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FDA Faults Red Cross for Hundreds of Blood Safety Violations

The Food and Drug Administration has found hundreds of violations in the way facilities in 12 American Red Cross (ARC) regions – one third of its total regional network – have been storing and distributing blood, the agency said yesterday.

In an Oct. 30 letter that FDA sent to J. Chris Hrouda, executive vice president of Biomedical Services at ARC's national offices in Washington, D.C., the agency said that it investigated the 12 sites from February to November 2008 and found "significant violations of the law, regulations, and the Amended Consent Decree of Permanent Injunction," which FDA had issued on April 15, 2003. The letter served as official notification to ARC that FDA had determined that it had violated the Federal Food, Drug, and Cosmetic Act; FDA regulations; and the decree, which was initially filed 16 years ago.

The inspections occurred at the following ARC facilities: ARC Biomedical Headquarters, Washington, D.C.; Great Lakes Region, Lansing, Mich.; River Valley Region, Louisville, Ky.; Greater Alleghenies Region, Johnstown, Pa.; Greater Chesapeake and Potomac Region, Baltimore, Md.; Lewis and Clark Region, Salt Lake City, Utah; Penn Jersey Region, Philadelphia, Pa.; Southeastern Michigan Region, Detroit, Mich.; Portland National Testing Laboratory, Portland, Ore.; New York Penn Region, West Henrietta, N.Y.; Heart of America Region, Peoria, Ill.; and New England Region, Farmington, Conn.

At those inspections, FDA found violations that included "failure to promptly conduct adequate investigations, failure to develop and implement adequate corrective actions, and failure to ensure their effectiveness to prevent recurrence of problems," according to the letter to Mr. Hrouda.

Specific Violations. FDA's 23-page letter contains a list of violations but emphasizes that it is not all-inclusive. Examples include a number of occasions when "suspect blood" – which may or may not have met safety, quality, identity, purity, and potency requirements – was released and adequate corrective actions were not taken quickly. Among other the examples:

- ◆ On Jan. 21, 2008, ARC's Arizona Region learned that a whole blood number had been mixed up but the case was not investigated. "Collection staff relabeled the units without determining whether test results were properly associated with the correct donor. Associated components of these units were improperly distributed."

(continued on page 12)

**OUR SPACE**

By ABC CEO Jim MacPherson

A \$375 Million Tax on Blood?

Within the last few weeks we learned from suppliers about a proposed tax on the medical devices blood centers buy, nationally estimated at \$1.5 billion a year, including everything from gauze and gloves to reagents, disease marker tests, IT systems, and pheresis disposables.

To pay for healthcare reform, Congress and the White House have been looking for revenue and savings to offset the trillion-dollar price tag over 10 years. In exchange for no cuts in Medicare and more paying customers (insureds), hospitals agreed to find \$155 million in savings over 10 years. Next, Big Pharma agreed to eat \$80 billion in profits in exchange for the government not setting drug prices.

Next on the list were the medical device manufacturers. From their perspective, there was “no horse to trade.” Many of these companies claim low margins in a highly competitive market. When negotiations broke down, the Senate and House both imposed a tax. The version that just passed in a historic House vote calls for a \$20 billion tax over 10 years. Blood centers’ share of the 2.5 percent tax on those \$1.5 billion in annual sales would amount to more than \$375 million over the 10-years period. The Senate version taxes just Class II and III devices, but that’s about 80 percent of all purchased devices.

The American Hospital Association and Congress want the device industry to eat these taxes through savings; otherwise hospitals will pay the bulk of the device tax. It is unclear if the manufacturers can or will do that.

No way, however, can blood centers pass through some \$375 million-plus that adds no direct value to an already safe blood supply. If we can’t eliminate or reduce the tax, what are the tradeoffs? Safety could suffer; there is not much else to cut these days. Please write those letters to Congress.

Jmacpherson@americasblood.org 💧

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety, and in finding efficiencies for the benefit of donors, patients, and healthcare facilities, by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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Records Show Red Cross Has Spent Nearly \$3 Million on Lobbying Since 1999

The American Red Cross (ARC) has spent \$2,954,911 on lobbying expenses since 1999, according to federally required lobbying reports the organization has filed. In 2006 alone, the nonprofit organization spent \$965,000 on lobbying; just five years earlier, it had spent only \$100,000.

Since 2004, the organization has received some \$270 million in congressionally appropriated federal funding. According to a federal disclosure document filed by the ARC in June 2008, the nonprofit had assets of \$3,997,280,210 and income of \$3,925,025,475 at that time.

Most of the reports indicate that ARC lobbying activities have been focused mainly on disaster relief and preparedness, services to the armed forces, appropriations, and issues that might concern any nonprofit, such as charitable incentives for individual giving, nonprofit tax issues, and charitable organization reforms.

But reports filed this year and in 2008 also named “American Red Cross Biomedical Services,” which refers to the ARC division that includes Blood Services, as among the issue areas for which the organization has lobbied Congress. The lobbyists working on that issue are listed as Cherae Bishop, Neal Denton, and Dawn Latham.

Contacted by telephone, Mr. Denton, senior vice president of Government Relations at the ARC, explained that the listing referred to lobbying the organization had done to obtain small earmarks to fund specific items like bloodmobiles as well as for “educating members of Congress” who sit on committees with FDA oversight jurisdiction. The organization is not pursuing any broad legislative initiative, he said, including anything to do with the 16-year-old consent decree that the organization’s blood services operate under. He acknowledged that President and CEO Gail McGovern’s top priorities include getting out from under the consent decree but that “it’s not going to happen legislatively.”

In each of the years from 2001 to 2004, the organization paid some 20 lobbyists, the reports indicate. The nonprofit organization turned to the federal government for help in responding to disasters in 2004, when it received \$70 million in federal aid after four hurricanes hit Florida.

During 2005, the year that the ARC became the focus of criticism for its disaster relief efforts after Hurricane Katrina struck the Gulf Coast, killing nearly 2,000 people, the organization employed 22 lobbyists. The following year, the nonprofit halved the number of its lobbyists to 10 and by 2009 that number was halved again to five.

In 2006, press and congressional reports uncovered lapses in the operations and governance of the Red Cross and the organization began reorganizing its chapter system while searching for a new leader. Late that year, legislation was introduced to amend the ARC charter to cut the size of its national board, change the way board members are nominated and mandate the appointment of an independent ombudsman to report annually to Congress, among other steps.

That year, ARC listed: “issues pertaining to 501 (C) (3) tax exempt organizations,” appropriations issues, “efforts related to the national response plan and catastrophic incident annex” and “legislation amending the charter of the American Red Cross” (also mentioned in 2007 reports).

In 2007, the group also lobbied on issues related to the aforementioned “lobbying reform legislation.” The same year, President Bush signed into law a defense appropriations bill that included \$20 million for the American Red Cross Service to the Armed Forces program.

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Red Cross Lobbying (continued from page 3)

In 2008, Congress appropriated \$100 million in emergency funding to the American Red Cross to replenish its disaster relief reserves, which were depleted when the charity provided shelter, food and other services during a string of hurricanes earlier in the year. The Red Cross appropriation was set out in two sections 10502-03 of the Homeland Security bill, HR 2638 (Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009) and is explicitly for disaster relief purposes.

So far this year, the organization reports spending \$154,890 on lobbying. Lobbyists for 2009 are listed as Cherae Bishop, Marc Decourcey, Neal Denton, Dawn Latham and Marin Reynes. (Sources: Senate Lobbying Disclosure Database; Implu Corp., an online business intelligence database) ♦

With Studies Showing Spread of Babesiosis, ARC Proposing to Test Donated Blood in Seven States

Three recent studies have discovered increases in the incidence of the parasite that causes babesiosis in donated blood and of transfusion-transmitted babesiosis (TTB). On the strength of that data, the American Red Cross (ARC) has developed two proposals to begin testing donated blood in states in the Northeast and the upper Midwest where the disease is endemic.

The picture emerging from the studies – each of which is forthcoming in *Transfusion* – shows babesiosis to be a growing threat. Each focuses on a different aspect of the problem. One study shows how widespread it is among blood donations in Connecticut and Massachusetts, another identifies the extent of its transmission through transfusions in Rhode Island, and the third determines the characteristics of infected donors and recipients, using cases reported through ARC's Hemovigilance Program.

Individually and collectively, the studies emphasize that concerns over the dangers of babesiosis and TTB are increasing. The ARC proposals involve setting up testing in affected areas, starting with Connecticut and potentially expanding to seven states – 16 percent of the nation's population.

Babesiosis is carried by *Ixodes* ticks; in the US, it is mostly caused by *Babesia microti*, a parasite that is similar to malaria and that infects red blood cells. Most people infected with it do not experience any symptoms or experience only mild symptoms that can be mistaken for the flu; however, the disease can be severe and even fatal, particularly for people with certain complicating health factors. Asymptomatic infection may last for months. Currently, there is no Food and Drug Administration-approved test for the disease, and blood centers merely ask potential donors whether they have a history of babesiosis. But the fact that most people with the disease do not know they have it casts doubt on the effectiveness of the question.

If a person who carries the parasites donates blood, the disease can be transmitted through transfusion to a susceptible recipient. To date, transmission has been reported only with red blood cells (both fresh and frozen) and platelets.

Concerns about TTB have risen as the number of complications and deaths related to it has jumped. The Food and Drug Administration received only one report of a TTB-related death from 1997 to 2004; however, from November 2005 to September 2008, it received at least nine (see *ABC Newsletter*, 12/5/08). In September 2008, FDA held a workshop on TTB in the US. In August 2009, AABB issued a bulletin on it, prompted by reports of more than 70 cases of it (see *ABC Newsletter*, 8/14/09).

(continued on page 5)

Babesiosis (continued from page 4)

The three forthcoming studies aim at shedding light on the epidemiology of the babesiosis. In one study, led by Stephanie T. Johnson, MT (ASCP), MPH, who is with the ARC branch in Farmington, Conn., scientists tested blood donated at selected drives in Connecticut and Massachusetts from 2000 to 2007 for the presence of immunoglobulin (Ig)G antibodies to *Babesia microti*. Using an immunofluorescence assay (IFA), they found the antibodies in blood donated in all eight counties in Connecticut and three counties in Massachusetts. They also found it in blood donated not just during the season peak for the tick that causes the virus – from July through September – but also during the rest of the year.

Although the results of this study helped them identify particular areas and times of the year when the likelihood of *Babesia microti* in blood is highest, they also made clear that the threat extended beyond certain areas and months, which led the scientists to conclude that year-round, regional testing may be necessary to fully safeguard the blood supply from the transmission of the disease.

Scientists in Rhode Island reached a similar conclusion when they carried out a retrospective study in which they analyzed babesiosis cases that were reported to the Department of Health in that state from 1999 to 2007. Led by Leonard Mermel, DO, an infectious disease specialist and the director of infection control for the Rhode Island Hospital, this team identified 21 cases of TTB in the nine years they studied.

Their analysis of information about where donors lived and when they donated reinforced the finding in Johnson's study that some people with babesiosis lived in areas without high tick populations and had merely traveled to an area where babesiosis is more common. Drawing also on other studies that show that the virus can survive for extended periods in blood bank conditions, including refrigeration up to 35 days, these researchers conclude that TTB is possible any time of year and in any location. Their study also revealed a troubling rise in cases of TTB: from 1999 to 2007, 326,081 units of red blood cells were transfused, according to the Rhode Island Blood Center. The 21 cases of TTB during that period give an incidence rate for TTB of just more than 1 in 15,000 transfusions. However, by the last three years studied, that rate had risen to 1 in 9,000 units transfused.

To determine the characteristics of infected donors and recipients, the third team of researchers – led by Laura Tonnetti, PhD, a scientist with the ARC's Transmissible Diseases Department, Jerome H. Holland Laboratory, in Rockville, Md. – analyzed cases of suspected TTB that were reported to ARC's Hemovigilance Program from 2005 to 2007.

They carried out follow-up testing of previously collected blood donations, by IFA, Western blot, and/or real-time polymerase chain reaction (PCR) analysis. They found 18 definite or probable *Babesia microti* infections among transfusion recipients. Five of those recipients died. Of the 18 cases, two recipients had sickle cell disease and four were asplenic; 13 were between the ages of 61 and 84 and two were 2 years old or younger. The researchers concluded that TTB "can be a significant cause of transfusion-related morbidity and mortality," particularly when transfusion recipients were elderly, very young, or asplenic. Like the researchers in Rhode Island, these scientists also found that TTB stemmed both from donors who lived in areas where the disease is endemic as well as those who had merely traveled to those areas. They also found that IFA testing was more effective than PCR analysis: the former identified all 18 donors, while the latter identified only one.

What Should Be Done? The conclusions of these studies – that babesiosis can occur anywhere at any time, that the number of TTB cases is rising, and that TTB can lead to serious complications from transfusions, including death – gave new data to support ARC proposals for testing donated blood for evidence of infection, which Dr. Tonnetti discussed in a presentation at the recent AABB Meeting.

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Babesiosis (continued from page 5)

The first proposal is to establish testing donated blood in Connecticut by IFA. ARC's recommendations include year-round IFA testing under investigational new drug regulations. Only whole-blood donations would be tested. Donors associated with positive results would be deferred, and their donations would be discarded. Testing could be done throughout the state or only in highly endemic areas. The latter approach would be less expensive, but it may only identify one-third of at-risk donors, so ARC favors testing across the state.

Depending on the results of that project, said Dr. Tonnetti, ARC would like to expand the area to include Rhode Island, Massachusetts, New York, New Jersey, Minnesota, and Wisconsin. Connecticut was chosen as the starting point, she explained in a phone call, because earlier studies had found a number of endemic areas in the state. But she emphasized that expanding the testing to other states would be important, given that babesiosis and TTB can spread so easily. No timeline has been set for testing under either proposal.

Citations. Asad S, *et al.* Transfusion-transmitted babesiosis in Rhode Island. *Transfusion*. 2009 Sep 16 [epub ahead of print]; Johnson ST, *et al.* Seroprevalence of *Babesia microti* in blood donors from *Babesia*-endemic areas of the northeastern United States: 2000 through 2007. *Transfusion* 2009 Oct. 10 [epub ahead of print]; Tonnetti L, *et al.* Transfusion-transmitted *Babesia microti* identified through hemovigilance. *Transfusion*. 2009 Jul 16 [epub ahead of print] ♦

FDA Finalizes Guidance on Testing Donated Blood for West Nile Virus

The Food and Drug Administration has finalized its guidance for blood centers on how they should test donations of whole blood and blood products for West Nile Virus (WNV). This guidance replaces the draft guidance dated April 28, 2008, and it takes into account a number of the comments FDA received from America's Blood Centers (ABC) and other sources.

While the draft guidance included recommendations for screening cells, tissues, and cellular-based products, the final guidance covers only donations of whole blood and blood products. Key recommendations are that blood centers should test whole blood and blood products for WNV year-round; that they may use minipool tests when there is not high WNV activity in their area; that each center may establish its own criteria for high WNV activity; that centers switch to individual testing as soon as possible, but not later than 48 hours, after high WNV activity is found in their area; and that if a minipool tests as reactive for WNV, each unit in that minipool should be tested with an individual test. It also recommended that, for individual units that test positive, additional testing "may be of value in donor counseling."

Background. It has been known since 2002 that donors who were infected with WNV could be viremic but not have any symptoms; it has also been known that the virus could be transmitted through blood transfusions and organ transplantation. FDA began studies the following year aimed at evaluating nucleic acid tests (NAT) for detecting WNV, and it has approved biologics license applications for two NAT since 2005. Both tests are used for individual donor samples, and for minipools of samples taken from either 6 or 16 donations.

Studies have found that the individual test (ID-NAT) has greater sensitivity than the minipool test (MP-NAT), and that, in fact, up to 25 percent of viremic units were not detected by the MP-NAT. However, it is not feasible or practical to test every unit individually, because of limited availability of the tests and personnel and logistical issues. This guidance, then, is meant to clarify when blood centers should use ID-NAT and when they may use MP-NAT.

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WNV Test Guidance (continued from page 6)

Input and Recommendations. ABC had asked FDA to recommend that centers could discontinue testing for WNV during times when there is low incidence of the virus. Instead, FDA recommended year-round screening, but it suggested the use of MP-NAT unless there was a high incidence of WNV in a particular area.

The administration left it to each blood center to determine the geographical area it would monitor, as well as the criteria it would use to trigger a switch to ID-NAT and back to MP-NAT. ABC sees this as “an excellent approach,” according to Ruth Sylvester, ABC Director of Regulatory Services.

FDA also took ABC’s advice about how quickly blood centers should switch to ID-NAT once they find high WNV activity. FDA had suggested that the switch happen within 24 hours in its draft guidance; in the final version, it extended that period to 48 hours, but urged centers to shift as soon as feasible.

The guidance also includes advice to centers about how to proceed based on various test results. If a an MP-NAT is not reactive, the units in the minipool may be released. If it is reactive, the individual units should be tested with an ID-NAT. Individual units that test positive should be discarded, the donor should be deferred for 120 days and counseled. Originally, FDA had recommended additional testing prior to the notification of the donor; now it says only that additional testing, such as a cleared test for WNV antibodies, may be helpful.

The guidance also lays out procedures for how blood centers should report the kinds of tests they use to FDA and how they should label units of whole blood and blood components. The full guidance is available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM189464.pdf>. (Source: FDA guidance, posted 11/6/09) ◆

RESEARCH

Study: Cold Storage, Virus Inactivation May Reduce Bacterial Growth in Platelets

A new study sheds more light on the mechanisms at work when platelets are refrigerated for a long period and how chilling could be used with viral inactivation technology to limit bacterial and viral growth, thus increasing platelet shelf life.

Bacterial sepsis is currently considered the major risk factor for transfusion-transmitted disease. Thus, regulatory agencies limit platelet storage to five days. The short shelf life compromises platelet inventories and creates chronic shortages. Despite improvements in platelet collection and handling techniques, the risk of bacterial infection transmitted through platelet concentrate transfusions is estimated to be 50 times higher than for transfusion of refrigerated red blood cell products.

However, platelets, unlike other transplantable tissues or cell types, do not tolerate refrigeration and disappear rapidly from the circulation if subjected to chilling before transplantation. Thus, platelets for transfusion are stored at room temperature. Cold storage *per se* does not prevent bacterial or viral contamination of donated blood. A combination of cold storage and virus inactivation technology, however, could reduce bacterial and viral growth, eliminating severely compromised platelet inventories and chronic platelet shortages.

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Clarification

As a result of unclear Web site branding, a story in the Nov. 6 issue of the *ABC Newsletter* about the response of area blood centers to the Fort Hood, Texas, shootings misstated the relationship between Scott & White Memorial Hospital in Temple and the Metroplex Health System in Killeen. The 233-bed Metroplex facility is operated by the Adventist Health System *and* Scott & White Healthcare. Adventist Health System manages 37 hospitals and is the 10th largest hospital system in the country. Scott & White Healthcare is one of the nation's largest multi-specialty group practice systems with more than 700 physicians and scientists. We regret the confusion. ♦

Chilled Platelets Study (continued from page 7)

A team of US and Swedish researchers found that transfused platelets stored long-term by refrigeration escape a macrophage-based surveillance system, but are instead removed primarily by the Ashwell-Morell asialoglyco protein receptor on hepatocytes. The study found that prolonged refrigeration increased the density and concentration of exposed galactose residues on platelets. This causes hepatocytes, through Ashwell-Morell receptor binding, to become increasingly involved in platelet removal. Macrophages rapidly removed a large fraction of transfused platelets independent of their storage conditions. With prolonged platelet chilling, hepatocyte-dependent clearance further diminishes platelet recovery and survival after transfusion.

The team found that macrophage depletion in mice substantially improves the survival of transfused platelets cooled for two hours but does not prevent the clearance of platelets chilled for 48 hours; transfused long-term refrigerated platelets are abundantly found in hepatocytes; and 48-hour platelet refrigeration markedly increases β -galactosidase exposure. Inhibition of chilled platelet clearance by both β integrin and Ashwell-Morell receptors may afford a potentially simple method for storing platelets in the cold.

Citation: Rumjantseva V *et al.* Dual roles for hepatic lectin receptors in the clearance of chilled platelets. *Nat Med.* 2009 Nov;15(11):1273-80. ♦

BRIEFLY NOTED

A new study by two researchers at Harvard School of Public Health finds a link between a hospital board's commitment to quality and the real thing. Hospitals' boards may influence the quality of care that hospitals provide, but their engagement in quality-related issues is largely unknown. A team led by Ashish Jha, MD, an associate professor in, and Arnold Epstein, MD, chair of the Department of Health Policy and Management, surveyed a nationally representative sample of board chairs of 1,000 US hospitals to understand their expertise, perspectives, and activities in clinical quality. The researchers found that fewer than half of the boards rated quality of care as one of their two top priorities, and only a minority reported receiving training in quality. The large differences in board activities between high-performing and low-performing hospitals suggest that governing boards may be an important target for intervention for policymakers hoping to improve care in US hospitals. Six in 10 respondents had a quality subcommittee and said quality performance was on the agenda at every board meeting; four in 10 identified clinical quality among the top two priorities for evaluating CEO performance; and three in 10 said their boards received formal training in clinical quality. The study found boards at hospitals with better quality scores were more likely to focus on quality. "Our data provide clear evidence of an associa-

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BRIEFLY NOTED (continued from page 8)

tion between an engaged board and high quality care, although we cannot yet pinpoint a causal link,” said lead author Dr. Jha. (Source: AHAnews.com, 11/6/09)

Citation: A. Jha and A.M. Epstein. Hospital governance and the quality of care. *Health Aff.* 2010;29 [epub before print, 11/6/09]

Doctors in the US are less likely than their counterparts in other countries to use health information technology, a new survey has found. Published online in the journal *Health Affairs* on Nov. 5, the 2009 Commonwealth Fund International Health Policy Survey reports that 46 percent of US doctors use electronic health records. That number is up from the 28 percent of US doctors who reported using them in 2006; it is far lower than the numbers in other countries. In the Netherlands, for example, 99 percent of doctors use electronic health records, as do 97 percent in New Zealand and Norway. More than 10,000 doctors in nine countries, the United Kingdom, and the US participated in the survey. The wide majority of doctors in the US said that they do not have advanced computer systems that would allow them to access electronic patient records. Commonwealth Fund officials said health reform legislation currently being considered by the US Congress could address many of the areas in which the US lags behind. “The study underscores the pressing need for national reforms to close the performance gap to improve outcomes and reduce costs,” said Commonwealth Fund Senior Vice President Cathy Schoen, lead author of the survey. (Source: www.healthcareitnews.com, 11/5/09) ♠

GLOBAL NEWS**Poor Farmers in Chinese Province Sell Blood to Make Ends Meet**

Nearly 6,400 poverty-stricken farmers in Central China’s Hubei province are selling their blood on a routine basis to bring in extra income, with some saying it’s the only way they can earn enough money to pay bills.

The farmers sell their blood – 600 cc at a time – every two weeks at the blood plasma collection station authorized by the local health bureau in Yunxian county. The farmers earn 168 yuan (\$25) each time. Nearly 20,000 people have sold their blood at the station since it open 11 years ago, *China Youth Daily* reported. The money earned is considered a “nutrition and traffic subsidy,” according to officials.

Located alongside the Han River, Yunxian has been listed as a poverty-stricken county for decades by the central government. Gao Congfen and her husband from nearby Zhengjiahe village have sold their blood there since 2000 in order to pay middle school and university tuition fees for their son. “If it were not for the blood donation, we could not make enough money to support my son,” the report quoted Gao.

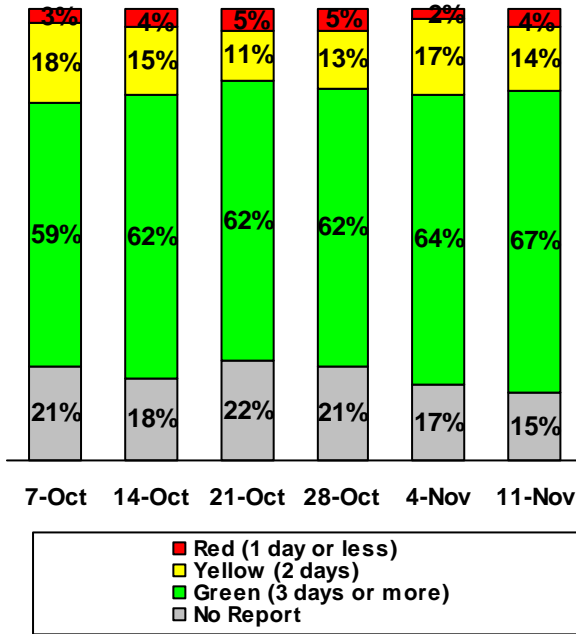
Zhou Wenfen, from Yangjiagou village, started to sell her blood regularly in 2007 when her 3-year-old grandson was diagnosed with aplastic anemia. Each time she sells her blood, she wakes up at 4 am, spends more than an hour to climb a mountain, travels down the Han River by boat for hours, and then arrives at the station around noon, the report said. “I have no other choice. I just want to get more money for my grandson for whom we have spent nearly half a million yuan in medical bills,” she said.

An official with the blood plasma collection station who only gave her surname as Chen told *China Daily*: “What the report said about nearly 6,400 regular donors and the subsidy are true. But the station's

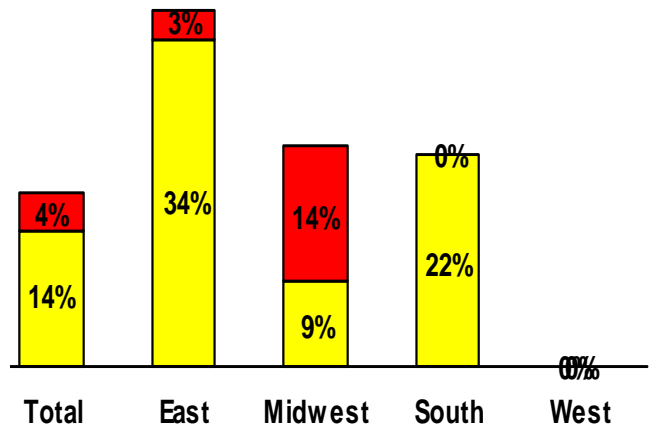
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STOPLIGHT: Status of America's Blood Centers' Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, Nov. 11, 2009



Daily Updates are available at:
www.AmericasBlood.org

GLOBAL NEWS (continued from page 9)

establishment and management including the subsidy are all in accordance with relevant laws and standards,” she noted. “We cannot forbid farmers from donating blood only because they come here for the subsidy,” she said. The station was set up in 1998 by Li Guangcheng, former deputy director of the county health bureau and head of the station now, she said. Every year, the station receives about 60,000 packages of donated blood and pays out about 10 million yuan to donors, Li was quoted by *China Youth Daily* as saying.

China implements an uncompensated blood donation system, in which healthy citizens aged 18 to 55 are encouraged to donate blood voluntarily. Relevant government departments or units can subsidize donors, according to the country's Blood Donation Law that went into effect in 1998. No more than 600 cc of blood can be collected each time. Donors are not allowed to donate more than once every two weeks, according to the Ministry of Health's blood plasma collection station administrative measures that took effect last March.

Donating blood frequently is safe, if the measures are followed properly, said Tan Xiaodong, professor at the School of Public Health of Wuhan University. “But instead of donating blood, the Yunxian county government and local farmers should take more active measures to change their poverty-stricken life,” he said. China has underground blood collection and supply gangs, which have been blamed for the spread of HIV/AIDS among people in the rural areas of Central China in the mid-1990s. (Source: *China Daily*, 11/5/09) ♠



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

INSIDE ABC

ABC, Nexcare World Blood Donor Campaign Picked Up by Variety of Media

America's Blood Centers has announced the results of the *give* campaign with Nexcare bandages, in celebration of World Blood Donor Day 2009. The campaign received more than 65 million media impressions from TV, online, newspapers, magazines, and radio stations nationwide. The estimated media value is over \$10 million.

Nexcare's microsite (www.nexcare.com/give) received more than 100,000 visitors during the campaign period. ABC members' donor centers and Nexcare distributed 600,000 free bandages.

An impression represents how many people see a story. For print media, impressions are based on the outlet's circulation times a small multiplier (assuming that it is often passed along to others). For broadcast, it's number of viewers (Nielsen), and for online media and blogs, it is the number of unique monthly visitors to those sites (measured by services like Compete, Quantcast or Technorati). Media value is based on the cost of paid advertising on those same media.

In addition to the media impressions the campaign received, Nexcare contributed \$10,000 to the Foundation for America's Blood Centers.

The partnership was, for the most part, exclusive for ABC members. The American Red Cross was invited to participate only in eight media markets where there are no ABC members present (Baltimore/Washington, Boston, Columbus, Detroit, Los Angeles, Philadelphia, Portland, and Salt Lake City). All national and regional press materials referred the media and the public to ABC.

The ABC Communications and Donor Recruitment Committees discussed these results recently and asked ABC to pursue a closer relationship with Nexcare for 2010. ABC staff subsequently met with executives from 3M, Nexcare, and Laforce+Stevens (Nexcare's PR agency) to discuss next steps and offer feedback and comments from the Committees. Nexcare is working on a plan for 2010 that will be presented to ABC by the end of the year.

Watch a short clip of the campaign at (allow time for download, file size = 50 MB):

<http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=2062>

(The first featured media interview is with an ARC representative in New England; all others are with ABC members.)

View a sample of media clippings:

<http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=2066>

ASK ABC

Editor's Note: ABC Newsletter periodically answers questions posed by members of America's Blood Centers in a recent survey.

Q: [How can members] access all of the surveys [conducted by ABC]?

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INSIDE ABC (continued from page 11)

A: To best accomplish ABC's objectives of representation and advocacy, ABC relies on aggregate data and information supplied by its members. To address the issue of repetitive or redundant calls for data, ABC developed the ABC Data Warehouse (DW), a central repository of data that introduces a standard protocol for data entry and definitions across our membership. Until the Data Warehouse is fully operational and adopted by a majority of members, you can locate survey information on the Members Web site or by simply asking ABC staff for the results of the specific survey, which we will be happy to share.

When fully operational, the DW will provide standardized data to be used for benchmarking and comparative analysis purposes. The DW also will reduce data collection workload and redundancy, as well as decreases errors and mismatches (common through "ad hoc" data requests or manual data transmissions). ABC members will "push" donation-level data electronically to the DW as well as manually enter other data (such as marketing budgets), and will be able to run a variety of reports on a secure, password-protected site. These reports and analyses will provide a snapshot of the membership's various issues at any given time sorted by geography, blood center size or other denominators. The reports will contain aggregate data and not member-specific data. The DW will also serve ABC by providing real-time, reliable data to support ABC's many legislative, regulatory, and public initiatives on behalf of the membership. ABC has begun phasing out most "ad hoc" surveys. To ensure your blood center is represented and to access comparative and benchmarking reports, sign up to the DW by reviewing the agreements and documents located at: <http://members.americasblood.org/go.cfm?do=Page.View&pid=5> ♦

Red Cross Violations Letter (continued from page 1)

- ♦ On April 21, 2008, "ARC's Northern Ohio Region learned that a whole blood unit was potentially contaminated by exposure to air during collection and the associated products were shipped before collections staff reported the error."
- ♦ Also in January 2008, FDA found two double red blood cell units that were released by the New England Region before required additional quality control testing was done. Also, in March and July 2008, two shipments of red blood cells were sent from the New England Region without the required coolant.
- ♦ Other violations include mix-ups of whole blood numbers, mistaken identification of donor genders, which then led to asking incorrect gender-specific health history questions; problems with instruments; and mishandling of donor sample tubes. In some cases, the problems were determined to result from staff members who did not understand proper procedures.

The letter also lists a number of examples of failure to investigate and correct problems in accordance with the consent decree and standard operating procedures established by ARC. These include, for example, failures to log units that had problems such as being overweight or mislabeled. A number of additional errors involve employees who failed competency assessments or committed errors while administering tests.

What's Next, and ARC's Response. FDA instructs ARC to provide monthly summaries and records of problems related to controlling suspect blood products, reviewing units of donated blood to determine which are overweight or have other problems, and studying problems with correctly identifying the gen-

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Red Cross Violations Letter (continued from page 12)

der of donors, among other steps. FDA is still evaluating fines and alternate or additional regulatory measures. However, it was reported on *Dow Jones Newswires* that the Red Cross has had to recall 7,363 “unsuitable” blood components and that FDA “may levy fines of up to \$5,000 for every unit of blood or blood component that was distributed that may have put the public’s health at risk.”

Efforts to contact Mr. Hrouda and Richard Benjamin, MD, PhD, chief medical officer at ARC, were unsuccessful. However, Stephanie Millian, director of Biomedical Communications at ARC’s national headquarters, e-mailed a statement in which the ARC insisted that it has made system-wide operational changes in the past 18 months that address these problems. The statement also pointed out that most of the violations cited by FDA happened before 2008, and that the recalls amount to less than one-tenth of 1 percent of the blood products produced by ARC each year.

“As a result of our changes, we have seen a 56 percent reduction in high-risk problems alone in the period between October 2008 and October 2009. The number of recall events has also dropped 47 percent in the past year. Recalls occur when the Red Cross or other blood banks self-identify a product that does not conform to stringent safety standards and notifies hospitals and the FDA.”

FDA “may levy fines of up to \$5,000 for every unit of blood or blood component that was distributed that may have put the public’s health at risk.”

Background. ARC has been operating under a consent decree from FDA since May 12, 1993. At that point, facing millions of dollars in fines, ARC agreed to improve the quality control of its blood. But when FDA began a new series of investigations of ARC facilities in 2000 and 2001, it found the organization in non-compliance with

the earlier decree. In December 2001 FDA asked a federal court to hold ARC in contempt of the consent decree; the result was the amended decree that was issued in May 2003. From 2003 to 2006, FDA fined ARC almost \$6 million for violations of the consent decree. The FDA has issued additional fines – each for millions of dollars – in September 2006, February 2008, and June 2008. FDA argued that ARC could have avoided the fines if it had followed the standard operating procedures it established in the wake of the consent decrees.

Some of the violations detailed in the Oct. 30 letter dovetail with conflicts reported between local ARC branches and their employees. For example, workers in Connecticut have been arguing that the local ARC branch is following unsafe procedures by allowing unlicensed personnel to perform double red donations. The state Department of Public Health agreed with the workers; in a letter to the Farmington ARC, it said the procedure should be performed only by licensed professionals, although it later said the ARC could use phlebotomists, who are trained but are not always licensed (see *ABC Newsletter*, 10/9/09).

In addition, a report issued Oct. 6 by Jobs with Justice and the National Workers’ Rights Board, which advocate on behalf of labor unions, details a number of blood safety problems stemming from a lack of adequately trained staff in several ARC regions. Among the contentions in the report are that “the Red Cross has reduced the presence of nurses and trained medical personnel at blood drives, while replacing them with barely trained, non-medical personnel to draw and supervise the handling of blood.” One Connecticut ARC employee said in the report that the Red Cross “has been steadily decreasing the number of RNs and LPNs – trained nurses – and replacing them with supervisors.” Donors often do not realize that, she said, because the technicians are called “blood service nurse technicians” and are often referred to as nurses, although they are not medically trained.

(Sources: FDA letter to J. Chris Hrouda, 10/30/09, www.fda.gov; *Dow Jones Newswires*, www.nasdaq.com, 11/12/09; Jobs with Justice report, 10/6/09) ♦

LEGISLATIVE NEWS

A new bill would promote the use of health information technology by addressing the chilling effect of anti-kickback laws in rolling out HIT systems. HR 3987, introduced on Nov. 3 by Rep. Roy Blunt (R-Mo.) with four Republican cosponsors, aims to make it easier for providers, such as hospitals and group practices, to supply physicians with HIT hardware, software, or related services. The bill would amend titles XI and XVIII of the Social Security Act by directing the secretary of Health and Human Services to conduct a study how “safe harbors” to anti-kickback laws might make it easier for physicians to obtain HIT technology and training. On the books since 1972, the federal anti-kickback law's main purpose is to protect patients and the federal healthcare programs from fraud and abuse by curtailing the corrupting influence of money on healthcare decisions. The law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal healthcare program business, including Medicare and Medicaid, can be charged with a felony. Because the law is broad, concerns arose among healthcare providers that some relatively innocuous – and even beneficial – commercial arrangements are prohibited by the anti-kickback law. Responding to these concerns, Congress over the years has designated a number of safe harbors for various payment and business practices that, while potentially prohibited by the law, would not be prosecuted. The bill was referred to the House Ways and Means Committee. (Sources: Rep. Blunt Web site; Gallerywatch, 11/11/09)

Rep. Chris Lee (R-N.Y.) introduced a bill on Nov. 3 that could authorize grants to establish medical malpractice tribunal pilot programs in five states. HR 4007, co-sponsored by Duncan D. Hunter (R-Calif.), would allow the secretary of Health and Human Services to make the grants, which would be awarded over three fiscal years. Each tribunal would include a state trial court judge, a physician, and a lawyer, and the threesome would provide the first hearing for medical malpractice cases. It would then decide whether the evidence in the case is “sufficient to support a finding for the plaintiff.” If so, the case would proceed. If not, the plaintiff would have to file a bond before continuing with the case. The bill was referred to the House Judiciary Committee. (Source: Gallerywatch, 11/7/09) ♦

REGULATORY NEWS

The Food and Drug Administration has released a draft guidance on preserving the blood supply during the 2009 H1N1 pandemic. It summarizes FDA’s current thinking about how blood donors should be assessed, how to assure blood products are safe and how to assure the availability of blood and blood products during the pandemic. It also identifies issues that blood centers are considering or have reflected in their pandemic plans. Among its recommendations are:

- ♦ Donors with confirmed or probable H1N1 influenza should be deferred until they have been free of fever without the use of fever-reducing medications for at least 24 hours.
- ♦ There is no deferral for donors following vaccination with live attenuated influenza or inactivated influenza vaccines, or after the preventative use of antiviral medications.
- ♦ Donors may be contacted within 24 hours of collection to clarify their responses to health history questions.
- ♦ Donors do not have to be deferred for exposure to or contact with a person with confirmed H1N1 influenza.

America’s Blood Centers will review the draft guidance and prepare comments; to contribute comments, contact Ruth Sylvester at rsylvester@americasblood.org. Interested parties may also submit comments to FDA at www.regulations.gov. The draft guidance has not yet been posted to the *Federal Register*, so the closing date for comments has not yet been set. The full draft guidance is available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM190373.pdf>. ♦

MEMBER NEWS

The Blood Alliance, headquartered in Jacksonville, Fla., recently announced the opening of a new chapter in South Carolina. The Blood Alliance center in Beaufort, S.C., will hold its first blood drive at Marine Corps Air Station on Nov. 19. A second drive will follow at Naval Hospital Beaufort on Dec. 4,



from a.m. to noon. The Blood Alliance is the Beaufort area's only community blood center and is the sole provider of blood products to patients at Beaufort Memorial Hospital. The center also supplies blood products to Naval Hospital Beaufort for use by local military families in need. A recently signed memorandum of understanding authorized the partnership with the Naval Hospital, which will

benefit military families as well as their civilian friends and neighbors. Additional blood drives at both the Air Station and the Naval Hospital are scheduled through 2010. The Blood Alliance provides blood and blood products to more than 20 hospitals and medical facilities in 10 counties serving Northeast Florida, portions of Georgia and South Carolina. (Source: The Blood Alliance press release, 11/3/09) ♦

COMPANY NEWS

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) ♦

IN MEMORIAM

Leader of Efforts to Improve AIDS Response, Blood Safety in Africa Dies

Gilbert Kombe, MD, MPH, 49, a public health systems and infectious disease specialist, a leader in the international response to HIV/AIDS and tuberculosis, and a tireless proponent of blood safety in Africa, died Nov. 6 at Sibley Hospital in Washington, DC. He lived in Takoma Park, Md.



Dr. Kombe, a native of Zambia, pioneered cost-effective approaches to delivering HIV/AIDS services in resource-constrained settings. Ann Lion, director of the US Agency for International Development (USAID)-funded Health Systems 20/20 project, said, "Gilbert was the most solid person I have met in my 32 years of professional experience. He inspired us to think bigger and, at the same time, more carefully. He knew to give us a bit more than we thought we could handle – and with him by our side, we reached it."

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IN MEMORIAM (continued from page 15)

Dr. Kombe wrote and spoke eloquently on the urgency of addressing the underlying health systems weaknesses impeding the delivery of HIV/AIDS and TB services in developing countries. His work contributed directly to changes in US legislation reauthorizing the President's Emergency Program for AIDS Relief (PEPFAR) in 2008.

As a young man, he was awarded a highly competitive Zambia Ministry of Education scholarship to study medicine in China, where he received his MD degree from Tongji Medical University. On his return to Zambia, he practiced medicine at Kitwe Central Hospital. Dr. Kombe moved into public health upon being appointed to coordinate the response to a cholera epidemic, and into advocacy by being forced to enlist media support in his effort to get treatment for the cholera victims. He also led the design and implementation of the first pilot program for HIV/AIDS home-based care in Zambia.

In the 1990s, while obtaining his Masters in Public Health and later teaching at The George Washington University School of Public Health and Health Services, he worked on public health issues in Washington, DC, Africa, and Eastern Europe. He conducted research on substance abuse prevention and barriers to accessing services by minority populations, and served on a team that provided HIV/AIDS, TB, and other health services to patients at the largest clinic for the homeless in Washington. Also in that period, he was a member of the Task Force on HIV/AIDS/STD Crisis Prevention and Mitigation for sub-Saharan Africa, and designed and implemented a Leadership for Health program for the countries of Eastern Europe.

In 2001, Dr. Kombe joined Abt Associates Inc. to develop and lead the health systems and HIV/AIDS practice, which now under the umbrella of the Health Systems 20/20 project alone is a multi-million-dollar activity that has worked in more than 30 countries.

"Dr. Kombe was widely admired and appreciated by colleagues and students for his unassuming manner, his warmth, his knowledge of global health issues, and his commitment to enhancing the health of the poor," said Dr. Richard Skolnik, Lecturer in Global Health at The George Washington University. "He enriched the lives of students and faculty with his broad perspective on health and his ability to bring to the classroom first-hand experiences from working in a large number of countries on the most critical health challenges."

"Gilbert was important to us professionally and personally and had a great impact throughout the world as a clinician, a professor, a project leader, a mentor and a friend," said Kathleen L. Flanagan, Abt Associates President and CEO. "His colleagues describe him as larger than life, one who could juggle multiple professional commitments but always putting his family first. Despite all of the demands on his time he personally touched so many of us."

Dr. Kombe is survived by his wife, Karin Theophile Kombe, and children Adrian Kafita, 12, and Emily Porter, 9. Survivors also include his mother, Hildah C. Kombe, in Zambia; and siblings Fridah Kombe Chasaya, Maybin Kombe, Dennise Kombe, Webby Kombe, Clement Kombe, Joseph Kombe, and Emmanuel Kombe.

To share condolences, tributes and memories, please visit: <http://rememberinggilbertkombe.wordpress.com>. To make a contribution to the Kombe Children College Fund, please send a check, payable to Kombe Children College Fund, c/o Abt Associates, 4550 Montgomery Avenue, Suite 800 North, Bethesda, MD 20814-3343. (Source: Abt Associates Web site, 11/10/09) ♦

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

Assistant Regional Manager. This individual will oversee daily operations of branch during absence of Branch Manager at our **McDonough, GA** location. Responsibilities will include assisting Branch Manager &/or District Director with oversight of blood collection, donor recruitment, component production & blood distribution. This individual may be expected to be continuously on call. Must have previous management exp. Bachelor's degree pref'd. Valid Georgia driver's license req'd. Submit cover letter & resume to: jcsmith@lifesouth.org & ddhemphill@lifesouth.org or visit our website at: www.lifesouth.org. Background check req'd. EOE/DFWP

Assistant Regional Manager. This individual will oversee daily operations of branch during absence of Branch Manager at our **Gainesville, GA** location. Responsibilities will include assisting Branch Manager &/or District Director with oversight of blood collection, donor recruitment, component production & blood distribution. This individual may be expected to be continuously on call. Must have previous management exp. Bachelor's degree pref'd. Valid Georgia driver's license req'd. Submit cover letter & resume to: smgable@lifesouth.org & ddhemphill@lifesouth.org or visit our website at: www.lifesouth.org. Background check req'd. EOE/DFWP

Quality Specialist. Blood Systems national, nonprofit organization is looking for professional to join our Quality team in St. Petersburg, FL. Ideal candidate will

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POSITIONS (continued from page 17)

possess strong organizational, presentation, written & verbal communications skills. Responsible for reviewing quality systems & compliance in all areas of technical & clinical operations within blood center. We are looking for professional with Medical Technologist certification with Transfusion Services & Reference Testing exp. Exp. should also include emphasis on Blood Bank & Clinical Laboratory. 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. Blood Systems offers highly competitive salary, comprehensive benefits, relocation, 401K w/match & more! For consideration, please submit resume via e-mail by **11/20/2009** to: jobs@bloodsystems.org. **ATTN: HR/2009/45**. Pre-employment drug testing req'd. Visit our website at: www.bloodsystems.org. EOE M/F/D/V

Corporate Director of Laboratory Quality & Regulatory Affairs. Blood Systems, non-profit, national blood banking organization is searching for Corporate Director of Laboratory Quality & Regulatory Affairs to join our corporate team in Tempe, AZ. This senior level Quality professional is responsible for establishing policy, goals & direction for laboratory Quality staff to ensure review of quality system & compliance in all areas of laboratory operations. Responsible for ensuring laboratory testing processes comply with all standards & regulations. Provides oversight for submissions to regulatory agencies & serves as primary regulatory liaison. Provides management system for audits & deviations; monitors data for trends. Serves as resource to operations on quality & regulatory related issues. Position also actively participates in Six Sigma & other performance improvement initiatives. Bachelor's degree in related area req'd. Masters or advanced degree in business, management or healthcare pref'd. CMQOE certification req'd within two years. CQA certification, certification as Medical Technologist or SBB certification pref'd. Nine years related exp. in regulated industry req'd. To include: Five years in quality, regulatory &/or auditing environment & five years of supervisory exp. Previous blood banking exp. is strongly desired. We offer excellent benefits, competitive salary, pension plan, 401k with match, relocation package & much more! For consideration, submit your resume via e-mail to: jobs@bloodsystems.org no later than **11/20/2009** to Blood Systems; **ATTN: 2009/HR/47**. Please visit our website at: www.bloodsystems.org. Pre-employment drug test req'd. EOE M/F/D/V

Quality Director II. Blood Systems, national non-profit blood bank seeks professional with strong organizational, presentation, written & verbal communications skills for our Quality Director II position in St. Petersburg, FL. This individual will be responsible for managing review of quality systems & compliance in all areas of technical & clinical operations. Serves as resource to operations on quality issues & participates in

Six Sigma & other performance improvement initiatives. Relevant Bachelor's degree & five years of related exp. in regulated industry to include three years in quality, regulatory & /auditing environment & two years of previous supervisory exp. req'd. Certification as Med Tech or SBB is pref'd. CQA, CQE &/or CMQOE certification within two years req'd. For consideration, please submit resume via e-mail by **11/20/2009** to: jobs@bloodsystems.org **ATTN: HR/2009/46**. We offer competitive benefits package, as well as relocation & much more! Pre-employment drug testing req'd. Visit our website at: www.bloodsystems.org. 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 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 pharmacoeconomics, 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

Chief Information Officer. Puget Sound Blood Center has created Chief Information Officer position reporting to President. Position provides innovative leadership for strategic development & maintenance of information technology, resources & applications. CIO will take lead in determining company-wide systems architecture, overseeing governance of systems & controls & partnering with leadership on shared vision of projects & IT resources. Eight + years in senior leadership role with bachelor's in IT, engineering or related field. Should have proven exp. in IT architecture design & project management. Up to 20% travel may be req'd. Please send resumes to: HumanResources@psbc.org.

Quality Manager. LifeSource, Chicagoland's blood center seeks highly functioning individual in its Quality Manager position. LifeSource, along with its parent company, Institute for Transfusion Medicine distribute over 400,000 units of product. Responsible for reviewing, monitoring & approving following new & revised

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POSITIONS (continued from page 18)

SOPs & forms, validation records, Quality Control records, Change Control, Error Management, Audits, SOP deviations, Training Plans, & other activities as assigned. This individual will assure timely & accurate corrective action & follow up to failures. Quality Manager will participate in development of work plans, oversee Quality Assurance meetings, committee meetings & quarterly Council meetings & other meetings of regulatory interest. This position will facilitate change control, review & approve Change Control documentation. Position requires Bachelors degree, Master's degree pref'd. ASQ certification is highly desirable. At least two years exp. in QA role in FDA regulated environment desirable; exp. in Blood Center setting or Transfusion Service setting highly desirable. Work requires thorough understanding of FDA, State & Accreditation agency requirements for Blood & Tissue Industries. This knowledge must be frequently used in decisions that directly impact organizational Regulatory compliance. Frequent contact internally & externally with other sites & employees of ITxM to give counsel, consult & influence decisions. Excellent oral & written communications is must. Please contact Nancy Sifuentes at: (847) 803-7845 or apply at: www.lifefsource.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

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POSITIONS (continued from page 19)

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