deficiencies counted for a large number of inspectional observations and continue to be cited in FDA warning letters. AdvaMed is holding a conference that will provide attendees with the tools to avoid warning letters, enable them to demonstrate their compliance initiatives, and teach attendees how to respond to warning letters. Participants can learn how to properly integrate and implement the CAPA program to improve internal processes and products and better achieve business objectives. The conference will be held at the Sheraton Crystal City in Crystal City, Va. More information and registration is available at http://bit.ly/JWGbmY. ♦

June 6 **SCABB Pre-Meeting Symposium at FABB. Gainesville, Fla.**

The South Central Association of Blood Banks (SCABB) will be hosting a pre-meeting symposium at the 2012 Florida Association of Blood Banks (FABB) meeting on Wednesday, June 6 from 9:30 a.m. to 4:30 p.m. This symposium will be focused on the practical application of new technologies and techniques to be presented by SCABB in partnership with FABB. Registration is $75. More information is available at: http://scabb.org/scabb-education-events/.

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**MEETINGS** (continued from page 18)

July 31 **SCABBinar (webinar).**

The South Central Association of Blood Banks (SCABB) will be holding a webinar on May 29 about interventions to reduce vasovagal reactions in young donors given by Peter Tomasulo, MD, of Blood Systems. More information is available at: http://scabb.org/scabb-education-events. ♦

## 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:

**Center Manager.** Community Blood Center of the Carolinas (CBCC) is seeking an experienced Manager to oversee our donation centers. CBCC is located in Charlotte, NC with additional collections sites in Gastonia, Concord, Monroe, and Hickory, N.C. A minimum of three to five years of supervisory experience in blood banking, plasma and/or medical environment working directly with FDA, CLIA and/or AABB is required. Prior experience writing SOPs; developing root-cause analysis and error management is required. Responsibilities also include the collection of whole blood, autologous, therapeutic, and automated procedures. Phlebotomy experience or accredited class required. High school diploma/GED required; MT, MLT (ASCP), RN or LPN preferred. Varied schedule including weekends, plus on-call rotation. Our ideal candidate understands and demonstrates the principles of excellent customer service. Qualified candidates should email their resume and salary requirements to cbccteam@cbcc.us, resumes w/o salary requirements will not be considered. Drug Free Zone/EOE .♦