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HHS Study Finds XMRV Does Not Pose Threat to Blood Supply

A study funded by the US Department of Health and Human Services (HHS) offers further evidence that there is likely no link between chronic fatigue syndrome (CFS) and the xenotropic murine leukemia virus-related viruses (XMRV) and related polytropic murine leukemia viruses (P-MLVs), HHS announced in a press release on Thursday.

Lombardi and colleagues of the Whittemore Peterson Institute (WPI), Reno, Nev., began in 2009 what has been an ongoing scientific debate over a possible link between CFS and XMRV. They reported in the journal *Science* to have detected XMRV in white blood cells of 67 percent of patients with CFS and 3.7 percent in healthy blood donor controls. Scientists in the new HHS-supported study, however, could not confirm previous findings of XMRV and P-MLV in the blood samples of people living with CFS.

The Study that Started It All. The initial findings from WPI set off serious concerns in the blood community. In 2010 AABB issued a bulletin recommending that medically diagnosed CFS patients be discouraged from donating blood and in December 2010, the FDA's Blood Products Advisory Committee (BPAC) recommended that blood donors with a history or diagnosis of CFS be deferred indefinitely.

Jerry Holmberg resigns from HHS positions. See page 16.

Since the original study by Lombardi, *et al* was published in 2009, scientists have published a number of other studies showing that they are unable to confirm the link between CFS and XMRV. Some of these studies have suggested possible inadvertent contamination of reagents used in the original study. The editors of *Science* also asked the authors to retract their study. An article published in the medical journal *The Lancet* in June stated that three research papers published around that time “provided the final nail in the coffin of the XMRV-CFS story” (see *ABC Newsletter*, 8/1/11).

Throughout this entire debate, the lead researcher of the original 2009 study, Judy A. Mikovits, has not backed down from her findings, asserting that there was no contamination in her lab and that her research team could repeatedly reproduce the same results. Most surprisingly to many researchers, Dr. Mikovits was a co-author in this most recent HHS-supported study. However, she still does not believe that the new findings rule out the possibility that the mouse retrovirus infects people with CFS, says an article published this week in *Science*.

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OUR SPACE

ABC President Dan A. Waxman, MD

Too Close for Comfort

Do you ever have one of those moments when you realize that you've dodged a major bullet – a moment when by luck or good fortune you were able to narrowly avoid a disaster? Well, over a week ago I experienced one of those moments. In the everyday grind of our busy work schedules, it is so easy for us to take the simple things in life for granted, let alone, life in general.

On a Friday afternoon, I was driving eastbound on US Highway 20 in northern Indiana when I saw a car in the westbound lane fishtail and go careening into a concrete median wall. The car then flew back across the westbound lanes and down an embankment. When it hit the wall, it sent the driver's side rear tire into the air 50 feet and over into the eastbound lanes. The tire struck my car at full-force, leaving a massive dent in the hood of my SUV.



It wasn't until I got out of my car that I realized the severity of what had just happened to me. After seeing the damage the tire caused my car, I couldn't help but think "What if that tire had shifted just six inches upwards and flown through my windshield or if I had swerved allowing the tire to collide with my car door or side window?" Instead of the typical frustration that follows any car accident, I was suddenly filled with gratitude that it was just my hood and not me that had suffered the blow of that speeding tire.

Fortunately, I was not injured nor was the other driver who was quite shaken up by her ordeal. Had the circumstances been different, we were a short ride by ambulance to Memorial Hospital South Bend, the northernmost hospital in my blood center's service area. It has an excellent Level II Trauma Center with an established and operational Massive Transfusion Protocol that is unique in that they use a thromboelastograph to drive blood component therapy.

After my close call on the highway, I am happy to be able to continue as one of the medical staff at Memorial Hospital instead of becoming an inpatient. It sure feels good to be alive.

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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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XMRV Study (continued from page 1)

“The conclusion...” of this new study “was that we don’t have a reproducible assay to detect XMRVs in the blood – not that they weren’t in the patients at all,” Dr. Mikovits told *Science*. She did, however, co-author a partial retraction of the 2009 study, published online in the Sept. 22 *Science Express*. The retraction states that two of the study’s co-authors reexamined samples of CFS patients and healthy control patients and found that some of the CFS peripheral blood mononuclear cell DNA preparations were contaminated with XMRV plasmid DNA. They therefore retracted a table and two figures related to that data.

HHS Working Group Looks For Answers. This new study comes from the HHS’s Blood XMRV Scientific Research Working Group, formed in 2009 and led by the National Heart, Lung, and Blood Institute (NHLBI), along with other HHS agencies, NIH’s National Cancer Institute, the NIH Clinical Center, the Centers for Disease Control and Prevention, and the Food and Drug Administration. The working group seeks to investigate the validity of testing techniques and to determine XMRV’s potential impact on the blood supply, said the release. The results were published online on Sept. 22 in *Science Express*.

Researchers took blood samples from healthy donors and from 14 patients with CFS who had previously tested positive for XMRV or P-MLV, and samples from another person who had tested positive for XMRV but did not have CFS. They also used blood samples from healthy volunteers whose blood tests previously had no signs of XMRV/P-MLV.

The samples were blinded as not to reveal their source and sent to nine laboratories supported by several HHS agencies along with Abbott Laboratories, Abbott Park, Ill., Gen-Probe Inc., San Diego, and WPI. The labs tested identical sets of the new blood samples for XMRV/P-MLV nucleic acid, for replication of the virus, and for antibodies to the virus.

“Two labs, which previously had reported the association of XMRV with CFS, reported the presence of XMRV in some samples. However, the labs reported similar rates of XMRV in samples from patients with CFS and from healthy donors who were not known to have XMRV. Additional tests run in the same and other labs on the same samples did not find XMRV, which strongly suggest that these persons were negative for XMRV/P-MLVs. This would be a sign that the few observed positive results were false positives,” said the release.

Because the XMRV Scientific Research Working Group sought to assess the best way to test blood samples on the virus, researchers in this study used 11 nucleic acid, five antibody, and three culture assays to determine the assays’ abilities to detect XMRV/P-MLVs. The study also checked for evidence of contamination with mouse DNA, an issue that some researchers say may have caused incorrect results in the Lombardi, *et al* study.

XMRV Does Not Threaten Blood Supply. “The results of this study, along with other recent findings, reassure us that these viruses do not pose a threat to the safety of the nation’s blood supply,” Susan B. Shurin, MD, acting director of the NHLBI and of the NIH, said in the release. “These data add to the mounting evidence that there is no need to screen blood donors for them at the present time.”

Another study to investigate the XMRV/CFS link is being led by W. Ian Lipkin, MD, of Columbia University’s Mailman School of Public Health.

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XMRV Study (continued from page 3)

This study is testing fresh blood samples from 150 people living with CFS and 150 similar but healthy people for the presence of XMRV, P-MLV, or related viruses. Researchers hope to release these results by the end of 2011.

To view the NIH News release please visit: www.nih.gov/news/health/sep2011/nhlbi-22.htm. (Sources: NIH news, 9/22/11; *Science*, 9/22/11. *ABC Newsletter*, 8/1/11)

Citations: Simmons, G, *et al.* Failure to confirm XMRV/MLVs in the blood of patients with chronic fatigue syndrome: A multi-laboratory study. *Science Express*. 22 Sept. 2011.

Silverman, R.H., *et al.* Partial retraction. *Science Express*. 22 Sept. 2011. 💧

International Research Team Offers Some Hope in Search for Malaria Vaccine

In the ongoing effort to stop the spread of malaria, a disease that kills more than 1million people each year, an international research team may have found a vaccine specific to an important malaria strain that is effective in preventing disease.

The researchers immunized children in Malia, Africa, with the FMP2.1/ASO2_A malaria vaccine, which contains a protein derived from the apical membrane antigen 1 (AMA1) expressed on the 3D7 strain of the *Plasmodium falciparum* malaria parasite. They found that this particular vaccine had a 64.3 percent efficacy rate in preventing clinical malaria caused by parasites with the AMA1 protein corresponding to the one used in the vaccine.



Christopher Plowe, MD, MPH, of the Howard Hughes Medical Center for Vaccine Development at the University of Maryland School of Medicine in Baltimore led the study along with colleagues at the Malaria Research and Training Center at the University of Bamako in Mali, Africa, and the Walter Reed Army Institute of Research in Silver Spring, Md. It was funded by the National Institute of Allergy and Infectious Diseases, among other organizations, and appeared in the Sept. 19 issue of *The New England Journal of Medicine*.

Malaria spreads to humans through a bite from a mosquito infected with the Plasmodium parasite, which multiplies in the liver and infects red blood cells. Infected individuals can experience fever, headache, and vomiting, and if untreated can die due to disruption of blood supply to vital organs.

There are medications to treat malaria, but in some parts of the world where the disease is rampant, such as Africa, the parasites have developed resistance to a number of these drugs. According to the World Health Organization, a child in Africa dies of malaria every 45 seconds.

Methodology. The researchers conducted a randomized double-blind trial in which 400 Malian children received either the FMP2.1/ASO2_A malaria vaccine or the control vaccine for rabies. They administered three doses of the vaccine to the children over a two-month period, and they continued to monitor the children for six months during scheduled clinic visits as well as with blood smears.

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Hope for Malaria Vaccine (continued from page 4)

They found that the malaria vaccine did not provide significant protection against clinical malaria when defined as fever and at least 2,500 parasites per cubic millimeter of blood. The vaccine had only a 17.4 percent efficacy rate against this type of clinical malaria. However, when researchers measured the vaccine's ability to prevent malaria caused by parasites with AMA1 corresponding to that in the vaccine, they found it to be effective.

"The finding suggests that it is possible for a malaria vaccine targeting a single blood-stage protein to provide protection against clinical malaria," wrote the authors. While it was not significantly effective in preventing clinical malaria defined by a fever and 2,500 parasites per cubic millimeter of blood, the researchers concluded that the FMP2.1/ASO2_A vaccine must offer some type of cross-reactive protein against malaria parasite strains other than those with AMA1 variant used in the vaccine.

They came to this conclusion because even the modest 17.4 percent reduction in this type of clinical malaria could not be solely attributed to patients with malaria strains expressing AMA1 variant. The vaccine did not cause any deaths or vaccine-related adverse events, however some participants experienced more minor reactions such as swelling and fever.

This study comes after the research team had a successful trial with the FMP2.1/ASO2_A with 100 Malian children in 2010. However, this is not the first or only malaria vaccine to show some possibility for malaria prevention. In 2008, for example, researchers published results of a phase II trial in *The New England Journal of Medicine* that showed a vaccine called RTS,S, may be 50 percent effective in preventing malaria among African children.

"Further analysis of molecular immunologic correlates of protection may provide insight into the extent of cross-protection and guide the development of more effective next-generation vaccines," wrote the authors. (Source: *Medscape Today*, 9/14/11)

Citation: Plowe, CV., *et al.* A Field Trial to Assess a Blood-Stage Malaria Vaccine. *N Engl J Med.* 2011 Sep 15;356(11):1004-13. ♦



ABC's Golden Anniversary Three-Day Celebration Event

ABC is turning 50 and we're having a ball...and you're invited! Save the date: March 24-26, 2012, Scottsdale, Ariz., hosted by Blood Systems, Inc., in connection with ABC's Annual Meeting. To be added to the invite list, e-mail meetings@americasblood.org with the subject line: "ABC Golden Anniversary Invitation."

Have a good memory? Been around blood for a while? The *Newsletter* will be featuring a series of stories detailing the last 50 years in blood banking. To contribute your story, e-mail newsletter@americasblood.org.



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INSIDE ABC

Miriam Bolaños Offers Project Management Expertise to America's Blood Centers

Miriam Bolaños has recently become the newest addition to the America's Blood Centers' staff, bringing more than 15 years experience in project management and executive level coordination to her new position as manager of Executive Services.

Ms. Bolaños has had a varied career, working at a myriad of organizations both in the US and Guatemala, where she is from. Most recently, she has worked for the Pan American Health Organization (PAHO) in Washington, D.C. where she was the consultant for the Gender, Diversity, and Human Rights Team.



In her new position with ABC, Ms. Bolaños will provide administrative support for ABC CEO Jim MacPherson, coordinate activities with all ABC departments on behalf of the CEO, and serve as the secretariat for the ABC Board of Directors as well as several ABC-affiliated alliances including the Cell Therapy Alliance, Alliance of Alliances, and a Latin American Blood Alliance that is in the planning phase.

As a consultant for PAHO, she worked for the United Nations-Interagency for Indigenous Peoples, developing materials in Spanish for civil society and indigenous organizations and collecting information to measure advances of the Implementation of PAHO's Gender Policy 2005-2011.

Prior to her work for PAHO, Ms. Bolaños worked as a consultant to the Inter-American Development Bank in Washington, D.C., as well as for the Norwegian Institute of International Affairs. As a program officer at the Norwegian Embassy in Guatemala, Ms. Bolaños was responsible for the Indigenous Peoples Program and general follow-up of all projects of the Norwegian Cooperation in Guatemala. She has also worked at UNICEF as a consultant and at the United Nations Development Program (UNDP) as a project manager.

Ms. Bolaños has had numerous other experiences working in project management, consulting, and social development, during which time she has gained a passion for issues such as exclusion, gender, sustainable development, indigenous peoples, and citizen participation.

"Much of my experience has been in human rights, in positions where I can improve the lives of others. Working with America's Blood Centers will allow me to continue making an impact in others' lives with an organization that focuses on giving the gift of life," said Ms. Bolaños.

She holds a master's degree in management from the Universidad Galileo and a Bachelor of Arts in international affairs from the Universidad Francisco Marroquín, both in Guatemala. She also completed a post-graduate program in Gender Issues with the Universidad Autónoma de México.

"We are thrilled that Miriam Bolaños has agreed to join ABC," said Mr. MacPherson. "She came highly recommended and her broad experiences will add more project management skills and business acumen to our national and international efforts. As ABC broadens its outreach, while flattening its management structure, she becomes the glue that holds us together."

INSIDE ABC (continued on page 7)

INSIDE ABC (continued from page 6)

ABC Human Resources Webinar Answers Tough Questions about Social Media

As more businesses and non-profit organizations use social media to promote their messages, questions about how to effectively use these tools and what is appropriate to post become more complicated. America's Blood Centers' Human Resources Committee recently held a webinar in which presenters tackled some of these emerging issues.

Last Thursday more than 60 people from various ABC member centers participated in the webinar, titled "Social Media...What is it? Why use it? HR's Role." It featured presentations by Rodney Green, manager of Human Resources and Compensation at Gulf Coast Regional Blood center, and Rae Lynn Spears, director of Corporate Human Resources at Blood Systems, Inc. (BSI).



Mr. Green presented a summary of basic tools and advantages offered through social media websites, including Facebook, LinkedIn, Twitter, and Wikipedia. He noted that social media in general are unique in that they are editable, popular, a conversation, fast, and historical.



As far as human resource's role in social media, Mr. Green explained that social media allow human resources personnel to increase their business exposure, build expertise, track resources, foster communications, and increase compliance and education.

He noted that only 20 percent of surveyed companies have defined social media policies, and that having a policy can impact and improve productivity by limiting or restricting social media use during work hours. He explained that the National Labor Relations Board (NLRB) issued a guidance stating that social media use that involves the terms and conditions of employment involving others may trigger protected activity.

For example, a protected activity would include employees complaining about work-related situations and soliciting feedback or opinions from other employees, such as complaining about meeting logistics or supervision. An unprotected activity would be complaining about customers or clients, criticizing elected officials, or airing personal gripes about management that do not solicit feedback from other employees.

Ms. Spears presented next, beginning with a summary of useful applications and advantages of social media. She explained further that social media allow a human resources department to listen to what people are saying, and see what information individuals are interested in and in turn share with others. This information can assist in enhancing an organization's marketing and hiring strategies.

She added that social media provide immediate engagement and remove barriers to action, for example they allow people to easily make donations, schedule appointments, and sign up to volunteer. Social media also save organizations money, because tools like Facebook and YouTube are free, she said.

Ms. Spears said that these tools have helped some blood centers with donor recruitment by increasing interactions and providing real-time conversations between the donors and the blood center. She added that social media have helped BSI to build its employment and career efforts by using professional networking tools like LinkedIn.

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Social Media Webinar (continued from page 7)

She also elaborated on some major social networking mistakes including, underestimating the amount of time it takes to upkeep social media accounts, being too formal in posts, and underestimating the power of the social media in their reach and ability to cause a reaction in customers.



Ms. Spears discussed human resource's role in social media as far as a policy or code of conduct, explaining that employees should not conduct personal social media interactions during work hours, but that they should rather use these websites to convey opinions and gain those of fellow employees. She added that at BSI, employees must make clear that they have expressed their own opinions and not those of BSI. She also reviewed the NLRB policies that Mr. Green covered earlier.

To conclude, Ms. Spears shared a quote from a Cisco media team blog: "A piece of content that is shared with a friend, or friends, or followers, or the world is the ultimate measure of its success... that person is validating that the piece of content they are sharing was valuable enough, interesting enough or topical enough to share with one or with many."

Members of America's Blood Centers may access the audio playback and presentations in the File Center of ABC's Member website <https://members.americasblood.org>. ♦

BRIEFLY NOTED

A group of National Institutes of Health (NIH) scientists recently identified a new subtype of T lymphocytes that behave like stem cells, which may enhance and prolong the immune response against tumor cells, NIH said in a press release on Sunday. T lymphocytes comprise a small fraction of white blood cells and may be more effective than any previously reported type of T cell for treating tumors. This study, led by the National Cancer Institute and the NIH, was published on Sept. 18 in the journal *Nature Medicine*. "The study describes how these stem-cell like T cells can trigger a prolonged immune attack against tumor cells by continuously generating killer T cells and regenerating themselves," said the release. Many therapies currently used to treat patients with metastatic cancers only persist for short periods of time after their administration, but the type of living cell therapy described in the study could offer a prolonged treatment option because the cells would be able to continually refresh themselves and integrate with the patient's immune system for longer periods, explained the release. The researchers studied T cells that had many characteristics of young immune cells in order to isolate the ones that showed the first changes in gene expression that occurred when lymphocytes make a memory response to an antigen, said the release. "The identification of human stem cell-like memory T cell population is of direct relevance to the design of vaccines and T cell therapies," said the study's abstract. The NIH release is available at: www.nih.gov/news/health/sep2011/nci-18.htm. (Source: NIH News, 9/18/11)

Citation: Gattinoni L, *et al.* A human memory T cell subset with stem cell-like properties. *Nat Med.* 2011 Sept. 18. [Epub ahead of print]

BRIEFLY NOTED (continued on page 9)

BRIEFLY NOTED (continued from page 8)

The Indian Institute of Technology, Kharagpur (IIT-Kgp), in partnership with the University of California (UCLA), Irvine, has developed a low-cost rapid diagnostic test (RDT) device to detect diseases such as malaria, dengue, and tuberculosis, said an article on the Indian news source, Live-mint.com, a partner of *The Wall Street Journal*. RDT devices generate immediate results and do not need skilled operators, making them especially useful in areas with limited healthcare infrastructures. Thus far, the device has been 100 percent accurate in tests at IIT-Kgp's laboratories. Clinical trials are set to begin next month in partnership with JSV Innovations Pvt. Ltd., a medical device firm in West Bengal, India. Suman Chakraborty, a professor at IIT-Kgp, began research on an RDT device in 2005 in collaboration with the biological micro-electrical mechanical systems (BioMEMS) laboratory at UCLA. The researchers have developed "a microfluidic compact disc, which when rotated with a motor, delivers blood samples into separate chambers filled with different reagents through microchannels embedded in the disk," said the article. The results are then derived from the sample's reaction with the reagents. Researchers say that a low-cost and simple RDT device could have a significant impact on areas such as rural India where healthcare facilities are in relatively poor condition and many people die due to delay in detecting deadly diseases. After clinical trials, IIT-Kgp, the UCLA BioMEMS laboratory, and JSV Innovations will jointly seek patents for the device, said the article. (Source: Livemint.com in partnership with *The Wall Street Journal*, 9/19/11)

The Joint Commission recently released its Annual Report on Quality and Safety 2011, which for the first time lists hospitals that are top performers in using evidence-based healthcare processes closely linked to positive patient outcomes, the commission announced in a press release last week. The Joint Commission is an independent, nonprofit organization that accredits and certifies more than 19,000 healthcare organizations and programs in the US. This year's report identified 405 organizations "identified as attaining and sustaining excellence in accountability performance measures for the full previous year." They "represent approximately 14 percent of the Joint Commission-accredited hospitals and critical access hospitals that report core measure performance data," said the release. The hospitals were rated according to 22 accountability measures for heart attack, heart failure, pneumonia, surgical care, and children's asthma care. The Joint Commission's sixth annual report presents data collected from 3,000 accredited hospitals, said the release. The report is available online for free at: http://www.jointcommission.org/improving_america%E2%80%99s_hospitals_-_the_joint_commission%E2%80%99s_annual_report_on_quality_and_safety_2011/. (Source: The Joint Commission press release, 9/14/11) ♦

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to Editor Betty Klinck at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

Democrats Would Shift Priorities on HealthCare Spending; CR Uncertain

All things being equal, the actions of the Democratic administration and the Democrat-controlled Senate in the past few weeks would signal a shift in federal spending away from the well-off elderly and rich and toward the needy poor. But all things are not equal, and both parties in the House can probably be counted on this autumn to upset that game plan.

With the fiscal clock set to run out in less than two weeks, Senate Majority Leader Harry Reid has not ruled out a government shutdown. The current continuing resolution expires at midnight on Sept. 30, but lawmakers in both houses were planning to break next week for a constituent work week and to observe Rosh Hashanah. It may be just brinkmanship, but Sen. Reid's veiled threat was being taken seriously by odds-makers witnessing the latest round of histrionics in Congress. Ignoring the deal they approved to raise the debt ceiling, 48 conservative House Republicans on Wednesday joined 182 angry Democrats to defeat a short-term stopgap measure. Then, early Friday morning, the House passed a stopgap bill but several hours later it was rejected by the Senate, 59-36, according to various news sources.

Administration Weighs In. Meanwhile, on the heels of its \$447 billion jobs plan laid out on Sept. 8, the Obama administration this week unveiled a longer-term deficit reduction plan that relies on a combination of spending cuts and tax increases to fund the president's proposed economic stimulus measures. As part of the \$3 trillion deficit reduction plan, the administration proposes to cut spending for Medicare and Medicaid by \$320 billion over 10 years. The lion's share, \$248 billion, would come from Medicare (actually, the projected growth of that program).

President Obama threatened to veto any bill coming out of the "super committee" that cuts Medicare benefits without raising new revenue, including by imposing higher taxes on the wealthy. The Joint Select Committee on Deficit Reduction has until Nov. 23 (under the law that raised the federal debt ceiling) to cut the federal deficit by \$1.2 trillion.

As expected, the American Hospital Association (AHA) sounded the alarm on the proposed Medicare/Medicaid cuts, sending a letter to the super committee stating that the plan would translate into at least 200,000 job losses to hospitals and their vendors by 2021. In a statement, Rich Umbdenstock, president and CEO of AHA, said the Obama proposal would also "jeopardize the ability of hospitals to train the next generation of physicians by reducing funding for teaching hospitals and harm care for the poor and people in rural communities by reducing rural hospital funding." America's Blood Centers has joined a coalition headed by AHA that opposes the cuts.

Appropriations for Health-related Agencies. Meanwhile, over in the Dirksen Senate Office Building, the Senate Appropriations Committee and one of its subcommittees have been busy in the past few weeks crafting, and approving along partisan lines, new spending levels for health-related agencies for fiscal year (FY) 2012.

After staff and panel leaders spent their August recess drafting legislation, the full committee met on Sept. 7 to mark up and pass the FY 2012 Agriculture, Rural Development, Food and Drug Administration appropriations (H.R. 2122), Homeland Security appropriations (H.R. 2017) and Energy and Water Development appropriations (H.R. 2354) bills.

H.R. 2122 provides \$2.497 billion for the FDA, a slight increase over the \$2.447 billion in the FY 2011

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Healthcare Spending (continued from page 10)

continuing resolution. As Committee Chairman Daniel Inouye (D-Hawaii) pointed out, FDA is one of the few agencies this year to receive increased funding. Part of the increase is to begin implementation of the recently passed Food Safety Modernization Act. On Tuesday, the Senate Subcommittee on Labor, Health and Human Services (HHS), and Education, and Related Agencies, passed a bill that provides \$70.18 billion in discretionary spending for other HHS programs, a decrease from the \$70.44 billion in discretionary funding for HHS laid out in the FY 2011 continuing resolution.

“Last year, 46 programs totaling \$1.3 billion were eliminated. This bill zeroes out 15 more programs totaling more than \$260 million,” said Chairman Tom Harkin (D-Iowa). “Last year we cut the meat to the bone; in this bill, we are now going into the bone marrow.”

Sen. Harkin said he was particularly proud that he was able to preserve funding that will implement provisions of the Patient Protection and Affordable Care Act. However, Republicans, led by Richard C. Shelby (R-Ala.), said they would refuse to support any bill that implements the healthcare reform law and called the bill “budgetary smoke and mirrors.” In particular they decried the Disease Prevention and Public Health Fund created by the healthcare law as a “virtual slush fund.” The bill was approved by a 10-8 vote along strict party lines.

Among the highlights, the bill includes:

- ◆ \$4 billion to fund operations at the Centers for Medicare and Medicaid Services (CMS), up from \$3.6 billion in FY 2011. The additional funding will be used to implement the PPACA and to cover more baby boomers enrolling in the program;
- ◆ \$581 million for CMS’ Health Care Fraud and Abuse Control activities, a \$270.6 million increase over the FY 2011 level of \$310.4 million;
- ◆ \$30.5 billion to fund biomedical research at the National Institutes of Health (NIH), a decrease of \$190 million. The bill creates the National Center for Advancing Translational Sciences (NCATS) as part of an NIH restructuring that included the termination of the National Center for Research Resources. According to the committee, the bill provides \$20 million for a new program called the Cures Acceleration Network (CAN). That program is designed to speed the translation and application of promising discoveries by making grants available to biotech companies, universities, and patient advocacy groups, and to help facilitate FDA review of critical vaccinations and tests;
- ◆ \$1.6 billion to expand the national health clinic network known as Community Health Centers (CHCs). Combined with funding from the health reform law, FY 2012 spending for CHCs will be \$2.8 billion, up \$200 million;
- ◆ \$896 million, an increase of \$139.5 million, for the Social Security Administration to conduct disability reviews and redeterminations of non-medical eligibility;
- ◆ A provision to institute a 0.1 percent user fee on 340B discount drugs. The fee is expected to generate \$5 million in FY 2012; and
- ◆ \$900 million for the AIDS Drug Assistance Program, an increase of \$15 million over the FY 2011 level.

On Thursday, the full Appropriations Committee voted 116-14 along party lines to pass the bill, according to the AHA’s *News Now* newsletter. How much of this will actually end up in the final FY 2012 budget? Stay tuned.

– Robert Kapler, rkapler@americasblood.org ◆

REGULATORY NEWS

The Food and Drug Administration announced in a news update last Thursday that it will hold a public workshop called, “Data and Data Needs to Advance Risk Assessment for Emerging Infectious Diseases Relevant to Blood and Blood Products.” Workshop presenters will discuss data and data sources currently used by FDA, possible new sources of data, and the development of new studies and information through collaboration with stakeholders, said the announcement. The workshop will include presentations and panel discussions with experts from stakeholders, academia, regulated industry, and government. “Quantitative risk assessments (QRAs) are an important tool for evaluating the risk associated with new emerging infectious diseases (EIDs) that are relevant to blood and blood products,” said the announcement. QRAs assist in making decisions about the benefits of mitigation options, and make it possible for decision-makers to develop policies for blood and blood product safety and availability using “sound science and the best data and information available,” explained FDA. Collecting and sharing information related to the probability of risk when evaluating an EID “can be expatiated by proactively building and maintaining critical relationships both within the Center for Biologics Evaluation and Research (CBER) and within external stakeholders,” FDA said in the announcement. CBER is seeking data on factors such as disease prevalence, incubation periods, behavioral risks associated with disease transmission, potential donor exposure risks, susceptibility to EIDs, and product handling and usage, said the announcement. Having insufficient data and information are major challenges that FDA faces when there is an EID. The workshop is set to take place from 8:30 a.m. to 5 p.m. on Nov. 29, 2011. It will be held at the Gaithersburg Hilton, at 620 Perry Parkway, Gaithersburg, Md. Early registration is recommended. Contact Lou Gallagher at lou.gallagher@fda.hhs.gov to register or for more information. To view the FDA announcement, visit:

www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm272047.htm.

(Source: FDA news announcement, 9/15/11)

The Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER) announced its next series of live training sessions for the e-Submitter Tool for Online Blood Product Submissions. CBER recently released an e-Submitter tool for Blood License Applications (BLA) and Supplements (BLS) submissions for establishments that collect whole blood and blood components, including source plasma. Representatives from CBER’s Division of Blood Applications described the e-Submitter in an America’s Blood Centers webinar on May 24. The e-Submitter is a tool that walks users through the process of compiling a complete and structured submission, has data capturing forms, and uses business rule logic to require the submitter to complete applicable sections based on previous responses. CBER has pilot tested the e-Submitter tool, and it is now available to all blood centers. CBER had made many enhancements during the pilot program and will continue to make improvements and corrections going forward. ABC encourages its members to begin using the e-Submitter tool for BLA/BLS and annual report submissions, because it is a key improvement that will enhance the submission process. Members are encouraged to contact Toni Mattoch, director of Quality Services, at tmattoch@americasblood.org or Ruth Sylvester, director of Regulatory Services, at rsylvester@americasblood.org with any feedback on the system. They will pass these suggestions along to FDA to continue improving this tool. Supporting documents for the e-Submitter can be found at: www.fda.gov/ForIndustry/FDAeSubmitter/ucm191387.htm. To listen to the ABC webinar about the e-Submitter, members may visit: <http://members.americasblood.org/go.cfm?do=Page.View&pid=63>. (Source: ABC MCN 11-142, 9/21/11)

The Centers for Disease Control and Prevention released a draft guidance on Wednesday recommending more stringent screening for organ donors, said a CDC press release. The guidance is called “Draft 2011 Public Health Services (PHS) Guideline for Reducing Transmission of HIV, HBV,

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REGULATORY NEWS (continued from page 12)

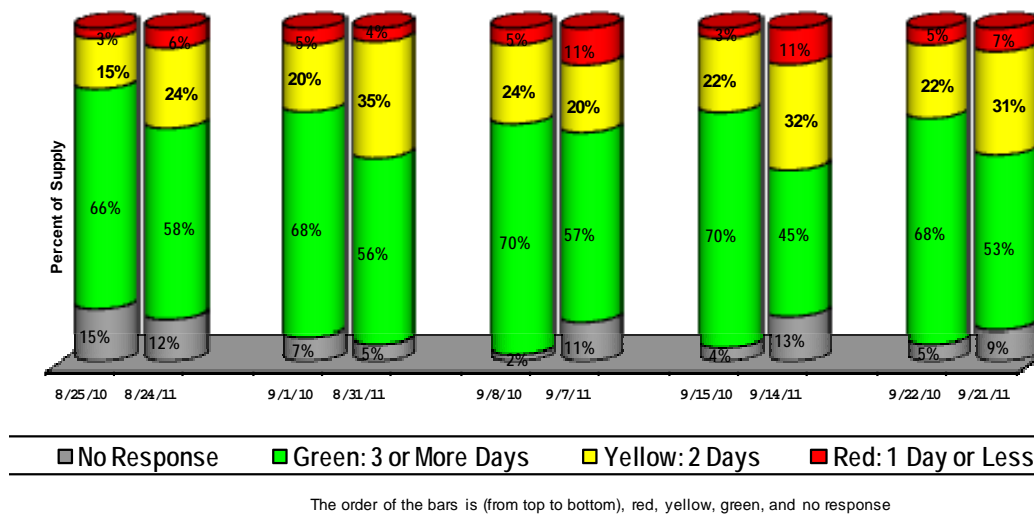
and HCV through Solid Organ Transplantation.” It suggests screening organ donors for HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) in order to prevent transmission to organ recipients. CDC provides recommendations based on more than 200 investigations of suspected unexpected transmission of HIV, HBV, and HCV through transplantations from 2007 to 2010. Of the confirmed cases, some led to death of the transplant recipient. Major changes to the 1994 PHS guideline include recommending the addition of HBV and HCV screening along with HIV screening, recommending updated and more sensitive laboratory tests for organs, revising the set of donor risk factors, and focusing only on solid organs and vessel conduits, not on other tissues. The guidance also discussed the potential use of organs from donors at increased risk in certain situations. To read the entire guidance, please view Docket No. CDC-2011-0011-0002 at: www.regulations.gov. The *Federal Register* announcement can be found at: www.ofr.gov/OFRUpload/OFRData/2011-24189_PI.pdf. (Source: CDC press release, 9/21/11)

America’s Blood Centers, in cooperation with the American Red Cross (ARC) and AABB, recently submitted comments to the Food and Drug Administration’s “Amendments to Sterility Test Requirements for Biological Products.” FDA proposed these amendments in June, which are “intended to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products,” said the *Federal Register* notice. This amendment would also suggest moving toward the adoption of rapid and alternative microbiological sterility methods. The proposed rule suggests several changes, such as eliminating the specific sterility test methods, culture media formulae, and culture media test requirements, eliminating specified membrane filtration procedure requirement for certain products, and eliminating specified sterility test requirements for most bulk material. Under the current FDA sterility requirements, sterility testing is not required for whole blood, cryoprecipitated antihemophilic factor (AHF) platelets, red blood cells, plasma, source plasma, small pox vaccine, reagent red blood cells, anti-human globulin, and blood grouping reagent. FDA’s proposal is to maintain the current exceptions for these products, but the agency asked for comments about the possibility of removing this exception for platelets. ABC, ARC, and AABB suggested that FDA maintain the exception for platelets. “Culture-based methods are in wide use as a quality control tool and more recently a non-culture-based method for use at point of issue has become available. However, early culture-based testing as it is practiced in the blood donor industry is not sterility testing and currently there are no available procedures or tests that will ensure the sterility of platelet products,” said the joint comment. The comment explains that if the exception for platelets is removed, then manufacturers of blood components will be unable to meet this new requirement. ABC and the other organizations also noted that the only technology that could possibly satisfy this requirement, pathogen inactivation, is not yet licensed for use in the US. The comments also suggest that FDA use a mechanism to require testing of all platelet products for bacterial contamination that does not tie it to biologics license applications. To view the *Federal Register* notice, please visit: www.gpo.gov/fdsys/pkg/FR-2011-06-21/pdf/2011-15346.pdf. (Sources: *Federal Register*, 6/21/11; AABB, ABC, ARC comments on Docket No. 2011-N-0080, 9/16/11) ◆

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

STOPLIGHT: Status of the ABC Blood Supply, 2010 vs. 2011



INFECTIOUS DISEASE UPDATE

INFLUENZA

Southeastern and Western states seem to have most of what little influenza activity there is in the US, according to the Centers for Disease Control and Prevention’s *Morbidity and Mortality Weekly Report* in an update of influenza activity in the US and rest of the world. Overall, the US experienced low levels of influenza activity. Specifically, the 2009 influenza A (H1N1), influenza A (H3N2), and influenza B viruses were reported worldwide and “sporadically” in the US. CDC collaborates with federal, state, and local partners and eight different systems to provide influenza information. From May 22 to Sept. 3, the US World Health Organization and the National Respiratory Enteric Virus Surveillance System collaborating laboratories tested 20,868 respiratory specimens for influenza viruses of which 122 tested positive. Of these, 87 (71 percent) were influenza A viruses, and 35 (29 percent) were influenza B viruses. Influenza viruses were reported from 26 states in all 10 US Department of Health and Human Services regions, said the report. The largest proportion of positive samples came from Southeastern US, followed by Western states. The US Outpatient Influenza-like Illness Surveillance Network reported that weekly percentages of outpatient visits to its providers for influenza like-illness remained below the national baseline of 2.5 percent, ranging from 0.5 to 1.2 percent. The percentage of deaths attributed to pneumonia and influenza, as reported by the 122 Cities Mortality Reporting System, remained below the epidemic threshold, except for three weeks in June, said the report. Looking at worldwide data, the report said influenza activity in the Southern Hemisphere was typical for the season. In Australia, influenza activity began increasing in mid-May with 2009 influenza A (H1N1) virus predominating and co-circulating with influenza B viruses. In New Zealand, influenza B viruses predominated, with lower levels of influenza A (H3N2) virus and 2009 influenza A (H1N1) viruses co-circulating. In South America, influenza activity was low and influenza A viruses were reported more frequently, but the predominant subtype varied by country. The predominant subtype identified in Asia was influenza

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INFECTIOUS DISEASE UPDATES (continued from page 14)

A (H3N2) virus, with a smaller number of influenza B viruses identified, although outbreaks of 2009 influenza A (H1N1) virus have been reported. In Europe and North America, small numbers of 2009 influenza A (H1N1), influenza A (H3N2), and influenza B viruses were identified. This *MMWR* is available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm6036a2.htm?s_cid=mm6036a2_w. (Source: CDC *MMWR*, 9/16/11) ♦

MEMBER NEWS

Community Blood Center of the Carolinas (CBCC), Charlotte, N.C., will be holding a blood drive that will also raise money to benefit the “Playground for Zahra” Project, CBCC announced Monday in a press release. The blood drive is being held in cooperation with the Kiwanis Clubs of Catawba County in order to raise money for a playground in honor of Zahra Baker, a 10-year-old girl from Catawba County, N.C., who was murdered in October. Zahra was disabled after having battled cancer twice, which left her with a prosthetic leg and impaired hearing. The new playground will be built in Hickory, N.C., and the organizations need to raise \$85,000 to fund the project. CBCC will donate \$10 to the playground fund for every unit of blood donated at the drive, set to take place in the Heart Center Lobby at Frye Regional Medical Center at 420 North Center St., Hickory, N.C. The drive will take place from 10 a.m. to 4 p.m. on Saturday, Sept. 24. “I believe we all can do more to support others in our communities,” CBCC President and CEO Martin Grable said in the release. “By giving blood at this special blood drive, donors not only have the chance to support local patients battling cancer, cardiac disease, and other life threatening illness, they also have the opportunity to build a playground for the children in our community in honor of Zahra Baker.” For more information or to make an appointment, please contact Lauren McNally at (704) 604-5473.



Memorial Blood Centers, St. Paul, Minn., held a grand re-opening of its newly renovated Plymouth Donor Center on Wednesday, said a press release issued on Monday. Over the past several months, the center has been under construction to improve the donation experience for both donors and staff and to add more donor beds to increase collections, said the release. The Plymouth Donor Center collects whole blood, platelets, and plasma. “Of the 11 donor centers we operate throughout Minnesota and northwestern Wisconsin, the Plymouth location is one of our busiest,” Anita Hove, Memorial Blood Centers’ Donor Centers manager, said in the release. “During construction, we were extremely grateful for the patience of our loyal donors. They continued to keep up a regular schedule of blood donation that has helped us ensure that we’ve been able to meet our commitments to local hospital partners.” The grand re-opening celebration included a ribbon-cutting ceremony.



Memorial Blood Centers CEO Donald Berglund and City of Plymouth Mayor Kelli Slavik with blood donors and business leaders at the ribbon cutting ceremony.

MEMBER NEWS (continued on page 16)

MEMBER NEWS (continued from page 15)

Marge Probasco recently won the 2011 Most Dedicated Blood Drive Coordinator Award on behalf of the Illinois Coalition of Community Blood Centers (ICCBC), after being nominated by ABC member Community Blood Services of Illinois

(CBSI). For nearly 20 years, Ms. Probasco has held a blood drive consistently every eight weeks at the River Valley Church of Christ for the Fisher, Ill., community.



Community Blood Services
of Illinois

The award is given as part of ICCBC's "Blood Drive Coordinator Recognition Program." The judges were impressed by the frequency with which Ms. Probasco holds blood drives, as many are held only annually or semiannually, said the release. "Marge exemplifies a dedicated blood drive coordinator and her efforts have helped save hundreds of patients. CBSI feels privileged to work with such a caring and devoted steward to the community," CBSI Director of Donor Relations Carrie Webb said in the release. (Source: ICCBC press release, 9/8/11) ◆

PEOPLE

Jerry Holmberg, PhD, recently stepped down from his position as both senior blood advisor for Blood Policy in the Office of the Assistant Secretary for Health and executive secretary for the Advisory Committee on Blood Safety and Availability (ACBSA). Dr. Holmberg left these positions to join Novartis' Vaccines and Diagnostics Division as director of its Office of Scientific Affairs in San Francisco, announced Assistant Secretary for Health Howard Koh, MD, MPH, in a letter to colleagues last week. Dr. Koh said that Dr. Holmberg has "been a key player in a number of important initiatives dealing with biovigilance and national preparedness." He said that Dr. Holmberg helped lead the government's review of its men who have sex with men deferral policy, as well as efforts to determine whether emerging infectious agents are a threat to the blood supply. Dr. Holmberg traveled to developing countries in Africa, South America, and Central Asia to provide technical assistance in blood safety and availability in his mission to eliminate the risk of transfusion-transmitted disease, said Dr. Koh in the letter. He also notes that Dr. Holmberg deserves enormous credit for increasing collaboration and cooperation in reaching agreements on important policy-related issues, such as those related to biovigilance. In 2009, Dr. Holmberg received the AABB award for his leadership in biovigilance. Dr. Holmberg said in a letter to colleagues that "ACBSA has made significant recommendations to improve not only blood safety and availability, but also an impact on the safety of tissues and organs." He said that after eight years in this position, he feels that progress has been made in donor and recipient safety. He notes that there is still progress to be made in biovigilance, and that he hopes he can continue to aid in such biovigilance activities from the private sector. James Berger, associate public health advisor for Blood, Organ and Tissue Safety, has stepped in and is currently serving in Dr. Holmberg's position with ACBSA. (Sources: Letter from Jerry Holmberg, PhD, 9/20/11; Letter from Howard Koh, MD, MPH, 9/13/11) ◆



CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: mnorwood@americasblood.org.

POSITIONS AVAILABLE:

QC Technologist. Thanks to the commitment and generosity of its donors, Community Blood Services in Paramus, N.J. has been serving our community's transfusion medicine needs for more than 50 years. The QC technologist will be responsible for maintaining operational standards by applying methods acceptable to various accrediting and inspecting agencies. The QC Technologist will work in conjunction with the Stem Cell Department to develop departmental manuals, prepare for external and internal audits or inspections while following the Standard Operating Procedure (SOP) Manual developed by the QA department as a guideline to accomplish these tasks and other tasks when required. Additionally, the QC Technologist will communicate quality improvement issues to include investigation and reporting of any errors and incidents. Bachelor's degree in Medical Technology (preferred) or a related discipline. Three to four years experience in clinical laboratory or blood center required, experience in a stem cell laboratory strongly preferred. Certification through a nationally recognized agency (ASCP or ASQ) preferred. NYS technologist license preferred. Interested and qualified candidates can email their resumes to careers@cbsblood.org. EOE

Director of IS. Seeking a Director of IS to join our growing Blood Bank. Responsible for the computer systems and medical records activities. Administers the network and computer systems including firewalls, systems operations, data and network security and backup, overseeing e-mail administration, website and communication equipment; coordinates all computer activities and projects; ensures proper system validation and documentation; ensures medical records management is properly handled; does strategic plan and budget for IS. Supervises IS staff. Handles other duties as assigned. Must have minimum of three to five years experience in IS or blood center management with demonstrated experience, skills and knowledge to effectively administer the network, security and systems; proficiency working in a Windows environment and using Microsoft Office, and detail-oriented with solid analytical skills and ability to recognize areas of concern, analyze data, assess/problem solve and resolve concerns. Must possess leadership, management and supervisory skills and be able to effectively communicate and motivate staff. Please send resume with salary requirements

to hr@bbh.org or mail to the Blood Bank of Hawaii, 2043 Dillingham Blvd., Honolulu, HI 96819.

District Specialist Process Improvement. Blood Systems seeks a professional with process improvement and project management skills. This individual will be responsible for driving performance improvement initiatives for the assigned district, leading process improvement projects and coaching employees on the use of process improvement tools. Bachelor's degree in related field required. Knowledge of performance improvement, statistical tools or cGMP systems and applications required. Black belt certification (by a recognized certifying agency) within 12 months of hire required. Lean Kaizen Event Facilitator Certification within six months of hire required. Five years related experience required. Lean Six Sigma or other process improvement implementation and/or project management experience preferred. Use of statistical techniques and other problem solving tools preferred. Experience in the healthcare, blood banking, or pharmaceutical industry preferred. Submit resume by **09/23/2011** to: jobs@bloodsystems.org ATTN: HR/2011/40. Pre-employment drug testing required. EOE M/F/D/V.

Sr. Director, Corporate Production & Inventory Management. Blood Systems seeks a professional with extensive knowledge of production planning, inventory and manufacturing processes to join our corporate team. This key position will be responsible for strategic production planning, management of system inventory, and oversight of manufacturing processes for our blood centers. Excellent planning, organization, analytical, problem solving and prioritizing skills are a must! Bachelor's degree in related area required. Master's degree preferred. Knowledge of federal, state and local regulations as they relate to the blood industry manufacturing activities required. Eight years related experience required. To include: three years supervisory experience, eight years experience in blood center operations, and three years experience in business software applications and blood bank manufacturing software. Previous experience supporting a multi-location environment

POSITIONS (continued on page 18)

POSITIONS (continued from page 17)

preferred. Submit resume via e-mail by **09/30/11** to: jobs@bloodsystems.org ATTN: HR/2011/53. Pre-employment drug testing required. EOE M/F/D/V.

Director, Operational Policy & Processes. Blood Systems has an excellent opportunity for an experienced blood banking process improvement and manufacturing professional! This key position is responsible for development of assigned blood center processes and procedures, provides oversight of quality operational systems and process improvement, oversees program development and provides direction to staff. Bachelor's degree in related area required. Knowledge of federal, state and local regulations related to the blood industry manufacturing activities required. Certification as a MT or SBB by a recognized certifying agency preferred. Six years related experience required. To include: three years supervisory experience, six years experience in blood center technical operations, and three years experience in business software applications and blood bank manufacturing software. Previous experience supporting a multi-location environment preferred. Submit resume by **09/30/11** to: jobs@bloodsystems.org ATTN: HR/2011/54. Competitive benefits package offered! Pre-employment drug testing required. EOE M/F/D/V.

Immunohematology Reference Laboratory Technologist (CLS). Performs and reports test results for all Reference Laboratory procedures in an accurate and timely manner in compliance with Federal and State Regulations, AABB Standards, Manufacturer's instruction, and internal operating procedures. In addition, successful candidate will resolve compatibility problems, perform molecular typing and provide consultation services to hospitals. Position will require individual to be able to work independently with sound judgment while following SOP's. Our range of benefits include 100 percent paid medical/dental benefits (for employees), paid life insurance, a long term care pro-

gram, critical illness program, generous Paid Time Off, paid holidays, and a wellness program are just the beginning. Education and Experience: Requires current California CLS license and at least two years of relevant experience with emphasis on antibody identification & SBB preferred. Previous experience in immunohematology reference lab is highly desired. **MUST PASS PRE-EMPLOYMENT DRUG SCREEN AND PHYSICAL EXAM TO APPLY.** Please visit our careers website at www.Lstream.org and apply directly to the Reference Laboratory Technologist position. You may also contact Brianna at (909) 885-6503, ext. 319.

Donor Recruitment Rep. This position is responsible for achieving annual and monthly territorial goals; schedules blood drives; develops new donor sources; maintains an ongoing public relations program in territory, develops an annual recruitment plan; develops and maintains donor recognition programs. Qualified candidates must have a relevant Bachelor's degree or equivalent combination of formal education and experience, effective oral and written communication skills and strong sales/territory management skills. Must be self-motivated and a self-starter with good organizational skills and the ability to meet deadlines, able to work some evenings and weekends, provide own vehicle for transportation, have a valid driver's license with a good driving record and good computer skills. Please visit our websites at www.unitedbloodservices.org and www.unitedbloodservices.org/careers.aspx. Applications are required. Apply online at: www.UnitedBloodServices.org, fax application/resume to 806-771-5024 or apply in person at 2523 48th Street, Lubbock, TX by October 7. EOE M/F/D/V "Employee Drug Testing Required" ♦