



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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ABC Opposes Tax on Medical Devices in Healthcare Package

America's Blood Centers (ABC) this week urged its members to send letters to federal lawmakers opposing a proposed new excise tax on medical devices and diagnostics products being considered by the House and Senate as part of the healthcare reform legislation wending through Congress.

There are two different taxing scenarios as House and Senate leaders head into a Conference Committee to hash out a final version of the healthcare reform bill. The Senate version would result in a tax of \$4 billion a year or \$40 billion over 10 years; the House version would generate \$20 billion over 10 years.

Even the less onerous House version would potentially raise the cost of blood in the US from not-for-profit centers to hospitals by \$37.5 million per year, or \$375 million over 10 years, according to a rough calculation by ABC. This is based on a 2.5 percent tax on the more than \$1.5 billion worth of all classes of medical devices and tests that blood centers (both ABC and other blood centers) purchase to collect, process, and test blood every year.

Depending how the tax is imposed, it could be added as a flat tax at point of sale, be levied at a rate that varies based on a manufacturer's market share, or be figured based on some other formula. One way or another, the costs invariably will be passed along to end users, such as non-profit blood centers.

"This tax adds no value to the safety or availability of the nation's blood supply," said ABC CEO Jim MacPherson. "Indeed, over the last decade US hospitals have had to absorb over \$1 billion annually in added blood safety costs without adequate reimbursement for those increases from Medicare and Medicaid. This added tax will force blood centers and hospitals to choose which blood safety measures may need to be eliminated or skipped. It makes no sense to tax blood safety in order to pass comprehensive healthcare reform."

The proposed Senate tax would be levied upon manufacturers of all Class II (except those costing less than \$100 and sold in retail settings) and Class III medical device and diagnostics products. Pheresis equipment, disposables and manufacturing software are Class III (needing preapproval, clinical safety and efficacy data). Presumably, gloves, test tubes, thermometers, centrifuges, refrigerators, freezers, sealers, shakers considered Class 1 (meaning "general controls" or submission of minimal data to show performance) would not be affected.

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OUR SPACE

By ABC CEO Jim MacPherson

Non-Profits, Volunteer Donors, and High Salaries

With Congress pressing not-for-profit hospitals again to show their charitable value, and blood center executive salaries being splashed all over local media, a colleague asked, mostly rhetorically, “Why are we non-profits? And why don’t we just pay for blood?” These issues are related.

Blood centers are among the most complex of pharmaceutical companies in what has become a highly competitive healthcare market that is all about driving efficiencies while improving quality. Doesn’t sound like we need a tax-exempt status for that.

It’s really about the volunteer donor. Time and again we have seen for-profits try and fail to recruit large numbers of volunteer donors. The simple answer from surveys and focus groups: we won’t give away our body parts to someone who makes a profit off them. The timeless and powerful idea remains that blood centers are stewards of the “gift relationship” between donor and recipient.

Would companies give employee time off for-profit blood drives? Would schools, churches, and Rotary Clubs organize the drives? So being not-for-profit, we are also beneficiaries of organizational largess.

Would it not be simpler just to pay donors? Many argue it’s an ethical question: that body parts should not be sold but be available equitably to all in need. That ethical argument is increasingly challenged, but the practical truth is with disease marker rates as low as one-one hundredth of the general population, altruistic donors are a safer starting material. As in the plasma industry, pathogen inactivation (or stem cell culture technologies) might change that equation, but we appear far away from that day.

And what about those six-figure salaries? Certainly I am biased, but the executive who can make sure her or his organization takes a potentially lethal substance and delivers adequate safe blood, day after day, saving thousands of lives in their community, year after year, is worth their weight in gold, or at least a salary equivalent to the executives in the not-for-profit hospitals they serve.

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.

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Fifteen States File Suit Accusing Amgen of Offering Kickbacks to Push Aranesp

New York, California and 13 other states are accusing biotech giant Amgen Inc. of offering kickbacks to medical providers to boost sales across the country of its anemia drug Aranesp, which increasingly has been beset by safety concerns.

In a suit filed last Friday in federal court in Massachusetts, the states accuse Amgen sales representatives of encouraging doctors and other healthcare providers to bill insurers for Aranesp that the practitioners received free from the company, according to a statement issued by New York Attorney General Andrew Cuomo.

The practice, which the suit contends was known to Amgen's upper management, allegedly cost taxpayer-funded Medicaid programs and other insurers millions of dollars in overpayments. The suit also alleges that Amgen, of Thousand Oaks, conspired with two other defendants – drug wholesaler ASD Healthcare and group drug-purchasing network International Nephrology – to offer “illegal inducements” to medical providers to increase sales of Aranesp. These allegedly included sham consulting agreements, weekend retreats, and other rewards.

“Drugs should be prescribed to patients on the basis of need, effectiveness and safety, not on a corporate giant's promise of an all-expense-paid vacation,” Mr. Cuomo said.

In a statement, Amgen said, “We believe that the allegations are without merit.” Mike Kilpatrick, a spokesman for AmerisourceBergen Corp., the Pennsylvania-based parent company of ASD Healthcare and International Nephrology (now known as Integrated Nephrology Network), also denied the allegations.

Anemia drugs, including Aranesp and two others produced by Amgen – Epoprostenol and Procrit – are given to kidney disease and cancer patients to boost red blood cell production and raise hemoglobin levels.

According to a report on a 2006 congressional hearing, the drugs are the single biggest medication expense for Medicare, another taxpayer-funded insurance program. Anemia drugs have come under increasing fire after a series of studies found that high doses can lead to increased risk of heart attack, stroke, heart failure, and tumor growth in some patients.

In 2007, the Food and Drug Administration issued a “black-box warning” for Amgen's anemia medications – the strongest warning possible about potential side effects. Darbepoetin, and most likely other

Study Finds Anemia Drug Offers Little Benefit, Increased Risk

A new study has cast doubt on whether patients with kidney disease, diabetes, and anemia should be treated with darbepoetin alfa. While the drug was found to slightly increase the number of patients who died, had a cardiovascular event, or developed end-stage renal disease, it also doubled their risk of stroke.

The research was carried out by a team led by MA Pfeffer, and results were published online by *The New England Journal of Medicine* in October, along with an editorial emphasizing the work's significance.

Kidney disease often interferes with the kidneys' production of erythropoietin, the hormone that regulates the production of red blood cells. Darbepoetin alfa is one of a number of synthetic versions of the hormone; it is marketed by Amgen under the trade name Aranesp (see story, this page). Reduced production of erythropoietin results in anemia, which elevates the risk of heart attacks and renal events for patients who have type 2 diabetes and chronic kidney disease. It has been assumed, then, that treatment with darbepoetin alfa or similar drugs – which elevate hemoglobin levels – would increase the survival rates of these patients. Because of that assumption, previous trials have not included control groups of patients who received placebos.

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Amgen Suit (continued from page 3)

erythropoiesis-stimulating agents (ESAs), fail to reduce transfusions or increase quality-of-life measures in cancer patients not undergoing chemotherapy or radiotherapy, South Carolina oncologists reported last month. In fact, in a randomized, placebo-controlled study, median survival was significantly shorter with darbepoetin than with placebo.

All three ESAs – the two recombinant ESAs (Epoen and Procrit) and the closely related protein darbepoetin alfa (Aranesp) – have been approved by the FDA for treatment of anemia in patients with non-myeloid malignancies who have undergone chemotherapy. They are not approved for use to treat anemia unrelated to chemotherapy, but they sometimes are prescribed off-label for such patients.

The Associated Press reported late Friday that a new study raised fresh safety concerns about the drugs, finding that Aranesp nearly doubled the risk of stroke in people with diabetes and chronic kidney problems who are not yet sick enough to need dialysis.

The lawsuit against Amgen focuses on a practice known as “overfill.” Aranesp is often sold in one-dose vials. Pharmaceutical industry standards require that drug makers include a small amount of medicine in excess of the prescribed dosage in such vials, according to the suit. However, the suit alleges that at least as far back as 2002, Amgen manufactured Aranesp with overfills that were well above the recommended amounts. According to the suit, the overfill allowed doctors, hospitals, and other medical providers to bill their patients’ insurers for medicine that the provider had essentially gotten free.

In the suit, one Amgen saleswoman alleges that she was trained “how to show medical providers the overfill and other economic incentives without leaving any documentation behind.” (Sources: *Los Angeles Times*, 10/31/09; The Associated Press, 10/30/09) ♦

Anemia Drug Study (continued from page 3)

Methodology. The study carried out by Dr. Pfeffer *et al.* was a large, randomized, international, double-blind, placebo-controlled clinical trial. It involved 4,038 patients with diabetes, chronic kidney disease, and anemia who were not undergoing dialysis. The researchers randomly assigned 2,012 patients to receive darbepoetin alfa and 2,026 to receive a placebo. They then monitored the number in each group who reached the end points of death, a cardiovascular event (a heart attack, congestive heart failure, a stroke, or hospitalization for symptoms of heart disease, like chest pain), or end-stage renal disease.

Findings. Death or cardiovascular events were experienced by 632 darbepoetin alfa patients and 602 placebo patients; death or end-stage renal disease were experienced by 652 patients who received the drug and 618 who did not. A more dramatic difference was seen with strokes, which occurred with 101 patients who received the drug and 53 who did not. The drug did lower the number of patients who needed red cell transfusions, from 496 in the placebo group to 297 in the darbepoetin alfa group. But it resulted in only a modest improvement in patient-reported fatigue among those who received the drug.

The researchers concluded that because treatment with the drug did not reduce the risk of cardiovascular or renal events and raised the risk of stroke, “the risk will outweigh the potential benefits.”

Although Philip A. Marsden, MD, consented in his editorial that there will be “naysayers” who contest the results, he argued that the work “will be a key study in the treatment of patients with chronic kidney disease,” and that it will “influence practice guidelines and inform physicians, patients, and policymakers.”

Citations. Pfeffer MA, *et al.* A Trial of Darbepoetin Alfa in Type 2 Diabetes and Chronic Kidney Disease. *N Engl J Med.* 2009 Oct 30. [Epub ahead of print]. Marsden PA. Treatment of Anemia in Chronic Kidney Disease – Strategies Based on Evidence. *N Engl J Med.* 2009 Oct 30. [Epub ahead of print] ♦

US Military Begins Sending Platelets to Afghanistan

The US military's handling of platelets in Iraq and Afghanistan is an indication of changing conditions for soldiers in the two countries: in October, the military began shipping platelets collected in Iraq, where falling injury rates mean platelets often go to waste, to Afghanistan, where the rise in violence is driving up the need.

The first shipment happened on Oct. 14. Platelets are collected at the Air Force Theater Hospital in Balad, Iraq; shipped by the Army to the Role 3 Multinational Hospital in Kandahar, Afghanistan; and used there by the Navy, which runs the hospital.

Platelets Valuable in Combat. Military doctors have found that platelets are particularly useful in treating wounded soldiers. In fact, a 2008 Army book on combat surgery in Iraq and Afghanistan argues that the availability of platelets has been crucial to the reduction of fatal bleeding, and that wounds that cause hemorrhages are “the most preventable cause of death on the battlefield.”

Air Force Lieutenant Colonel Thomas Jordan, the apheresis chief of the 332nd Expeditionary Medical Group, said in August that when doctors used platelets to treat soldiers who were hemorrhaging, “We noticed an increase in the survival rate compared to when we were using whole blood.”



Maj. Margaret Vallejo, incoming 332nd Expeditionary Medical Group (EMDG) apheresis chief, and Staff Sgt. Philip Reichert, 332nd EMDG medical laboratory technician, inventory bags of platelets at the Joint Base in Balad, Iraq. (Air Force photo/Senior Airman Andria J. Allmond)



Sgt. Jason Westlund loads platelets into a black hawk helicopter at the Joint Base in Balad, Iraq. (Air Force photo/Allmond)

He added that platelets “serve as the main factor in stopping bleeding and are used in any situation in which there is excessive blood loss.”

US troops in Iraq have been donating about 60 bags of platelets each week since 2006 at the hospital in Balad, which is the sole platelet provider in the country. As the situation there has stabilized, though, the need for platelets has fallen, and units that were not used within their one-week shelf life were destroyed. Shipping them to Afghanistan puts them to use.

Army Sergeant Jason Westlund, a flight medic who helps transport platelets to Afghanistan, told an Air Force writer that “the thought that we may be part of the process that saves someone's life makes me feel very good about what we're doing here.”

But the process is a complicated one. The hospitals in Balad and Kandahar are more than 1,000 miles apart. Technicians in Iraq place the platelets in special coolers, called Golden Hour Boxes, which keep them cooler than 73 degrees Fahrenheit while they are on the four- to six-hour flight. The blood specialists in Iraq also had to send an incubator to their colleagues at the hospital in Afghanistan, so the platelets can be stored there. (Sources: www.af.mil, 10/22/09; www.time.com, 10/30/09) 💧

Lawsuit Challenges Ban on Compensating Bone Marrow Donors

A lawsuit filed in Los Angeles on Oct. 26 challenges a law that makes it a felony to compensate bone marrow donors, arguing that being able to offer payments to donors could help ease “a desperate shortage of unrelated marrow donors, particularly for minorities,” according to the complaint.

The suit was filed in the US District Court for the Central District of California on behalf of the Institute for Justice (IJ), a libertarian law firm based in Arlington, Va. It challenges the constitutionality of the National Organ Transplant Act (NOTA), arguing that NOTA makes compensating bone marrow donors – even with modest scholarships or charitable gifts on the donor’s behalf – punishable by up to five years in jail.

When NOTA passed in 1984, it originally included just solid organs. Congress later added bone marrow to the act, Jeff Rowes, a senior attorney at IJ, told *The National Law Journal*. IJ’s contention is that that addition reflects a lack of knowledge about bone marrow. IJ attorney Bob McNamera told *The Colorado Springs Gazette* that it is obvious “that Congress just didn’t understand what bone marrow is,” pointing to a line in a report produced when NOTA was in the works that specified that renewable tissue, like blood, should not be included in the act.

Now that it is more fully understood that bone marrow is regenerated by the body – and thus is more like plasma, sperm, and eggs, all of which can be legally sold – IJ is arguing that bone marrow should be removed from NOTA.

The Details of the Case. IJ is making its case by suing US Attorney General Eric Holder. It is arguing that NOTA is unconstitutional because it violates due process laws in two ways, according to the document filed in California. First, by “arbitrarily and irrationally treating renewable bone-marrow cells like nonrenewable solid organs such as kidneys,” NOTA denies equal protection to the plaintiffs. Second, NOTA violates their right “to participate in safe, accepted, lifesaving medical treatment.”

Among the plaintiffs are a number of parents whose children will need or have needed bone marrow transplantations; John Wagner, MD, an expert in bone marrow transplantation at the University of Minnesota; and the three board members of MoreMarrowDonors.org: Shaka Mitchell, Akiim DeShay, and Mike Hamel, a freelance writer who lives in Colorado Springs and is battling lymphoma.

MoreMarrowDonors.org is a nonprofit based in California that plans to implement a pilot program that would investigate the effectiveness of offering incentives to potential donors. If the results are promising, it would offer modest grants to those who donate. The money could be used for college scholarships, gifts to charity, or housing allowances, according to a post on www.usnews.com.

IJ emphasized that its goal is not to challenge the entire ban on organ sales; it merely would have bone marrow removed from NOTA, which would open the door to try using financial compensation to get more people to donate bone marrow.

Background on Bone Marrow Donation. So far, about 7 million people in the US have signed up to be bone marrow donors, according to Mr. Rowes. Many of them are registered through the Be the Match program run by the National Marrow Donor Program (NMDP).

However, because donors must be so closely matched to recipients, as many as 1,000 Americans die each year because they can’t find a matching donor, according to a fact sheet on IJ’s Web site. The fact sheet also mentions that at any one time, about 7,500 people are searching for a bone marrow donor, and

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Bone Marrow Lawsuit (continued from page 6)

that finding a closely matched donor is particularly difficult for minorities. While 75 percent of Caucasian patients can find a bone marrow donor, African American patients can only do so about 25 percent of the time, and multi-racial people face even worse odds.

Some patients resort to accepting transfusions from donors who do not match them as closely as they should; the result can be serious medical complications, according to examples in a Web release from IJ.

Resistance to the Change. The case is drawing opposition, particularly from people who worry that payment for donations makes the process less safe, because it increases the chances that people will be motivated by the financial reward to lie about their health or behaviors. Jonathan Moreno, a bioethicist and a professor at the University of Pennsylvania, told *The Colorado Spring Gazette*, “The weight of the expert community and advocates is going to be against” allowing compensation for bone marrow donors, because they would see the measure as setting “a bad precedent that they’d oppose.”

Dr. Choon Kee Lee, an associate professor at the University of Colorado School of Medicine and a bone marrow transplant doctor at the University of Colorado Hospital, told the *Gazette* that the idea behind the suit was “completely misguided” and “pretty dangerous.” His concern is that the measure would commercialize the use of a human organ, and that paying donors increases the chances of exploitation and corruption.

When contacted about the suit, NMDP President Jeff Chell, MD, said that the organization’s donors are motivated by altruism, not compensation; therefore the group did not plan to issue a statement or take a position on the lawsuit. (Sources: US District Court Case CV09 07772, filed 10/26/09; *The National Law Journal*, 10/28/09; *The Colorado Springs Gazette*, 10/29/09; USNews.com, 10/28/09; Freakonomics.blogs.nytimes.com, 11/3/09) ◆

Medical Device Tax (continued from page 1)

The House version would tax all three classes of medical devices; it would exclude only those sold in retail settings.

Although Rep. Mark E. Souder (R-Ind.) filed an amendment to strip the medical device tax provision from the House version this week, at this point it seems likely the final bill will include a tax in some form when it goes to the House floor for a vote this week or next.

The Pension Protection Act of 2006 exempted “qualified blood collection organizations” from paying excise taxes on fuel and tires purchased for the purpose of collecting, storing, or transporting blood and on electronic communications used for the purpose of recruiting blood donors. The proposed excise tax on medical devices would effectively result in excise taxes being passed along to blood centers. ABC staff are pursuing the possibility of seeking an excise tax exemption, using the 2006 exemption as a precedent, but the chances for success will largely rest on the final version of the tax plan if passed.

To fight the tax, which some refer to as a new excise tax, ABC has asked its members to send a “Dear Congressman” letter and an ABC position paper opposing the medical device excise tax or requesting an exemption for blood safety measures to any lawmaker whose district or jurisdiction touches their service areas.

According to press reports, Congress hopes to pass the legislation and President Obama hopes to sign it by Dec. 25. ◆

Letter to the Editor: Plasma Centers' Impact Depends on Economy

Dear Editor,

I noted the article regarding competition between plasma centers and blood centers (*ABC Newsletter*, 10/30/09) with some interest. I was the general manager of six plasma centers and I can attest that the donor demographics between plasma centers and blood centers were vastly different. But that was 17 years and an unemployment rate of roughly 6 percent ago. At least in Michigan, it is a whole different environment now. We have three plasma centers in Grand Rapids and they are bursting at the seams. I personally know several multi-gallon blood donors who are now donating plasma, and our blood center gets calls from the plasma centers every day to confirm last dates of donation. Competition from plasma centers has without doubt eroded our donor base.

I believe the impact of plasma centers on blood collections comes down to two things: the state of the economy and the quality of the plasma center operation. At 6 percent, many of those unemployed may not fit the typical blood donor demographic and there is reasonable hope of finding employment. Michigan currently stands at 15 percent unemployment, and that means job losses have cut deep into the middle and upper middle class and prospects for finding work are not good. In this environment many employers have had to cut wages and benefits, so even those employed feel they are sliding backward economically. If it comes down to donating for altruistic reasons or making ends meet, there really is no choice.

Secondly, the plasma centers here have done an excellent job of positioning themselves further upscale. They have moved their facilities from the inner city to the suburbs, the facilities are beautiful, donations are by appointment only, and they avoid loitering by insisting that donors can clock in no more than plus or minus 10 minutes from their appointment. In a brilliant marketing move they have partnered with area businesses to give their donors discounts, adding value for the donor. The plasma centers also advertise on TV and the pitch is more focused on saving lives than on earning money. All and all they have removed any stigma associated with donating plasma.

It is not so much a question of whether plasma centers have impact on blood donation, as it is how much impact in what region.

Doug Klynstra
Recruitment Manager
Michigan Community Blood Centers

Blood Centers Meet Patient Needs in Aftermath of Fort Hood Shootings

As an investigation began into the shootings at Fort Hood Army Base in Texas that left 13 dead and some 30 wounded, two blood centers in Central Texas jumped into action to ensure that hospitals receiving the patients had adequate blood supplies.

Carl R. Darnall Army Medical Center at Fort Hood has a primary supply agreement with the Armed Services Blood Program, but also has supplemental contracts with Carter BloodCare, The Blood and Tissue Center of Central Texas, and Scott & White Memorial Hospital in Temple.

Carter BloodCare, based in Bedford, with a satellite office in the Waco area close to Fort Hood. According to Wendy Stewart, a spokesperson for the blood center, Carter sent Darnall Army Medical

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Fort Hood Shootings (continued from page 8)

Center in Killeen 50 O positive leukoreduced red blood cells (LRBCs), 13 platelets, 40 units of type O cryprecipitate, and 20 units of AB fresh-frozen plasma. It sent Scott & White's Metroplex Health System in Killeen 11 O positive RBCs, 15 A positives, and seven type O LRBCs, and it sent the Veteran's Administration in Temple 20 O positive RBCs, 12 A positive RBCs, and three B positive LRBCs.

Meanwhile, The Blood and Tissue Center of Central Texas, based in Austin, supplied red blood cells, plasma and platelets to the three of the four hospitals to which the injured were transported, said Nancy Stugart, chief operating officer at Central Texas. Ms. Stugart said her blood center shipped 50 units of O positive RBCs and 20 AB plasma units to Darnall. The center also sent about 40 O positive units, 10 O negative units, and five platelets units to Scott & White Hospital and several units for the two patients sent to Seton Medical Center Williamson in Round Rock.

She said there were no additional blood drives planned, nor did the blood center expect to open any satellite facilities that would normally be closed today. "Our stock is really good today," Ms. Hood said. "We're discouraging donors from coming out right now and encouraging them to donate during the holiday season when we need it more. We don't want to get into another situation like we had after 9/11."

Joseph Schifano, MT(ASCP)SBB, CEO of Lifeline Blood Services/West Tennessee Regional Blood Center, said that his blood center received several requests from veterans groups to hold blood drives after someone caught wind that Scott & White was in need of blood. But given that there is an adequate supply through normal channels, none are planned, he said.

According to investigators, an Army psychiatrist facing deployment to Afghanistan was responsible for shootings. The gunman, identified as Maj. Nidal Malik Hasan, 39, was shot four times by a Fort Hood police officer responding to the scene. Mr. Hasan remained hospitalized on a ventilator on Friday morning, but was in stable condition, Army officials said. Army officials said they had declared a day of mourning on the base. (Source: *The New York Times*, 11/6/09) ♦

RESEARCH NEWS

Researchers seeking ways to fight malaria are taking up some unusual weapons – including cell phones, chocolate, and chewing gum – and they're winning the support of the Bill and Melinda Gates Foundation for their innovation. The foundation announced the winners of 76 \$100,000 Grand Challenges Explorations grants on Oct. 21; 36 of the grants went to scientists studying innovative approaches to diagnosing malaria, developing new vaccines for it, and accelerating its eradication. The grantees include Daniel Fletcher of the University of California, Berkeley, who will develop a microscope that will be attached to cell phones, capture fluorescent images of malaria parasites, and transmit data to clinical centers. Steven Maranz of the Weill Medical College of Cornell University will study whether providing children with high levels of flavanols – which are found in chocolate, green tea, cola, and shea nuts – helps build their immunity to malaria. Margaret Nioroge and Thomas Egwang, who work at Med Biotech Laboratories in Uganda, will work on a nasal vaccine that they hope will, if taken by women before and after pregnancy, pass immunity to malaria to their babies. Vanderbilt University's David Wright is working on a new process by which a drop of malaria-infected blood will leave a "coffee ring stain" on a glass slide as it evaporates, making interpretation and diagnosis easy. And Andrew Fung, Jack Judy, and Theodore Moore, researchers at the University of California, Los Angeles, will work with Michel Bergeron of l'Université Laval in Canada to develop a chewing gum that will react with malaria proteins in saliva, which then will be detectable when the gum is scanned with a magnet. Since 2008, Grand Challenges grants have been given to 262 researchers from 30 countries. (Sources: *The Seattle Times*, 10/20/09; www.grandchallenges.org, accessed 11/6/09) ♦

Donor Hemovigilance System Demonstrated at AABB

Inside a small theater at the Biovigilance Pavilion during the AABB Meeting in New Orleans recently, staffers attached to the US Biovigilance Network demonstrated a new Donor Hemovigilance system.

The Donor Hemovigilance system captures and analyzes donor reaction information from blood centers. The browser-controlled, Web-based system collects, monitors, analyzes, and researches data on the risks involved for donors during and after a blood donation. Users can capture and view data on donor reactions along with denominator data. The system also performs targeted searches and can generate reports with snazzy, multi-colored charts and graphics.

Four Kinds of Reports. The system has four kinds of reports available:

- ◆ A Key Metrics Report can be exported to an Excel spreadsheet that displays the calculated values for key donation and reaction metrics, including reaction rates, for a specified time period.
- ◆ A Custom Analysis Report analyzes the factors that influence reactions, comparing reaction rates of different denominator classes.
- ◆ A Drill Down Report is a graphic display of the overall reaction rate for each month in a given time period, using, for example, the total needles in the arm as a denominator.
- ◆ A Confidence Interval Report can be generated to indicate the reliability for the calculated reaction rates.

Users can be assigned roles that will control the types and amount of data that they can upload and download. The system is compatible with Microsoft Internet Explorer v. 7.0 and 8.0 and Firefox v. 3.5.3.

The application is the product of a collaboration of the Department of Health and Human Services, AABB and other organizations, using software developed by Knowledge Based Systems Inc. Data formats and definitions used to provide data for the program were developed based on input from AABB's Donor Hemovigilance Working Group. The demonstration was held in concert with an update session on the system at the AABB Meeting, moderated by Peter Tomasulo, MD, of Blood Systems Inc. ◆

US Biovigilance Network Background

Initiated in 2006, the US Biovigilance Network is a collaboration between the federal government and organizations involved in blood collection, transfusion, and tissue and organ transplantation. The Department of Health and Human Services, including the Centers for Disease Control and Prevention, is developing and hosting the surveillance system through its National Healthcare Safety Network, or NHSN. Private organizations are involved in program development, operation, and management, and fundraising to support the project.

Supported by HHS' Advisory Committee on Blood Safety and Availability, the program eventually will have four components: a Recipient Hemovigilance Module, which will focus on patients who receive blood and blood components; a Donor Hemovigilance Module, which will track adverse reactions associated with the donation process; a Tissue Transplantation Sentinel Network, which will report on adverse events and incidents associated with tissue and organ transplantation; and a Cell Therapy Module, which will track outcomes for cellular therapies.

In April, nine medical centers across the nation launched a pilot program to collect data to track adverse reactions experienced by patients receiving blood transfusions and adverse events affecting blood donors.

More information about the US Biovigilance Network is available at: [www.aabb.org/Content/Programs and Services/Data Center/US Biovigilance Network](http://www.aabb.org/Content/Programs_and_Services/Data_Center/US_Biovigilance_Network). ◆

On Ryan White and Sen. Edward Kennedy

“I say that today as we take up health reform, we are gripped by fear, we are gripped by frenzy where all kinds of myths and misconceptions are out there. The debate is prickly. It is tense. We don’t listen to each other. We are out there, hurtling, hurling accusations.

“I want to go back to a day in 1990, a day in the HELP Committee chaired by Sen. Ted Kennedy, when this young boy, Ryan White, came to testify. Ryan White was diagnosed with AIDS at age 13. He came to testify at the committee when we were trying to figure out what to do with this new disease, where people in our urban communities were dying.

“Here was this little boy who was so frail, who was so sick, and he wrenched our hearts that day as he talked about this new disease that he had gotten through a blood transfusion. But what he also told us about was what he was going through. He testified that day, mustering every bit of energy he had, speaking with verve and pluck about his plight. He told us about what had happened to him – how he was shunned in class, how he was locked in a room, how children were forbidden to play with him. He lived a life of isolation and of desolation. He was treated like a pariah.

“He wasn’t the only one. Anyone who had AIDS in those days was greeted as if they were the untouchables. I remember it well. ... Firefighters and emergency people were afraid to touch people bleeding because they were concerned they could get it. Funeral homes would not bury people who had AIDS.

“As that little boy spoke, we were gripped by tears and by shame; we were so embarrassed at what was happening in our country. Both sides of the aisle were touched. I was so proud that day when Sen. Kennedy said: ‘Tell me, young man, what can we do for you?’ And he said: ‘Help the other kids. Help the other people who have AIDS.’ Ted said: ‘I certainly will.’ And Sen. Orrin Hatch immediately stepped up – sitting next to Kennedy – and said: ‘I want to be involved. I want to work on that legislation.’ Ted Kennedy, Orrin Hatch, Chris Dodd, Tom Harkin, Barbara Mikulski, Nancy Kassebaum – we all came together. We worked on a bipartisan basis. And we did move the Ryan White bill against the grain of many people in this country and in the face of the fear and frenzy.

“As Ryan White left with his mother that day, as he walked out in a very halting way, [there was] a media frenzy. They were pushing and shoving to try to get a picture of this poignant little lad. Sen. Kennedy jumped up, built like the linebacker he once was in Harvard, and ran out and he said, ‘Barb, come with me; Chris, get over there; Orrin, grab that chair.’ We all ran out and Ted Kennedy literally threw himself in front of Ryan White to protect him from being run over by TV cameras. Again, both sides of the aisle, we were there – Ted, calling this out – ‘Chris, you go there; Barb, open the door; Orrin, stick with me,’ and Orrin stuck with him. They put their arms around him and got him into a safe haven in one of our offices. Ted Kennedy literally put himself on the line that day of fear and frenzy, and Republicans were right there with him, helping him out to get that young man to a safe room. Ted Kennedy protected that little boy that day, literally and figuratively, and he had the support of the committee.

“So as we move ahead today, as we reauthorize the Ryan White program for four more years, remembering that it is the largest source of federal funding for HIV/AIDS programs, I want us to remember how we worked together, what it is like when we literally stand up for each other.”

– Sen. Barbara Mikulski (D-Md.) speaking at a signing ceremony for the reauthorization of the Ryan White Care Act, excerpted from the *Congressional Record*, 10/20/09 ♦

BRIEFLY NOTED

The first index price for blood and organ banks to be issued by the federal government showed a modest rise in the last year, according to data the Bureau of Labor Statistics (BLS) released last week as part of a report of the Producer Price Index for Finished Goods. The index rose from 110.7 in May this year to 111.0 in September. From September 2008 to August 2009, the index rose 2.9 percent, a tenth of a percentage point lower than the hospital price index increase for that period of 3 percent. The blood and organ bank index appears under the selected healthcare industries grouping in Table 4 of the report. Overall, the PPI declined 0.6 percent in September, seasonally adjusted, BLS said. This decrease followed a 1.7-percent rise in August and a 0.9-percent decline in July. The Centers for Medicaid and Medicare's (CMS) mechanism for evaluating the fast rising prices hospitals pay for specific goods and services is the market basket. Blood products had not previously been included in the market basket, but that changed on Oct. 1. As a result of BLS monitoring blood costs, Medicare reimbursement for blood should better reflect the actual costs of blood to hospitals. A group of sentinel blood centers and organ banks provides the data to BLS. Using the indexes in the market basket, CMS can adjust specific Medicare reimbursements when the cost of a medical procedure involving a particular good or service exceeds the rate of medical inflation. Previously, it could take up to five years for hospital reimbursement to catch up to cost increases when Medicare's payments to hospitals for a patient admission under the MS-DRG system were "rebased." As of October, blood costs can be monitored quarterly and the reimbursement adjusted as needed. (Source: BLS press release, 10/20/09)

After four decades of operation and a recent Food and Drug Administration warning letter, Cooley Dickinson Hospital (CDH), based in Northampton, Mass., closed its blood donor program last week for financial reasons, the hospital announced. The blood donor program includes services at the hospital as well as Cooley Dickinson's Blood Mobile, which offered blood collection services at area businesses. The hospital said it has "taken the necessary corrective action steps that have met the outside regulatory agencies' expectations," but that it must focus on its core services and that "services such as blood acquisition are best left to agencies that have a greater economy of scale and can give a higher degree of specialization." CDH will continue to offer blood transfusion services and will continue to offer therapeutic phlebotomy services to hemochromatosis patients and others who need to give blood for medical reasons. The hospital is not closing any of its laboratory drawing stations, which are separate from the blood program. To meet immediate blood needs, Cooley Dickinson Hospital has contracted with an outside agency. Catherine Reed, director of Laboratory Services, is speaking with agencies that specialize in blood donor programs. In August, FDA sent a warning letter to the hospital saying Cooley Dickinson's Blood Bank failed to defer blood donors who had tested "reactive" to HIV and Hepatitis B and C. The hospital emphasized that its blood supply was safe, and no patient ever received contaminated blood. The hospital will call blood donors who have donated 10 gallons or more and mail all blood donors a letter notifying them of the changes. (Source: CDH web page, accessed, 11/2/09)

Four lawsuits were filed in St. Clair County, Ill., against Bayer recently, alleging that the plaintiffs or their deceased relatives have experienced physical and emotional damage after their use of Trasylol. The drug was approved by the Food and Drug Administration in 1993, and it was used to control bleeding during coronary artery bypass surgery. However, a number of studies published in 2006 found that it increased the risk of serious renal toxicity and ischemic events (which cause a shortage of blood to an organ); a study of 67,000 patients found increased risk of renal failure, heart attack, stroke, congestive heart failure, and death. Bayer removed the drug from the market temporarily in Nov. 2007 and permanently in May 2008. Three of the recent lawsuits were filed on Sept. 22, with a combined total of 55 plaintiffs. The suits allege that the plaintiffs or their relatives experienced renal damage, renal insufficiency, multi-system organ failure, and death. In addition, the plaintiffs complain of anxiety, distress, fear of death, pain, suffering, and depression. The fourth suit was filed on Aug. 20, with two plaintiffs whose allegations include defective design, intentional infliction of emotional distress, fraud, and negligence. (Source: *The Madison County [Ill.] Record*, 10/15/09) 💧

GLOBAL NEWS

A new chip-based mobile blood test allows doctors in the field to detect pathogens in blood in minutes, according to a team of German and Egyptian researchers working with an Egyptian company.

In Egypt, mobile blood drives are the norm in towns and villages. To detect infectious diseases such as HIV, hepatitis and syphilis, conventional rapid tests are not suitable in most cases for use aboard a mobile collection and testing vehicle. The research team says it has developed an improved chip-based test for mobile blood collection using only a small sample of the potential donor's blood. The researchers work at the Fraunhofer Institute for Biomedical Engineering (IBMT) in Sankt Ingbert, Germany, under a European Union project involving the Egyptian company Vacsera. "Our consortium has developed a glass chip which has antibodies on it. Tiny surface oscillations are induced in the chip. If the relevant virus binds with an antibody, the oscillation changes," said Thomas Velten, MD, of IBMT. The technique is not new, but the new chip offers some advantages over current technology. On other chip-based tests, there is one measurement field and a reference field next to it, positioned a few millimeters apart. On the new chip, the measurement and reference fields are divided into narrow strips located right next to each other. As a result, the chip is more resistant to fluctuations in temperature. What's more, the new chip consists of four analysis squares, allowing detection of four different pathogens during each test. To protect lab workers from possible exposure to infected blood, the chip is encapsulated. A prototype of the device is being presented at the Medica trade conference, Nov. 18-21 in Dusseldorf. Dr Velten estimates that the device could come onto the market in about three years' time. (Source: eyugoslavia, 11/2/09)

Most of the private blood banks in Islamabad, Pakistan are without mandatory licenses called for by blood safety rules approved by the federal government in 2005, putting citizens there at risk for infectious diseases, according to a press report.

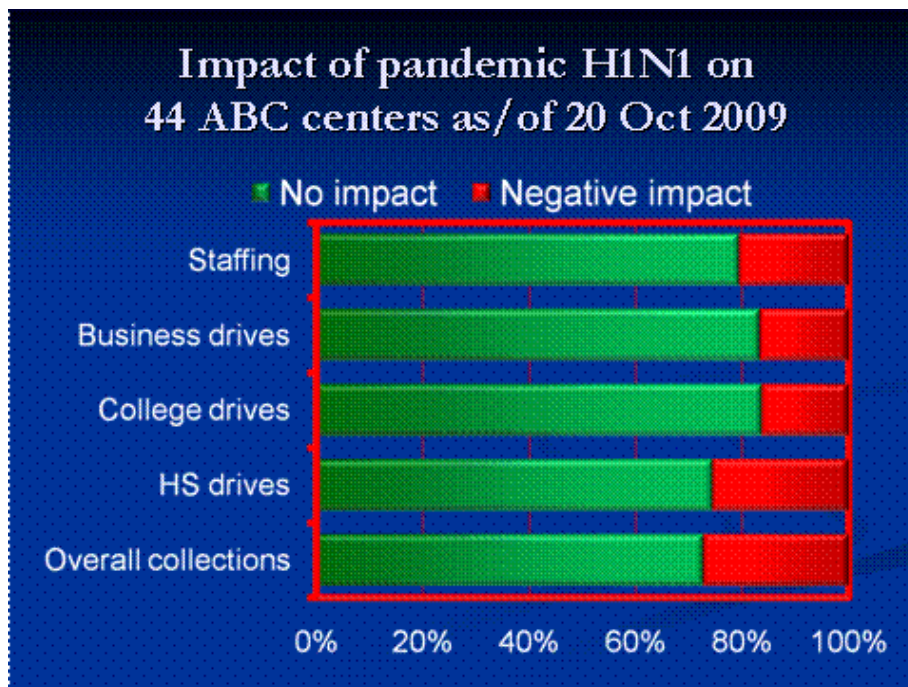
The Islamabad Blood Transfusion Authority (IBTA) has been unable to enforce the Islamabad Transfusion of Safe Blood Rules of 2005, which helped establish the IBTA some three years ago. According to an article in *The Nation*, IBTA is not taken seriously by blood banks and lacks the necessary financial and staff resources to enforce the blood safety rules. So far, it has managed to register only nine blood banks and does not have the manpower to regularly inspect them. Of all registered blood banks in the city, four are in public sector hospitals, including one in Shifa International Hospital. Three are in autonomous organizations: NESCOM, PAEC and Pakistan Red Crescent Society, and two are in armed forces facilities. (Source: *The Nation*, Pakistan, 10/17/09) ♦

LEGISLATIVE NEWS

A bill aimed at increasing funding for research about and prevention of hepatitis B and C (HBV and HCV) was introduced into the US House of Representatives by Mike Honda (D-Calif.) on Oct. 29.

The bill, which was referred to the House Committee on Energy and Commerce on the same day, would devote \$90 million by 2011 to prevention and immunization efforts, as well as research. The bill has three Republican and eight Democratic cosponsors, as well as the support of the National Viral Hepatitis Roundtable, a coalition of organizations committed to fighting hepatitis. Lorren Sandt, chair of that group, said in a statement, "We have a wave of chronic liver disease that will crash like a tsunami on the US healthcare system if we do not address this problem now. This simple legislation will help identify the people who are chronically infected and get them into treatment, which can save millions in future healthcare costs." In a blog post on *The Hill/Congress*, Rep. Honda said that HBV and HCV are highly contagious blood-borne viruses that cause liver disease, liver cancer, and death. Only some kinds of the viruses can be cured; early detection is necessary for the treatment of others. He said that HBV costs \$658 million annually in medical costs and lost wages, and that HCV will cost \$85 billion from 2010 to 2019. The bill, called the Viral Hepatitis and Liver Cancer Control and Prevention Act of 2009, aims to support a prevention, research, and medical management referral program for chronic HBV and HCV. It also would support the prevention, immunization, and surveillance efforts of the Centers for Disease Control and Prevention and the states. (Sources: *The Hill/Congress Blog*, 10/30/09; AFP, 11/2/09) ♦

DATA POINTS: Impact of Pandemic on Blood Centers, October 2009



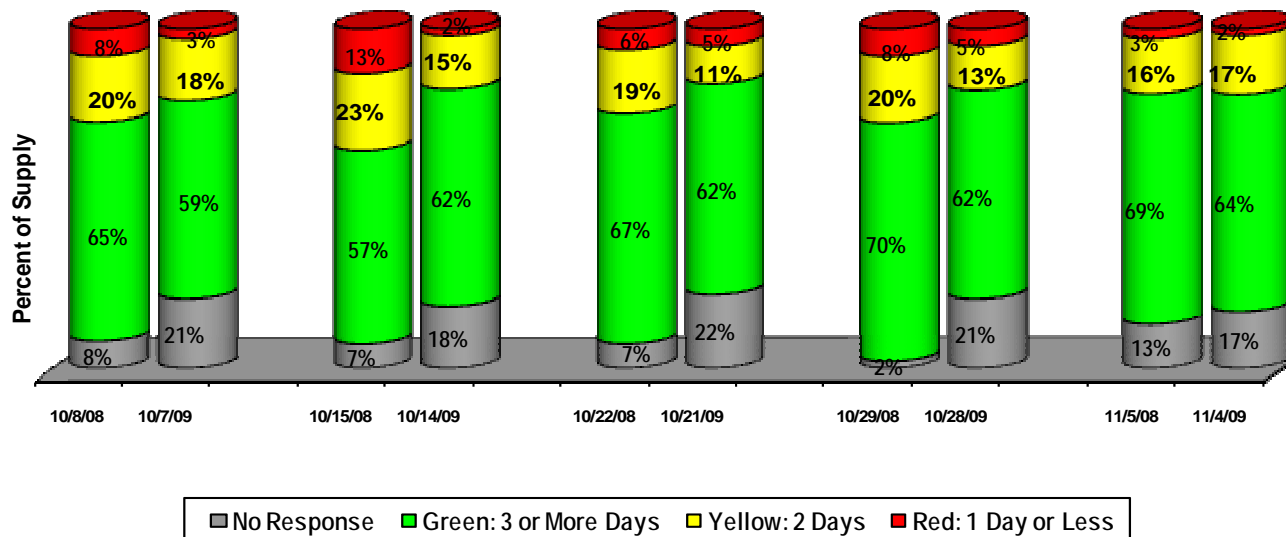
America's Blood Centers (ABC) conducted a survey last month to assess the potential impacts of the Novel H1N1 Influenza A outbreak on ABC members. A total of 44 responses were received. Overall, most ABC members reported experiencing little or no impact on staffing, blood drives, and overall collections. Those who have seen some impact have experienced decreases in high school and college blood drives. ♦

MEMBER NEWS

Miller-Keystone Blood Center, based in Bethlehem, Pa., is refraining from using volunteers under age 18 at its blood drives and centers because of the high rate of flu cases among young people. The restriction on teen volunteers, however, will not apply to students assisting at high school blood drives, Joseph Yelo, vice president of administration, said last week. Miller-Keystone decided to adopt the restriction on teen volunteers based on recent steps taken by area hospitals to limit visitors under 18. Miller-Keystone also is asking people experiencing flulike symptoms to postpone a donation until they recover. A person who is feeling well and free of fever for a minimum of 24 hours is considered fully recovered, center officials said. (Source: ReadingEagle.com, 10/30/09)

The Community Blood Center of the Carolinas (CBCC), based in Charlotte, N.C., announced last week that it has opened a third regional donation center, this one housed at Carolinas Medical Center-Union (CMC-Union) in Monroe, N.C. The CBCC is also teaming up with the Union County Chamber of Commerce to host a ribbon-cutting ceremony and grand opening celebration of the new CMC-Union center on Friday, Nov. 13 at 10 a.m. "We are excited to partner with CMC-Union so that the Union County community has a convenient location, in addition to our mobile drives, to donate blood," said Martin Grable, president and CEO of the blood center. "Our goal is to make it as easy as possible for the community to donate blood. We rely on local donors to meet the life-saving blood needs of local patients." CBCC is an independent, locally-managed, non-profit community blood center providing more than 90 percent of the blood supply to the 14 area hospitals that serve 11 North Carolina and three South Carolina counties. (Source: Community Blood Centers of the Carolinas press release, 10/28/09) ♦

STOPLIGHT: Status of the ABC Blood Supply, 2008 vs. 2009



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

PEOPLE

Lane Memorial Blood Bank (LMBB), based in Eugene, Ore., announced this week the election of a new slate of officers for the October 2009-September 2010 term. The new officers were elected at LMBB's Annual Board Meeting, held on Sept. 23. They include: **Sandy Farmer**, a community activist, as the new president; **Gerald Fleischli, MD**, a physician at the University of Oregon, as immediate past president; **Don Nau**, a financial adviser, with Insurance & Financial Services, as vice president; **Timothy Mahalak**, a financial planner with Caprai-Mahalak Financial Group, as treasurer; and **Wendy Apland**, chief financial officer, vice president of Finance at PeaceHealth in Eugene, as secretary. Two new members of the board of directors were elected. They are: **Joe Cavanagh**, owner of Century Lighting; and **Robert Weaver**, laboratory manager, McKenzie-Willamette Medical Center. LMBB is Lane County's sole provider of donated blood products. 💧

MEETINGS AND TELECONFERENCES

May 26-27,
2010

IPFA/PEI 17th Workshop on "*Surveillance and Screening of Blood Borne Pathogens*," The Regent Esplanade Zagreb Hotel, Croatia

This annual workshop, jointly organized by the International Plasma Fractionation Association (IPFA) and the Paul-Ehrlich-Institute (PEI) has become widely recognized as an authoritative international scientific meeting for discussion of developments concerning the microbiological safety of blood and blood products. The meeting attracts internationally renowned experts from blood services, regulatory agencies and industry.

Contact: The IPFA secretariat, Plesmanlaan 125, NL-1066 CX Amsterdam. The Netherlands, Tel. +31 20 512 3561, E-mail: ipfa@sanquin.nl, 💧

POSITIONS AVAILABLE:

Notices of positions available & wanted are published free of charge for a maximum of three weeks for ABC institutional members. There is a charge of \$100 per placement for ABC Newsletter subscribers & \$250 for non-subscribers. Notices ordinarily are limited to 150 words. To place an ad, contact Deanna Du Lac at the ABC office. Tel: (202) 654-2917; Fax: (202) 393-5527; E-mail: ddulac@americasblood.org.

Medical Director. Community Blood Services collects blood donations, offers cord blood banking & operates one of NMDP's largest bone marrow registries. We seek results driven Medical Director. Responsible for scientific & medical activities which include assuring medical & technical practices meet or exceed regulatory requirements & generally accepted practices; providing medical/technical leadership to all aspects of blood center operations; developing educational programs & promoting business partnerships; developing peer-to-peer relationships; engaging in scientific exchange on research & clinical trends; & overseeing & participating in research projects & presentations as req'd. He/she will be part of management team collaborating on operating issues, developing new business ideas & procedures, & interacting with area hospitals drive current & future programs. Must hold MD or DO, be boarded or board eligible in transfusion medicine & clinical pathology, & be appropriately licensed to practice medicine in state of New Jersey. We offer team orientated work environment, competitive compensation, benefits & relocation package. Send resume, cover letter & salary requirements to: careers@cbsblood.org or Fax: (201) 265-4021. EOE

President/CEO & Medical Director. South Texas Blood & Tissue Center (STBTC), San Antonio, Texas, seeks physician to supervise & coordinate daily operations of center to include managing & growing non-testing-related business units of organization, including traditional blood banking, tissue banking, cord blood banking (Texas Cord Blood Bank), bone marrow registration, foundation-related activities, as well as forward-looking research initiatives focused on stem cells & regenerative medicine. Responsibilities include supervision of support services, such as quality assurance, IT/IS functions, human resources, community relations, financial services, education & training & property/logistics. Qualifications req'd include Medical Doctorate degree, with extensive blood banking management exp. Tissue services exp. pref'd. For information, please contact Sandra Munoz, Vice President of Human Resources: (800) 292-5534, ext. 1544 or Rebecca James, Human Resources Director: (800) 292-5534, ext. 1111. To apply, E-mail resume to: hr_dept@bloodtissue.org or Fax: (210) 731-5581. EOE/AAP

Technical Director, Blood Bank of Hawaii. Seeking exp. team member as Technical Director to provide leadership & overall technical expertise for Blood Bank of Hawaii (BBH). TD is industry expert who keeps abreast of regulations, emerging issues & technology,

notifies BBH management of FDA changes, researches, assesses & recommends appropriate actions & is designated FDA contact for organization. Responsibilities include overseeing organizations quality programs, ensuring regulatory compliance for all departments, overseeing & supervising QA department, providing technical expertise to all BBH departments & working with project teams. Require ASCP MT (able to be licensed by State of Hawaii DOH), eight to ten years of blood banking management exp., SBB pref'd. Must be detail-oriented; have good time management, interpersonal, supervisory & communication skills; have excellent analytical & problem solving ability & be able to flex working hours with operational needs. Please send resume to: hr@bbh.org; Fax: (808) 848-4791 or mail to: Blood Bank of Hawaii, 2043 Dillingham Blvd., Honolulu, HI, 96819

Quality Specialist. Do you want to make difference in peoples' lives every day? Blood Systems, national leader in blood management & hospital transfusion services support, is searching for Quality Specialist to join our team in Tempe, AZ. Ideal candidate will possess strong organizational, presentation, written & verbal communications skills. Responsible for reviewing quality systems & compliance in all areas of technical & clinical operations within blood center. In this role, you will serve as resource to operations on many types of Quality issues. Position also uses Six Sigma & other performance improvement initiatives. Some travel will be req'd. Occasional nights/weekends; on-call will be req'd. Relevant Bachelor's degree & three years of related exp. in regulated industry req'd. Certification as Med Tech, or SBB pref'd. CQA, CQE &/or CMQOE certification within two years will be req'd. Prior exp. with Microsoft programs including Excel. Previous exp. with Donor Testing pref'd. Blood Systems offers highly competitive salary, comprehensive benefits, relocation, 401k with match & more! For consideration, please submit your resume via E-mail by **11/13/2009** to: jobs@bloodsystems.org; **ATTN: HR/2009/44**. Visit our website at: www.bloodsystems.org. Pre-employment drug testing req'd. EOE M/F/D/V

Manager, Global Access. Biopharmaceutical trade association seeks manager to assist in developing programs to ensure access to plasma protein therapies in matrix with Senior Director, Global Access & North

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POSITIONS (continued from page 16)

America division. Manager will review scientific & health care publications & databases; perform analysis of data related to clinical outcomes, health technology assessments, comparative effectiveness models & similar health economic strategies; write papers for industry & peer-review journals; & participate in industry task force activities & other internal/external meetings. Successful candidate will have degree in science or economics with further studies in pharmacoconomics, health economics or equivalent; at least three years exp. with scientific research, review & writing; excellent interpersonal, written & oral communication skills; ability to manage databases. Exp. in pharmaceutical industry helpful. Excellent benefits. Send resume or C.V. & salary requirements to: PPTA Human Resources, 147 Old Solomon's Island Road, Suite 100 Annapolis, MD, 21401. E-mail: cizzi@pptaglobal.org

Supervisor, Clinical Lab (Blood Bank). Franklin Square Hospital Center, member of esteemed MedStar Health, is progressive facility providing comprehensive care to residents of our community. Located in White Marsh area of Baltimore, Franklin Square is third largest hospital in Maryland, with 380 beds & more than 3,000 employees. We're full-service, acute care teaching hospital & our team members are committed to providing our patients with highest quality healthcare possible. Right now, we're looking for: Supervisor, Clinical Lab (Blood Bank). Requirements: Three to five years exp. in Blood Bank, preferably in leadership position; Medical Technologist Blood Bank, (MTBB) req'd; Specialist Blood Bank (SSB) pref'd; Exp. & working knowledge in American Association of Blood Bank & FDA standards req'd. In return for your skills, we offer competitive salary & comprehensive benefits, along with FREE parking! To apply, visit us online at: www.franklinsquare.org. EOE

Medical Technologist, Blood Bank of Hawaii. Seeking Medical Technologist to work in Reference Laboratory. Responsibilities include conducting general laboratory tests & processes & work-up of complex antibody identification. MT oversees work of other laboratory personnel, ensures that QC is done, reviews tests for product release, prepares component products, participates in programs for interning students & follows-up on test result &/or case concerns. Handles after-hours calls on rotating basis. Must have understanding of scientific principles & technical & procedural aspects of laboratory testing, general comprehension of immunologic & genetic factors affecting health & disease, as well as patient & laboratory testing. Require ASCP MT (able to be licensed by State of Hawaii DOH). Must be detail-oriented with excellent analytical & problem solving ability; have good time management skills, ability to work under time constraints & good oral & written communication skills. Please send resume to: hr@bbh.org; Fax: (808) 848-

4791 or mail to: Blood Bank of Hawaii, 2043 Dillingham Blvd., Honolulu, HI, 96819

Blood Collections Director Quality/Projects. Kentucky Blood Center, located in Lexington, Kentucky, seeks detail-oriented professional to oversee quality initiatives for Blood Collections & facilitate management/implementation of special projects. Responsibilities will include development, review & implementation of process improvement plans. Will coordinate quality improvement investigations, root cause analysis, and maintain direct communication with Quality Assurance department while developing & implementing corrective action plans. Will oversee regulatory compliance, SOP revision annual review process & error management reporting. Directs activities of Blood Collections QA/QC coordinator. Qualified applicants must have four-year degree, MT(ASCP). Three years exp. working in organization regulated by good manufacturing practice with FDA, AABB, CLIA & EU regulated exp. pref'd. Exp. with data analysis & equipment/process validation pref'd. Supervisory exp. pref'd. Must be proficient with MS Office products. Must be highly organized, reliable & have outstanding interpersonal skills. Strong written & oral communication skills, do-what-it-takes work ethic & team player attitude req'd. Competitive salary, comprehensive benefits including health/dental/life, LTD, paid vacations/holidays, EAP, 403(b) retirement savings plan & pension plan. For more information or to apply online please visit www.kybloodcenter.org. Drug free & EOE/AAP

Clinical Laboratory Scientist/Medical Technologist. Denver-based Bonfils Blood Center seeks Med Tech to perform & interpret complex serologic tests, provides blood products for patients with antibodies, answers technical questions, maintains inventories & participates in continuing education & competency programs. Bachelor's degree from accredited college or university in scientific field or equivalent & MT(ASCP) or BB(ASCP) or equivalent certification req'd (no exceptions). Previous Transfusion Service/Blood Center exp. pref'd; five years of immunohematology reference lab exp. &/or transfusion service exp. strongly pref'd; SBB pref'd. Knowledge of immunohematology & general laboratory testing practices. Manual dexterity; strong organizational skills; excellent oral & written communication skills; detail & accuracy; ability to lift maximum of 40 pounds & ability to handle multiple projects. Full-time "float" with mixture of day, evening & occasional night shifts. Monday through Friday, eight-hour variable shifts (day/evening/occasional night) with rotating holidays & on-calls. Full-time benefits. Pay commensurate with exp., ranging between \$22.39 & \$26.62 per hour with additional shift differentials for

(continued on page 18)

POSITIONS (continued from page 17)

evening & night shifts. Relocation expenses will be responsibility of candidate. To apply, go to: www.bonfils.org

Medical Director. American Red Cross Blood Services Northern California Region, Oakland, CA seeks dynamic transfusion medicine physician. Responsibilities

include blood donor & recipient management & safety, consulting & conducting educational seminars for clinicians & hospital customers. USCAP Board certification in Pathology or Hematology/Oncology req'd; TM/BB fellowship training & Board eligibility req'd. Reports to Chief Medical Director. Excellent benefits; salary commensurate with exp. E-mail resume & references to: randolphkl@usa.redcross.org 