



# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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August 31, 2012

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**AABB Joins ABC and ARC in Telling IRS of Medical Device Excise Tax Concerns**

AABB last week sent a letter to the Internal Revenue Service (IRS) supporting comments that America’s Blood Centers (ABC) submitted to federal tax officials in May outlining the possible impacts on blood centers of an impending medical device excise tax.

In an Aug. 20 letter, AABB CEO Karen L. Shoos told the IRS that her organization “has significant concerns the device tax, if inappropriately interpreted to include many products used in the collection and processing of blood, would subject blood centers to burdensome costs and hinder their ability to dedicate resources to improving blood safety and availability.”

On July 9, the American Red Cross sent a similar letter to the IRS, signed by J. Chris Hrouda, executive vice president of Biomedical Services.

The 2.3 percent tax will be levied on manufacturers, importers, and suppliers of medical devices starting in January 2013, with initial tax payments, based on reported transactions, due after the first quarter of that year. The tax is expected to generate more than double the \$20 billion in revenue over 10 years originally envisioned by the Obama administration when it included the tax in the Patient Protection and Affordable Care Act. Earlier this year, the IRS issued a notice of proposed rulemaking to implement the tax, offering only limited exemptions, mostly for commonly used retail medical devices.

Blood centers purchase about \$2 billion worth of medical devices annually to ensure the safety and availability of the nation’s blood supply. A rough calculation made by ABC suggests that the tax, if passed directly by manufacturers to blood center customers, could add \$2 to the cost of each blood collection.

“By expressing its support for our comments, AABB became the third national blood organization to raise concerns about the tax, meaning that the blood community now speaks to the IRS with a single voice,” said Jim MacPherson, CEO of ABC. “We are very grateful to our colleagues at AABB for joining us on this issue.”

In its letter, AABB asked the Treasury/IRS to take steps to ensure that its final rule for implementation of the tax will:

(continued on page 3)



## OUR SPACE

ABC CEO Jim MacPherson

### The NHS is Coming

Nurses and doctors dancing around sick children? Most Americans scratched their heads as they watched this spectacle at the Summer Olympics. More British humor? In celebrating all things British at the opening ceremony, it appeared that showcasing pride in the National Health System (NHS) was really a political statement.

What was fun became serious this week when the NHS announced it was exploring the possibility of exporting its healthcare model to other countries as a source of income. I sure hope they come here. The argument between our free-market healthcare system (the last in any developed country) and the “socialist” model needs to be settled for the sake of US patients. Nothing would be better than head-to-head competition between an NHS franchise and, for example, Kaiser Permanente.

Just last month US House Speaker John Boehner said that the US has “the best healthcare system in the world.” He cited no studies and, of course, that’s not what others say. In 2000, the World Health Organization ranked the US as No. 1 in expense per capita but No. 37 in quality of patient care (behind the Dominican Republic and Costa Rica, but ahead of Slovenia and Cuba.). France was No. 1 in quality and fourth in expenditures.

In 2010, a study by the non-partisan US-based Commonwealth Fund ranked US healthcare seventh out of seven countries. Overall, the Netherlands came in first, followed by the UK (NHS), Australia, Germany, and New Zealand. Canada, ranked sixth overall, was ranked seventh in quality of care and timeliness of treatment (the US was sixth and fifth, respectively). But then our neighbor to the north only spends about half of what we do in per capita healthcare expenses (\$3,895 vs. \$7,290). By the way, No. 1 Netherlands spends the same as Canada per capita.

For those who think the upcoming election will resolve the issue, think again. The politics is all about HOW healthcare will be paid for and controlled (i.e., government vs. private insurers). Private doctors and hospitals will still be the deliverers of our care. The US issues of low quality and access at very high costs still need to be addressed. Maybe competition from NHS will be the answer.

A handwritten signature in black ink, appearing to be 'J. MacPherson'.

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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.

#### America’s Blood Centers

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Medical Device Tax (continued from page 1)

- Specify that all products licensed by the Center for Biologics Evaluation and Research (CBER) are not to be treated as medical devices, and therefore not subject to the excise tax.
- Exclude from the tax combination products and kits when a majority of the cost of such a product is attributable to products not considered medical devices, or impose a tax only on the portion that is by definition a medical device. This issue is particularly important to blood centers, which purchase blood collection kits (including sterile containers, integral tubing, and anticoagulants), apheresis kits and reagent kits used to detect infectious diseases or determine blood types.
- Clarify that certain medical devices used by the blood banking community are not taxable since they are not “intended for humans.” Devices used to manufacture blood products more closely resemble products used to produce and manufacture drugs and biologics, not medical devices related to patient care.

It is unknown exactly how manufacturers ultimately will handle cost of the tax – whether some will absorb part or pass along all of the tax in the form of a line item on an invoice. Therefore, it is difficult to calculate the precise impact of the tax on blood centers. The IRS is expected to issue its final rule sometime in the fourth quarter of this year. ABC has submitted a request to the Advisory Committee on Blood Safety and Availability to place the medical device tax as a topic for discussion on the agenda of its meeting in December. 💧

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## NYBC Study Identifies First Probable Transfusion-Transmitted Chagas Cases Since T. Cruzi Testing Implementation

After a lookback analysis of its blood donor screening for *Trypanosoma cruzi* (T. cruzi) infection from 2007 to 2011, New York Blood Center (NYBC) has identified the first two probable cases of T. cruzi infection since national screening of blood donors for the parasite was implemented in 2007. T. cruzi is the parasite that can cause Chagas disease.

The results of NYBC's lookback for Chagas disease were published on Aug. 15 online in *Transfusion*, and Debra A. Kessler of NYBC led the study. T. cruzi is generally spread by a bite from an infected triatomine insect, often found in poor living conditions, such as mud huts; it is common in rural Latin America. Although rare, T. cruzi can be transmitted through organ transplants and blood transfusions from an infected individual. Autochthonous human transmission in the US is rare due to better housing conditions, T.cruzi infected triatomines and mammals are widely distributed in the southern US.

In Dec. 2006, the Food and Drug Administration approved an enzyme-linked immunosorbent assay (ELISA) to screen for antibodies to T. cruzi in blood donors, with a second T. cruzi antibody screening test approved in April 2010. According to FDA guidance from 2010, all blood donors must be screened once for Chagas disease, and if the test is negative, no further testing is necessary. NYBC began T. cruzi donor testing on April 16, 2007, with all donors screened at each donation until April 1, 2010 when it switched to initial screening only.

Donors that were repeatedly reactive using the ELISA underwent confirmatory testing with a radioimmunoprecipitation assay (RIPA). For the cases in this report, further analysis of the T. cruzi positive plateletpheresis donor using quantitative real-time (RT)-polymerase chain reaction (PCR) was performed at Blood Systems Research Institute and qualitative PCR, RT-PCR, and hemoculture by the American Red Cross. NYBC contacted hospitals that received the units from a confirmed infected donor and requested that hospitals test recipients by immunofluorescence assay (IFA) and report results to the blood center.

From April 2007 through December 2011, 1,066,516 unique donors were tested and 205 were ELISA-repeatedly reactive, representing 0.019 percent of unique donors. Of those, 77 had their infection confirmed by RIPA testing, representing 0.007 percent of donors. Most of the RIPA-confirmed donors (61 of 77; 79 percent) identified themselves as Hispanic. Lookback to track recipients of the blood products from the 77 donors uncovered 29 with prior donations distributed to hospitals, consisting of 163 red blood cell (RBC) units, 62 apheresis platelet or whole blood-derived platelet units, 60 plasma units, and 23 cryoprecipitate units.

NYBC received information about 154 products transfused to a total of 141 recipients, 48 of whom were alive and 93 deceased. Seven of the 48 living recipients were successfully tracked and underwent T. cruzi IFA screening by their hospital, which identified two IFA-positive patients. Each of the two recipients had received a single leukoreduced plateletpheresis unit from the same RIPA-confirmed donor (two separate donations). One of the two patients was a 64-year-old white male transfused with platelets in 2004 while undergoing treatment for non-Hodgkin's lymphoma. The other was a 62-year-old white male who received platelets in 2006 after a subdural hematoma.

From 1984 to 2007, the implicated donor, a 72-year-old female, had donated 16 times and a total of 25 blood products, which were transfused to 35 recipients. She was born in the endemic area of Cordoba,

(continued on page 5)

Chagas Lookback (continued from page 4)

Argentina, and she lived there until moving to New York City at 31 years old. Although Chagas disease was common in her community, she did not recall having a vector bite or clinical signs of the disease.

These cases identified by NYBC bring the number of reported transfusion-transmitted cases in the US to eight. They “support the contention that platelet products constitute the primary risk for transfusion transmission of *T. cruzi*,” the authors added. Most *T. cruzi*-infected individuals in the US are immigrants from endemic areas in Latin America, as confirmed in this study. The authors noted that there are no large representative surveys, using contemporary methods, of Latin American populations living in the US to know the true prevalence of *T. cruzi* infection in this target group.

As the case donor was born in Argentina, her infection was likely vector-borne or congenital transmission, write the authors. Although these cases are considered “probable” transfusion-transmissions, *T. cruzi* infection by transfusion cannot be confirmed without pretransfusion donor serology and parasite genotype matching between donor and recipients, and also because complete recipient risk histories were not available regarding travel to endemic areas. However, autochthonous human transmission in the US is rare – only 16 cases of autochthonous vector-borne infections have been reported in the US since 1944.

**Citation:** Kessler DA, *et al.* Results of lookback for Chagas disease since the inception of donor screening at New York Blood Center. *Transfusion*. 2012 Aug. 15. [Epub ahead of print.] ♦

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## INSIDE ABC

### R&B Singer/Songwriter Phil Perry to Perform at Unity Gala

Guests at the Unity Gala on Thursday, Sept. 27 will be treated to smooth R&B and urban jazz music performed by singer/songwriter Phil Perry. The Unity Gala, to be held in Baltimore, Md.'s Inner Harbor, is hosted by the Sickle Cell Disease Association of America (SCDAA) and the Foundation for America's Blood Centers (FABC) to support the life-saving work that these organizations do for the sickle cell disease and blood donation communities.

"The FABC is excited to offer the Unity Gala guests this special opportunity to listen to a live performance by an acclaimed R&B artist like Phil Perry. We hope that this wonderful entertainment combined with the lively setting of Baltimore's Inner Harbor provides our guests with an unforgettable evening," said FABC Director of Fund Development Jodi Zand. "We are also thankful to the SCDAA who worked with us to plan this live entertainment for the gala."

Mr. Perry launched his musical career as the lead vocalist and writer of the 1970s soul group The Montclairs, then formed the duo Perry & Sanlin, and recorded a pair of albums with Capitol Records in the 1980s. After going solo in 1991, Mr. Perry had a hit R&B single, "Call Me," a remake of Aretha Franklin's 1970s-hit, and released his debut solo album, "The Heart of a Man."



After four well-received albums during the '90s, Mr. Perry's fifth solo album, *MAGIC*, was released in September 2001. Devastated by the 9/11 terrorist attacks, Mr. Perry did not record again until he was invited to be a part of the all-star Grammy nominated CD/DVD project *The Hang*, released in 2004. Mr. Perry soon returned to the recording studio, collaborating with Chris "Big Dog" Davis, and released several popular albums. Voted 2007 Male Vocalist of the Year in the SoulTracks Readers Choice Awards, his career began to regain momentum as he went on tours with musical artists Dave Koz, Norman Brown, Pieces of a Dream, Maysa, the Angela Bofill Experience, and Men of Soul.

Often performing at some of the most notable jazz venues, festivals, and cruises, Mr. Perry's popularity continues to grow. He has released eight solo albums and recently released a duo album in 2009 called *The Gift of Love*, featuring songstress Melba Moore. A two-disc re-mastered set of Perry & Sanlin hits was released last year with Funky Town Grooves.

Frequent blood transfusion is a common therapy for sickle cell disease patients, making a partnership between the SCDAA and the FABC an obvious choice for these two organizations. SCDAA and the FABC are thrilled that guests at the Unity Gala will be able, not only to network with blood banking and sickle cell professionals while supporting a worthy cause, but also to enjoy a performance by a talented R&B artist. 💧

### **Alianza Latinoamericana de Sangre – ALAS Latin American Blood Alliance**

Durante la reciente reunión de ISBT, representantes de los servicios de sangre de 12 países de Latinoamérica acordaron iniciar una red de trabajo auspiciada por Americas's Blood Centers. Organizaciones no lucrativas en el campo de donación de sangre y transfusión en Latinoamérica están invitadas a participar. Para más información y requisitos de asociación, contactarse directamente con Miriam Bolaños, [mbolanos@americasblood.org](mailto:mbolanos@americasblood.org).

During the recent ISBT meeting, representatives of Latin American blood services in 12 countries agreed to facilitate a Latin American Network hosted by America's Blood Centers. Non-profit blood organizations in Latin America are invited to apply for membership in this ALAS Network. Contact Miriam Bolaños, [mbolanos@americasblood.org](mailto:mbolanos@americasblood.org), for more information and membership requirements.

### **BRIEFLY NOTED**

**A study recently published by the Belgian Red Cross in the *Journal of Hepatology* found that blood donated by hemochromatosis patients is safe to use for transfusion, reported Reuters Health.** Although many US centers have been drawing hemochromatosis patients since 2001, this is one of the first European studies concluding that donations from these patients is as safe as blood from donors without this condition. Hemochromatosis causes the patient to have too much iron in his or her body, and it is usually treated with periodic phlebotomy in order to remove excess iron. The Belgian Red Cross investigators said that the blood collected in these phlebotomies often gets discarded “because of the non-voluntary character of this donation, and because a potential risk of microbial contamination of the blood donor is assumed,” reported Reuters. The researchers conducted a systematic review of the literature on this subject, which included six observational studies, and found that there was no evidence that blood derived from hemochromatosis patients does not comply with quality requirements from a hemato-physiological point of view. In two studies that examined the safety of the blood, there was no statistically significant differences between hemochromatosis donors and regular donors in positive screening test results for viruses. Although two studies suggested that blood obtained from these patients would be more susceptible to bacterial growth, the authors of this review note that with normalized iron levels and uncomplicated disease, there is no evidenced of more bacterial growth, reported Reuters. In the US, prior to 2001, the Food and Drug Administration did not promote blood donation from hemochromatosis patients, but in September 2001 the National Institutes of Health published a study in the *Journal of the American Medical Association* showing that hemochromatosis patients' blood is as safe as other donated blood. Since August 2001, FDA has permitted blood centers to apply for variances from 21CFR640.3, allowing individuals with hereditary hemochromatosis to donate blood and blood components more frequently than every eight weeks without examination or certification of health by physician at time of donation and to be exempt from placing special labeling about the donor's disease on the blood components. Many US centers have successfully applied for this variance, and drawing blood from such patients is quite common in the US. Emmy De Buck, MD, of the Belgian Red Cross-Flanders in Mechelen told Reuters that there is much variation in hemochromatosis blood donation policies between countries and called for harmonization of these policies. (Source: Reuters, 6/14/12)

**Citation:** De Buck E, *et al.* Is blood of uncomplicated hemochromatosis patients safe and effective for blood transfusion? A systematic review. *J Hepatol.* 2012 May 30. [Epub ahead of print]

**BRIEFLY NOTED** (continued on page 8)

**BRIEFLY NOTED** (continued from page 7)

**The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule for Hospital Outpatient Prospective Payment Systems (OPPS) for calendar year 2013.** The proposed rule, published in the Federal Register on July 30, would increase reimbursements for some blood products while decreasing them for others. CMS has proposed to continue to establish payment rates for blood and blood products using the blood specific cost-to-charge ratios from the most recently available hospital cost reports. Blood products are part of a market basket that CMS uses to calculate aggregate costs and their rates are determined using the producer price index furnished by the Bureau of Labor Statistics, which gathers reports from a number of sentinel blood centers.

<b>OPPS Payment rates CY 2012 and Proposed CY 2013</b>			
<i>Blood product</i>	<i>Reimbursement 2012</i>	<i>Proposed Reim. 2013</i>	<i>Difference in \$</i>
Whole blood	\$190.76	\$170.00	-\$20.76
Blood split unit	\$117.35	\$141.73	+24.38
Cryo unit	\$82.78	\$81.05	-1.73
RBC leukoreduced	\$198.90	\$193.19	-5.71
Plasma unit	\$79.87	\$77.30	-2.57
Platelet unit	\$89.77	\$89.62	-0.15
Platelet rich plasma	\$141.83	\$174.29	+32.46
RBC	\$149.16	\$151.02	+1.86

(Source: CMS)

**A US appeals court last week upheld the legality of federally funded human research on human embryonic stem cells (hESCs), reported *ScienceInsider*, a scientific news source by the journal *Science*.** This ruling is the latest in a string of wins for the National Institutes of Health (NIH) in a three-year legal battle with groups that for moral reasons want to block the use of these cells, reported *Science*. Although this ruling favors hESC researchers, the 27-page decision suggests that the battle is not yet over. "It's a clear victory for us. We're very happy with the opinion," says Amy Comstock Rick, an attorney and president of the Coalition for the Advancement of Medical Research, which defends hESC work. However, because the three judges in the appeal of *Sherley v. Sebelius* issued separate opinions in favor of NIH and used different reasoning, the plaintiffs who filed suit against NIH might have luck with another review, some legal experts say. "We are disappointed by the Court of Appeals decision and, given the reasoning in the two concurring opinions, we are evaluating whether, and on what grounds, our clients will be seeking certiorari before the US Supreme Court," said Samuel Casey, an attorney for the plaintiffs. The case was filed in August 2009, a month after NIH issued guidelines implementing an executive order from President Barack Obama that eased Bush-era limits on hESC research. Pro-embryo groups and others, including two scientists who study adult stem cells, argued that the NIH guidelines violated the Dickey-Wicker Amendment, a 16-year-old law banning federal funds for research that destroys embryos. (Human ESCs are usually derived from days-old embryos in a process that destroys them.) The two scientists won a preliminary injunction in August 2010 and in April 2011, the appeals court threw out the preliminary injunction, finding that NIH was likely to win the case. Then in July 2011, a judge granted NIH's request for a summary judgment dismissing the suit, but noted that he was not obliged to follow the appeals court ruling. The plaintiffs then appealed to the same appeals court, the US District Court for the District of Columbia. Now, in his 15-page opinion for the court, Chief Judge David Sentelle noted that the court's earlier ruling relied on a legal principle known as Chevron that says if a statute is ambiguous, courts must defer to the agency's interpretation. Under Chevron, NIH "had reasonably interpreted" Dickey-Wicker to allow for federal funding of hESC research because research on hESCs and their derivation are "discrete." He also rejected the plaintiff's argument that NIH's policy puts embryos

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**BRIEFLY NOTED** (continued from page 8)

at risk because it “incentivizes” their destruction. Judge Sentelle also ruled that NIH did not err in ignoring plaintiffs’ comments in a public docket calling for an end to all federally funded hESC research. The other two judges concurred with the opinion, but cited different legal reasons. The three fractured opinions increase the chances that the plaintiffs can successfully petition for a new review by the full court, known as an en banc hearing. However, Ms. Comstock Rick is confident that the plaintiffs are unlikely to prevail in a review. More information is available at <http://bit.ly/T7uBpd>. (Source: *ScienceInsider*, 8/24/12) ♦

**REGULATORY NEWS**

**The Food and Drug Administration recently published a revision to 21 CFR 606.122, eliminating the six-hour, post-thaw storage time limit for fresh frozen plasma (FFP).** An Exceptions and Alternative Procedures (commonly known as a variance) Approved Under 21 CFR 640.120 posted on Aug. 28 noted that a variance was no longer required to extend the storage time of thawed FFP stored at 1-6° C to 24 hours, instead of six hours. The FDA website noted that the regulation has been changed. America’s Blood Centers staff has checked the April 1, 2012 version of 21 CFR 606.122 and it now states, “For plasma, the circular of information must contain ... when applicable, instructions to begin administration of the product within a specified time after thawing,” rather than within six hours. This change is part of changes noted in the Jan 3 Federal Register notice that became effective on July 2. The original Federal Register notice can be found at <http://1.usa.gov/RuACyF>. More information is available at <http://1.usa.gov/OxUFvq>. (Source: FDA website, 8/28/12; Federal Register, 1/3/12) ♦

**MEMBER NEWS**

**America’s Blood Center’s members along the Gulf Coast in Hurricane Isaac’s path began preparing for the storm last week, and thus far have been able to continue providing blood to the community, in some cases with the help of fellow ABC members.** Last week Florida’s Blood Centers (FBC) and Florida Blood Services (FBS), both divisions of OneBlood, sent press releases urging Florida residents to donate before then-Tropical Storm Isaac hit. On Monday, FBC reported that it had to close operations in South Florida due to Isaac’s impact and encouraged Central Florida residents to donate before the storm hit that region. Despite the wind, rain, and power outages in some areas of South Florida, OneBlood reported to ABC and Blood Centers of America (BCA) that its centers are well stocked due to preparations for the Republican National Convention currently being held in Tampa, Fla. On Monday, The Blood Center in New Orleans, La., began hurricane preparations and had an adequate blood supply as Tropical Storm Isaac headed its way with hurricane potential. When Isaac hit New Orleans on Tuesday it had become a slow-moving Category 1 hurricane. Although the impact of Isaac is nowhere near the destruction that Hurricane Katrina brought in 2005, Hurricane Isaac has flooded many areas of New Orleans and left more than 730,000 residents of Louisiana and Mississippi without power. The hardest hit area was Plaquemines Parish, outside New Orleans, where floodwaters overtopped at least one levee on Wednesday and left many homes under about 12 feet of water. In other areas, residents were forced to evacuate due to the storm. The Blood Center reported to ABC on Thursday that its headquarters and several fixed sites have roof and water damage, although its laboratories and distribution sites did not sustain any damage. The Blood Center anticipated as of Thursday evening that its centers would be up and running again today. BCA sent blood to LifeShare’s Lake Charles center on Wednesday, as a few of LifeShare’s donor centers were closed down. Many community blood centers have sent blood and continue offering assistance to those centers affected by Isaac. It seems that ABC members in

(continued on page 10)

**MEMBER NEWS** (continued from page 9)

Isaac's path have gotten through the storm without any major damages, but if any blood centers have extra O-negative red blood cell and/or AB-fresh frozen plasma units, they are encouraged to contact BCA to coordinate future shipments as needed. Blood centers can reach BCA by contacting Anne Darcy at [adarcy@bca.coop](mailto:adarcy@bca.coop) or (401) 381-0600. As blood centers deal with Isaac's impact, the Food and Drug Administration issued an update on Thursday about the "Impact of Severe Weather Conditions on Biological Products." These guidelines provide "interested persons with information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions." This document offers guidance on dealing with blood and products and plasma derivatives in the case of power outages or floods, noting that problems affecting the blood supply should be brought to the attention of FDA. The *AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism Disaster Operations Handbook* (<http://bit.ly/OM8O6G>) can be referenced when preparing for and responding to disasters at blood centers. More disaster preparedness resources may be found at <http://members.americasblood.org/go.cfm?do=Page.View&pid=6>. (Sources: FBC press release, 8/27/12; FBS press release, 8/23/12; FDA "Impact of Severe Weather Conditions on Biological Products, 8/30/12; WKYT 27 News, 8/29/12; wane.com, 8/29/12)

**Blood Bank of Delmarva is hosting a Hero Blood Drive from Sept. 6 through Sept. 14 in memory of Wilmington Fire Chief James Ford, an avid blood donor who recently passed away.** The blood drive

will be launched on Sept. 6 at the Wilmington Donor Center with Mayor James Baker in attendance, as well as family members of Chief Ford donating in his honor. Chief Ford was not only an avid blood donor, but part of the Wilmington Fire Department for 30 years. Following his retirement, his service to the city of Wilmington continued when he became part of the Riverfront Development Corporation. He lost his battle with cancer earlier this year. "He was a loving father and husband and a truly selfless individual who held the best interest of others in his heart," said Tom Ford, Chief Ford's son. "He donated blood, not because he thought it made him a hero, but because he thought it was the right thing to do." Mayor Beck added, "Chief Ford has left a legacy of honor, integrity, and service to Wilmington. He touched the lives of everyone who knew him, and through his frequent blood donations, he touched the lives of so many that he never even met. This Hero Drive is a way to honor his dedication and commitment to blood donation and our community." Those interested in donating to honor Chief James Ford can schedule an appointment at any Blood Bank of Delmarva location. (Source: Blood Bank of Delmarva press release, 8/23/12)



The legacy of selfless giving left by the late Chief James Ford (above) of the Wilmington Fire Department will live on through the Hero Blood Drive hosted by Blood Bank of Delmarva in his honor.

**In commemoration of September being Sickle Cell Awareness Month, the Community Blood Center of the Carolinas (CBCC) is working to increase blood donors – particularly African-American donors – to help treat sickle cell patients, CBCC announced in a press release this week.** This effort is part of CBCC's new Sickle Cell Program aimed at creating a registry of African-American volunteer donors whose blood type and traits are matched with a local sickle cell patient. "There is a real value and need for this program in our community," said CBCC President and CEO Martin Grable. "Nationally, the number of African-



(continued on page 11)

**MEMBER NEWS** (continued from page 10)

Americans who need blood transfusions exceeds the number of African-Americans who donate blood. The same is true in our own community where we simply do not have enough local African-American donors to meet local patient needs.” Studies show that one in 500 African-Americans are born with sickle cell anemia each year, said the release. Although sickle cell is not unique to African-Americans, it is more frequently diagnosed in the African-American patient population in the US. Frequent blood transfusion is a common therapy for most sickle cell disease patients. Often times, the best-matched blood for African-American sickle cell patients comes from African-American donors who are more likely to have certain rare blood types needed to help such patients. “These blood donations are necessary to support local sickle cell patients who need our help,” said Mr. Grable. CBCC is teaming up with various organizations throughout the region to host blood drives in honor of Sickle Cell Awareness Month, said the release. (Source: CBCC press release, 8/28/12)

**Three generations of the Goodman family donated blood side-by-side today at the LifeShare Community Blood Services donor center in Elyria, Ohio, LifeShare announced in a press release this week.**

The patriarch of the family, Arthur Goodman of Lorain, Ohio, first donated blood in a tent on the battlefield of France in World War II. It was a body-to-body direct transfusion to save a fellow soldier. He’s donated blood ever since, and now at age 86, he is donating his 330<sup>th</sup> unit of blood, making 41.25 gallons donated to date. When asked how he feels about the inter-generational donation, Mr. Goodman said, “During my lifetime and in my very own family, I have



witnessed how blood is the substance of life; our donations can and do save lives. It has always been a goal of mine to encourage others to donate. With this special donation, the goal of fulfillment of Dor LDor, (Hebrew for ‘generation to generation’) is now a reality for me.” Joining Mr. Goodman, is son Mark B. Goodman, 55, of Lorain, and great niece, Anna Moore, 32, of Denver, Colo. “Art is a legend at LifeShare,” said Lisa Mayles, LifeShare spokesperson. “He is one of the kindest, humblest people I have ever known. That two other generations of his family have adopted his lifesaving mission, speaks volumes about the family culture he’s established.” (Source: LifeShare Community Blood Services press release, 8/29/12) ♦

**PEOPLE**

**Jim Decker**, CEO of MEDIC Regional Blood Center in Knoxville, Tenn., recently earned the “Doctor of Health Administration” degree from the Medical University of South Carolina. Dr. Decker’s dissertation, titled “The Impact of Blood Center Consolidation in Florida from 1991-2011,” used aggregated data to evaluate selected financial and operational indicators resulting from recent blood center merger and acquisition activity. ABC President Dan Waxman, MD, and Bob Carden, MBA, PhD, along with other full-time Medical University of South Carolina faculty, served on Dr. Decker’s dissertation committee. Dr. Decker was appointed CEO of MEDIC in 2006 after a 22-year career as a hospital CEO. He also holds a Bachelor of Science and a Master of Science in microbiology from Louisiana State University, a Master of Science in healthcare administration from the University of Alabama at Birmingham, and a Master of Business Administration from the University of Tennessee. The staff at MEDIC Regional Blood Center sends Dr. Decker their congratulations on his recent accomplishment. (Source: submission from MEDIC Regional Blood Center, 8/24/12)

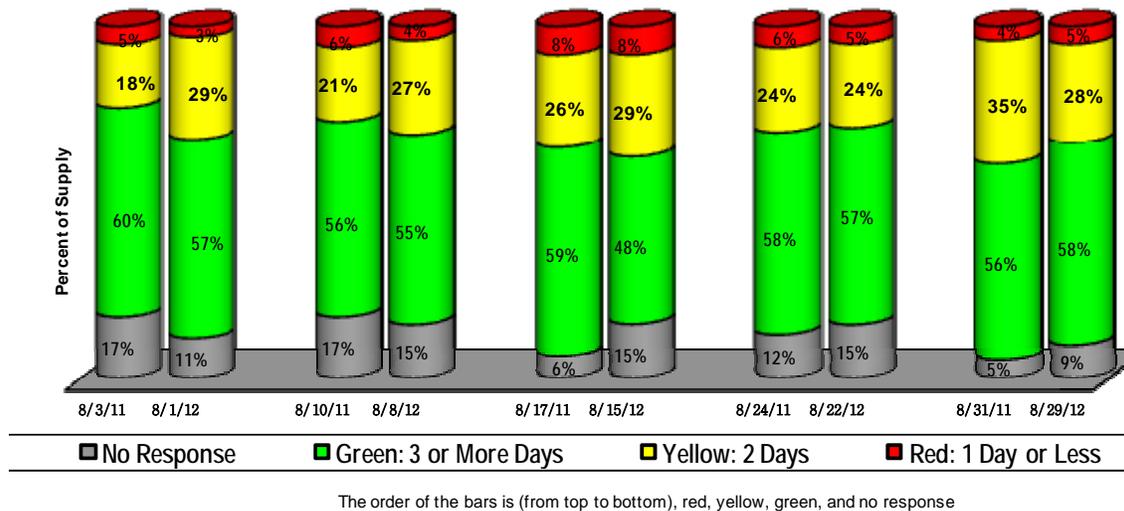
**PEOPLE** (continued on page 12)

PEOPLE (continued from page 11)

**Michelle Miao, PhD**, assistant director at the Mayor’s Office of Contract Services in New York City, was recently elected to New York Blood Center’s (NYBC) Board of Trustees, reported an NYBC press release. Dr. Miao’s previous experience includes tenure as the chief statistician at the New York City Office of Comptroller. Michelle was most recently project leader for the implementation of the city’s first electronic procurement solution, which will support billions of dollars of contracts annually. Dr. Miao has extensive experience in research, data analysis, public policy, audit, community initiatives, and nonprofit organizations. She holds a bachelor’s degree in English from Peking University of China, as well as a master’s and doctorate in sociology from the State University of Buffalo. Born and raised in China and fluent in Mandarin, Dr. Miao serves the Chinese and Asian populations in New York City as the Mayoral representative to these communities. NYBC looks forward to the business, technical, and leadership capabilities Dr. Miao will bring to the organization and her experience promoting relationships between US and Chinese institutions in the research and clinical areas of hematology, said the release. “Michelle’s talent, energy, skills, experience, and commitment to the community will make an invaluable contribution to the Board, the entire NYBC organization, and the millions of people we serve,” said Howard P. Milstein, chairman of the Board of NYBC. “We are honored to have a person of Dr. Miao’s level of commitment and dedication join as a trustee. I truly look forward to working with her,” said Christopher D. Hillyer, MD, NYBC’s president and CEO. (Source: NYBC press release, 8/27/12) ♠



**STOPLIGHT®: Status of the ABC Blood Supply, 2011 vs. 2012**



## 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: [lnorwood@americasblood.org](mailto:lnorwood@americasblood.org).

## POSITIONS AVAILABLE:

**Application Administrator.** The Institute for Transfusion Medicine (ITxM) has an opening for an Application Administrator. This position has the overall responsibility and oversight for the administration of business technologies ensuring the application is aligned with the strategic objectives of the business unit. Evaluates, coordinates, tests and implements new software releases, system upgrades, and patches to support the associated application system. Develop and execute validation plans for applications to support Operations. In charge of overall maintenance of the application, data, and standard operating procedures as it relates to the use of the application and operational business processes. Directs, identifies and implements processes which integrates the application and optimizes the operations workflow for the appropriate department. Provides work direction, evaluation and coordination of training for all aspects of the application. Works closely with the vendor to ensure that the application meets the needs of ITxM and guides the vendor in delivery of new enhancements. This position is 1st shift with on-call responsibilities. Bachelor's degree in a related field preferred. Three to five years of experience in a related technical field required. Experience with Master Control and Title21 Quality Manager Software application preferred. Apply online at [www.centralbloodbank.org/jobs.asp](http://www.centralbloodbank.org/jobs.asp).

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responsibilities. Bachelor's degree in a related field preferred. Three to five years of experience in related technical field required. Experience with the Hemosphere Software application preferred. Apply online at [www.centralbloodbank.org/jobs.asp](http://www.centralbloodbank.org/jobs.asp).

**Senior Director – IT.** The Community Blood Center (Kansas City) is a not-for-profit company that has been collecting blood and saving lives in our community for more than 50 years. Under supervision of vice president of Quality Systems, this person will: provide leadership/vision in development/implementation of IT, develop and maintain an effective IT organization that manages/controls information security/processing and develop/manage relationships with vendors. Requirements: Bachelor's degree in related area required. MBA preferred. Eight to 10 years IT senior management experience. Experience leading IT function in complex/regulated environment/organization. Skills and Knowledge: Visionary leader able to foster commitment to shared mission/vision. Demonstrated ability to solicit/manage development of innovative approaches to current/emerging business challenges. Results-orientated with high level leadership skills. Participative management style including strong team building skills/active listening skills/ability to direct/develop/motivate others. Business acumen with strong customer focus. Demonstrated commitment to own personal development/learning. Possesses functional/technical skills to guarantee high level of accomplishment. Strong knowledge of application development/network planning/control/data center operation. Strong problem identification/resolution skills. Excellent oral/written/presentation communication skills. Proficiency in project planning/design/implementation. Strong interpersonal skills. Learns quickly/stays abreast of industry technology. All applicants must apply online at [www.savealifenow.org](http://www.savealifenow.org). EEO/AA/M/F/D/V

**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

POSITIONS (continued on page 14)

**POSITIONS** (continued from page 13)

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](http://www.LStream.org). E-mail: [employment@LStream.org](mailto:employment@LStream.org). LifeStream is an Equal Opportunity Employer, M/F/D/V.

**Manager Donor Recruitment.** Indiana Blood Center located in Indianapolis, Ind. 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 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](http://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](mailto:ckelley@bbd.org).

**Medical Technologist.** LifeSouth is currently seeking to fill the Medical Technologist position in Palatka, Fla. 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-\$21 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>. ♦

## CALENDAR

*Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Norwood by e-mail ([mnorwood@americasblood.org](mailto:mnorwood@americasblood.org)) or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)*

### 2012

Sept. 13. **Thirty-First Symposium of Immunohematology and Blood Transfusion, Bethesda, Md.** Registration is available online at [www.cc.nih.gov/dtm/research/symposium.html](http://www.cc.nih.gov/dtm/research/symposium.html).

Sept. 14. **Red Cell Genotyping 2012: Clinical Applications, Bethesda, Md.** To register visit: [www.bcw.edu/rcg2012](http://www.bcw.edu/rcg2012) or call (414) 937-6271.

Sept. 19-20. **IT Workshop, America's Blood Centers, Fort Lauderdale, Fla.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org).

Sept. 20-21. **FDA Blood Products Advisory Committee Meeting, Rockville, Md.** More information is available at <http://1.usa.gov/pEo8O> and <http://1.usa.gov/OrLkIE>. Meeting Contact: Brian Emery or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM-71), FDA, 1401 Rockville Pike, Rockville, MD 20852, or (301) 827-1281.

Sept. 27. **Unity Gala with Sickle Cell Disease Association of America, in Baltimore, Md.** For more information, please contact Jodi Zand: (202) 654-2994; e-mail [jzand@americasblood.org](mailto:jzand@americasblood.org).

Sept. 29 (or Nov. 3). **Clinical and Laboratory Standards Institute Workshop, Houston and Boston.** 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. 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>.

October 3-5. **INNO-VENTION 2012, Rochester, Mich.** A Medical Main Street Conference, focused on the complete life cycle of medical device development, Royal Park Hotel, Rochester, Mich. Organized by Oakland County, Michigan. \$95 US, register at [www.MedicalMainStreet.org](http://www.MedicalMainStreet.org).

Oct. 6-9. **AABB Annual Meeting and CTTXPO, Boston, Mass.** For more information: [www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx](http://www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx).

Oct. 15-16. **AdvaMed 510(K) Submissions Workshop, Arlington, Va.** Details and registration information are available at: [www.advamedmtli.org/go.cfm?do=Wercs.Show&WID=184](http://www.advamedmtli.org/go.cfm?do=Wercs.Show&WID=184).

Oct. 19. **FDA Public Workshop: "Statistical Process Controls for Blood Establishments," Silver Spring, Md.** More information is available at <http://1.usa.gov/ODwelt>. Meeting Contact: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM-302), FDA, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852. Call (301) 827-6128 or e-mail [CBEROBRRWorkshops@fda.hhs.gov](mailto:CBEROBRRWorkshops@fda.hhs.gov) with questions.

Oct. 22. **3rd Annual Links for Life Golf Tournament, Evans, Ga.** For more information, please contact Jodi Zand: (202) 654-2994; e-mail [jzand@americasblood.org](mailto:jzand@americasblood.org).

Nov. 14-18. **ESTM Course on "The Appropriate Use of Plasma Products," Zagreb, Croatia.** Meeting Contact: Hand Erik Heier, Theirry Burnouf, Vincenzo De Angelis, and Magdy El Ekiaby. Questions may be directed to the ESTM Secretariat at [estm.secretariat@estm.info](mailto:estm.secretariat@estm.info) or 0039-02-58-31-65-15.

Dec. 3-4. **Supply Chain Management Workshop, America's Blood Centers, San Antonio, Texas.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org).

### 2013

Feb. 13-15. **Children's Medical Center Sixth Annual Transfusion Medicine Conference, Plano, Texas.** Contact [LENA.PATE@childrens.com](mailto:LENA.PATE@childrens.com) with questions or comments.

Mar. 16-19. **Annual Meeting, America's Blood Centers, Washington, DC.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org).

April 23-24. **IPFA/PEI 20<sup>th</sup> International Workshop on "Surveillance and Screening of Blood Borne Pathogens," Helsinki, Finland.** Visit [www.ipfa.nl/events/ipfa-pei-workshop-2013-20th-anniversary](http://www.ipfa.nl/events/ipfa-pei-workshop-2013-20th-anniversary) for more information and registration details.

CALENDAR (continued on page 16)

**CALENDAR** (continued from page 15)

June 18-21. **Fund Development, Donor Recruitment and Communications Workshop, America's Blood Centers, San Antonio, Texas.** Attendance restricted to ABC members and invited guests. Contact: Abbey Nunes. Phone: (202) 654-2980; fax: (202) 393-1282; e-mail: [anunes@americasblood.org](mailto:anunes@americasblood.org)

Aug. 3. **Medical Directors Workshop, America's Blood Centers, Milwaukee, Wis.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org)

Aug. 4-5. **Interim Meeting, America's Blood Centers, Milwaukee, Wis.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org).

Oct. 12-15. **AABB Annual Meeting and CTTXPO, Denver, Colo.** For more information: [www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx](http://www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx).

**2014**

June 5-8. **5th International Monoclonal Antibody Workshop, New York, N.Y.** Contact: Gregory Halverson, New York Blood Center, phone: (212) 570-3026 or e-mail: [ghalverson@nybloodcenter.org](mailto:ghalverson@nybloodcenter.org).

Aug. 2. **Medical Directors Workshop, America's Blood Centers, Seattle, Wash.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org)

Aug.3-4. **Interim Meeting, America's Blood Centers, Seattle, Wash.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: [meetings@americasblood.org](mailto:meetings@americasblood.org)

Oct. 25-28. **AABB Annual Meeting and CTTXPO, Philadelphia, Pa.** For more information: [www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx](http://www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx). ◆