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FDA Delays Ban on Blood Center Distribution of Derivatives

The Food and Drug Administration will delay until December 1, 2008 the effective date of a ban on the distribution of blood derivatives by registered blood establishments that meet the definition of a "healthcare entity." According to an advance copy of a *Federal Register* notice scheduled for publication on Monday, the delay will give the agency more time to address comments received in response to a proposed rule modifying a portion of the Prescription Drug Marketing Act (PDMA).

On February 1, 2006, FDA published a proposed rule that would amend a section of the final PDMA rule to allow a registered blood establishment that provides healthcare services and also distributes blood derivatives to continue in both capacities, as long as the blood establishment does not provide healthcare services unrelated to its activities as a registered blood establishment.

FDA received "substantive comments" on that proposal, the agency said. The one-year delay on the ban is needed to give the agency additional time "to address comments on the proposed rule, consider whether regulatory changes' are appropriate, and, if so, to initiate such changes," FDA said.

The blood service organizations have long argued that a ban on the distribution of blood derivatives by blood centers would interfere with longstanding relationships between blood centers and other healthcare providers such as hospitals, hemophilia treatment centers, and other providers.

"We applaud FDA's decision in the proposed rule to allow certain registered blood establishments that qualify as healthcare entities to distribute blood derivatives," America's Blood Centers said in comments on the February 2006 proposed rule. (The ABC comments were also filed on behalf of AABB, the American Red Cross, and Blood Centers of America.)

"However, to be faithful to Congress's intent in enacting PDMA, and to avoid disrupting the current ability of FDA-licensed blood establishments to perform their core blood-related mission, the exclusion in 21 CFR, section 203.22 should be broadened," ABC said.

(continued on page 2)

FDA Delays Ban on Blood Center Distribution of Derivatives (continued from page 1)

The blood service organizations asked FDA to broaden the proposed rule to allow the “sale, purchase, or trade of, or the offer to sell, purchase, or trade any transfusion medicine and cellular and related biological therapy product by a registered blood establishment that qualifies as a healthcare entity, so long as any healthcare services that it provides are predominantly related to its activities as a registered blood establishment.”

If the rule were not broadened, the blood service groups said, patient care could suffer as a result of the disruption to the supply of these drugs to patients, who also benefit from nonprofit community blood centers’ economies of scale, group purchasing arrangements, and the ability to handle market fluctuations. ♦

Dr. Margaret Chan of China Elected New WHO Director-General

Margaret Chan, MD, of China, an expert on avian influenza and SARS, will be the next Director-General of the World Health Organization (WHO), the organization announced yesterday.



In her acceptance speech, Dr. Chan said: “what matters most to me is people. And two specific groups of people in particular. I want us to be judged by the impact we have on the health of the people of Africa, and the health of women. ... Improvements in the health of the people of Africa and the health of women are key indicators of the performance of WHO.”

“All regions, all countries, all people are equally important,” Dr. Chan said. “This is a health organization for the whole world. Our work must touch on the lives of everyone, everywhere,” she said. “But we must focus our attention on the people in greatest need.”

Dr. Chan told the Assembly that as Director-general she would focus on six key issues for WHO: health development, security, capacity, information and knowledge, partnership, and performance.

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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 accomplishes its mission by providing leadership in donor advocacy, education, national policy, quality, safety, 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 its members to share information and best practices.

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Dr. Chan emphasized the importance of global health security in her vision of WHO's role: "Health security brings benefits at both the global and community levels. New diseases are global threats to health that also bring shocks to economies and societies. Defense against these threats enhances our collective security."

Dr. Chan succeeds Joon-wook Lee, MD, who died suddenly on May 22. She was nominated as WHO director-general on Wednesday by the WHO Executive Board and her appointment was confirmed on Thursday by the World Health Assembly. The director-general is WHO's chief technical and administrative officer. She was previously WHO assistant director general for Communicable Diseases and representative of the director-general for Pandemic Influenza.

Dr. Chan received her medical degree from the University of Western Ontario in Canada and a public health degree from the National University of Singapore. She joined the Hong Kong Department of Health in 1978, and was appointed as director of Health in 1994. In that post, she launched new services focusing on prevention of disease and promotion of health. She also introduced new initiatives to improve communicable disease surveillance and response, enhance training for public health professionals, and improve local and international collaboration. She has managed outbreaks of avian influenza and the world's first outbreak of severe acute respiratory syndrome (SARS).

Addressing the challenges ahead, Dr. Chan said: "As we know, not all of the problems faced by WHO in its efforts to improve world health are subject to scientific scrutiny, or yield their secrets under a microscope. You know the ones I mean: lack of resources and too little political commitment. These are often the true 'killers.'"

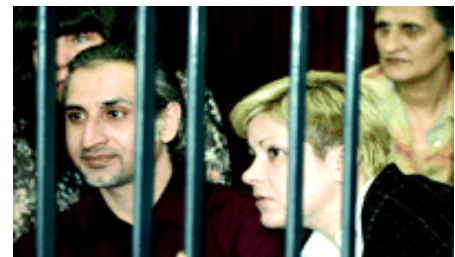
Dr. Chan concluded her address by repeating her pledge to work hard to improve the health of people around the world. "The work we do together saves lives and relieves suffering. I will work with you tirelessly to make this world a healthier place." ♦

Death-Penalty Trial in Libyan AIDS Case Ends

International Science Community Pleads for Objectivity

The fate of six healthcare workers accused of deliberately infecting more than 400 Libyan children with HIV should be known before Christmas. The verdict in the case of the six foreign health workers facing the death penalty will be announced on December 19, a Tripoli court announced last week at the end of a six-month trial.

Over the past month, protests from the international scientific community have mounted over the refusal of the court to hear scientific evidence from international AIDS experts. On October 27, the British journal *Nature* published an open letter to Colonel Muammar al-Gaddafi from 114 Nobel laureates expressing their concern over the injustice of the proceedings. A letter published on the same date in *Science* by Robert Gallo, MD, director of the Institute of Human Virology in Baltimore, Maryland, and 43 other scientists called for release of the six.



Scientists say Palestinian doctor Ashraf Hajjuj (left), Bulgarian nurse Nasia Nenova, and fellow defendants did not get a fair trial. Photo credit: Mahmud Turkia/AFP/Getty

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Libyan AIDS Trial (continued from page 3)

In 1999, Libyan police rounded up the five Bulgarian nurses and a Palestinian doctor and used torture to extract confessions that they had deliberately infected the children as an act of bioterrorism, according to

“They are innocent, and the law and science can prove it, if they get the belated opportunity.”

– Joint letter to *Nature* by 114 Nobel laureates

human rights organizations. The six were condemned to death in May 2004 on charges of having deliberately infected 426 children with HIV at the Al-Fateh Hospital in Benghazi in 1998. Those verdicts were overturned by Libya’s Supreme Court on December 25, 2005, which ordered a retrial that began in May of this year.

The Libyan court held just 12 hearings in the retrial, half of them adjourned shortly after they began. Lawyers representing the six defendants claim that they

were not given a fair opportunity to make their case, with the court refusing to allow independent scientific evidence to be heard.

Scientific Basis for Prosecution Bogus, Epidemiologists Say. Earlier this year, the *Nature* editors acquired a copy of the 2003 document written by five Libyan physicians that is the basis for the case against the six. After having the document translated into English, *Nature* asked leading experts to evaluate it.

The report “wouldn’t meet the lowest standards of epidemiological evidence for establishing any causal relationship,” said Janine Jagger, MD, an expert in blood-borne diseases who leads the International Health Care Worker Safety Center at the University of Virginia, in an October 27 *Nature* report.

“There are no grounds for suspicion of deliberate infection by any staff, and strong evidence of hospital-acquired infection before the arrival and after the departure” of the six workers, said Robin Weiss, MD, an AIDS virologist at University College-London.

The *Nature* investigation further criticized the Libyan court for disregarding a report, written by HIV co-discoverer Luc Montagnier, MD and Vittorio Colizzi, MD, an AIDS expert at Tor Vergata University in Rome, that said the infections began before the medics arrived and were caused by contaminated needles. Evidence for this is the fact that many of the children were co-infected with hepatitis B and C, and that two hospital nurses were infected with the same HIV strain as the children, their report said.

In their open letter published in the same issue of *Nature*, the Nobel laureates expressed their “grave concern” over the fairness of the trial. “We appreciate the agony and the sadness of the parents of these children and we sympathize with the difficult situation of the Libyan authorities in trying to deal with this matter,” they said. “However, we feel that if justice is to be served it is essential that the defense should be permitted to present its case.”

“Strong scientific evidence is needed to establish the cause of this infection. However, independent science-based evidence from international experts has so far not been permitted in court,” the Laureates said.

“International diplomacy, dealing as it does with geopolitical and economic realpolitik, by necessity often involves turning a blind eye. But its lack of progress in response to the medics’ case in Libya is an affront to the basic democratic principles that the United States and the European Union espouse. Diplomacy has lamentably failed to deliver,” the Laureates wrote in *Nature*.

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Libyan AIDS Trial (continued from page 4)

“The most likely diplomatic compromise – that the medics will be condemned to death, with this being commuted to a life sentence – is unacceptable,” the Laureates said. “They are innocent, and the law and science can prove it, if they get the belated opportunity.”

If the six, who already have spent seven years in prison, are convicted on December 19, the case will go to an ultimate appeal in Libya’s Supreme Court. ♦

Blood Donor Test for Chagas’ Disease on the Horizon

With the expectation that the Food and Drug Administration soon will approve Ortho-Clinical Diagnostics’ (OCD) test for Chagas’ disease as a blood donor screen, there was standing room only at a special OCD seminar on the new assay held during the AABB meeting last month in Miami. Adding fuel to the fire, earlier in the meeting, American Red Cross Blood Services Medical Director, Richard Benjamin, MD reported that the organization is considering implementing a Chagas’ test – first in its donor service regions with a high risk for the disease and subsequently in other regions.

Opening the OCD seminar, David Leiby, MD, PhD, chief of Parasitology at Red Cross estimated that about 700 potentially infectious blood components are transfused each year in the United States. He based this statement on an estimate that 2.5 percent of donors are at risk for being infected with Chagas’ and an estimated 1 in 625 of these donors is positive.

Michael Busch, MD, PhD, vice president of Research and Scientific Programs at Blood Systems Research Institute and of Blood Systems Laboratories, reported data on OCD’s pre-clinical and clinical trials with the new Chagas’ test. The test is a parasite lysate ELISA that detects antibodies against diverse antigens – so it is very sensitive, he said. The test also has a high signal to cutoff, which produces a very low false positive rate.

In a pre-clinical trial in the US, the test detected 753 of 755 pedigreed specimens from Latin America. The two negative specimens were also RIPA negative. Subsequently, an unlinked study of 10,192 sequential donations from donors at United Blood Services in El Paso, Texas found three positive donations (two from the same donor) that were positive with a radioimmune precipitation assay (RIPA).

OCD’s clinical trial – a linked study of 44,381 donations (exceeding the company’s target of 40,000 donations) –found no true positives, Dr. Busch reported. He noted that, “at FDA’s request, donor sites were spread around the US, with about 8,000 donations per site.” Eight test samples were initially reactive and six were repeatedly reactive, for a “remarkable” specificity of 99.995 percent.

Red Cross Conducting Study in High Prevalence Areas. FDA asked OCD to expand its clinical studies to areas in the US where infection with Chagas’ is prevalent, Susan Stramer, PhD, executive scientific officer at American Red Cross Blood Services said. She reported that Red Cross currently is testing blood donor samples in Los Angeles, Oakland, California, and Tucson, Arizona.

To date, Red Cross has tested more than 60,000 donations, Dr. Stramer reported. Nineteen donations have been confirmed positive using RIPA. The positive donations came from all three regions and included one positive donor who had made 51 apheresis donations.

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On Blood Donation in Iraq

“Worst E-Mail Message: ‘The Walking Blood Bank is Activated. We need blood type A+ stat.’ I always head down to the surgical unit as soon as I get these messages, but I never give blood – there’s always about 80 Marines in line, night or day.”

– From a Marine’s letter from Iraq, published in Time Magazine, 10/6/06

Chagas’ Test (continued from page 5)

A challenge for the trial is FDA’s requirement for a specific donor consent for the test, Dr. Stramer said. Nearly 15 percent of donors in the trials declined to be tested.

In response to a question about the long-term future of Chagas’ testing, Dr. Stramer responded: “I think Chagas’ is for life – we’re not looking at recent infections.”

Confirmatory Testing. There currently is no gold standard for a confirmatory test for Chagas’ because no test has adequate sensitivity, not even RIPA, Dr. Stramer said. But RIPA is being used for the licensure studies and post-licensure, the assay could be performed by a reference laboratory.

Infection vs. Infectivity. There was considerable discussion about the meaning of positive ELISA test for Chagas’ followed by a positive RIPA. About 63 percent of RIPA positive samples are parasitemic, albeit intermittently so, Dr. Leiby said. “Not every case will be parasitemic, but how do you know which one is and which one isn’t,” he asked. It was also reported that a study of 7,296 donors at five Mexican blood banks located nine living recipients of RIPA positive blood donations. Four of the nine patients were RIPA positive. Two had received platelets and two had received whole blood.

FDA Silent, For Now. At a 2002 meeting of FDA’s Blood Products Advisory Committee, a FDA official said that if a good test for Chagas’ came along that fit the necessary criteria for a blood donor screen, it would be recommended. Although a representative of FDA was listed on the original program for the OCD seminar, FDA later decided against participation in the session. Speakers at the seminar predicted that the agency would issue recommendations to the blood services community when a test is licensed.

Donor and Patient Notification Troublesome Issue. “How are we going to handle informing donors and recipients about positive tests?” a member of the audience asked. Responded AABB Senior Medical Adviser Steven Kleinman, MD: “It reminds me of the early days of HIV when we were concerned about how to get recipients of HIV-repeatedly-reactive units tested.” The blood banking community may need to ask Ortho for help, he said, since “who will have the Ortho test other than blood banks?”

It was reported that a group of blood service representatives plan to meet with Centers for Disease Control and Prevention epidemiologists to “thrash out a protocol for people who are RIPA positive.”

An OCD representative said the company is planning to submit a protocol for testing cadavers in the first quarter of next year.

Abbott Laboratories is also developing a Chagas’ test, based on a recombinant antigen. According to informed sources, the company will soon meet with FDA for formal discussions about the licensure of its test. ♦

Northwest Florida Blood Center Holds Grand Opening for New Facility

Northwest Florida Blood Center (NFBC) yesterday welcomed donors and the public to its new laboratory and donor facility with a ribbon cutting by the Pensacola Bay Area Chamber of Commerce, a building tour, and a reception.

“The opening of this facility denotes a landmark event in the 56-year history of the non-profit blood center,” the blood center said in a press release (11/6/06).

NFBC was founded in 1948 and has operated since 1960 out of a 7,200-square-foot building. The new \$4.7 million, 28,000-square-foot building, completed in the summer, nearly quadruples the available space. It features a five-bed donor collections room, recruitment and administrative offices, and a 24-hour laboratory.



The new center features an expanded walk-in freezer for blood storage, an expanded blood component irradiation system, and an information technology department that uses research and other internal programs to protect donor information and blood products.

The old facility will be torn down to make way for an expanded parking lot. An adjacent building will be used as a donor collection site.

NFBC supplies blood and blood products to 20 hospitals throughout Florida and Alabama. It must collect 175 units of blood each day to keep up with the demand from the local hospitals. Last year, the blood center's lab processed more than 87,000 blood components and handled more than 500,000 test results. ♦

FDA Plans to Impose Stricter Medical Device Safety Standards

The Food and Drug Administration yesterday released recommendations for improving the post-market surveillance of medical devices. The plan includes a controversial proposal for marking each device with a unique number to serve as an identifier should there be post-marketing concerns.

Safety concerns for post-market monitoring of medical devices “grew after last year’s slew of high-profile recalls or safety warnings affecting more than 200,000 defibrillators,” according to the *Los Angeles Times* (11/10/06). The Heart Rhythm Society also has criticized FDA for not adequately responding

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On Tracking Medical Devices

“Companies like General Motors, Ford and Honda have a tracking number for every bolt and screw that goes into a car. Do we expect medical device companies to be less rigorous than automakers? No.”

–Michael Fitzmaurice, MD of the Agency for Healthcare Research and Quality in an interview with the Associated Press (10/24/06). The Food and Drug Administration met on October 25 with medical device makers and healthcare administrators to discuss whether medical devices sold in the US should be tracked through an electronic database.

New Medical Device Standards (continued from page 7)

to safety concerns and issued a call for action after announcements of the recalls, which involved devices manufactured by Medtronic, St. Jude Medical and Guidant.

“Many of today’s medical devices are smaller and more complex than ever, offering new medical opportunities that have benefited literally millions of people,” Scott Gottlieb, MD, FDA’s deputy commissioner for Medical and Scientific Affairs said in a FDA press release (11/9/06).

“But this technical sophistication sometimes means that the margin for error with device manufacturing shrinks and so we need to be working even harder, after devices and engineering changes are approved, to monitor for potential safety problems.”

Earlier this year, FDA assembled an in-house task force to investigate the problems. The task force’s report cites poor communication, a flawed safety reporting system and inadequate enforcement within the agency. In addition, the task force found that problems with devices are “vastly underreported” and that most data submitted to the agency on devices include “incomplete and unreliable” information. The task force released several recommendations to improve device surveillance that include the following:

- Overhauling FDA’s data system, expanding its current reporting system – called MedSun, which involves a network of 350 hospitals – and disseminating its findings to more medical professionals outside the network;
- Increasing access to outside databases, such as those maintained by doctor groups and other clinical professional organizations;
- Adopting a “culture of collaboration” between FDA and outside experts on safety issues to improve communication between groups that assess the safety of devices before and after they reach the market;
- Developing a unique tracking number for each medical device to serve as an identifier in the event of post-market concerns about a device;
- Improving the way FDA communicates with the public about recalled medical devices;
- Integrating the medical device data maintained by the Department of Veteran Affairs, the Department of Defense and CMS; and
- Expanding a pilot program that collects safety reports from hospitals in real time.

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Medical Device Safety (continued from page 8)

“The agency is committed to improving its medical device safety program and ensuring that medical devices and radiation-emitting products remain safe and effective once they are in the hands of health professionals and the public,” said Daniel Schultz, MD, director of FDA’s Center for Devices and Radiologic Health. “Postmarket systems that enable constant learning and feedback not only help support best medical practices to ensure safe use of devices with maximum effectiveness but they also spur continued innovation. This plan is a major step in that direction.”

Stephen Ubl, president of device maker trade group AdvaMed, said that manufacturers do not oppose the recommendations. But AdvaMed believes that a tracking system should be voluntary except when there is a well-documented patient safety issue that could be addressed by a tracking system. Any new requirements should be phased in over time, Mr. Ubl said.

According to today’s issue of the *Boston Globe*, a new Democratic-led Congress appears willing to make changes at FDA. John Manthei, FDA counsel for the Medical Device Manufacturers Association, said, “With congressional oversight, [FDA] is going to face a much tougher, much tougher environment,” adding that Democratic Reps. Henry Waxman (CA), John Dingelle (MI) and Bart Stupak (MI) “have made it very clear that FDA is squarely within their crosshairs.” ♦

UK to Pilot Electronic Tracking System for Blood and Transfusion Recipients

The UK National Patient Safety Agency (NPSA) has developed new measures to improve the safety of blood transfusions, including an electronic tracking system for patients and blood. NPSA has worked with Serious Hazards of Transfusion and the Chief Medical Officer’s National Blood Transfusion Committee (NBTC) on a ‘Right patient, right blood’ project to develop and evaluate new safety strategies, NPSA said in a November 9 press release. A key feature of the proposed system an outline specification for an Electronic Clinical Transfusion Management System (ECTMS).

The national specification was developed with the following objectives:

- to address the patient safety risks in the transfusion process;
- to identify IT requirements for a blood tracking system;
- to provide an initial specification for IT suppliers; and
- to provide an initial specification that can be extended to cover other clinical tracking operations.

The ECTMS specification focuses on the steps in the blood transfusion pathway. It was based on a widely used Software Requirements Specification template. The document does not yet provide sufficient detail for IT suppliers to develop the systems and software required for a complete solution, officials said, but it does give an overall context of the development, and a series of “use cases” describing the possible scenarios in each stage of the blood transfusion process.

The scope of the specification includes the automated tracking of blood products from “vein to vein,” including the initial ordering of a blood transfusion for a patient, through the taking of a blood sample for cross-matching, to administration of the blood transfusion. The document incorporates the traceability requirements of the UK’s 2005 Blood Safety and Quality Regulations.

The system can utilize either bar code technology or Radio Frequency Identification technology to eliminate errors during each stage in the chain of events. Starting in March 2007, the Welsh organization Connecting for Health and Informing Healthcare, with the support of the NPSA, will conduct a pilot with one or more acute healthcare organizations. ♦

EC Adopts Additional Regulations for Tissues & Cells

The European Commission last week adopted a second set of technical rules to help implement European Union legislation on quality and safety standards for human tissues and cells. A first set of regulations was adopted in February, setting out safety rules for the first phases of the process: donation, procurement and testing.

This second set of rules covers the subsequent phases: processing, preservation, storage and distribution. It also incorporates tissue coding requirements, measures to ensure traceability between donor and recipient and vice versa, and rules for reporting serious adverse reactions and events.

Among the measures specified in the directive are requirements for the accreditation of tissue establishments and tissues and cell preparation processes. It also details the procedures that tissue establishments must follow for notification of serious adverse reactions and events to the national health authorities, as well as the procedures for annual reporting on these notifications to the European Commission.

To ensure that all human tissues and cells are traceable from the donor to the end user and vice versa, the rules also defines the basis for a single European identifying code for all donated material.

“These rules will help to ensure a high level of public health protection in all Member States, and prevent the transmission of diseases via donated tissues and cells,” EC said in an October 25 press release.

The new rules and a Q & A document on the EC’s regulatory scheme for tissues and cells are available on the Web at: ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm under “What’s New.” ♦

West Virginia Trains Nonprofit Boards on Fiduciary Responsibilities

Following a high-profile charity fraud case, the State of West Virginia has teamed up with a nonprofit leadership-training group to offer a series of free, one-day seminars covering the financial, legal, and ethical responsibilities of not-for-profit board members, the *Chronicle of Philanthropy* reported (9/28/06)

“The average board member in a nonprofit in West Virginia, and I believe elsewhere, is a good person with good intentions but no experience in running an organization.”

**– First Commitment Director
John Hazlett**

The program was launched just weeks after a trial in federal district court of Robert Graham, director of a West Virginia nonprofit center for the elderly, who was accused of embezzling more than \$360,000 from his charity. In August, he was found guilty of improperly taking more than \$30,000 in sick leave, although he was cleared of the 38 other fraud and embezzlement counts brought against him. He will be sentenced in December.

The nonprofit First Commitment Corporation, a Wheeling group that trains board members, held six trustee-education seminars in October throughout the state. Betty Ireland,

West Virginia’s secretary of state, spoke at the seminars, and the state government promoted them, but they were funded by private sources.

Mr. Graham’s case included accusations that he hoodwinked elderly trustees while using charity funds to support a lavish lifestyle, and it helped focus public attention on the importance of active, educated charity boards.

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Fiduciary Responsibility of Nonprofit Boards (continued from page 10)

However, the need for greater trustee training has long been an issue, said First Commitment Director John Hazlett. Based on surveys his group has performed, he estimates that only 15 percent of trustees at the state's 7,700 charities know how to read a financial statement.

“The average board member in a nonprofit in West Virginia, and I believe elsewhere, is a good person with good intentions but no experience in running an organization,” Mr. Hazlett told *The Chronicle*. “We’re reaching just the tip of the iceberg.”

Mr. Hazlett stopped short of suggesting that West Virginia should require some form of training for anyone seeking to serve on a nonprofit board in the state. A bill requiring such training has been introduced in the state legislature but has not passed. “Such a move is premature and a practical challenge, and wouldn’t be able to get off the ground unless the state put up substantial funding, Mr. Hazlett said.” ♦

Stem Cell Products Should be Brought to Market with Care

Food and Drug Administration regulations for human cells, tissues, and cellular and tissue-based products provide “an appropriate regulatory structure” for the wide range of stem cell-based products that may be developed to replace or repair damaged tissue said former FDA Commissioner, David Kessler, MD and Dina Gould Halme, PhD, both of the School of Medicine at the University of California at San Francisco wrote last month in the *New England Journal of Medicine* (10/19/06).

Nevertheless, “basic and clinical scientists, as well as scientists working in the biotechnology and pharmaceutical industries, need an increased awareness of the questions that must be answered before a stem cell-based product can be used clinically,” they said.

Unlike pharmaceutical products, many stem cell-based products may originate in academic laboratories where researchers are unfamiliar with the applicable regulations, the authors noted. In a *NEJM* perspective, they outlined existing regulations for cell and tissue products that FDA is likely to apply to the preclinical development and testing of various types of stemcell-based therapies. They also made specific recommendations about how scientists should address the inherent safety and efficacy issues associated with these therapies.

Before filing an investigational new drug application for a stem cell-based product, the authors said, an applicant should be able to address the following questions:

- Does the donor pose a risk of transmitting infectious or genetic diseases?
- Does cell or tissue processing pose a risk of contamination or damage?
- What are the types of cells, and what are the purity and potency of cells in the final product?
- Will the product be safe and effective *in vivo*?

Scientists still have much to learn about determining the safety and efficacy of stem cell-based products, the authors asserted. In particular, the more that is known about the biology of self-renewal and differentiation, the more readily the risks of inappropriate cell function can be assessed. In addition, developing techniques to identify cells within a mixed population in culture and to track transplanted cells non-invasively *in vivo* will be critical for ensuring safety.

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Regulatory Framework for Stem Cell Therapies (continued from page 11)

As new stem cell-based therapies are developed, the regulatory framework is likely to evolve. Meanwhile, existing regulations pertaining to biologic products and human cells, tissues, and cellular and tissue-based products provide an appropriate structure for ensuring the safety and efficacy of the next generation of products. As they conduct research on stem cells, scientists should be aware of the relevant regulations and their likely application to stem cell-based products, the authors concluded.

Citation: Halme DG and Kessler DA. FDA Regulation of Stem Cell-Based Therapies. N Engl J Med 2006. Free full text available at: content.nejm.org/cgi/content/full/355/16/1730?query=TOC ♦

ABC MEMBER NEWS:

The Coastal Bend Blood Center's (CBBC) double red cell program tied for first place among 62 blood collection centers participating in a national campaign to increase the blood supply during the traditionally difficult summer months. Using Haemonetics' automated blood collection technology, CBBC achieved 132 percent of its targeted campaign goal. From July 17 through September 17, 2006, 251 blood donors donated using the technology, approximately doubling the amount of red cells obtained from a typical donation. CBBC's goal was to perform 190 procedures during the campaign. "The blood donor is becoming more and more precious every day," said Corey Survant, CBBC director of mobile collection. "By equipping our region with automated technology, we are able to secure twice the number of much-needed red cells from each donor, helping us to meet the increasing transfusion needs of our region's hospitals." He added: "Our goal is to continue to leverage technology and our success with this campaign to ensure that we have an adequate blood supply for all patients whenever and wherever it is needed." The "Save Lives this Summer" campaign was sponsored by the Haemonetics Corporation. Participating blood centers each utilized automated, double red cell collection technology from Haemonetics to collect two transfusable units of red blood cells, the most commonly transfused blood product, from a single donor. (Source: CBBC press release, 11/8/06) ♦



From July 17 through September 17, 2006, 251 blood donors donated using the technology, approximately doubling the amount of red cells obtained from a typical donation. CBBC's goal was to perform 190 procedures during the campaign. "The blood donor is becoming more and more precious every day," said Corey Survant, CBBC director of mobile collection. "By equipping our region with automated technology, we are able to secure twice the number of much-needed red cells from each donor, helping us to meet the increasing transfusion needs of our region's hospitals." He added: "Our goal is to continue to leverage technology and our success with this campaign to ensure that we have an adequate blood supply for all patients whenever and wherever it is needed." The "Save Lives this Summer" campaign was sponsored by the Haemonetics Corporation. Participating blood centers each utilized automated, double red cell collection technology from Haemonetics to collect two transfusable units of red blood cells, the most commonly transfused blood product, from a single donor. (Source: CBBC press release, 11/8/06) ♦

BRIEFLY NOTED

A Portland, Oregon woman who posed as the daughter of a hemophilia patient who contracted HIV through a blood transfusion was indicted last week by a federal grand jury on a single count of theft of government property and identity theft. Susan Rae Daily was accused of defrauding the Ricky Ray Hemophilia Relief Fund, which was set up in 1998 and provides for a \$100,000 payment to hemophilia patients who contracted HIV through blood transfusions or their survivors. The case centers on Michael Durr who died in 1990. According to court records, Mr. Durr was divorced at the time of his death, and his two children were entitled to inherit the payment. His son, Christian, received a \$50,000 government payment. A woman who claimed to be Michael Durr's daughter, Shannon, also received a \$50,000 payment. Court records say the woman was Christian Durr's girlfriend, Susan Rae Dailey. Christian Durr is serving a four-year sentence for first-degree robbery. The rightful beneficiary, Shannon Durr, said she was unaware that she was entitled to funds due to her father's death. (Source: *The Oregonian*, 11/2/06)

The House Energy and Commerce Committee last month released a letter sent to Centers for Disease Control and Prevention Director Julie Gerberding seeking information about the agency's reorganization, financial management office, and handling of human tissue samples and laboratory equipment. Dr. Gerberding launched the reorganization effort in June 2003. In their letter, Representa-

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BRIEFLY NOTED: (continued from page 12)

tives Joe Barton (R-TX), the committee's chair, and Ed Whitfield (R-KY), chair of the committee's oversight and investigations subcommittee, state: "Some CDC employees have raised concerns that these changes will make CDC more cumbersome and bureaucratic, taking time and resources away from scientific programs directly benefiting the public." In addition to requesting a copy of a draft report that in July identified problems with CDC's financial management office, the lawmakers requested a variety of information about the agency's activities, which have been under scrutiny by the Senate Finance Committee and Representative Henry Waxman (D-CA), ranking member on the House Government Reform Committee. According to the letter, "The committee's oversight interest is to ensure that the CDC effectively manages its financial resources and its reorganization." The requested information concerning CDC's handling of tissue samples stems from problems discovered during a separate investigation of National Institutes of Health, which found that a senior NIH scientist had shared thousands of tissue samples with a pharmaceutical company, a House Energy and Commerce Committee release states. Representatives Barton and Whitfield asked the agency to respond to the letter by November 6. CDC spokesperson Tom Skinner said the agency will cooperate with the committee's requests. (Source: *Atlanta Journal-Constitution*, 10/25/06).

Provena Covenant Medical Center, a nonprofit hospital in Urbana, Illinois that was stripped of its property-tax exemption in a dispute over how much charity care it provides, has appealed the decision. Lawyers for the hospital said the September ruling by Brian Hamer, director of the Illinois Department of Revenue, contained many errors. The hospital lost its tax-exempt status because Mr. Hamer said the hospital's 2002 charitable care amounted to \$832,000 or 0.7 percent of its \$113.5 million in revenue. Provena argued that Mr. Hamer's figure showed only free care and did not include other expenses, like the hospital's coverage of patients' bad debt, and costs not covered by the Medicaid health-insurance program for the poor, or other community programs it offers patients. The hospital says it provided more than \$13 million in care and services for which it was not compensated in 2002. The hospital first lost its tax exemption three years ago when the Champaign County Board of Review said it aggressively attempted to collect money from poor and uninsured patients. The case is being watched closely by other nonprofit hospitals, officials at the American Hospital Association said, because such challenges are becoming more common and the Provena case is the furthest along in the legal process. (Source: *Chicago Tribune*, 10/27/06)

More US not-for-profit healthcare providers are revising investment policies and reallocating portfolios to include alternative investments, Standard & Poors reported last month. And despite perceived risks, the trend is expected to continue, with providers using the slightly more aggressive strategy to diversify risk and boost investment returns. Much of the money allocated to alternative investments has gone into hedge funds, although the term generally also includes private equity investments and real estate. S&P said its not-for-profit healthcare group is neutral on the use of alternative investments as it relates to credit ratings, but such investments' unique risks and characteristics require more disclosure, analysis and monitoring of portfolios and oversight procedures. Many of S&P's 700 rated healthcare providers have unrestricted cash and investment balances that can constitute as much as half of their total assets, S&P said. (Source: *AHA News Now*, 10/20/06)

REGULATORY NEWS

Dupaco, Inc. this month recalled of four lots of its Blood/Fluid Warming Set (Product Number: D25480) after learning of two leakage failures out of approximately 12,000 distributed. Customers have been asked to contact Dupaco to arrange for product return. (Source: Center for Biologics Evaluation and Research Web site: www.fda.gov/cber/recalls/dupaco101106.htm)

(continued on page 14)

Nominations for International Women in Transfusion Award Due Nov. 3

In 2004, for the first time in their collective histories, three of the major transfusion medicine organizations in the world – AABB, the British Blood Transfusion Society and the International Society for Blood Transfusion (ISBT) – were led by women professionals. To commemorate this occurrence, the three organizations established a unique award to honor women for lifetime achievements in transfusion medicine and science. Each year, the award acknowledges women professionals whose cumulative record – in original research, innovative educational methods or outstanding clinical practice – demonstrates important and significant contributions to the body of medical and/or scientific knowledge or to the understanding and practice of transfusion medicine. The awardee will receive full travel support to present an award lecture during the annual meeting of one of the three societies and a prize of 1,000 Euros. Eligible for nomination are female physicians or scientists with an advanced degree, mature in their career in transfusion medicine and/or science, and a member of at least one of the three societies.

Application forms can be downloaded at www.isbt-web.org/awards/womenintransfusion.asp

REGULATORY NEWS (continued from page 13)

CBER has posted on its Web site three lists of Donor Screening Tests for Testing HCT/P Donors: Licensed Donor Screening Tests with Approved Indications for Testing HCT/P Donors (HBV, HCV, HIV and WNV); Cleared Nucleic Acid Tests (NAT) for *Chlamydia trachomatis* and *Neisseria gonorrhoea*; and cleared Donor Screening Tests for Cytomegalovirus. According to CBER, all donor screening tests for HCT/P donors have indications for use for individual donor testing (not for testing in mini-pools). The lists are available at: www.fda.gov/cber/tissue/prod.htm. Additional information on other donor screening tests with indications for use in living donors can be found at www.fda.gov/cber/products/testkits.htm

SCIENCE, MEDICINE, AND TECHNOLOGY

The Food and Drug Administration has posted on its Web site a transcript and slides from its recent Workshop on Molecular Methods in Immunohematology. The transcript is available at www.fda.gov/cber/minutes/workshop-min.htm#immuno and slides from the workshop are available at: www.fda.gov/cber/summaries.htm#immuno

The Medical College of Wisconsin has received a five-year, \$9.7 million National Heart, Lung and Blood Institute Program Project Grant for genetic studies to improve the molecular and clinical understanding of von Willebrand disease (VWD). Pediatric hematologist Robert Montgomery, MD, professor of pediatrics at the Medical College and senior researcher at the Blood Research Center of the BloodCenter of Wisconsin, is principal investigator for the grant. “There is a lack of understanding of the genetic causes of low or abnormal VWF, and the molecular mechanisms involved in the disorder,” Dr. Montgomery said. “While a large number of individuals have low VWF with abnormal bleeding symptoms, it is not scientifically clear if this is a disease, or if VWF is a continuous risk-factor for bleeding. For many practicing physicians, the general understanding of this group of disorders has not been optimal, and how to evaluate and treat these patients has been unclear.” The program involves three distinct research projects and two core facilities, one for administrative support and participant recruitment, and another for clinical laboratory and genetic sequencing services. The projects will determine the clinical

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SCIENCE, MEDICINE AND TECHNOLOGY (continued from page 14)

and genetic characteristics of a large number of VWF patients as well as carriers of genes for various forms of the disease. They will also explore the impact specific combinations of these genes and unrelated genetic mutations may have on individuals and families, in terms of their clinical symptoms and other traits revealed by laboratory analysis. NHLBI's program project grant mechanism is designed to support synergistic research, in which the funding of several interdependent projects as a group offers significant scientific advantages over supporting these projects as individual research grants. (Source: Medical College of Wisconsin, 10/26/06)

Autologous platelet-rich plasma (PRP) can promote healing in a wide range of medical and surgical situations, but evaluation of its effectiveness has been limited by the lack of a universally accepted approach to measuring platelet concentrations. A study in the current issue of *The Journal of Craniofacial Surgery* (September/October 2005) presents an approach to accurately measuring platelet counts in PRP preparations, using standard hematology equipment. Jennifer Woodell-May, PhD, and colleagues at Biomet, Inc., of Warsaw, Indiana used a conventional automated hematology analyzer that was capable of measuring platelet counts of up to 2 million platelets per microliter – relatively high, but below the very high counts contained in PRP preparations. They measured platelet concentrations in PRP specimens in two ways: using their automated approach and a time-consuming manual count technique. They found no significant difference between the automated and manual counts. The average amount of variation was significantly lower with the automated technique: about three percent, compared to seven percent with the manual count technique. The automated counts were highly accurate, even though the platelet concentrations contained in the PRP preparations were beyond the limit of the hematology equipment in typical use, the authors said. Platelet concentrations of over 3 million cells per microliter were accurately measured. Further studies suggested that accurate measurements could be made at platelet concentrations up to 4.8 million per microliter. “The ability to accurately measure platelet counts in PRP preparations is an important step forward in determining the true clinical value of these blood concentrates,” said Dr. Woodell-May. “We hope our platelet suspension technique and system validation method will aid in creating standardized PRP preparations with more predictable results, as well as in comparing the results of studies from different research groups.” (Source: Newswise, 9/29/06).

COMPANY NEWS

The Food and Drug Administration last month approved Octapharma's blood license application for Albumin (5% and 25%). The product is labeled for restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of a colloid is appropriate. FDA's approval letter and product labels are available on the Web at: www.fda.gov/cber/products/-albocla101706.htm

Biotest Diagnostics Corporation (BDC) last month submitted biologic license application and 510(k) premarket notification submissions to the Food and Drug Administration for an expanded test menu on its TANGO Automated Blood Bank System. TANGO originally was cleared by FDA in July 2005 and is marketed in North America to hospitals through BDC and to donor centers through Olympus. The system currently is licensed for applications that cover the majority of the normal test workload in the transfusion service. Current assays include patient and donor ABO/Rh testing, antibody screening using three different Reagent Red Blood Cell configurations, and donor ABO and Rh confirmation testing. The new applications that are currently under FDA review include antibody identification, Rh phenotyping, K1 phenotyping, crossmatching, direct antiglobulin testing and a weak D assay. US market release for the new applications is anticipated in 2007, Biotest said. The expanded TANGO test menu is currently available in Europe through Biotest AG, the manufacturer of the system. (Source: BDC press release, 10/20/06)

COMPANY NEWS (continued from page 15)

Australia's CSL Ltd. this week agreed to buy the drug CytoGam – used to protect organ transplant patients from cytomegalovirus (CMV) – for US \$120 million from MedImmune Inc. MedImmune reported annual sales of \$40 million from CytoGam in 2005, and CSL's investor relations manager Mark Dehring said sales are expected to increase to around \$50 million over time. Australian market analyst Andrew Goodsall estimated the acquisition would add around A\$10 million to CSL's profit next year. CSL has forecasted a net profit between A\$400 million and A\$420 million for this year. "It's a nice, straight bolt-on acquisition," Mr. Goodsall said. The acquisition includes patents and trademarks and manufacturing contracts associated with the products. (Source: Reuters, 11/9/06) ♦

INFECTIOUS DISEASE UPDATES

Chronic diseases are being overlooked worldwide even though they kill more people than any other type of illness, a panel at the Center for Strategic and International Studies said recently. Chronic diseases – most of which are noncommunicable illnesses such as heart disease, cancer and diabetes – often go ignored because they are not as "dramatic" as infectious diseases such as HIV/AIDS or avian flu, according to panelist Olusoji Adeyi, coordinator of public health programs at the World Bank. According to the World Health Organization, more people die annually from cardiovascular disease than AIDS, tuberculosis and malaria combined. WHO estimates that chronic diseases account for 60 percent of global deaths and will account for about three-quarters of deaths by 2020. According to Rachel Nugent, director of health and economics at the Population Reference Bureau, many people hold the inaccurate view that chronic diseases mostly affect old and rich populations. In fact, about 50 percent of the people who die from chronic disease are younger than age 70, and 80 percent of chronic disease deaths occur in low- and middle-income countries, Ms. Nugent said. She called the current approach to treating such diseases "nonexistent to fragmented," adding that chronic diseases lead to increased medical costs and a dwindling workforce. The panel called for more research and an open approach to chronic disease that encompasses an array of ailments and countries worldwide (Source: *CQ HealthBeat*, 10/12/06).

AIDS

After years of international criticism over its handling of the AIDS epidemic, the South African government is taking steps to turn its HIV/AIDS program around by expanding prevention, treatment and testing, observers say. Driving the change is the government's growing realization of the severity of the problem, an estimated 5.4 million of its 47 million citizens have HIV, and concern that the controversy surrounding its efforts is harming South Africa's international image. First, the appointment of Deputy President Phumzile Mlambo-Ngcuka to lead an urgent review of South Africa's AIDS response. In public comments and private meetings over the past six weeks, she has emphasized that the government now believes unequivocally that HIV causes AIDS, a connection President Thabo Mbeki once publicly questioned. She has also acknowledged "shortcomings" in the government's response to HIV/AIDS thus far. Second, after years of hostility and legal clashes, AIDS groups like Treatment Action Campaign say government officials are reaching out to them to meet activists' long-standing demands, such as setting targets for expanding the country's free antiretroviral program to reach 1 million South Africans. "There's clearly a shift taking place," said Treatment Action Campaign leader Zackie Achmat. Finally, government officials privately acknowledge that Health Minister Manto Tshabalala-Msimang, who has long supported a diet of lemons, beets, and garlic while downplaying the effectiveness of ARVs in HIV treatment, has become an embarrassment. Activists say they are confident she has been effectively marginalized by Mlambo-Ngcuka's appointment. "The beetroot and all that lemon stuff is out the window," said an adviser who spoke on the condition of anonymity. "These guys are now serious about

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INFECTIOUS DISEASE UPDATES (continued from page 16)

getting it right.” “[The government] has lost at least five years,” said Mark Heywood, director of the AIDS Law Project at Witwaterstrand University in Johannesburg. “They’re behind on prevention. They’re behind on treatment. They’re behind on planning for the social impact of HIV. But it’s not too late to prevent a whole other generation of people from getting HIV.” (Source: *The Washington Post*, 10/27/06)

New HIV diagnoses in Australia jumped by 41 percent in five years, from 656 cases in 2000 to 930 in 2005, the Australian National Center in HIV Epidemiology and Clinical Research (NCHECR), reported last week. The report is fueling concerns that advances in treatment are giving people a false sense of security about needing to practice safe sex. Of the new cases, the study found that gay men made up 70 percent and heterosexuals 19 percent, while IV drug use and unknown transmission routes accounted for the rest. New HIV infections in Australia hit an all-time high of around 1,700 in 1984, then steadily declined in the late 1990s before increasing in 2000, the report said. “It’s very possible that people are just not prioritizing safe sex as they maybe used to in the very serious HIV/AIDS era” of the late 80s and early 90s, said NCHECR Deputy Director John Kaldor. “It might be here that improvements in HIV treatments have lessened the motivation for people to protect themselves sexually.” (Source: Associated Press, 10/12/06)

BACTERIAL CONTAMINATION/DETECTION

Abbott has entered into an exclusive distribution agreement with Verax Biomedical Inc., which is developing rapid tests for detecting bacterial contaminants found in blood cells and tissue. The pact gives Abbott worldwide rights to market and distribute the Verax Platelet PGD Test, which is currently being evaluated in clinical trials. The test is a disposable device designed to detect the presence of a broad range of bacterial contaminants in platelets just prior to transfusion. “Our partnership with Verax will allow us to provide our blood bank and hospital customers with an important test to address the risk of bacterial contamination in transfusion medicine, and further emphasizes Abbott’s commitment to enhance the safety of the world’s blood supply,” said Jeff Binder, senior vice president, Diagnostic Operations, Abbott. The Verax Platelet PGD Test is based on Verax Biomedical’s “Pan Genera Detection” technology, which targets common antigens found on the surface of all species of bacteria known to be pathogenic to humans. Clinical trials of the test currently are underway. (Source: PR Newswire, 10/20/06)

TICK-BORNE INFECTIONS

African tick bite fever, unknown outside of endemic areas a decade ago, now is considered the most important rickettsial infection that occurs in international travelers. In the September issue of the *Archives of Dermatology*, investigators from the Germany and the United States reported three cases of African tick bite fever, endemic in sub-Saharan Africa, among international travelers – two from Germany and one from Kentucky. All three – who had flu-like symptoms, rash, and crusted ulcers at the site of tick bites – were diagnosed and successfully treated within a short time after returning from Africa. “Early antibiotic treatment is necessary to avoid systemic involvement, including renal failure, myocarditis, pneumonia, encephalitis, hepatitis and death,” the German authors cautioned in their report. Risk factors for African tick bite fever include game hunting, safari tourism, travel in the rainy season between November and April, and travel to southern African. “With the increase in international travel, it is important to recognize the illness in those who have been to endemic countries and to counsel patients regarding preventive measures for planned travel,” the American authors cautioned. (Citations: Owen CE *et al.* African tick bite Fever: a not-so-uncommon illness in international travelers. *Arch Dermatol* 2006;142:1312-14; Buchau AS *et al.* Fever, episcleritis, epistaxis, and rash after safari holiday in Swaziland. *Arch Dermatol* 2006;142:1365-6)

(continued on page 18)

INFECTIOUS DISEASE UPDATES (continued from page 17)**WEST NILE VIRUS**

The Ontario Court of Appeal has dismissed a lawsuit brought for damages against the government of Ontario by 40 people who contracted West Nile virus. The plaintiffs alleged that the provincial government failed to take reasonable steps to curtail the West Nile outbreak and to warn them and others about the risk. The province moved to dismiss the lawsuit on grounds that Ontario's only duty of care lay with the public at large, and not with specific individuals. The Ontario Court of Appeal agreed with the province and, in overturning two lower court decisions on the matter, held that Ontario owed no private duty to the individual plaintiffs and that the case could not proceed. In his holding, Justice Robert Sharpe stated, "I agree with Ontario's submission that to impose a private law duty of care on the facts that have been pleaded here would create an unreasonable and undesirable burden on Ontario that would interfere with sound decision-making in the realm of public health." Douglas Elliot, a lawyer for the plaintiffs, responded to the ruling with dismay. "If this ruling is allowed to stand, it may mean that ordinary people can never hold public health officials accountable in a court of law when their careless mistakes hurt and even kill people," he said. Among other allegations, the lawsuit argued that the province of Ontario established a plan to protect citizens from the virus but failed to carry it out. The Ontario Court of Appeals' decision in *Eliopoulos and Her Majesty the Queen in Right of Ontario*, is available on the Web at: www.ontariocourts.on.ca/decisions/2006/november/C44577.pdf

PEOPLE:

After serving 25 years as executive director of United Blood Services in Louisiana, **Dwight Sledge** recently moved to Mississippi to become executive director of UBS, Natchez Trace Region, which includes most of Mississippi, and western Alabama. In a letter to donors, Mr. Sledge said the move will, "allow me to be closer to my granddaughters and eldest daughter and spend more time with them." In 1971, Mr. Sledge walked into a blood bank in Jackson, Mississippi to meet a friend, and his life changed forever. The branch-manager at United Blood Services desperately needed a new delivery man, and Mr. Sledge, who was in college at the time, could use the money. He was hired on the spot for a job he knew nothing about, and he delivered blood to an area hospital that day. Mr. Sledge instantly fell in love with the non-profit organization and moved up through the ranks of UBS. He worked in the lab, recruited blood donors and became an administrator in 1977. He was named executive director of UBS-Louisiana in 1981. **Susan Begnaud** has been named interim executive director of UBS in Louisiana.

Canadian Blood Services has named **Dana Devine, PhD** vice president of medical, scientific & research affairs (MSRA) and a member of its executive management team. Dr. Devine has served since March as acting MSRA vice president. She joined Canadian Blood Services in 1999 as executive director of Research and Development. Since that time, she "has played an integral role in a number of the initiatives that have transformed this organization including the development of our Network Clinic for Advancement and Development, a development lab at the University of British Columbia in Vancouver, for which she was the visionary," said blood services CEO Graham Sher, MD. In her new position, Dr. Devine is responsible for the direction and management of Canadian Blood Services' medical division, leading the organization in knowledge creation and dissemination, surveillance and epidemiology activities, and research and development.

Cynthia Dunbar, MD, a senior investigator at the National Institutes of Health, has been selected as the 2008-2012 editor-in-chief of the hematology journal, *Blood*. Dr. Dunbar has been an associate editor of the journal for nearly nine years, and has served on the editorial boards of other journals, including *Molecular Therapy*, *Cancer Gene Therapy*, and *Stem Cells*. She will succeed **Sanford J. Shattil, MD**. During the next year, Dr. Dunbar will assume increasing responsibilities under Dr. Shattil's guidance,

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PEOPLE (continued from page 18)

and her five-year term will officially begin with the January 1, 2008, issue of *Blood*. She will be the first female editor-in-chief of *Blood*, which was first published in 1946. Noting that her appointment sends a positive message to the many other women active in hematology, Dr. Dunbar has said that she hopes to increase the diversity of the pool of associate editors during her tenure. Dr. Dunbar graduated *magna cum laude* from Harvard University with a degree in the history of science and received her doctorate from Harvard Medical School. She currently heads the Molecular Hematopoiesis Section of the National Heart, Lung, and Blood Institute. ♦

INFORMATION RESOURCES**Employer Rights and Responsibilities Following an OSHA Inspection, Occupational Safety and Health Administration**

www.osha.gov/Publications/osha3000.pdf

OSHA has updated its informational guide on Employer Rights and Responsibilities Following an OSHA Inspection and posted it on the agency's Web site. Topics include: types of violations; posting requirements; informal conference and settlement, how to contest citations, petition for modification of abatement, follow-up inspections and failure to abate, employer discrimination, and resources for assistance.

HIV Testing Laws Compendium

www.ucsf.edu/hivcntr/PDFs/WEB2006State%20Laws.pdf

The National HIV/AIDS Clinicians' Consultation Center has released an updated *State HIV Testing Laws Compendium*. The 1,100-page document describes each state's policies, rules, and regulations on HIV testing and provides state-by-state comparisons. ♦

FROM THE MEDICAL LITERATURE:

A paper published earlier this year in *Blood* challenges the common belief that hemophilia carriers are not at risk for bleeding. Dutch researchers reported the largest survey to date of hemophilia carriers, compared their factor levels to non-carriers; and demonstrated that, even at levels of coagulation factors considered hemostatic, these patients bleed substantially more than expected. Using questionnaires, the researchers studied analyzed 274 carriers and 245 non-carriers for bleeding patterns, use of oral contraception, DNA analysis, and factor levels. "This large series of women studied in the Netherlands teaches us a great lesson. Carriers, *per se*, need to be evaluated, assayed and counseled, prepared to deal with bleeding, and appropriately managed for surgical intervention, Louis Aledort, MD, of the Mount Sinai School of Medicine in New York City said in a related commentary. The major contribution of the paper, he said, is the demonstration that carriers with factor levels between 40 percent and 60 percent had an increased risk of bleeding compared with controls and that the risk increases as the levels decrease. "These findings, as stated in the paper, challenge the International Society on Thrombosis and Haemostasis (ISTH) definition of hemophilia, which states that the disease is defined as present in persons with factor levels less than 40 percent." He continued: "The importance of measuring the factor level of carri-

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FROM THE MEDICAL LITERATURE (continued from page 19)

ers is highlighted by these data not only to better understand the natural history of carriers, but to optimize perioperative and postoperative management of these patients.”

Citations: Plug I *et al.* Bleeding in carriers of hemophilia. *Blood* 2006;108 52-56; Aledort L. Do hemophilia carriers bleed? Yes. *Blood* 2006;108:6. ♦

Cell salvage is effective in reducing the need for allogeneic red cell transfusion in adult elective surgery, Australian researchers reported last month after a review of published studies. However, “as the trials were unblinded and lacked adequate concealment of treatment allocation, transfusion practices may have been influenced by knowledge of the patients’ treatment status biasing the results in favor of cell salvage,” they cautioned. The authors selected controlled parallel group trials in which adult patients, scheduled for non-urgent surgery, were randomized to cell salvage, or to a control group, who did not receive the intervention. Two authors independently screened the search results, extracted data and assessed methodological quality. The main outcomes measures were the number of patients exposed to allogeneic red cell transfusion, and the amount of blood transfused. Other outcomes measured were re-operation for bleeding, blood loss, post-operative complications (thrombosis, infection, non-fatal myocardial infarction, renal failure), mortality, and length of hospital stay (LOS). Overall, the use of cell salvage reduced the rate of exposure to allogeneic RBC transfusion by 39 percent. The absolute reduction in risk of receiving an allogeneic RBC transfusion was 23 percent. In orthopedic procedures the relative risk of exposure to RBC transfusion was 0.42 compared to 0.77 for cardiac procedures. The use of cell salvage resulted in an average saving of 0.67 units of allogeneic RBC per patient, the study found. “Cell salvage did not appear to impact adversely on clinical outcomes,” the authors reported.

Citation: Carless PA *et al.* Cell salvage for minimising perioperative allogeneic blood transfusion. *Cochrane Database Syst Rev.* 2006;18:4.

MEETINGS:

Nov. 15, 2006 ***ISBT 128: Making the Transition, Audioconference, AABB, 2:00 - 3:30 pm (ET); 7:00 - 8:30 pm (GMT); Program #064589***

Suzanne Butch, University of Michigan Hospitals, and Kim Peck, Community Blood Center of Greater Kansas City will provide an overview of ISBT 128 and how it is used in process control. They also will describe the implementation of ISBT 128: planning, process validation, and troubleshooting strategies.

Contact: AABB Meetings and Programs Department. Tel: (301) 215-6482; E-mail: meeting@aabb.org; Web site: www.softconference.com/aabb/AC.asp

Feb. 17-18, 2007 ***SBB “Last Chance” Review for Specialist in Blood Banking Registry Exam. Gulf Coast Regional Blood Center, Houston, Texas***

This program is designed for individuals preparing to take the ASCP Registry examination for Specialist in Blood Banking. Physicians who are preparing for the Board examination in Blood Banking and individuals wishing a refresher in blood banking can also benefit from this program.

Contact: Clare Wong. Tel: (713) 791-6201, E-mail: cwong@giveblood.org; Web: www.giveblood.org/education/lastchance.htm ♦

CLASSIFIED ADVERTISING:

Classified ads (including positions available and wanted) are published free of charge for ABC institutional members. There is a charge of \$100 per placement for ABC Newsletter subscribers and \$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) 393-1282; E-mail: ddulac@americasblood.org.

LOST & FOUND. Bracelet found at ABC reception in Miami Beach. To claim, contact Lori Beaston lbeaston@americasblood.org or call (202) 654-2901.

POSITIONS AVAILABLE:

Operations Data Manager. New York Blood Center, one of nation's largest community based independent research, blood & clinical services organizations, has challenging opportunity for Operations Data Manager in our Core Operations department. Position requires knowledge of all databases as well as ability to write & understand business information needs using SQL queries & VBA. Position will interact with all levels of organization to educate in utilization of reports & other solutions through our internal & external database systems. Ideal candidate will have B.S. with concentration in Science, Engineering or Accounting. Significant experience with Microsoft Excel and SQL required. Strong quantitative & analytical skills required. The candidate must be able to work independently on various assignments, as well as, collaboratively with project members. Competitive salary & benefits package. Send resume with salary requirements to: New York Blood Center, HR/JG, 150 Amsterdam Avenue, New York, NY 10023. Fax: 212-721-2752. Email: careers@nybloodcenter.org. EOE M/F/D/V

Director of Patents & Licensing/Business Development, New York Blood Center, one of nation's largest community based independent research, blood & clinical services organizations, has challenging opportunity for Director of Patents & Licensing/Business Development to serve as principal resource, negotiator & advisor to senior management for Intellectual Property & Bus. Development. Individual will possess scientific education with eight yrs. exp. in licensing & contract administration with min. five yrs. management exp. MBA also pref'd. Ideal candidate will be responsible to advise management of contractual rights & obligation & provide interpretation of terms & conditions. He/She will have excellent negotiating, time management, decision-making & communication skills to work with all levels of research professionals. Candidates must be able to present clear & compelling manner to internal & external customers & provide executive summaries for new & existing products. Must have excellent interpersonal/oral/written communication skills. Competitive salary & benefits package. Send resume with salary requirements to: New York Blood Center, HR/JG, 150 Amsterdam Avenue, New York, NY 10023. Fax: 212-721-2752. Email: careers@nybloodcenter.org. EOE M/F/D/V

Director, Business Solutions, New York Blood Center, one of nation's largest community based independent research, blood & clinical services orgs. has challenging opportunity for Director, Bus. Solutions in Core Operations dept. Blood centers have high regulatory burden for maintaining information on donors, products & patients. This information has been historically accessible through proprietary systems, incapable of processing & delivering data for purposes of business management. Within this year, NYBC has developed database/web solution (called BOSS) that can access legacy system, connect information with other data sources & delivery content to blood center users. BOSS has delivered savings of over \$five million/yr & begun to change culture of organizations. Based on demand from blood centers worldwide, NYBC will provide BOSS as an IT solution/consulting service. The Dir. of Bus. Solutions will be responsible for leading application of BOSS to business problems for NYBC and its future customers. The role will be part internal& part external consultant in order to meet organizational needs for operations support. The role will begin with three direct reports & is expected to grow. Intl. travel is req'd, but should not exceed 20%. This requires excellent analytical & communicative skills, ability to understand, rectify, & troubleshoot blood center processes & potential processes, & hands-on understanding of modern database/web technology that will enable leadership of creating solutions. MBA + science/engineering/math undergrad or PhD in science/engineering/math two+ years consulting exp. Competitive salary & benefits package. Send resume with salary requirements to: New York Blood Center, HR/JG, 150 Amsterdam Avenue, New York, NY 10023. Fax: 212-721-2752. Email: careers@nybloodcenter.org. EOE M/F/D/V

Executive Director/VP, Long Island, New York Blood Center, one of nation's largest community-based independent research, blood & clinical service organizations in country, seeks Executive Director/VP to oversee Blood Center's operation in Long Isl. Region. You will be responsible for region's recruitment efforts, blood collection, blood products & services, & the product distribution. Essential to role is local development of community product corporate relationships. Additional responsibilities include, but are not limited to: Developing short & long term plans that address competition, market

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share, customer service, employee morale; Hiring, counseling, motivating & assessing staff performance, which includes developing staff goals & objectives; Assuring legal & regulatory compliance; Establishing & measuring staff productivity, efficiency of blood drives, donor retention & donation frequency; Preparing annual budgets to support attainment of strategic plans; Collaborating with two unions on labor relation matters, etc. Req'd: Candidate must have BA or BS degree, preferably in management, healthcare, or medical technology. Must have eight plus yrs of management exp., preferably in Healthcare, Pharmaceuticals or FDA controlled industry. Must have exp. & knowledge of FDA regulations & other related federal, state & local health governing agencies, which is inclusive of maintaining legal & regulatory compliance. Exp. working in collaborative environment at executive level where consensus building & independent leadership traits are needed. Strong leadership & team building skills necessary. Demonstrated ability to hire, counsel, motivate & assess staff performance. This includes developing goals & objectives that will have overall impact on growth of respective region & its employees. Ability to develop short & long term plans that address competition, market share, customer service, & employee morale issues is essential. Exp. working with unions & labor negotiations req'd. **Pref'd Qualifications:** Advanced &/or professional degree desired in related healthcare field (MS, MBA, MD, etc); Exp. managing Blood Banks/Collections desirable; Working knowledge of Not-for-Profit operations desirable; Exp. with Donor Recruitment; Exp. with mobile staff working in large geographic area. Exp. with Logistics/Transportation Department; Exp. managing medical laboratories. Competitive salary & benefits package. Send resume with salary requirements to Attn: HR Dept – MC, email: mcurrin@nybloodcenter.org or Fax: 516-478-5243. Qualified candidates will be contacted. EOE M/F/D/V. NO CALLS PLEASE.

Executive Director/VP, Hudson Valley. New York Blood Center, one of nation's largest community-based independent research, blood & clinical service organizations in country, seeks Exec. Director/VP to oversee Blood Center's operation in Hudson Valley Region. Responsible for region's recruitment efforts, blood collection, blood products & services, & product distribution. Essential to role is local development of community & corporate relationships. Additional responsibilities include, but are not limited to: Developing short & long term plans that address competition, market share, customer service, employee morale; Hiring, counseling, motivating & assessing performance of staff, which includes developing staff goals & objectives; Assuring legal & regulatory compliance; Establishing & measuring productivity of staff, efficiency of blood drives, donor retention & donation frequency; Preparing annual budgets to support attainment of strategic plans; Collaborating with two unions on labor relation matters, etc. **Req'd:** BA or BS degree, preferably in management, healthcare, or medical technology; eight plus yrs of management exp., pref'd in Healthcare, Pharmaceuticals or FDA controlled

industry. Must have exp. & knowledge of FDA regulations & other related federal, state & local health governing agencies, which is inclusive of maintaining legal & regulatory compliance. Exp. working in collaborative environment at executive level where consensus building & independent leadership traits are needed. Strong leadership & team building skills. Demonstrated ability to hire, counsel, motivate & assess staff performance. Developing goals & objectives that will have overall impact on growth of respective region & its employees. Ability to develop short & long term plans that address competition, market share, customer service, & employee morale issues. Exp. working with unions & labor negotiations req'd. **Pref'd Qualifications:** Advanced &/or professional degree desired in related healthcare field (MS, MBA, MD, etc); Exp. managing Blood Banks/Collections desirable; Working knowledge of Not-for-Profit operations desirable; Exp. with Donor Recruitment; Exp. with mobile staff working in large geographic area. Exp. with Logistics/Transportation Dept.; Exp. managing medical laboratories. Competitive salary & benefits package. Send resume with salary requirements to Attn: HR Dept – LR, with HV E. D. in Subject; email: Lrobinson@nybloodcenter.org or Fax: 914-784-4638. Qualified candidates will be contacted. EOE M/F/D/V. NO CALLS PLEASE.

Training & Education Manager #294. Inland Northwest Blood Center, located in beautiful Pacific Northwest, is seeking Training & Education Manager responsible for managing identification, development, maintenance, & implementation of system-wide training policies & programs. Bachelor's degree in Education, Training & Development, or healthcare technical field; four-years' related exp. to include exp./training in development of training systems, curriculum design, &/or training assessment, or equivalent combination of education/exp. Exp. with e-Learning & Learning Management Systems desired. Exp. in blood banking/healthcare environment &/or related technical background pref'd. Demonstrated knowledge of adult learning theory, & design, development/implementation of variety of methodologies; ability to conduct needs surveys, establish training goals/objectives; excellent presentation/training skills; ability to develop/motivate others to accomplish goals. Competitive compensation/benefits package; Applicants send/fax completed INBC Application & Resume to Human Resources, INBC, 210 W Cataldo Ave, Spokane WA 99201; FAX (509) 232-4530 on/before 11/30/06. Applications are available on our Web site at www.inbc2.org. EOE/AAP

Director, Technical Services II. Exciting opportunity to head great team for national leader in blood banking. United Blood Services is seeking exp'd, results-oriented individual to provide center management in Meridian, MS. Responsible for technical oversight of laboratory & technical support functions. Serve as technical subject

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matter expert. Oversee blood center management of assigned departments. Assures cGMP are in place for manufacturing processes including SOP's, training & competency, & error management. Bachelor's degree in chemical, physical, biological, medical technology or clinical laboratory science req'd. Certification as Medical Technologist by recognized certifying agency req'd. BB or SBB pref'd. State licensure (as req'd by regulations). Five years laboratory exp. req'd. Three years supervisory exp. req'd. Previous blood bank or blood center exp. pref'd. Excellent benefits, competitive salary, & solid relocation package. **Send resume by 11/17/06**, indicating job #216-1601-2006-42 to: United Blood Services, Attention: Human Resources, 1115 25th Ave, Meridian, MS 39301 or visit our Web site at www.unitedbloodservices.org Pre-employment drug testing req'd. EOE M/F/D/V.

Director. Quality Assurance & Regulatory Affairs. Southeastern Community Blood Center, Tallahassee, FL, seeks director for compliance & quality programs. Manage & direct compliance program of small community blood center with multiple branches & active transfusion services; work closely with CEO & department directors to accomplish goals. Responsibilities include development & coordination of blood center quality program, coordination of educational program requirements of blood center staff & students, & management of QA specialist staff. Education: Medical Technologist MT(ASCP); CQA(ASQ); or other professional certification pref'd. Strong computer skills helpful. Two years of blood banking or QA exp. in blood center operation req'd; transfusion service exp. desirable. Qualified persons should send their resumes to: Southeastern Community Blood Center, 1731 Riggins Road, Tallahassee, FL 32308, ATTN: Human Resources or e-mail kanderson@scbcinfo.org. FAX: (850) 877-7435. Web site: www.scbcinfo.org. SCBC is Drug Free Workplace & EOE. Pre-employment drug testing req'd.

Quality Assurance Specialist. COME JOIN OUR TEAM! Are you outgoing, friendly, patient, & conscientious? Are you precise, accurate, & attentive to details? Do you have bachelor's degree & exp. in medical technology, or related field? Do you have three to five years exp. in blood industry or laboratory medicine. Do you have familiarity with quality assurance practices, quality improvement, AABB standards & federal regulatory requirements? If so, you might be our ideal candidate! In this challenging role you will perform & assist in quality assurance activities, to provide confidence that all systems & their elements, which influence product & service quality are operating as intended. We offer starting salary between \$37,000 & \$43,000 based on exp., & competitive benefits package. This is full-time position with normal hours of 8 to 5, Monday through Friday. If you're right person for this job, please stop by our main office to

submit your resume & complete application & applicant-assessment form or e-mail resume to ntetzlaff@communityblood.org. 4406 W. Spencer Street, Appleton, WI. Equal Opportunity Employer

Assistant Director, Quality Assurance. Coffee Memorial Blood Center in Amarillo, Texas has opening for Assistant Director of Quality Assurance. This position provides daily oversight for QA department including supervision of staff of six. Relevant Bachelor's degree or equivalent combination of education & exp. desired. Working knowledge of regulatory & accreditation standards including FDA, OSHA, CLIA & HIPAA strongly pref'd. Knowledge of biosafety, chemical hazard & fire safety requirements helpful. Licensure or certification in healthcare or laboratory fields plus. For more information & to obtain printable application, please visit our Web site at www.thegiftoflife.org/jobs.htm. Resumes & requests for additional information may be submitted to Kathy Mitchell, PHR by FAX (806) 358-2982 or e-mail kmitchell@thegiftoflife.org. No phone calls, please. EOE

Technical Manager. Puget Sound Blood Center is seeking highly motivated laboratory professional to provide leadership, expertise, & oversight for all technical aspects of our centralized Transfusion Service Laboratories (TSL). Incumbent will participate in Administrative Management team to set vision & direction for TSL, assure that operational departments have adequate equipment & supplies to perform, verify & deliver continuous service to meet customer requirements. Assure departmental processes & procedures are compliant with accreditation & regulatory standards. Provide direct supervision of procedures, processes, & staff in Red Cell Reference Laboratory (RCRL), as well as oversight to Technical Specialists. Requirements include: MT (ASCP), with SBB certification, & minimum of five years laboratory technical exp. with at least four years exp. in red cell reference testing (or equivalent combination of education & exp.). Send resumes to: Human Resources, Job #4993ABC, 921 Terry Ave, Seattle, WA 98104-1256, humanresources@psbc.org.

Quality Coordinator. Assist in development, implementation & ongoing oversight of all aspects of quality management for Transfusion Service Laboratories at Puget Sound Blood Center. Participate in Administrative Management team to set vision & direction for Transfusion Service Laboratories. Lead process improvement efforts & provide quality tools for frontline supervisors & staff. Coordinate & facilitate quality meetings with hospital customers. Coordinate error management & internal assessment programs. Requirements include: MT or MLT (ASCP), with SBB certification pref'd, & two years QA/AC experience in blood banking. Send resumes to: Human Resources, Job #4995ABC, 921 Terry Ave, Seattle, WA 98104-1256, humanresources@psbc.org.

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Director, Accounting/Controller (Job #5006). Puget Sound Blood Center is seeking Director of Accounting/Controller to be responsible for financial operations including accounts payable, billing, payroll, cash management, & financial reporting functions. Responsibilities: Direct annual budget process; develop, analyze, & interpret financial data; ensure proper internal controls; oversee all accounting functions; coordinate all financial related audits; oversee preparation of all req'd financial reports; participate in financial software upgrades & implement cost accounting systems. Requirements: BA/BS in Finance or Accounting – CPA or masters pref'd, five plus years exp. in Controller or Assistant Controller role, five plus years supervising & developing staff; ability to develop & implement cost accounting system & manage multiple projects & deadlines. Excellent interpersonal & communications skills must. Exp. working in "lean" organization pref'd. To apply please submit resume via e-mail to HumanResources@psbc.org or mail resume to Puget Sound Blood Center, 921 Terry Avenue, Seattle, WA 98104.

Apheresis Coordinator. Cascade Regional Blood Services is seeking full time Apheresis Coordinator to oversee Donor & Therapeutic Apheresis services. Responsibilities include performing donor apheresis collections, therapeutic apheresis procedures, & peripheral blood progenitor collection. Coordinator also performs training, schedules staff & procedures, reviews & maintains records, manages SOPs, & ensures regulatory compliance throughout department. Valid Washington Nursing License, CPR Certification, & valid driver's license are req'd. Hemapheresis Practitioner (ASCP) Certification pref'd. RN with minimum of 1-3 years in apheresis will be considered. Right candidate will have excellent oral & written communication skills, & must be able to work flexible schedule including weekends & on-call. Cascade Regional Blood Services is independent community-based blood center that serves local hospitals in Pierce County, & South King County, Washington. Our full time benefits package includes medical, dental, vision, life insurance, employer paid pension & 403(b) plan. EOE/Drug free workplace. Pre-employment background check & drug screening is req'd. Contact Info: E-mail resume to: donna@crbs.net. Or application can be downloaded from our Web site www.cascadebloodcenters.org & mailed to: Donna Hyder, Human Resources Manager, Cascade Regional Blood Services, 220 South I Street, Tacoma, WA 98405. (253) 383-2553 ext. 262

Director, Quality Assurance & Regulatory Affairs. Hoxworth Blood Center, Cincinnati, OH seeks Director, Quality Assurance & Regulatory Affairs. This leadership role in quality assurance is responsible for submission of

all license applications for FDA. Investigates & submits deviation reports. Coordinates all external assessments & inspections & responds to findings. Supervises internal auditor & metrology staff. Develops new SOPs for QA procedures & policies, reviews departmental SOPs, validation protocols & training plans. Reviews & maintains proficiency test results for all laboratory area. Maintains supplier qualification program & calibration database. **Minimum Qualifications:** Bachelor's degree in medical technology, biology, chemistry or related field & is req'd. At least three years exp. in quality assurance activities is also req'd. Blood center exp. & some supervisory exp. are also desirable. Apply directly on line to www.jobsatuc.com. University of Cincinnati is affirmative action/equal opportunity employer. For more information about Hoxworth Blood Center visit www.hoxworth.org

CEO/President. Bonfils Blood Center in Denver, Colorado is now accepting resumes for position of CEO/President. This position reports directly to board of trustees on matters of blood center & its subsidiaries (\$70M in consolidated annual revenue). It is responsible to board to assure that quality system & all operational activities are performed according to their wishes & those tenants described in by-laws of corporation(s). This position also serves as ultimate authority in matters of operation of corporation & its subsidiaries, is responsible for fiscal & legal matters of corporation(s) & for assuring that activities of management comply with mission, quality manual & all applicable regulatory requirements. Ideal candidate must have BS/BA Degree & MBA, MT(ASCP) or MT(ASCP)SBB certification is pref'd. Application process closes 11/30/06. For consideration, please forward letter of interest & CV to attention of Anne Burtchael at Bonfils Blood Center 717 Yosemite Street Denver, CO 80230 or CEO_Application@bonfils.org.

Director, Technical Services. Coastal Bend Blood Center, is seeking individual to manage technical, administrative & regulatory operations of donor testing & reference laboratory, component department & distribution. Position offers opportunity to join management staff of blood center that serves 13 medical facilities in 10 county area. Qualifications: Bachelor Degree, MT(ASCP), SBB pref'd but not mandatory, blood bank management exp., strong communication & leadership skills, SOP writing skills, knowledge of FDA regulatory requirements & cGMP training applicable to blood center operations pref'd. Competitive salary & benefit package, relocation assistance. Interested candidates should submit resumes to Coastal Bend Blood Center, Human Resources, 209 N. P. I. D., Corpus Christi, Texas, 78406, FAX: (361) 855-2641 or e-mail hr@coastalbendbloodcenter.org. ♦